Exploring the EPA's Chemical Data Reporting (CDR) Rule

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Speaker

Kami Blake – Discussion Host

- Assess regulatory requirements, information management technology and effectiveness of existing HazMat programs to develop and re-engineer compliance solutions
- Prior to joining 3E in 2002, served in Quality Assurance, Supply Chain Management and Process Engineering roles in the biotech and medical device manufacturing industries
- U.S. Marine
  - Computer Programmer / Systems Analyst
  - Two time Navy Achievement Medal recipient for small systems implementation and training

Agenda

- TSCA Overview: Applicable Scope
- IUR vs. CDR
- Reporting Challenges – Byproducts
- Reporting Requirements under CDR
- Reporting Challenges
- Proactive Compliance Strategies
- A Look Ahead
- CDR Information Resources
- Questions

Understanding the Scope

- **Section 4**, authorizes EPA to require testing of certain chemical substances or mixtures to determine potential risk to human health or the environment; (any all links to 12b)
- **Section 5**, grants EPA authority to regulate the manufacture, processing, distribution in commerce, use, and disposal and to require testing of new chemical substances or significant new uses of existing chemical substances; (cradle to grave, PMNs et al)
- **Section 6**, provides EPA with authority to regulate the manufacture, processing, distribution in commerce, and use and disposal of chemical substances; (existing)
- **Section 8**, requires manufacturers and others to keep certain records and to submit reports to EPA; (a, b, c, d, e)
- **Section 12**, requires exporters to notify EPA when exporting certain chemicals (export)
- **Section 13**, requires importers to certify the TSCA status of the chemicals in an import shipment (import)

Understanding the Scope

40 CFR Part 720

The Inventory – **Section 8b** of TSCA requires EPA to compile, keep current, and publish a list of each chemical substance that is manufactured or processed in the United States.

New Chemicals – **Section § 5(a) (1) (B)**

"…prohibits manufacture of any new chemical substance unless manufacturer submits a PMN…"

Existing Chemicals - **Section § 6**

gives EPA the authority to protect against unreasonable risk of injury to health or the environment from "existing" chemical substances.

Enforcement – **Section §§ 11, 15, 16, 17 –**

Gives EPA the authority to inspect establishments , lists prohibited acts and their penalties eg. "$32,500 per day, per violation; may include imprisonment"

The Responsible Parties

- Required and administered by EPA
- Applies to all parties developing new, manufacturing/importing, processing, distributing and disposing regulated chemicals in the US
- TSCA trained personnel are needed to assure compliance
- Submission to EPA requires responsible signatures

Dispelling the Myths

- "TSCA does not apply to everyone"
- "They only go after the big guys"
- "EPA Personnel are ignorant, mean & powerless"
- "It is us against them"
- "I did not know, so I am not responsible"
- "I'll just pay the stupid fine – how much could it be?"
- "My chemical substance has a CAS RN, therefore it is listed on the TSCA Inventory."

IUR to CDR Timeline

- August 2010, the EPA proposed amendments to the IUR rule
  a) Reporting volume of ≥ 25,000 lbs. in any calendar year
  b) Electronic reporting requirement
  c) Reporting frequency decreased from 5 years to 4 years
  d) Increased transparency and public access to information
  e) Subjective "readily obtainable" reporting standard replaced with objective "known to" or "reasonably ascertainable by" standard
- May 11, 2011 EPA suspended 2011 IUR Submission Period
- August 2, 2011, EPA released a pre-publication final Amended IUR rule named the Chemical Data Reporting (CDR) rule
- August 16, 2011, the EPA formally updated the IUR and published the CDR rule in the Federal Register
- September 6, 2011, final revision published to the CDR rule

IUR vs. CDR

Key Changes

- CDR enables the EPA to collect and publish data on manufacturing sites and the manufacturing, processing, and use of chemical substances
- Mandatory electronic reporting (e-CDRweb) via Internet
- Upfront substantiation for CBI
- 4 Year Reporting Cycle
- Reductions in Processing and Use Threshold
- Elaboration on "Byproducts"
- New exemptions
- 40 CFR 710.23-710.39 and 710.43-710.59 are removed. New 40 CFR Part 711 TSCA CDR emerged

Who Does/Doesn't Report?

Manufacturers and Importers DO

- To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage
- Applies to chemical produced coincidentally during manufacture, processing, use, or disposal of another substance/mixture, including byproducts that are separated and impurities that remain in a substance/mixture

Processors DON'T

- The preparation of a chemical substance or mixture **AFTER** its manufacture for **DISTRIBUTION IN COMMERCE** with the purpose of obtaining an immediate or eventual commercial advantage for the processor.

