TSCA CDR – Practical Strategies for Ensuring Compliance with Federal Regulations

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Thomas C. Berger, Esq.
Keller and Heckman LLP
Washington, DC Office
+1 202.434.4285
berger@khlaw.com

Martha E. Marrapese, Esq.
Keller and Heckman LLP
Washington, DC Office
+1 202.434.4123
marrapese@khlaw.com
Preliminary Word

- This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual's specific circumstances. The interpretation and application of the law to an individual’s specific circumstance depends on many factors. This presentation is not intended to provide legal advice.

- The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the authors’ alone and not those of the authors’ clients.
Speakers

Thomas C. Berger, Partner
berger@khlaw.com

Martha E. Marrapese, Partner
marrapese@khlaw.com
Agenda

- Who must report
- What chemicals must be reported
- Reporting quantity thresholds
- Exemptions and exclusions
- Practical considerations
- Complex reporting cases
  - Change of ownership, electronics,
  - Byproducts
- Q&A
Chemical Data Reporting (CDR)

- Every 4 years. Current submission period: June 1 - September 30, 2016
- Electronic reporting only
  - required through CDX system – must be registered
- Useful Guidance on EPA Website:
  - [www.epa.gov/chemical-data-reporting](http://www.epa.gov/chemical-data-reporting)
  - Contains instructions, FAQs, fact sheets, etc.
- Basis:
  - Section 8(a) of TSCA, 40 C.F.R. Part 711
  - 76 Fed. Reg. 54,933 (Sep. 6, 2011)
What EPA Says.....

- Updated TSCA Inventory is significant tool for:
  - Identifying, prioritizing, and evaluating toxic chemicals
  - Developing profile of U.S. chemical industry
  - Monitoring and evaluating exposure to a chemical and its total impact on health and environment
  - Justifying testing and regulatory actions taken by EPA

- “The only reliable source” of national production/importation volume information for organic chemicals
Covered Companies and Chemicals

- Applies if at one or more U.S. sites you:
  - Manufactured or imported
  - A TSCA Inventory-listed substance (as of 6/1/16) that is not otherwise exempt from reporting
  - In a quantity greater than 25,000 lbs (11,340 kg)
  - In any of the covered calendar years 2012, 2013, 2014, or 2015
Low Threshold Substances (§ 711.8(b))

- Applies to substances subject to regulatory actions
- Reporting threshold = 2,500 lb/yr/site (1,134 kg) if substance subject to:
  - proposed or final § 5(a)(2) Significant New Use Rule (SNUR)
  - proposed or final § 5(b)(4) Chemical of Concern List rule
  - proposed or final TSCA § 6 rule
  - § 5(e) or 5(f) order
  - relief granted under TSCA § 5 or § 7
- Determined as of June 1, 2016
Determining if a Substance is Regulated

- **TSCA Chemical Data Reporting Fact Sheet:** Chemical Substances which are the Subject of Certain TSCA Actions

- **SRS:** The Substance Registry Services (SRS) is EPA’s central system for information about substances that are tracked or regulated by EPA or other sources. It is the authoritative resource for basic information about chemicals, biological organisms, and other substances of interest to EPA and its state and tribal partners.
Exemptions and Exclusions from Reporting
Full Exclusions/Exemptions (§ 711.6(a))

- (1) Polymers (“*polym”, etc.)
- (2) Microorganisms
- (3) “Naturally occurring” substances
- (4) Six listed natural gas streams and water

Exempt from CDR so long as (other than (3)) substance is not as of 6/1/16 subject to:
  - proposed or final rule issued under § 4, 5(a)(2), 5(b)(4), or 6 of TSCA
  - ECA under Part 790
  - order issued under § 5(e) or 5(f)
  - relief granted under § 5 or § 7
“Polymer” means any substance described with word fragments “*polym*”, “*alkyd*”, or “oxylated” in its Inventory name, where (*) indicates that any sets of characters may precede or follow character string defined.

