Overview of TSCA Chemical Data Reporting Requirements and e-Reporting

November 16, 2011

Office of Chemical Safety and Pollution Prevention

AGENDA

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INTRODUCTION

- In August 2011, EPA published the Chemical Data Reporting (CDR) rule, formerly known as the Inventory Update Reporting (IUR) rule.
- To prepare for the next submission period, which starts February 1, 2012, EPA has developed a variety of informational materials
  - Guidance documents.
  - Webinar to demonstrate e-CDR web tool, 9/23/11.
  - Preview period for e-CDR web, 9/26-30/11.
  - **Today's webinar.**

BACKGROUND ON THE TSCA Inventory AND IUR/CDR

- EPA created the TSCA Chemical Substance Inventory (TSCA Inventory) in the late 1970's
  - Comprehensive listing of chemicals in commerce
  - Chemicals added through the New Chemicals program
  - Currently lists over 85,000 chemicals
- EPA created the Inventory Update Reporting (IUR) rule in 1986
  - Used to collect updated information initially on the manufacture and now also on the processing and use of a subset of TSCA Inventory-listed chemicals
  - In August 2011, EPA updated the IUR, changing the name to the Chemical Data Reporting (CDR) rule to clarify that it is a data collection rule

BACKGROUND: USES OF CDR DATA

- CDR data constitute the most comprehensive source of basic screening-level, exposure-related information on chemicals available to EPA and will:
  - Help EPA, other agencies, and the general public develop an understanding of potential chemical risks.
  - Provide the American public with greater access to a wide range of information on those chemicals to which their children and families may be exposed every day.
- EPA needs both hazard and exposure data to:
  - Prioritize chemicals for further assessment
  - Assess data needs for particular chemical substances under TSCA sections 4 or 8
  - Inform risk management decisions made under TSCA sections 5 and 6

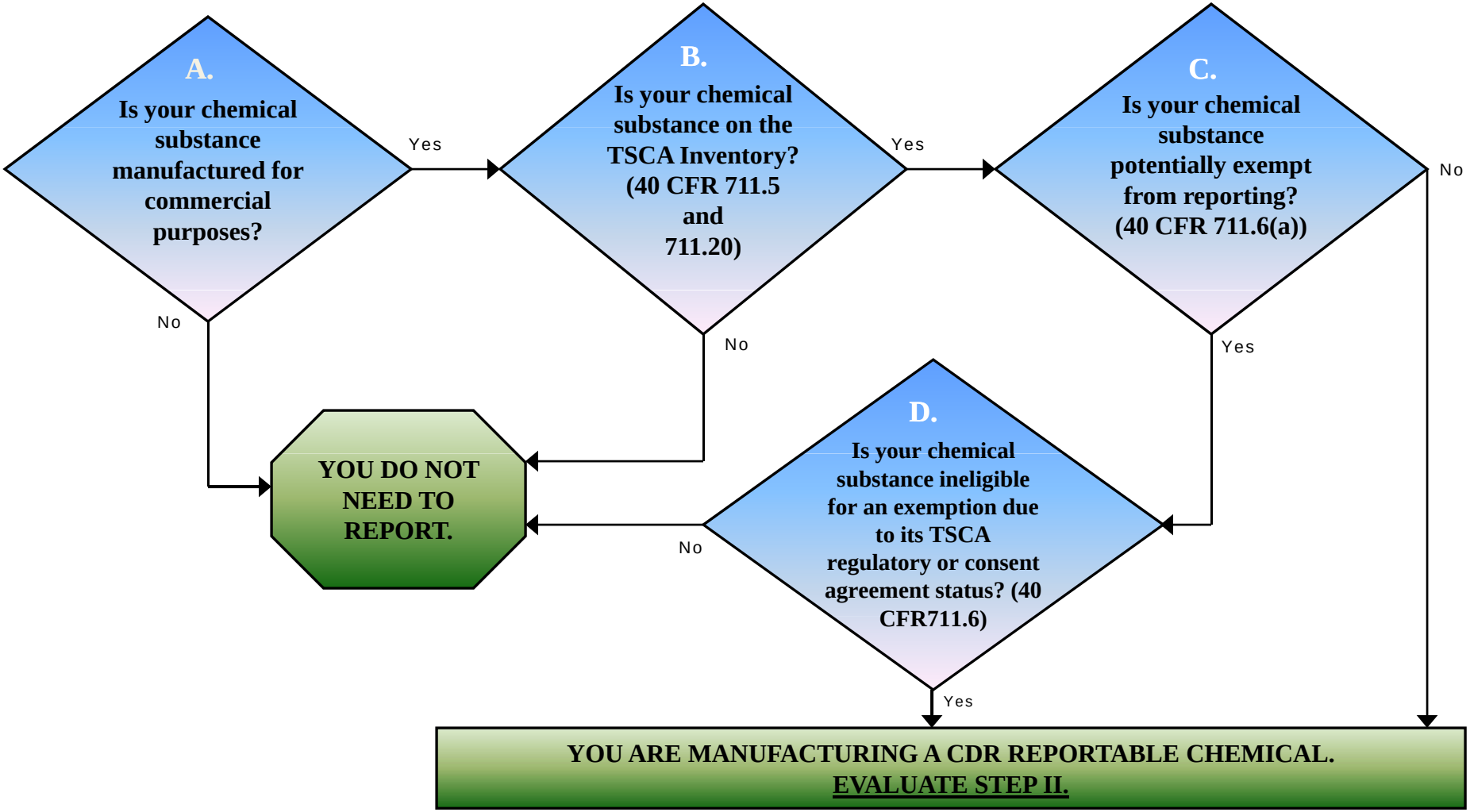
The 2012 CDR: Overview

- **Who:** Manufacturers, including importers, of:
  - TSCA Inventory-listed chemical substances
  - Manufactured for commercial purposes
  - With a 2011 production volume of 25,000 lb or greater at a site
  - Unless otherwise exempted
- **When:** The next submission period is February 1, 2012 through June 30, 2012.
- **How:** Submitters are required to use e-CDR web, the CDR reporting tool, and EPA's CDX to create and submit Form U electronically.
  - Form U is used to submit the required CDR information.
  - EPA will no longer accept paper submissions or electronic media, such as diskettes or CD-Roms.
  - Submitters must first register with CDX to access e-CDR web.

