# *Exploring the EPA's Chemical Data Reporting (CDR) Rule Part II*

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# Agenda

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

# IUR / TSCA Overview

**Important Toxic Substances Control Act (TSCA) Sections**

Section 3 – Definitions

Section 4 – Test rules/orders

Section 5 – Pre Manufacture Notification

Section 6 – Unreasonable Risk Regulation

**Section 8 – Recordkeeping and Reporting**

Section 12 – Exports

Section 13 – Imports

Sections 15 and 16 – Penalties

# 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

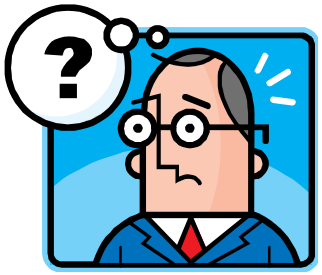
## Impact of Definitions under CFR

| | |
|---|---|
| **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. |
| **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.

# Challenges: Byproducts

How does the company determine chemical identification of a byproduct to comply with the reporting element “Is Chemical Substance Being Recycled, Remanufactured, or Reused”?

Generally, EPA considers each combination of substances resulting from a reaction to be either:

1. A mixture, composed of two or more well-defined chemical substances (named and listed separately)
   or
2. A reaction product, to be listed as a single chemical substance, using one name that collectively describes the products, or, the reactants used to make the products

# Byproducts

## Gray Areas – excerpts from EPA 16-page Guidance Document

(http://www.epa.gov/iur/tools/Q&A_DOCUMENT-Recycling_and_TSCA_Chemical_Substance_Inventory%20-_revised%208-1-11.pdf)

- *Is it possible I am manufacturing a chemical byproduct in the course of manufacturing an article?*
  Response: Yes, potentially.
- *Is a byproduct required to be listed on or added to the TSCA Chemical Substance Inventory (the Inventory)? Are byproducts not listed on the TSCA Inventory subject to the TSCA section 5 PMN requirements?*
  Response: It depends.
- *Are some byproducts with a commercial purpose exempted from the TSCA Inventory listing requirement?*
  Response: In some circumstances.

# Byproducts

## Postponement Request

On January 13, 2012, Chairman of the Committee on Energy and Commerce, Congressman Fred Upton, sent a letter to EPA administrator, Lisa Jackson, requesting to postpone the implementation deadlines of the CDR regulation.

## Unofficial EPA Response

3E was advised this past Monday by an important, high-level EPA source that no delay is planned. It was stated that this would be unfair to those who, through substantial effort and expense, are prepared to comply with the standard. It was mentioned that there is a possibility of extending but NOT postponing the deadline. Our source was clear that the EPA is still pursuing compliance, as scheduled, with the CDR regulation.

# Compliance Strategies

## Program/Process:

- Data Gathering – best practice, automated reports that can "drop" into Form U
  - → taking a look at 2006 records may be instructive
  - → don't forget 2011 data that applies
- Data Review – confirm accuracy and applicability
- Data Input – complete Form U
- Submit – AO to push the button
- Save 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 | QA for compliance, confidentiality claims…can be SR |
| 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 |

# Compliance Strategies

## Preparation and Planning

1. Now! – we are out of time
2. Are flags set?
3. Are exemptions confirmed? (subscription based lists can assist
4. Is Team trained, orientation complete, R&R clearly defined?
5. Are AO and SR CDX-registered?
6. Is e-CDRweb functional?
7. Do you have D&B numbers?
8. What data points will be claimed as confidential? Why?
9. Has Management committed – OT$ may be well spent!

# 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**

# 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.<br>2013 PV: 0 lb.<br>2014 PV: 25,000 lbs.<br>2015 PV: 0 lb. | **Must report**<br>**2012, 2013, 2014, and 2015**<br>(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.

# 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

# Questions?

# Thank you!