



New CBI Rules:

How can you comply with your Hazard Communications requirement and Still Protect Business Critical Information

Rose Passarella, Ph.D., J.D., Associate Director
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New CBI Rules

Confidential Business Information (CBI) is critical to most companies. In this session, we will discuss the new CBI rule under the Toxic Substances Control Act (TSCA).

Assertion and Substantiation claims: The 2016 amendment added these requirements. The rule strengthens these and adds them to other parts of the TSCA.

Masking chemical names: The rule narrows the ability to mask multiple structural elements.

Health and Safety Studies: The rules concerning these are also narrowed.

Agenda



01

Background

02

CBI

03

The New CBI Rule

04

What's in a Name

05

PFAS Reporting Rule

06

Chemical Data Reporting Rule (CDR)

07

Other Items to Keep in Mind

01

Background



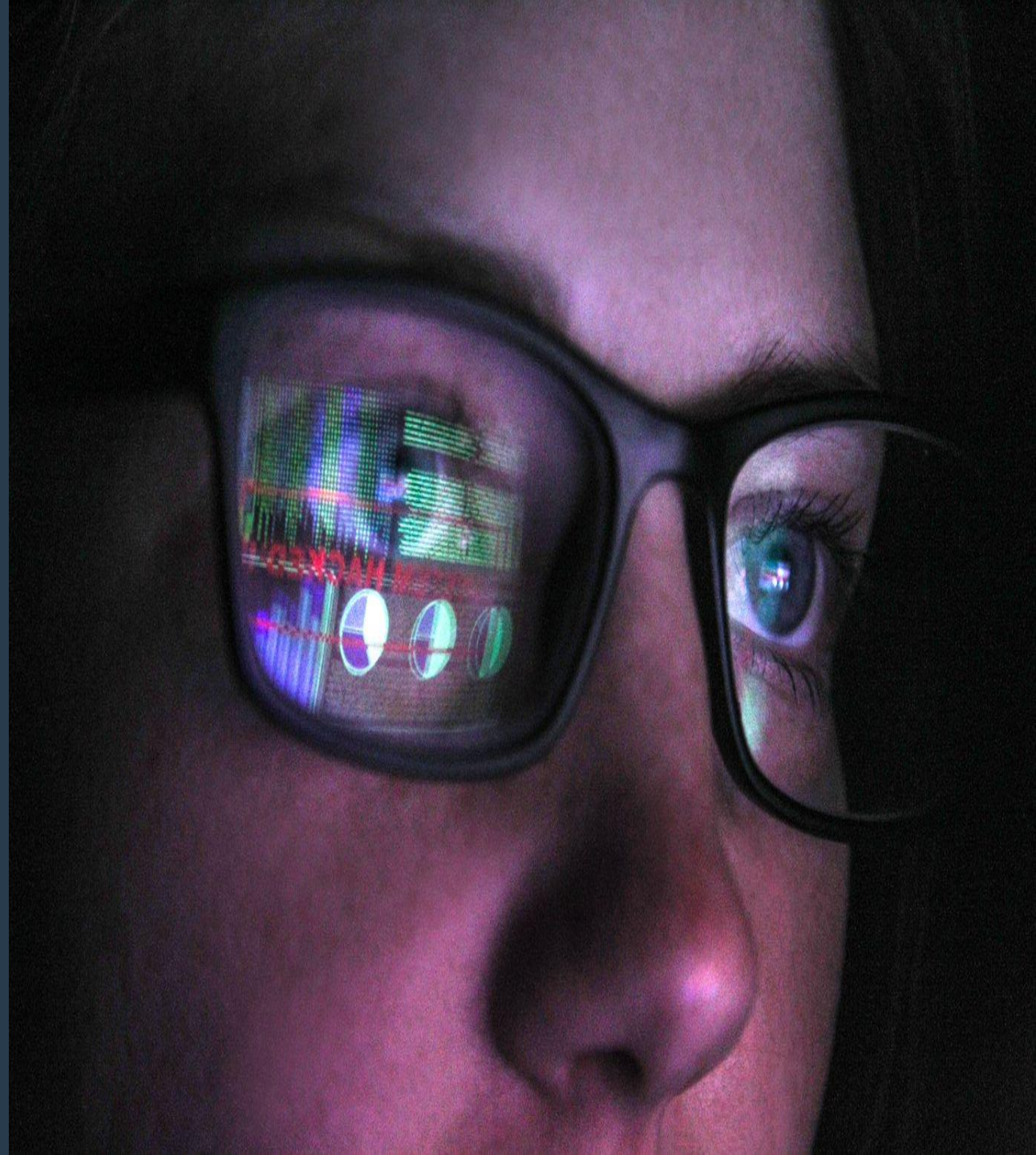
Background TSCA Reform

- Toxic Substances Control Act (TSCA) from 1976 to 2016
- Some NGOs believed that there was weak federal oversight
- States were acting - Regions were enacting
- Labeling acts; hazard warning (Proposition 65)
- Interrupting commerce
- The 2016 TSCA Reform was to create a strong Federal system to instill confidence
- Major changes
- Must have a discussion by the EPA
- Must substantiate CBI - upfront



02

CBI

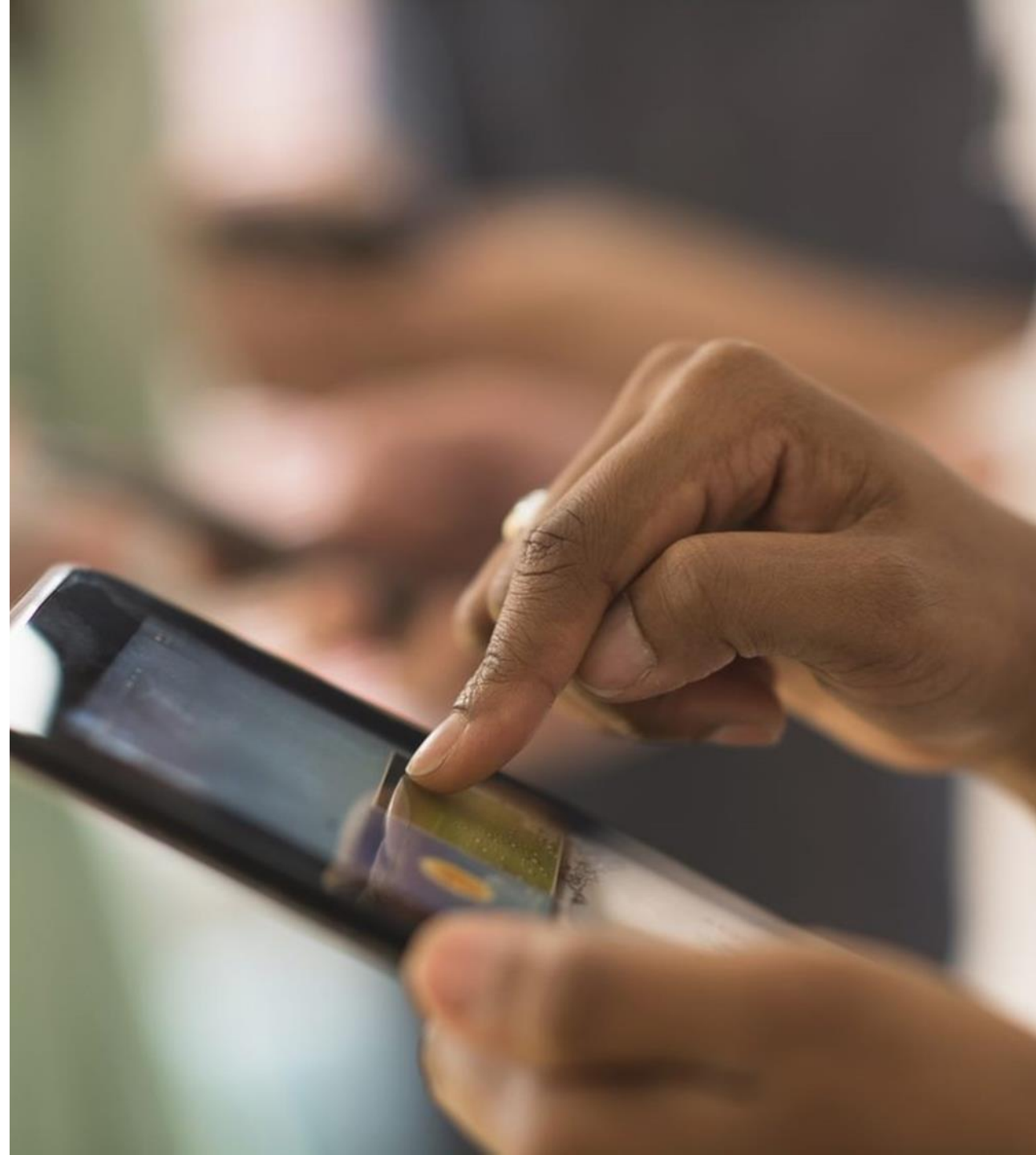


What is CBI?

