



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

*Ensuring the safety of chemicals
Compliance with the law*

EPA's Chemical Data Reporting Rule Largely Implemented as Intended, but Opportunities for Improvement Exist

Report No. 18-P-0226

July 27, 2018



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Abbreviations

CBI	Confidential Business Information
CCD	Chemical Control Division
CDR	Chemical Data Reporting
EPA	U.S. Environmental Protection Agency
HQ	Headquarters
IUR	Inventory Update Rule
OECA	Office of Enforcement and Compliance Assurance
OIG	Office of Inspector General
OPPT	Office of Pollution Prevention and Toxics
TSCA	Toxic Substances Control Act
U.S.C.	United States Code

Cover Photo: Miscellaneous chemicals. (EPA image)

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At a Glance

Why We Did This Project

The U.S. Environmental Protection Agency (EPA), Office of Inspector General (OIG), conducted this audit to determine (1) how the EPA is ensuring that companies are compliant with Chemical Data Reporting (CDR) Rule requirements under the Toxic Substances Control Act (TSCA) and (2) whether the EPA is using CDR data to prioritize chemicals for the purpose of identifying their potential risks to human health and the environment.

Under the CDR Rule, the EPA collects information about the types, quantities and uses of chemical substances produced domestically and imported into the United States. The EPA uses this information, which manufacturers and importers are required to submit every 4 years, to screen and prioritize chemicals for the purpose of identifying potential human health risks and environmental effects, per the methodology outlined in the agency's *TSCA Work Plan*.

This report addresses the following:

- *Ensuring the safety of chemicals.*
- *Compliance with the law.*

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EPA's Chemical Data Reporting Rule Largely Implemented as Intended, but Opportunities for Improvement Exist

What We Found

As required by the TSCA, the EPA is using CDR data to help assess the risks of chemicals in U.S. commerce. We determined that the EPA is implementing the risk evaluation process as outlined in its *TSCA Work Plan* to assess chemicals for human health and environmental risks.

Implementing policies for data quality checks will help tailor the information reported by manufacturers and importers to meet the EPA's needs and improve its usefulness.

In addition, the EPA uses tools such as on-site inspections to monitor companies' compliance with the CDR Rule, and the agency takes enforcement action when violations are identified. However, we noted that while the EPA conducts data quality checks of the chemical information submitted by companies every 4 years, the agency lacks documented policies and procedures that specify how to select and conduct these data quality checks. Policies and procedures would help the EPA implement future data quality checks that meet its information needs, as well as help prevent the possible loss of institutional knowledge during periods of staff turnover or absence.

We also noted that public stakeholders and EPA employees we interviewed cited issues regarding accessing and extracting CDR information from the EPA's CDR database. Our attempt at accessing information from the agency's database also proved difficult. However, during the course of our audit, the EPA took steps to help users more easily navigate the data by providing Microsoft Excel files and a data dictionary. These improvements are intended to enhance the public's ability to obtain information about chemicals in U.S. commerce.

Recommendation and Planned Agency Corrective Action

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention develop and implement a policy and/or procedures for how the agency will conduct data quality checks of CDR Rule data submitted by companies to the EPA.

The Office of Chemical Safety and Pollution Prevention concurred with our recommendation and provided an acceptable corrective action with a milestone date. The proposed corrective action, when completed, will meet the intent of the recommendation.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

July 27, 2018

MEMORANDUM

SUBJECT: EPA's Chemical Data Reporting Rule Largely Implemented as Intended,
but Opportunities for Improvement Exist
Report No. 18-P-0226

FROM: Arthur A. Elkins Jr.

A handwritten signature in black ink, appearing to read "Arthur A. Elkins Jr.", is written over the printed name.

TO: Charlotte Bertrand, Acting Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject audit conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this audit was OPE-FY17-0025. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position.

The EPA's Office of Chemical Safety and Pollution Prevention is responsible for implementing the recommendation in this report.

In accordance with EPA Manual 2750, your office provided an acceptable corrective action and milestone date in response to the OIG recommendation. The recommendation is resolved, and no final response to this report is required. However, if you submit a response, it will be posted on the OIG's website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

We will post this report to our website at www.epa.gov/oig.

