

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

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Agenda



- Brief Overview: IUR under TSCA
- IUR v. CDR
- 2012 Reporting Requirements under CDR
 - Who reports?
 - What?
 - When and How?
- Electronic Reporting Guidelines
- CDR Information Resources
- Questions

IUR under 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 under TSCA Overview



The Inventory Update Reporting (IUR) Rule was promulgated under TSCA section 8(a)

Requires manufacturers (including importers) of certain chemical substances on the TSCA Chemical Substance Inventory (TSCA Inventory) to report information regarding the ...

- Manufacturing (including import)
- Processing
- Use

... of those chemical substances.

TSCA Inventory currently has about 84,000 chemicals.

IUR under TSCA Overview



- EPA created the TSCA Inventory in the late 1970s.
- Chemicals in the TSCA Inventory are referred as "existing chemicals" .
- EPA established the Inventory Update Reporting (IUR) rule back in 1986.
 - Initially to collect manufacturing data of chemicals in the TSCA Inventory
 - Also to collect the processing and use data
 - Major changes took place in 2003 and 2006.

IUR v. CDR



- In August 2010, the EPA proposed amendments to the IUR rule.
- Goal of modifications was to provide more detailed information for EPA to better identify and manage risks associated with chemical substances and mixtures.
 - a) Reporting volume of $\geq 25,000$ lbs. in any calendar year
 - b) Requires electronic reporting
 - c) Reporting frequency changes from 5 years to 4 years
 - d) Requirements to assert confidentiality claims or CBI
 - e) Replacing subjective “readily obtainable” reporting standard with objective “known to or reasonably ascertainable by” reporting standard

IUR v. CDR



- On May 11, 2011 EPA suspended 2011 IUR Submission Period (June 1, 2011 to Sep. 30, 2011).
- On August 2, 2011, EPA released a pre-publication final Amended IUR rule named the Chemical Data Reporting (CDR) rule. On August 16, 2011, the EPA formally updated the IUR and published the CDR rule in the Federal Register. However, due to a technical error, incorrect section numbers appeared throughout the regulatory text, and the latest publication of the final CDR rule took place on September 6, 2011.
- 40 CFR §§ 710.23-710.39 and 710.43-710.59 are removed. New 40 CFR Part 711 TSCA CDR emerged.



IUR v. CDR



No Change:

- **Manufacturers (and importers) are to report**
- **Report on TSCA Inventory-listed Substances**
- **Strict Liability for Violations or Failure to Report**
- **Penalties up to \$24,000/Chemical/Site**



Key Changes

- CDR enables the EPA to collect and publish data on the manufacturing sites and manufacturing, processing, and use of chemical substances (More transparency to the public).
- 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

2012 Reporting Requirements: Who Reports?



Manufacturers (including importers)

- 40 CFR 704.3 Definition of Manufacture for commercial purposes:
 - 1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer;
 - 2) Manufacture for commercial purposes also applies to chemicals that are produced coincidentally during manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated and impurities that remain in a substance or mixture.

Who Reports?



- **Not for Processors**
- 704.3 definition of process for commercial purposes:
 - 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?



- Who fills out the electronic Form-U?
- According to the EPA guidelines (<http://www.epa.gov/iur/pubs/QandA.pdf>) **two** kinds of submitters:
 1. Authorized official (AO)
 2. Support Registrant (SR)
- AO is the person legally responsible for the site's CDR submission, who can certify the form (Typically, a senior official with management responsibility for the person (or persons) completing the form).
- SR is the person designated by AO to provide supporting information for submission (i.e. on-site contact, a technical contact, employee, or an agent). SRs are not allowed to certify for the CDR submission but may enter or modify data.

Who Reports?



- For manufacturers in the U.S., it seems simple. For importers, more complicated
- **Hypo**) Your company is an importer from Japan. Its headquarter is in Japan but uses an agent in the U.S. to receive chemicals from Japan. Who certifies the Form-U and who fills it out? Company official in Japan or the agent in the U.S.?
 - *“To certify, the certification statement must be electronically signed and dated by an authorized official at your company”*

Who Reports?

- Does this mean a senior official in Japan can certify the form and act as an AO?
 - EPA's answer: **NO**.
 - 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.



Who Reports?

