

Chemical Data Reporting: Importance of Data and Need for Data on Inorganic Byproducts

The Chemical Data Reporting (CDR) collection is unique, providing a comprehensive basic database of the manufacture (including import), processing, and use of TSCA (Toxic Substances Control Act) chemicals in commerce. Key to understanding the universe of chemical substances in commerce in the United States, the data are provided by the manufacturers (including importers) of the chemical substances for both organic and inorganic substances, and include manufacturing-related information such as production volumes, whether the chemical substance is domestically manufactured or imported, if it is used at the reporting site, the physical form of the chemical substance and its maximum concentration, and whether the chemical substance is recycled, reprocessed, or reused. Reporters also provide basic information on the industrial processing and use and the consumer and commercial use of the chemical substance.

Changes implemented for the CDR collection during the last three reporting cycles resulted in data that are more transparent, more useful, and in a more useable format. An increased quality and reliability of the data, faster access to the data, and an increased amount of data for the public have vastly expanded the usefulness of the CDR data. These changes were fully implemented with the 2016 CDR, and EPA and other users are increasingly finding applications for these data.

With these changes and the increased attention of the CDR reporting, the requirement to report for byproducts that are used for a commercial purpose, and especially for inorganic byproducts, became more widely known.

What is a byproduct?

Byproducts are chemical substances that are produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s) (40 CFR 704.3). Byproducts may or may not, in themselves, have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage because they are part of the manufacture of a chemical product for a commercial purpose. Thus, chemical substances that are the byproducts of the manufacture, processing, use, or disposal of another chemical substance or mixture, like any other manufactured chemical substance, are subject to CDR reporting unless they are specifically exempted.

Why is CDR information important for byproducts that are recycled, reprocessed, or reused?

A byproduct that is recycled, reprocessed, or reused is one which otherwise would be disposed of as a waste, but instead is being removed from the waste stream and is being used for a commercial purpose.

A byproduct that is used for a commercial purpose is a chemical substance which is manufactured, processed, and/or used in some manner that may involve exposure to persons or the environment. As with all manufactured chemical substances, CDR information on byproducts is of interest to the EPA because such exposure-related information is not otherwise available, and it is necessary for the Agency to manage risks associated with these chemical substances, to fulfill its mandate of protecting human health and the environment. EPA does not believe chemicals manufactured in a way that characterizes them as byproducts inherently pose lower exposures or risks than chemicals manufactured in other processes.

Without reporting under CDR, the fact that these byproducts exist and that they are recycled, reprocessed, reused, or that they are directly used, would be unknown. This information is not reported elsewhere.

In addition to the uses described elsewhere in this document, the reporting of activities specific to reducing waste or specific to making better use of already existing substances (rather than using virgin materials) is useful to identify the success of programs designed to encourage recycling and other related activities, and could be used to recognize companies, industries, and sectors that are using “green” practices. This information would also help to identify sectors where recycling is not occurring, providing useful data to measure the effectiveness of relevant EPA programs and informing other Agency efforts to encourage practices that reduce waste.

Why is CDR information important for inorganic chemical substances?

The requirement to report information on inorganic chemicals was phased in beginning with the 2006 submission period, and inorganic chemicals were subject to full reporting for the first time with the 2016 submission period. At the time reporting requirements for inorganic chemicals were added, EPA stated that it intends to screen potential risks associated with inorganic chemical substances to set priorities for testing, more detailed risk assessment and potential risk management. The basic impetus for collecting information on organic chemicals also holds for inorganic chemicals.

TSCA, as amended by the Lautenberg Act, requires EPA to “systematically prioritize and assess existing chemical substances.” The statute defines a chemical substance to mean “any organic or inorganic of a molecular identity.”

- CDR information for the recycling, reprocessing or reuse of these chemicals can help in evaluating the extent of chemical use on-site and off-site and aid in chemical prioritization and risk evaluation efforts

As stated by one of the NGO representatives during the June 2017 Negotiating Committee meeting, “you don’t know what you don’t know.” Her point was that when a chemical substance is exempted from reporting, we have no information on it.

This same point was made in the 2003 IUR Amendments FRN, when EPA discussed the reasons for adding the need to report for inorganic chemicals:

For example, EPA recently learned that certain imports of zinc sulfate were contaminated with cadmium. Using the IURA processing and use data on inorganic substances, EPA could have quickly identified importers of zinc sulfate and segments of industry or the general population that might use the chemical. EPA then could have targeted warnings of the potential for exposure to cadmium more effectively, thereby preventing exposures to the groups likely to be the most highly exposed. (68 FR 864-66).

Without the CDR/IUR information on inorganic chemicals, EPA would not have been able to include inorganics in the work plan chemicals prioritization exercise. As described later, the choice of the work plan chemicals relied heavily on information from CDR (previously known as IUR (Inventory Update Rule)). In August 2014, EPA published a risk assessment for antimony trioxide (CASRN: 1309-64-4), one of the TSCA work plan chemicals. The risk assessment document itself directly references both the 2006 and 2012 CDR data.

In general, why is the CDR information important and how has the information been used?

This collection of information is key to strengthening EPA's TSCA program, providing exposure-related data needed to put hazard data into context, in order to develop an understanding of chemical risks. Changes implemented for the CDR collection during the last three reporting cycles resulted in data that are more transparent, more useful, and in a more useable format. An increased quality and reliability of the data, faster access to the data, and an increased amount of data for the public have vastly expanded the usefulness of the CDR data.

