UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, Center for Environmental Health, Earthjustice, Environmental Health Strategy Center, and Natural Resources Defense Council on Proposed Revisions and Small Manufacturer Definition Update for Chemical Data Reporting Under TSCA Section 8(a)

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Safer Chemicals Healthy Families (SCHF), Center for Environmental Health, Earthjustice, Environmental Health Strategy Center, and Natural Resources Defense Council submit these comments on the April 25, 2019 proposal of the Environmental Protection Agency (EPA) to revise Chemical Data Reporting (CDR) requirements and size standards for small manufacturers under section 8(a) of the Toxic Substances Control Act (TSCA).[1] Our organizations are national and grassroots groups committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. We took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

CDR reporting is the central mechanism under TSCA for collecting production volume, plant site location, processing, use and exposure information for chemicals listed on the TSCA Inventory. EPA will soon set in motion the 2020 CDR reporting update, required every four years under the CDR rule. Industry submission of reports for manufacture and import activities during the 2016-2019 reporting period will provide invaluable information to EPA and the public as the Agency continues to implement the 2016 TSCA amendments. The revisions to the CDR rule proposed by EPA are intended to adjust the reporting requirements that industry follows during the 2020 update.

We have reviewed the proposed revisions to examine whether they will maintain and enhance the value of CDR reporting in supporting the Agency's risk evaluation and reduction mission under TSCA. Our comments underscore the following key points:

- CDR reporting plays a critical role in carrying out EPA's expanded responsibilities under TSCA and providing essential chemical risk information to the public
- Current CDR reporting requirements must be augmented to provide information necessary for complete and informed risk evaluations under TSCA
    - EPA should add processor reporting requirements to the CDR rule for chemicals undergoing, or expected to undergo, TSCA risk evaluations
    - EPA should also lower the CDR reporting threshold for chemicals undergoing risk evaluations
- The proposed expansion of the exemption of small manufacturers from reporting should be withdrawn because EPA has not determined the extent to which the proposal will weaken the CDR rule, contrary to law

[1] 84 Federal Register 17692.

- EPA is not required to raise the small manufacturer standards in proportion to inflation but has discretion whether and how to modify these standards in light of the goals of TSCA
- EPA has failed to evaluate whether and how the proposed standards will affect its ability to implement the law effectively, contrary to its Section 8 mandate
- Raising the small manufacturer standards will have minimal economic benefits
- In any event, the proposed small manufacturer standards should not apply to mercury reporting under the CDR rule

- EPA should eliminate the reporting exemption for naturally occurring chemical substances
- EPA's provisions for streamlining reporting of inorganic byproducts must retain safeguards to assure the absence of any human exposure or environmental release
- EPA needs to do more to prevent unjustified CBI claims and increase transparency for CDR data
- EPA should revise Form U so consumer and commercial uses are reported separately
- The byproduct exemptions in the CDR rule are out-of-date and no longer justified, and should be removed or restricted

I. CDR Reporting Plays a Critical Role in Carrying Out EPA's Expanded Responsibilities under TSCA

CDR reporting provides essential information on the manufacture, importation and use profile of chemicals in US commerce. With the enactment of legislation strengthening TSCA, EPA's responsibilities for evaluating chemical risks and assuring chemical safety have increased significantly. The CDR database is a critical tool for informed decision-making under the new law.

Our organizations and many others in the public health community view CDR reporting as a vital resource for commenting on EPA actions under TSCA, and therefore access the CDR database frequently. Following EPA's designation of 10 chemicals for initial risk evaluations under the new law, the Agency initiated a scoping process to gather data on chemical exposures and uses. To participate in that process, our organizations obtained, under the Freedom of Information Act (FOIA), the CDR Form Us for the 10 chemicals. We then analyzed these forms closely and used them to recommend use and exposure pathways for inclusion in the EPA scoping documents. The final scoping documents and subsequent problem formulations made extensive use of CDR data to lay the foundation for risk evaluations on the 10 chemicals. Data reported for the 2020 CDR update will perform a similar function in the upcoming round of risk evaluations EPA will conduct on the 20 chemicals soon to be listed as high priority under section 6(b) of TSCA.

Apart from TSCA implementation, CDR reports are uniquely valuable to communities and vulnerable populations seeking to better understand potential risks and exposures they may face. By accessing CDR reports, these groups and individuals can identify production and importation facilities in their locales, the chemicals produced or stored at these facilities and their volumes, the type of production process employed, the number of workers at each facility and the nature of the chemicals' uses. In at-risk communities exposed to multiple sources of chemicals, this information is particularly important in pinpointing facilities that are contributing to aggregate risk and assessing the overall magnitude of their

impacts. Other EPA databases for chemicals like the Toxics Release Inventory (TRI) cover a much smaller universe of substances and lack the breadth of information in CDR reports and thus have less utility to at-risk communities.[2]

Our experience has been that all the information captured by Form Us is useful and important. The EPA proposal retains all the current reporting elements (although it unjustifiably narrows the scope of reporting by expanding the small manufacturer exemption, as discussed more fully below). However, the proposal does not seek to expand reporting, nor does it discuss whether experience during the first three years of amended TSCA implementation highlights the need for additional information to support EPA's expanded responsibilities under the revised law.

