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Submitted via regulations.gov

Michal Freedhoff
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Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: Proposed Rule, Request to Submit Unpublished Health and Safety Data Under the Toxic Substances Control Act, 89 Fed. Reg. 20,918 (Mar. 26, 2024)
Docket No. EPA-HQ-OPPT-2023-0360

Dear Dr. Freedhoff:

The Styrene Information and Research Center, Inc. (SIRC) appreciates the opportunity to submit comments on EPA's proposed rule, Request to Submit Unpublished Health and Safety Data Under the Toxic Substances Control Act.[1] SIRC was formed in 1987 to be the focal point for the research and public information on styrene. SIRC's charter also addresses the interests of ethylbenzene producers. SIRC is a non-profit organization consisting of voting member companies involved in manufacturing or processing of styrene, and associate member companies that fabricate styrene-based products. Collectively, SIRC's membership represents the vast majority of the North American styrene manufacturing industry.[2]

I. SIRC's Interest in the Proposed Rule and Summary of Comments

SIRC's direct interest in this rule arises from EPA's designation of both styrene and ethylbenzene among the 16 substances for which submission of studies and lists of studies would be required under the proposed rule. SIRC serves as a resource for industry, federal and state governments, and international agencies on issues related to the potential impact of exposure to styrene and ethylbenzene on human health and the environment. It has supported that effort through an extensive and costly research program over the past 37 years, including the completion of a full

[1] 89 Fed. Reg. 20,918 (Mar. 26, 2024).

[2] SIRC member companies include Americas Styrenics, INEOS Styrolution America LLC, LyondellBasell Industries, Polynt Composites USA, Inc., SABIC Petrochemicals Holding US, Inc., Shell Chemical LP, TotalEnergies Petrochemicals & Refining USA, Inc., and Trinseo PLC.

systematic review risk assessment of styrene in 2019.[3] This work will contribute to the agency's efforts to base risk evaluations on the best available science.

SIRC appreciates the desire of the Agency to collect available health and safety information on substances currently undergoing prioritization or slated to begin prioritization in the next 18 months. However, portions of EPA's proposal should be amended in the final version of the rule. As discussed further herein, SIRC has the following principal comments on the proposed section 8(d) rule:

(a) The response period for submitting copies of studies, lists of studies and completed OECD electronic study summary templates should be bifurcated and extended. Copies of studies and lists should be due no less than 120 days after the effective date of the rule (estimated total of 150 days) and completed OECD templates should be due no sooner than 180 days after the effective date (estimated total of 210 days).

(b) Eliminate the proposal to make the impurity exemption inapplicable and add a *de minimis* concentration reporting threshold.

(c) Confirm the continuing applicability of existing reporting exemptions and exclusions for mixtures including impurities and low concentration substances not specifically made inapplicable by the proposal.

(d) Confirm that the investigation due diligence standard would not be altered by the absence of the impurities exemption and a *de minimis* threshold.

(e) Confirm that, notwithstanding seemingly contrary language in the preamble, raw data, underlying studies and unanalyzed monitoring data are not reportable.

(f) Confirm that HPV Program data and published REACH data generally are not reportable.

(g) The OECD templating requirement is not applicable to section 8(d) reports unless CBI claims will be made for submitted studies.

(h) The Agency must confirm that it is ready to receive and properly manage populated IUCLID templates containing CBI, CBI claims and CBI substantiation and provide additional guidance for submitters.

(i) Submitters must be permitted to submit *lists* of known studies into CDX; SIRC recommends making offline templates available for efficient loading.

[3] M.I. Banton, et al. (2019): Evaluation of potential health effects associated with occupational and environmental exposure to styrene – an update, J. Tox.& Environmental Health, Part B, DOI: 10.1080/10937404.2019.1633718.

II. Comments on Proposed Section 8(d) Rule

A. The response period for submitting copies of studies, lists of studies and completed OECD electronic study summary templates should be bifurcated and extended.

The default 60-day reporting period specified in 40 C.F.R. § 716.60(a) is an insufficient period for the proposed responses. There are a number of circumstances that would be applicable to section 8(d) reporting for the proposed 2024 set of substances not contemplated when the default 60-day period was set in the Part 716 rules in 1980s. These include expanded CBI substantiation procedures and requirements under new Part 703, the requirement to extend the search back nearly 50 years, to 1977 for most study types, as opposed to 10 years or less when the rule was adopted; EPA's proposal to override the standard exemption and include a requirement to search for studies involving a reportable substance where it is present only as an impurity; the similar requirement to search for and report studies involving mixtures where the reportable substance is present in any amount (no *de minimis*); and perhaps most importantly, the very burdensome new requirement described in the preamble (but not the regulation) purporting to require manufacturers to abstract study information into electronic OECD/IUCLID6 template forms. EPA has estimated that it will take at least 12 hours of highly skilled labor to convert a single study to the electronic OECD template based on its past estimates of time to prepare voluntary narrative robust study summaries for section 8(d).[4] We believe this is an inappropriate model and underestimates the necessary time and cost given, among other things, the variety of study types that may need to be abstracted, U.S. companies' lack of familiarity with the format and the uncertainty on how CBI claims and substantiation procedures will apply to information submitted in electronic template form.