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Purpose

The Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA) conducted this audit to determine the following:

- How the EPA is ensuring that companies are compliant with Chemical Data Reporting (CDR) Rule requirements under the Toxic Substances Control Act (TSCA).
- Whether the EPA is using CDR data to prioritize imported and manufactured chemicals for the purpose of identifying the potential for human health and environmental risks.

Background

CDR Rule

The TSCA provides the EPA with the authority to develop reporting, record-keeping and testing requirements and to establish restrictions relating to chemical substances and/or mixtures. Since the TSCA was enacted in 1976, the EPA has taken a number of actions to support its statutory responsibilities:

- In 1977, the EPA promulgated a rule under TSCA Section 8(b), 15 U.S.C. § 2607(a), that requires the agency to compile an inventory of chemical substances in commerce. This inventory is referred to as the *TSCA Inventory*.
- In 1986, the EPA promulgated the Inventory Update Rule (IUR) under Section 8(a) of the TSCA to facilitate the periodic update of information about chemical substances listed in the TSCA Inventory. The IUR also supports other activities associated with the implementation of the TSCA.
- In 2003, the EPA promulgated extensive amendments to the IUR that require the reporting of additional data for certain chemicals to assist the EPA in screening potential exposures and risks.
- In 2007, the EPA identified areas where IUR data collection could be improved to allow the agency to better identify and take follow-up action on chemicals that may pose potential risks to human health or the environment.
- In 2011, the EPA amended the IUR, changing its name to the *CDR Rule*. This name change was intended to better reflect the distinction between CDR data collection, which includes exposure-related data, and the TSCA Inventory itself, which only involves chemical identification information.

During the CDR rulemaking process, which the agency undertook in 2011, the EPA outlined its four primary goals for the reporting of chemical data (Table 1).

Table 1: Primary goals of the CDR rulemaking

	Goal
1	Tailor the CDR information collected to better meet the EPA's overall information needs.
2	Increase the EPA's ability to effectively provide public access to CDR information.
3	Obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Inventory.
4	Improve the usefulness of the information reported.

Source: *TSCA Inventory Update Reporting Modifications; Chemical Data Reporting, Final Rule.*

In the preamble to the final CDR Rule, the EPA stated that it believes the goals outlined in Table 1 can be accomplished in two ways:

1. Expanding the range of chemical substances for which more in-depth processing and use information is to be reported.
2. Adjusting the specific information to be reported, the method and frequency of collecting that information, and confidential business information (CBI) requirements.

Under the CDR Rule, the EPA collects basic exposure-related information from manufacturers (including importers) on the types, quantities and uses of chemical substances produced domestically or imported into the United States. This information constitutes the most comprehensive source of basic exposure-related data on chemicals available to the EPA, and it is used by the agency to assess potential chemical risks to human health and the environment.

Manufacturers (including importers), with certain exceptions, are required to report CDR data every 4 years on chemicals in commerce when yearly production volumes for those chemicals are 25,000 pounds or greater during that 4-year reporting cycle. If manufacturers meet or exceed the yearly production volume in any 1 year (or more) of that cycle, they must report yearly production volumes for all 4 years. Collecting the information every 4 years provides the EPA and the public with up-to-date information on chemicals that are produced in large quantities.¹ For the 2016 CDR 4-year reporting cycle, which comprised years 2012–2015, the EPA received information from 2,247 companies regarding 8,707 chemicals in commerce.

EPA Chemical Risk Evaluation Process

A primary use of CDR data is in the EPA's chemical risk evaluation process. The EPA developed a *TSCA Work Plan Chemicals: Methods Document* in 2012 to

¹ The public only has access to non-CBI for these chemicals.

identify existing chemicals with the highest potential for exposure and hazard; to assess those chemicals as part of the agency's chemical safety program; and, if warranted, to subject those chemicals to risk reduction actions. The work plan methodology details the use of hazard, exposure and persistence/bioaccumulation criteria;² the use of data sources; and how the EPA scores chemicals to identify candidate chemicals for further assessment. The initial 2012 *TSCA Work Plan* resulted in the identification of 83 chemicals for the EPA to assess.

