Staying Compliant: The Chemical Data Reporting (CDR) Rule of TSCA

WELCOME

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Today's Speakers

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Today's Topics

- CDR Overview and 2020 Updates
  - Devin Millions - Exponent
- Legal Considerations in Performing CDR Reviews
  - Reza Zarghamee

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Agenda

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- Chemical Data Reporting (CDR) Background
  - What is CDR?
- Overview of 2020 CDR Reporting Requirements
  - Submission Period
  - Reporting Responsibility
  - Information Required
  - Where to report
  - Exemptions
- Changes from the 2016 CDR cycle

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What is CDR?

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- Chemical Data Reporting (CDR) is required by section 8(a) of TSCA
- Formerly known as the Inventory Update Rule (IUR)
- EPA collects basic exposure-related information on the types, quantities, and uses of chemical substances produced in the US (includes domestic manufacturing and importation)
- CDR data are collected every four years for certain chemicals in commerce, generally when production volumes for the chemical are 25,000 lbs or greater for a given reporting year.
  - 2016 CDR: 2012 – 2015
  - 2020 CDR: 2016 – 2019

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What is CDR? (cont.)

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- Reporting standard is “known to or reasonably ascertainable by” for all data
- 2020 CDR Revisions Rule published in March 2020 – affects 2020 CDR requirements

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2020 CDR Reporting Requirements

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Reporting Period

- Submission Period: June 1 – November 30

Reporting Responsibility

- Producers of chemical substances (including domestic manufacture and import) that:
  - Are not eligible for an exemption from CDR reporting
  - Are on the TSCA Inventory (as of June 1, 2020)
  - Have a production volume ≥ 25,000 lbs at a site in at least one year from 2016-2019

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2020 CDR Reporting Requirements (cont.)

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- Certain TSCA actions may have one or more of the following effects on specific chemical substances:
  - Reduction in the threshold production volume that triggers reporting requirements (2,500 lbs)
  - Limitation on certain full or partial exemptions from reporting requirements
  - Limitation on use of the small manufacturer exemption

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2020 CDR Reporting Requirements

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Information Required

- 2016 - 2018
  - Production Volumes (manufacture and import)
- 2019 (Principal Reporting Year)
  - Chemical Identity
  - Production Volumes (manufacture and import)
    - Volumes used on site
    - Volume directly exported from site

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2020 CDR Reporting Requirements (cont.)

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- Physical form and percentage of production volume in that form
- Maximum concentration
- Number of workers reasonably likely to be exposed
- Processing and use information
- Indicate if the substance is being recycled or treated as a waste
- Percent production volume that is a byproduct (voluntary)

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2020 CDR Reporting Requirements

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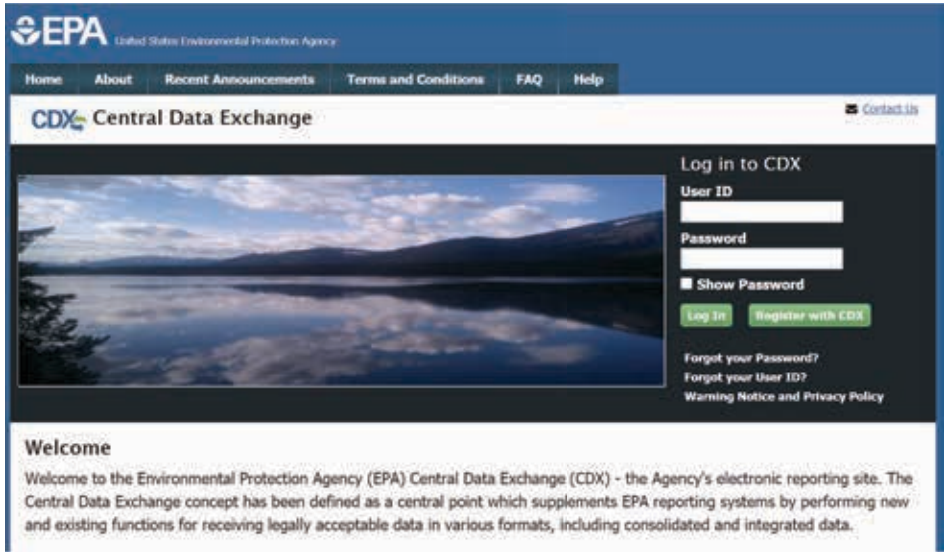
Where to report?

