ChemCon The Americas 2020

International Conference on Chemical Control
Legislation & Trade Aspects

Workshop on TSCA CDR-rule (Chemical Data Reporting)

March 2nd - 6th
Philadelphia
USA

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Organiser's Message

Dear Ladies and Gentlemen,

Philadelphia was the host city for our 28th ChemCon Conference, **ChemCon The Americas 2020**. Another successful conference in the global series of ChemCon Conferences, which took place from March 2nd to 6th, 2020 in Philadelphia, USA.

With thanks to the enthusiastic support of the distinguished speakers and partners of **ChemCon The Americas 2020**, we were able to set up a great event in this historic city. Almost 200 experts from 21 countries representing over 125 companies, authorities and associations attended our seminars, conference sessions and exhibition. Together, they contributed to an inspiring exchange of experiences and discussions about regulatory affairs around the globe.

During the hands-on workshop '*TSCA CDR-rule (Chemical Data Reporting)*', experts provided industry with information to better understand the updated requirements of the CDR rule as well as guidance on the actual reporting as of June 1st, 2020.

For this electronic handbook, we have slightly adapted some papers and presentations in order to provide an easily accessible overview of the content of the workshop.

We would like to express our gratitude to all speakers and the chairwoman for their preparations, as well as the partners, supporters and of course all the delegates for joining us in this workshop.

From October 26th – 30th, 2020, London, United Kingdom will be the host city for **ChemCon Europe 2020**. In 2021 we will return to Asia and in 2022 we would like to welcome you at ChemCon The Americas again. For more information, please have a look at our website: www.chemcon.net.

Thank you for your continued interest and support in ChemCon Conferences. We are looking forward to meeting you at one of our future conferences.

Yours faithfully,
Tjeerd Bokhout
Conference Director

ChemCon The Americas 2020

Philadelphia March 2nd – 6th

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Workshop

TSCA CDR-rule (Chemical Data Reporting)

Reporting for the 2020 CDR begins June 1, 2020 – this workshop enables industry to better understand the updated requirements of the CDR rule as well as guidance on the actual reporting.

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  Susan Sharkey, US EPA
- US TSCA CDR: Basic Principles & Practicalities
  Mark Herwig, United Technologies Corporation
- Practicalities of CDR Reporting
  Kathleen M. Roberts, Bergeson & Campbell, P.C.

Speakers and Chairwoman

ChemCon TV

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Philadelphia
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Overview of TSCA Chemical Data Reporting (CDR) for 2020

Susan Sharkey
U.S. Environmental Protection Agency

TSCA Chemical Data Reporting

Presentation Overview

- Background: Chemical Data Reporting
- 2020 Reporting Requirements (Including proposed changes from the CDR Revisions rule)
- Non-Regulatory Updates
- Additional Information

TSCA Chemical Data Reporting

Background: Chemical Data Reporting (CDR)

- CDR is a collection of basic exposure-related information on the types, quantities, and uses of chemical substances manufactured domestically or imported into the United States
  - Chemical substances listed on the TSCA Inventory
  - Certain classes of chemicals, such as polymers, are exempted from reporting
- EPA uses the data for a variety of purposes, including:
  - Early screening of chemicals, their uses, and potential exposures so EPA can prioritize chemicals
  - Developing risk evaluations under TSCA
  - Measure the success of a regulatory or voluntary program

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TSCA Chemical Data Reporting

Background: Chemical Data Reporting (CDR)

- Information is submitted every four years
  - Most recently submitted in 2016, covering calendar years 2012-2015
  - Next submission period is in 2020, covering calendar years 2016-2019
- The reporting threshold is 25,000 pounds per site or 2,500 pounds for chemical substances subject to certain TSCA actions
- In 2016, about 5,660 sites reported approximately 8,700 chemicals, resulting in close to 42,500 chemical reports

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TSCA Chemical Data Reporting

Overview: New and Revised CDR Requirements

- CDR Revisions Final Rule proposed April 24, 2019
- Goals of the proposed CDR Revisions:
  - Make regulatory updates to align with new statutory requirements of TSCA
  - Improve the CDR data as necessary to support the implementation of TSCA
  - Reduce burden for CDR reporters
- Proposed changes impact:
  - Confidentiality requirements
  - Data elements, including processing and use information
  - Reporting process for co-manufactured chemicals
  - Byproduct reporting, including exemptions

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TSCA Chemical Data Reporting

2020 Reporting Requirements

Including Updates from the CDR Revisions Proposed Rule

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TSCA Chemical Data Reporting

Overview of 2020 CDR Requirements

- **When:** The submission period is June 1 to September 30, 2020
- **Who:** Manufacturers, including importers, of chemical substances that:
  - Are listed on the TSCA Inventory as of June 1, 2020
    - Have a production volume of 25,000 lbs or greater at a site in at least one of the years 2016-2019
  - Unless subject to certain TSCA regulatory actions
    - Have a production volume of 2,500 lbs or greater in at least one of the years 2016-2019
  - Are not eligible for a full exemption from CDR

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TSCA Chemical Data Reporting

Overview of 2020 CDR Requirements

- **What:** Report for each chemical substance at a single site:
  - Annual production volume for 2016-2019
  - Manufacturing, processing, and use information for 2019
  - Exemptions may reduce reporting
- **How:** Report electronically
- **Where:** Use EPA's Central Data Exchange (CDX)
  - Register with CDX
  - Access *e-CDRweb*, the CDR reporting tool
  - Create and submit a separate Form U for each site
  - Submit completed Form U following instructions in *e-CDRweb*

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TSCA Chemical Data Reporting

Important to Know

- Reporting is site-specific:
  - One Form U per site
  - One or more chemical substance reports on each Form U
- Reporting standard is “known to or reasonably ascertainable by” for all data
- Changes to reporting due to the CDR Revisions proposed rule are in green text

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TSCA Chemical Data Reporting

Important to Know: Confidentiality Claims

- Confidentiality claims must be made at the time the information is submitted
  - General use data elements cannot be claimed as confidential
    - Industrial: type of processing and use, industrial sectors, functions
    - Commercial/Consumer: product categories, functions, whether consumer or commercial, whether intended for use by children
  - EPA will not assume confidentiality of information
- Upfront substantiation required for claims for most data elements
  - Updated substantiation questions and certification statement
  - Upfront substantiation not required for:
    - Production volume
    - Supplier identity, trade name, and formulation information associated with joint submissions