II. CDR Reporting Must be Augmented to Provide Additional Information Essential to Conducting Complete and Informed Risk Evaluations under TSCA

As EPA proceeds with the first 10 risk evaluations under section 6(b)(2)(A), it has been constrained by serious gaps in use and exposure information. Unless addressed, this limitation will remain a basic weakness during the next round of risk evaluations and will continue to undermine the quality of EPA's assessments of human and environmental exposure. As required by section 6(b)(2)(B), on March 21, EPA initiated the prioritization process for 20 candidates for high-priority listing and will make final designations for these chemicals at the end of 2019 or early in 2020.[3] Risk evaluations on the 20 listed chemicals will then be immediately initiated. The 2020 CDR submission period will overlap with the initial stages of these evaluations and thus will be an important source of use and exposure information on the listed chemicals. This information will not only improve the quality and completeness of the evaluations but will aid the public in commenting meaningfully on EPA's findings and conclusions.

The ongoing CDR rulemaking provides an opportunity to expand reporting – and thus the amount of useful information available to EPA and the public – for chemicals undergoing risk evaluations. As discussed below, we recommend that the final CDR rule revisions promulgated by EPA target three classes of chemicals for additional reporting: (i) substances designated high-priority, (ii) substances included on the 2014 TSCA Work Plan list,[4] and (iii) substances subject to industry risk evaluation requests.[5] In this manner, EPA will receive expanded information on chemicals now undergoing, or likely to undergo, TSCA risk evaluations.

[2] The TRI's utility is also limited because EPA has not added all the chemicals that meet the criteria for listing. For example, no per- and polyfluoroalkyl substances (PFAS) are on TRI.

[3] 84 Fed. Reg. 10491.

[4] The 2014 Work Plan list was developed to set priorities for risk assessments before enactment of the new law and now contains 73 chemicals. In section 6(b)(2)(B) of amended TSCA, Congress directed EPA to draw at least 50 percent of high-priority listings from the Work Plan list until the list is exhausted. All 20 of the candidates for high-priority listing from which EPA initiated prioritization on March 21 are on the Work Plan list.

[5] TSCA Section 6(b)(4)(C)(ii) requires EPA to conduct risks evaluations on chemicals whose manufacturers request such evaluations.

A. EPA Should Add Processor Reporting Requirements to the CDR Rule for Risk Evaluation Chemicals

The current reporting rule does not apply to processors and thus relies on manufacturers and importers to provide information about downstream conditions of use. This limits the specificity and quality of the information on such uses reported to EPA. The absence of reports from processors is most problematic for chemicals undergoing risk evaluations because these evaluations depend on a detailed understanding of exposure pathways and chemical uses for the most important sources of potential risk, which often are downstream processing activities or uses flowing from such activities.

To address this gap in the current rule, EPA should add a processor reporting module for chemicals listed as high priority, included in the TSCA 2014 Work Plan list, or subject to industry risk evaluation requests. Some adjustment in the current Form U to reflect the circumstances of processors would be necessary, but the form would not need to be radically overhauled. To minimize paperwork burdens, EPA could target reporting at certain classes of processors (i.e. those using the chemical in their own operations or incorporating it in a formulated product for downstream use) but exempt others (e.g. retailers and distributors). Given the in-depth information reported by processors, the Agency could in parallel exempt manufacturers from reporting downstream use information in Part 3 of Form U; manufacturers would still report onsite processing activities.

While we believe the 2020 CDR update will enable timely reporting for the 20 upcoming high-priority chemicals, for other Work Plan chemicals and for substances for which industry has requested risk evaluations, there may need to be some timing adjustments to facilitate the conduct of future risk evaluations. For example, the next round of high-priority designations will likely occur in 2023 and the 2024, and the CDR update may occur too late to provide EPA with timely information for risk evaluations. Thus, CDR reporting on these chemicals might be triggered a year earlier. In addition, industry risk evaluation requests could be submitted at any time between CDR updates; reporting on the subject chemicals should thus be triggered when the requests are received. Processor reporting requirements could be sunset when EPA completes its risk evaluation and any subsequent risk management rulemaking since the Agency would no longer need detailed processor use and exposure information.

B. EPA Should Lower the CDR Reporting Threshold for Risk Evaluation Chemicals

We also recommend amending section 711.8(b) of the CDR rule, which sets a threshold production volume for reporting of 2500 pounds per site for chemicals regulated under certain TSCA provisions, so that this lower threshold applies to risk evaluation chemicals as described above.[6] It is clear from the ongoing 10 risk evaluations that the current reporting threshold of 25,000 pounds per site fails to capture lower-volume production and related conditions of use that may play a significant role in human exposure or environmental release and should be assessed both during the scoping process and the evaluation itself. This may result in incomplete evaluations that understate risk and fail to identify risk scenarios for vulnerable subpopulations that EPA is required to address under TSCA. If a lower reporting threshold is warranted for chemicals subject to TSCA requirements under sections 4, 5 and 6, then it is

[6] If EPA requires processing reporting for these chemicals, the lower per site volume threshold would apply to processors as well.

equally justified for the small universe of chemicals subject to risk evaluations under the new law, since EPA has a compelling interest in identifying exposure and release pathways and uses for these chemicals that are critical for informed determinations of risk.