Also includes substances identified in Inventory as a siloxane(s) and silicone(s), silsesquioxane(s), a protein (albumin, casein, gelatin, gluten, hemoglobin), an enzyme, a polysaccharide (starch, cellulose, or gum), rubber, or lignin.
Other Full Exclusions/Exemptions (§ 711.10)

- Manufactured/imported solely in small quantities for R&D
- Imported solely as part of “article”
- Manufactured solely in manner described in 40 C.F.R. 720.30(g) or (h)
  - certain byproducts*, impurities, substances formed on “end use”, * etc.

- **No exemption for** export-only substances

  * more on this later........
Partial Exemptions (§ 711.6(b))

- Numerous listed petroleum process streams ((b)(1)) and listed substances “of low current interest” ((b)(2)) (e.g., sunflower oil) exempt from having to provide process and use information.

- So long as not (as of 6/1/16) subject to:
  - proposed or final rule issued under § 4, 5(a)(2), 5(b)(4), or 6 of TSCA
  - ECA under Part 790
  - order issued under § 5(e) or 5(f)
  - relief granted under § 5 or § 7

- This is only a partial exemption so still need to report manufacturing information for these substances.
Recently-Added Partially-Exempt Chemicals

- § 711.6(b)(2) – To add substances, submit petition for a rulemaking. New listings:
  - fatty acids, C14-18 and C16-18 unsaturated, methyl esters (CASRN 67762-26-9)
  - fatty acids, C16-18 and C-18 unsaturated, methyl esters (CASRN 67762-38-3)
  - fatty acids, canola oil, methyl esters (CASRN 129828-16-6)
  - fatty acids, corn oil, methyl esters (CASRN 515152-40-6)
  - fatty acids, tallow, methyl esters (CASRN 61788-61-2)
  - soybean oil, methyl esters (CASRN 67784-80-9)
  - D-Fructose (CASRN 57-48-7)
  - 1,2,3-propanetricarboxylic acid, 2-hydroxy-, sodium salt (1:3) (CASRN 68-04-2)
  - 1,2,3-propanetricarboxylic acid, 2-hydroxy- (CASRN 77-92-9)
  - 1,2,3-propanetricarboxylic acid, 2-hydroxy-, potassium salt (1:3) (CASRN 866-84-2)
  - corn, steep liquor (CASRN 66071-94-1)
  - soybean oil, epoxidized (CAS RN 8013-07-8)
  - 1,3-Propanediol (CASRN 504-63-2)
  - Palm Kernel Oils (CASRN 8023-79-8)
  - Bentonite, (Acid Leached) (CAS RN 70131-50-9)
“Small Manufacturer” Exemption (§ 711.9)

- No need to report if:
  - Total sales (including parent) < $40 MM/y and <100,000 lb/yr per site, per chemical; OR
  - Total sales (including parent) < $4 MM/y regardless of manufacture/import volume

- Possible to be “small” for some substances but not others

- Not exempt if as of 6/1/16 substance subject to proposed/final rule under § 4, 5(b)(4), or 6; final § 5(e) order; or relief under § 5 or § 7 civil action
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<th>Not eligible for certain full or partial exemptions from reporting</th>
<th>Not eligible for small manufacturer exemption</th>
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Mechanics of Reporting
What Must be Reported

- For Principal Reporting Year (PRY) (CY2015) must provide:
  - Company, site (need D&B number), and chemical identity information (with CASRN or TSCA Accession Number)
  - Production Volume (PV) “(b)(3)”
  - Manufacturing Activity (MA) information “(b)(3)”
  - Processing and Use (P&U) information “(b)(4)”
- P&U required only for PRY
- Separate Form U for each site for which you are responsible
- Must substantiate confidential business information (CBI)
MA Information (§ 711.15(b)(3))