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TSCA Chemical Data Reporting

What is Reported? – Company and Site Identification

- **Highest level U.S. parent company and, if applicable, the foreign parent company (proposed new parent company definition in 40 CFR 711.3)**
  - Company name and address (Following the naming convention as per 40 CFR 711.35)
  - Company Dun & Bradstreet number
- **Manufacturing (including importing) site**
  - Site name and address
  - Site Dun & Bradstreet number
  - Importers must report a U.S. address for the site
  - NAICS code for the site of manufacture
- **Technical contact(s) and voluntary public contact information**
  - Name and address
  - Telephone number and email address

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TSCA Chemical Data Reporting

What is Reported? Manufacturing Related Data

- Chemical Identity
  - CASRN and Chemical Name
  - Accession Number and Generic Chemical Name for confidential substances
  - Inorganic byproduct chemicals category reporting
- Production Volume (PV) Related:

2019 Data	2018 Data	2017 Data	2016 Data
Domestically Manufactured PV	Total PV only	Total PV only	Total PV only
Imported PV			
Indicate whether chemical never physically at reporting site			
Volume used at reporting site			
Volume directly exported from reporting site			

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TSCA Chemical Data Reporting

What is Reported?
Manufacturing Related Data (cont'd)

- Number of workers that are reasonably likely to be exposed (in ranges)
- Maximum concentration
- Physical form and percent production volume in the form
- Indication of whether a chemical is recycled instead of being treated as a waste
- The percent production volume that is a byproduct

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TSCA Chemical Data Reporting

What is Reported?
Processing- and Use-Related Data

- Industrial Processing and Use

Report up to 10 unique combinations:			For each unique combination, report:		
Industrial function category	Industrial sector	Functional use	Percent production volume	Number of reasonably likely to be exposed workers	Number of sites

- Consumer and Commercial Use

Report up to 10	For each unique category, report:					
Product Categories	Commercial or consumer?	Functional use	Is use a product intended for children?	Percent production volume	Maximum concentration	Number of reasonably likely to be exposed commercial workers

Proposed changes:
- New OECD-based functional use and product category codes
- Report functional use for commercial/consumer products

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TSCA Chemical Data Reporting

Reporting Imported Chemicals and Mixtures

- If two or more persons meet the "importer" definition, they may determine who will report (but both are liable)
- Site is defined for importers in 40 CFR 711.3
  - U.S. site of the unit directly responsible for importing
  - Must be a U.S. address, even if it is for an agent acting for the importer
- An importer will indicate whether each imported chemical is never physically present at the reporting site
- If a mixture is imported, the importer reports the individual chemical components of the mixture, including the percent composition
  - A joint submission with the supplier is used when the chemical identity or composition is unknown
  - The secondary submitter reports the function of the chemical within the mixture
  - Both the primary and secondary submitters are able to identify parts of their submission as confidential
- Imported articles are exempt under 40 CFR 711.10(b)

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TSCA Chemical Data Reporting

Reporting Co-Manufactured Chemicals

- When is a chemical co-manufactured?
  - Contracting company determines the specific chemical identity and controls the amount produced and the basic technology for the plant process
  - Producing company provides the site, staff, and equipment necessary to make the chemical
- How to report?
  - Contracting company initiates the co-manufactured chemical report and notifies the producing company using the e-CDRweb reporting tool

Data Elements	Contracting Company	Producing Company
Chemical Identity	✓	
Production Volume	✓	✓
Manufacturing Information		✓
Processing and Use Information	✓	

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TSCA Chemical Data Reporting

Reporting Byproduct Chemicals

- Byproduct chemicals used for a separate commercial purpose are reportable unless exempted
- Current byproduct exemptions continue (40 CFR 711.10(c))
- New byproduct exemptions (40 CFR 711.10(d))
  - Exempt Certain Byproduct Substances from Selected Industries
  - Exempt Byproducts Manufactured in Certain Non-Integral Equipment

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TSCA Chemical Data Reporting

New Exemption for Certain Byproduct Substances from Selected Industries

- Specifically listed byproducts that are recycled in a site-limited manner when:
  - Recycled or used in physically enclosed systems; *and*
  - Remains on site; *and*
  - Site is reporting the byproduct substance or another substance from the same overall manufacturing process
- Industries and byproducts for exemption are:
  - Portland Cement manufacturing: *cement kiln dust*
  - Kraft pulping cycle: *black liquor* and *calcium carbonate*
- Petition process to identify additional industries and byproducts

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TSCA Chemical Data Reporting

Petition Process to Add Industries and Byproducts

- Petition needs to include information to identify:
  - That the byproduct could meet the requirements of the exemption.
  - That the byproduct would be reported under CDR if not listed under this exemption.
  - Provide information to assist EPA in determining current interest in the byproduct.
- Submit petition to EPA before January 1, 2022, for consideration for the 2024 submission period

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TSCA Chemical Data Reporting

Exemption for Byproducts Manufactured in Non-Integral Equipment

- Byproducts that are generated in equipment that is not chemically integral to the production process; specifically:
  - pollution control equipment
  - boiler equipment
- A ***chemically integral process*** is the portion of the manufacturing process that is chemically necessary or provides primary operational support for the production of the intended product.

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TSCA Chemical Data Reporting

Integral vs. Non-Integral Equipment

- Equipment likely to be integral to the production process:
  - Utilities using boilers to produce electricity as a product
  - Reverberatory furnaces used for smelting as part of production process
- Equipment likely to be non-integral to the production process:
  - A site uses boilers to produce heat or electricity for their building but does not produce the heat or electricity as a product
  - Flue gas desulfurization and selective catalytic reduction systems
  - Manufacturer produces a byproduct while treating wastewater from cleaning tanks from their production process

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TSCA Chemical Data Reporting

Small Manufacturer: Proposed Definition

- EPA proposed a new TSCA Section 8(a) definition for Small Manufacturer

Current Definition	Proposed Definition
First standard	
Total annual sales <$40 million and annual PV ≤ 100,000 lbs at a site	Total annual sales <$110 million and annual PV ≤ 100,000 lbs at a site
Second standard	
Total annual sales <$4 million, regardless of PV	Total annual sales <$11 million, regardless of PV