- EPA's Central Data Exchange (CDX)
- A separate Form U must be created and submitted for each site
- EPA has provided extensive documentation on how to use CDX for CDR reporting



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2020 CDR Reporting Requirements

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CDR 2020 Exemptions

- Full exemption from reporting
  - Polymers, microorganisms, certain forms of natural gas & water
  - Naturally occurring chemical substances
  - Articles
- Partial exemption from processing & use reporting
  - Listed petroleum process streams
  - Chemicals of low current interest
- Updated exemptions
  - Small manufacturer definition
  - New exemptions for reporting byproducts

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CDR 2020 Changes

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Overview of changes

- Modifications to reportable data elements
- Confidentiality (CBI) claim process updated to align with Lautenberg Act
- Exemptions for certain byproducts
- Small manufacturer definition update
- Modified reporting process for co-manufactured chemicals

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CDR 2020 Changes

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Modifications to reportable data elements

- Added function category for commercial/consumer products
- Implementation of a phased replacement of the CDR “industrial function and commercial/consumer product” use codes with codes based on the OECD based codes
  - Use of OECD-based codes is required for the 20 “high priority” risk evaluation substances
  - Use either the OECD-based codes or the current CDR codes for all other substances
  - OECD-based codes will be fully implemented and required for all chemicals during 2024 CDR

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CDR 2020 Changes

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Confidentiality Claims

- Upfront substantiation is required for all claims at the time they are made, except for:
  - Supplier identity, trade name and formulation data associated with joint submissions
  - Production volume
- Updated questions and certification statement
- Use data elements cannot be claimed as confidential:
  - Industrial: type of processing and use, industrial sector, function
  - Commercial and Consumer: product categories, functions, commercial or consumer use, used in products intended for children

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CDR 2020 Changes

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New Exemptions for Byproducts

- Specifically listed byproducts that are recycled in a site-limited manner when:
  - substance is recycled or used in physically enclosed systems
  - substance remains on site
  - site is reporting the byproduct substance or another substance from the same overall manufacturing process

  Includes the following byproducts and industries:
  - Kraft Pulping Cycle: black liquor, oxidized black liquor and calcium carbonate
  - Portland Cement Manufacturing: cement kiln dust
- Petition process for the public to request changes to the list of exempted manufacturing processes and related byproduct substances for CDR 2024

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CDR 2020 Changes

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New Exemptions for Byproducts

- Byproducts that are generated in equipment that is not integral to the chemical manufacturing process of the site; specifically:
  - pollution control
  - boiler equipment

Integral Process - the portion of the manufacturing process that is chemically necessary or provides primary operational support for the production of the intended product

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CDR 2020 Changes

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Small Manufacturer Definition

- EPA provided a new two-standard definition for Small Manufacturer
- Total annual sales includes submitter plus parent company, domestic or foreign (if any)

First Standard:

Total annual sales of < $120 million ***and*** annual production volume ≤ 100,000 lbs. at a site

Second Standard:

Total annual sales of < $12 million, regardless of production volume

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CDR 2020 Changes

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Co-Manufactured Chemicals

1st Reporting Methodology

- Contracting company creates the “co-manufactured” chemical report and sends a notification to the producing company via CDX

Reporting responsibilities:

Data Element	Contracting Company	Producing Company
Chemical ID	X	
Production Volume	X	X
Manufacturing Info		X
Processing & Use Info	X	

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CDR 2020 Changes

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2nd Reporting Methodology

- Contracting and producing companies work together to complete the reporting
- Producing company initiates and completes reporting and provides exposure information from their manufacturing site
- Contracting company provides additional supporting information
- Both parties are responsible for the report

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Legal Considerations in Performing CDR Reviews

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Introduction

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- CDR as an internal compliance review
- Maximizing privilege and confidentiality
- Resolving potential non-compliance (EPA's Audit Policy)
- Improving compliance (now and in the future)

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I. Internal Compliance Reviews

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Issues That May Arise in CDR Review