To be clear, strengthening CDR is not the only step EPA should take to assure that it has sufficient information for high quality risk evaluations under TSCA. We have separately advocated triggering section 8(d) submission of "health and safety studies" on risk evaluation chemicals and called for targeted use of EPA's subpoena authority to obtain additional use and exposure information from particular companies.[7] We have also recommended that EPA fill data gaps on risk evaluation chemicals through testing orders under section 4. In combination, these complementary strategies for boosting use of EPA's mandatory information collection and development authorities in sections 4, 8 and 11 of TSCA will go far to provide a sound scientific foundation for determining the risks of chemicals of concern evaluated under the law.

III. Because EPA Has Not Evaluated How the Proposed Expansion of the Exemption of Small Manufacturers from Reporting Will Weaken the CDR Rule, It Should Be Withdrawn

The proposed CDR revisions would also modify the TSCA section 8(a) small manufacturer size standards. The proposed standards would apply to small manufacturers under all TSCA section 8(a) rules, including CDR, unless a different standard is established in a specific rule. The new standards represent EPA's first change in the small manufacturer definition since 1984.[8] The proposed update of the current two-standard definition at 40 CFR 704.3 is based solely on inflation over the past 35 years. The annual sales threshold for the first part of the standard would be increased from $40 million to $110 million and the threshold for the second from $4 million to $11 million. Under the first standard, a qualifying manufacturer would still need to report if production or import of a specific chemical at a given site exceeds 100,000 pounds per year.

These proposals represent a significant expansion of the TSCA 8(a) reporting exemption for small manufacturers. As EPA explains:

> "[t]he proposed definition would eliminate reporting entirely for 93 industry sites and would reduce reporting by eliminating the need to report at least one chemical for an additional 129 industry sites (Ref. 5). Overall, 888 chemical reports from industry sites would no longer be submitted to CDR."[9]

This reduction in reporting is not legally required and would compromise the effectiveness of the CDR rule at a time when EPA's expanded responsibilities under the new law place an increased premium on access to comprehensive use and exposure information.

[7] Comments of Safer Chemicals Healthy Families on Initiation of Prioritization for 20 High-Priority and 20 Low-Priority Candidates under Section 6(b)(1) of TSCA, June 19, 2019, Docket ID EPA-HQ-OPPT-2019-0131
[8] 49 Fed. Reg. 45425 (November 16, 1984).
[9] 84 Fed. Reg. 17711.

A. EPA Is Not Required to Raise the Small Manufacturer Standards in Proportion to Inflation but Has Discretion Whether and How to Modify These Standards

In the 2016 TSCA amendments, Congress modified section 8(a)(3)(C) to direct EPA to review the TSCA small manufacture definition within 180 days and make a determination whether revision of the definition is warranted. EPA conducted this review as required and, on November 30, 2017, concluded that the current size standards should be modified.[10] While inflation was one factor in determining that "the currently promulgated standards are clearly outdated with respect to the current understanding of what qualifies a business as small," the Agency made clear that it had "not yet proposed any revisions to the size standards" and would establish such changes "through future notice and comment rulemaking."[11]

As the November 30, 2017 notice recognizes, the amount of inflation is relevant to whether the small manufacturer standards should be modified, but EPA is under no obligation to automatically raise the standards in proportion to how much inflation has occurred since the existing standards were put in place. Thus, EPA regulations at 40 CFR 704.3 state that the Agency "may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent" since the last revisions, but they do not direct EPA to make changes in the standards based solely on inflation. Indeed, EPA recognizes as much in the CDR proposal by "soliciting comments regarding the extent to which this approach would reduce the reporting burden for those small manufacturers with fewer available resources, while ensuring Agency information needs are still met."[12]

B. EPA Has Failed to Evaluate Whether and to What Extent the Proposed Standards will Affect Its Ability to Implement the Law Effectively

While TSCA recognizes the need to reduce reporting burdens for small business, the recent revisions to the law also emphasize the importance of supporting EPA's expanded TSCA programs with comprehensive data on the manufacture, use and exposure profiles of chemicals. Section 26(k) requires EPA to base its decisions on "information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." Section 8 reporting is one of the key tools Congress provided for obtaining "reasonably available information," and section 8(a)(1)(A) calls for submission of such information as EPA "may reasonably require." And in Section 8(a)(5)(C) of TSCA, Congress mandated that "In carrying out this section, the Administrator shall…apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title."

While EPA's authority is expansive in scope, the law contains safeguards to prevent overly broad or poorly justified reporting rules: under section 8(a)(5), reporting may not be "unnecessary or duplicative," and EPA must limit "reporting obligations to those persons likely to have information

[10] 82 Federal Register 56824.