- Total annual sales means annual sales of submitter combined with a parent company, domestic or foreign (if any)
- Proposed rule asked for comment on alternate definitions
- Final rule status: In Interagency review with the Office of Management and Budget (OMB)

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TSCA Chemical Data Reporting

Planned Non-Regulatory Updates

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TSCA Chemical Data Reporting

IT Enhancements

- New application platform resulting in better functionality, less lag and faster validations
- Completely new reporting tool with a more intuitive user interface
- Streamlined and application-integrated CBI substantiations
- Improved uploading of data
  - XML upload failure explanations
  - Spreadsheet (CSV file) upload enabled
  - Auto-filling submission data from 2016 submissions to reduce time completing electronic submission

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TSCA Chemical Data Reporting

e-CDRweb Management and User Roles

e-CDRweb Activities	E-CDRweb User Roles		
	Authorized Official (AO)	Agent (new)	Support
Create Form	X		
Creates Passphrase	X		
Generate Joint Submission Unique ID	X	X	
Generate Producing Company Unique ID	X	X	
Edit Form	X	X	X
Submit an original Form	X		
Unlock Form Submission (Create an amendment)	X	X	
Submit an Amendment of a Form	X	X	
Assign Supports	X		

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TSCA Chemical Data Reporting

More Information

- CDR website
  - www.epa.gov/cdr
  - Check for updated guidance for 2020 reporting
- CDR Revisions rule docket
  - https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0321-0001
- E-Mail
  - eCDRweb@epa.gov
- Phone
  - Susan Sharkey at 202-564-8789

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US TSCA CDR: Basic Principles & Practicalities

Mark Herwig
United Technologies Corporation

US EPA TSCA CDR

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US EPA TSCA CDR

- Chemical Substance:

TSCA defines a “chemical substance” as any organic or inorganic substance of a particular molecular identity, including any combination of these substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.

Chemicals substances on the Inventory include:

- Organics;
- Inorganics;
- Polymers; and
- Chemical substances of unknown or variable composition, complex reaction products, and biological materials (UVCBs).

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US EPA TSCA CDR

CDR Reportable chemical substance:

- Chemical substance that is manufactured (including imported), on the TSCA Inventory as of June 1,2020, and not otherwise exempted by 40 CFR 711.6(a).
- As of Jun 1, 2020 = **substances on the “Active” Inventory**.
- Manufacture / Import annual aggregate volumes 2016-2019 based on “Active Inventory” even though Final “Active Inventory” was published on Aug 5, 2019.

EPA

Exclusions:

- Any mixture (as such, but components of mixture are chemical substances)
- Any pesticide
- Tobacco or tobacco product
- Source Material, Special Nuclear Material, or related byproduct material (AEA)
- Fire-arms / cartridges, etc.
- Food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.

Exemptions: R&D, Polymer, LVE, LoREx, M(I) for Export Only

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US EPA TSCA CDR

Exemptions

- Low Volume Exemptions (LVEs)
- Low Release/Low Exposure Exemption (LoREXs)
- Test Market Exemptions (TMEs)
- Substances used for Research and Development
- Polymers that meet the 1995 Polymer Exemption Rule Amendments *
- Manufacture (Import) for EXPORT Only (under certain circumstances)

* Note: Not all polymers are exempt. There are many on TSCA Inventory

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US EPA TSCA CDR

Manufacture (of a chemical substance)

- Creation of a chemical substance via chemical reaction
- Includes extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances
- Under TSCA, manufacture = Import

Commercial use means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.

A + B = C OR **Import** (from outside the US) of A, B or C

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US EPA TSCA CDR

Importer

Any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the United States, and includes:

- The person primarily liable for the payment of any duties on the merchandise, -or-
- An authorized agent acting on his or her behalf
- Importer also includes, as appropriate:
  - The consignee
  - The importer of record (IoR)
  - The actual owner if an actual owner's declaration and superseding bond have been filed in accordance with 19 CFR Section 141.20
  - The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR Part 144 (40 CFR Section 704.3, referenced by 40 CFR Section 711.3)

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US EPA TSCA CDR

Do you have to report?

- Did any company site report in 2016? (The last reporting cycle)
  - Can check at: 2016 CDR Inventory
  - If so, has anything changed?
- What activities/processes have occurred at your site(s) in 2016-2019 (annual aggregate)?
  - Manufacture chemical substance?
  - Imports of chemical substance (as such) or in a mixture. %'s?
  - For imported articles, identify chemical components that are **NOT ELIGIBLE** for the TSCA "Article" exemption

TSCA Article Exemption:

- Chemical substances in articles that are not intended to be removed from the article and have no separate commercial purpose from the article are exempt.
- Chemical substances designed to be used and released from articles **are subject to the CDR**

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US EPA TSCA CDR

The term "known to or reasonably ascertainable by" is defined at 40 CFR 704.3. It 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." By contrast, "readily obtainable" information does not even cover all the information in a submitter's possession or control.

This standard requires that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). The inquiry would be as extensive as a reasonable person, similarly situated, might be expected to perform within the organization.

Thus there is no need to conduct new customer surveys for purposes of the CDR. As described above, however, existing customer survey data may nevertheless be "known to" the organization.

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US EPA TSCA CDR

Information could be possessed by employees or other agents of the company reporting under the CDR rule, including persons involved in the research, development, manufacturing, or marketing of a chemical substance.

This information includes knowledge gained through discussions, symposia, and technical publications.

Other examples include:

- Files maintained by the submitter or employees in the submitter's company, such as marketing studies, sales reports, or customer surveys;
- Information contained in standard references, such as MSDSs, that contain use information or concentrations of chemical substances in mixtures; and
- Identification numbers from the Chemical Abstracts Service (CAS) and from Dun & Bradstreet.

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US EPA TSCA CDR

A little more on Articles….