Determining Your Need to Report

- **Reporting requirements have changed.**
  - If you reported under the 2006 IUR, you should review the 2012 reporting requirements
  - Reporting may be required for chemical substances that you did not previously report in past IUR reporting cycles.
- Consider the following steps to determine whether you are required to report for **each chemical substance** that you domestically manufacture (including import) during calendar year 2011:
  - **Step I:** Is Your Chemical Substance Subject to the CDR Rule?
  - **Step II:** Are You a Manufacturer Who is Required to Report?
  - **Step III:** What Information Must You Report?

Step I: Is Your Chemical Substance Subject to the CDR Rule?



Step I. Question A.: Is Your Chemical Substance Manufactured for Commercial Purposes?

- For the purposes of the CDR rule, a chemical substance is manufactured (including imported) only if it is manufactured (including imported) for commercial purposes.
- NEW EPA modified the definition of ***manufacture*** at 40 CFR 711.3 to include:
  - **Extraction of a component chemical substance** from a previously existing chemical substance or complex combination of chemical substances, and
  - **Contract (toll) manufacturing** which involves co-manufacture of a chemical substance by the toll manufacturer and the contracting company.
- ***Manufacture for commercial purposes*** is defined at 40 CFR 704.3 to include:
  - Import, produce or manufacture for a commercial advantage
  - Substances produced coincidentally during manufacture, processing, use or disposal of another substance or mixture
    - Byproducts separated from the other substance or mixture
    - Impurities that remain in the other substance or mixture

Step I. Question B.: Is Your Chemical Substance on the TSCA Inventory?

- The following are sources of information which may help determine if your chemical substance is listed on the TSCA Inventory:
  - Public TSCA Inventory
    - Chemical substances whose identity is not considered confidential
    - Generic identification of chemical substances whose identity has been claimed CBI
  - Substance Registry Service (SRS) Database
    - EPA database at www.epa.gov/srs
    - Regulatory status info, including TSCA Inventory status
  - Company records
    - Letters regarding TSCA Inventory status
    - Previous IUR submissions
    - Commenced Premanufacture Notice (PMN) substance information

Step I. Question B.: Is Your Chemical Substance on the TSCA Inventory?

Question B: *(cont'd)*

- For mixtures, you may need to determine if chemical substances that are components of the mixture are on the Inventory.
  - When a mixture is imported, determine Inventory status for each component chemical substance.
  - If you domestically manufactured a mixture, determine Inventory status for any component chemical substances that were formed from a chemical reaction that occurred as part of manufacturing the mixture.

Step I. Question C.: Is Your Chemical Substance Potentially Exempt from Reporting?

Five TSCA Inventory substances or groups of substances are largely exempt from reporting under the CDR rule:

