On May 12, 2022, the U.S. Environmental Protection Agency (EPA) proposed new and amended requirements concerning the assertion and treatment of confidential business information (CBI) claims for information reported to or otherwise obtained
by EPA under the Toxic Substances Control Act (TSCA). \textit{87 Fed. Reg. 29078}. The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) amendments to TSCA in 2016 included many new provisions concerning the assertion, EPA review, and treatment of confidentiality claims. EPA proposes procedures for submitting such claims in TSCA submissions and addresses issues such as substantiation requirements, exemptions, electronic reporting enhancements (including expanding electronic reporting requirements), maintenance or withdrawal of confidentiality claims, and provisions in current rules that are inconsistent with amended TSCA. The proposed rule also addresses EPA procedures for reviewing and communicating with TSCA submitters about confidentiality claims. Comments are due on or before \textbf{July 11, 2022}.

This memorandum summarizes and comments on the provisions concerning the purpose and applicability of the proposed new Part 703 and the requirements for asserting a confidentiality claim. A separate memorandum will address EPA’s review of confidentiality claims and related or corresponding revisions to other TSCA rules.

\section*{Purpose and Applicability}

EPA states that it intends for the proposed requirements to apply broadly to any information that is reported to, or otherwise obtained by, EPA under TSCA. This would include information submitted pursuant to a requirement of TSCA or its implementing regulations (e.g., a TSCA Section 5 premanufacture notification (PMN) or a TSCA Section 8(e) notice of substantial risk), information that is collected in the course of a TSCA inspection or other TSCA enforcement-related activity, and materials that are subpoenaed pursuant to TSCA. The proposed rule would also cover information that is first obtained by EPA under an authority other than TSCA but that meets the following criteria: (1) EPA has authority to collect the information under TSCA; and (2) the information is either used to satisfy the obligation of a person under TSCA or used by EPA in the course of carrying out its responsibilities under TSCA.

According to EPA, there may be instances where information covered under proposed new Part 703 was originally submitted to EPA pursuant to a statute with provisions regarding confidentiality, disclosure, and treatment of information that materially differ from those in TSCA. EPA states that an example of a scenario in which such a situation may occur is where a health and safety study is originally submitted to EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), but is subsequently used for TSCA purposes (e.g., in support of a TSCA Section 6 risk evaluation) and where the health and safety study could have been collected under a TSCA authority (e.g., pursuant to TSCA Section 8(d)). EPA notes that under FIFRA Section 10(g), the disclosure of such a study is limited to protect against disclosure to foreign or multinational pesticide producers, but if the study were submitted under TSCA, much of the information in the study would not be protected from disclosure under TSCA Section 14(b)(2). EPA proposes that when there is a conflict between statutory data protection regimes, the rules regarding the treatment of information in that statute under which the information was originally collected should continue to apply to the information, regardless of how EPA uses the information under TSCA.
EPA states that it recognizes that there are several options for dealing with these potential conflicts. EPA proposes that in certain circumstances, information obtained under authorities other than TSCA are considered information obtained under TSCA. EPA also seeks to ensure that when information is submitted to EPA under a statutory provision that provides an assurance of privacy, those privacy protections continue to apply even when the information is used for a different purpose. Thus, EPA proposes that when there is a conflict between statutory data protection regimes, the rules regarding the treatment of information in that statute under which the information was originally collected should continue to apply to the information, regardless of how EPA uses the information under TSCA.

Requirements for Asserting a Confidentiality Claim

Assertion of Confidentiality Claim upon Submission of Information to EPA

TSCA Section 14(c)(1)(A) requires an affected business to assert a claim for protection from disclosure concurrent with submission of the information. Consistent with this provision, proposed 40 C.F.R. Section 703.5 would require persons to assert confidentiality claims at the time of submission. If a person fails to make a claim, EPA may make the information available to the public without prior notice to the person who submitted the information. EPA notes that while similar language appears in some of the existing regulations that implement TSCA (e.g., 40 C.F.R. § 711.30(e)), the proposed rule would clarify that the up-front assertion requirement is applicable to all non-exempt TSCA CBI claims, in accordance with TSCA Section 14(c)(1)(A).