*Do not get confused with the requirement on reporting "processing" information. The word, processing, is mentioned quite often but CDR does not apply to processors.

Who Reports?

Per EPA guidelines, there are **two** kinds of submitters:

1. Authorized Official (AO)
   Person legally responsible for the site's CDR submission, who can certify the form – typically a senior staff member with management responsibility for the person (or persons) completing the form
2. Support Registrant (SR)
   Person designated by the AO to provide supporting information for submission (i.e. on-site contact, a technical contact, employee, or an agent) – may enter and modify data SRs but not permitted to certify the CDR submission

Who Reports?

For manufacturers in the U.S., it seems simple. For importers, it can be more complicated

If your company is an importer, headquartered internationally, using a U.S. agent to receive chemicals then

- Who certifies the Form-U and who fills it out?
- The Company official outside the U.S., or the agent in the U.S.?

Who Reports?

- Under 40 CFR 704.3 "Importer means any person who imports any chemical substance… into the customs territory of the U.S., and includes… (ii) an authorized agent acting on his/her behalf…"
- Therefore, the agent in the U.S. acts as an AO for a U.S. site
- However, the international party can act as a SR if they are more knowledgeable about the chemical substances being imported
- This Support Registrant can fill out the form **but cannot certify it**

Who Reports?

In cases where the international company is a supplier to a manufacturer or importer in the U.S., and they want to keep the chemical identity confidential,

- The U.S. manufacturer can begin a Form U and create a joint submission.
- The international supplier can send in the chemical identity directly to EPA.
- U.S. manufacturer = the Primary AO (and can be Primary SR)
- International supplier = the Secondary AO (Secondary SR)
- Third party AOs and SRs can exist and may be necessary depending on the number of confidential substances from different suppliers.

Exclusions & Exemptions

Manufacture/Import for R&D only Exemption	Small quantities (reasonably necessary)
Small Manufacturer/Importer Exemption	<$4 million/year in total sales
Small Manufacturer/Importer Exemption	<$40 million/year AND <100,000 lbs. in the production volume at any site

What to Report?

For the 2012 CDR

1. **Site Identification Information**
2. **Manufacturing Information**
   - Production volume of 25,000 lb or more during the principal reporting year (PRY of year 2011)
   - Production volume during 2010
   - Non-CBI chemicals = CAS RN and CA index name
   - CBI chemicals = accession # and generic chemical name
   - # of workers reasonably likely to be exposed in ranges
   - Max concentration, physical form, and % PV in the form
   - Whether a substance is being recycled, remanufactured, reprocessed or reused (issue of "byproduct")

What to Report?

3. **Processing and Use Information**
   - For each reportable substance with a 2011 production volume of **100,000 lbs** or more
   - Changed from 300,000 lbs in IUR
   - More information to report if PV is high
   - Industrial Processing and Use (up to 10 combinations to select)
   - Commercial and Consumer Use (up to 10 product categories)

What to Report: Exemptions

- 40 CFR 711.6(b), Partially Exempt (exempt from processing and use reporting) Chemical Substances Termed "Petroleum Process Streams" For Purposes of Inventory Update Reporting and Partially Exempt Chemical Substances are listed
- 40 CFR 711.6(a), totally exempt substances are polymers (with certain exceptions), enzymes, lignin, a polysaccharide (cellulose, gum, starch), a protein (albumin, casein, gelatin, gluten, hemoglobin), rubber, siloxane and silicone, or silsesquioxane
- Microorganisms and naturally occurring chemical substances as described in 40 CFR 710.4(b) are also exempt

What to Report: Exemptions

Additionally, under the new CDR rule, the following will be fully exempt:

1.CASRN 7732–18–5 Water
2.CASRN 8006–14–2, Natural gas
3. CASRN 8006–61–9, Gasoline, natural
4. CASRN 64741-48-6, Natural gas (petroleum), raw liq. mix
5. CASRN 68410–63–9, Natural gas, dried
6. CASRN 68425–31–0, Gasoline (natural gas), natural
7. CASRN 68919–39–1, Natural gas condensates

Reporting Challenges

New Rules for CBI: Focus on Transparency

- Provide upfront substantiation for each processing and use data element claimed as CBI. Submitters cannot claim those data elements as confidential when they are identified as "not known to or reasonably ascertainable by". Rejection of confidentially claims have significantly increased
- **What does that mean?**
  - Higher standard for claiming CBI
  - Identity and use data of the substance must be reported
  - Generic chemical name must be provided
  - Increased public access to previously restricted information

Reporting Challenges

Impact of Definitions under CFR

(from) Readily obtainable	710.43- Information which is known by management and supervisory employees of the submitter company who are responsible for manufacturing… Extensive file searches are not required.
(to) Known to or reasonably ascertainable by	704.3- All information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

What to Report?

