Before the United States Environmental Protection Agency

Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA); 87 Fed. Reg. 29078 (May 12, 2022); Docket EPA-HQ-OPPT-2021-0419/FRL-8223-01-OCSPP

Comments of the Chemical Users Coalition

Introduction

Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments in response to the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") recent notice announcing the availability of and requesting public comment on new and amended requirements concerning Confidential Business Information ("CBI") Claims Under the Toxic Substances Control Act ("TSCA"). The proposal is intended to implement changes to the Agency's CBI regulations due to the 2016 amendments to the CBI provisions in TSCA. Additionally, EPA is reorganizing and consolidating provisions concerning CBI that are currently spread over a large number of parts in the Code of Federal Regulations. Certain enhancements to EPA's existing electronic reporting requirements as well as expansion of the electronic reporting requirements are addressed in the proposal. CUC's members will likely be affected by the proposed changes being considered.

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances.[1] To thrive in a competitive global economy, our members depend on the availability of certain existing substances as well as a reliable pipeline for innovative new chemistries. Consequently, our members encourage EPA to develop regulatory approaches that encourage innovation and enable sustainability. Thus, CUC supports measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. This is critical in the area of chemical regulatory policy, which necessarily addresses emerging information about health and environmental risk. Mandates to make this information available must be balanced with measures that allow intellectual property and trade secrets to be appropriately secured, so that entities will devote resources to the development of new sustainable and innovative substances, confident that their investments will be protected. Consequently, ensuring that EPA develops a balanced and equitable regime for the protection of CBI under TSCA is of paramount importance.

Comments

CUC agrees there is a need for consolidated, simplified, and predictable CBI policies and procedures that are applicable to all submissions under TSCA. In achieving this objective, CUC encourages EPA to recognize that CBI claims protect information that is of value not only to chemical manufacturers, but also to processors, formulators, importers, and downstream users of chemical substances and formulated mixtures. EPA must ensure that new policies and regulatory changes strike the balance between making information accessible and readily available to the

[1] CUC's Members include Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

interested public, while at the same time appropriately protecting intellectual property and the competitiveness of industry. However, EPA's proposal contains aspects that are not adequately protective of this sensitive information or that create needless obstacles to ensuring that the information is indeed protected.

The following comments are responsive to the topics on which EPA solicited input in its recent notice and are intended to encourage EPA to carefully reconsider certain aspects of the proposal that could unfairly and prematurely reveal certain confidential business information without offering sufficient process for those entities that could be negatively affected and who wish to respond.

I. Information Originally Collected Under Other Statues

Under EPA's proposal, confidential information originally submitted under another statute but used by EPA for a TSCA purpose will be subject to the TSCA CBI regulations. If there is a conflict between the TSCA CBI protections and the protections of the statute under which information was originally submitted, the provisions of the original statute would apply.

CUC agrees that when EPA has information that was generated under another statute but is being used for TSCA purposes, EPA should use the information protection provisions of the first statute. The generator of that information had certain expectations as to the use and availability of that information, and those expectations should be upheld and respected under TSCA.

II. Assertion of CBI Protection and Specific Chemical Identity

EPA proposes that if a TSCA submission identifies a chemical substance on the confidential Inventory but does not assert a CBI claim for the specific chemical identity of the substance, the specific chemical identity will no longer be eligible for CBI protection (and the substance will be moved to the public version of the Inventory). Moreover, under the proposal, if this were to occur (i.e., if a confidential chemical identity were to lose CBI protection because of one company's failure to assert CBI), the Agency would not provide notice to other submitters that previously asserted their own CBI claims for the same chemical identity information.

Multiple entities may have a commercial and intellectual property interest in protecting CBI claims for the identity of the same chemical substance. Moreover, it is foreseeable that TSCA 8(e) submittals, information submitted in response to one or more TSCA 8(a) or (d) rules, or even a public comment or TSCA Section 21 petition, might include one or more specific chemical names which are not accompanied by a CBI claim. It also is foreseeable that a processor of a chemical substance might submit a Significant New Use Notice for a substance and unwittingly fail to assert a confidentiality claim for a substance on the confidential portion of the Inventory for which the original manufacturer or importer of the substance has asserted, and wishes to maintain, a CBI claim for the specific chemical identity.

EPA must recognize that multiple (other) stakeholders may have an interest in maintaining the confidentiality of a specific chemical identity. Although one stakeholder may believe that confidential treatment is no longer needed, or even be aware that the substance has been the subject

of a CBI claim, that may not be the case for other interested entities. EPA must not determine that confidential treatment of an identity will be lifted on the basis of one entity's submission when other entities have a stake in the matter. EPA must allow other interested entities to assert and justify continued confidentiality before EPA takes any action. Consequently, EPA must notify interested stakeholders using multiple methods of any contemplated changes. Such stakeholders receiving written notice should include: all entities that have reported the same substance under any TSCA rule or submittal, including the Chemical Data Reporting rule (CDR), as well as the Toxics Release Inventory (TRI). Notification should be provided by methods reasonably likely to provide adequate notice and in a timely manner (including certified mail and CDX). The opportunity to respond prior to the release of the chemical identity should also be provided to notice recipients.

