

ALERT

More Work and Scrutiny Lies Ahead for Companies Who Have Made Confidentiality Claims for Chemicals on the TSCA Inventory

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The U.S. Environmental Protection Agency (EPA) has issued a new final regulation for businesses on substantiating confidential business information (CBI) claims for chemical names on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory (TSCA Inventory). This rule includes important changes and added responsibilities for manufacturers (including importers) and processors who rely on the confidential portion of the TSCA Inventory to safeguard the identity of chemical ingredients.

The deadline for the CBI substantiation filings triggered by this rule ranges from 90 days to 240 days from the day the rule is published in the Federal Register.¹ Therefore, this rule will affect companies differently, and one of the first things companies will have to do is figure out which deadlines apply for the active chemicals they manufacture, import, and process. Even companies that have already given their CBI substantiations for chemical identity to EPA will be obligated to supplement their prior filings in many cases. All companies should take this opportunity to review their CBI substantiations to ensure that they have been thoroughly answered and explained. Failure to do so could lead EPA to conclude that a chemical identity does not merit CBI protection, leaving litigation as a company's only recourse to reverse the agency's final CBI determination.

[Why is EPA requiring CBI substantiation?](#)

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The 2016 Lautenberg Amendments completely overhauled TSCA's CBI procedures. Section 8(b) of TSCA requires EPA to issue a rule for reviewing all CBI claims for specific chemical identities for chemicals reported as "active" in U.S. commerce in response to the TSCA Inventory Notification (Active-Inactive) Requirements Rule, also known as TSCA Inventory "Reset" rule. On February 19, 2020, EPA finalized these review procedures.

The Reset rule called on manufacturers (including importers) to identify chemicals as active on the TSCA Inventory using Notice of Activity (NOA) Form A on EPA's electronic Central Data Exchange (CDX) reporting platform during a one-time submission period, which ended on October 5, 2018. Processors could make these filings voluntarily. In all cases, however, it was optional at that time for companies to include CBI substantiations with their CBI claims. During the transition period following Reset and subsequently, manufacturers (including importers) and processors must submit a NOA Form B to EPA to activate an inactive Inventory listing. A company must submit an NOA Form B for chemicals currently designated as inactive not more than 90 days prior to the anticipated date of the manufacturing or processing of those inactive chemicals. In those cases, CBI substantiations need to be provided within 30 days of the initial submission.

From Reset, we learned that fewer than half of the 86,228 chemicals on the TSCA Inventory (47% or 40,655) are currently in commerce. Of those, this final rule applies to less than 20% (7,757 chemicals) of the active chemicals in commerce for which CBI claims have been made to protect the specific chemical identities of substances on the confidential portion of the TSCA Inventory.

What does the final rule do?

This rule is a hallmark of the 2016 changes in TSCA. It will culminate in EPA's review of each and every CBI claim for active chemical identities on the TSCA Inventory.

In the final rule, EPA added two questions and modified other questions in the agency's substantiation questions for chemical identities claimed as CBI. The rule also establishes how the agency will review the claims, the timeframes for EPA to complete reviews, and the annual posting of results.

Is the final rule different than the proposed rule?

Yes. The rule adds two required questions to 40 C.F.R. § 710.37(c). The substantiation questions in § 710.37(c) that must be answered adequately for making these claims now include two questions on reverse engineering. The two additional questions are in response to last year's D.C. Circuit ruling in *Environmental Defense Fund v. EPA*, 922 F.3d 446 (D.C. Cir. 2019). In that case, the court found that EPA's decision to drop that line of questioning in the original final rule was arbitrary and capricious. This rule is intended to satisfy the remand of that portion of the TSCA Inventory Reset rule.