Proposed Section 703.5 would further clarify and reiterate that where a TSCA submission identifies a chemical substance listed on the confidential portion of the TSCA Inventory but does not assert a confidentiality claim for the chemical identity as required by TSCA Section 14 or in the manner required by the applicable rule, the specific chemical identity would no longer be eligible for confidential treatment on the TSCA Inventory. EPA would update the TSCA Inventory to list publicly the specific chemical name and Chemical Abstracts Service Registry Number (CAS RN), if available, without further notice (to any person who may have made a CBI claim for this substance). Updates to individual submissions that contain a prior claim for what appears to be the same information would occur only after that claim is withdrawn or as a result of a review and final determination in accordance with TSCA Section 14 denying the claim in that submission. EPA notes that under some existing rules, once the chemical identity is listed on the public portion of the TSCA Inventory, claims can no longer be asserted for such information. This is also intended to clarify that EPA will not provide notice to submitters with previously approved or pending claims for the same chemical identity prior to such disclosure on the TSCA Inventory. In addition, EPA states that it would likely deny upon review other chemical identity CBI claims for the substance. Claims for information related to the chemical identity, e.g., the identity of the submitter, would not be precluded, however.

Substantiation and Exemptions
As reported in our January 26, 2017, memorandum, EPA previously published an interpretation concerning the requirement to substantiate CBI claims in TSCA Section 14(c)(3). In that document, EPA stated that the statute requires persons asserting CBI claims to substantiate those claims at the time the affected business submits the claimed information to EPA. This proposed rule, in proposed 40 C.F.R. Section 703.5(b)(1), would make EPA’s TSCA confidentiality regulations consistent with TSCA Section 14(c)(3).

EPA notes that subsequent to its January 2017 interpretation, it updated some TSCA rules to include a set of required substantiation questions and to apply the substantiation exemptions in TSCA Section 14(c)(2). Proposed Sections 703.5(b)(3) and (4) include a standard set of substantiation questions that would be applicable to any confidentiality claim in any TSCA submission for which substantiation is required and include additional substantiation questions specific to chemical identity claims. Proposed Section 703.4(b)(3) would provide that individual TSCA rules may modify the questions (by, for example, not requiring answers to substantiation questions that are not applicable in a particular TSCA submission type), however.

EPA states that it designed the substantiation questions to elicit information to allow it to determine whether the submitter’s claim for confidentiality meets the substantive review criteria in proposed Section 703.7(f). EPA requests comment concerning the proposed question set, including whether some questions might be consolidated or revised to minimize burden while also ensuring that responses are adequate to support a confidentiality determination. According to EPA, the proposed questions are similar to those included in the 2020 amendments to the Chemical Data Reporting (CDR) rule that EPA believes are adequate to support its review of confidentiality claims in those submissions.

**Patents**

EPA proposes a question on patents in proposed Section 703.5(b)(3)(iii)(C) and seeks comment on alternatives to the proposed question language, or whether a stand-alone patent question is necessary. EPA requests comment on whether a patent question can be reasonably added to the publications question found in proposed Section 703.5(b)(3)(iii)(B). Alternatively, EPA requests comment on whether the stand-alone patent question used in the 2020 CDR rule (40 C.F.R. § 711.30) and in the proposed Section 703.5(b)(3)(iii)(C) is adequate, or whether it can be improved to elicit more pertinent responses from submitters regarding the potential public disclosure in a patent of the information claimed as confidential in the TSCA submission.

**Trade Secrets**

EPA states that it has observed that the question concerning trade secrets found in several existing TSCA rules, e.g., at 40 C.F.R. Section 711.30(b)(4), “tends to elicit answers that are either redundant with the answers to other substantiation questions, or otherwise do not tend to include information that is useful for the agency to consider whether the information meets the specific legal standard for trade secrets.” According to EPA, this is rooted in confusion about trade secrets and
CBI, “which are distinct but related concepts.” While the trade secret standard and CBI standard could theoretically provide two avenues to protect information from disclosure, EPA states that it is not aware of any situation where information submitted under TSCA was determined to be entitled to trade secret protection but not CBI protection. EPA seeks comment on whether the trade secret question still has value in the context of TSCA confidentiality claims.