The same is true for when an entity wants to voluntarily withdraw a previously asserted CBI claim for a specific chemical identity. For example, the original PMN submitter for a chemical subsequently listed on the confidential Inventory might divest of a product line or even cease to manufacture a chemical substance and fail to renew its CBI claim. However, one or more other entities may have commenced manufacture based on the confidential Inventory listing. EPA must notify and allow other interested stakeholders the opportunity to assert and substantiate continued confidential treatment for that chemical identity. Such entities receiving notice should include those having submitted bona fide intent to manufacture inquiries (pursuant to the new chemical and significant new use provisions of 40 CFR Part 720 and 721), all entities having filed CDR reports for the substance, those having submitted Section 8(e) or (d) reports, and those filing TRI submittals for the same substance. Adequate time must be provided to respond.

III. Substantiation Questions: Specificity of Harm

EPA requested comments on how the Agency can most effectively frame a question to elicit information on the nature of the harm that would result from the release of information that is claimed as CBI.

Although EPA has proposed a substantiation question that focuses on "substantial competitive harm" in greater detail than the question currently used in the context of reporting under the CDR Rule, EPA has not given any indication that the formulation used for CDR purposes has been problematic. Unless the Agency can explain why the CDR substantiation question that has been used previously, and with which submitters are familiar, needs to be revised, the current form of the question should continue to be utilized.

IV. Deficient CBI Claims: Timing of Corrections

Under the proposed regulations, a CBI claim will be deemed deficient if it does not include the required substantiation, certification, redacted copies, or generic name (if applicable) at the time of submission. Companies would be notified by CDX - and only by CDX - of a deficient CBI claim and be given 10 business days to correct the deficiency -- during which EPA review of the underlying submission (such as a CDR report or PMN) will be suspended. If the deficiency is not corrected within the 10-day period, the CBI claim may be denied. Ten days is simply too small a window to provide for adequate notice to be received and corrections to be made.

The use of CDX as the sole mode of communications with information submitters creates certain concerns among CDX users. Many companies have a single CDX account holder, and if such person becomes unavailable for that short period of time, CBI protections could inadvertently lapse. Accordingly, a 45-calendar day window is more appropriate. During those 45 days, EPA should send automatically generated notification reminders at day 20 and 30 to ensure receipt of the original communication and to determine if any correction or resubmission will be made. In addition, EPA should notify the submitters of deficient CBI claims by certified mail sent to the physical address EPA has on file for the submitter and via email to the submitter's email address on file with EPA. (See also comments below in Section V on the use of CDX generally.)

It also would be appropriate for the regulations to provide time limits for certain EPA actions. CUC proposes that when an original CBI claim is submitted to EPA, the Agency should have 45 days to identify any deficiencies in the submission, after which time the submission would be automatically deemed complete. A similar timeline, of perhaps 30 days, should pertain to EPA review of corrections submitted in response to deficiencies.

V. Use of CDX

EPA proposes to require that: (i) all submissions containing CBI must be submitted through CDX, except for information submitted in response to a TSCA subpoena or inspection and (ii) submitters must maintain current contact information for each submission in CDX. EPA also proposes to provide submitters with notices and other correspondence regarding their CBI claims via CDX, using the contact information maintained by the submitter in CDX. This includes notices of EPA's review of a CBI claim and opportunity to substantiate or re-substantiate under TSCA Section 14(f). Communications regarding expiring CBI protections pursuant to TSCA Section 14(e) would be sent to the submitter by CDX and also published in the Federal Register.

Electronic reporting does streamline reporting, document processing, retention, and retrieval. Unfortunately, CDX is not a "secure" system in the sense of Department of Defense, Department of State (ITAR[2]), or Department of Homeland Security standards. There are potentially TSCA related submissions with CBI claims that could have national security related implications for which a paper submission with the appropriate markings might result in a more secure transmittal and handling. For this reason, EPA should allow for such paper submission when accompanied by justification and/or substantiation for the security related claims. In the alternative, if a more secure electronic reporting system were developed, that perhaps could be a viable alternative.