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- CDR review, and other statutorily mandated file reviews, may identify:
  - Evidence of non-compliance with CDR reporting for past reporting cycles (2016)
  - Evidence of non-compliance with TSCA Sections 5, 12, and 13
  - Evidence of systemic non-compliance with TSCA requirements
  - Corporate governance shortcomings
- EPA uses CDR to prioritize specific businesses for inspections and regulatory scrutiny
  - CDR reporting can serve as the beginning of lengthier interactions with EPA on TSCA

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TSCA Penalty Provisions

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- Section 15 makes it a violation to fail to comply with:
  - Any provision of Title I (§ 15(1))
  - Use for a commercial purpose a chemical that is known to have been manufactured or imported in violation of TSCA Sections 5 and 6 (unofficial "quarantine" clause, § 15(2))
- Section 16 imposes civil and criminal liability
  - Civil liability: Maximum daily civil penalty of $37,500 per violation, subject to equitable factors (§ 16(a))
  - Criminal liability: Maximum fine of $50,000 per violation and incarceration up to one year (§ 16(b))

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Statute of Limitations

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- TSCA violations are subject to the "catch-all" 5-year statute of limitations at 28 U.S.C. § 2462
- 3M v. Browner, 17 F.3d 1453 (DC Cir. 1994): Limitations period begins to run on the date of the violation, irrespective of when the non-compliance was discovered
  - Applied faithfully by EPA ALJs and the DC Cir., ***but***:
  - Language of decision allows for flexibility;
  - Regulators disagree with the principle;
  - Has been scaled back recently in certain contexts (*In re Elementis Chromium, Inc.*, TSCA Appeal No. 13-303 (March 13, 2015)); and
  - Potential for *de facto* penalization for expired claims.

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II. Maximizing Privilege and Confidentiality

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Concepts of privilege and confidentiality applicable to environmental audits:

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- Attorney-client privilege
- Attorney work product
- Self-evaluation privilege
- State environmental audit privilege laws are inapplicable, as the relevant TSCA provisions lack state analogues

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Attorney-Client Privilege

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- What is protected?
  - Communications, counsel's evaluation of compliance, and recommendations for corrective action
- What constitutes the "client"?
  - "Control group" test: Only upper-level management
  - *Upjohn Co. v. United States*, 449 U.S. 383 (1981): Low- and mid-level employees also are included
  - Most states follow *Upjohn*; exceptions include Arkansas, Illinois, Maine, Oklahoma, Oregon Nevada, North Dakota, South Dakota
- How may privilege be defeated?
  - Failure to prepare a document that constitutes or informs a legal opinion, failure to circulate the document to appropriate individuals at a corporation, inadvertent disclosure or failure to preserve confidentiality

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Attorney Work Product

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- Applies to notes and memoranda of interviews with company officers and employees prepared “in anticipation of litigation”
  - Phased approach to CDR review
  - Identify the potential for systemic compliance shortcomings upfront
- Can be defeated in the context of environmental audits prepared by non-lawyers
- Can be defeated if the other party to a legal proceeding demonstrates “substantial need”

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III. Resolving Potential Non-Compliance

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Deciding Whether to Self-Disclose

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- The merits of self-disclosure versus correcting without reporting should be made on a case-by-case basis
- EPA Audit Policy: Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations, 65 *Fed. Reg*. 19,618 (April 11, 2000)
  - Up to 100% mitigation of gravity-based penalty component
  - EPA discretion to seek economic benefit penalty component
- Special incentives for:
  - Small Business Owners (65 *Fed. Reg*. 19,630 (April 11, 2000))
  - New Owners (73 *Fed. Reg*. 44,991 (August 1, 2008))

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Conditions for Audit Policy Relief

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1. Systematic discovery
2. Voluntary discovery
3. Prompt disclosure in writing to EPA within 21 days of discovery
4. Independent discovery and disclosure
5. Correction and remediation within 60 calendar days from the date of discovery
6. Prevent recurrence of the violation
7. Repeat violations are ineligible
8. Violations that result in imminent and substantial endangerment are ineligible
9. Cooperation

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Mechanism of Self-Disclosure

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- e-disclosure on EPA's CDX database
  - Exception: New Owner Policy
- Two-step process:
  - Step 1: Initiation of self-disclosure within 21 days of discovery
  - Step 2: Certification of return to compliance within 60 days of Step 1
- System is set up to screen out minor violations
- Companies can control the narrative