Byproducts are **NOT** subject to reporting if they are not used for a commercial purpose.

- Under 720.30(g) or (h) byproduct is excluded from reporting, if a manufacturer (1) burns it as a fuel, (2) disposes of it as a waste, or (3) extract component chemical substances from it for commercial purposes.

EPA guidelines are not clear at this point

Byproducts

Affected Industries

- **Chemical manufacturers and importers**
- **Chemical byproduct users and processors**
- **Electronic component manufacturers**
- **Utilities**
- **Paper manufactures**
- **Metal Manufacturers**

Challenges: Byproducts

Definitions:

"40 CFR 704.3 - A chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture."

This also includes

•Mixture – any combination of two of more chemical substances if the combination does not occur in nature and is not, in whole or part, the result of a chemical reaction...(TSCA Section 3). *Not included in the TSCA Inventory*.

•Complex Byproduct – can be identified as UVCB substances that represent the process stream. Volumes of individual substances do not need to be determined. *Included in the TSCA Inventory*.

•Impurity – a chemical substance which is unintentionally present with another chemical substance.

Challenges: Byproducts

When is a Byproduct Subject to the CDR Rule?

- TSCA Inventory → Byproduct is listed on the TSCA Inventory.
- Commercial Purpose → Byproduct is used for a non-exempt commercial purpose
- Production Volume Threshold → Byproduct is manufactured in volumes of **25,000 pounds** or more during the principal reporting year at a single site.

EPA Office of Chemical Safety and Pollution Preven5on

Challenges: Byproducts

A byproduct is EXEMPT if: (1) it is not used for a commercial purpose, or (2) "its only commercial purpose is for use by public or private organizations that:

a) burn it as fuel,
b) dispose of it as waste, including in a landfill or for enriching soil, or
c) extract component chemical substances from it for commercial purposes."* 40 CFR 720.30 (g) and (h)(2)

*Note that this last part of the exemption only applies to the byproduct, and not to the extracted component chemical substance.

Summary of TSCA Regulations

- Compliance Challenges
  - Broad Scope
  - On-going Regulatory Reform (non-legislative, through agency interpretation)
  - Increased data requirements
  - No one-size fits all automated system
- Required Resources (internal and external)
  - Internal expertise at the substance, mixture and product-level
  - Technical and regulatory expertise and tracking
  - Automated infrastructure
  - 3rd Party expertise and solutions
- Compliance Considerations
  - # of sites, production volume
  - Alternate formulations

Questions to ask!

If you do not SOLELY handle food, drugs, cosmetics, alcohol, tobacco, articles, nuclear products, pesticides, begin with the following questions:

1. Do you have a TSCA Compliance Program? Is it written? Who manages program?
2. Do you have a TSCA Compliance Officer or team? How often are they trained?
3. What types of products does your company manufacture/import, process, dispose or export?
4. What function and end use applications do your products provide?
5. Are your products blends (mixtures) or new substances? Do they have CAS RNs?
6. Are the materials you are using, manufacturing or exporting listed on the TSCA 8b Inventory? How do you access changing TSCA data? Changing/updated requirements?
7. Have you been audited by EPA for TSCA Compliance? What was the outcome?
8. Have you filed an CDR (IUR) report previously? Do you mfg/imp any chemical >25000 lbs?
9. Do your Customers ask you for TSCA Status of the materials you provide?

Compliance Strategies

Preparation and Planning

1. Are all mfg/imp processes documented and reviewed (audited) regularly?
2. Are exemptions confirmed?
3. Is Team trained and at work, R&R clearly defined?
4. Are AO and SR CDX-registered?
5. Is e-CDRweb functional? Form U available?
6. Do you have D&B numbers?
7. What data points will be claimed as confidential? Why?
8. Is a system in place to manage historical, chemical, production, etc. data?
9. Is Management committed?