The CDR data helps EPA fulfill its mandate by providing a starting point of basic exposure information.

- It provides a "first look" at a chemical, industry, or use by providing information not otherwise available for chemicals listed on the TSCA Inventory.
- It enables more effective early screening of chemicals, their uses, and potential exposures so EPA can prioritize resource expenditures.
- It provides information useful for measuring the success of a regulatory or voluntary program.
- It allows EPA to be proactive rather than reactive by providing information needed to identify industry trends.

Although EPA has used the CDR data for past efforts, changes to TSCA made by the Lautenberg Act made the data even more important. TSCA section 6 now requires EPA to develop and use a process to designate the priority of chemical substances, and that the process:

...shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed. [TSCA section 6(b)(1)(A)]

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.

More specifically, CDR data are used in risk evaluation (including scope development and exposure assessment) to:

- 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

Specific examples:

- In 2012 (and updated in 2014), EPA screened all existing chemicals to identify candidates for assessment over the next several years. The screening process used to identify these chemicals is detailed in the [TSCA Work Plan Chemicals Methods Document](#). This process used CDR data to develop an exposure score, which included identifying if children were likely to be exposed, determining the potential for release when TRI data were not available, identifying the production volume and number of sites, and developing rankings based on the industrial processing and use and on the consumer/commercial uses. Ultimately, 345 chemical substances or chemical compound categories were screened, from which 90 in 2014 were identified as the TSCA Work Plan Chemicals, or chemicals the Agency identified as high priority for risk evaluation. Of this group of 90 high priority chemicals, **11 are inorganic chemicals and include categories**. From 2012 to 2015, five risk assessments were completed, including the inorganic chemical antimony trioxide (CASRN: 1309-64-4) (see discussion later in this document).
- The TSCA Work Plan will continue to inform future prioritization of chemicals for risk evaluation under TSCA as amended by the Frank L. Lautenberg Chemical Safety for the 21st Century Act.
- In 2016, EPA announced the [first 10 chemicals](#) that prioritized for risk evaluation, as required by the Lautenberg Act. As part of this process, EPA [published the scope of the risk evaluation](#) to be conducted. These scope documents utilized CDR data to identify potential exposures, conditions of use and potentially exposed or susceptible subpopulations that the Agency expects to consider during the risk evaluation.
- OPPT develops OECD Emission Scenario Documents (ESDs) and industry-specific generic scenarios for use in developing occupational exposure and environmental release estimates of chemicals for specific use scenarios. CDR data are used in generic scenario / ESD development to:
 - identify types of chemicals commonly used and their functions in the industry of interest
 - estimate number of potentially exposed workers per site
 - develop estimates of exposure levels and releases

Other offices in EPA rely on CDR data:

- ORD (Office of Research and Development) uses CDR data in the development of life-cycle inventories (LCIs) to:
 - aid in characterizing the life cycle of the chemical
 - develop standardized emission/release estimates (i.e., per 1 kg chemical) during chemical production
- OW (Office of Water) uses CDR data in the development of effluent guidelines to:
 - identify facilities in industry sectors of interest for development of new effluent guidelines
 - identify chemicals of interest and their associated processing and use activities (part of Annual Effluent Guideline Review Reports)
- OECA (Office of Enforcement and Compliance Assurance) uses CDR data to:
 - analyze chemical manufacturing production volume trends over time and correlate production with facility discharges to evaluate potential noncompliance and define compliance assistance efforts

Other Federal Agencies:

- Department of Homeland Security (DHS):
 - e.g., useful for tracking or identifying potential illegal drug manufacturing
- Occupational Safety and Health Administration (OSHA):
 - uses the production and use information to better understand worker exposure and industries where exposure may occur ([FR Doc No: 2014-24009](#))
- Center for Disease Control (CDC)
 - the Agency for Toxic Substances and Disease Registry (ATSDR) uses CDR data to develop toxicological profiles
- National Institute of Health (NIH)
 - uses CDR data for exposure and use information published in the Hazardous Substances Data Bank (HSDB)

Under the 2016 Lautenberg Act, states are expected to have increased access to TSCA data and to have more opportunity to assist with and monitor US EPA chemical risk evaluation processes. Because these are new opportunities, the state-federal process is not yet in place. In addition, states are developing internal capacity and expertise. However, states have identified actual and potential data uses:

- State chemical risk evaluation processes
- Emergency Response Planning/Community Right to Know
- State OSHA/worker health and safety
- Facility Siting and Permitting (most likely air and water permits)
- Compliance and enforcement for disposal/releases/mismanagement
- Pollution Prevention Planning and Implementation
- Technical Assistance Programs
- Legacy site cleanup – in the future
- Development of Policy and Legislation

Specifically, states have identified:

- Quality data must be available for use in the future for known and 'unknown' purposes, because there have been only three reporting cycles for inorganic byproducts and TSCA was revised in 2016, potentially enabling states to have better access to the CDR data
- Given pre-emption issues, states want to ensure that EPA has complete and reliable data for effective implementation of new TSCA
- States and the general public are interested in the fate of inorganic byproducts when they are exempt from reporting, including incineration, land disposal, 'soil enrichment,' and 'not used for a commercial purpose.'