**Specificity of Competitive Harm**

To evaluate properly the various CBI claims in a single submission, EPA states that it needs a separate explanation from the submitter for each type of information claimed as confidential to explain why disclosure of that information would be likely to cause substantial competitive harm. To that end, EPA proposes two versions of the substantiation question concerning substantial competitive harm in this rulemaking. The first version of the question comes directly from the CDR rule: “will disclosure of the information claimed as confidential likely cause substantial harm to your business's competitive position? If you answered yes, describe the substantial harmful effects that would likely result to your competitive position if the information is disclosed, including but not limited to how a competitor could use such information, and the causal relationship between the disclosure and the harmful effects” (40 C.F.R. § 711.30(b)).

The second version for consideration is in proposed Section 703.5(b)(3)(i): “Please specifically explain what harm to the competitive position of your business would be likely to result from the release of the information claimed as confidential. How would that harm be substantial? Why is the substantial harm to your competitive position likely (i.e., probable) to be caused by release of the information rather than just possible? If you claimed multiple types of information to be confidential (e.g., site information, exposure information, environmental release information, etc.), explain how disclosure of each type of information would be likely to cause substantial harm to the competitive position of your business.”

According to EPA, the version of the question in proposed Section 703.5(b)(3)(i) may enable it to determine better whether disclosure of the information is likely to cause substantial harm to the competitive position of the submitter. EPA requests comment from submitters and the public on which of the two proposed versions of the question would be most likely to elicit information from submitters that will best allow EPA to determine that the submitter has demonstrated a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of its business. EPA is also seeking comment on how “substantial” and “likelihood” should be defined.

**Exemptions**

Proposed Section 703.5(b)(5) addresses the TSCA Section 14(c)(2) exemptions from the substantiation requirement. This proposed provision includes criteria for the exemption in TSCA Section 14(c)(2)(G) pertaining to substances that have not been offered for commercial distribution. The other proposed exemptions include:

- Specific information describing the processes used to manufacture or process a
chemical (e.g., information reported under 40 C.F.R. Section 720.45(g)(2));

- Marketing and sales information (note that submitting company identifiers are not generally themselves considered marketing and sales information);

- Information identifying a supplier or customer (such as the identities of some joint submitters reporting information under 40 C.F.R. Sections 720.40(e) or 711.15);

- Details on mixture composition and percentage (such as might be included in a TSCA Section 8(e) notice of substantial risk that concerns a mixture);

- Specific chemical substance use information (such as is required to be reported under 40 C.F.R. Sections 720.45(f) and 725.155(g)); and

- Specific production or import volumes (such as are required to be reported under 40 C.F.R. Sections 711.15 and 720.45(e)).

EPA states that it expects to update the reporting forms and applications for most TSCA submissions to prompt the submitter for substantiation where required, but not to prompt the submitter for types of data that EPA has concluded are always covered by a substantiation exemption.

**Public Copies of Submissions**

Proposed Section 703.5(c) would require public copies of submissions that include confidentiality claims. EPA would not require preparation of a separate public copy where the reporting form or electronic reporting application contains a specific CBI designation identifying specifically what is claimed as CBI. Where the submission is made without the use of such a TSCA reporting form, however (e.g., subpoena responses), or includes attachments or other “non-fielded” data, EPA would require the submitter to produce and submit a public (sanitized) copy of the submission and/or attachments. EPA notes that some existing TSCA rules already include such a requirement. The proposed rule would consolidate existing requirements in proposed new Part 703 and extend them generally.

**Supporting Statement and Certification**

TSCA Section 14(c)(1)(B) requires that each claim of confidentiality be accompanied by a standard supporting statement regarding the eligibility of the information for confidential treatment. TSCA Section 14(c)(5) also requires a certification that the TSCA Section 14(c)(1)(B) statement and information required to substantiate the claim are true and correct. According to EPA, it has already incorporated this supporting statement and certification language in most TSCA reporting forms. To the extent that the submission is not being made on such a reporting form, proposed Section 703.5(a) provides language that may be included in a cover letter or other attachment to a submission.

