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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.

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.

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[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.

Changes to Confidential Business Information Disclosure Under the Reformed Toxic Substances Control Act

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;
>
> (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]

B. The New Exceptions

The revised TSCA now provides a total of nine exceptions that permit the disclosure of CBI.[12] Below is a chart listing the old and new exceptions.

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[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 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).

[12] H.R. Res. 2576 § 11(d).

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	Exceptions under the old law	**Exceptions under the new law**
1	Permitting disclosure to U.S. officers or employees "in connection with the official duties of such officer or employee ***under any law*** for the protection of health or the environment, or … for specific law enforcement purposes." 15 U.S.C.A. § 2613(a)(1) (emphasis added).	Permitting disclosure to U.S. officers and employees when it is "in connection with the official duties of that person under any ***Federal law*** for the protection of health or the environment; or … for a specific ***Federal*** law enforcement purpose." H.R. Res. 2576 § 11(d)(1) (emphasis added) (limiting the disclosure to duties imposed under federal law).
2	Permitting disclosure to contractors of the United States and the contractor's employees if the Administrator believes that disclosure is necessary "for the satisfactory performance by the contractor of a contract with the United States ***entered into on or after October 11, 1976***, for the performance of work in connection with this chapter…." The Administrator can set conditions for the disclosure. 15 U.S.C.A. § 2613(a)(2) (emphasis added).	Same, except the October 1, 1976 date was removed. H. R. Res. 2576 § 11(d)(2) (removing the time restriction).
3	Permitting disclosure "if the Administrator determines it [is] necessary to protect health or the environment against an unreasonable risk of injury to health or the environment." 15 U.S.C.A. § 2613(a)(3).	Permitting disclosure "if the Administrator determines that disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment, ***without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use***." H.R. Res. 2576 § 11(d)(3) (emphasis added) (clarifying that nonrisk factors need not be considered).
4	Permitting disclosure ***when relevant in any proceeding*** under TSCA, but requiring that the disclosure preserve confidentiality as much as possible. 15 U.S.C.A. § 2613(a)(4).	Permitting disclosure ***if the Administrator determines that disclosure is relevant*** under TSCA but requiring that the disclosure preserve confidentiality as much as possible. H.R. Res. 2576 § 11(d)(7) (limiting disclosure to when the Administrator

		believes disclosure is relevant).
5		Permitting disclosure to states, political subdivisions of a state, and tribal governments when the purpose of the disclosure is to administer or enforce the law. The request must be in writing, and the requesting entity must have entered into a confidentiality agreement with the Administrator and have procedures in place to safeguard the information. H.R. Res. 2576 § 11(d)(4).
6		Permitting disclosure to "a health or environmental professional employed by a Federal or State agency or tribal government or a treating physician or nurse in a nonemergency situation." To obtain disclosure the requesting person must submit a "statement of need"[13] and agree to sign a confidentiality agreement. H.R. Res. 2576 § 11(d)(5).
7		Permitting disclosure when an emergency occurs. Disclosure can be provided to a "treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a State, or tribal government, or first responder." The person requesting the information must "have a reasonable basis to suspect that — (i) a medical, public health, or environmental emergency exists; (ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or (iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance or mixture concerned, or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred." The requesting

[13] "[T]he statement of need shall be a statement that the person has a reasonable basis to suspect that -- (i) the information is necessary for, or will assist in — (I) the diagnosis or treatment of 1 or more individuals; or (II) responding to an environmental release or exposure; and (ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance or mixture concerned, or an environmental release of or exposure to the chemical substance or mixture concerned has occurred…." H.R. Res. 2576 § 11(d)(5)(B).

		person will need to sign a confidentiality agreement and submit a statement of need, but these two documents need not be submitted prior to disclosure. H.R. Res. 2576 § 11(d)(6).
8		Requiring disclosure if the information must be made public under any Federal law. H.R. Res. § 11(d)(8).[14]
9		Requiring disclosure when required by court order, such as discovery orders, or as otherwise permitted by Federal or State law. H.R. Res. § 11(d)(9).[15]

As noted in the chart above, there are some alterations to the original four exceptions. In some instances, the exception has become more narrow, e.g., the first exception is now limited to duties imposed by federal law; and in others, the exception has broadened, e.g., the third exception expressly notes that nonrisk factors need not be assessed. With the addition of the five new exceptions, information that does obtain protection will be afforded less protection, but note that many of the new exceptions require that the person obtaining disclosure take steps to safeguard the confidential material.