In light of these differences and execution uncertainties, the default Part 716 reporting period should be extended as it was in connection with EPA's most recent prior 8(d) rule in 2021, which extended the reporting period by approximately 60 days for most substances (for a total of 150 days from the publication date).[5] Copies of studies and lists should be due no less than 120 days after the effective date of the rule (estimated total of 150 days for reporting) and completed OECD templates should be due no sooner than 180 days after the effective date (estimated total of 210 days).

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[4] U.S. EPA, ECONOMIC ANALYSIS FOR THE FINAL RULE ENTITLED: TSCA SECTION 8(A)(7) REPORTING AND RECORDKEEPING REQUIREMENTS FOR PERFLUOROALKYL AND POLYFLUOROALKYL SUBSTANCES (RIN 2070-AK67), Doc. No. EPA-HQ-OPPT-2020-0549-0265 (Sept. 2023), at 3-21, *citing*, U.S. EPA, SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUESTION (ICR) UNDER THE PAPERWORK REDUCTION ACT. HEALTH AND SAFETY DATA REPORTING, SUBMISSION OF LISTS AND COPIES OF HEALTH AND SAFETY STUDIES. OMB Control No. 2070-0004, Doc. No. EPA-HQ-OPPT-2021-0728-0002 (Mar. 1, 2022). Notably, EPA's existing Information Collection Request (ICR) for the 8(d) framework rule does not include the costs for preparing OECD templates. EPA must also issue an updated ICR to properly account for these costs under the Paperwork Reduction Act.

[5] Health and Safety Data Reporting; Addition of 20 High-Priority Substances and 30 Organohalogen Flame Retardants; Extension of Submission Deadline, 86 Fed. Reg. 54,386 (Oct. 1, 2021).

B. Eliminate the Proposal to Make the Impurity Exemption Inapplicable and Specify a De Minimis Concentration Reporting Threshold

EPA has proposed to make inapplicable the standard reporting exemption for studies where the subject chemical is present only as an impurity, see proposed 40 C.F.R. § 716.120(d) ("§ 716.20(a)(9) does not apply"); and to otherwise decline to set a *de minimis* concentration level for studies of mixtures, see proposed 40 C.F.R. § 716.21(a)(11); ("*Studies showing any measurable content of the substance in the tested substance (single substances or mixture) must be reported.*"). While we understand that the anticipated TSCA section 6 risk evaluation process will include consideration of conditions of use of the subject chemicals when manufactured, processed used or disposed only as an impurity, any information on health and safety studies involving impurities or target substances in very small quantities should be limited to those studies that will provide useful information about the subject chemical for the risk evaluation. For example, long- and short-term toxicity and ecotoxicity studies of mixtures that contain the subject chemical only as an impurity or in low concentrations are unlikely to provide any useful information on hazard of the subject chemical and such studies should be excepted. *See, e.g.*, 40 C.F.R. § 716.20(a)(6)(i)-(vi) (exempting toxicity studies of mixtures); 40 C.F.R. § 716.20(b)(4) (exempting most mixtures where the subject chemical is present at less than 1%).

Before requiring reporting on studies where the subject chemical is present only at low concentrations or only as an impurity, the Agency must tailor the requested study types to those that will generate useful information for risk evaluation, supported by some analysis of how the requested study information would be used. It is insufficient merely to recite that the section 6 risk evaluation will include consideration of impurities. An appropriate category might include analyzed aggregations of monitoring data on mixtures known to contain a reportable substance in low concentration or as an impurity, provided that the monitoring data are analyzed to determine the exposure or concentration levels of the subject substance, as this reasonably may provide information on exposure for particular conditions of use. *See, e.g.*, 40 C.F.R. § 716.20(a)(7) (limited to past five years).

C. Confirm Applicability of Existing Reporting Exemptions Not Specifically Made Inapplicable

EPA's proposed actions eliminating the § 716.20(a)(9) impurity exemption, and its proposed 40 C.F.R. § 716.21(a)(11) statement that all studies showing any measurable content of the subject substance must be reported may cause confusion as to the applicability of other exemptions not expressly made inapplicable by EPA's proposal. To avoid confusion, the Agency should confirm in the final rule and preamble (as appropriate) that:

1. The reporting exemptions for mixtures in 40 C.F.R. § 716.20(a)(6)(i)-(vii) continue to apply (including for physical and chemical property studies of mixtures that include the subject chemical).

