AmericanCoatings
ASSOCIATION℠

July 11, 2022

Jessica Barkas
Project Management and Operations Division
Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention.
1200 Pennsylvania Ave. NW,
Washington, DC 20460–0001

Re: EPA Docket No. EPA-HQ-OPPT-2021-0419
Confidential Business Information Claims Under TSCA, Proposed Rule

Dear Mrs. Barkas:

The American Coatings Association ("ACA")[1] appreciates the opportunity to comment on the proposed rule implementing TSCA Section 14 affecting claims of confidential business information. ACA has provided comment and interacted with the agency at all stages of implementation of the *Lautenberg Amendments* to TSCA. We are committed to working with EPA to help ensure accurate understanding of chemical risk and appurtenant issues, such as confidentiality of information.

The Association's membership represents 90% of the paint and coatings industry, including downstream processors and users of chemicals, as well as chemical manufacturers. ACA appreciates EPA's willingness to interact with stakeholders during this process. We are optimistic that through continued involvement with the public and stakeholder community, EPA will successfully implement a strong, risk-based approach to managing risk posed by PFAS chemicals.

ACA and its members respectfully submit the following comments:

I. Introduction

ACA supports and commends EPA's initiative in developing a proposed regulations affecting assertion, EPA review and treatment of confidentiality claims. ACA further supports EPA's initiative in drafting

[1] ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services. ACA's membership represents over 90 percent of the total domestic production of paints and coatings in the country.

regulations to more clearly specify procedures related to assertion and review of confidential business information (CBI) based on requirements implemented in 2016 with revisions to Section 14 of TSCA under the *Lautenberg Amendments*. ACA's concerns relate to providing claimants with an adequate opportunity go engage with the Agency to provide supplemental information and corrections. Additional procedures suggested below would enhance EPA's ability to review and evaluate CBI claims on the merits rather than denying claims due to insufficiency of information or incomplete documentation. Further, the procedural changes suggested below would not impede public disclosure of information that warrants disclosure for a public health or environmental benefit. Rather, these changes would promote consistency in how and when such information should be disclosed.

To this end, ACA would like to bring the following issues to EPA's attentions:

- CBI claimants may not be prepared to claim CBI during site inspections, effectively waiving CBI protections that would apply to any information collected during inspection, under the rules as proposed.
- CBI claimants may require additional time to substantiate claims beyond the time of submission, as currently proposed.
- The 10-day period proposed to correct supporting documentation, certification and substantiation, correct a generic name or file substantiation after an inspection is an unreasonably short period of time.
- Procedures related to evaluation of CBI under TSCA for information obtained under other statutes but used for TSCA purposes do not adequately provide the claimant with notice and an opportunity to address CBI factors under TSCA.
- Procedures to request review after a denial of a claim do not allow the claimant to provide additional explanation or information addressing EPA's denial.

ACA provides the following comments.

II. CBI claims allowed for a period after inspection would allow for a more efficient, collaborative and efficient site inspection process.

Under Section 703.5(b)(1) as proposed, EPA proposes that submitters must assert a claim of confidentiality at the time of inspection for any documentation obtained during an EPA site inspection pursuant to Section 11. Section 11 provides EPA with broad authority to inspect a facility for TSCA compliance where chemicals are "manufactured, processed, stored, or held before or after their distribution in commerce,"[2] including any related vehicles or conveyance. EPA has broad authority inspect:

> all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act [*15 U.S.C. §§ 2601* et seq.] applicable to the chemical substances, mixtures, or products subject to title IV [*15 U.S.C. §§ 2681* et seq.] within such premises or conveyance have been complied with.[3]

[2] TSCA §11(a), 15 U.S.C. 2610(a)
[3] TSCA §11(b), 15 U.S.C. 2610(b)

EPA seems to have predicated the proposed rule on TSCA §14(c)(1)(A) providing that generally a claimant seeking protection from disclosure must make the claim at the time of submission:

> A person seeking to protect from disclosure any information that person submits under this Act (including information described in paragraph (2)) shall assert to the Administrator a claim for protection from disclosure concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.[4]

As a practical necessity, ACA recommends that EPA provide an official "submission" period of 45 days after site inspection pursuant to Section 11 to finalize document submission, confidentiality claims and supporting documentation. Without a post-inspection submission period, under the proposed rule, facilities would be required to assert confidentiality during inspection or effectively waive all protection. A facility would have an incentive to withhold documentation from EPA, to allow for internal legal review and assertion of confidentiality claims by submitting responsive documents later. This delays and hinders an effective inspection process, potentially further requiring EPA to subpoena responsive documents from a facility. Companies that choose to cooperate with EPA's request for documents during an inspection would be placed a distinct disadvantage by waiving protections, if unable to assert confidentiality. This waiver can be affected by unassuming employees, whose intentions are merely to cooperate with EPA's request.

