

Keller and Heckman presents
TSCA 30/30™
A Webinar Series



Chemical Data Reporting 2020 – Proposed Amendments

May 15, 2019



Please Don't Forget to Dial-In:

Conferencing Number: (800) 768-2983

Access Code: 434 4318

(View the slides via webinar, and the sound via phone)

Herbert Estreicher, Ph.D.



Herbert Estreicher, Ph.D. has a broad practice in international environmental regulatory law.

Dr. Estreicher has an interdisciplinary approach combining law and science. He represents leading manufacturers of chemicals, pesticides, insect repellents, food additives, and consumer products before Federal and State regulatory agencies.

Dr. Estreicher provides advice on product liability risk control and assists clients with crisis management for embattled products, including chlorinated pesticides, wood preservatives, dioxins, and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on responding to the CEPA challenge program, and provides advice on European chemical directives and initiatives, such as the EU Biocidal Products Directive, the Classification, Labelling and Packaging Regulation, the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, and the Prior Informed Consent (PIC) Regulation. Dr. Estreicher also represents clients in the negotiation and development of various international environmental instruments governing persistent organic pollutants (POPs), has been actively involved in the Great Lakes Binational Toxics Strategy, and has participated in the Canadian Strategic Options Process (SOP). He is actively engaged in the areas of TSCA Reform and the California Green Chemistry Initiative. His extensive background in organic chemistry, risk assessment and bioengineering is valued highly by clients in the chemical, nanotechnology, and biotechnology industries.



estreicher@khlaw.com • 202.434.4334

Taylor Johnson



Taylor Johnson is an environmental lawyer specializing in the area of environmental regulation of products, including chemical control, pesticides, energy efficiency regulation, and importantly, domestic and international transportation of hazardous materials. Mr. Johnson also advises clients on community-right-to-know laws, Proposition 65, occupational safety and health matters, and supports a wide variety of commercial tort and other litigation issues.

Mr. Johnson has special expertise in the area of hazardous materials transport, including enforcement defense and compliance counseling. Mr. Johnson helps companies secure competent authority approvals, special permits, and letters of interpretation from regulatory authorities around the world. He has also prepared successful petitions to PHMSA on behalf of shippers seeking regulatory relief.

Prior to joining Keller and Heckman, Mr. Johnson promoted the development of energy and environmental legislation and policy at the state level.



- Proposed Amendments to the 2020 CDR
- Impact of EDF v EPA Decision on CDR Reporting

Chemical Data Reporting (CDR) Overview



- Section 8(a) of TSCA
 - 40 C.F.R. Part 711
- Successor to TSCA § 8(a) Inventory Update Rule (IUR) (1986, 1990, etc.)
- Requires reporting every four years
- For the 2016 CDR, EPA received Form U's from 5,660 sites with an associated 42,464 chemical reports, providing information on 8,717 unique chemicals.

CDR Reporting Basics



- For the upcoming 2020 CDR, companies required to complete and submit detailed “Form U” to EPA via CDX by 9/30/2020 if at one or more US sites the company:
 - Manufactured or imported
 - TSCA Inventory-listed substance (as of 6/1/20)
 - That is not exempt (see 40 CFR § 711.6 for substance exemptions)
 - In quantity >25,000 lbs (>2,500 lbs for certain substances) at that US site
 - In calendar year 2016, 2017, 2018, **or** 2019

CDR Reporting Basics (cont.)



- Submission period: 6/1/2020 – 9/30/2020
 - CY 2019 = “Principal Reporting Year” (PRY)
- Required to provide via CDX:
 - Company, site, and chemical identity information
 - Production Volume (PV)
 - Manufacturing Activity (MA) information
 - Processing and Use (P&U) information
- Required to report PV for 2016, 2017, 2018, and 2019
- MA and P&U required only for PRY (2019)
- **Must substantiate CBI**

Proposed CDR Amendments



- April 25, 2019 (84 Fed. Reg. 17,692), EPA publishes proposed rule to amend:
 - CDR requirements
 - Section 8(a) size standards for small manufacturers
- Agency believes proposed amendments “may better address EPA and public information needs by providing additional information that is currently not collected; improve the usability and reliability of the reported data; and ensure that data are available in a timely manner.”
- Comments due June 24, 2019

Proposed CDR Amendments (cont.)



- Replace processing/use codes with codes based on OECD codes
- Include requirement to report NAICS code(s) for sites of manufacture
- Modify requirement to indicate whether chemical is removed from waste stream and recycled, remanufactured, reprocessed, or reused, with requirement to indicate whether chemical is removed from waste stream and recycled
- Add requirement to report the percent total production volume for a chemical substance that is a byproduct

Proposed CDR Amendments (cont.)



- Require secondary submitter of joint submission to report chemical-specific function along with percentage of chemical in imported product
- Add voluntary data component to provide public contact
- Modify/clarify definition of “parent company”, add requirement to report a foreign parent company, when applicable, and codify reporting scenarios

Proposed CDR Amendments (cont.)