- According to the EPA, Confidential Business Information (CBI) is the proprietary information, considered confidential to the submitter, the release of which would cause substantial business injury to the owner.

Section 14 of the TSCA

- Requires up front and more substantiation of confidential business information (CBI)
- Unless requested for less or re-substantiated, CBI claims sunset after ten years
- Broadens who may access TSCA CBI





CBI Claim Review

- EPA must review all CBI chemical identity claims
- EPA must review at least 25 percent of all other CBI claims

Confidential substances make up around 8,000 of the nearly 42,000 active chemicals listed in US commerce on the TSCA inventory. Those designated as confidential business information (CBI) are not directly identified, but instead given a generic name and accession number.



March 2021:

After a review of an original list of substances of 390, the EPA said 13 were found to already be on the public inventory or were reported using an invalid accession number.

The remaining 377 chemicals "were reported as non-confidential by one or more manufacturers" during one or more of the quadrennial chemical data reporting (CDR) submission periods in 2012, 2016 or 2020, the agency said. "Therefore, these substances are no longer eligible for continued confidential inventory status."

That broader list included not only substances companies had reported as non-confidential in a CDR submission, as well as those flagged during the 2017-18 inventory reset process, in which they had to identify chemicals that were manufactured, imported or processed in the US during a ten-year 'look-back' period.

03

The New CBI Rule





August 2023. It revised the CBI provisions to delete most provisions and replace them with a cross-reference to Part 703.

CBI TSCA and Other Statutes

If the other statute provides more protection from disclosure than TSCA, the other statute's public disclosure protections would apply. This could arise concerning studies submitted under the Federal Insecticide, Fungicide, and Rodenticide (FIFRA).

Assertion and Substantiation

The 2016 amendments to TSCA added more requirements.

The rule incorporates EPA interpretations into regulation, thereby codifying the interpretations.

- require submitters to assert and substantiate their CBI claims at the time of submission.
- cautions against claiming most information in a document as confidential.

Must assert a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position:

Revises the substantiation questions in current CBI provisions:

- What harmful effects to your competitive position, if any, do you think would result if EPA publishes on the Inventory the identity of the chemical substance?
- How could a competitor use such information given the fact that the identity of the substance otherwise would appear on the Inventory of chemical substances with no link between the substance and your company or industry?
- How substantial would the harmful effects of disclosure be? What is the casual relationship between the disclosure and the harmful effects?





Specifically explain what harm to the competitive position of your business would be likely to result from the release of the information? How would that harm be substantial? Why is the substantial harm to your competitive position likely (i.e., probable) to be caused by release of the information rather than just possible?

Patent

In the Agency's experience, patents related to information claimed as CBI under TSCA rarely if ever disclose information in the same context or with the same level of detail as in the related TSCA submission.

Alternatively, the preamble suggests that the existence of a patent may negate a claim of competitive harm: if the information is covered (i.e., legally protected) by a patent in such a way that no substantial harm to the competitive position of the business would result from the release of the information, then the information is not subject to confidential treatment on that ground as well.

The new question would require patent numbers to be provided, so that EPA may determine for itself whether a patent negates a CBI claim.

Health and Safety Studies

With some exceptions, health and safety studies are not protected from disclosure.

Proposed rule would require all submitters of studies to provide both the studies and a summary of the studies using an appropriate OECD template, if one exists. The template would have boxes available to indicate specific CBI claims. This provision would have particular relevance under the PMN regulations and the section 8(d) regulations, both of which require submission of studies.





Reporting by CDX

Most current TSCA regulations require submission of CBI claims and substantiations electronically through EPA's Central Data Exchange.

What you have to do

Ensure that they keep that contact information current.

In circumstances where ownership of the company or unit of a company has changed, such that contact information for one or more prior TSCA submissions that include confidentiality claims is affected, a notice of transfer of ownership must be directed to EPA via CDX.

EPA also plans to provide public notice of expiring CBI claims.

In summary:

The new rule is intended to narrow CBI claims and make assertion, substantiation, and tracking of CBI claims more rigorous. The proposed changes may affect every company that submits confidential information to EPA.