Further, Section 11 does not stipulate a time period for advance notice prior to inspection, resulting in varying amounts of time to plan for document submission and evaluation of confidentiality. Even with ample prior notice, the nature of site inspection does not allow for complete review and evaluation of all documents that may be relevant to an inspection. Issues arise during an inspection that may require production of documents not previously anticipated. To facilitate cooperation and production of documents, ACA suggests a 45 day official "submission" period after site inspection.

III. Allowing a substantiation period after the time of submission would enhance the quality of information submitted for evaluation of the claim.

ACA recommends extending the timing of substantiation to 45 days after submission of documentation. EPA currently proposes that a submitter must substantiate confidentiality claims at the time of submissions, as described at Section 703.5(b)(1) as proposed. Substantiation of claims requires careful coordination between departments of submitting entities, including legal, regulatory and technical staff, often requiring additional time than what's allowed prior to submission to provide a submission clearly and accurately addressing confidentiality criteria. Substantiation goes to the essence of a submitter's claim, with EPA's evaluation of substantiation directly affecting protections of information. Due to the importance of substantiation, a 45-day post-submission substantiation period is appropriate. Moreover, substantiation at the time of filing does not provide an environmental or public health benefit.

[4] TSCA §14(c)(1)(A)

IV. Ten day period to correct a confidentiality claim or provide supporting documentation is an unreasonably short period.

In several instances, EPA proposes a 10-day time-period for filings designed to correct a prior deficient submission or to provide supporting documentation. ACA suggests that anything less than 45 days would unnecessarily penalize submitters by not allowing for adequate time to identify responsive information or provide missing documentation. EPA proposes a 10-day filing period in the following situations:

- After asserting confidentiality, a company would have ten days after notification by CDX to remedy a failure to provide a supporting statement and certification, substantiation, public copies of documents or a sufficient generic name. (40 CFR 703.5(e), as proposed)
- After a site inspection under Section 11, a company would have 10 days to substantiate confidentiality claims asserted at the time of inspection (40 CFR 703.5(b)(1), as proposed).
- After a site inspection under Section 11, a company must provide redacted, public version of any documents where it has asserted a claim for confidentiality. (40 CFR 703.5(c), as proposed).
- Company would have 10 business days to correct generic name that EPA deems non-compliant with requirements at 15 USC 2613(c)(1)(C). If EPA deems the revised generic name as insufficient, it will hold the submission for an additional 10 days before proceeding with final evaluation. (40 CFR 703.5(d)(4)).

In complex entities, submissions often require coordination between departments including legal, regulatory and technical staff, requiring at least 45 days to coordinate submissions after a site inspection, provide missing documentation and/or revise a generic name. Under the proposal, failure to correct deficiencies within the allotted time can result in denial of a confidentiality claim or publication with a generic name designated by EPA. Generic names designated by EPA may not adequately mask a chemical's composition. Disclosure of names or denial of a claim devalues a company's investment in bringing chemicals to market, usually a multi-million dollar investment. Failure to provide procedures that adequately support innovation function as a disincentive for the development of safer and more sustainable chemicals.

Further, limiting time to correct or supplement submissions to 10 days would not provide a public benefit related to environmental protection or human health. Although the public has an interest in disclosure to enhance understanding of chemical risk, EPA should resist compelling disclosure through a procedural mechanism of an inadequate response time, especially considering that the statute has already provided procedures for disclosure of health and safety information. The statute also provides for disclosure where companies cannot substantiate a claim. The public also benefits from CBI procedures that encourage innovative "green" chemistries by providing companies with adequate opportunity to engage with EPA to evaluate CBI claims purely on their merits.

Allowing additional time to correct or supplement a confidentiality claim is aligned with current TSCA requirements. EPA typically allows flexibility in submissions and corrections of technical and responsive information for PMN submissions under Section 5, test rule reporting under Section 4 and responses to reporting rules under Section 8. None of these submission requirements function with a 10-day cut off

period that could result in denial of a request or a non-compliance order. In the CBI context, this 10 day cut-off is severe, punitive and potentially a violation of due process.

V. A process for a claimant to supplement a confidentiality claim related to information submitted under other statutes but used for TSCA purposes is appropriate.

ACA recommends amending proposed Section 703.1(b) to provide a process for companies to assert and substantiate confidentiality of information obtained by EPA by means other than TSCA but used for TSCA purposes. As proposed, Section 703.1(b) allows EPA to apply TSCA confidentiality and substantiation requirements proposed in this rule to any information obtained by EPA through non-TSCA means, but used for TSCA purposes, regardless of whether the submitter intended the information be used for TSCA purposes and regardless of whether the information was submitted by a third party.