[11] Id. at 56826.

[12] 84 Fed. Reg. at 17711. Similarly, EPA's recognition that the proposed standards can be modified for individual reporting rules acknowledges that changes in the standards based on inflation are not automatic but involve Agency discretion.

relevant to the effective implementation of this title." These safeguards assure that section 8 rules, like CDR, will be framed carefully to focus reporting on information for which the Agency has a strong articulated need under the law. The ''small business exemption" provides additional protections against reporting costs for firms lacking the financial capability to bear them but must be interpreted in light of the important public health and environmental goals of reporting and the constraints already in place to prevent reporting that is unnecessary to effectively implement the law.

In the case of the CDR rule, EPA's proposal preamble explains the benefits of reporting as follows:[13]

> "EPA uses the data reported pursuant to the CDR rule to support health, safety, and environmental protection activities related to chemical manufacturing and use. Manufacturing, processing and use information about chemicals in commerce helps EPA understand exposure to these chemicals and screen and prioritize chemicals to identify potential human health and environmental effects. EPA uses the data reported under the CDR rule to support many activities under TSCA and to provide overall support for EPA and other federal, state, local, and tribal health, safety, and environmental protection activities.
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> CDR provides basic exposure-related data which EPA uses in a wide variety of its activities, from choosing the chemicals EPA will focus on for prioritization and assessment activities to informing response actions, such as to hurricanes and other disasters. For example, in accordance with TSCA section 6(b)(1)(A), EPA is required to consider 'the conditions of use or significant changes in conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.' CDR provides information directly pertaining to the conditions of use, such as the number of sites, the number of workers reasonably likely to be exposed, and how and why the chemical is used, based on the CDR processing and use information. In addition, CDR provides the production volume, the production volume over time, and changes in the volumes under different conditions of use. Such information is expected to contribute to improved understanding of the chemical, including during the prioritization process."

EPA further elaborated on the critical uses of CDR in its supporting documentation for the proposal.[14]

> The CDR data will be instrumental in making initial determinations of the priority designation for chemical substances, addressing the exposure potential, potentially exposed or susceptible subpopulations, the conditions of use, and the volume or significant changes in the volume. Additionally, the CDR data will be instrumental for identifying trends in the manufacturing, processing or use of the chemical substance, serving as an indicator that the priority designation should be revisited.
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> More specifically, CDR data are used in risk evaluation (including scope development and exposure assessment) to:

[13] Id. at 17696-7.

[14] See Chemical Data Reporting: Importance of Data and Need for Data on Inorganic Byproducts, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0321-0007, p. 3.

- aid in characterizing the life cycle and conceptual model of the chemical (from manufacture, processing, use, and recycling activities)
- identify existing conditions of use based on industrial processing and use scenarios as well as commercial and consumer products
- identify potentially exposed or susceptible subpopulations (e.g. number of workers, use in children's products)
- develop release and exposure scenarios for each conditions of use
- estimate releases and exposures associated with conditions of use

Given these broad objectives, comprehensive industry-wide reporting is critical. If EPA is unaware of critical uses of a chemical or understates overall or site-specific production volume, these gaps in understanding will impair its prioritization, risk evaluation and risk management decisions. Thus, EPA has explained that:[15]

> "[W]hile recognizing the burdens on small firms, EPA is required to make risk management decisions based on reasonably available information, such as that collected through CDR. The information collection authority of TSCA section 8(a) reflects congressional recognition of EPA's need for sufficient data from the chemical industry. EPA has concluded that if a firm produces a subject chemical in substantial quantities, it is inappropriate to exempt that company from TSCA section 8(a) reporting requirements. Production data is valuable to EPA as an indicator of chemical exposure and high volume chemical production reflects a greater potential for environmental release."

Significantly, in preparing the proposal, EPA simply adopted the same 100,000 pounds production cutoff from 1984. EPA did not evaluate the impacts of different production caps, even though it did so for the SBA definitions of small manufacturer.[16] Given the importance of CDR under the revised TSCA, EPA's failure to assess the benefits of lower production caps for the proposed inflation adjustment option is contrary to statute, and arbitrary and capricious.[17]

In addition, while EPA estimated the quantitative impacts of the proposed standards, specifically the loss of reports from 129 factories in entirety, and the loss of 888 chemical reports in total, EPA did not assess qualitatively the impact of this loss of information. EPA did not determine whether this universe of reporters provided unique or significant information on conditions of use, potential exposure scenarios, exposures of susceptible populations, and/or other significant life cycle data. This failure to consider the qualitative impacts of the loss of information violates Section 8 of TSCA.

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[15] 84 Fed. Reg. at 17712

[16] See Economic Analysis for the Proposed Rule on the TSCA Section 8(a) Small Manufacturer Definition Update, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0321-0006.

[17] We note the CDR rule already reduces reporting burdens by setting a general reporting threshold for production and import of 25,000 pounds per chemical per site. EPA should evaluate whether thresholds of 50,000 or 75,000 pounds can better achieve the statutory objectives sought in the instant rulemaking.

