wiley

ARTICLE

EPA is Getting it Right on TSCA Confidential Business Information (CBI) – but You Should Still Comment on the Proposed Rule

June 23, 2022

This article was originally published in Wiley's The WELL blog.

Let's kick start a conversation on Toxic Substances Control Act confidential business information (TSCA CBI). Maybe I've just missed it, but I have not seen much public discussion about the U.S. Environmental Protection Agency's (EPA's) proposed rule. 87 Fed. Reg. 29078 (May 12, 2022) (EPA-HQ-OPPT-2021-0419). Comments are due July 11, 2022.

According to Travel Agent Central, the next two weeks between now and then is shaping up to be a busy travel time with 49% of us going somewhere for at least a weekend or more over the Fourth of July.

Meanwhile, there is a grand total of two public comments in the public docket on this proposed rule so far. One is an anonymous public comment opposing any CBI protection under TSCA, and the other one is a request that the Environmental Defense Fund filed on June 16 asking for an extension of the comment period until August.

My take is that this proposal is well thought out and it shows promise for effectively implementing the complete overhaul of TSCA CBI intended by the 2016 Lautenberg Amendments. It's not perfect though, particularly if you keep your safety data sheets (SDS) close to the vest in your supply chain or are worried about industry competitors having free access to your expensive and time-consuming toxicology study reports.

Authors

Martha E. Marrapese
Partner
202.719.7156
mmarrapese@wiley.law

Practice Areas

Environment & Product Regulation
Toxic Substances Control Act (TSCA)

It is important to appreciate that this proposal affects any company that voluntarily submits or is required to submit sensitive information on their products and processes to EPA under TSCA.

There are many moving parts in this proposal, and I don't think EPA's summary does justice to them. Here's my take-aways on the important features:

- EPA will consolidate TSCA CBI procedures in a new 40 C.F.R. Part 703 within EPA's existing body of TSCA regulations. This means that the CBI provisions sprinkled throughout the TSCA regulations will be extracted and replaced with cross-references to the new Part 703.
- EPA is offering instructions on when redacted copies of CBI documents are required (always) and on how to construct generic chemical names.
- EPA plans to have prompts in its submission forms to remind companies to substantiate when CBI is claimed.
- EPA is consolidating and harmonizing CBI substantiation questions – the docket includes a number of new proposed forms, and the proverbial reverse engineering question is included. Here:
    - EPA is asking for feedback on whether to include a patent question and whether the existence of a patent defeats a CBI claim (the proposed rule states that "if the exact same information appears in both a published patent and in the TSCA submission, then the information should not be entitled to confidential treatment," a statement which fails to account for the confidentiality of the timing of the commercialization. The timing of a rival's regulatory approval and product launch plans is exactly the kind of sensitive information that competitors would love to have).
    - There are presumptive statements in the proposal expressing the view on the part of the agency that SDSs are not eligible for CBI protection.
    - EPA is seeking to explain and clarify that the substantiation needed to demonstrate that disclosure of CBI will be likely to cause harm must establish that the harm is "probable" rather than just "possible."
    - EPA is asking for comment on eliminating the need to substantiate trade secret protection with the reasoning that this is a subset of CBI and establishing CBI status serves to protects the trade secret – EPA asks if this is sufficient to not have to substantiate further.
- The proposal provides a new and important opportunity for industry to request EPA reconsideration of a denial of a CBI claim before having to challenge the decision in court (any company that has received a letter denying a CBI claim should comment in favor of this one).
- EPA will remind companies about the 10 year sunset deadline for CBI and is requiring companies to keep their contact information current on CDX for this purpose.
- EPA proposes a time limit of 90 days from date of submission to complete their CBI reviews.
- EPA provides an extensive discussion around the proposal that the requirement to review 25% of TSCA CBI claims as a representative subset should not include reviews of amendments to already submitted documents.

- Rules are proposed for providing access to TSCA CBI by the list of authorities in section 14 of TSCA such as first responders, etc.
- EPA continues to maintain its longstanding position that one company's decision to make a chemical name public defeats the CBI claims of all who came before. I have to wonder if this is really the only solution here. It may be just an uninformed action on the part of the latest company to the TSCA table. Maybe there should be a way to inform that company of the prior claims and have them certify their understanding they are releasing CBI before letting it go altogether.
- Last, but certainly not least, EPA is proposing that the following information is "not part of a health and safety study" and therefore may be eligible for CBI protection:
    - Name of submitting company
    - Name of laboratory
    - Names of laboratory personnel
    - Internal product codes
    - Names of study subjects and other private information
    - Cost and financial data
    - Product development, advertising and marketing plans

Admittedly it's a long list but it is not exhaustive. I don't recommend waiting to read it during your upcoming vacation (does anyone else read the Federal Register at the beach besides me?). There is something in here for everyone.