



Are You Ready for the 2024 CDR?

June 27, 2024

James Votaw

Partner

Washington, DC

+1 202.434.4227

votaw@khlaw.com

Gregory A. Clark

Partner

Washington, DC

+1 202.434.4302

clarkg@khlaw.com



James Votaw

- ◆ James Votaw is an environmental law partner at Keller and Heckman focusing on regulation of new and existing conventional, biotech and nanoscale chemicals under TSCA and pesticides and pesticidal devices under FIFRA. Among other things, James obtains pre-market approvals, conducts transactional due diligence, and defends enforcement actions under these and other health, safety, and environmental laws.



Gregory A. Clark

- ◆ Gregory (Greg) Clark counsels clients on regulatory and environmental issues, focusing on the Toxic Substances Control Act (TSCA), the Clean Air Act (CAA), state volatile organic compound (VOC) regulations, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA).
- ◆ He assists clients needing approval of new chemical substances, genetically modified organisms (GMOs), and pesticides under TSCA, FIFRA, and similar laws abroad. Clients value his extensive experience guiding them through the PMN, Low Volume Exemption, Microbial Commercial Activity Notice (MCAN), and TSCA Environmental Release Application (TERA) review processes.
- ◆ Greg's extensive background enables him to provide guidance to companies and trade associations on the prioritization, risk evaluation, and risk management of existing chemicals, including chemicals on the 2014 TSCA Work Plan, following the Lautenberg Act amendments to TSCA. He assists companies with periodic reporting under the TSCA Chemical Data Reporting Rule and other agency reporting programs. He also designs, conducts, and coordinates comprehensive internal audits of TSCA compliance for existing operations under EPA's "Audit Policy," as well as under other penalty mitigation policies.



Chemical Data Reporting (CDR) Rule



- ◆ Section 8(a) of TSCA - 40 C.F.R. Part 711
- ◆ Reporting required every four years
- ◆ Reporting is per chemical, per site
- ◆ Current reporting deadline: September 30, 2024
- ◆ 2020 CDR:
 - ◆ 5,240 sites
 - ◆ 8,649 unique substances
 - ◆ 43,481 Forms U

CDR Reporting Basics

- ◆ Required to submit via CDX:
 - ◇ Company, site, and chemical identity information
 - ◇ Annual Production Volume
 - ◇ Manufacturing Activity (MA) information
 - ◇ Processing and use (P&U) information
- ◆ Required to report PV for four prior calendar years
- ◆ MA and P&U required only for the Primary Reporting Year (2023)
- ◆ New for 2024: OECD codes for P&U information

CDR Reporting Basics – Who Must Report?



- ◆ **Manufacturers** (including importers) of each chemical substance that:
 - ◆ Was listed on TSCA Inventory on or before June 1, 2024, and
 - ◆ Manufactured in quantity **≥25,000 lbs.** (*≥2,500 lbs. for certain regulated substances*) at a single site
 - ◆ In any one or more calendar years, 2020, 2021, 2022, or 2023
 - ◆ Unless excluded (not subject to TSCA) or exempt
- ◆ **“Site” for imports** – location of business unit making import decision

Lower Production Volume Threshold (§711.8(b))



- ◆ Reduced reporting threshold applicable to substances subject to certain regulatory actions = **2,500 lb./yr./site**
 - ◆ Proposed or final § 5(a)(2) SNURs
 - ◆ Proposed or final TSCA § 6 rules
 - ◆ Test order under § 4
 - ◆ New chemical control order under § 5(e) or 5(f)
 - ◆ Relief granted under TSCA § 5 or § 7
- ◆ *Regulatory status assessed as of **June 1, 2024***

Exclusions and Exemptions [§711.6(a)]

- ◆ ***Caveat: Burden is on manufacturer to show exemption applies***
- ◆ **Excluded from TSCA [TSCA § 3(2)(B)]**
 - ◇ Quantities for foods, drugs, cosmetics, medical devices
 - ◇ Pesticides (but not separate pesticide inerts or pesticide devices)
- ◆ **Polymers**
 - ◇ Anything with these word roots: *polym”, “*alkyd”, “*oxylated”,
 - ◇ Enzymes, lignins, polysaccharides (cellulose, gum, starch), proteins (albumin, casein, gelatin, gluten, hemoglobin), rubber, siloxanes and silicones, or silsesquioxanes
 - ◇ Recyclers - Not including polymers that have been depolymerized, hydrolyzed, or otherwise chemically modified (unless products are also polymers)

Exclusions and Exemptions (2)