Expansion of the small manufacturer exemption would also undermine another important goal of CDR reporting identified by EPA:[18]

> "The [small manufacturer] standards should not prevent TSCA section 8(a) rules from providing information that is representative of firms of different sizes. Large and small firms have varying amounts of capital available, and therefore may utilize different production processes, techniques, and equipment. Different methods of production may cause the potential for chemical exposure to vary among large and small firms. It is important for the Agency to be able to monitor these differences."

Exempting producers with sales of $110 million or less except where production of a specific chemical exceeds 100,000 pounds per site would limit EPA's ability to understand how chemical uses and exposure vary across the industry for firms of different sizes and thus undermine its goal of obtaining data that is broadly "representative" of the industry as a whole. The Agency did not address in the proposal whether and to what extent this CDR objective would still be met.

C. Raising the Small Manufacturer Standards Will Have Minimal Economic Benefits

These significant downsides of raising the small manufacturer standards should be weighed against the limited economic benefits of providing additional relief from reporting. Although industry commenters and SBA have advocated raising the standards, they have identified no adverse financial consequences from applying the current standards under the CDR rule. Firms with annual revenues of $110 million have significant resources and should be able to absorb the modest costs of reporting. At the time it promulgated the CDR rule, EPA estimated it would take 13.57 hours and $1,176 to complete a full report for one chemical substance.[19] These are minimal costs and should have negligible financial impacts for all but the smallest manufacturers and importers. Indeed, on an industry-wide basis, EPA has estimated that the proposed standards will reduce reporting costs by only $1,089,341 per year.[20] Accordingly, EPA's failure to assess the impact of the loss of data is particularly concerning. The Agency's proposal reflects a rush to judgment to achieve a limited economic benefit.

D. In Any Event, the Proposed Small Manufacturer Standards Should Not Apply to Mercury Reporting Under the CDR Rule

Regardless of how EPA ultimately decides to modify the small manufacturer standards generally, the application of the proposed standards to mercury has unique impacts that EPA must address. Under the mercury reporting rule promulgated by EPA on June 27, 2018, companies manufacturing or importing mercury (or mercury compounds) in quantities equal to or greater than 25,000 pounds are exempt from reporting on the amount of mercury manufactured or imported, and the amount of mercury exported.[21]

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[18] 84 Fed. Reg. at 17713.
[19] 76 Federal Register 50816, 50854 (August 16, 2011).
[20] 83 Fed. Reg. at 17696.
[21] Compare 40 CFR 713.9(a) and (b).

The sole basis for this exemption, according to EPA, was that "comparable" data would be provided under the CDR rule.[22]

However, this assumption may no longer be correct if EPA modifies the small manufacturer standards as proposed. Under the proposal, companies producing or importing mercury (or mercury compounds) in quantities less than or equal to 100,000 pounds would be exempt from reporting under CDR. If the CDR revisions are finalized as proposed, the net result will be that companies with annual sales of less than $110 million dollars, and producing or importing between 25,000-100,000 pounds of mercury (or mercury compounds), will not be providing critical quantity data under either the CDR or the mercury reporting regime. Without this information, EPA cannot produce the inventory of mercury supply, use, and trade mandated by Congress under Section 8(b)(10) of TSCA. Thus, as applied to mercury, the proposed small manufacturer exemption under CDR would violate TSCA.

When the mercury reporting rule was promulgated, EPA identified three companies reporting under CDR that would be exempt under the mercury reporting rule. There may prove to be others as well, since many more companies report the import of mercury compounds under TRI. In this CDR rulemaking documentation, EPA failed to provide any data or analysis as to the impact of the proposed definition of small manufacturer on the mercury reporting regime, or its independent obligation to prepare the triennial inventory of mercury supply, use, and trade.[23] Without data or analysis demonstrating that the proposed definition of small manufacturer will not affect mercury or mercury compound reporting under CDR, the proposed definition as applied to mercury producers would violate EPA's statutory obligations under Section 8(b)(10) of TSCA. Whatever else it does, accordingly, EPA should retain the current small manufacturer standards for mercury and mercury compounds.

IV. EPA Should Eliminate the Reporting Exemption for Naturally Occurring Chemical Substances

During the 2016 CDR update, it emerged that certain imports of raw asbestos were not reported to EPA. After this situation was brought to EPA's attention, it advised the manufacturer in a letter dated July 28, 2017 that asbestos imports were not subject to CDR requirements because, under 40 CFR §711.6(a)(3), reporting is not required for "naturally occurring chemical substances." In a September 25, 2018 petition under section 21 of TSCA, the Asbestos Disease Awareness Organization (ADAO) and other public health groups requested that EPA modify the CDR rule to require reporting on asbestos. However, EPA denied the petition on December 21, 2018,[24] and its proposed CDR revisions make no mention of changing the "naturally occurring" substance exemption.

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[22] See 83 Fed. Reg. 30063 (June 27, 2018). NRDC is currently challenging the legality of this exemption in the US Court of Appeals. These comments are submitted in the event the Court does not vacate the exemption.