CONFIDENTIAL BUSINESS INFORMATION (CBI)

Upfront substantiation for all CBI claims except for:

- PV
- Supplier identity, trade name, and formulation information associated with joint submissions
- Updated questions and certification
- General use data elements cannot be CBI
- **Industrial:** type of processing and use, industrial sectors, functions.
- **Commercial/Consumer:** categories, functions, whether consumer or commercial, whether used in products intended for use by children.

04

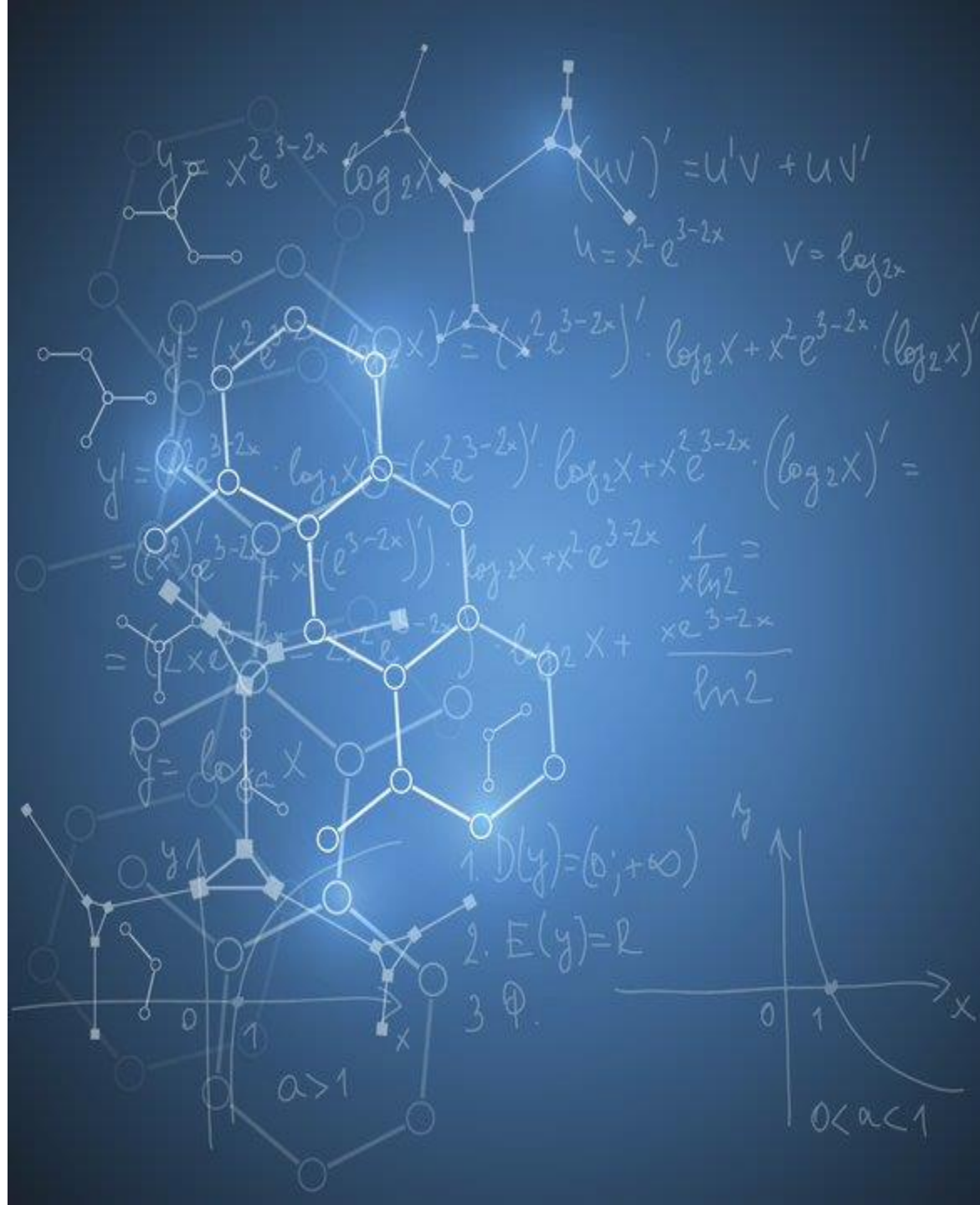
What's in a name?