In 2014, the EPA issued an updated work plan to reflect updated industry data about chemical releases and potential exposures submitted to the EPA through the 2011 Toxics Release Inventory³ and the 2012 TSCA CDR cycle. The updated 2014 *TSCA Work Plan* identified a total of 90 chemicals for the EPA to assess. This updated work plan modified the original list of 83 chemicals identified in 2012 by “removing 15 of the original chemicals ..., consolidating one chemical, and adding 23 chemicals.”

In 2016, the TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The amended TSCA provided a framework for progressing the understanding and management of risks associated with existing chemicals, with the goal of preventing unreasonable risks posed by the manufacturing, processing, distribution, use or disposal of these chemicals. The act requires the EPA to identify high- and low-priority chemicals and to evaluate high-priority chemicals against a new risk-based safety standard. By December 2019, the EPA must complete risk evaluations for the first 10 high-priority chemicals, ramp up the risk evaluation process so that 20 high-priority chemicals are under evaluation at all times, and identify 20 low-priority chemicals that will not undergo further evaluation.

The EPA's chemical risk evaluation process for assessing the safety of existing chemicals consists of three stages:

- During the *prioritization* stage, the EPA conducts a risk-based screening process to designate chemical substances as either high-priority or low-priority substances for risk evaluation.
- The chemicals designated as high-priority substances undergo a *risk evaluation*, which determines whether these chemicals, under the

² Hazard criteria are used to assess risks to human health (e.g., carcinogenicity and toxicity), while exposure criteria are used to assess how widely used the chemicals are (e.g., in consumer products or commercial use) and where they can be found (e.g., in drinking water or indoor air). Persistent and bioaccumulation criteria are used to assess how long organisms will possibly remain exposed to the chemicals.

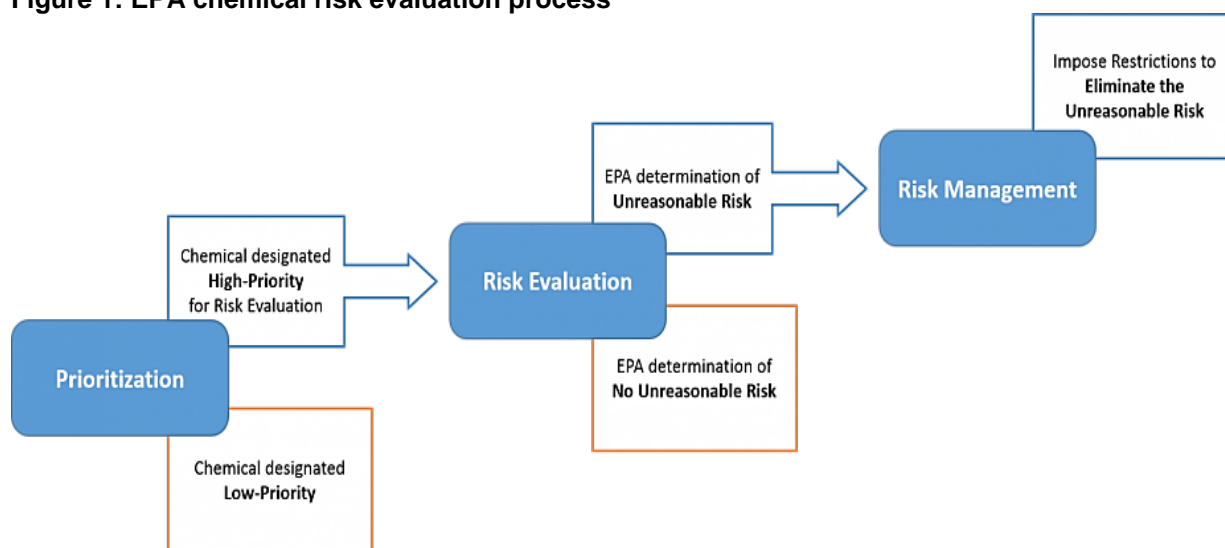
³ Unlike the TSCA Inventory, which lists all chemicals in commerce, the Toxics Release Inventory tracks the management of toxic chemicals that may pose a threat to human health and the environment. U.S. facilities in different industry sectors must report annually how much of each chemical listed in the Toxics Release Inventory is released to the environment and/or managed through recycling, energy recovery and treatment.

conditions of use,⁴ present an unreasonable risk to human health or the environment. Chemicals designated as low-priority substances are taken out of consideration for further assessment at this time.