[23] In the Economic Analysis for the Proposed Rule on the TSCA Section 8(a) Small Manufacturer Definition Update, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0321-0006, EPA reviewed the impact of the proposed definition on eight chemical-specific reporting rules, but not on the mercury reporting rule. See Table 2-1.

[24] 84 Fed. Reg. 3396 (February 12, 2019). The petitioners are challenging the petition denial in federal district court. A similar petition was later filed by the Attorney Generals of 14 states and the District of Columbia and was also denied. 84 Fed. Reg. 20062 (May 8, 2019).

There is no conceivable justification for a CDR exemption for asbestos, a uniquely hazardous substance responsible for millions of deaths globally that is subject to multiple EPA regulations and is among the first 10 chemicals undergoing TSCA risk evaluations. Apart from asbestos, moreover, bulk metals and other minerals that EPA would classify as "naturally occurring" are frequently mined or imported in the US and often used to produce substances and products with known hazards and widespread exposure. Knowing the sources and amounts of these naturally occurring materials in US commerce is important to understanding the potential risks of the products they are used to produce as well as any hazards that may arise in transport, processing or disposal. EPA has failed to articulate a rationale for not requiring CDR reporting for naturally occurring substances, except to note that this exemption appears in other TSCA regulations, such as those for Inventory reporting and premanufacture notification (PMN) of new chemicals.[25] However, these reporting rules are now nearly 40 years old and there is no reason to assume that they are justified in the context of CDR reporting and EPA's expanded responsibilities under amended TSCA.

We urge EPA to remove this exemption from the CDR rule or, at a minimum, rephrase it to exclude naturally occurring substances that are subject to regulation under any of the provisions of TSCA, or that have been designated as high priority chemicals that will undergo risk evaluation, or that have been nominated for risk evaluation by a manufacturer.

V. EPA's Provisions for Streamlining Reporting of Inorganic Byproducts Must Retain Safeguards to Assure that There Will Be No Exposure or Environmental Release of These Byproducts

As amended in 2016, section 8(a)(6) of TSCA directed EPA to initiate a negotiated rulemaking process to develop proposed revisions to the CDR rule that would reduce reporting on inorganic byproducts. As instructed, EPA convened this stakeholder process in 2017[26] and, although it did not result in consensus, EPA has now used the input it received from stakeholders to scale back requirements for inorganic byproduct reporting.

It is well-known that byproducts (organic and inorganic) can be important sources of exposure and risk; they therefore should be captured under the CDR rule so EPA can assess their health and environmental impact. We support the proposed addition to the rule of a requirement to report the percent total production volume of a chemical substance that is a byproduct.[27] As EPA notes, it "will be able to identify those manufacturers that recycle portions of their substances or only report to CDR due to their byproduct production. . . .[and would] be better able to understand a larger spectrum of potential exposure scenarios . . ."

The proposed rule also includes three separate provisions for streamlining reporting of inorganic byproducts. EPA has framed these provisions carefully to avoid creating reporting loopholes for inorganic byproduct production activities that could be important for an understanding of exposure

[25] 76 Fed. Reg. 50818.
[26] EPA–HQ–OPPT–2016–0597; 82 Fed. Reg. 47423 October 12, 2017.
[27] 84 Fed. Reg. at 17702-3.

scenarios of concern. It is essential that the final rule continue to place these limits on the scope of the streamlining provisions.

For example, EPA is proposing to allow, but not require, reporting within defined metal compound categories for certain elemental metals and inorganic metal compounds that are produced as inorganic byproducts. As the Agency explains, "[m]anufacturers of these inorganic byproducts would have the option to combine and report multiple inorganic byproduct metal substances, that otherwise would be reported individually as listed on the TSCA Inventory, into one or more specifically-listed categories (*e.g.,* Chromium & Chromium Compounds)."[28] However, this category reporting option would not be available for certain inorganic byproducts of concern, which would need to be reported using their specific TSCA Inventory listings. Falling in this group would be substances that are (1) listed in the 2014 TSCA Work Plan, (2) subject to previous TSCA actions under sections 4, 5, 6 or 7, or (3) undergoing prioritization or risk evaluation under section 6.

The second proposed streamlining provision would exempt specifically identified byproducts that are recycled on-site from two industries: Portland cement manufacturers that produce *Flue dust, Portland cement* (CASRN 68475–76–3) (referred to as cement kiln dust) and wood products manufacturers using the Kraft pulping process to produce *Sulfite liquors and Cooking liquors, spent* (CASRN 66071–92–9). The exemption would be available only if (1) the byproducts are recycled or otherwise used to manufacture another chemical substance within an enclosed system, within the same overall manufacturing process, and on the same site as the byproduct was originally manufactured and (2) the site is reporting under CDR the byproduct substance or a different chemical substance that was manufactured from the byproduct or manufactured in the same overall process. The proposal would allow for petitions to add inorganic byproducts and manufacturing sectors to the exemption list, but they would need to show that these two conditions are met and that the byproduct is not of ongoing regulatory interest to the Agency.

