Reports

Protecting Confidential Business Information: An Evolving Challenge

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I. Introduction

The concept of confidential business information (CBI) is sometimes considered at odds with the concept of the 'right-to-know.' When Congress amended the Toxic Substances Control Act (TSCA) in 2016 through enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg), it was mindful of the public's growing interest in knowing more about the identity of chemicals to which they may be exposed, but equally mindful of a business' legitimate interest in protecting highly proprietary and commercially sensitive trade secret and other information entitled to protection from disclosure. Congress enacted several significant TSCA modifications in an effort to balance these competing interests, amendments that the U.S. Environmental Protection Agency (EPA) has been implementing through rulemaking and guidance documents over the past three years. This article discusses key CBI initiatives, and the stakeholder community's response to them.

II. Key Lautenberg Amendments Addressing CBI

TSCA has long required regulated entities to submit to EPA business sensitive and proprietary information (referred to generally as CBI) that is needed by the Agency to meet its obligations and achieve TSCA's underlying purposes. Much of the data and information required to be submitted under TSCA are considered commercially sensitive information. In connection with reporting requirements under TSCA, manufacturers may submit, for example, information about new products, new technologies, new chemical substances, and/or business plans, manufacturing schedules, and financial information. The inadvertent disclosure of such information could adversely affect the submitter's competitiveness. It is essential that such information is protected so that those entities and the U.S. economy are not adversely impacted.

TSCA Section 14(a) prohibits EPA, except in limited circumstances, from disclosing to the public trade secrets and commercial or financial information that is exempt from disclosure under Section 552(a) of Title 5, United States Code (Freedom of Information Act (FOIA)) that is reported to or otherwise obtained by EPA and meets the requirements under Section 14(c). TSCA Section 14(b) outlines the information that is not protected from disclosure. Information from health and safety studies for chemicals offered for commercial distribution, or for testing required under TSCA Section 4, or for notification under Section 5 is not protected from disclosure. Similarly, general information describing the manufacture, aggregate volumes, or, if EPA determines aggregate volumes might disclose CBI, ranges of aggregate volumes are not protected from disclosure. General descriptions of processes used in manufacture or processing, functions and use, and information specific to a certain sector that would customarily be shared with the general public is also not protected from disclosure.

The TSCA 2016 amendments occasioned under Lautenberg impose new requirements that submitters must meet when claiming information as CBI. These changes reflect Congress's recognition that greater disclosure of certain kinds of information and to certain classes of entities was needed, as well as a belief that certain CBI claims should be time-limited unless reaffirmed as CBI. Some of these new requirements include: assertions that the submitter must make; upfront substantiation of CBI claims, except

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for those on information exempt from substantiation; and if a CBI claim is for a specific chemical identity, a structurally descriptive generic name. The Agency may also review and make determinations on CBI claims in other circumstances, including when information that is claimed as CBI is responsive to a request under FOIA.

Importantly, Lautenberg expands the parties to or circumstances in which EPA is authorized to disclose CBI. The groups now able to access CBI include U.S. employees in connection with discharging official duties under a law for the protection of health or the environment, for a specific law enforcement purpose, including U.S. government contractors if EPA believes disclosure is needed for the performance of the contract; circumstances in which EPA determines that disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment; state, political subdivision of a state, or tribal government upon written request if certain conditions are met; circumstances in which EPA determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding; and circumstances in which information is required to be made public under any other provision of federal law, among other circumstances.

TSCA also now requires that when a CBI claim is made for a specific chemical identity, the claim must include a structurally descriptive generic name. The EPA is required to develop a system for identifying these generic names in a manner that is consistent with past EPA guidance in this regard.

As with old TSCA, new TSCA mandates that CBI will no longer be protected under Section 14 if the person asserting the claim informs EPA that the claim has been withdrawn or if EPA becomes aware that the information no longer qualifies for CBI protection. Unlike old TSCA, however, new TSCA Section 14(e) includes a specific sunset provision for CBI protection of 10 years. EPA is to inform the claimant 60 days before the 10-year CBI expiration date so the claimant may, if desired, submit a reassertion of the claim no later than 30 days before the CBI expiration date. EPA must review the reassertion submission before the CBI expiration date and decide whether to grant an extension of 10 years or deny the request. There are no limits to the number of extensions that can be granted provided EPA determines the reassertions meet the EPA requirements and demonstrate the need for the extension.

III. EPA Implementation of Lautenberg CBI Provisions

Over the past three years, EPA has been timely implementing the new law's requirements. The CBI implications of Lautenberg are many and no attempt is made here to explore them all. Outlined below are several major CBI regulatory initiatives of which stakeholders should be aware.

1. Substantiating CBI Claims

On January 19, 2017, EPA issued an interpretation of TSCA Section 14 concerning substantiation of CBI claims for information submitted to EPA. Under the interpretation, EPA expressed its view that Lautenberg requires substantiation of all non-exempt CBI claims at the time the information claimed as confidential is submitted to EPA. In the notice, EPA also stated that the action will 'facilitate [its] implementation of TSCA section 14(g) to review all CBI claims for chemical identity, with limited exceptions, as well as to review a representative sample of at least 25% of other non-exempt claims.' Unsurprisingly, how upfront substantiation was to occur and how EPA would review the 25% of CBI claims to be selected for review inspired disarray and confusion early on. EPA has since routinized this function and stakeholders are relatively well aware of how the process works. Care needs to be taken by submitters, however, in selecting CBI claims and, of course, in substantiating them.

