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ALERT

EPA Issues Proposed Rule on Chemical Identity CBI Claims Substantiation and Review

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The 2016 amendments to the Toxic Substances Control Act (TSCA) require the Environmental Protection Agency (EPA) to establish a plan to review all confidential business information (CBI) claims for specific chemical identities on the TSCA Inventory. On April 23, 2019, EPA issued a proposed rule to add provisions to 40 C.F.R. Part 710 to establish the plan, including the procedures and deadline for substantiating these claims. Comments on the proposal must be received on or before **June 24, 2019**.

As proposed, this is a reporting deadline that companies can't afford to miss – and the stakes associated with a mistake are high. If a substantiation, or a notice of a prior CBI substantiation made in the past 5 years, is not filed within the proposed 90-day filing period or does not meet the substantiation requirements of the proposed rule, EPA "may make the information public without further notice." In that case, the only remedy companies have under the proposed rule is to go to court within 30 days to seek to prevent disclosure.

As a result, this public comment period is a particularly important opportunity for companies to ask EPA for better safeguards in association with the agency's treatment of commercially sensitive information.

Who Must Report to EPA?

There are at least three groups that are affected by this proposal whose members may include manufacturers, importers and processors. First, companies who filed a Notice of Activity (NOA) Form A during Inventory Reset with a CBI chemical identity claim, but

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without substantiation, will need to report. Second, any company that filed a substantiation for a CBI chemical identity claim in the last 5 years will need to notify the agency of the existence of these filings. Examples include substantiations for chemical identity that were submitted per the Chemical Data Reporting (CDR) rule, or in association with premanufacture notifications (PMNs), microbial commercial activity notifications (MCANs), notices of commencement (NOCs), section 8(e) submissions, or in public comments. As noted above, EPA is proposing to give companies only 90 days to prepare these important submissions. Finally, even companies who already submitted their substantiations voluntarily during Inventory Reset should be alert to the consequences of this proposed rule if they think there is a possibility that their substantiation may not pass muster.

What Must They Report?

For companies that have made a substantiation submission to EPA less than five years before the substantiation deadline in the rule, EPA is proposing that they submit a notification that includes the date of the submission; the submission type and case number; a CDX or other transaction ID; or an equivalent identifier that uniquely identifies the previous substantiation submission. Because EPA's recordkeeping system prior to 2016 was not set up to easily track these claims, it is probably in the best interest of companies to have the opportunity to remind EPA about these claims.

In addition, EPA is proposing to require companies who have not yet submitted a substantiation for chemical identity CBI to respond to the following seven questions to establish the validity of a confidentiality claim for chemical identity:

a. Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)? If you answered yes, you must individually identify the specific information claimed as confidential and specify the applicable exemption(s).

b. Will disclosure of the information likely result in substantial harm to your business's competitive position? If you answered yes, describe with specificity the substantial harmful effects that would likely result to your competitive position if the information is made available to the public.

c. To the extent your business has disclosed the information to others (both internally and externally), what precautions has your business taken? Identify the measures or internal controls your business has taken to protect the information claimed as confidential: Non-disclosure agreement required prior to access; access is limited to individuals with a need-to-know; information is physically secured; other internal control measure(s). If yes, explain.

d. Does the information appear in any public documents, including (but not limited to) safety data sheets, advertising or promotional material, professional or trade publications, or any other media or publications available to the general public? If you answered yes, explain why the information should be treated as confidential.

e. Is the claim of confidentiality intended to last less than 10 years? If so, indicate the number of years (between 1-10 years) or the specific date/occurrence after which the claim is withdrawn.

f. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If you answered yes, explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.

g. Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States? If you answered yes, explain why the information should be treated as confidential.

84 Fed. Reg. 16829. These questions may sound familiar to many, but they bear closer examination. For example, does it make sense to ask question (a) on whether a company believes chemical identity is exempt from substantiation under section 14(c)(2) of TSCA, when it is already apparent from a plain reading of the statute that chemical identity is not a listed (c)(2) exemption. It might be more relevant to ask whether disclosure of chemical identity could inadvertently reveal other confidential information that is expressly listed as exempt from substantiation under section 14(c)(2). Questions (d) and (g) above seem so closely related that they should follow one from the other rather than be separated by two unrelated lines of inquiry. In addition, the substantiation questions under this proposal need to better align with the criteria EPA says it will use to review them in 40 C.F.R. §§ 2.208 and 2.306(g). So, for example, in addition to asking what steps a company has taken to protect its information in the past, question (c) should also ask companies to state whether they intend to continue to take such measures. In connection with question (f) above on whether a federal agency has made a confidentiality determination, companies also should be asked whether any statute specifically requires disclosure of the information, and to address state government determinations as well.