Materials intended to be removed or released

NOT EXEMPT

- Substances imported in a drum, barrel, or other container for use at the facility
  - That substance is intended to be removed from the article and has an end use separate from the container
- Ink in pens, caulk in canisters, fire extinguisher fluid, substances or mixtures in aerosol cans, windshield washer fluid in vehicles, lighter fluid in refill cans
  - While these substances are contained within an article at the point of import, they are intended to be removed from or released by that article and have an end use or commercial purpose separate from the containing article

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US EPA TSCA CDR

Materials formed to specific shape or design and end use

Dependent on shape or design

NOT EXEMPT

- Metal ingots, billets, blooms, or other bulk metal raw material imported in a shape suited for shipping convenience
- Blocks of plastic or other plastic shapes, such as polymer pellets imported and converted into finished plastic articles
  - Items imported in a shape suited for shipping convenience; shape does not serve a function with respect to end use
  - The processing to occur in the U.S. will result in the imported products losing the shape that they had at the point of import (*e.g.*, by being melted down, molded, extruded, cut up extensively or into small pieces, or further reacted)

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US EPA TSCA CDR

Materials formed to specific shape or design and end use dependent on shape or design

EXEMPT

- Metal or plastic sheets, wire, coated fabric, rolled carpet, and sheets of plywood have specific shapes or designs for a particular end use application, and these shapes or designs are maintained as essential features in the finished products
  - Even if items are later rolled or drawn thinner, cut or trimmed, printed on, laminated, drilled, welded together, polished, buffed, or thermoformed, the shape and design are essential features of the finished product
- Thermoformed plastics
  - If an imported plastic sheet is molded into a plastic box after import, the characteristic shape of the plastic sheet is essentially maintained by virtue of the flat, rectangular sides and bottom of the box, even if the thickness of the sheet is somewhat changed
- Molded plastic parts, machined metal parts, finished pipes, and other shaped and finished construction materials
  - These items are imported with specific shapes or designs for particular end uses

NOT EXEMPT

- Thermoset plastic moulding compound with no specific shape or design

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US EPA TSCA CDR

Change in chemical composition with commercial purpose

EXEMPT

- Batteries, instant photographic film
  - Even though these imported items undergo changes of composition after import, the composition change has no commercial purpose separate from that of the imported item

NOT EXEMPT

- Soldering wires and welding rods
  - These items contain chemical substances that change to a fluid or particle form or are intended to be released during end use of the article.

Document basis for determination that imported article meets exemption criteria.

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US EPA TSCA CDR

Reporting thresholds = 2,500 or 25,000 pounds per year

- 2,500 pounds / site if subject to certain TSCA regulatory actions
  - Section 5(a)(2) significant new use rules (SNUR) (proposed or promulgated)
  - Section 5(b)(4) rules (proposed or promulgated)
  - Section 5(e) orders
  - Section 5(f) orders
  - Section 5 civil actions
  - Section 6 rules (proposed or promulgated)
  - Section 7 civil actions
- Otherwise, 25,000 pounds / site
- Reporting required if threshold reached in any of these four years (2016, 2017, 2018, or 2019). AGAIN – based on TSCA "Active" Inventory

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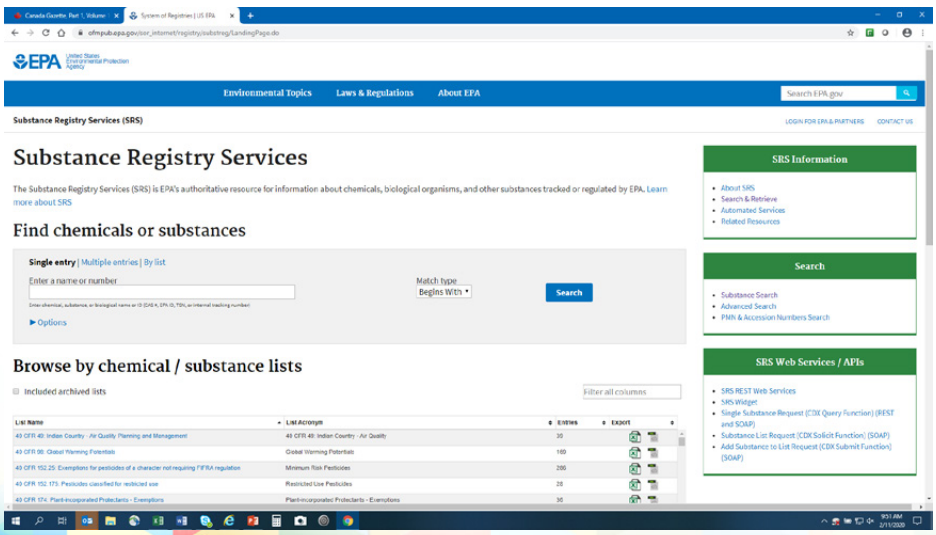
US EPA TSCA CDR

US EPA SRS



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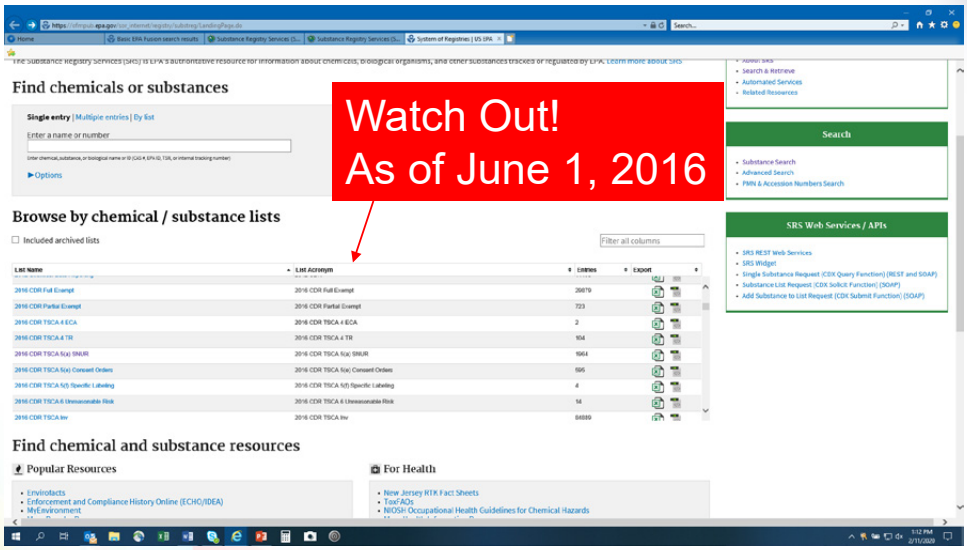
US EPA TSCA CDR