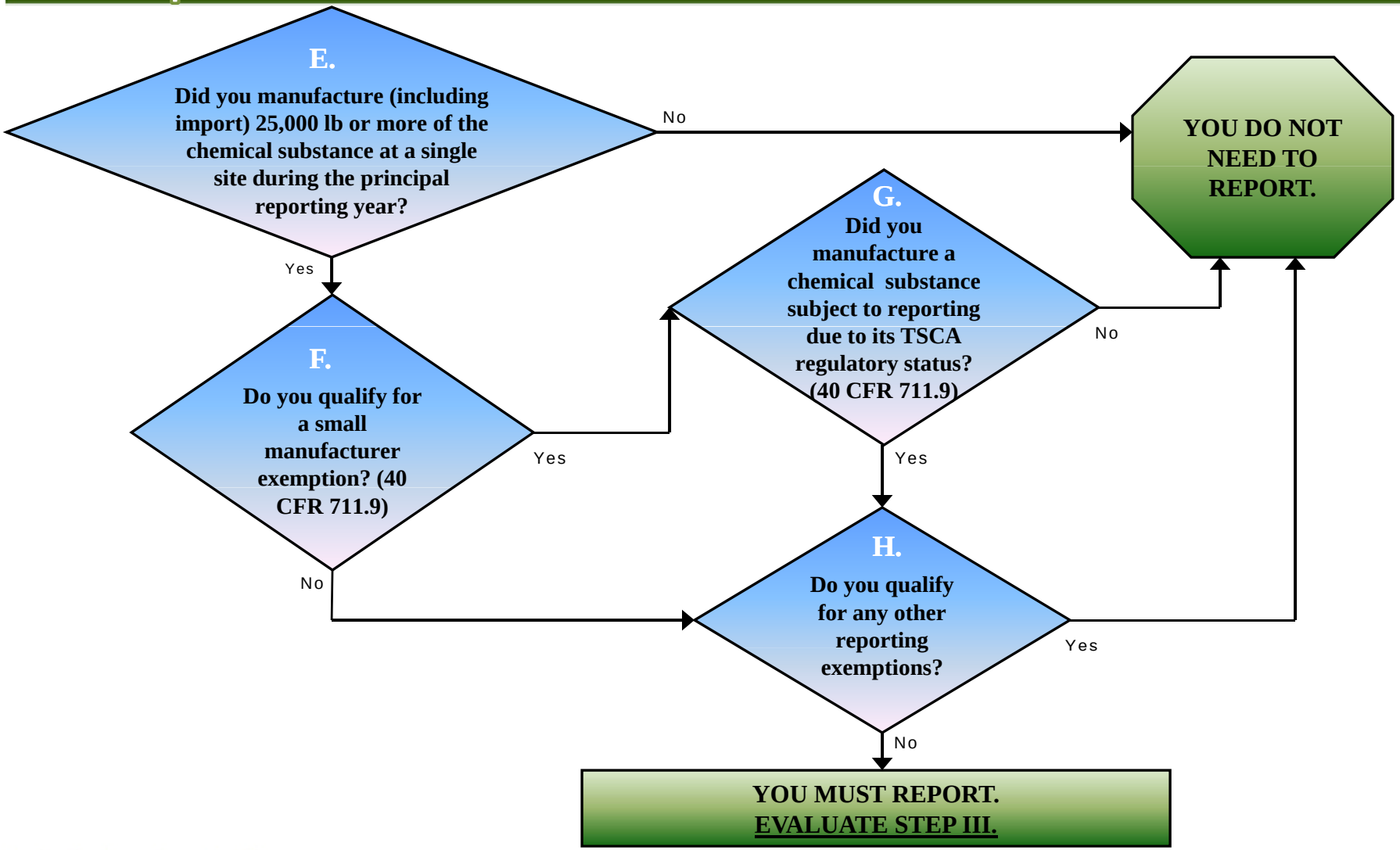
- **Polymers**: Most substances that are generally considered polymers.
- **Microorganisms**: Living organism as defined at 40 CFR 725.3.
- **Certain forms of natural gas**: Listed at 40 CFR 711.6(a)(4).
- **Naturally occurring substances**: Based on production method.
- **Water**: Naturally occurring and manufactured.

Step I. Question D.: Is Your Chemical Substance Ineligible for Exemption?

With the exception of naturally occurring substances, chemical substances must be reported if they are the subject of any of the following, even if the chemical substance is otherwise exempt:

- A rule proposed or promulgated under **TSCA Sections 4, 5(a)(2), 5(b)(4), or 6**
- An order issued under **TSCA Sections 5(e) or 5(f)**;
- Relief that has been granted under a civil action under **TSCA Sections 5 or 7**; or
- NEW An enforceable consent agreement (ECA) under **40 CFR Part 790**.

Step II: Are You A Manufacturer Who Is Required to Report?



Step II. Question E.: Did You Manufacture (Including Import) 25,000 lb or More In 2011?

- Evaluate each chemical substance separately for each site.
- The 25,000 lb reporting threshold is for the principal reporting year of 2011 only
  - If your 2010 production volume for a chemical substance is over 25,000 lb, but your 2011 production volume is less than 25,000 lb, you do not meet the reporting threshold and do not have to report.
- If you both domestically manufacture and import the same chemical substance:
  - Add the domestically manufactured and imported volumes at each site for calendar year 2011 to determine production volume.
- Mixtures are not reportable, but their components may be
  - The 25,000 lb threshold is applicable to each manufactured component chemical substance of a mixture.

Step II. Questions F. & G.: Small Manufacturers

Question F: Do You Qualify for a Small Manufacturer Exemption?

You are considered a small manufacturer and may qualify for an exemption for a chemical substance if:

- **Total 2011 annual sales < $4 million**
  Combine yours + your parent company's sales; production volume (PV) not an issue.
  OR
- **Total 2011 annual sales < $40 million and annual PV ≤ 100,000 lb at a site**
  Combine yours + your parent company's sales.

Question G: Did you manufacture a chemical substance subject to reporting due to its TSCA regulatory status?