- If the EPA determines that a chemical presents an unreasonable risk to health or the environment, the chemical then enters the **risk management** stage. At this point, the EPA imposes regulatory restrictions on the manufacture, processing, distribution, use or disposal of this chemical to eliminate the unreasonable risks.

Figure 1 illustrates the three stages of this risk evaluation process.

Figure 1: EPA chemical risk evaluation process



Source: The EPA, “How EPA Evaluates the Safety of Existing Chemicals” webpage.

In 2016, the EPA announced the first 10 high-priority chemicals that it had identified to undergo risk evaluation, as required by the amended TSCA. In addition, the EPA continues to consider strategies for the future use of CDR data for pre-prioritization and risk assessment. On December 11, 2017, the EPA held a public meeting to focus on possible approaches for identifying candidate chemicals to be prioritized for the risk assessment process under the TSCA. The EPA described and took comments regarding a number of possible approaches that could guide the agency in this identification process.

EPA Monitors CDR Rule Compliance

The Office of Enforcement and Compliance Assurance (OECA) monitors compliance with the CDR Rule and takes enforcement actions against companies

⁴ The term *conditions of use* refers to the circumstances, as determined by the EPA, under which a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.

that are not compliant with CDR requirements. OECA oversees compliance and enforcement pertaining to the manufacture, import, use, processing and distribution of chemicals in U.S. commerce. Under the New and Existing Chemicals Program, which is known as the *Core TSCA Program*, OECA works with five participating EPA regional offices to execute its CDR Rule compliance and enforcement responsibilities. The Core TSCA Program is a federal-only program; there is no state compliance monitoring or enforcement.

Public Access to CDR Rule Data

The EPA makes non-CBI CDR data available to the public. The EPA's 2016 CDR cycle database and ChemView database, both available on the agency's website, provide the public, government officials, nongovernmental organizations and industry with access to non-CBI data regarding the manufacture, import, processing and use of chemicals in commerce.

Responsible Offices

The Office of Pollution Prevention and Toxics (OPPT), within the Office of Chemical Safety and Pollution Prevention, is responsible for implementing the CDR Rule. Under the TSCA and the Pollution Prevention Act, the OPPT evaluates new and existing chemicals and their risks. The Office of Civil Enforcement and the Office of Compliance, both within OECA, are responsible for monitoring compliance with the CDR Rule and taking enforcement action against companies that are not compliant with CDR requirements.

Scope and Methodology

We conducted this performance audit from September 2017 through June 2018 in accordance with generally accepted government auditing standards. These standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

We reviewed the TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and the federal regulations for implementing the CDR Rule. We reviewed the EPA's policies, procedures, guidance and TSCA work plans. We reviewed compliance and enforcement information, including the OECA TSCA compliance monitoring strategy; the EPA TSCA enforcement response and penalty policy; and inspection, enforcement and penalty information. We also reviewed documentation related to the EPA's quality assurance and quality control activities for CDR data.

We interviewed EPA headquarters (HQ) management and staff within the Office of Chemical Safety and Pollution Prevention and OECA, as well as

representatives from an environmental nongovernmental organization and an industry trade association. We also queried the EPA’s publicly available CDR data to better understand the transparency and ease of use of the data.

Results

The EPA uses CDR data to prioritize imported and manufactured chemicals to undergo the chemical risk evaluation process for potential human health and environmental risks. In addition, the EPA uses tools—such as inspections and data quality checks of submitted chemical data—to verify that companies are compliant with CDR Rule requirements, and the agency takes enforcement actions as appropriate. However, some improvements can be made to the internal controls for CDR data quality checks so that the EPA can adapt to shifting environments, evolving demands, changing risks and new priorities.

EPA Uses CDR Data to Assess the Risks of Chemicals in Commerce

The EPA uses CDR data, along with additional exposure and hazard data sources, to assess the risks of chemicals in commerce, as required by the TSCA.