- ◆ **Microorganisms**
- ◆ **“Naturally occurring” substances** [§ 710.4(b)]
 - ◇ Naturally occurring, and
 - ◇ Processed, if at all, only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or extracted from air by any means
 - ◇ Caveat: trace the source for all quantities/document to confirm processing method
- ◆ **Six listed natural gas streams and water**
 - ◇ Listed at § 711.6(a)(4)

Exclusions and Exemptions (3)

- ◆ **Manufactured solely in manner described in 40 C.F.R. §720.30(g) or (h)**
 - ◆ *Byproducts* not used for commercial purpose or only burned as a fuel, disposed as a waste or source for extracting other substances
 - ◆ *Impurities*
 - ◆ *Non-isolated intermediates*
 - ◆ Other incidental manufacture without separate commercial intent (h)(3)-(7)

Exclusions and Exemptions (4)

- ◆ **“Small manufacturers”** [§ 704.3]
 - ◇ Total sales < \$120 million
 - ◇ Total sales < \$12 million (if <100,000 lbs of substance)
 - ◇ Except substances subject to lower production threshold
- ◆ **Solely for R&D**
- ◆ **Imported solely as part of “article”**
- ◆ **Certain byproducts –**
 - ◇ Portland cement manufacture
 - ◇ Kraft pulping process
- ◆ **“Export-only” substances are not exempt!**

CBI Claims

- ◆ Persons submitting information under the CDR may assert confidential business information (CBI) claims
- ◆ Cannot make CBI claims for:
 - ◆ Chemical identities listed on the public portion of the TSCA Inventory
 - ◆ Certain industrial, consumer, and commercial processing and use information
 - ◆ Responses left blank or designated as “not known or reasonably ascertainable”
- ◆ Information not claimed as confidential may be made public without further notice to submitter

CBI Substantiation

- ◆ Upfront substantiation is required for all confidentiality claims except:
 - ◆ Production volume
 - ◆ Joint submission information from the primary submitter (trade name and supplier identification)
 - ◆ Joint submission information from the secondary submitter (percentage of formulation)
- ◆ Certification statement required for all claims

CBI Substantiation (2)

- ◆ For each data element claimed confidential, must submit detailed written answers to six questions on the following:
 - Substantial harm to business’s competitive position
 - Precautions taken to protect information when disclosed to others
 - Availability of information in public documents (e.g., SDS, patents)
 - Trade secrets
 - Duration of claim
 - Prior confidentiality determinations

CBI Substantiation (3)

- ◆ If chemical identity is claimed confidential, must include answers for four additional questions:
 - ◆ Whether publicly known to be in U.S. commerce
 - ◆ Whether it leaves the site in any form (product, effluent, emission)
 - ◆ Discoverability by analysis of the substance
 - ◆ Whether chemical identity reveals confidential process information

CDR Fact Sheets and Guidance from EPA



- ◆ Chemical Subject to Certain TSCA Actions
- ◆ Reporting Thresholds for 2024
- ◆ Company Ownership Changes
- ◆ Importers
- ◆ Imported Articles
- ◆ Toll Manufacturing
- ◆ Examples and Case Studies for the CDR
- ◆ Byproduct, Impurities, and Recycling Scenarios
- ◆ Byproducts Reporting for the Printed Circuit Board Industry
- ◆ Non-Isolated Intermediates
- ◆ Reporting for Electricity Generating Sites
- ◆ Metal Mining Activities
- ◆ Kraft and Pulp Paper Process

CDR Compliance Notes

- ◆ **Submit report**, on time
- ◆ Include **all** chemicals
- ◆ Protect CBI chemical identities
- ◆ Report production volume accurately
 - ◇ Clear, concise records; robust reporting system = critical
- ◆ Data errors/omissions can create substantial enforcement liability
- ◆ Possibility of citizen suits



Please join us at 1:00 PM Eastern U.S.
Wednesday, July 24, 2024
<https://www.khlaw.com/OSHA3030>





Please join us at 10:00 AM Eastern U.S.
Wednesday, August 28, 2024
<https://www.khlaw.com/REACH-3030>



Please join us at 1:00 PM Eastern U.S.
Wednesday, July 17, 2024
<https://www.khlaw.com/TSCA-3030>

[Register Now!](#)



 Keller &
Heckman

**NAVIGATING TSCA:
BASICS AND BEYOND 2024**

NOVEMBER 14-15, 2024
RENAISSANCE ARLINGTON
CAPITAL VIEW HOTEL

A large, light gray diamond shape composed of a grid of small dots, positioned on the left side of the slide.

Thank You

Any questions?

James Votaw
Partner

Washington, DC
+1 202.434.4227
votaw@khlaw.com



Gregory A. Clark
Partner

Washington, DC
+1 202.434.4302
clarkg@khlaw.com