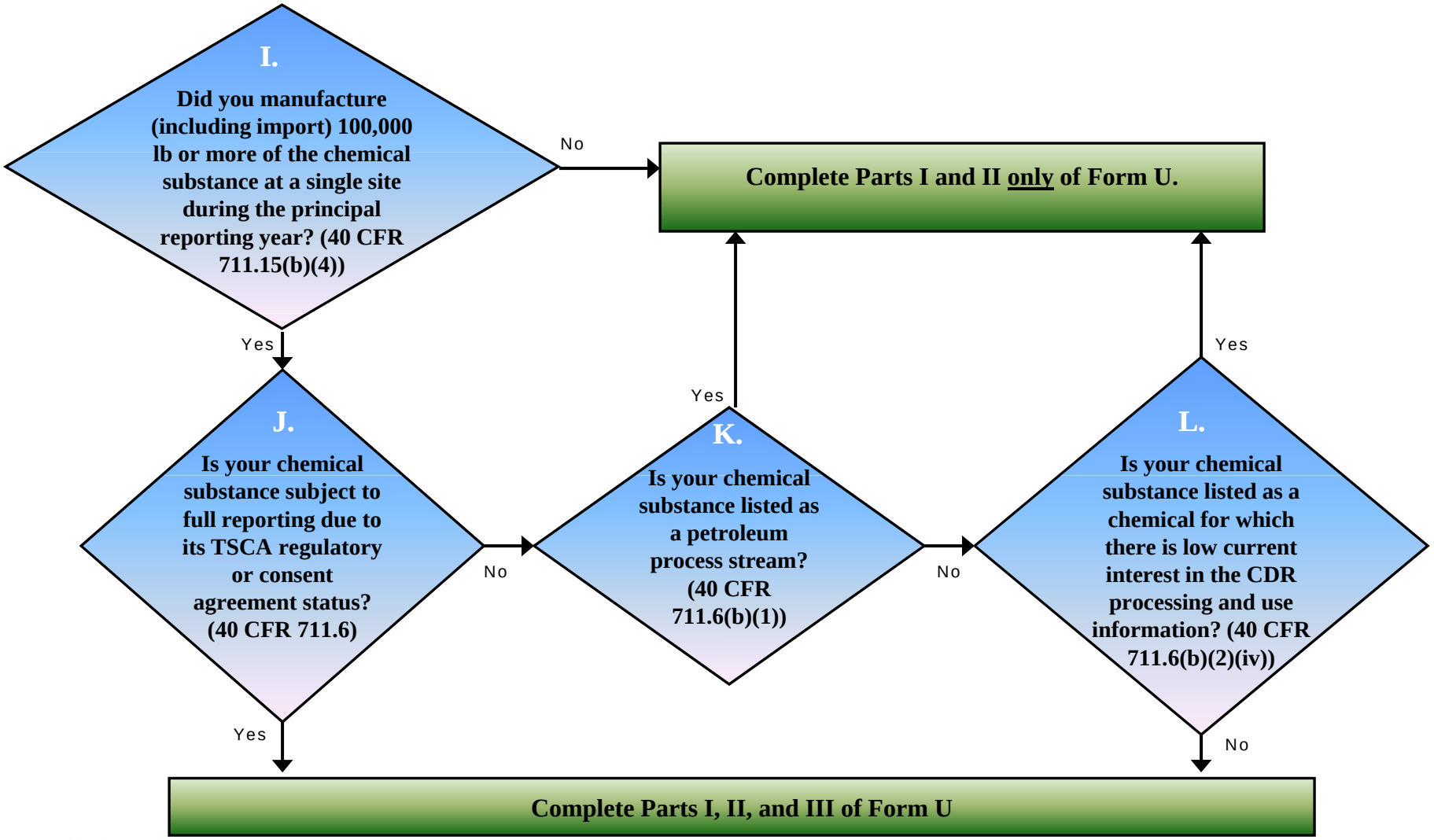
Small manufacturers are not exempt if the chemical substance manufactured (including imported) is the subject of any of the following:

- A rule proposed or promulgated under **TSCA Sections 4, 5(b)(4), or 6**, or
- An order in effect under **TSCA Section 5(e)**, or
- Relief granted under a civil action under **TSCA Sections 5 or 7**.

Step II. Question H.: Do You Qualify for Any Other Reporting Exemptions?

- You are exempt from reporting under CDR if the reportable chemical substance is solely:
  - Manufactured in **small quantities for research and development.**
  - Imported as part of an **article**.
  - Manufactured under any of the circumstances identified in **40 CFR 720.30(g) and (h)**, such as impurities, non-isolated intermediates, certain byproducts.
  - Manufactured (including imported) and within one year of the start of the submission period you submitted all of the information required by the CDR rule in response to another rule promulgated under **TSCA section 8(a).**

Step III: What Information Must You Report?



Step III. Question I.: Did You Manufacture (Including Import) 100,000 lb or More of a Chemical Substance?

- Evaluate each chemical substance separately for each site you are reporting.
- NEW The 100,000 lb reporting threshold for processing and use is for the principal reporting year of 2011 only
  - If you manufacture (including import) 100,000 lb or more of a reportable chemical substance at a single site in calendar year 2011, you are subject to full reporting, which includes Part III of Form U, in addition to Parts I and II.
  - If you manufacture (including import) over 100,000 lb of a reportable chemical substance in 2010 and less than 100,000 lb in 2011, you do not meet the reporting threshold for processing and use and are not required to complete Part III for that chemical substance.

Step III: Question J: Is Your Chemical Substance Subject to Full Reporting Due to Its TSCA Regulatory Status?

Chemical substances, with the exception of naturally occurring substances, manufactured in amounts of **100,000 lb or more** are subject to full reporting (Parts I, II, III of Form U), regardless of any exemptions for which the chemical substances would otherwise qualify, if they are the subject of any of the following:

- A rule proposed or promulgated under **TSCA Sections 4, 5(a)(2), 5(b)(4), or 6**;
- An order issued under **TSCA Sections 5(e) or 5(f)**;
- Relief that has been granted under a civil action under **TSCA Sections 5 or 7**; or
- NEW An enforceable consent agreement (ECA) under **40 CFR Part 790**.

Step III: Questions K & L: Partial Exemptions

A partial exemption under CDR means that only Parts I and II of Form U must be completed, regardless of the production volume.

Question K: Is Your Chemical Substance Listed as a Petroleum Process Stream?

If your chemical substance is listed as a *petroleum process stream* at 40 CFR 711.6(b)(1), it is partially exempt from CDR requirements.

Question L: Is Your Chemical Substance Listed as Low Current Interest in the CDR Processing and Use Information?

If your chemical substance is listed in 40 CFR 711.6(b)(2)(iv), EPA has determined there is a *low current interest in the CDR processing and use information* and this chemical is partially exempt from CDR requirements.

The 2012 CDR: What Information is Reported?

