United States Environmental Protection Agency

Module 1: IUR Modifications and CDR Final Rule (August 2011)

December 2011

Office of Chemical Safety and Pollution Prevention

PREFACE

Welcome to *Training Module 1: IUR Modifications and CDR Final Rule (August 2011)*

This is the first in EPA's series of seven Training Modules to assist you in complying with the requirements of the CDR rule. This Training Module will cover all the changes that were included in the 2011 CDR rule, those for the 2012 submission period as well as those starting with the 2016 submission period.

Detailed information about the 2012 reporting requirements can also be found in the *Instructions for the 2012 TSCA Chemical Data Reporting* guidance document available on EPA's website at www.epa.gov/cdr.

This Training Module does not substitute for the CDR rule and does not impose legally binding requirements on the regulated community or on the U.S. Environmental Protection Agency.

Training Agenda: Module 1

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Introduction

EPA published the final Chemical Data Reporting (CDR) modifications rule in August 2011. Because the rule imposes a variety of changes on reporting, some of the requirements will be phased in over the next two submission periods. Therefore, some of the requirements are effective for the 2012 submission period, and some requirements will be effective for the 2016 submission period.

This Training Module discusses the changes based on when they become effective, so that if you are preparing to report for the 2012 submission period, it will be clear which requirements will affect your reporting immediately and which requirements are delayed until 2016. However, it is important to be aware of the changes effective for the 2016 submission period, because some of the information to be reported begins with calendar year 2012.

Regulatory Text

Regulatory Text for CDR Rule

Regulatory text associated with the CDR rule has been moved to its own part in the Code of Federal Regulations (CFR).

- **New 40 CFR 711** now contains an updated version of the regulatory text that used to be in 40 CFR part 710, subpart C (710.43–710.59).
- Definitions copied from 40 CFR 710.3 and 40 CFR 710.43 have been consolidated into new 40 CFR 711.3. Certain definitions have been modified.

Changes Relating to How to Report for 2012

Electronic Reporting

- **CDX** registration is required for electronic submission.
  - All submitters (including joint submitters) are required to first register with **EPA's Central Data Exchange (CDX)**.
  - Through CDX, submitters access **e-CDRweb** and use the reporting tool to prepare and submit their CDR reports electronically.
- **e-CDRweb** is required to submit Form U.
  - All CDR data (including Form U) must be submitted electronically, **using e-CDRweb**, the CDR web-based reporting tool.
  - Paper submissions will no longer be accepted.

Changes Relating to Who is Required to Report for 2012

Reporting Thresholds

Manufacturing – 25,000 lb threshold: You must complete Parts I and II on Form U if:

- You manufactured (including imported) a chemical substance listed on the TSCA Inventory during the principal reporting year, which is 2011.
- Your chemical substance is not otherwise exempt.
- You manufactured (including imported) **25,000 lb or more** of the chemical substance at a single site during the principal reporting year.

The reporting threshold is the same as the 2006 IUR, but is a change from the 2010 proposed rule.

See 40 CFR 711.8(a)(1)

Processing and Use – 100,000 lb threshold: You must also complete Part III, processing and use information, on Form U, if:

- Your chemical substance is not otherwise exempt from Part III.
- You manufactured (including imported) **100,000 lb or more** of the chemical substance at a single site during the principal reporting year (2011).

EPA replaced the 300,000 lb threshold, which was the previous trigger for processing and use reporting data, with the **100,000 lb** threshold for the 2012 CDR submission period.

See 40 CFR 711.15(b)(3)(iii)

Changes Relating to Who is Required to Report for 2012

Reporting Thresholds, cont'd

Manufacturing by Contract:

- The definition of *manufacturer* at 40 CFR 711.3 now clarifies that both a toll manufacturer and the person who contracts with another person, such as a toll manufacturer, to manufacture a chemical substance are considered to be **co-manufacturers.**
- The CDR rule also added paragraph (c) to 40 CFR 711.22 to clarify the reporting relationship between the contracting company and the toll manufacturer to avoid duplicative reporting but make both co-manufacturers liable if no report is made.

See 40 CFR 711.3 and 40 CFR 711.22(c)

Chemical Substances Subject to Enforceable Consent Agreements (ECAs):

- Under 40 CFR part 790, EPA may enter into an ECA with a manufacturer to obtain testing information, instead of issuing a TSCA section 4 test rule.
- ECAs are considered for chemical substances for which EPA has demonstrated heightened concern and for which EPA needs testing information.
- ECAs are included in the list of TSCA actions which make a chemical substance ineligible for exemption at 40 CFR 711.6.
- As a result, chemical substances subject to ECAs are addressed under CDR in the same manner as chemical substances subject to proposed and final TSCA section 4 test rules.

See 40 CFR 711.6

Changes Relating to What to Report for 2012

Revisions to Requirements for Form U, Part I

Required Company Information:

- The company name and mailing address must be that of the U.S. parent company.
- The U.S. parent company name is the name of the highest level company in the U.S. that directly owns at least 50% of the voting stock of the manufacturer (40 CFR 711.3).