- However, the person in Japan can act as a SR in case he/she is more knowledgeable about the chemical substances being imported.
- This Support Registrant can fill out the form but cannot certify it.
- **Primary** Authorized Official v. **Secondary** Authorized Official
- **Primary** Support Registrant v. **Secondary** Support Registrant



Who Reports?



- Use Secondary AO and Secondary SR in case of joint submission for CBI.
- **Hypo)** The Japanese company is a supplier to a manufacturer or importer in the U.S. The supplier wants to keep the chemical identity confidential.
- The U.S. manufacturer can begin a Form U and create a joint submission. The Japanese supplier can send in the chemical identity directly to EPA.
- In this case, the U.S. manufacturer = the Primary AO (can have Primary SR)
- The Japanese supplier = the Secondary AO (Secondary SR)
- Tertiary, quaternary, and so on AOs and SRs can exist depending on the number of confidential substances from different suppliers.

Who Reports?



- Exclusions and Exemptions

Manufacture/import for Research and Development only Exemption	Small quantities (reasonably necessary)
Small Manufacturer/Importer Exemption	Less than \$4 million/yr. in total sales
Small Manufacturer/Importer Exemption	Less than \$40 million/year AND less than 100,000 lbs. in the production volume at any site

What to Report?



For the 2012 CDR

1. Site Identification Information

- Company name and U.S. address
- Company Dun & Bradstreet number (request one if you do not have one)
- CDR is site-specific. One Form-U per manufacturing site.
- Technical contact(s) information

What to Report?



2. Manufacturing Information

- Production volume of 25,000 lb or more during the principal reporting year (PRY of year 2011)
- Production volume during 2010
- For Non-CBI chemicals, CAS RN and CA index name
- For CBI chemicals, accession number and generic chemical name

What to Report?



- For the 2012 CDR, Production Volume for PRY 2011 matters!

Scenarios using PVs:

2010 – \emptyset lb. 2011 – 25,000 lb.	Must report PVs of 2010 and 2011 even if the 2010 PV was 0 lb.
2010 – 25,000 lb. 2011 – \emptyset lb.	Not subject to reporting in 2012

What to Report?

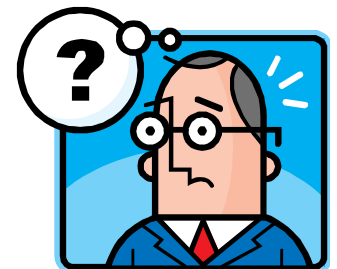


2. Manufacturing Information (cont'd)

- Number of workers that are reasonably likely to be exposed in ranges
- Maximum concentration, physical form, and % PV in the form
- Whether a substance is being recycled, remanufactured, reprocessed or reused (issue of “byproduct”)

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.



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?



- 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”.
- **What does that mean?**
 - Higher standard for claiming CBI
 - You must report the identity and use data of the substance.
 - Provide EPA the generic chemical name.

What to Report?



- **The 2016 Reporting 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.	Must report 2012, 2013, 2014, and 2015 (2014 data must include processing and use information)
2013 PV: 0 lb.	
2014 PV: 25,000 lbs.	
2015 PV: 0 lb.	

2012 v. 2016 Reporting 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.

What to Report?



- Reporting standard changed for processing and use information
 - **Old:** “Readily obtainable” standard (subjective to the submitter)
 - **New:** “Known to reasonably ascertainable” standard (objective to a reasonable person)



What to Report?

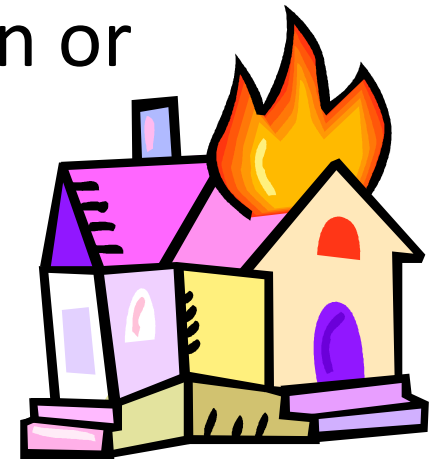


• Definitions under CFR

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?

- Under “Known to or reasonably ascertainable” standard, what other companies in the industry normally do becomes important.
- **Hypo:**
 - Fire at your site and loss of production or import records
 - Reasonable inquiry and due diligence



What to Report?

Exemptions



- Under 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.
- Under 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

When and How to Report?