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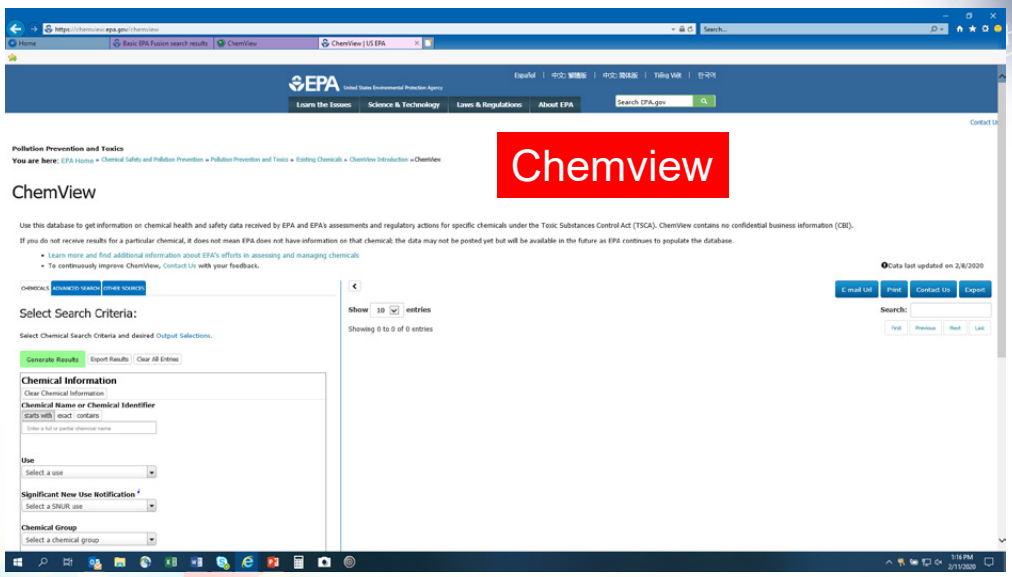
US EPA TSCA CDR



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US EPA TSCA CDR

Summary

- Chemical Substances on "Active" Inventory, Not otherwise Exempted, and intended to be released…….are subject to CDR
  - If you discover any listed "In-Active" substances, get Counsel
- Establish applicable "Activity" (M/I) subject to CDR
- Calculate / evaluate aggregate annual volume for each year of the years 2016-2019
  - Use weight and % composition in imported formulations / mixtures
  - NOTE: hydrates are considered mixtures. Calculate on non-water components
- Parse between 25,000 lb VS. 2,500 lb thresholds per substance / per year
- Exemptions Eligibility?
- Effected by any "proposed changes" to CDR?
- Plan to Report (as appropriate) in the 2020 Reporting Window via CDX

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Practicalities of CDR Reporting

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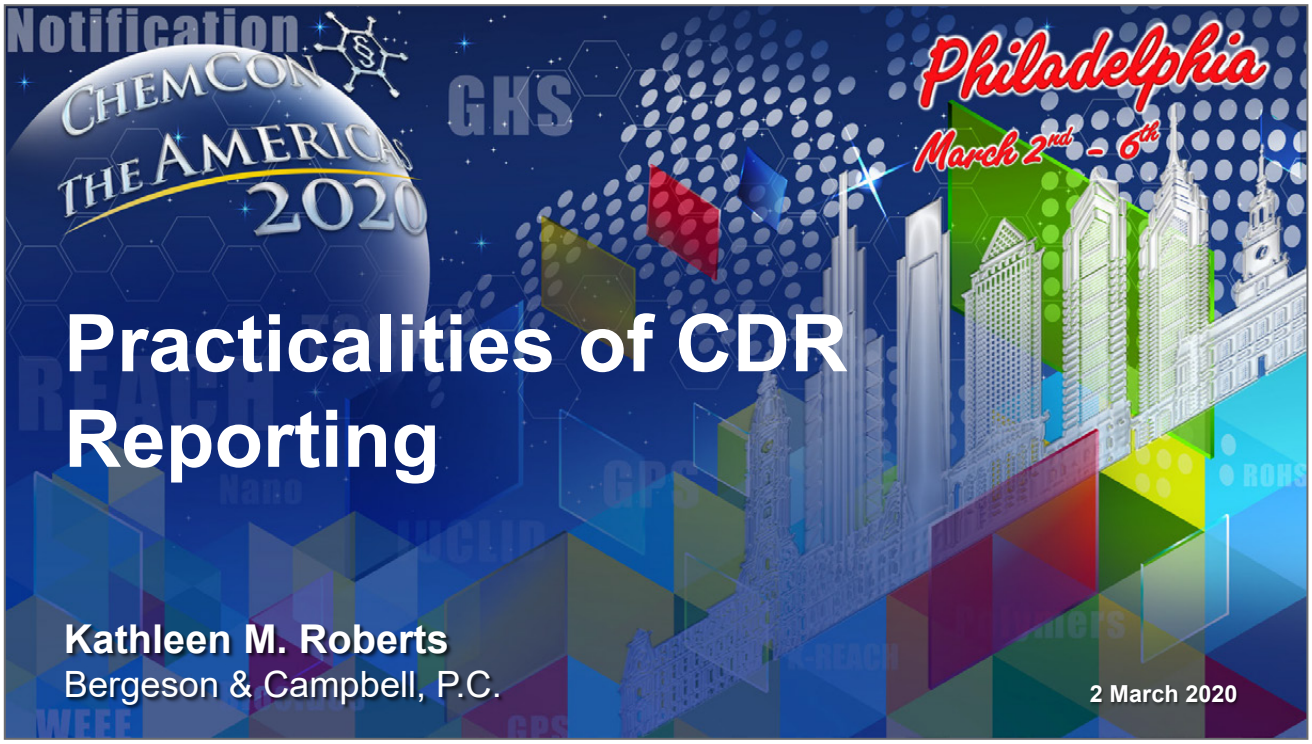

How to Determine If My Facility Has to Report

- Did you report previously?
  - Has anything changed at the site from previous reporting?
- What activities/processes occur at facility?
  - Manufacturing chemical substances?
  - Importing raw materials?
  - Importing products, articles, or other items?
    - Include items returned to U.S. for servicing
  - Are the chemicals associated with these activities exempt?

