AmericanCoatings ASSOCIATION℠

May 28, 2024

Michal Friedhoff
Assistant Administrator
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC

Submitted via www.regulations.gov
Re: Docket No. EPA–HQ–OPPT–2023–0360

Dear Assistant Administrator Freedhoff:

The American Coatings Association ("ACA")[1] appreciates the opportunity to submit comment regarding EPA's Request to submit unpublished health and safety studies under Section 8(d) of TSCA. ACA is committed to working with EPA to help ensure an accurate understanding of chemical risk through implementation of the *Lautenberg Amendments*. The Association's membership represents 90% of the U.S. paint and coatings industry, including downstream users of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture a variety of formulated products including paint, coatings, sealants and adhesives and their raw materials. ACA and its members respectfully submit the following comment:

I. Introduction

EPA proposes to add 16 chemical substances to lists at 40 CFR 716.120, triggering a reporting requirement within 90 days of finalizing the rule. Chemical substances include those undergoing prioritization and chemicals that EPA may select for future prioritization. Manufacturers and importers would be required to submit health and safety studies "know to" them or lists of studies where appropriate, including studies describing physical characteristics, environmental degradation, general population monitoring, etc.

[1] ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services. ACA's membership represents over 90 percent of the total domestic production of paints and coatings in the country.

Reporting is triggered by manufacture and import at any purity level, including *de minimis* amounts, as an impurity or as a by-product. Companies must report via CDX, including templates describing health and safety effects, overlapping with data included in OECD reporting templates submitted as part of REACH registration. Generally, health and safety information is not protected from disclosure once submitted to EPA. Some information within a study may be eligible for confidentiality protection, such as confidential identities, process information, etc., as described in TSCA, Section 14.

II. Reporting of impurities, by-products and small amounts leads to a significant burden on industry that EPA has not considered in its proposal.

Paint and coatings manufacturers, including small businesses, often import raw materials to supplement domestic supply. Companies may also import as the main source of a raw material. Companies importing small amounts of a raw materials that include impurities are subject to reporting. Although such companies are unlikely to have reportable studies, a company must expend resources to: 1) identify reportable chemicals in raw material; and 2) identify any studies "known to" it. ACA recommends establishing a *de minimis* level, while implementing an exemption for impurities and by-products to minimize this burden, considering manufacturers and importers of small amounts are unlikely to have responsive studies. ACA further requests that EPA provide an exemption based on SDS listing thresholds or at a minimum specify that downstream importers can rely on information provided in an SDS.

EPA has not adequately estimated costs to small businesses, when concluding that only 44 small businesses will be affected and only 1 small business is estimated to incur annualized cost impact of more than 1% of revenue. EPA also underestimates total costs to industry for the first year of reporting at $301,956, based on 3,388 paperwork hours. These estimates are based on the number of companies that submitted relevant CDR reports, triggered by significantly higher CDR reporting thresholds than those triggering reporting under this rule. CDR reporting is triggered by manufacture and import at 25,000 pounds per year or at 2,500 pounds per year for chemicals subject to a SNUR or other EPA rule. Because ACA members will be reporting import or manufacture of *de minimis* by-products and impurities or any amount in mixtures, the number of affected businesses and related costs are significantly higher than EPA's estimates.

III. Additional time for submitting information is appropriate and would not delay EPA's schedule.

ACA suggests extending the reporting period to 180 days after finalizing the rule. A 90 day reporting period does not provide adequate time to respond. Companies must identify reportable chemicals, including those imported (or manufactured) in mixtures, followed by a thorough internal investigation to identify any related studies. Companies would then need to evaluate and claim confidential information contained in the studies, such as confidential identities, formulations and process information. This is a significant undertaking for small businesses who may not have internal legal counsel.

Companies also require additional time to format and submit reports via CDX. CDX reporting is often a time consuming process, usually taking more time than EPA estimates. Companies importing or manufacturing small amounts may be using CDX for the first time, and they will require additional time to familiarize themselves with CDX. An extension of time will not affect EPA's schedule since information about the 16 chemicals is already well known in available sources and 10 of the proposed chemicals are not currently undergoing prioritization.

IV. Unpublished studies are not a reliable information source and could lead to greater inaccuracy in risk assessments and unnecessary risk mitigation requirements.

ACA supports EPA efforts to identify and gather information. One possible outcome of this reporting rule is the identification of specific information relevant to downstream uses. ACA remains concerned however that EPA will not accurately contextualize information to incorporate any studies into an EPA risk evaluation or when considering risk mitigation requirements. A health and safety study may remain unpublished for a variety of reasons that could include deficiencies in methodology, samples and lack of peer review.

An unpublished study is not going to provide EPA with data that meets TSCA's standards of scientific integrity. EPA should further consider that hazard and risk-related information for this set of chemicals is already well known from reputable, peer-reviewed sources.

V. Conclusion

ACA appreciates EPA's willingness to engage with stakeholders during this process. ACA respectfully submits the following suggestions:

- ACA recommends establishing a *de minimis* level for reporting, while implementing an exemption for impurities and by-products.
- ACA further requests that EPA provide an exemption based on SDS listing thresholds or at a minimum specify that downstream importers can rely on information provided in an SDS.
- ACA suggests extending the reporting period to 180 days after finalizing the rule.
- ACA suggests limiting the use of unpublished data that does not meet TSCA's standards for scientific integrity and/or TSCA's requirement of being fit for purpose.

Please feel free to contact me if ACA can provide any additional information or clarification.

Sincerely,

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