- Volume of substance manufactured or imported
- Number of workers reasonably likely to be exposed to substance at each site
- Physical form(s) of the substance as it leaves submitter’s possession and associated percent of production volume
- Maximum concentration of substance as it leaves submitter’s possession
- Volume of substance used on site
- Volume of substance directly exported and not domestically processed or used
- Whether imported substance is physically present at reporting site
- Whether substance is being recycled, remanufactured, reprocessed, or reused
P&U Information (§ 711.15(b)(4))

- Reporting standard = "known to or reasonably ascertainable by" manufacturer or importer
- Activities classified using list of industrial function categories and list of 48 Industrial Sectors (IS) (no NAICS codes)
- Report separately on:
  - Consumer vs. commercial activities
  - Number of workers reasonably likely to be exposed to substance
- For principal reporting year 2015 only
P&U Information (cont.)

- Report up to 10 unique combinations of
  - Industrial function category
  - Industrial sector
  - Functional use
- For each combination report
  - Percent production volume
  - Number of workers reasonably exposed
  - Number of sites
- Include sites that receive chemical directly or indirectly
P&U Information (cont.)

- Type of industrial processing or use operations at downstream sites
- Approximate number of sites and estimated number of industrial processing and use workers reasonably likely to be exposed to each substance for each combination of P&U code and industrial function category
- Estimated percentages of PV for each P&U code and corresponding industrial function category
- Whether products intended for use by children (14 or under)
- Maximum concentration of reportable substance in each commercial and consumer product category
Known or Reasonably Ascertainable

- Defined at 40 CFR § 704.3:
  - “all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.”

- Requires submitters to conduct reasonable inquiry within full scope of organization for information manufacturer has in its possession
Known or Reasonably Ascertainable (cont.)

- Standard does **not** require manufacturer to conduct exhaustive survey of all employees
- May entail inquiries outside the organization to fill gaps in the submitter’s knowledge
- No requirement to conduct new customer surveys for purposes of CDR
  - *existing* customer survey data must be considered
CBI Handling (§ 711.30)

- Form U allows much to be claimed CBI
  - Use check (“X”) boxes on form
- Upfront CBI substantiation required for:
  - chemical identity
    - Can only claim chemical identity as CBI if substance on confidential Inventory
  - site identity
  - P&U information
- Must answer a series of questions
- Joint submission procedure for importers
  - Foreign supplier completes Part IV
Enforcement
Enforcement

- Civil penalties for failure to comply with CDR:
  - up to $25,250 per chemical per site
- Seemingly minor violations still violations
  - e.g., late reporting, reporting slightly inaccurate manufacture or import volume
- Correction of erroneous information within 30 days of due date may result in lower penalties compared to making changes more than 30 days after due date
Enforcement Example 1

- Company fails to report 1 chemical for CDR at 4 different sites
- Six months later, company is bought by another company who discovers failure to report and immediately notifies EPA
- Non-reporting, level 1, significant, 4 counts, one-time penalty
  - $25,250 x 4 = $101,000
  - Less 25% for self-disclosure
  - Less 25% for disclosure w/i 30 days of reason to believe violation exists
- Total penalty - $55,000
Enforcement Example 2

- Same facts from Example 1 except company self-discloses 4 CDR Form U reports less than 30 days after due date
- Late reporting, level 4, significant, 4 counts
  - $8,900 x 4 = $35,600
  - Less 25% for self-disclosure
  - Less 25% for disclosure w/in 30 days of reason to believe violation exists
- Total penalty = $17,800
EPA “Audit Policy”

- Consider EPA’s “Audit Policy” (65 Fed. Reg. 19,618 (April 11, 2000)) for disclosure to mitigate or eliminate penalties for reporting errors or omissions
  - 21 day clock
  - consult with legal counsel before examining past CDR compliance…
Common Causes of Non-Compliance

- Failure to report/file all or some reportable substances
- Inaccurate manufacture and import volume tracking
  - or lbs. vs. kg…
- Incorrect conclusions as to who is “importer”
  - site or company
- Failure to report production volume to required two significant figures of accuracy
Causes of Non-Compliance (cont.)