- Reporting frequency is every four years
- Industry will also now have a five month window for reporting data (February 1, 2012 and June 30, 2012)
- Use e-CDRweb, the EPA's electronic reporting tool, to submit all CDR information via Internet
- For 2016 CDR, submission period is June 1 to Sep. 30 of 2016

When and How to Report?

Electronic Reporting Guidelines



- Register with EPA's Chemical Data Exchange (CDX)
 - Can add CDR to current eTSCA and easy transition
- e-CDRweb operational in November of 2011
- Complete electronic Form U
- Submit completed report through e-CDRweb
- Submissions on paper or CD-ROM will not be accepted

Electronic Reporting Guidelines



- E-CDRweb Tool Highlights
 - Web-based Client
 - Built in Validation
 - Secure Data Transmission
 - Portable Solution
 - XML Import Capability
- Step by step process
 - If you forget your password, you must create a new Form U.

Electronic Reporting Guidelines



Logged in as: IURPRIMARY2, Primary Authorized Official

[Home](#) | [Forms](#) | [User Management](#) | [Resources](#) | [Logout](#)

2012 Form U | 2012 Form U > EXXON CO USA NUMBER 24502 > Chemical Report > Manufacturing Information (2.B)

Primary Authorized Official

Company & Site Identification Information

- Parent Company Information (1.A)
- Site Information (1.B)
- John Doe
- John Doe

Chemical Report

- John Doe
- Technical Contact Information (1.C)
- Chemical Identification (2.A)
- Manufacturing Information (2.B)**
- Industrial Processing and Use (3.A)
- Consumer and Commercial Use (3.B)
- CBI Substantiation Summary

Amendment and Late Submission

- Explanation

SECTION 2.B - MANUFACTURING INFORMATION

Company Identification (2.B.1)	CBI	Number of Workers (2.E.10)	CBI
Site Identification (2.B.2)	<input checked="" type="checkbox"/>	Max Concentration (2.B.11)	<input type="checkbox"/>
Technical Contact Information (2.B.3)	<input type="checkbox"/>	Is chemical being recycled, remanufactured, reprocessed, reused, or reworked? (2.B.12)	<input type="checkbox"/>

Report CY 2011 Production

Activity (2.B.4) **Manufacture** **CBI** **Import** **CBI**

Domestically Manufactured (2.B.5) lbs.

Imported (2.B.6) lbs.

Imported Chemical Never Physically at Site (2.B.7)

Volume Used on Site (2.B.8) lbs.

Volume Exported (2.B.9) lbs.

Report Physical Form	Applies	CBI	% Production Volume of 0 lbs.	CBI
Dry Powder (2.E.13)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>
Pellets/Large Crystals (2.B.14)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>
Water/Solvent Wet Solid (2.B.15)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>
Other Solid (2.B.16)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>
Gas/Vapor (2.B.17)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>

Add Chemical

Add Joint Submission

Upload XML

Validate |
 Save |
 Preview |
 Submit

[CDX Homepage](#) | [MyCDX Homepage](#) | [EPA Homepage](#) | [Terms and Conditions](#) | [Privacy Notice](#) | [CDX Helpdesk \(866\) 890-1995](#)

Electronic Reporting Guidelines



TSCA

Home Forms User Management Resources Logout

2012 Form U
Primary Authorized Official

2012 Form U > EXXON CO USA #20799 > Methylanes Chemical Report > Industrial Processing and Use (3.A)

SECTION 3.A - INDUSTRIAL PROCESSING AND USE

Not Applicable

	Type of Process or Use		Sector(s)		Industrial Function Category		Percent Production Volume		Number of Sites		Number of Workers			
	Code	CBI	Code	CBI	Code	CBI	%	CBI	Code	CBI	Code	CBI		
(3.A.1)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	X
(3.A.2)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	X
(3.A.3)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	X
(3.A.4)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	X
(3.A.5)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	X
(3.A.6)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	X
(3.A.7)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	X
(3.A.8)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	X
(3.A.9)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	X
(3.A.10)	-	<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>		<input type="checkbox"/>	-	<input type="checkbox"/>	-	<input type="checkbox"/>	<input type="checkbox"/>	+

PREVIOUS Next

Add Chemical
Add Joint Submission
Upload XML

Validate Save Preview Submit

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>
- TSCA-Hotline@epa.gov
- 3E Company's CDR Services

Questions?

Thank you!