**Generic Names**
TSCA Section 14(c)(1)(C) requires the submission of a generic name any time a specific chemical identity is claimed as confidential. EPA notes that this provision further requires that the generic name be “structurally descriptive” and that it “describe the chemical structure [...] as specifically as practicable” while also protecting the features of the chemical substance that are claimed as confidential or where disclosure would likely cause substantial harm. The generic name must also be consistent with the generic name guidance developed in accordance with TSCA Section 14(c)(4)(A). The generic name guidance document provides information to assist companies in creating structurally descriptive generic names for chemical substances whose specific chemical identities are claimed as confidential, for the purposes of protecting the specific chemical identities from disclosure while describing the chemical substance as specifically as practicable, and for listing substances on the TSCA Inventory. According to EPA, the proposed rule acknowledges that the TSCA Inventory already includes generic names for confidential substances, and that in most cases, it expects such generic names to be acceptable for the purposes of compliance with TSCA Section 14(c)(1)(C).

For substances that are not on the TSCA Inventory (e.g., new chemical submissions under TSCA Section 5 or Section 8(e) submissions concerning pre-market chemical substances), the proposed rule includes a few basic criteria, drawn mainly from the TSCA Section 14(c)(4)(A) guidance (e.g., the generic name should mask only the confidential portions of the specific chemical name, generally only one structural element of a specific chemical name may be masked to protect a confidential chemical identity), and would require that where the submitter believes those criteria are in some way inappropriate or inapplicable to a particular substance or generic name, the submission must also include an explanation for why more extensive masking of the specific chemical identity is necessary in the particular case.

In proposed Section 703.5(d)(3), EPA proposes that where a generic name submitted for a substance that is not on the TSCA Inventory is acceptable for the purposes of meeting the requirements of TSCA Section 14(c)(1)(C), the generic name might nonetheless be later subject to additional review and potential change when commercial manufacture of the substance is commenced (e.g., when a notice of commencement (NOC) is submitted).

Proposed Section 703.5(d)(4) would provide an opportunity to revise proposed generic names that EPA concludes are not in compliance with TSCA Section 14(c)(1)(C). EPA states that it would provide an electronic notice of the deficiency to the submitting company, who would then be afforded ten days to propose a revised generic name. If the submitter does not submit a compliant generic name, EPA would reject the underlying submission and may ultimately deny the CBI claim.

## Deficient Submissions

Proposed Section 703.5(e) would specify that confidentiality claims, identified for review pursuant to proposed Section 703.7(a), that are missing the certification, substantiation, or generic name (where applicable) required by TSCA Section 14(c) will be considered deficient. Submissions that are missing a public copy or where the public copy does not meet the requirements of proposed Section 703.5(b)(6)
would also be considered deficient. EPA would also consider to be deficient submissions that include a generic name that does not meet the requirements of proposed Section 703.5(d) or rely on inappropriate substantiation exemption assertions.

When EPA identifies such deficiencies, it would initially place a hold on the submission and provide notice of the deficiency to the submitter. The submitter would have ten (10) business days to fix the deficiency. Meanwhile, any applicable review periods for the underlying submission and for the confidentiality claim would be suspended while the hold is in place. If the deficiency is not remedied within ten (10) business days of EPA providing the notice of deficiency, EPA states that it will “resume the review of the submission and will likely deny the CBI claim(s).”

**Electronic Reporting**

According to EPA, the proposed Section 703.5(f) would fill most of the current gaps in electronic reporting requirements by requiring that nearly all TSCA confidentiality claims be asserted electronically. For example, while current TSCA Section 8(e) notices of substantial risk may be made either on paper or via an optional electronic reporting form, EPA proposes that all TSCA Section 8(e) notices that include a confidentiality claim would be required to be submitted electronically, using an EPA-provided reporting tool. Similarly, electronic reporting applications would be developed or updated for TSCA Section 12(b) notices of export and TSCA Section 5 polymer exemption notifications.