In explaining the importance of exempting only byproducts that are confined to enclosed systems within the same production process and site, EPA emphasized that it considers an "enclosed system to be a system of equipment directly connected to the production process that is designed, constructed, and operated in a manner which *prevents emissions, or the release of any chemical substance into the facility or environment during the production process*," thereby preventing "exposures to workers, the public, or the environment."[29]

This condition for a reporting exemption is critical to avoid compromising CDR requirements and must be carried forward into the final rule without change.

VI. EPA Needs to Do More to Prevent Unjustified CBI Claims and Increase Transparency for CDR Data

Public access to CDR Form Us has been limited because of the large amount of reported data redacted based on claims of confidential business information (CBI). Such CBI claims have been asserted for numerous information elements that are vital for public understanding,

[28] Id. at 17706.
[29] Id. at 17708 (emphasis added).

including the name of the reporting company and technical contact, the identity of the reported chemical, the site of the production or import facility and basic characteristics of chemical production and use, such as whether the chemical is recycled, is site-limited and is present in gas, liquid or solid form, the type of the industrial processing or use operation conducted and the nature of downstream use activities. Our experience is that these CBI claims often lack a credible basis and are asserted either to reduce transparency for the submitter's activities or as a result of a flawed understanding of the applicable legal criteria. Challenging CBI claims for CDR data through the FOIA process has been time-consuming and frustrating, due in part to the protracted process for EPA review of these claims and lack of responsiveness by CBI claimants. These extended delays have made timely access to CDR data (for example, to provide input to the scoping process) virtually impossible.

A top priority of the 2016 TSCA amendments was to reform the process for CBI protection by boosting transparency and imposing greater rigor and accountability on CBI claimants and EPA staff. Reflecting these goals, section 14(c)(3) requires substantiation of all CBI claims at the time of information submittal with the exception of a few narrow information categories. Initially, EPA did not implement this new requirement for 2016 CDR reporting. On January 19, 2017, however, EPA announced that the upfront substantiation requirements in the new law were self-executing and provided a grace period for manufacturers to provide this substantiation for previously submitted Form Us.[30] Unfortunately, the ensuing process was confusing and time-consuming and public access to the 2016 Form Us was more limited than if the substantiation requirements had been in place at the time reports were submitted.

The proposed CDR revisions explicitly require upfront substantiation in accordance with section 14(c)(3). As a result, during the 2020 CDR update, submitters will be substantiating CBI claims as part of their Form Us. This is a positive if overdue step toward implementing the 2016 CBI reforms. However, in itself, it will not reduce unwarranted CBI claims or assure timely access to CDR data. EPA must also step up and expedite review of the adequacy of the substantiation to justify CBI withholding under the law. Recognizing EPA's failure to police CBI claims under the old law, TSCA section 14(g)(1)(A) provides that EPA must review and approve or deny all CBI claims within 90 days; section 14(g)(1)(C) clarifies that this deadline applies to all CBI claims for chemical identify and at least 25 percent of all other claims. So far, there is no evidence that EPA is in fact meeting these deadlines. EPA needs to picks up the pace of CBI reviews or else the lack of timely and meaningful access to Form Us will persist for the 2020 update. This would be a blow to the transparency that Congress sought to achieve in amending TSCA and would impede public participation in TSCA implementation.

As our organizations have previously emphasized, section 14(b)(3) states that general descriptions of processes used in manufacture and processing, as well as of industrial, commercial and consumer functions and applications of chemicals, are not protected from disclosure and cannot be claimed CBI. EPA's proposed CDR revisions explicitly recognize the application of this disclosure mandate to certain industrial processing and use and consumer and commercial use data elements.[31] This is a step in the right direction, but we believe there are other data elements – such as the physical form of the reported chemical and whether it is site-limited or produced as a byproduct – that qualify as "general" processing

[30] 82 Fed. Reg. 6522.
[31] 84 Fed. Reg. 17699.

information that cannot be withheld from disclosure. EPA should acknowledge in the final rule that these data elements cannot be claimed CBI.

VII. EPA Should Revise Form U to Separate Consumer and Commercial Uses

One simple but beneficial improvement in CDR reporting would be to subdivide question b in Part III.B. of Form U into two boxes – one for commercial uses and the second for consumer uses. Because the current Form U combines these two use categories, EPA has acknowledged that it lacks the ability to determine whether the downstream uses of chemicals reported by manufacturers include consumer applications, commercial applications, or both when assessing the Work Plan chemicals.[32] This is an unfortunate result given EPA's intent to capture consumer uses on the Form U, and should be corrected for the next CDR reporting cycle.

VIII. The Byproduct Exemptions in the CDR Rule are Out-of-Date and No Longer Justified, and Should be Removed or Restricted

EPA should eliminate or restrict the exemptions listed in 720.30(g) (referenced by 711.10(c)) from CDR reporting because they are outdated, no longer justified, and are in conflict with EPA's obligation to identify conditions of use in its decisions under the revised TSCA. These exemptions were carried over from the PMN program, are decades old and were not seriously reviewed for their continued relevance to the CDR program, and can no longer be justified under the revised TSCA. The exemptions can be found in 40 CFR 710(c), cross-referencing 40 CFR 720.30(g).