2. Guidance for Creating Generic Names for Confidential Chemical Substances

In June of 2018, EPA issued a new guidance for creating generic names, *Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under the Toxic Substances Control Act*. The guidance was developed in response to the requirement under new TSCA Section 14(c)(4) that EPA 'develop guidance regarding – (A) the determination of

structurally descriptive generic names, in the case of claims for the protection from disclosure of specific chemical identity...' and the requirement under new TSCA Section 14(c)(1)(C) that submitters who assert a confidentiality claim for a specific chemical identity must include a structurally descriptive generic name developed consistent with EPA guidance. The guidance updates and replaces the 1985 guidance published in the TSCA Inventory, 1985 Edition (Appendix B: 'Generic names for Confidential Chemical Substance Identities')

Consistent with TSCA Sections 14(c)(4) and 14(c)(1)(C), EPA will be reviewing generic names for consistency with the guidance upon receipt in TSCA filings where chemical identity is claimed as confidential. EPA encourages companies to consult EPA's Office of Pollution Prevention and Toxics (OPPT) if they believe that it will be necessary to mask more than one structural element of a specific chemical name to mask a chemical's confidential identity.

The requirement under TSCA Section 14 that generic names be structurally descriptive does not reflect a substantive shift away from previous EPA guidance on generic names. EPA's earlier 1985 guidance illustrates generic names as being crafted by masking a single structural feature of the specific substance name. Masking multiple structural features, which may cause a chemical name to no longer be structurally descriptive, is permitted only if the submitter justifies the need in writing for the additional masking.

In contrast to the 1985 guidance, which distinguished only between constructing generic names for class I and class II chemical substances, the new guidance distinguishes between inorganic chemical substances, class I organic chemical substances, and class II organic chemical substances. The new guidance refers to Unknown or Variable composition, Complex reaction products and Biological materials (UVCB) substances when addressing class II organic chemicals, unlike the 1985 guidance. The new guidance also lists an additional structural element of a class I organic chemical substance that can be masked when creating a generic name: stereochemical or isomeric identifiers.

Similarly, the new guidance focuses on generic names that mask a single structural feature only and encourages companies to consult OPPT if they wish to do multiple masking of a generic name. The major difference between the two appears to be not so much the type of generic name that EPA advises submitters to provide, but the strictness with which EPA determines what constitutes an acceptable generic name. The many new examples provided for class II organic chemical substances, in particular UVCBs, and inorganic substances, suggest that these chemical classes are ones for which EPA will be expecting more specific generic names than those submitted according to the 1985 guidance.

On the practical implementation side, submitters should expect significant scrutiny of generic names and may find TSCA Section 5 premanufacture notifications (PMN) being rejected as invalid if the generic names are too generic. This is one of the many implications of new TSCA and care will need to be taken to understand thoroughly the new rules and EPA's guidance on how best to protect chemical identity.

3. Guidance on Expanded Access to TSCA CBI

EPA announced the availability of guidance in June of 2018 for each of three new expanded TSCA CBI access provisions implementing Lautenberg. As noted above, Lautenberg expanded the categories of people to whom EPA may disclose TSCA CBI by specifically authorizing EPA to disclose TSCA CBI to state, tribal, and local governments; environmental, health, and medical professionals; and emergency responders. This was an important driver of TSCA reform initiatives as many stakeholders objected to first responders being denied information that many claimed was essential to discharging their emergency functionalities. The guidance documents cover the content and form of the agreements and statements of need required under each provision, and include some basic logistical information on where and how to submit requests to EPA. The conditions for access vary under each of the new provisions, but generally include the following:

- The requester must show that he or she has a need for the information related to their employment, professional, or legal duties;
- The recipient of TSCA CBI is prohibited from disclosing or permitting further disclosure of the information to individuals not authorized to receive it (physicians/nurses may disclose the information to their patient or person authorized to make med-

ical or health care decisions on behalf of the patient); and
- EPA generally must notify the entity that made the CBI claim at least 15 days prior to disclosing the CBI. There is an exception for disclosures in emergency situations, which require that EPA make the notification as soon as practicable.

In addition, under these new provisions, requesters are generally required to sign an agreement and may be required to submit a statement of need to EPA. Emergency requesters only need to sign an agreement and submit a statement of need if the person who made the claim so requests.

IV. Issues and Controversies

On the whole, EPA has done a good job of implementing the CBI-related amendments to TSCA required by Lautenberg. As is always the case, however, not everyone agrees and when it comes to balancing the need for the non-disclosure of competitively sensitive information and the public's right to know, there are many competing interests and EPA's approach has invited controversy.