- “Toll” manufacturing issues
- Misinterpretation of exemptions
- Failure to account for reportable “byproduct” and related stream “manufacture,” recycling
- Fractionation issues
Other Reporting Considerations

- Nomenclature considerations critical to CDR (and other TSCA requirements)
- For, e.g., FDA/non-FDA uses, must subtract volume for exempt use
- Storage = isolation and may trigger reporting
- In the case of toll manufacturing, only one party reports
- Consistency –
  - with other reporting, e.g. EPCRA, CAA, CWA, RCRA, 2012 CDR
  - re pounds and kilograms – do not confuse the two
Other Reporting Considerations (cont.)

- **Accuracy/rounding considerations**
  - Production volumes
    - 2 significant digits
  - % Production Volume (P&U)
    - to nearest 10%
    - if < 5% but 25,000 lb then nearest 1%
  - For hydrates, must subtract mass of associated water

- Retain records for at least 5 years from submission

- Important to review policies for change of ownership, toll manufacturing, byproducts, etc.
Examples of Complex Reporting
Complex Areas

- Important to review policies for change of ownership

- Account for reportable “byproduct” and related streams associated with reuse and recycling

- Electronics industry
ISSUE: Changes in Ownership

- Post-2012, name change only: use current name.
- Manufacture at sites closed 2012-2015 must be reported.
- Purchased a site in 2013:
  - Seller and Purchaser report only those quantities produced during their respective ownership periods 2012-2015.
- Co-manufacturers: Only one company must report.
Examples – Changes in Ownership

- **Company A takes 50% ownership of Company B; they remain separate legal entities.**
  - B reports its own quantities, identifies A as parent on form.

- **Company X splits into X and Y:**
  - If Y is the continuation of X, Y reports volumes from when it was still a division of X
  - If Y is not the continuation of X, only report manufacture after it was created.
ISSUE: Byproducts

- **Definition OF A BYPRODUCT:**
  - “a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.”
  - 40 C.F.R. § 704.3.
- **Exempt from reporting if only commercial purpose is for use by public/private organizations that**
  1. burn it as fuel,
  2. dispose of it as a waste, including in a landfill or for enriching soil, or
  3. extract component chemical substances from it for commercial purposes.
Byproducts

- First, properly characterize as a:
  - Mixture of well-defined chemicals
  - Single well-defined substance, or
  - Complex reaction products (unspecified or variable composition (UVCB))

- Second, report the byproduct if it has a subsequent, non-exempt commercial purpose
  - Calls for knowledge about what the purchaser is doing with your spent material.
Third: Is Chemical Being Recycled?

- Answer is based on the pertinent substance
  - Ask if the manufactured byproduct itself is what is being recycled. If so, correct response is yes

- Answer is no if:
  - Subsequent use of pertinent substance is a reaction to form another substance
  - You are not removing a chemical substance from a waste stream
    - *E.g.*, product finishing or reuse of a solvent is not removing the substance from a waste stream
Example 1 – Byproducts

- Company P manufactures Byproduct X, which is sold as a feedstock which is reacted to produce a zinc fertilizer.
- Byproduct X is not disposed of as a waste or burned, and it is reacted rather than having a chemical extracted from it. Therefore it does not meet the byproduct exemption at 40 CFR 720.30(g)(2).
- Company P must report Byproduct X. Answer to whether the chemical is recycled is no.
- Fertilizer producer reports the fertilizer reaction product.
Example 2A – Byproducts

- Company A manufactures a byproduct mixture of 70% cupric chloride, 20% cuprous chloride, 5% hydrochloric acid, and 5% other unknown substances. Sells to Recycler B who will react cupric chloride and cuprous chloride to recover copper and dispose of remainder.
  - Company A reports cupric chloride, cuprous chloride, but not the remainder which will be disposed of as a waste
  - Recycler B reports copper
Example 2B – Byproducts

- If byproduct is characterized by Company A as a UVCB, but Recycler B still extracts cupric chloride and cuprous chloride, does the answer change?
  - Yes.
  - Company A does not report the byproduct. This is because Recycler B only extracts the two copper compounds.
  - Recycler B reports cupric chloride, cuprous chloride, and elemental copper.