Generic Names for Confidential Chemical Identities

Structurally descriptive generic names must be consistent with guidance developed by the Administrator. June 22, 2018

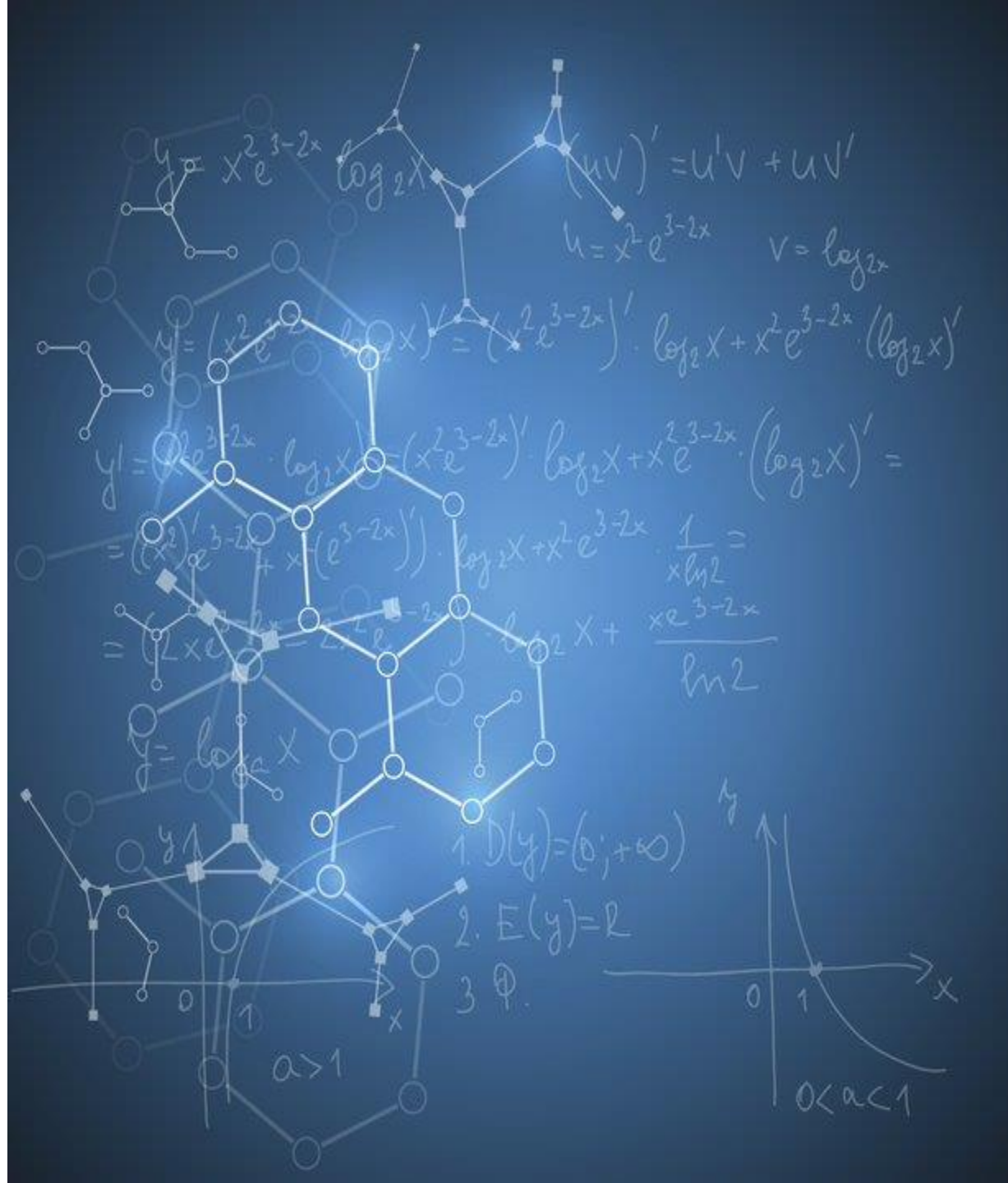
Although examples primarily include masking one structural element, masking more than one structural element can be acceptable, provided that the submitter can justify their need for any additional masking.



The rule is narrower:

In most cases, only one structural element of a specific chemical name may be masked. If the submitter of a proposed generic name wishes to mask more than one such element, the submission must include an explanation of why masking only one element is insufficient to protect the confidential identity.

The generic name should generally only obscure one structural feature, but in any case, should conceal only the feature(s) necessary to avoid a likelihood of substantial competitive harm to the submitter.