- Part I: Site Identification Information
  - Reported once for each site
- Part II: Manufacturing Information
  - Required for each reportable substance with a 2011 production volume of **25,000 lb** or more
- Part III: Processing and Use Information
  - Required for each reportable substance with a 2011 production volume of **100,000 lb** or more

NEW

NEW

- Reporting standard for all Parts:
  - *Known to or reasonably ascertainable by (*aka *KRA)*
  - Replaces *readily obtainable* for processing and use information
  - Not *KRA* (or *NKRA*) may not be claimed as CBI

The 2012 CDR: *KRA* Reporting Standard

- *KRA* defined: "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." *See 40 CFR 704.3*
- *KRA* information includes, but is not limited to information that may be possessed by employees or other agents of the submitting company.
  - Employees or other agents may include persons involved in the research, development, manufacturing, or marketing of a chemical substance;
  - *KRA* information may include knowledge gained through discussions, symposia, and technical publications.
- Some inquiry outside the organization may be needed.
  - This would only be to fill gaps in the submitter's knowledge.
  - Submitters are **not required** to conduct a new or additional customer surveys (i.e., a comprehensive set of identical questions sent to multiple customers) to obtain the information for a Form U.

The 2012 CDR: What Information is Reported?

Part I: Site Identification Information

- Parent Company:
  - NEW – Highest level U.S. parent company
  - Company name, address, and Dun & Bradstreet number
- Manufacturing (including importing) site:
  - Site name, address, and Dun & Bradstreet number
  - NEW – Importers must report a U.S. address for the site
  - NEW – When manufacturing under contract, the site is the location where the chemical substance is physically manufactured
  - Upfront substantiation of CBI claims
- Technical contact(s) information:
  - Name, address, phone number and email address.
  - May have multiple technical contacts

The 2012 CDR: What Information is Reported?

Part II: Manufacturing Information

- Chemical Identification:
  - NEW – Use of Substance Registry Service (SRS) database required - free
  - For Non-CBI chemicals: CAS RN and CA index name
  - For CBI chemicals: TSCA accession number and generic chemical name
  - NEW – PMN numbers may not be used
  - Upfront substantiation of CBI claims for each claim
- Chemical Production Volume (PV):

2011 Data	2010 Data
Domestically Manufactured PV	**Total PV only** (domestically manufactured + imported) NEW
Imported PV	
NEW Indicate whether chemical is physically at reporting site	
NEW Volume used at reporting site	
NEW Volume directly exported from reporting site	

The 2012 CDR: What Information is Reported?

Part II: Manufacturing Information *(cont'd)*

- Number of workers that are reasonably likely to be exposed *(select codes for range of workers)*
- Maximum concentration *(select codes for concentration range)*
- NEW Indication of whether a manufactured chemical substance is being recycled, remanufactured, reprocessed or reused
- Physical forms and percent production volume in each form

The 2012 CDR: What Information is Reported?

Part III. Processing and Use Information:

- Based on 2011 production volume
- NEW All CBI claims require upfront substantiation.
- **Industrial Processing and Use Data**
  - Report codes for unique combinations of:
    - Type of Process/Use (TPU) +
    - NEW Industrial Sector (IS) +
    - Industrial Function Category (IFC)
  - For <u>each</u> of these unique combinations, also report:
    - % Production Volume; # Sites; # Workers
- **Consumer and Commercial Use Data**
  - Report Product Category codes
  - For <u>each</u> Product Category, also report:
    - NEW Consumer use/Commercial use/Both;
    - Used in Products Intended for Children;
    - % Production Volume;
    - Maximum Concentration;
    - NEW # Commercial Workers

Joint Submissions Overview

- **Joint submissions are allowed only when:**
  - A supplier claims the chemical identity is confidential; **AND**
  - The supplier will therefore not disclose to the manufacturer (including importer) the chemical identity
- **Participants in joint submissions must register with CDX**
  - **Primary submitter:** Manufacturer, including importer; requests that supplier directly provide EPA with Form U, Part IV, as a secondary submitter.
  - **Secondary submitter:** Supplier; may voluntarily submit chemical identity in Part IV directly to EPA or may ask its own supplier to complete Part IV as a tertiary submitter
  - **Tertiary Submitter:** Company providing confidential identity to supplier; may voluntarily submit chemical identity in Part IV directly to EPA

Byproducts Overview

- ***Byproduct* is defined under 40 CFR 704.3 and 40 CFR 720.3(d)**

  Byproducts are chemical substances that are produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

- **Byproducts can be subject to CDR requirements**

  1. Did you manufacture a byproduct for commercial purposes?
  2. Is your byproduct then used for a separate commercial purpose?
  3. Is your byproduct exempt from reporting because its only commercial purpose is covered by one or more of the following:
     a. To burn byproduct as a fuel?
     b. To dispose of byproduct as a waste, including in a landfill or for soil enrichment?
     c. To extract a component chemical substance from the byproduct for commercial purposes?

Changes for 2016

- **Reporting**
  - Submission period will be June 1 – September 30, 2016.
  - Principal reporting year will be 2015.
- **Reporting Threshold -- Manufacturing and Processing and Use:**
  - **25,000 lb** is the sole reporting threshold for all parts of Form U
  - **2,500 lb** is the reporting threshold for chemical substances subject to:
    - 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**
  - The need to report is triggered by meeting the 25,000 lb (or 2,500 lb as applicable) reporting threshold~~s~~ in **any calendar year** since the last principal reporting year (i.e., **2012-2015**).
- **Reporting Requirements**
  - New requirement for total annual production volume for each complete calendar year since the last principal reporting year (i.e., **2012-2015**).