See 40 CFR 711.15(b)(2)

Required Site Identification:

- **Importers:** The site where you import a chemical substance is considered the site of the operating unit within your organization that is directly responsible for importing and controls the import transaction.
  - All importers must provide a U.S. address for the controlling site; it may be a company's headquarters in the U.S.
  - If there is no such site in the U.S., the site address is the U.S. address of an agent acting on your behalf who is authorized to accept service of process for you.
- **Manufacturing under contract:** The site is the location where the chemical substance is physically manufactured.
- **Portable manufacturing units:** The site is the distribution center.

See 40 CFR 711.3, definition of "site"

Changes Relating to What to Report for 2012

Revisions to Requirements for Form U, Part II, Section A

Required Chemical Substance Identification:

- The specific currently correct Chemical Abstracts (CA) Index Name used to list the substance on the Inventory is required.
- The corresponding Chemical Abstracts Service Registry Number (CASRN) is required.
  - In lieu of a CASRN, an EPA-designated TSCA Accession Number must be used for a chemical substance listed on the confidential portion of the TSCA Inventory.
  - The Pre-Manufacture Notice (PMN) number can no longer be used to identify a chemical.
- You will be able to connect directly to EPA's Substance Registry Service (SRS) database from EPA's reporting tool.
- SRS is used to report the correct chemical substance identification information including:
  - CA Index Names and CASRNs for non-confidential chemical substances.
  - TSCA Accession Numbers and generic chemical names for chemical substances on the confidential portion of the TSCA Inventory.
  - See Module 6 (to come) regarding jointly submitting the chemical identity.

See 40 CFR 711.15(b)(3)(i)

Changes Relating to What to Report for 2012

Revisions to Form U, Part II, Section B

Manufacturing-Related Data Elements:

Manufacturers (including importers) are required to report for each reportable chemical substance at each site:

- For calendar year **2010, only** the production volume (domestically manufactured plus imported).
- For the **principal reporting year 2011**:
  - The production volume of the manufactured (including imported) chemical substance used at the reporting site.
  - The volume of the chemical substance directly exported and not domestically processed or used.
  - Whether an imported chemical substance is physically at the reporting site.
  - Whether a manufactured chemical substance, such as a byproduct, is being recycled, remanufactured, reprocessed, or reused.

See 40 CFR 711.15(b)(3)(ii)-(vi)

Changes Relating to What to Report for 2012

Revisions to Form U, Part III, Processing and Use Reporting

Reporting Standard

"Known to or reasonably ascertainable by" (KRA) has replaced "readily obtainable" as the reporting standard.

- KRA means 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. *(40 CFR 704.3)*
- It does not require submitters to conduct new surveys of their customers.
- The level of information that is KRA depends on the submitter's particular circumstances. It may include:
  - Files maintained by the submitter or employees in the submitter's company;
  - Information contained in standard references such as MSDS's;
  - Information from the Chemical Abstracts Service and from Dun & Bradstreet;
  - Customer surveys already in the submitter's possession or control.

"Not known to or reasonably ascertainable by" (NKRA): If any information is NKRA by you (including your company), enter **"NKRA"** in the corresponding box for that data element.

See 40 CFR 711.15(b)(4)

Changes Relating to What to Report for 2012

Revisions to Form U, Part III, Processing and Use Reporting

Upfront Confidential Business Information (CBI) Substantiation

- You may assert a CBI claim for each required processing and use data element only if the linkage of the information with a reportable chemical substance is confidential and not publicly available.
- For each data element claimed CBI, you must submit with Form U detailed written answers to specific questions in order to substantiate the CBI claim.
- Your answers must be signed and dated by an authorized official.

See 40 CFR 711.30(d)

No CBI Claims for NKRA

- When any information is **not known to or reasonably ascertainable by** you and you enter **"NKRA"** in the corresponding box, you may not claim an "NKRA" response as CBI.

See 40 CFR 711.30(a)

Changes Relating to What to Report for 2012

Revisions to Form U, Part III, Section A

Industrial Processing and Use-Related Data Elements

New List of Industrial Sector (IS) Codes

- EPA replaced the 5-digit North America Industrial Classification System (NAICS) codes with 48 Industrial Sector (IS) codes describing industrial activities.
- EPA provides a listing of the corresponding NAICS and IS codes, so that if you know the NAICS code, you can easily identify the IS code.
- When you choose the IS "Other" code, you also need to provide a written description of the industrial activity. Your description may include NAICS codes.

Revised List of Industrial Function Category (IFC) Codes

- EPA revised the Industrial Function Category (IFC) descriptions and codes for the 2012 CDR.
- There are 35 IFC codes that can be used to describe the function of the chemical.
- If you select the IFC "Other" code, you must provide a description of the industrial function of the chemical substance.