C. Some Types of Information Cannot Obtain Protection

Under the new law, the types of information that cannot obtain confidential protection have expanded.[16] Under the new statute, general manufacturing information, such as manufacturing volumes and/or the general description of the processes used, are not afforded protection.[17] If a chemical is banned or phased out, the submitted information in relation to the banned or phased-out chemical is presumed to lose protection.[18] One can request that the information remain protected by submitting a request to the EPA within 30 days of receiving notice that the information is no longer subject to protection.[19] There are a few limitations to the banned and phase-out exemption. The presumption against protection is limited (thus, protection may be permitted) when the information is related to a critical use

[14] With respect to the sixth and seventh exceptions, the EPA must consult the Centers for Disease Control and Prevention to develop a "request and notification system" that will expedite access to CBI during emergencies. H.R. Res. 2576.

[15] With respect to the sixth and seventh exceptions, the EPA must consult the Centers for Disease Control and Prevention to develop a "request and notification system" that will expedite access to CBI during emergencies. H.R. Res. 2576. Note the regulations previously provided an exception for court-ordered disclosure. 40 C.F.R. § 2.209(d).

[16] H.R. Res. 2576 § 11(b).

[17] H.R. Res. 2576 § 11(b)(3).

[18] H.R. Res. 2576 § 11(b)(4).

[19] H.R. Res. 2576 § 11(b)(4)(C), (g)(2)(A).

chemical, an export chemical (if certain criteria is met), or a specific conditions of use chemical.[20]

Under the old statute, health and safety studies were not protected but information related to the manufacturing process of a chemical substance and the mixture portions of a chemical mixture were.[21] The new statute adds an additional protection, permitting the protection of chemical formulas, including molecular structures.[22]

When a submission contains both information that can be protected and information that cannot be protected, protection will not be lost merely because the submission contains both types of information.[23]

D. Effect on Prior CBI Assertions

The previous version of TSCA required the EPA to "compile, keep current, and publish a list of each chemical substance that is manufactured or processed in the United States."[24] Manufacturers and processors could designate which information they believed qualified as CBI.[25]

The revised TSCA requires the EPA to designate which substances in this inventory list are active or inactive. To implement this provision, by June 21, 2017, the EPA must promulgate a new rule requiring manufacturers and processors who currently have chemicals on the EPA's inventory to notify the EPA Administrator whether they manufactured or processed the chemical for a nonexempt chemical purpose since June 21, 2006.[26] This notice will need to be provided to the EPA within 180 days of the publication of the final rule.[27] The EPA will designate chemicals for which notices are received as "active" and those for which no notices are received as "inactive."[28]

The revised TSCA also requires that the EPA's inventory include both a confidential and a nonconfidential portion to protect CBI.[29] In the rule referenced above, the EPA will require any manufacturer or processor seeking to maintain an existing CBI claim to provide notice to the EPA.[30] The notice must comply with the requirements under revised section 14.[31] If the EPA does not receive a request to maintain an active substance's CBI claim, the Administrator will move the substance's information from the confidential to the nonconfidential portion of the inventory list.[32] The EPA will review all notices that assert a

[20] H.R. Res. 2576 § 11(b)(4)(B).
[21] 15 U.S.C.A. § 2613(b).
[22] H.R. Res. 2576 § 11(b)(2).
[23] H.R. Res. 2576 § 11(b)(1).
[24] 15 U.S.C.A. § 2607(b)(1)(A).
[25] 15 U.S.C.A. § 2613(c)(1).
[26] H.R. Res. 2576 § 8(b)(4)(A).
[27] H.R. Res. 2576 § 8(b)(4)(A)(i).
[28] H.R. Res. 2576 § 8(b)(4)(A)(ii)–(iii).
[29] H.R. Res. 2576 § 8(b)(4)(B)(i).
[30] H.R. Res. 2576 § 8(b)(4)(B)(i)–(ii).
[31] H.R. Res. 2576 § 8(b)(4)(B)(ii)–(iii).
[32] H.R. Res. 2576 § 8(b)(4)(B)(iv).