2012 CDR: Information Resources

- www.epa.gov/cdr
  - Resources Page
    - Instructions for the 2012 TSCA CDR
    - Q&A Document on Byproducts
  - About Submissions Page
    - Information from the Sept 2011 webinar
    - Schema for e-CDRweb as of Sept 2011
  - Additional items to be added to Resources page
    - CDR Training Modules
    - General Q&A and Case Studies Documents
  - Send questions to **ecdrweb@epa.gov**

Electronic Reporting Overview

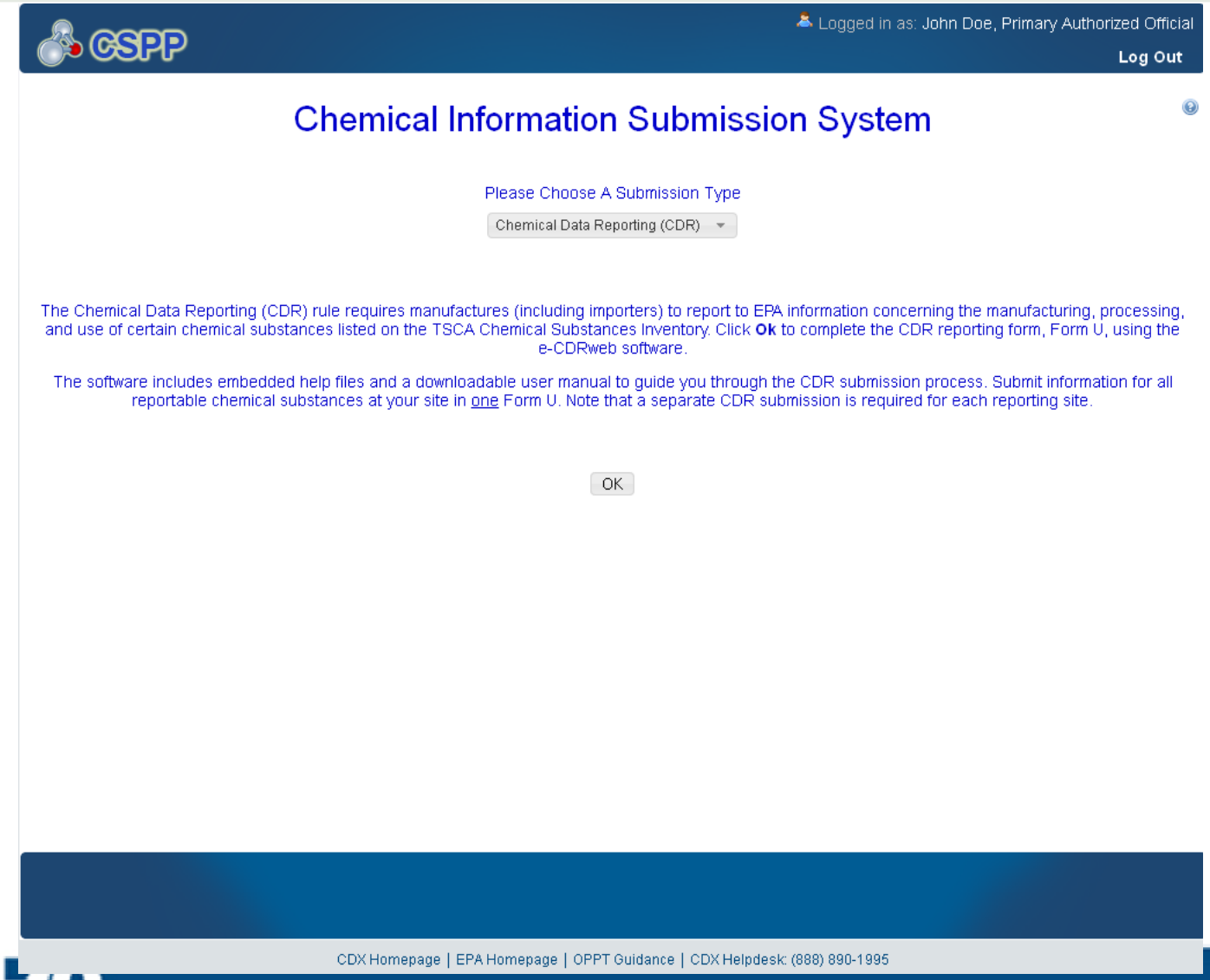
EPA's Central Data Exchange (CDX)

- Enables companies to electronically submit data
- Is secure for confidential business information (CBI) data exchange
- Improves security using digital encryption
- Automates and expedites validation and receipt acknowledgment
- Provides access to the e-CDRweb reporting tool

The following e-CDRweb features assist Form U preparation:

- Form U can be completed in more than one session.
- Form U can be saved for site records.
- For companies with their own data collection process, e-CDRweb allows direct data transfers.
  - Companies can enter data directly into e-CDRweb by uploading an Extensible Markup Language (XML) file.
- Amendments to previously submitted Form Us can be easily completed.
- Joint submissions can be completed separately by manufacturer and supplier.