Through our analysis of documents and interviews with EPA personnel, we determined that the EPA is implementing the risk evaluation process documented in its *TSCA Work Plan* and is using CDR data to assess chemicals with the highest potential for exposure and hazard according to this work plan.

Chemicals released into the environment as a result of their manufacture, processing, use or disposal **can threaten human health and the environment.** The EPA gathers and assesses information about the risks associated with chemicals, and it implements risk management strategies when needed.

EPA Targets CDR Noncompliance Through Monitoring, Inspections and Penalties

As one component of the EPA’s Core TSCA Program, OECA works with five participating EPA regional offices to monitor compliance and take enforcement actions against companies in violation of CDR Rule requirements.

Since fiscal year 2001, the Core TSCA Program has been centralized in OECA HQ, except for a field presence at EPA Regions 2, 4 and 5. According to OECA management, OECA has been working with the regional offices since fiscal year 2016 to re-establish a Core TSCA Program enforcement presence. As of April 2018, OECA and EPA Regions 2, 3, 4, 5 and 9 conduct compliance monitoring activities and enforcement. EPA Regions 1, 6, 7, 8 and 10 do not participate in the Core TSCA Program. These regions make referrals to OECA for review and potential follow-up.

According to OECA staff, there are approximately five full-time employees at HQ dedicated to Core TSCA compliance monitoring and enforcement. The five participating EPA regions use, on average, one and one-half full-time employees for Core TSCA Program activities.

The OECA *Compliance Monitoring Strategy for the Toxic Substances Control Act (TSCA)* (2016) provides overarching, multiyear guidance on developing and implementing compliance monitoring activities for the Core TSCA Program. When a potential CDR violation is suspected, OECA and regional offices may use the following compliance monitoring tools found in the TSCA compliance monitoring strategy:

- **Telephone inquiries** with a potential violator that may provide the EPA with useful information regarding compliance and/or that may clarify previously reported data.
- **Information request letters** to formally request the submission of additional information or records by a potential violator. This tool can be particularly effective when followed by on-site inspections.
- **Subpoenas** to request additional information from a potential violator to determine compliance. Subpoenas can be issued in lieu of conducting an inspection.
- **Desk inspections or audits**, where EPA staff conduct a documentary inspection (e.g., review and analyze documents submitted in response to an information request).
- **On-site inspections** of a company's facility to determine compliance. Inspections can be *for-cause* in response to a suspected violation or tip, *criteria-based* in response to selected criteria or targeting, or *neutral scheme* for general deterrent effects.

The fiscal years 2016-2017 OECA *National Program Manager Guidance* suggests that regions implementing the Core TSCA Program focus on the 2016 CDR Rule requirements when conducting monitoring activities.⁵ OECA HQ staff said that their highest priority for CDR Rule monitoring and enforcement activities is nonreporting companies. OECA also listed other priorities, such as priority chemicals, sectors with lapsed review and facilities in remote locations.

OECA said that staff review the EPA's internal data from the CDR cycle and ChemView databases, as well as data from external sources and the internet, to identify leads about potential noncompliance related to companies, specific

⁵ The fiscal years 2018–2019 OECA *National Program Manager Guidance* directs EPA regions to adhere to the OECA *Compliance Monitoring Strategy* as appropriate for TSCA programs.

chemicals of concern being manufactured or imported, or industrial sectors. OECA also coordinates with the Office of Chemical Safety and Pollution Prevention to identify particular focus areas for CDR compliance monitoring, address questions about which chemicals are required to be reported under the CDR Rule, and participate in quarterly conference calls to discuss topics related to the CDR Rule.

OECA HQ staff said that previously submitted CDR data are used for both data mining and targeting the office’s compliance and enforcement activities. For data mining, OECA has reviewed CDR data from past reporting cycles to identify companies that did not report chemicals in the current CDR cycle that were reported in previous CDR cycles. For enforcement activities, OECA has used CDR data to identify manufacturers of certain chemical compounds that are in close proximity to impacted communities or contaminated water supplies. OECA HQ staff said that CDR data are also used to identify trends and target on-site inspections.