**Requirement to Report Health and Safety Information Using Harmonized Templates**

Proposed Section 703.5(g) would require that health and safety studies and information from health and safety studies be provided in a templated format, using Organization for Economic Cooperation and Development (OECD) Harmonized Templates, where an applicable template is available. EPA states that many TSCA submitters may be familiar with and already have created templated versions of health and safety study reports that they may be required to submit under TSCA, owing to reporting requirements in other countries. For these submitters, the burden associated with this requirement to submit templated data is expected to be minimal. EPA notes that the proposed requirement to provide data in a templated format does not supersede existing regulatory requirements also to submit a full study report, however.

**Maintenance of Company Contact Information and Communications Concerning Claims**

EPA proposes to require companies to maintain current contact information for all individuals associated with a submission, enhance the means by which companies update contact information, and require the submission of notices of transfer of ownership via the Central Data Exchange (CDX). This reinforces and complements existing CDX terms and conditions concerning maintenance of CDX accounts, particularly the requirement to notify EPA when individual account access is no
longer needed so that the account can be deactivated.

EPA notes that the proposed rule describes how it expects to furnish the required notices concerning expiration of confidentiality claims under TSCA Section 14(e). The first expirations will occur in 2026, for claims that were asserted in 2016 and that were not exempt from substantiation and review according to TSCA Sections 14(c)(2) and 14(g). EPA proposes to publish periodically a list of TSCA case numbers that are approaching claim expiration on the EPA website, or other appropriate platform. In addition, EPA states that it intends to send individual notices of upcoming claim expiration and other individual notices concerning CBI claims to the company via CDX.

For TSCA submissions that were not originally made via CDX, EPA proposes to send the notice by certified mail or courier to the address provided in the most recent TSCA submission from that company, or via other means that allow verification of the fact and date of receipt. For example, EPA states that it is also considering further development of two-way CDX communication to permit EPA to also send these notices, likely using the contact information in the most recent CDX submission from the same company.

**Withdrawing Claims**

Proposed Section 703.5(i) includes instructions for voluntarily withdrawing confidentiality claims prior to automatic expiration or denial. EPA states that the preferred approach is for the company to amend the submission electronically, via CDX, to withdraw the claims (i.e., “uncheck” the CBI boxes or unredact the submission and resubmit it). When this is not possible (for example, when the submission was not originally submitted via CDX, or because the company does not have access to the electronic submission), claims may be withdrawn by CDX submission as well, using a new correspondence tool that enables efficient linking of the withdrawal letter with the related submission and permits EPA to communicate with the company about the withdrawal.

**Amending a Public Copy Following Claim Denial or Expiration**

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. According to EPA, the proposed rule “would encourage companies to prepare this updated public copy themselves.” EPA states that it believes that submitters are in the best position to assert and indicate their remaining claims accurately. In the case that 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.”

**Commentary**

The proposed rule addresses important issues related to TSCA CBI under the Lautenberg Act. The proposed rule seeks to address inconsistencies between the current regulations and Lautenberg's statutory text, to codify substantiation procedures, to codify review of generic names, to resolve conflicting CBI standards.
between statutes (e.g., TSCA and FIFRA), to clarify what information in a health or safety study may be claimed as confidential, and to establish a formal procedure to manage the sunsetting or withdrawal of CBI claims.

Unsurprisingly, EPA is proposing to embed its current guidance and policies into the updated CBI regulations. In our view, EPA is correct to consolidate, to the extent it is able, the CBI provisions into a single Part 703 and refer to this part in other sections of the Code of Federal Regulations. Doing so maximizes consistency and minimizes opportunities for misunderstanding between and among the various TSCA sections. Most of EPA’s proposals merit support, and we encourage readers to comment to that end.

There are several key questions on which readers should consider commenting; among them are new policies and procedures discussed below.

**Data Submitted under Different Statutes or Voluntarily**

EPA requests comment on the appropriate standard EPA should apply if data were originally submitted under another statute (FIFRA in particular). Should the regulation with the greatest transparency apply, or should the regulation under which the data were submitted apply? In our view, it is particularly problematic for a submitter’s data to be disclosed by default if EPA pulls those data from a more protective scheme into a less protective scheme. Companies that submit data under a particular CBI scheme have a reasonable expectation that the data will be protected under that scheme. It would an inappropriate taking for EPA to transfer the data unilaterally to a less protective scheme and release those data. EPA can decide that absent specific permission by the data holder to move the data from the submitted scheme to TSCA that EPA will not consider the data in its TSCA risk assessments or EPA can use the data and release those data to the extent permitted by the original CBI scheme. EPA is proposing relying upon the protection available to the submitter at the time of the original submission. This construction is, in our view, the appropriate standard, and we suggest that readers support this proposal in comments.