Additionally, EPA's desire to communicate via CDX is understandable and reliance on CDX should be appropriate and adequate for routine matters. For more significant communications from EPA, such as CBI claim denials, claim expirations, and deficiency notifications, additional forms of communication are necessary. At a minimum, non-CBI e-mails

[2] The International Traffic in Arms Regulations (ITAR) is the United States regulation that controls the manufacture, sale, and distribution of defense and space-related articles and services. Aside from munitions and other military hardware, the requirements also restrict the plans, diagrams, photos, and other documentation used to build ITAR-controlled military gear, including "technical data" such as chemical content.

outside of CDX are warranted and can provide notice to infrequent CDX users of the need to check the system for CBI-related transmissions. Paper notifications (such as via certified mail) should be provided when EPA is proposing to deny a CBI claim and release previously confidential information to the public. These notifications could be automatic, and system generated, so it should not be burdensome for the agency to take this simple but protective measure. These communications would be to the physical address and e-mail addresses EPA has on file for the submitter. EPA should also consider requiring the submitter of CBI information to identify a lead and backup company contact. This will assist in the event of employee departures, reorganizations, and even prolonged absences due to illnesses, to help ensure that all consequential communications are supplied and properly received in timely fashion.

VI. Review of CBI Claims

EPA will be reviewing CBI claims under a number of different scenarios. EPA will be reviewing the substantiation of initial claim assertions. EPA will be reviewing resubstantiation upon the expiration of confidentiality claims after 10 years. EPA is also proposing to codify its current practice of reviewing all CBI claims in every fourth submission received via CDX besides those pertaining to chemical identity. Bona Fide Intent to Manufacture submissions and prenotice submissions under TSCA Section 5 would be excluded. In addition, all CBI claims for chemical identity information would be reviewed.

To implement the proposed regulatory changes, EPA will need to identify and standardize its methods to notify information submitters of the need to reconsider or revise its CBI claims, and to inform information submitters when and how such events are likely to occur. Therefore, when EPA is reviewing in detail a select 25% of CBI-containing submissions, proper notice should be provided to the information submitters that their claims are being scrutinized and of the time for that review. EPA also should provide timely notice when the 10-year interval for a CBI claim is subject to review and reconsideration. Once such notice is provided, and the obligation to respond has been triggered, it is reasonable for EPA to expect that the information submitter must review and determine whether to revisit or resubstantiate its CBI claims. Requiring information submitters to automatically anticipate and amend previously submitted documents is potentially burdensome.

The need for ample time and opportunity to review is particularly important as it allows the submitter to identify collateral information for which it may need to assert CBI protection given the change in circumstances or denial of a claim. For example, because the linkage between a chemical identity and a company name can be commercially sensitive, it is reasonable to anticipate that a company that claimed a chemical identity to be CBI in a CDR submittal, but did not claim the company name to be CBI, might wish to assert the company name to be CBI if the company were to learn that the chemical identity claim was being denied by EPA (perhaps because a second entity failed to assert a CBI claim for the same chemical name). Having the opportunity to review and reconsider all CBI claims in a submittal if EPA intends to deny or revoke a CBI claim may be of critical importance to a particular entity.

VII. Modification of Original Submissions Following CBI Denial/Withdrawal

EPA stated that following the denial or expiration of a confidentiality claim, the public copy of the submission must be revised to provide public access to the newly non-CBI information. For some TSCA submissions, the denied or expired claims may be intermingled with still-valid or approved claims, or the claims may have been indicated by numerous redactions throughout a voluminous text. The proposed rule encourages companies to prepare this updated public copy themselves. If the submitter is unavailable or otherwise unable to update the public copy, the proposed rule makes clear that EPA will undertake this function, as needed.

CUC agrees that if denial or withdrawal of a CBI claim necessitates the modification of a sanitized document, the original submitter of the sanitized document (or its successor) should be given the first opportunity to prepare a revised document. This will allow the original submitter to identify information that should continue to be subject to CBI protections. Other simpler and more routine modifications (e.g., "unchecking" the CBI box on an EPA form) should be implemented by EPA. However, EPA should identify some trigger for requiring such amendments, such as a Freedom of Information Act Request. Once the obligation is triggered, EPA should then notify the original submitter of the need to revise the document. Otherwise, requiring automatic amendment of all documents once the CBI protection expires or is removed is potentially burdensome.

VIII. Prospective Application of the New Regulations

The new CBI rules should only apply prospectively - not retrospectively. Those who previously submitted information did so with certain understandings and expectations and those should not change. Perhaps, if information is subsequently amended, or upon the required substantiation of the CBI claim, the new CBI rules could then govern.

Conclusion

As articulated above, CUC is concerned that EPA's policy changes regarding its approach to the assertion and treatment of confidential business information (CBI) claims for information reported to or otherwise obtained by EPA under TSCA may not be sufficiently protective and could compromise the integrity and protection of intellectual property, trade secrets, and other important information. Such protection is critical to support measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. Further, it enables entities to devote resources to the development of new sustainable and innovative substances and have that investment protected, and at the same time protect national security interests. Consequently, ensuring that EPA develops a balanced and equitable regime for the protection of CBI under TSCA is of paramount importance.

CUC Members would be pleased to meet with EPA personnel to discuss these comments and related issues.