As proposed, reporting companies have to assert and certify under penalty of law (knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001) that there is a reasonable basis to believe that the information is not readily discoverable through reverse engineering. However, none of EPA's proposed questions are designed to further probe for the potential for reverse engineering, an issue that EPA has been directed to re-assess in a recent decision by the D.C. Circuit Court of Appeals (*Environmental Defense Fund v. EPA*, Case No. 17-1201, D.C. Cir., April 26, 2019).

Who is Exempt from Reporting?

The only complete exemption from reporting under this rule applies to manufacturers, importers, and processors who have already provided substantiations for specific chemical identity CBI claims in NOA Forms A that were submitted during Inventory Reset. What happens if these companies have concerns about the quality of their past substantiations, given the proposed outcome of disclosure without further notice? It is not clear if they will be allowed to redo or supplement a past submission during the reporting period in this rule. As one specific example, the companies that voluntarily submitted substantiations per 40 C.F.R. § 710.37(a)(1) during Inventory Reset were not asked to provide a response to proposed question (g) above. Are the

voluntarily submitted substantiations deficient if the questions those companies responded to turn out to be different than the questions finalized in this rule?

Can Competitors Defeat or Shorten Each Other's CBI Claims?

Yes. EPA is proposing to continue to apply an earlier ruling that a decision by one company to abandon CBI protection of a chemical identity eliminates the ability of any other company to claim the chemical name CBI. Moreover, if one company filed a CBI claim for a chemical identity earlier in time, EPA is proposing to use that as the date that the 10 year protection period begins to apply for any company that asserts a CBI claim for the same chemical. This means that the period of CBI protection will be determined on a per chemical basis rather than per claimant. The tables have turned on CBI, with the effect of this being that companies have completely lost the ability to control their own chemical identity CBI claims or the length of time for which they can make them. Companies who currently claim chemical identities as CBI and relied on their upstream suppliers to file the NOA Form A should let these suppliers know that continued CBI protection is important.

When Must Substantiation Reports be Filed?

EPA is proposing to require that all substantiations be filed not later than 90 days after the effective date of the final rule. If the rule becomes effective the day the final rule appears in the Federal Register, companies will have only a very short time to craft substantiation support specific and detailed enough to pass review. If EPA decides that a substantiation is inadequate, the only recourse for a company is to challenge the decision in court within 30 days of being notified by EPA that the substantiation is deficient. The rule allows no opportunity for companies to rectify or supplement their substantiation claims. Moreover, EPA is proposing that the failure to substantiate at all will result in publication of the name on the public Inventory without further notice. Companies should comment and ask EPA for a 30 day period to cure deficient notices and require notification before information is made public.

When Must the Final Rule be Adopted and CBI Claims Reviewed?

Under section 8(b)(4)(E) of TSCA, since the updated TSCA Inventory was released on February 19, 2019, the deadline for issuing a final rule is February 19, 2020, and the 5 year deadline for EPA to complete all CBI claim reviews is 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. With approximately 7,000 chemicals on the TSCA Inventory, this means that the agency needs to review 1,000 or more substantiations per year.

Are There Record-Keeping Requirements?

Each company subject to the rule must retain records that document any information reported to EPA. Records must be retained for a period of 5 years beginning on the last day of the submission period.

Commenting on the Proposed Rule

EPA is seeking public comment on the filing requirements, the proposed exemptions, annual goal setting, duration of protection from disclosure, Agency reviews, economic burden, and the scope of the substantiation questions.

We think the proposed provision to allow EPA to release unsubstantiated chemical identities without giving prior notification to the associated manufacturer is particularly problematic and runs counter to the express wishes of Congress to exempt this group of companies from reporting by statute. EPA is particularly interested in comments concerning the automatic release of CBI where a claimant submitted a substantiation to EPA less than five years before the substantiation deadline that will be set in the final rule, but failed to report and identify that previously-submitted substantiation to EPA within the 90-day filing period. Companies should ask EPA to provide notice. These claims are already substantiated, and while it is probably in the best interest of these companies to assist in the process by reminding EPA that they submitted a substantiation within the last five years, it is a harsh outcome for their CBI claims to be completely defeated without any recourse if they do not. Disclosure of their CBI is contrary to the language in this section of statute, since TSCA does not require any additional reporting to be eligible for the exemption.

We think EPA should give companies additional time to report, and that 180 days is more appropriate. CBI substantiation requires more specific information and more attention than before in order to ensure claims are upheld. Finally, the whole matter of allowing companies to wield power over the CBI claims of their competitors deserves further public debate and better accountability, as well as evaluation for how consistent EPA's policy is with other trade secret protection laws in the U.S.

To discuss these issues further, please contact Martha Marrapese at mmarrapese@wiley.law or 202-719-7156.