The first exemption excludes from reporting any byproduct burned as a fuel. As applied to inorganic byproducts, this exemption is extremely inappropriate since inorganic byproducts have no value as a fuel, and the burning of inorganic byproducts is a condition of use with exposures of interest to EPA and the public for risk prioritization and risk evaluation purposes. There is no EPA guidance under CDR limiting the applicability of this exemption for inorganic byproducts,[33] in stark contrast to TRI guidance that indicates metal and metal compounds cannot be reported as burned for energy recovery.[34]

The second exemption is for a byproduct "disposed as a waste," including in a landfill or for enriching soil. This exemption is subject to great confusion, since reporting under CDR is currently limited by rule to uses for a "commercial purpose." Since most "disposal" is not for a commercial purpose, it would

[32] TSCA Work Plan Chemicals: Methods Document, February 2012, Appendix C, p. 22. https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf

[33] During the regulatory negotiation, EPA staff pointed to the 2016 CDR Reporting Instructions, at p. 2-5, as guidance potentially limiting the scope of this exemption. However, this guidance refers to where a byproduct is burned for multiple purposes, and thus does not address where the burning purpose is solely as a fuel or otherwise for energy recovery. Nor is there CDR guidance specifying a minimum BTU value where the inorganic byproduct comprises a significant portion of a fuel mixture.

[34] See e.g., Factors to Consider When Using TRI Data, 2015, p. 23, available at https://www.epa.gov/sites/production/files/2015-06/documents/factors_to_consider_6.15.15_final.pdf. During the negotiations, EPA indicated it believed very few facilities were taking advantage of this exemption, citing TRI data, but this argument is circular since under TRI, companies are precluded from reporting burning inorganics for energy recovery under TRI. Moreover, during the negotiations, the oil and gas industry admitted its member companies were taking advantage of the exemption. See https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0597-0073, p. 7.

appear the exemption has limited applicability. However, there are instances where disposal can serve a commercial purpose, such as where a byproduct is sold as landfill cover or as fill in a road bed. EPA guidance is critically needed for defining those activities that could potentially be covered, and then at a minimum, EPA should require one-time reporting to identify the chemicals and uses now falling within the exemption.

However, more fundamentally, since the definition of "conditions of use" under the revised law expressly includes disposal, the fundamental concept of an exemption from CDR based upon "disposal" is inconsistent with the use of CDR to identify conditions of use and potential exposure routes. Possible duplication with TRI or RCRA reporting is a separate issue that can be easily addressed on the CDR reporting form.

Furthermore, the exemption as it applies to "soil enrichment" is both vague and overly broad. It is vague because it is unclear how the exemption applies to inorganic byproducts used to produce a fertilizer or other product used for alleged soil nutrient purposes. To us, it is clear that product usage is not "disposal as a waste," and thus not covered by the exemption, but there is no EPA guidance to this effect.[35]

The exemption is overly broad because "soil enrichment" is a condition of use capable of potentially widespread exposures, through a variety of exposure routes. Particularly for the highly toxic inorganic chemicals listed on EPA's Workplan or identified as PBTs, the exemption for soil enrichment is inconsistent with the purpose of the CDR program.[36] For these inorganic byproducts, EPA has an immediate and compelling need for comprehensive and timely data on conditions of use and exposure routes. And in the case of PBTs and toxic metals on EPA's Workplan, EPA should devote particular attention to the use of these chemicals for soil enrichment purposes because of their hazard, persistence, and bioaccumulation potential, as the Agency evaluates potential risks and considers TSCA regulatory action. Reliance on TRI data alone may be insufficient due to applicable reporting thresholds and other factors limiting TRI reporting. To the extent there is real duplication of data between CDR and TRI, EPA should develop a simple and universal mechanism within CDR to refer to the data already provided.

The third exemption is for byproducts extracted from chemical substances (or mixtures) by physical means.[37] Under the revised TSCA, EPA must identify conditions of use applicable to a chemical or byproduct, and this exemption prevents EPA from using CDR to identify downstream uses of the byproduct once it is physically extracted from a substance. Even assuming arguendo relevance in a PMN context, whether a byproduct is extracted by physical means prior to use in a product downstream is irrelevant in the CDR and chemical prioritization contexts.

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[35] Since TRI covers disposal operations (such as land treatment), but does not cover releases from product usage, there is no duplication issue for CDR to collect product usage information, which is precisely what CDR is designed to do.

[36] In this context, we use the term PBT in a general sense, not to refer to any particular list. See, e.g., The Canada -- United States Strategy For The Virtual Elimination Of Persistent Toxic Substances In The Great Lakes, in which Appendix A lists cadmium, lead, mercury, and tin compounds.

[37] Chemical extraction methods are not covered by the exemption.

Conclusion

We appreciate the opportunity to comment on EPA's proposal. If the Agency finalizes its proposed CDR revisions, we urge that they be finalized in accordance with the recommendations presented above.

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