Compile List of Potentially Reportable Items

- Substances produced via chemical reaction that have a commercial purpose
- List of chemical components in imports and associated percentages
  - ➢ Information from product safety data sheets (SDS)
  - ➢ Information from foreign suppliers
    - If foreign supplier will not provide information due to proprietary issues, use joint reporting option
- For imported articles, identify chemical components that are not eligible for article exemption

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Inventory of Potentially Reportable Items

- Confirm chemicals are on the Toxic Substances Control Act (TSCA) Inventory as “active”
- Check if listed chemicals are considered exempt
  - ➢ Use EPA Substance Registry Services (SRS)
    - Use 2016 listings, but recheck in **June 2020**
    - Exemption status should be verified

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Inventory of Potentially Reportable Items

- Calculate aggregate annual volume for 2016, 2017, 2018, and 2019 per individual chemical component
  - Use weight and percent composition of the chemical substance in imported formulations
  - If the same chemical component is in more than one imported product or manufactured (reacted) on-site, be sure to calculate total aggregate volume
  - Hydrates are considered mixtures -- Calculate total volume of non-water component(s)

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Volumes of Potentially Reportable Items

- Reporting thresholds = 25,000 or 2,500 pounds per year
  - 2,500 pounds if subject to certain TSCA regulatory actions
    - Section 5(a)(2) significant new use rules (SNUR) (proposed or promulgated)
    - Section 5(b)(4) rules (proposed or promulgated)
    - Section 5(e) orders
    - Section 5(f) orders
    - Section 5 civil actions
    - Section 6 rules (proposed or promulgated)
    - Section 7 civil actions
  - Otherwise, 25,000 pounds
  - Reporting required if threshold reached in any of the four reporting years (2016, 2017, 2018, or 2019)

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Check Regulatory Status of Potentially Reportable Items

- Use EPA SRS to check regulatory status for lower reporting threshold
- Use EPA SRS to check exemption status
  - Exemption not applicable for chemicals subject to certain regulatory actions:
    - Section 4 test rules (proposed or promulgated)
    - Enforceable consent agreements
    - Section 5(a)(2) SNURs (proposed or promulgated)
    - Section 5(b)(4) rules (proposed or promulgated)
    - Section 5(e) orders
    - Section 5(f) orders
    - Section 5 civil actions
    - Section 6 rules (proposed or promulgated)
    - Section 7 civil actions

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Compile List of Reportable Items

- Compare identified reporting thresholds with calculated annual volumes to identify chemicals subject to reporting

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EPA Central Data Exchange (CDX)

- EPA's centralized portal for electronic data reporting
  - This portal MUST be used to submit Chemical Data Reporting (CDR) data
- Who must have a CDX account?
  - Authorized Official (AO) -- Person legally responsible to certify and submit reports
  - Support Registrant -- A person with access to enter data and prepare reports
    - Support registrants must have their own accounts to enter data and prepare reports
    - AOs give access rights to Support Registrants to edit a site's CDR report
  - Determine if existing CDX users can support and/or certify and submit CDR reports

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EPA CDX

- Determine facility and staff registration statuses
  - If not registered, start process immediately
    - See CDX site for help if registered but do not know user name or password
    - No sharing single CDX account -- each user must have an account
  - Make sure program for TSCA CDR is in account
    - Click "Add New Program Service" from the MyCDX page
    - Select "CSPP: Submissions for Chemical Safety and Pesticide Programs"

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Protect the Passphrase

- AOs create a passphrase when creating the CDR report for their facility
  - Passphrase required to access the form to print, submit, or make changes
  - AOs should provide passphrase to authorized Support Registrants only
  - DO NOT LOSE THE PASSPHRASE
    - If you forget the passphrase, you will not be able to access the CDR Form U to print, submit, or make changes
    - CDX system administrator cannot access, retrieve, or reset the passphrase

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Information Threshold for Reporting -- Known or Reasonably Ascertainable

- Information to be reported for CDR should be reasonably ascertainable by the facility
  - Reasonably ascertainable is information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess
  - Need to engage beyond information known by supervisory employees to include marketing/sales staff
  - Does not necessarily require that the manufacturer conduct an exhaustive survey of all employees or customers
- If requested information is not known or reasonably ascertainable, submitter can report NKRA

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Form U, Part I -- Company and Site Info

- Official who will electronically sign/certify and submit the CDR report (CDX AO)
- Parent company name, address, and Dun & Bradstreet (D&B) number
- Site name, address, and D&B number
- Technical contact
  - Staff person that EPA will contact with follow-up questions

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Form U, Part II – Manufacturing-Related Information

- Chemical identifying number (Chemical Abstracts Service (CAS) Registry Number (RN) or Accession number)
- Amounts of chemical manufactured on-site, amounts imported by site, and total amounts
  - If imported, determine if chemical was ever physically on-site or if the facility arranged for it to be shipped directly elsewhere
- Volume used at site in 2019
- Volume exported from site in 2019

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Form U, Part II -- Manufacturing-Related Information

- Total volumes (pounds) manufactured and imported in 2016, 2017, and 2018
  - NOTE: For volume values, report to two-significant figures to the extent you are reasonably able to do so
- Indication of whether the chemical is part of a mixture that is to be recycled (either on-site or off-site) in 2019

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Form U, Part II

- Physical form(s) of the chemical substance and annual volume per form in 2019
  - Powder
  - Pellets
  - Water or solvent wet solid
  - Other solid
  - Gas or vapor
  - Liquid

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Form U, Part II

- Maximum concentration of the chemical at the time it was reacted to product, a different chemical substance, or as it left the site in 2019
  - Less than 1% by weight
  - At least 1% but less than 30% by weight
  - At least 30% but less than 60% by weight
  - At least 60% but less than 90% by weight
  - At least 90% by weight

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Form U, Part II

- Number of workers reasonably likely to be exposed to the chemical at the site in 2019
  - Exposures that might occur in typical workday, plus cleaning equipment, materials transfer, analytical operations
  - Include workers that might pass through area as well as temporary or contract workers whose jobs are associated with potential exposure

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Form U, Part II

- Reporting to occur in ranges
  - Fewer than 10 workers
  - At least 10 but fewer than 25 workers
  - At least 25 but fewer than 50 workers
  - At least 50 but fewer than 100 workers
  - At least 100 but fewer than 500 workers
  - At least 500 but fewer than 1,000 workers
  - At least 1,000 but fewer than 10,000 workers
  - At least 10,000 workers

Form U, Part IIIA -- Industrial Process & Use Information

- SECTION A: Compile the following information on where and how the chemical substance was being used within industrial sectors for 2019
  - Industrial use and processing information requires reporters to identify up to ten unique combinations of the type of processes or use operations for the chemical, the industrial sectors using the chemical, and the industrial functions of the chemical