- If Recycler B instead adds the UVCB directly to an electrolytic process to produce copper, does the answer change?
  - Yes. Company A reports the UVCB, Recycler B reports copper.
Example 3 – Byproducts

No CDR reporting needed when manufacturing a polymer in the presence of Solvent A in a reactor, and *recycling a mixture of unreacted starting materials, unspecified impurities, and Solvent A.*

Why? The polymer is exempt, the solvent was manufactured by another company, and the impurities have no separate commercial purpose other than disposal as waste.
Example 4 – Byproducts

- Company A removes Company B’s wastewater. Company A will recover Metal G from metal compounds in the wastewater if market value is high. It will dispose of the wastewater if market value is low.
  - Company B needs to determine the chemical identity of the wastewater stream.
  - Company B need not report portion of wastewater that is disposed. If it does not know, it can estimate or it must report full volume.
  - Answer is yes to whether it is recycled.
  - Company A reports volume of Metal G because it is not simply extracted. A reaction takes place.
Electronics – 3 Distinct CDR Scenarios

- **Domestic manufacture**: Reactions during etching and plating baths may form oxidized salts and or metal complexes and these byproducts may be reportable depending on subsequent activities conducted with them.

- **Imports**: Need to determine whether the chemical substance is part of an article.

- **End-of-life**: Sending outdated computers, cell phones, and other office equipment for recycling.
Domestic Manufacture, Spent Etchant

- EPA considers spent etchant to be a byproduct of the use of etchant to make printed circuit boards.
  - It is manufactured for a commercial purpose.
  - It is subject to CDR unless it qualifies for an exemption.
  - Must determine if it is used for a non-exempt purpose.
Electronics and Importation

- Substances imported solely as part of “article” are exempt from CDR.
- A substance is considered to be imported “as part of an article” if it is not intended to be removed from that article and has no end use or commercial purpose separate from the article of which it is a part.
- No reporting of substances in articles even if the substance in question is a regulated substance under section 4,5,6.
Some things imported for the purpose of making articles are themselves articles.
- E.g., Metal or plastic sheet, thermoformed and molded plastic parts, batteries
- Desiccant packets (including the contained silica gel beads), foam packing, the packing box itself all are articles.

A chemical substance that you import and later incorporate into an article for commercial purposes is not exempt on this basis.

Printer cartridges are designed to release ink and therefore are not articles. The ink is reportable.
Example – Outdated Equipment

- Company A collects and sends outdated phones to Company B who refurbishes them or reclaims metals by chemical oxidation/reduction or another reaction
  - Company A has no reporting obligation. Simply collecting is not manufacturing. Imported, outdated phones are articles.
  - Company B is subject to CDR for reporting the reclaimed metals.
Other Useful EPA CDR “Fact Sheets”

- Reporting Thresholds for 2016
- Importers
- Imported Articles
- Toll Manufacturing
  - Parties can assign responsibility but both liable
- Non-Isolated Intermediates
- Reporting for Electricity Generating Sites
- Reporting Manufactured Chemical Substances from Metal Mining and Related Activities

- [https://www.epa.gov/chemical-data-reporting](https://www.epa.gov/chemical-data-reporting)
Closing Thoughts

- This is an important requirement, subject to frequent and efficient EPA inspection
  - Still within SOL for 2012
- Penalties are assessed per-chemical per site
- Significant time and effort needed to comply.
- Don’t wait until Sept. 29th…
THANK YOU

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Washington, DC • Brussels • San Francisco • Shanghai • Paris