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IV. Improving Future Compliance

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TSCA Compliance Recommendations

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- The CDR requirement directly or indirectly touches upon a host of TSCA-related issues and will invariably shed light on a company's TSCA compliance profile
- EPA recommends Environmental Management Systems ("EMS") or equivalent documents to improve environmental compliance
- An EMS is both a quick reference guide and a corporate policy outlining roles and responsibilities of key participants
- A true EMS follows the ISO 14001 standard
- An EMS can focus on just one set of environmental requirements or all environmental requirements relevant to a business

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Core Elements of an EMS

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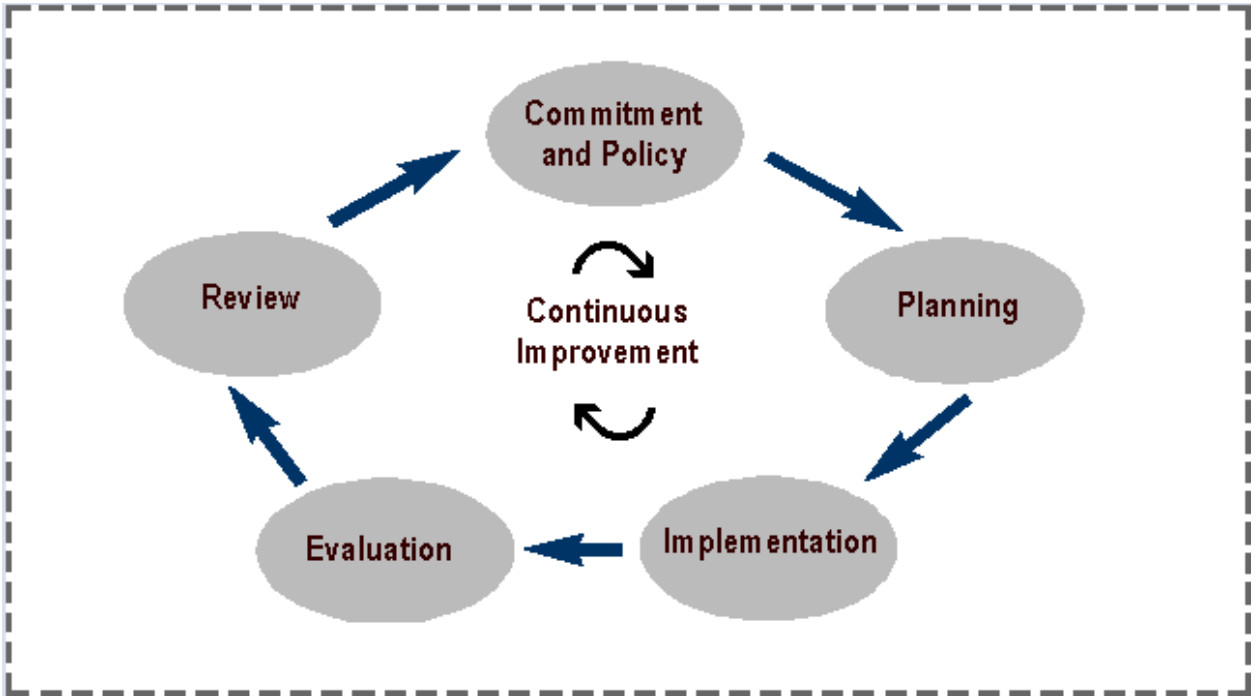
- Continuous loop of improvement
  - Commitment and policy
  - Planning
  - Implementation
  - Evaluation
  - Review (and corrective action)



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Further Considerations

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- Once an EMS or EMS-equivalent is in place, it must be implemented
  - U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs (Updated June 2020)
- For corporate conglomerates, should subsidiaries have their own EMS?
  - Uniformity v. indicia of parent corporation control

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Conclusions and Takeaways

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- Treat CDR review like an audit
- Involve attorneys and specialists
- Be prepared for the unexpected
- Develop proactive strategies to mitigate potential liabilities
- Use it as an opportunity to improve overall TSCA compliance program

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THANK YOU

For questions about today's content, please contact:

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