Electronic Reporting Overview



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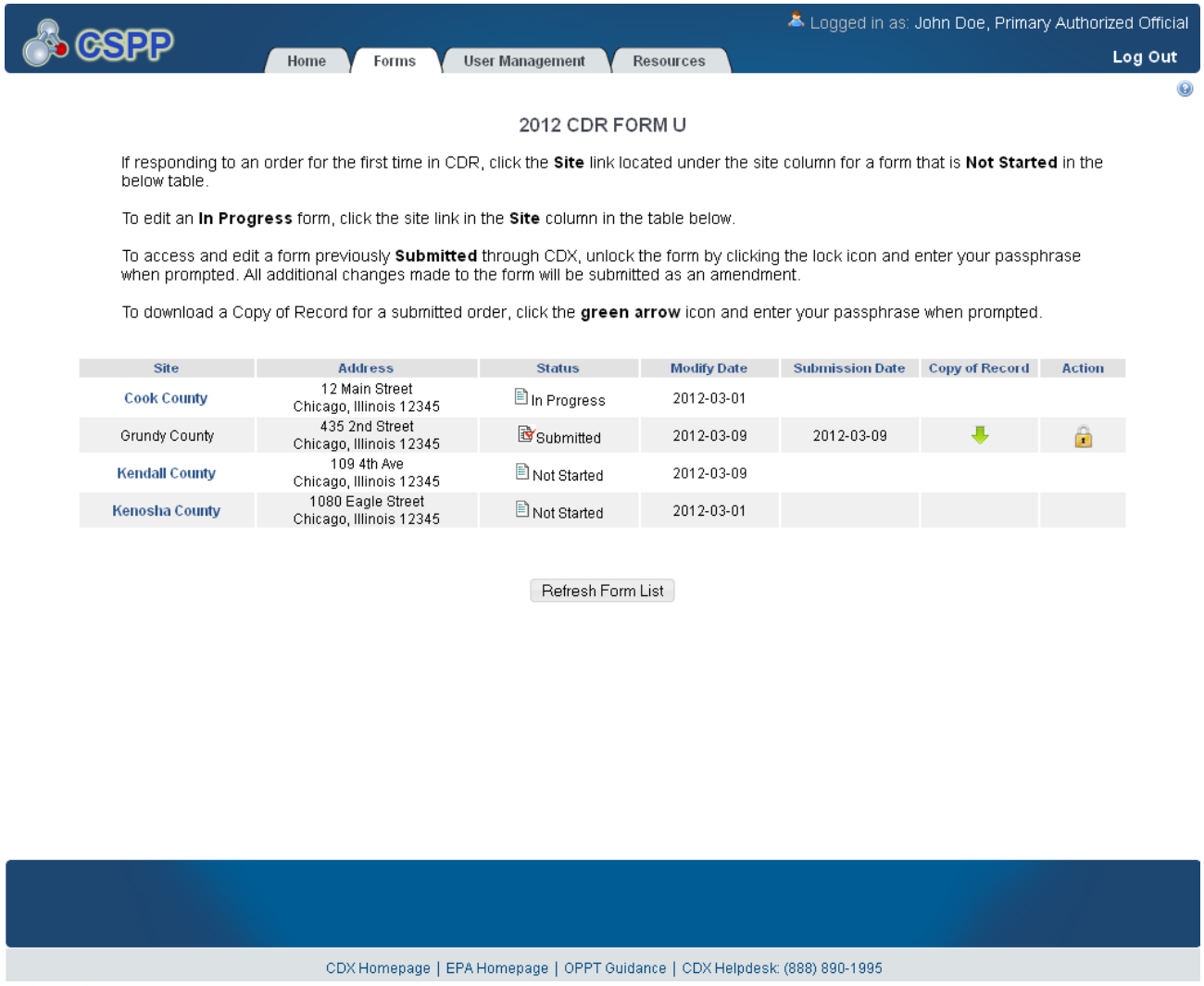