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Compiling Top Ten Code Combinations

- Recommended first step is to identify the top ten industrial sectors using/processing the reported chemical from the site
  - Include all industrial sites that receive the reportable chemical substance from the site -- directly or indirectly
  - If your site is also processing the reported chemical, the industrial sector for your site should be included
  - If more than ten codes are relevant, pick the top ten based on volumes used per sector

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Compiling Top Ten Code Combinations

- For each industrial sector code selected, identify the appropriate industrial function code(s) per sector
  - The industrial function code relates to the function of the chemical substance, which may not necessarily be the function of the product containing the chemical substance
    - Example: An additive that prevents corrosion and is contained in a metal working fluid

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Compiling Top Ten Code Combinations

- For each unique combination of industrial sector and industrial function codes, identify the appropriate process code, which is how the chemical substance is processed
  1. Processing -- Incorporation into article
  2. Use -- Non-incorporative activities
  3. Processing -- Incorporation into formulation, mixture, or reaction product
  4. Processing -- Repackaging
  5. Processing as a reactant (meaning the chemical is reacted into a different chemical)

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Compiling Top Ten Code Combinations

- Review the entire list of unique code combinations for all three items and identify those combinations that represent the highest volumes for 2019
  - ➢ Report on the top ten by production volume

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For Each Unique Industrial Code Combination

- Report the percentage of production/importation volume for 2019
- Report total number of sites using/processing the chemical within that code combination
  - Fewer than 10 sites
  - At least 10 but fewer than 25 sites
  - At least 25 but fewer than 100 sites
  - At least 100 but fewer than 250 sites
  - At least 250 but fewer than 1,000 sites
  - At least 1,000 but fewer than 10,000 sites
  - At least 10,000 sites

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For Each Unique Industrial Code Combination

- Report total number of workers potentially exposed to the reported chemical within each code combination
  - Fewer than 10 workers
  - At least 10 but fewer than 25 workers
  - At least 25 but fewer than 50 workers
  - At least 50 but fewer than 100 workers
  - At least 100 but fewer than 500 workers
  - At least 500 but fewer than 1,000 workers
  - At least 1,000 but fewer than 10,000 workers
  - At least 10,000 workers
- Remember -- If information is not known or reasonably ascertainable, submitter can report NKRA

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Form U, Part IIIB -- Consumer and Commercial Uses

- If there are consumer and/or commercial applications for which the chemical is processed or used, identify the top ten categories by percent production volume
  - Commercial use means the use of a chemical substance or a mixture (including as part of an article) in a commercial enterprise providing saleable goods or a service
- Identify whether product category is commercial, consumer, or both

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Form U, Part IIIB -- Consumer and Commercial Uses

- Identify whether chemical is used in product intended for use by children
  - Commonly recognized for use by children age 14 or younger?
  - Product labeling or other written material indicates product is intended or will be used by children?
  - Advertising or marketing of the product aimed at children?

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For Each Consumer/Commercial Code

- Report the percent production volume to the nearest ten percent
- Maximum concentration of the chemical in product
  - Less than 1% by weight
  - At least 1% but less than 30% by weight
  - At least 30% but less than 60% by weight
  - At least 60% but less than 90% by weight
  - At least 90% by weight

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For Each Consumer/Commercial Code

- Number of commercial workers potentially exposed
  - Fewer than 10 workers
  - At least 10 but fewer than 25 workers
  - At least 25 but fewer than 50 workers
  - At least 50 but fewer than 100 workers
  - At least 100 but fewer than 500 workers
  - At least 500 but fewer than 1,000 workers
  - At least 1,000 but fewer than 10,000 workers
  - At least 10,000 workers

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Reported Information Should Be Reasonably Ascertainable

- If the requested information is not known or reasonably ascertainable, report NKRA

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Confidential Business Information (CBI) Claims

- TSCA allows companies to protect proprietary information as CBI
  - Most information elements on Form U can be claimed as CBI but TSCA has clear steps on what is needed to make those claims
- Work with business unit level legal counsel to determine which information elements should be claimed as CBI and to provide substantiation responses
  - During submission process, you will need to provide responses to EPA questions to support the basis for each CBI claim
    - Substantiation statements can also be claimed as CBI

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Information Needed for CBI Substantiation

- Citations for elements exempt from substantiation pursuant to TSCA Section 14(c)(2)

	Basis for Exemption
Secondary Company Name	§ 14(c)(2)(C)
Secondary Company Address	§ 14(c)(2)(C)
City	§ 14(c)(2)(C)
State or Province	§ 14(c)(2)(C)
Zip Code	§ 14(c)(2)(C)
Country	§ 14(c)(2)(C)
Production Volume -- Domestically Manufactured	§ 14(c)(2)(F)
Production Volume -- Imported	§ 14(c)(2)(F)
Past Production Volume – Calendar Year (CY) 2016, 2017, 2018, 2019	§ 14(c)(2)(F)

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Type of Information Needed for CBI Substantiation

- Specific information on potential harm to competitive position
- Precautions taken to protect information
  - Non-disclosure agreements
  - On TSCA confidential Inventory
  - Not included in public communications
- Past findings by EPA or other agencies

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CBI Claims Taken Very Seriously by EPA

- Certification statement signed by AO:

  I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

  I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

  (i) My company has taken reasonable measures to protect the confidentiality of the information;

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CBI Claims Taken Very Seriously by EPA

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

- Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001

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Foreign Supplier Engagement and Joint Reporting

- Importers must attempt to obtain chemical identity information from foreign suppliers
- Joint submission if supplier will not disclose chemical composition
  - A unique ID number is sent by the importer to notify the supplier of the partial CDR submission
  - The supplier does not have access to any of the information submitted by the importer to EPA
  - Likewise, importers cannot see the information the supplier reports to EPA

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Foreign Supplier Engagement and Joint Reporting

- Each entity must register with CDX and submit its own section of the same Form U report
- This requires a great deal of coordination and may require education of a foreign supplier

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Toll Manufacturing/Co-Manufacturing

- Chemical is produced domestically exclusively for another person who contracts for such production
  - ➢ Contracting company specifies chemical identity, production volumes, and basic technology
    - If manufactured for other purposes -- not co-manufactured
    - If imported -- not co-manufactured
- PROPOSAL -- Joint submission process in which contracting company is primary submitter and producing company is secondary submitter

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Take Home Assignments

- Ensure CDX registration completed
- Compile list of chemicals subject to reporting
  - ➢ Chemical inventory
  - ➢ Annual volumes per chemical
  - ➢ Reporting threshold per chemical
- Engage with foreign suppliers if joint submission needed
- Gather information needed for reporting
- Confer with legal counsel on CBI elements
- Document basis for non-reporting

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Thank You

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Speakers and Chairwoman

Chairwoman

- **Lynn Vendinello,** US EPA

Speakers

- **Mark Herwig,** United Technologies Corporation
- **Kathleen M. Roberts,** Bergeson & Campbell, P.C.
- **Susan Sharkey,** US EPA

Curriculum Vitae

Mark Herwig

United Technologies Corporation (UTC)

Mark Herwig is currently employed by United Technologies Corporation (UTC), Corporate Headquarters, in Farmington, CT (USA), as Senior Director, Global Chemicals Compliance and Risk Management Program.