See 40 CFR 711.15(b)(4)(i)(B)

Changes Relating to What to Report for 2012

Revisions to Form U, Part III, Section B

Consumer and Commercial Use-Related Data Elements

You must report information **concerning consumer and commercial uses of your chemical substances separately by:**

- Using the revised list of Consumer and Commercial Product Categories (PC) to identify actual uses.
- For each PC, selecting whether the use is consumer or commercial or both.
- Reporting the total number of commercial workers reasonably likely to be exposed for each commercial use identified.

Revised List of Consumer and Commercial Product Categories

- EPA revised the list of descriptions and codes for product categories (PC) corresponding to actual consumer and/or commercial uses of chemical substances.
- The new list provides 33 PC codes grouped under five broader groups of similar uses.
- If you select the PC "Other" code, you must provide a description of the PC.

See 40 CFR 711.15(b)(4)(ii)

Other Changes for 2012

Submission Period:

- Form U reports must be submitted during a submission period.
- For the 2012 CDR, the submission period is February 1 through June 30, 2012.

See 40 CFR 711.20

Water is Now Fully Exempted from Reporting:

- The need to report water (both naturally occurring and manufactured) under CDR has been eliminated.
- Water was removed from the petroleum streams partial exemption list.

See 40 CFR 711.6

Joint Submissions:

- Clarifies procedures for joint submissions between importers and their foreign manufacturer counterparts.
- See Training Module 6 (to come) for further information.

See 40 CFR 711.15(b)(3)(i)(A)

Definitions: Modifications

The following existing definitions were modified as part of the 2011 CDR rule:

- **Principal Reporting Year**: The latest complete calendar year preceding the submission period.
- **Submission Period**: The period in which manufacturing, processing, and use data are submitted to EPA.
- **Site**: A contiguous property unit. Property divided only by a public right-of-way shall be considered one site. More than one plant may be located on one site.
  a) For chemical substances manufactured under contract, the site is the location where the chemical substance is physically manufactured.
  b) The site for an importer who imports a chemical substance is the U.S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance.
  c) For portable manufacturing units sent out to different locations from a single distribution center, the distribution center shall be considered the site.

See 40 CFR 711.3

Definitions: Modifications (continued)

- **Manufacture:** To manufacture, produce, or import for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances.

  When a chemical substance, manufactured other than by import, is: (1) produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production.

See 40 CFR 711.3

Definitions: New

The following definitions were introduced in the 2011 CDR rule:

- **Central Data Exchange (CDX)**: EPA's centralized electronic document receiving system, or its successors, including associated instructions for registering to submit electronic documents.
- **e-CDRweb**: Electronic, web-based CDR tool provided by EPA for the completion and submission of the CDR Form U report.
- **Industrial Function**: The intended physical or chemical characteristic for which a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product, or article; repackaged; or used.
- **Manufacturer:** A person who manufactures a chemical substance.

See 40 CFR 711.3

Changes Relating to Reporting for 2016

Determination of the Need to Report

Meeting the Threshold for Basic Reporting:

You are required to complete Form U if:

- You manufactured (including imported) **25,000 lb or more** of a chemical substance at any single site during **any calendar year since the last principal reporting year** (i.e., 2012–2015).

See 40 CFR 711.15(b)

Exception for Certain TSCA Regulated Substances:

You are required to complete Form U if:

- You manufactured (including imported) **2,500 lb or more** of a chemical substance at any single site during any calendar year since the last principal reporting year (i.e., 2012–2015), if that chemical substance **is the subject of:**
  - A rule proposed or promulgated under TSCA section **5(a)(2), 5(b)(4), or 6**; or
  - An order in effect under TSCA section **5(e) or 5(f);** or
  - Relief that has been granted under a civil action under TSCA section **5 or 7.**

A list of chemical substances subject to the above TSCA actions is available in Appendix B to the *Instructions for Reporting*.

See 40 CFR 711.15(b)

Changes Relating to Reporting for 2016

Changes to Processing and Use Reporting Threshold

- The separate reporting threshold for processing and use has been eliminated, so that any one reporting will complete all three parts of Form U, unless otherwise exempted.

See 40 CFR 711.15(b)

Manufacturing-Related Data Elements

- You must report the total annual volume (domestically manufactured plus imported) of each reportable chemical substance at each site for each complete calendar year since the last principal reporting year (i.e., 2012–2015).
- This replaces the 2012 CDR requirement to report production volume for 2010 and 2011.

See 40 CFR 711.15(b)(3)(iii)

When to Report

- The reporting frequency is every four years, therefore the next report is due in 2016.
- For the 2016 CDR, the submission period will be from June 1 to September 30, 2016.
- The principal reporting year will be 2015.

See 40 CFR 711.20

Training Modules for CDR Rule

There are 7 Training Modules for the CDR rule. The Training Module you have just completed is highlighted below in the list of all seven Training Modules. You may select another Training Module if you wish to continue your review of the CDR.

Module 1: IUR Modifications and CDR Final Rule (August 2011)

Module 2: Reporting Requirements for the 2012 CDR

Module 3: Completing Form U for 2012

Module 4: Registering with CDX for CDR Reporting

Module 5: Using the e-CDRweb Reporting Tool

Module 6: Joint Submissions

Module 7: Byproducts