Compliance Strategies

Commitment vs. Priority

- Executable Plan
- Sustainable Program
- Budget
- Resources
- Tools

Compliance Strategies

Managed risk through organizational commitment

- Resources
- Budget

Investment	Return
Data Management	Access, Aggregate , Integrate and Analyze multiple data sources (internal and external)
Expertise & Proficiency	At all levels of participation, utilizing internal staff and third party SMEs
Environmental Systems	Integrated infrastructure to push/pull data, provide necessary decision making tools

Risk: $24,000 Per Chemical / Per Site

Day-to-Day Compliance

Section 4 – requires health and safety Testing of certain listed chemicals, Links to TSCA 12b
- EPA liaison
- Compile testing dossiers

Section 5 – requires PMNs, SNUNs, *bonafide, consent orders* allows for Exemptions – *R&D, Polymer, LVE*
- Preparation of submissions
- EPA Liaison
- SNUR compliance
- Exemption assessments
- Training – QA PMNs, Train Personnel

Section 6 – management of compliance for existing chemicals

Day-to-Day Compliance

Section 8a – Preparation of CDR Form U
- Collate all data
- Make calculations
- Choose codes
- Claim exemptions
- Compile Form U

Section 8b – Inventory Searches and Certifications
Search and obtain TSCA 8b Inventory Certifications and other global inventories

Section 8c – Allegations of Adverse Effects
Review, Track and Report all TSCA 8C allegations of significant adverse effects

Section 8e – Disclosure of Substantial Adverse Effects
Collate all data and information, compile submission

Day-to-day Compliance

Section 12b – Export Review and Notification to EPA
Conduct 12b Review, prepare and send letter, track and report

Section 13 – Import Review for ALL Shipments
Evaluate and prepare TSCA Stamp

All Sections –
- TSCA Consulting Coordinator – manage all TSCA functions
- Training – general awareness and function-specific
- Internal Audit
- Overall TSCA Compliance – set-up and manage comprehensive program – policies, procedures, documents, records,

Compliance Strategies

People – Super 7 set of roles

Role	Responsibility
AO	Responsible official, signs and submits
SR	Can be Consultant, fills in Form U
IT	Install software, trouble shoot with EPA helpdesk, development programs for interface between your data reports and electronic Form U
TSCA Specialist	Report Scope, CBI, Substantiation, QA for compliance,
Site Production Manager	Confirm data for Part II and III
Sales and Marketing Managers	Confirm data for Part II and III, track new rules and revisions for P & U data /reporting requirements
Supply Chain Manager	Confirm data for Parts I, II, and III

2012 Submission Difficulties

Technical Difficulties with eCDRweb

1. System glitches- slowness, system freeze, error messages, temporarily out of service, etc.
2. Document your form U information separately.
3. One more month to file.

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2012 Submission Difficulties

Heightened disclosure level for Processing and Use Information

- For each reportable substance with a 2011 production volume of **100,000 lbs** or more (Changed from 300,000 lbs in IUR)
- More information to report if PV is high
- Complicated coding system
  - Industrial Processing and Use (up to 10 combinations to select)
  - Consumer and Commercial Use Data, designate up to **10** product categories which correspond to the actual use of the chemical substance

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2012 Submission Difficulties

- 33 product categories are under main topics of:
  1) Chemical Substances in Furnishing, Cleaning, Treatment/Care Products
  2) Construction, Paint, Electrical, and Metal Products
  3) Packaging, Paper, Plastic, Hobby Products
  4) Automotive, Fuel, Agriculture, Outdoor Use Products
  5) Chemical Substances in Products not Described by Other Codes

- Refer to http://www.epa.gov/cdr/tools/InstructionsManual.013112.pdf

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2012 Submission Difficulties

- Upfront substantiation for each processing and use data element claimed as **CBI**
  - Submitters cannot claim those data elements as confidential when they are identified as "not known to or reasonably ascertainable by"
  - Must report the identity & use data of the substance
  - Provide EPA the generic chemical name
- Reporting standard changed
  - **Old:** "Readily obtainable" standard (subjective to the submitter)
  - **New:** "Known to or reasonably ascertainable" standard (objective to a reasonable person)
  - How to determine what is reasonable??

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Lessons Learned

The Main Lesson….

Document, document, document

- → Prepare all ascertainable information
- → Keep detailed and comprehensive records
- → Maintain all historical information indefinitely
- → Justify all applicable exemptions
- → Proactively submit corrections, as necessary

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Errors and Omissions

Violations & Citations
- Liability for Violations or Failure to Report
- Penalties up to $24,000/Chemical/Site

How to Respond
- Cooperate and provide documentation
- Engage consultant or 3rd party provider

CDR Submission Corrections
- Make corrections but that does NOT grant immunity from punitive measures by the EPA. (Strict Liability)
- Always better to self-correct
- Historic pattern of IUR violations has been mostly egregious, deliberate and without regard to the necessity to comply
- EPA has recognized and acknowledged good faith efforts to comply and has helped to mitigate potential fines for non-compliance