UTC serves global customers in the aerospace and defense industry, and ranks among the world's most respected and innovative companies.

Mark joined UTC in October 2017, after nearly 28 years with the General Electric Company, serving in various capacities including Corporate Chemicals Program Leader. Prior to GE, Mark served in professional roles in the oil production and electrical production/distribution sectors, as well as a little consulting.

Mark's educational background stems from undergraduate work at Clarkson University, graduate work at Rensselaer Polytechnic Institute, and has completed numerous employer sponsored management and executive leadership programs over his career.

Mark is a respected and accomplished Corporate Leader of global chemical regulations affecting industrial businesses, supporting their ability to operate, produce product, access global markets, sell, distribute and service customers while managing risk and supporting sustainability and brand.

He currently serves on the Board of both the Chemical Users Coalition and Product Stewardship Society.

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As Vice President of B&C® Consortia Management, L.L.C. (BCCM), Kathleen Roberts is an essential resource for industry groups, providing cost effective administrative and management services to ensure their interests are protected and their voices heard on issues of concern. She offers demonstrated success and an impressive track record in this capacity, and is a recognized expert in chemical control regulations specifically under the Toxic Substances Control Act (TSCA). Ms. Roberts is highly regarded as a leader in domestic and international science and policy program management, for industry groups engaged in legislative and regulatory advocacy, research, and public outreach and communications.

Ms. Roberts has more than 20 years of experience in chemical control issues related to TSCA. Her background as a toxicology lab technician gives her unique insights in contracting for research or regulatory-required testing. She has a large network of colleagues to draw from in various trade associations and chemical companies.

She has been lauded for her logical and pragmatic approach to problem solving, and her ability to break down complicated programs and regulatory compliance issues into easy to understand concepts and simple stepwise approaches.

In her work, Ms. Roberts provides strategic management, technical input, and administrative support for industry consortia, including meeting / conference logistics, recordkeeping, budget development, accounting services, and membership recruitment and retention. She develops communication materials, including testimonies, press releases, web materials, and industry guidance. She enhances the benefits of a consortium, providing timely and accurate communications on domestic and international regulatory and legislative issues, and providing as needed access to specific experts to help consortia members achieve their advocacy goals.

Kathleen M. Roberts (cont'd)

Before joining BCCM, Ms. Roberts was a Senior Director with Regulatory and Technical Affairs at the American Chemistry Council (ACC) where she directed strategic efforts to improve the current chemical management system. Under ACC's product stewardship programs, she developed guidance materials and performance measures, advocated Council policies, and provided managerial support to several action groups engaged in regulatory advocacy and public outreach activities. Prior to ACC, she monitored research testing for several pesticide registrations for Jellinek, Schwartz, Connolly & Freshman, and conducted inhalation and genetic toxicology testing for Hazleton Laboratories.

EDUCATION

BS, University of North Carolina, Chapel Hill (1986)

Susan Sharkey

U.S. Environmental Protection Agency (EPA)

Susan Sharkey leads the U.S. Environmental Protection Agency's (EPA's) Toxic Substances Control Act (TSCA) Chemical Data Reporting (CDR) program. During her 30 years with EPA, Susan worked primarily in the Office of Chemical Safety and Pollution Prevention (OCSPP) where she gained expertise in policy, program, and regulatory development with the CDR program and other efforts. Susan also worked in EPA's Office of Research and Development (ORD) as part of the team that studied the potential impacts of hydraulic fracturing on drinking water resources. Throughout her career at EPA, Susan has worked extensively with industry to collect and use their confidential business information.

Prior to joining EPA, Susan worked in the chemical industry. Susan has a bachelors in chemical engineering from the University of Delaware and a masters in business administration from Loyola College.

Lynn Vendinello

U.S. Environmental Protection Agency (EPA)

Ms. Vendinello joined the EPA in 1989 as a Presidential Management Fellow after receiving an undergrad degree from Williams College and a Master's Degree in Public Policy from the Ford School of Public Policy at the University of Michigan. Between college and grad school she worked at an environmental non-profit in NYC called INFORM and on the hill promoting the concept of pollution prevention.

She joined EPA in its newly formed Office of Pollution Prevention, where she created a regulatory development process to ensure that pollution prevention options were considered as viable means for compliance means. She later went on to the newly formed Office of Enforcement and Compliance Assurance, as the Special Assistant to the Deputy Assistant Administrator (DAA). Working with the DAA, they created a new way of measuring the benefits of enforcement cases that involved calculating pollution reduced and behavioral changes as opposed to solely counting penalties and numbers of cases.

After time off for her first child, she joined the Office of Compliance as Team Leader for the Compliance Assistance Centers program, a creative web-based outreach tool for industry that still exists today. She later became the Team Leader for Performance Measures and was a subject matter expert on performance measurement for OECA, where she initiated several statistically-valid compliance rate studies that are often referred to in the Next Generation Enforcement training classes. She then moved onto the Office of Pollution Prevention and Toxics where she served as a branch chief for seven years overseeing regulations and outreach for PCBs, asbestos, mercury and launched the first major regulation on formaldehyde in compressed wood products.

Most recently became the Deputy Division Director in the Chemical Control Division of OPPT, a Division that implements Section 4, 5, 6, 8 and other parts of TSCA for new chemicals and existing chemicals risk management. Since January, she has been the Acting Division Director for CCD, where she has been working to implement the newly amended TSCA's impacts on the new chemicals review program.