right to protection.[33] The EPA must develop a plan to assess all these notices and the plan must be developed within one year of when the initial active substance list is created.[34]

E. Duration and Extensions of Protected Periods

Under the old law, CBI claims did not expire. However, under the revised TSCA, CBI claims generally expire after ten years.[35] Manufacturers may request an additional ten-year extension.[36] The EPA may grant an unlimited number of extensions.[37] To obtain an extension, one must request an extension, substantiating the need for the extension in the request, no later than 30 days before the expiration of the original 10-year term.[38]

If a claimant withdraws a nondisclosure claim within the 10-year period, then the protection can be removed.[39] If the EPA Administrator "becomes aware that the information does not qualify for protection," then after taking certain actions the EPA may remove CBI protection.[40]

However, for certain types of CBI (such as marketing information, customer data, or manufacturing processes), the 10-year period does not apply. Instead, the information remains protected unless the claimant withdraws the claim or the EPA Administrator learns that the information is no longer eligible for protection.[41]

F. Denial – Protecting Against Disclosure

If a manufacturer's CBI request is denied by the Administrator, he or she may appeal the decision in a court of appeals of the United States.[42] One also may bring an action to *prevent the disclosure* in a federal district court where the claimant resides or maintains a principal place of business or in the U.S. District Court for the District of Columbia.[43] The codification of the right to prevent disclosure affords a little more protection than previously provided under the regulations because the statute now requires that the information not be disclosed while the action is pending (with a few exceptions), effectively removing the EPA's ability to disclose information, after notice, when it appears that the person seeking protection is not acting in an appropriate and expeditious manner.[44] The EPA Administrator generally is prohibited from disclosing information that is the subject of an appeal until the relevant court rules on the action.[45]

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[33] H.R. Res. 2576 § 8(b)(4)(C).
[34] *Id.*
[35] H.R. Res. 2576 § 11(e)(1)(B).
[36] H.R. Res. 2576 § 11(e)(1)(B)(i)–(ii).
[37] H.R. Res. 2576 § 11(e)(2)(C).
[38] H.R. Res. 2576 § 11(e)(1)(C)(i)–(ii), 11(c)(3), 11(e)(2)(B).
[39] H.R. Res. 2576 § 11(c)(2),(e)(1)(B)(ii)(II).
[40] *See* H.R. Res. 2576 § 11(e)(1)(B).
[41] H.R. Res. 2576 § 11(e)(1)(A)(i)–(ii).
[42] H.R. Res. 2576 § 19(m)(1)(B).
[43] H.R. Res. 2576 § 11(g)(2)(D).
[44] *See* H.R. Res. 2576 § 11(g)(2)(D)(ii); 40 C.F.R. § 2.205(f).
[45] H.R. Res. 2576 § 11(g)(2)(D)(ii)(I).

G. Criminal Penalties

The revised TSCA provides specific criminal penalties for releasing protected CBI. Anyone who "obtain[s] possession of" or "has access to" protected CBI, knows that the information is protected, and "willfully discloses the information in any manner to any person not entitled to receive [it]" is subject to a fine and/or may be imprisoned for a maximum of one year.[46] This new provision is broader than the prior statute in that the new version does not limit the penalty to an officer or employee (or former officer or employee) of the United States or contractors or their employees; rather, the penalty can apply to any person who obtained information pursuant to TSCA.[47]

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[46] H.R. Res. 2576 § 11(h)(1)(A)–(B).

[47] *Compare id.*, *with* 15 U.S.C.A. § 2613(d). Note, in part, the expansion of this provision likely is due to the additional exceptions.