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Preparation for the Future

- **Best Practices**
  - Establish a contact with EPA
    - → Ask questions and seek help if needed….demonstrates good faith efforts to comply
  - Document, document, document
  - Enlist professional TSCA consulting and/or information (substance, product, regulatory) services
  - Industry associations such as SOCMA can assist you with training and communicating with EPA

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2016 Highlights

- Processing and use info. threshold further reduced to 25,000 lb/year from 100,000 lb. of the 2012 CDR
- Must report on substance if 25,000 lb threshold is exceeded in **any** calendar year since 2012
- Must report on PV for substance in each year since 2012
- For example:

2012 PV: 0 lb. 2013 PV: 0 lb. 2014 PV: 25,000 lbs. 2015 PV: 0 lb.	**Must report** **2012, 2013, 2014, and 2015** (2014 data must include processing and use information)

2012 vs. 2016 Requirements

- For the 2012 CDR, **no** chemical substance under the 25,000 lbs production volume needs to be reported.
- However for the **2016 CDR**, if your substance is subject to:
  - TSCA section 5(a)(2) SNURs;
  - Section 5(b)(4) Concern List;
  - Section 6 Actions;
  - An order under 5(e) or 5(f);
  - Or relief under a civil action through section 5 or 7;
- Then you must report under the CDR if you import or manufacture equal or greater than 2,500 lbs.

Outsourced Services

- Partial to Full outsource approach
- Scheduled/On-going TSCA compliance support
  - Function-specific
  - Project/Program management
  - Data management
  - Alerts, Notifications, Certifications, Submission, etc.
  - Agency outreach/communication

Outsourced Services

- **TSCA Section 5** - New Chemical Substance Compliance Support, PMN requirements (Low volume exemption (LVE)), Notice of Commencement (NOCs), bona fide letters
  - Consulting with client
  - Consulting with EPA
  - Review of test data and other documents
  - Collaboration with customer chemists and regulatory personnel, industrial hygiene and other professionals
  - Completion of Form 7710-25
  - Proof of submission
  - Duplication of supporting documents
  - Sanitization of PMN
  - Submission of Notification
  - Fee Filing (3E will advise on process)
  - Notice of commencement

Outsourced Services

- **Significant New Use Rules (SNUR) -** Notify EPA 90 days before activity
- **Significant New Use Notice (SNUN)**
- **Inventory Update Rule Support (IUR)**
  - Review inventory update report requirements including result from most recent amendment
  - Review current mechanisms for tracking volumes and other required information of imported and manufactured products and materials at substance level
  - If required information is not currently tracked, recommendations will be made on the best way to do so
  - Complete report for signature and submission
- **TSCA 8b Status Reviews and Certifications**
- **TSCA 8c and 8e Review and Submission**

Outsourced Services

- **Import Certifications -** TSCA Stamp and FIFRA Notice of Arrival of Pesticides
  - Review incoming shipments for TSCA Import Status
  - Provide proper TSCA Import Certification paperwork for all shipments coming into US from overseas
  - If necessary, file FIFRA Notice of Arrival of Pesticides forms with EPA
- **TSCA 12(b) Export Notification Support**
  - Review raw materials and mixtures for presence of substances subject to TSCA 12(b)
  - File any necessary Export Notifications with EPA
- **Exemptions Assessments and Certifications:** R&D, Polymer, LoRex
- **CAS RN Number Application**
  - CAS Inventory Expert Services Purchase Order
  - Complete required documentation

Outsourced Services

- **Day-to-day Compliance**
  - TSCA Compliance Awareness (8c included)
  - R&D Exemption Compliance Support
  - Inventory Update Reporting
  - Global Inventory Status of New Ingredients
  - Export Notification
  - Import Certifications
  - FIFRA Notice of Arrival of Pesticides
- **Training and Auditing**

Cost Comparisons

• EH&S Consultants	$195 - 325/hour
• Law Firms	$325 - 425/hour
• Training	
– Webinars	$99 - 125
– 1 to 2 day Workshops	$900 - 1200
• Audits	
– 3-5 days	$12,000 - 15,000
• Software & Data	Wide Range

2012 CDR Information Resources

- http://www.epa.gov/iur/pubs/guidance/aboutsub.html
- http://www.epa.gov/iur/tools/index.html
- http://www.epa.gov/cdx/index.htm
- http://www.lawbc.com/share/cdrworkshop011912/
- TSCA-Hotline@epa.gov
- 3E Company's CDR Services
  - http://3ecompany.com/products-services/professional-services/tsca-services/
  - 800-360-3220

Questions?

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Thank you!