Core TSCA Inspections

OECA HQ staff said that they typically conduct 20–25 Core TSCA inspections per year (Table 2). In addition to OECA HQ, EPA Regions 2, 3, 4, 5 and 9 also conduct Core TSCA inspections. OECA HQ staff said that most—if not all—Core TSCA inspections of a company’s facility include a CDR compliance review.

Table 2: Core TSCA inspections conducted by EPA region

Fiscal year	EPA region						Total
	2	3	4	5	9	HQ ^a	
2013	5	0	15	0	0	28	48
2014	5	0	16	9	0	27	57
2015	8	0	13	5	0	27	53
2016	12	2	14	1	14	25	68
2017	12	3	16	1	23	^b 0	55
Total inspections	42	5	74	16	37	107	281

Source: EPA Integrated Compliance Information System.

^a OECA HQ conducts Core TSCA inspections on behalf of EPA Regions 1, 6, 7, 8 and 10.

^b According to OECA management, in fiscal year 2017, HQ staff conducted joint inspections with EPA Regions 3 and 9. These inspections were recorded in the agency’s Integrated Compliance Information System as regional inspections.

An OECA HQ inspector we interviewed said that companies are typically given advance notice of an inspection and what information they will need to provide for review. Some companies will then aggregate data and prepare quality control procedural documentation, flow charts and other records that an inspector will use to identify types of chemicals, including any intermediate chemicals, byproducts and other chemicals that are exempt from

the CDR Rule. The inspector said that during this review, the EPA and companies have the opportunity to identify any gaps or deficiencies in the data that the companies are reporting to the agency under the CDR Rule. In some cases, these inspections can result in an EPA request for additional information from a company or the detection of a violation.

Core TSCA Enforcement

Violations of the CDR Rule found by the EPA during an inspection or other compliance monitoring can include nonreporting of chemicals; late reporting; false, incorrect or misleading reporting; or failure to report after the EPA has requested missing information or a correction of erroneous information. For example, in fiscal year 2016, the EPA found that several companies failed to report the manufacture or import of multiple chemicals and that other companies submitted production data after the CDR deadline had passed.

When a violation is found, the EPA can issue a notice of noncompliance, assess a civil penalty, seek injunctive relief or criminal sanctions, or perform some combination of these actions. According to the EPA's *Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13* (1999), an administrative civil penalty is the appropriate response for most violations. Not all enforcement actions taken are a result of inspections. For example, under the EPA's audit policy, companies can voluntarily disclose to the EPA violations of the CDR rule in exchange for penalty reductions. From fiscal year 2013 through fiscal year 2017, the EPA has taken 49 enforcement actions with penalties assessed at over \$6 million (Table 3).

Table 3: CDR enforcement actions and penalties

Fiscal year	EPA region						Total
	2	3	4	5	9	HQ ^a	
2013	1	0	2	2	0	3	8
2014	0	0	6	0	0	1	7
2015	0	0	4	0	1	0	5
2016	3	0	6	0	0	5	14
2017	3	1	5	0	2	4	15
Total enforcement actions	7	1	23	2	3	13	49
Total penalties assessed	\$729,270	\$18,063	\$1,776,557	\$157,099	\$337,845	\$3,446,653	\$6,465,487

Source: The OIG.

^a OECA HQ conducts inspections and takes enforcement actions on behalf of EPA Regions 1, 6, 7, 8 and 10 since those regions do not currently participate in the Core TSCA Program.

The EPA is using CDR data not only to prioritize chemicals for risk evaluation but also as tools to help target potential noncompliance with the CDR Rule.

EPA Needs Policies and Procedures for CDR Data Quality Checks

The EPA conducts quality checks of the chemical data submitted by companies to determine whether data are submitted correctly and to look at chemical information of interest to the agency. However, a lack of documented quality assurance and quality control policies and procedures presents a risk that there may be a loss of institutional knowledge about how data quality checks should be conducted in cases of staff turnover or absence. Policies and procedures would help the OPPT to more consistently implement future data quality checks to meet the agency's information needs each reporting cycle.