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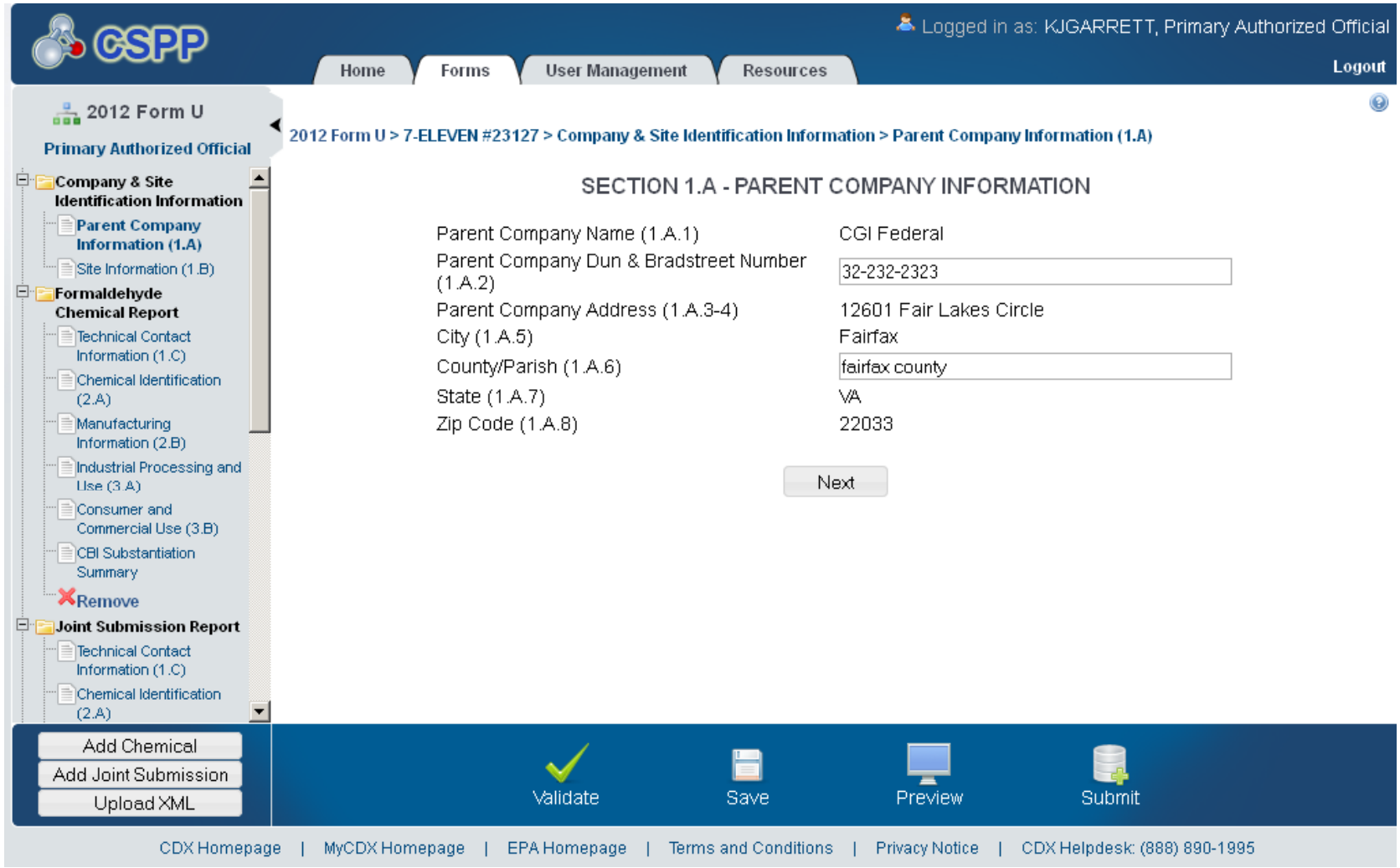
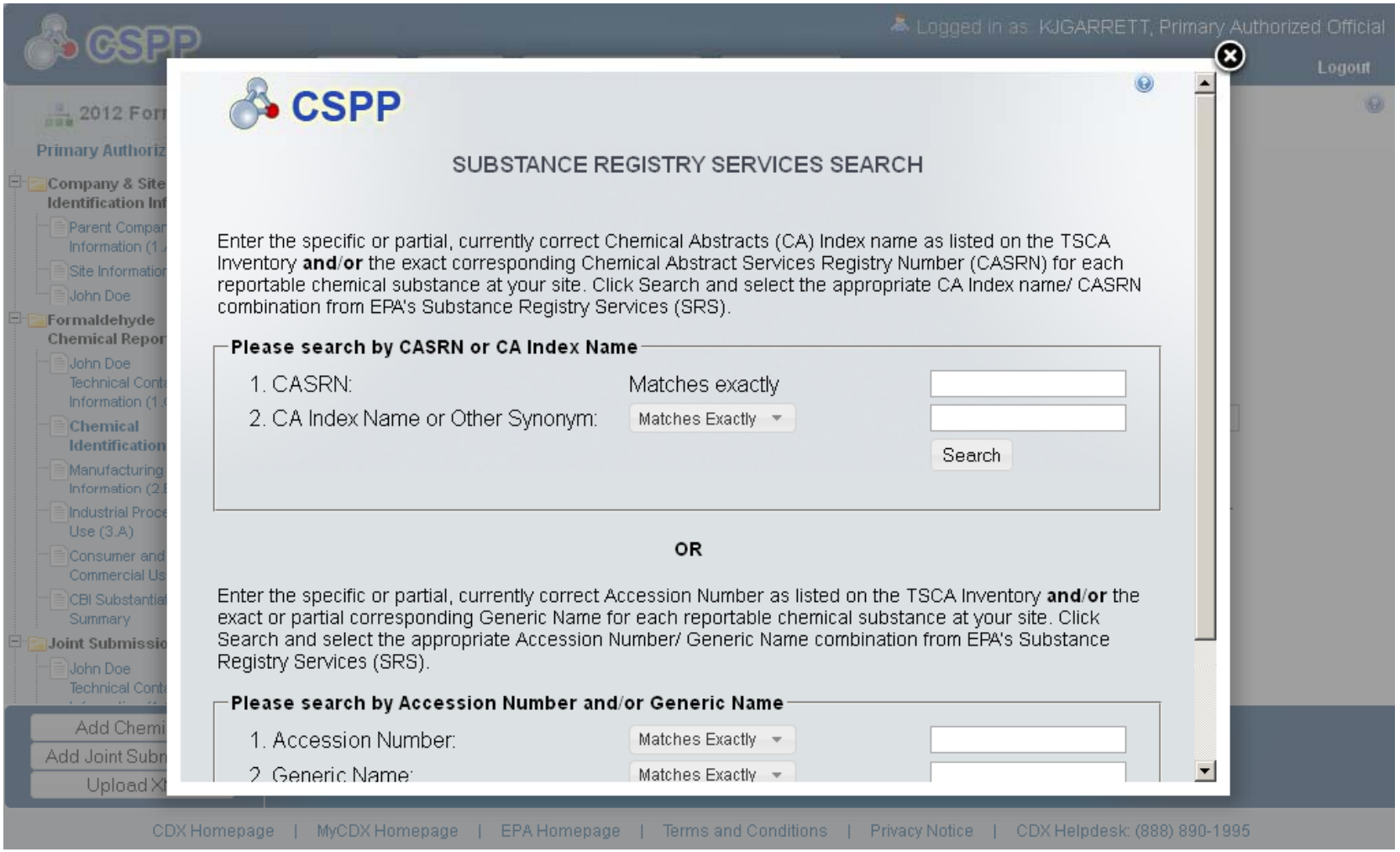


Electronic Reporting Overview



2012 CDR: Questions

QUESTIONS ?

You may also send questions to

ecdrweb@epa.gov