

EPA Confidential Business Information Procedural Rule

Chemical Regulation



Issue Summary

The Toxic Substances Control Act (TSCA) contains provisions to protect confidential business information (CBI) – proprietary information that if released, would cause substantial business injury to the owner.

EPA recently revised the regulations for the CBI claim process to ensure it is more standardized and would be centralize it in the CDX system. The new CBI ruling makes the submission for claims of confidentiality more specific and requires the submission of additional information that was not required under the previous rule.



The ruling contains many positive provisions, several of which SOCMA advocated for, including:

- A 10-day grace period during which companies may adjust their CBI claim to fix any errors or mistakes.
- Clarity that companies can negotiate the adequacy of a generic name in new chemical submissions.
- Specificity on which components of health and safety studies can be claimed as CBI (for example, the name of the lab and lab personnel).

The final rule also contains some problematic provisions, including:

- Removal of the administrative appeal process, whereby companies can appeal EPA denials with the agency before litigation.
- A non-timely response to additional
- A non-timely response to additional requirements for substantiation of claims can lead to the release of this information publicly without notice to the submitter.
- Re-submissions of deficient claims can lead to denial of CBI claim if they do not meet EPA's requirements.

SOCMA's Goal

As confidentiality of proprietary information is of utmost importance for specialty chemical companies, SOCMA advocates for EPA to afford all applicable confidentiality protections as established under TSCA.

Current Status

The new CBI submission rules are effective as of August 7th, 2023.





Business Impact on the Chemical Industry

The proposed rule adds clarity to certain components of the CBI process by increasing specificity in the information EPA requires when granting approval. The centralization of the CBI process within the CDX system will also be beneficial for streamlining applications. However, the removal of an administrative review process may force companies into costly litigation in the case of a denial.

SOCMA Activity

- May 2022: EPA issues proposed rule.
- June 2022: SOCMA provides initial analysis for members.
- July 2022: SOCMA provides feedback to EPA via the public comment process.
- June 2023: EPA publishes final rule.
- June 2023: SOCMA produced members-only Guidance Document to assist with compliance with final rule.