2. The corresponding exclusion for studies of mixtures in 40 C.F.R. § 716.10(a)(2) remains applicable.

3. The reporting exemption for mixtures in 40 C.F.R. § 716.20(a)(8), exempting monitoring reports for mixtures known to contain a subject substance if the study data are not already analyzed to determine the exposure or concentration level of a reportable substance, remains applicable.

D. Confirm that the Investigation Due Diligence Standard Would not Be Altered by the Absence of the Impurities Exemption and De Minimis Threshold

1. Companies May Rely on Indexing Systems

The extent of the required file search for responsive studies is limited by 40 C.F.R. § 716.25. It limits the search 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) who is/are responsible for keeping such records or advising the person on the health and environmental effects of chemicals.

In the case of searches for studies of mixtures containing only low concentrations of reportable substances or reportable substances only as impurities, company indexing systems may not identify such low concentration components. Manufacturers may be able to infer that the test substance, under the circumstances, may contain a low level of the reportable substance; however, they would not be able to confirm this without individually pulling and examining each of the studies or aggregated and analyzed data sets. This might arise, for example, where the reportable substance is a monomer processed to form a polymer. Most polymers can be expected to include some level of unreacted monomer as an impurity. Nevertheless, we understand that individual monomer manufacturers would not need to search for and assess all studies of the polymer that may contain monomer impurities.

EPA has addressed analogous circumstances in the past and explained that, consistent with the due diligence standard in the regulation, manufacturers may limit their searches to "records in the location(s) where the required information is typically kept," including use of indexing systems used by a company to track health and safety information. Where studies are not indexed to identify impurities or other substances present in low concentrations in a mixture, companies may rely for reporting purposes on their index systems to identify studies where the reportable chemical was listed and studied, and do not have to collect and individually review studies not directed at the subject chemical to determine whether the test substance nevertheless included some quantity of the reportable chemical and was quantified, even if the presence of the substance might be inferred. As explained in the 1989 General Guidance, such individual review is more than is required by the 40 C.F.R. § 716.25 due diligence standard.[6] This is consistent with EPA's estimated burden effort for searches, which it estimates at three hours per facility.[7]

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[6] *See*, 1989 General Guidance at 3- 4 (questions 8, 9 and 10).

[7] U.S. EPA, SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUESTION (ICR) UNDER THE PAPERWORK REDUCTION ACT. HEALTH AND SAFETY DATA REPORTING, SUBMISSION OF LISTS AND COPIES OF HEALTH AND SAFETY STUDIES. OMB Control No. 2070-0004, Doc. No. EPA-HQ-OPPT-2021-0728-0002 (Mar. 1, 2022).

2. Companies do not need to search files of foreign or domestic affiliates

Given the Agency's discussion suggesting that reporting companies may have possession of studies submitted for purposes of REACH, the Agency should confirm that the due diligence standard has not been altered in respect of responsibility by reporting companies for information held by affiliates. Unlike in 40 C.F.R. § 704.3, the terms "known," "possess" and "person" as used in the 8(d) rule to define who must report or list are *not* given special, expanded regulatory definitions and therefore ordinary definitions apply. Accordingly, while the legal entity that manufactures one of the listed substance is required to search its files and to report on studies in its passion or known to it (wherever located), U.S. companies are not required to search plant sites outside the U.S. and U.S. companies are not required to acquire copies of studies possessed by foreign or domestic subsidiaries or parents.

E. Confirm that Raw Data, Underlying Studies and Unanalyzed Monitoring Data Are Not Reportable

The preamble erroneously suggests that manufacturers must submit raw data and supporting studies, and unanalyzed monitoring data, reciting in relevant part that,

> [T]hose subject to this rulemaking must submit … underlying data as support documents. The full study reports and support documents are necessary for EPA to understand the full context and evaluate the quality of the data …. Such information may include, but is not limited to, raw monitoring data (regardless of having been aggregated or analyzed) of human or environmental exposure assessments and toxicity tests for either human health effects or ecological other environmental effects.

This preamble language is contradicted by the terms of the existing regulation, such as 40 C.F.R. § 716.10(a)(4), which is clear that underlying data, monitoring data, supporting studies and the like do not have to be submitted. EPA may request such information on a case-by-case basis as 40 C.F.R. § 716.40 "further information requests," but such information is not reportable in the first instance. Likewise, the Part 716 definition of "Health and safety study" is clear that monitoring data is not even potentially reportable unless it is in a form where the underlying data have been "aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture." 40 C.F.R. § 716.3 (definition of Health and safety study).

Our understanding is fully consistent with EPA's long-standing interpretation of the reporting requirements. For example, EPA's 1989 section 8(d) reporting guidance[8] (1989 General Guidance) explains that the reportable "copy of a study" includes only the analysis of summarized, tabulated or aggregated data, where the data have been studied and their meaning analyzed and discussed. Likewise, consistent with 40 C.F.R. § 716.10(a)(4), the 1989 General Guidance is clear that raw data or reports of raw data and other underlying data and studies are not reportable.