In the proposal, EPA also takes the view that language added to TSCA by the Lautenberg Act amendments supports a proposed interpretation that any information EPA has the authority to collect under TSCA and is used for TSCA purposes should be considered obtained “under” TSCA. EPA refers to TSCA Section 4(h)(3)(A). This refers to the submission “under this subchapter” of voluntary information. TSCA Section 26(j)(4) further provides that subject to TSCA Section 14, the Administrator shall make available to the public “a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies.” TSCA Section 26(k) requires the Administrator to consider “reasonably available” information when conducting a risk evaluation. While we question the strength of these points, EPA should avoid discouraging the voluntary submission of information in public comments or otherwise.

**Do Patent Claims Negate TSCA CBI Claims?**

Another critical question on which EPA requests comment is the issue related to
patent protection. Information disclosed in patents often covers a wide range of possibilities to maximize the protection for the preferred construct as well as adjacent space. It is unusual for a patent to include the same level of specificity that is included in a PMN. EPA asks whether there is a difference between what appears in a patent and what is covered by a patent. In the former case, the specific information is disclosed in a patent; in the latter case, the specific information is among the possibilities covered by the patent. In our view, these are two distinct cases. The former is less likely to be eligible for CBI protection, while the latter is more likely to be eligible. Because the question of whether the specific TSCA information has been disclosed in a patent is fact-specific, in our view, publishing a patent should be one consideration in EPA’s determination of whether the information is eligible for CBI protection.

The counterargument -- that the patent provides sufficient protection -- is a naïve understanding of the competitive space. Patents may not be protective globally, and patents require effort -- sometimes significant effort -- to enforce. In fact, there may be substantial commercial harm to the property holder just from seeking to enforce patent protection. The fact that a broad patent covers the information in a PMN provides some protection, but that protection is not as robust as CBI protection. In our view, vague or broad statements about the underlying technology are not disclosure of that specific information per se, and therefore TSCA submitters are entitled to the full protection of the CBI provisions of TSCA, even when a patent might also provide some additional protection. Stakeholders are encouraged to opine on this point in comments on the proposed rule and the related substantiation questions.

Use of CDX to Provide Legal Notice of Loss of CBI Claims

One of the most significant issues in this proposal is ensuring that EPA can rely upon CDX to communicate with submitters for purposes of CBI review. EPA proposes using CDX instead of formal letters with delivery verification to satisfy EPA’s requirement to provide notice of its CBI review decision or CBI sunsetting dates, among others. This may be problematic. If a submitter fails to receive notice through CDX due to a technical issue or because the submitting official is not available to log in to receive the notice, the response window (ten or 30 days, depending on the notice type) may expire before anybody at the company is even aware of the notice in CDX. There are both technical issues (e.g., is CDX sufficiently reliable to serve this function?) and logistical issues (e.g., is the submitting official still at the company?) that could make EPA’s proposed scheme unreliable. EPA proposes requiring submitters to keep current the contacts on submissions -- that is, EPA proposes requiring that a company ensure that the technical contact is current on all submissions so that EPA has a point of contact for each submission. In our view, this could present a significant burden on companies that have many submissions, especially as EPA is proposing to move even more data flows to CDX.

Rather than forcing a company to update contacts on each submission, a more practical approach would be for EPA to send legal notices to all authorized officials (AO) registered under the appropriate organization and to have CDX push an e-mail notification to each AO outside of the CDX system. This will minimize the likelihood that any particular contact on any particular submission is absent for any reason in
the (potentially) short window that a company has to respond. EPA might also notify all agent/consultants (AC) sponsored by a company AO so that an AC can alert the company so that it can intervene timely. A key aspect of the requirement to keep contacts current is that whatever system EPA relies upon, it must not rely upon access to a form using the passphrase for that form. A company can provide redundancy on AO registrants, but a company cannot prevent with certainty a particular AO from creating a form with a passphrase and then forgetting or losing the passphrase. Because the system does not allow reset or recovery of passphrases, if EPA proposes using CDX to send legal notifications with specified response timelines, that system must operate independently of the availability of the passphrase of any particular submission. If EPA’s system cannot operate independently of the availability of a passphrase, in our view, EPA should not use CDX in lieu of a hard copy letter to the submitter.