According to the U.S. Government Accountability Office's *Standards for Internal Control in the Federal Government*, GAO-14-704G (September 2014), program managers should continually seek ways to improve accountability in achieving an

entity's mission. A key factor in improving accountability is to implement an effective internal control system, which helps an entity adapt to shifting environments, evolving demands, changing risks and new priorities.

Known as *The Green Book*, the ***Standards for Internal Control in the Federal Government*** provides managers with criteria for designing, implementing and operating an effective internal control system. *The Green Book* defines the standards through components and principles and explains why they are integral to an entity's internal control system.

entity's mission. A key factor in improving accountability is to implement an effective internal control system, which helps an entity adapt to shifting environments, evolving demands, changing risks and new priorities.

For each 4-year CDR cycle, OPPT staff said that the OPPT Chemical Control Division (CCD) team

determines what data areas the agency wants to examine (e.g., production volume or where each chemical is used) and the conditions of each check or query. For example, for the 2016 CDR cycle, the CCD conducted 30 different data quality checks of chemical data submitted by companies. These checks included production volumes, chemicals used in children's products, and chemicals that were reported but were not required to be.

CCD staff said that the responsibility for selecting the data queries for each CDR cycle depends on who is on the CCD CDR team at each 4-year interval. Some queries are removed, added and modified based on CCD CDR team feedback. For the 2020 CDR cycle, OPPT staff projected that some of the 30 data quality checks from the 2016 reporting cycle will be replaced with new queries. Once the queries are selected, the OPPT Information Management Division builds a database of the requested information so that OPPT staff can run the queries.

CCD staff said that data quality checks have helped to identify reporting errors. For example, in the 2016 CDR reporting cycle, one company misreported an industrial use chemical as being intended for use in children's products. These checks have also, in some cases, alerted the OPPT to CBI issues or resulted in referrals to OECA.

For the 2016 reporting cycle, CCD staff developed a summary document that lists which CDR data reporting fields should be used for each individual data check or query, how the data should be displayed, and the results. The CCD said that this

document can be used by staff for future reference during the next reporting cycle. Another summary document developed by the CCD provides a detailed overview of some of the steps and challenges associated with data quality checks during the 2016 reporting cycle. However, none of these documents describe the overall data quality check process, such as how roles and responsibilities should be assigned based on division or staff position, how queries should be selected, or what general processes and steps should be followed when conducting a data quality check. Policies and procedures would help the OPPT consistently implement data quality checks for each CDR cycle and meet the agency's information needs.

EPA Can Improve CDR Data Transparency and Accessibility

CDR data inform the EPA, other agencies and the public about chemicals manufactured in, imported into and used in the United States. In addition, an EPA website provides the public, government officials, nongovernmental organizations and industry with access to non-CBI data regarding the manufacture, import, processing and use of chemicals in commerce. Making CDR data readily available to the public enhances the transparency and accuracy of EPA prioritization, assessments and regulatory development.

Under the EPA's fiscal years 2018–2022 strategic plan (Objective 2.2), the EPA aims to **increase transparency and public participation** with industry, environmental groups and other stakeholders.

Difficulties Extracting Data from the CDR Database

Nongovernmental organization and industry stakeholders we interviewed identified difficulties accessing the CDR data in the publicly available database. These stakeholders stated that the CDR database platform lacks functionality for public use of information. In addition, the stakeholders said that the system could use updates to make it user friendly and that data reporting, analysis and dissemination systems for the CDR are not reflective of current technologies or practices.

EPA staff also cited issues accessing the agency's database. According to EPA staff, the system is not user-friendly, and extracting data is a grueling process for anyone not familiar with the system. In addition, EPA staff stated that it is very difficult for them to query the system and that system queries could not be easily viewed. EPA staff reported that they have identified and use "workarounds" to complete their queries.

To test CDR data transparency and accessibility, we accessed the public CDR cycle database to conduct queries. We queried two of the 10 priority chemicals that the EPA identified in 2016 for risk evaluation, per the amended TSCA: Trichloroethylene and 1-Bromopropane. For both chemicals, we queried the database for the total pounds of aggregate production volume and the total number of manufacturers and importers for each; this information is used by the agency to identify chemicals for a risk evaluation. We were able

to obtain the information but noted that accessing data from the public database required downloading a Microsoft Access database to run queries. When opened in Access, the data were displayed in a series of specific tables and queries. We had difficulty identifying the correct tables or queries to retrieve information about these chemicals due to our unfamiliarity with the data and the fields within the database. In addition, the category names of the fields were not easily identifiable. We searched for but were unable to find an online user guide for the database. We contacted the agency staff and requested access to a user guide, and we were informed that a user guide and data dictionary were under development.