[8] U.S. E.P.A., GENERAL QUESTIONS AND ANSWERS ABOUT REPORTING UNDER TSCA §8(D) HEALTH AND SAFETY STUDIE REPORTING RULE (rev. as of Feb. 16, 1989) ("1989 General Guidance") at questions 2, 7.

To avoid confusion arising from the unsupported statements in the preamble, EPA should confirm that existing exclusions and guidance for raw and supporting data and unaggregated or unanalyzed monitoring data continue to apply.

F. Confirm that HPV Program Data and Published REACH Data Generally Are Not Reportable

We appreciate EPA's determination to exclude studies previously voluntarily submitted to EPA (and not limited to mandatory and similar causes listed under 40 C.F.R. § 716.20(a)(2)) are excluded from reporting obligations. See 40 C.F.R. § 716.21(a)(11) ("[s]tudies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord … are exempt from the submission of lists of health and safety studies … and the submission of studies required under this rule"). EPA should confirm that this would include HPV program data submitted in the past.

ECHA makes summaries of studies submitted in connection with REACH dossiers publicly available. While the underlying studies should be reported by a U.S. manufacturer that possesses an otherwise reportable full study, other U.S. manufacturers should not be required each to list the studies in the published version of the dossier as this would be unnecessarily duplicative. EPA is already aware of these studies and EPA may treat such studies as published in the scientific literature. Likewise, EPA should confirm the 1989 General Guidance that studies only generally known to a U.S. manufacturer, but for which the manufacturer does not know the specific identity and contact information for a person that possesses the study, do not have to be included on lists of known studies. This is consistent with the 1989 General Guidance and the CDX program service data entry screen for submitting lists of studies (submission cannot be completed without specific contact information).

G. The OECD Templating Requirement Is Not Applicable to Section 8(d) Reports Unless CBI Claims Will Be Made

The preamble erroneously suggests that the requirement to submit electronic OECD/IUCLID templates for submitted studies is applicable to *all* studies submitted, but this is not accurate. The requirement to prepare such templates does not exist at all in Part 716. It exists only 40 C.F.R. § 703.5(g) ("Requirements for asserting and maintaining confidentiality claims"), which, by its terms, is applicable only to submissions of confidential information and not generally applicable to all submissions.[9] The final rule should clarify that the OECD templating requirement is applicable only to studies submitted with CBI claims.

H. The Agency Must Confirm that it is Ready to Receive Populated IUCLID Templates Containing CBI, CBI Claims and Substantiation and Provide Additional Guidance

To the extent that CBI claims are made for portions of submitted studies, the Agency must clarify how CBI claims may be asserted and substantiated in and for completed IUCLID templates. The templates themselves may have fields to assert CBI claims, but more IUCLID specific guidance is

[9] In addition, the citation to the OECD templating requirement in the preamble to the section 8(d) proposed rule erroneously refers to 40 C.F.R. § 705.15(f); however, that provision applies only to submission under the PFAS reporting rule and it is not applicable to 8(d) reports.

needed to assure that these claims will be recognized by EPA substantively, and that they will be recognized and protected by EPA's data systems if submitted. These matters are not addressed by Part 703. This may be another reason to bifurcate the reporting period and defer submission of IUCLID templates until EPA has confirmed how CBI claims are made for the information they contain and that its systems are ready to re8cve the templates.

I. Submitters Must Be Permitted to Submit *Lists* of Studies Into CDX

The statute and regulations call for manufacturers to submit "lists" of known studies not possessed by them (or underway but incomplete). EPA's past analysis has treated the preparation of such lists as so inconsequential (after the file search is complete) that its section 8(d) Information Collection Requests allocate no additional time to the burden estimate. However, the CDX interface for submitting lists of known studies does not comport with the statute or regulations. It does not allow manufacturers to submit/upload any list. Rather, it requires manufacturers to complete an extended data-field-by-data-field entry of study related information for each study, which is not a list and not an inconsequential effort.

To correct the issue, meet the requirements of the statute and Part 716, and simplify the process for submitters, EPA must modify the interface to allow, at least as an option, for submitters to upload a list prepared offline and meeting the information requirements in the regulation. Good models for EPA to consider as a compromise are the MS Excel templates used to populate CDR reporting forms and the TSCA Inventory Reset Form A submissions. Submitters could prepare their lists and all data fields offline, and then load them directly into EPAs systems, with minimal clerical/ministerial effort by submitters.

III. Conclusion

SIRC and its member companies appreciate the opportunity to comment on the proposed section 8(d) reporting rule. We would be pleased to discuss further the several issues raised in the comments. If you have any questions, please contact me.

Very truly yours,

/S/

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