There are other important changes and clarifications as well. EPA dropped a question it had originally proposed on whether the chemical identity CBI claim is exempt from substantiation pursuant to TSCA section 14(c)(2), as no such exemption from substantiation exists in TSCA for CBI claims for specific chemical identities. The agency rewrote other questions in response to public comments. Furthermore, EPA will deny a CBI claim

when a person who asserted a CBI claim for a specific chemical identity fails to submit a timely substantiation or notice of prior substantiation. In that situation, EPA will provide the submitter with notice and an opportunity to seek judicial review within 30 days in accordance with TSCA section 14(g)(2) and 40 CFR 2.306(e). To avoid this outcome, companies should plan to meet the new filing deadline in the rule.

From whom is EPA requiring CBI substantiations?

First, all companies who voluntarily substantiated their CBI claims for specific chemical identities with their previously filed NOA Form A submissions need to answer the two new questions in the final rule on reverse engineering.

Second, NOA Form A submitters who have not yet answered the substantiation questions must respond to all required questions.

Third, this rule may also apply to companies who are partially exempt from Reset because they previously substantiated their CBI claims for chemical identities in TSCA submissions made to EPA less than five years before the substantiation deadline in the rule. We advise these companies to review their substantiations to confirm that they include information that is responsive to all of EPA's questions in this rule, including the new questions on reverse engineering.

Fourth, companies who have filed NOA Form B submissions, either during the Reset transition period or subsequently, and claimed the chemical identity as confidential, must supplement their CBI substantiations with responses to two new questions.

These submissions need to be made on EPA's CDX system. Companies that filed an NOA Form A will have 240 days after publication of the final rule in the Federal Register (i.e., effective date of 60 days after publication + 180 days). Any company that submitted a CBI claim with an NOA Form B before this rule goes into effect, however, will have only a total of 90 days after the final rule is published in the Federal Register (i.e., effective date of 60 days after publication + 30 days) to add responses to the two new questions.

Why does the rule have different deadlines?

EPA's CBI substantiation announcement affects companies differently depending on whether they reported their chemicals using NOA Form A or Form B. The requirement to file a Form B to activate an inactive chemical on the TSCA Inventory is a comparatively recent development, and companies are required to submit their CBI substantiation within 30 days for those filings by rule. This rule therefore provides a comparable period of time - 30 days from the effective date of the rule - to update those substantiations. Generally speaking, companies filed many more Form A's. Some of them may have waited to substantiate CBI until now. The time allowed by this rule for these submissions is similar to the amount of time companies had to file NOA Form A's under the Reset rule.

If I think I've answered all of EPA's substantiation questions, do I need to do anything more?

Companies who already filed these CBI substantiations claims are advised to take another look at them to make sure your responses will survive EPA scrutiny in the coming years. This rule provides a unique and one-time opportunity to review what you've given EPA one more time before the agency conducts its own review and decides whether the information you've provided is enough. After this opportunity, if EPA rejects your CBI claim, you'll have to go to court to defend the CBI listing.

When will EPA begin to review confidential chemical identity claims for the TSCA Inventory?

EPA's review of these claims is scheduled to get underway in 2021.

If I process a chemical that is on the confidential TSCA Inventory, does this rule apply to my company?

It may. CBI Substantiation applies to processors who make NOA Form A or B submissions and claimed specific chemical identities on the TSCA Inventory as CBI.

Can competitors defeat or shorten the duration of CBI claims under this rule?

Yes. Under § 710.55(b), a decision by one company to abandon CBI protection of a chemical identity eliminates the ability of another company to claim the chemical as CBI. Also, in the case where multiple companies claim a chemical identity as CBI, the claim earliest in time will be used as the date when the 10-year protection period begins to apply. It may be advisable to consider additional steps beyond relying on the confidential TSCA Inventory to protect your proprietary information.

When must the CBI claims be reviewed?

EPA has 5 years from now to complete CBI claim reviews for chemical identities on the confidential portion of the TSCA Inventory, by February 19, 2024. If EPA decides in the future to invoke the 2-year extension allowed by TSCA, the deadline for completing CBI claim reviews would move to February 19, 2026. To meet the deadlines, the agency will need to review 1,000 or more substantiations per year.

¹ The pre-publication version of the regulatory text used an incorrect deadline for submitting NOA Form B substantiation answers. We understand that the agency will correct this mistake in the final published regulatory text.