CHANGES TO CONFIDENTIAL BUSINESS INFORMATION DISCLOSURE UNDER THE REFORMED TOXIC SUBSTANCES CONTROL ACT

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This client alert is the fourth in a series that discusses the significant changes instituted by the passage of a new federal Toxic Substance Control Act (TSCA). The first alert addressed broadly the law's myriad of changes. The second alert addressed how changes in the law will impact manufacturers, processors, and importers of new chemical and existing chemicals. The third alert addressed how TSCA, as amended, preempts state regulation of chemicals and preserves certain state laws and regulatory authority. A future alert will cover international impacts of the amendments.[1]

On June 7, 2016, the Senate passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act,[2] which altered the Toxic Substances Control Act of 1976 ("TSCA").[3] President Obama signed this new legislation into law on June 22, 2016.[4]

While continuing to protect trade secrets, the new law provides greater transparency and disclosure of information by tightening and expanding the conditions that companies must demonstrate before the U.S. Environmental Protection Agency ("EPA") can protect trade secrets. Critics of the old TSCA law successfully argued that the EPA was obligated to protect virtually any confidential business information ("CBI") claim that was made and to protect the claims forever.

The new law dramatically changes this. It now requires companies seeking protection from disclosure to assert their claims to the EPA concurrent with data that substantiates their claims and places a ten-year time limit on protecting the claims unless they are re-substantiated by the company. Unlike the old law, the new law also obligates the EPA to review all existing CBI claims to determine if the claims are still warranted. The new law also explicitly prohibits protection for certain types of information. In all likelihood, these changes will mean that fewer claims will qualify for CBI protection and those that do will need to take steps every 10 years to keep their information confidential.

A. REQUIREMENTS FOR ASSERTING CONFIDENTIALITY

Under the new law, generally, to obtain protection from disclosure, a nondisclosure claim must be submitted at the time information is submitted to the EPA.[5] The submitter now must make a statement that he or she has:

> (i) taken reasonable measures to protect the confidentiality of the information;

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> (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
> (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
> (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.[6]

It also requires that submitters substantiate their claims for nondisclosure in accordance with rules already promulgated and those promulgated in the future.[7] Under the old statute, the regulations required that a submitter substantiate its claim by providing a detailed report that addressed several issues. Many of the points addressed in the affirmative statement were previously addressed in the regulations. The scope of the affirmative statement is a little broader than the requirements under the regulations because it requires that the information not be readily available via reverse engineering and that the information not be subject to disclosure under other laws.[8] Thus, the broadened standard will make it more difficult to obtain protection.

The EPA must respond to general nondisclosure claims within 90 days of receiving the claim.[9] The EPA may fully approve, fully deny, or partially approve and partially deny the request.[10] If the request is partially or fully denied, the EPA Administrator must provide the claimant with the reasons for the denial.[11]

To read the full alert, click here.

Notes:

[1] We thank our K&L Gates summer associate, Khahilia Shaw, for her assistance with this alert

[2] Frank R. Lautenberg Chemical Safety for the 21st Century Act, H.R. 2576, 114 Cong. (2016) [hereinafter *H.R. Res. 2576*]. This alert largely cites section 11 of H.R. Res. 2576, which amends section 14 of TSCA. Note, all citations to 15 U.S.C.A. § 2601 *et seq*. are to TSCA prior to the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

[3] Toxic Substances Control Act, 15 U.S.C.A. § 2601 *et seq*.

[4] *See* The White House, Remarks by the President at Bill Signing of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (June 22, 2016), https://www.whitehouse.gov/the-press-office/2016/06/22/remarks-president-bill-signing-frank-r-lautenberg-chemical-safety-2st.

[5] H.R. Res. 2576 § 11(c)(1)(A).

[6] H.R. Res. 2576 § 11(c)(1)(B).

[7] H.R. Res. 2576 § 11(c)(3) ("Except as provided in paragraph (2), a person asserting a claim to protect information from disclosure under this section shall substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section."). Under the new law, however, one does not need to substantiate certain types of information, such as specific manufacturing processes, marketing information, customer information, supplier information, or import volumes, among others. H.R. Res. 2576 § 11(c)(2)(A)–(G), 11(c)(3). The EPA has stated that this new substantiation provision does not conflict with the current regulations because the current regulations do not require the substantiation of the information specifically excluded in the new law. EPA, Asserting Confidential Business Information (CBI) Claims and Certified

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Statements (last updated June 30, 2016), https://www.epa.gov/chemical-data-reporting/asserting-confidential-business-information-cbi-claims-and-certification.

[8] *Compare* H.R. Res. 2576 § 11(c)(1)(B), *with* 40 C.F.R. § 711.30.

[9] H.R. Res. 2576 § 11(g)(1)(A).

[10] *Id.*

[11] H.R. Res. 2576 § 11(g)(1)(B).

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