- Simplify reporting process for co-manufacturers by initiating multi-reporter process to separately report directly to EPA within e-CDRweb
- Allow reporting in specified metal categories for inorganic byproducts (not required)
- Add exemptions for certain byproducts
- Removing outdated text, consolidate exemptions, etc.

- EPA proposing to:
 - Amend §8(a) “small manufacturer” definition
 - Following EPA’s determination on November 30, 2017 that revision to the current size standards is warranted (82 FR 56824)
 - Based on inflation
 - Update current two-standard definition appearing at §704.3 by increasing sales level
 - First standard \$40 million → \$110 million
 - Second standard \$4 million → \$11 million

- First standard exception
 - If annual production or importation volume of a substance at any site is greater than 45,400 kilograms (100,000 pounds), you will not qualify as a small business unless you meet standard (2)
- Impacts
 - Sites that meet the small manufacturer requirements are exempted from the need to report either for the full site (based on the second standard) or for particular chemical substances (based on the first standard) (exceptions apply)

Proposed CDR Amendments: CBI Claims



- Persons submitting information under the CDR may assert confidentiality claims for information at the time it is submitted
- Cannot make confidentiality claims for:
 - Public contact information if voluntarily provided
 - Chemical identities listed on the public portion of the TSCA Inventory at the time of submission
 - When a response is left blank or designated as “not known” or “reasonably ascertainable”
- Information not asserted as confidential may be made public without further notice to submitter

Proposed CDR Amendments: CBI Substantiation

- The Agency is proposing to amend the CDR substantiation provisions to require substantiation for all confidentiality claims **except** for information listed in TSCA section 14(c)(2) including (but not limited to):
 - Production volume information
 - Joint submission information from the primary submitter, including trade name and supplier identification
 - Joint submission information from the secondary submitter, including the % formulation
 - Marketing and sales information
 - Information identifying a supplier or customer

- For each data element claimed confidential, must:
 - Submit with report detailed written answers to 6 questions
 - Substantial harm to business' competitive position
 - Precautions taken to protect information
 - Availability of information in public documents
 - Trade secrets
 - Duration of claim
 - Prior confidentiality determinations

Impact of EDF v. EPA



- Case No. 17-1201 (D.C. Cir. Apr. 26, 2019)
- Case arose in the context of CBI substantiation for specific chemical identity in connection with notice of activity reporting.
- EPA did not require companies to provide substantiation that the chemical identity “is not readily discoverable through reverse engineering.” 15 U.S.C. § 2613(c)(1)(B)(iv).
- Court held

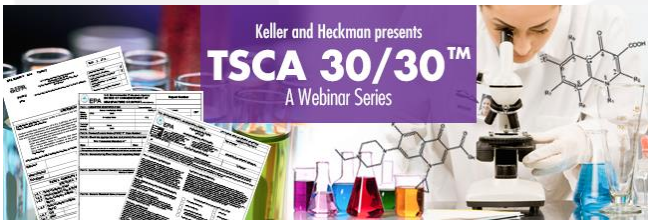
- EPA had deleted from the proposed rule the following substantiation questions:
 - Does this particular chemical substance leave the site of manufacture in any form, e.g., as product, effluent, emission?
 - If so, what measures have been taken to guard against the discovery of its identity?
 - If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?
- Court held EPA's elimination of questions pertaining to reverse engineering was arbitrary and capricious

- As the Court stated, “it makes no sense to treat as confidential the chemical identity of a substance that can readily be discovered through reverse engineering.”
- Implications for CDR reporting and maintaining CBI for substance on confidential inventory.

FURTHER THOUGHTS



Please join us at 1:00 PM Eastern U.S.
Wednesday, May 22, 2019
www.khlaw.com/TSCA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, June 12, 2019
www.khlaw.com/TSCA3030



Please join us at 1:35 PM Eastern U.S.
Wednesday, July 10, 2019
www.khlaw.com/REACH-3030



Keller and Heckman presents
TSCA 30/30™
A Webinar Series

The Next TSCA 30/30:
Wednesday, June 12th

For more information on past and future **TSCA 30/30** programs, please visit **www.khlaw.com/tsca3030** and **www.TSCAReformCenter.com** for the most up-to-date TSCA news

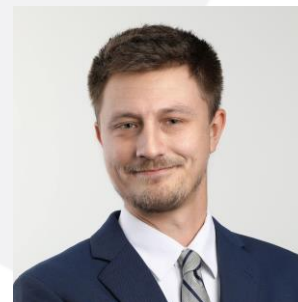
Keller and Heckman presents
TSCA 30/30™
A Webinar Series



THANK YOU



Herbert Estreicher, Ph.D.
estreicher@khlaw.com
202.434.4334



Taylor Johnson
johnson@khlaw.com
202.434.4255