Use of OECD Templates to Submit Health and Safety Information

Another change that is a bit outside of the CBI issues is that EPA is proposing to require that companies that submit health and safety information do so in an appropriate OECD template. EPA would be wise to clarify the authority for this broad requirement, as it relates to matters beyond the scope of TSCA Section 14. Presumably, EPA’s expectation is that a submitter would prepare a robust study summary (RSS) in, for example, IUCLID and submit the RSS along with the study in CDX. For submitters that have prepared RSSs in IUCLID for other jurisdictions, this is a relatively minor burden, but for those that do not routinely use IUCLID (e.g., U.S. companies that do not have a legal entity presence in the European Union (EU) or the United Kingdom (UK) and rely upon Only Representatives to meet registration obligations), this could be a substantial burden. An experienced IUCLID user might prepare an RSS in one to five hours per study, depending on the complexity of the study. This represents a significant increase in the burden of the preparation of a submission, especially for IUCLID novices. We are concerned that EPA is making unwarranted assumptions about TSCA submitters’ familiarity with IUCLID. The burden might be justified, but not if EPA will routinely replace its judgment for the study author’s conclusion.

If EPA is going to substitute its judgment for the study author’s in even a moderate percentage of cases, EPA should not require submitters to extract the study information into a template because doing so will represent a significant burden on the submitters’ part and will add no efficiency to EPA’s review or conclusions. Relatedly, we note that EPA, in its economic analysis supporting the proposed rule, estimates that it takes persons just 0.05 hours (i.e., three minutes) to log into CDX and submit previously completed OECD templates, and that this will happen in 95 percent of the cases where an OECD template is required. We believe that three minutes is an underestimate of the time needed to submit previously completed templates and that EPA overestimates the proportion of studies that will have previously completed templates. For completion of the templates, which EPA estimates will be needed for only 5 percent of the submissions, EPA estimates that it will take 0.7 hours (i.e., 42 minutes). We believe that this too is an underestimate of the time needed.

Finally, EPA estimates that it will receive 350 submissions per year requiring a
template. Considering that this proposed requirement would cover certain TSCA Section 8(a) submissions, as well as TSCA Sections 8(d) and 8(e) information to support manufacturer-requested risk evaluations, and apparently, voluntarily submitted information, we think this is an underestimate.

**Appeal of CBI Denials**

Another proposal that we view as worthy of support is EPA’s proposal that a submitter can appeal the Office of Pollution Prevention and Toxics’ (OPPT) CBI denial to EPA’s Office of General Counsel (OGC) prior to having to seek judicial review. EPA proposes that OGC will review the submission *de novo* and will review the submission as it existed at the time of OPPT’s final determination -- that is, subsequent amendments would not be considered during the appeal.

**Other Issues**

There are other issues on which readers may wish to comment. One of the bedeviling questions in the TSCA CBI substantiation questions is the question related to trade secrets. There is often significant misunderstanding related to the term. EPA proposes that the question provides little additional value to its CBI review because essentially all trade secret information is eligible for TSCA CBI protection, either with substantiation or as one of the categories of CBI that are exempt from substantiation. EPA is also proposing requiring justification for masking more than one element of generic chemical names. It is not clear how EPA might automate review of whether generic names meet the current guidance.

We comment here and in our companion memorandum covering this proposed rule on just some of the many proposals and encourage readers to review carefully and thoroughly EPA’s proposal. Most of EPA’s proposals merit support, but some of the issues highlighted here are complex, and EPA needs to hear from submitters that will have to comply with the final regulations. We strongly encourage companies to comment, either individually or through associations. CBI protections are a cornerstone of TSCA, and stakeholders must comment to ensure that EPA has the correct balance between transparency and CBI protection.

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