Since our communication with agency staff regarding CDR data access issues, the EPA has provided additional options for accessing CDR data. The EPA's website, *Chemical Data Reporting under the Toxic Substances Control Act*, has been updated to include Microsoft Excel files (specifically, Comma Separated Values files) that contain 2016 CDR public database information. The EPA has also provided a data dictionary on this website, with the stated purpose of providing users with assistance in navigating CDR data.

Conclusions

The EPA uses CDR data to prioritize imported and manufactured chemicals for the purpose of identifying their potential risks to human health and the environment. The agency also uses tools—such as targeted inspections, enforcement actions, and data quality checks of company submitted data—to determine whether companies comply with the CDR Rule. However, policies and/or procedures for data quality checks would help tailor information to meet the EPA's needs and improve the usefulness of information reported.

As a result of our audit, the EPA made publicly available on its website Excel files to improve access to CDR information and a data dictionary to help users navigate the CDR data. Improving public accessibility to CDR data helps the EPA to increase the agency's ability to effectively provide public access to CDR information—which ultimately enhances the public's ability to obtain exposure-related information about chemicals in U.S. commerce.

Recommendation

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention:

1. Develop and implement a policy and/or procedures that identify staff roles, staff responsibilities and the general process for how the agency will conduct data quality checks of Chemical Data Reporting Rule data each reporting cycle.

Agency Response and OIG Evaluation

The Office of Chemical Safety and Pollution Prevention concurred with Recommendation 1 and provided an acceptable corrective action and planned milestone date. Recommendation 1 is resolved with corrective action pending.

In addition to a response to our recommendation, the agency provided technical comments on the draft report. Based on the technical comments received, we made revisions to the report where appropriate. Appendix A contains the complete agency response.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date	Potential Monetary Benefits (in \$000s)
1	12	Develop and implement a policy and/or procedures that identify staff roles, staff responsibilities and the general process for how the agency will conduct data quality checks of Chemical Data Reporting Rule data each reporting cycle.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	10/25/18	

¹ C = Corrective action completed.

R = Recommendation resolved with corrective action pending.

U = Recommendation unresolved with resolution efforts in progress.

Agency Response to Draft Report



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL -3 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Draft Report entitled "EPA's Chemical Data Reporting Rule Largely Implemented as Intended, but Opportunities for Improvement Exist."

FROM: Charlotte Bertrand 
Acting Principal Deputy Assistant Administrator

TO: Arthur A. Elkins Jr.
Inspector General

This memorandum is in response to the Office of Inspector General's (OIG's) June 11, 2018, Draft Report entitled "EPA's Chemical Data Reporting Rule Largely Implemented as Intended, but Opportunities for Improvement Exist," Project No. OPE-FY17-0025.

I. General Comments:

The Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's effort in evaluating the following:

- Whether the EPA is using Chemical Data Reporting (CDR) data to prioritize imported and manufactured chemicals for identifying the potential for human health and environmental risks.
- How the EPA is ensuring that companies are compliant with CDR Rule requirements under the Toxic Substances Control Act (TSCA).

OCSPP agrees with OIG's evaluation of how the agency uses CDR data and ensures that companies are compliant with requirements.

II. OCSPP's Response to the Recommendation:

Recommendation 1: Develop and implement a policy and/or procedures that identify staff roles, staff responsibilities and general process for how the agency will conduct data quality checks of Chemical Data Reporting Rule data each reporting cycle.

OCSPP Corrective Action: OCSPP will develop a standard operating procedure document that describes roles and responsibilities and the process to ensure that quality Chemical Data Reporting information is received and used by the agency.

Target Completion Date: October 25, 2018.

cc: Janet L. Weiner, OCSPP
John Latham Jr., OPPT
Bobbie Trent, OCFO

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