Most recently, several U.S. Senators expressed their disappointment with certain aspects of EPA's implementation of Lautenberg, including its treatment of CBI. On June 20, 2019, Senators Tom Udall (D-NM), Cory Booker (D-NJ), Ed Markey (D-MA), Jeff Merkley (D-OR), and Sheldon Whitehouse (D-RI) sent a letter to EPA Administrator Andrew Wheeler requesting information on EPA's implementation of Lautenberg, including information on CBI issues. The Senators' letter requests EPA's responses to questions regarding the following areas of concern, including: Section 4 and EPA's failure to date to use its enhanced information authorities under TSCA regarding existing chemicals; Section 5 and EPA's alleged failure to protect workers when reviewing new chemicals and to identify and review 'reasonably foreseen' conditions of use when reviewing new chemicals under TSCA; Section 6 and EPA's alleged failure to assess known conditions of use and pathways of exposure in conducting risk evaluations of existing chemicals under TSCA; and, most relevant for purposes of this article, Section 14 and EPA's alleged failure to provide timely public access to non-confidential information and access by eligible parties to CBI under TSCA.

As described above, Lautenberg amended Section 14, and specifically requires EPA to provide to emergency responders expanded access to CBI. The letter calls EPA out for not having a more 'defined program' for providing third party emergency responders and other health care professionals with access to CBI. They claim EPA's implementation of the requirement is inadequate, although they offer no real explanation of any identified deficiency. Currently, the system relies upon a defined course of conduct at EPA where several identified EPA employees are tasked with responding to such requests. While the 'system' is not fancy or necessarily all that transparent, there is no record evidence to suggest it is deficient or not working as intended. Indeed, there is no evidence the expanded access to CBI has even been requested in the three years since Lautenberg was enacted, but we assume such information has been requested and provided as contemplated by Congress.

Similarly, several non-governmental organizations (NGO) have expressed deep displeasure with many aspects of EPA's implementation of TSCA and specifically with certain CBI provisions. Not long after EPA issued the TSCA Inventory Notification framework rule, the Environmental Defense Fund (EDF) sued EPA in the U.S. Court of Appeals for the D.C. Circuit claiming that the final rule authorizes confidentiality claims that are not consistent with Lautenberg. EDF has been especially critical of EPA's TSCA implementation and has commented frequently and helpfully on implementation measures urging EPA to go in a direction other than its stated direction.

On April 26, 2019, the D.C. Circuit in response to this challenge issued an order on EDF's challenge, denying all but one claim. EDF challenged five distinct features of the final rule: (i) EPA's exclusion of substantiation questions regarding reverse engineering; (ii) the final rule's criteria for 'maintaining' a confidentiality claim; (iii) EPA's choice not to incorporate certain regulatory requirements into the final rule; (iv) EPA's failure to implement the Act's 'unique identifier' requirements in this rulemaking; and (v) the final rule's exemption of exported chemicals from its notification requirements. The D.C. Circuit's order states that only the first claim succeeds past the standard of review required under both the Administrative Procedure Act and TSCA, however, specifically, EPA acted arbitrarily and capriciously via its 'omission of any inquiry into a chemical identity's suscep-

tibility to reverse engineering [which] effectively excised a statutorily required criterion from the substantiation process.' Even though EPA included several substantiation questions to address reverse engineering in the proposed rule, EPA did not include any 'substantiation questions related to the requirement that a substance's chemical identity not be susceptible to reverse engineering' and declined altogether to ''secure answers' substantiating a company's 'assertion' that its chemical product cannot be reverse engineered' in the final rule.' The court concluded that this error was fatal and remanded the issue back to EPA to address.

Regarding the other four claims that it denied, the court made the following statements: 'EPA acted well within its discretion in concluding that, as part of the Inventory update, any manufacturer or processor of a chemical substance can file a claim to maintain the chemical substance's confidentiality'; 'There is nothing facially troubling about the failure to copy every relevant statutory obligation into the regulation'; 'Agencies need not address all regulatory obligations 'in one fell swoop' ... nothing in [TSCA] requires the EPA to develop and implement the unique identifier system alongside its Inventory review process'; and, finally, 'EPA's decision [to exclude export-only chemicals from the final rule's requirement that chemical companies notify EPA of chemical substances being manufactured or processed] reflected a reasonable interpretation of [TSCA].'

V. Conclusion

EPA's implementation of Lautenberg is a work in progress and will remain so for years to come. That EPA has timely issued implementing regulations that are thoughtful, clear, and well written should be acknowledged and applauded. Similarly, that stakeholders disagree with EPA's interpretation of certain aspects of the law is not unexpected. Stakeholders will undoubtedly clash forever over the scope of CBI protections. They will do so because the stakes are high and the views of those advocating their respective positions run deep, the law is unsettled, and the rules and policies will continue to emerge, evolve, and reflect the policies of those in power.

The take home message is the scope of CBI protections will continue to evolve and likely contract. Chemical stakeholders need to monitor these issues carefully, advocate their views relentlessly, and be mindful of the consequences of not getting it right. Legally, the cost of non-compliance is high and invites penalties. Commercially, once EPA releases information, there is no putting that toothpaste back in the tube.