EPA's proposal does not include a process for the information's owner to claim and substantiate potentially confidential information obtained in this manner. Since EPA generally requires the submitter to claim confidentiality at the time of submission (See Section 703.5, as proposed), EPA presumably would evaluate confidentiality based on any assertion of confidentiality and substantiating information made when the information was originally obtained by EPA for non-TSCA purposes. Company protections of proprietary information can be severely compromised by this section.

Owners of submitted information or a submitting third party had no reason to anticipate extent of disclosure allowed, and in some instances required, by the 2016 *Lautenberg Amendments*. Companies having submitted information under other statutes in the past would not have known to assert and substantiate confidentiality with TSCA requirements, resulting in full disclosure, if EPA evaluated confidentiality under its proposed rules.

EPA attempts to mitigate retro-active application of its newly proposed rule with a conflict of laws provision, requiring that to the extent a conflict exists between the law governing original submission of the information and TSCA, the law governing original submission applies, as proposed in Section 703.1(c)(2). ACA agrees that this provision is helpful, however it does not provide a clear threshold for what would qualify as a conflict, triggering this provision. In most cases, confidentiality requirements of older statutes and TSCA may be complimentary without presenting a clear conflict, but not quite harmonized to TSCA's advanced confidentiality and substantiation requirements.

When using information obtained by non-TSCA means for TSCA purposes, ACA recommends EPA notify the data submitter and allow the submitter 45 days to assert confidentiality and provide substantiating information. At a minimum, ACA recommends:

- EPA must notify the submitter of its intent to use the data for a TSCA purpose.
- EPA must inform the submitter of the CBI rules that will govern EPA's handling of the information.
- EPA must provide an explanation of how the information will be used under TSCA.
- EPA must allow the submitter to supplement additional information as necessary.

VI. Claimants should have the opportunity to address EPA's denial of a claim with additional information or explanations.

Under proposed Sections 703.7(d), EPA would provide notice to the submitter when a denying a claim. EPA will publish the information claimed as CBI after 30 days from issuing a notice of denial via CDX, if the submitter does not appeal for reconsideration to the Office of General Counsel as described in proposed Section 703.7(g). Upon receiving a request for review, OGC would review the claim de novo based on information included in the original submission. At this stage, a submitter cannot provide additional information.

ACA can envision situations where a business has met the substantive criteria for confidentiality determinations under Section 14 but has failed to provide data in a manner that clearly articulates a reasonable basis for the claim, as EPA interprets or understands it. A submitter would not receive notice of EPA's reasoning until receiving a notice of denial as described in Section 703.7(d). At this stage, it is too late for the submitter to address issues EPA identifies as a basis for denial.

ACA suggests amending Section 703.7 to add a 45-day period after receiving a notice of denial, for a claimant to provide EPA with any additional information or explanation to address EPA's reasons for denial. If upon further review EPA denies the claim, the submitter could then file for de novo review with the OGC, as specified in Section 703.7(g). An opportunity to substantively address EPA's determination would advance consistency and transparency in EPA's decision-making process. Currently, submitters have no guidance about threshold levels of proof required to address substantive criteria of Section 703.7(f). Meeting the threshold depends on vague, subjective phrases such as, "reasonable measures," "reasonable basis," "*likely* to cause *substantial* harm," etc. (italics added). A post-denial period allowing for additional information or explanation would promote a common understanding of this section and the substantiation questions in Section CFR 703.5(b)(3)).

VII. Conclusion

ACA appreciates the opportunity to submit comment on EPA's proposed rule affecting confidentiality claims and their evaluation. ACA requests EPA to modify the proposal as follows:

- ACA recommends that EPA provide an official "submission" period of 45 days after site inspection pursuant to Section 11 to finalize document submission, confidentiality claims and supporting documentation.
- ACA recommends extending the timing of substantiation to 45 days after submission of documentation.
- ACA recommends requiring at least 45 days to coordinate submissions after a site inspection, provide missing documentation and/or revise a generic name.
- When using information obtained by non-TSCA means for TSCA purposes, ACA recommends EPA notify the data submitter and allow the submitter 45 days to assert confidentiality and provide substantiating information.
- ACA suggests amending Section 703.7 to add a 45-day period after receiving a notice of denial, for a claimant to provide EPA with any additional information or explanation to address EPA's reasons for denial. If upon further review EPA denies the claim, the submitter could then file for de novo review with the OGC, as specified in Section 703.7(g).

Please feel free to contact me if I can provide any additional information.

Respectfully submitted,

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