Take away

Narrow CBI claims

Substantiation more rigorous

Do not ignore!



05

PFAS Reporting Rule





Key Items

EPA is issued a final rule to update the **Toxics Release Inventory (TRI)** chemical list to identify nine additional PFAS subject to reporting requirements. The addition of these PFAS supports the commitment to address the impacts of these forever chemicals, and advances EPA's PFAS Strategic Roadmap to confront the human health and environmental risks of PFAS.

- **PFAS Reporting Rule - It is official September 28, 2023**
- Rule includes new data-gathering program
- Requires regulated entities to provide detailed reports containing information about the entity's usage of PFAS dating back to January 1, 2011, including not only the identities of PFAS chemicals and amounts used, but also the byproducts resulting from their manufacturing, use, or disposal; the potential environmental and health effects of each substance; the manner of disposal; and the number of individuals potentially exposed, as well as the duration of such exposure.
- The reach of the rule is vast, because it defines PFAS broadly and because it does not contain the same de minimis exceptions found in similar TSCA data reporting programs.
- Don't forget the States rules are increasing for example CA ME MN.



Key Items

- Exemption changes low volume exemptions (LVEs) and low release and exposure exemptions (LoREX).
 - deny without substantive review any LVE or LoREX notice for a PFAS;
 - codify ineligibility for PBT;
 - Adding SNURs to existing substances;
 - allow the EPA to proactively notify LVE or LoREX holders when their substance becomes subject to a proposed or final significant new use rule (SNUR); and
 - require companies to first receive approval before they can begin manufacturing an LVE or LoREX chemical, replacing the agency's current practice of either denying or suspending the review of exemption notices nearing the end of the 30-day review period.

06

CHEMICAL DATA REPORTING (CDR)





CHEMICAL DATA REPORTING (CDR)

- Certain classes of chemicals, such as polymers, are exempted from reporting.
- The next CDR will be 2024
- The reporting period is from 2020, 2021, 2022, 2023.

Manufacturers, including importers, of chemical substances that meet the following criteria must report:

- Annual production volume of a chemical substance at a site is $\geq 25,000$ lbs in at least one of the last four years (*i.e.*, 2020, 2021, 2022, or 2023);
- Reportable threshold is 2,500 lbs or greater for substances subject to certain TSCA regulatory actions;
- Production Volume reporting required for all four years (2020, 2021, 2022, and 2023); and
- Processing and use information must be reported for 2023.

Submitters are required to report electronically through EPA's Central Data Exchange (CDX)-Form U.

DETAILED INFORMATION NEEDED FOR 2023



Physical Form: Identify physical form from the dropdown list in spreadsheet.

Percent Production Volume in Physical Form: Percentage of each physical form of the chemical at the time it leaves your site or is reacted on-site.

Recycled, Reprocessed, Remanufactured, Reused: Select YES/NO if the chemical substance, which otherwise would be disposed as waste, was recycled, reprocessed, remanufactured, or reused.

Percent Production Volume as a Byproduct*: Percentage of the chemical that is produced without a separate commercial intent during the manufacture, processing or use of another chemical substance.

Waste, Fuel or Extraction*: Select YES/NO/N.App. if the byproduct's only fate is disposal as waste, burning as fuel or extraction of component chemical substances from it.

Report total number of workers "reasonably likely to be exposed: Exposure to a chemical substance under foreseeable conditions of manufacture, processing, distribution in commerce.

Industrial Processing and Use Information: For each chemical substance, select from the dropdown list.

Used in Products Intended for Use by Children

Percent Production Volume

Maximum Concentration

REPORTING STANDARD

“Known to or Reasonably Ascertainable by”

- Not required to conduct new or additional customer surveys.
- Report information that is:
 - Known to you or that which you are expected to possess, control, or know.
 - In your possession or control.
- Select “NKRA” from the dropdown box for “not known or reasonably ascertainable” if any information is not known or reasonably ascertainable.



07

Other Items to Keep in Mind





Key Items

- Bio Fuels and Mixed Metal groups – dedicated risk assessment groups
- Fees increasing - look for Polymer Exemptions, Notice of Commencements, and consolidation- prenotice rule and comment period complete-
- PBT and Articles – Most rules are in effect- revisions scheduled to be published in 2023.
- Increase in Inspection

Keep Calm But Take Action



Rose Passarella, Ph.D., J.D.



+1 302-287-3650



Rose.Passarella@Intertek.com

