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Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Attention: EPA-HQ-OPPT-2021-0419

Re: Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA)

1.0 INTRODUCTION

The American Fuel & Petrochemical Manufacturers (“AFPM”) respectfully submits these comments on the Environmental Protection Agency’s (“EPA” or “the Agency”) *Federal Register* notice titled “Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA)” (“the proposed rule”).¹ Specifically, EPA is soliciting information and requesting comments on its proposal to modify regulations in accordance with the Lautenberg Chemical Safety Act (LCSA), concerning submission and protection of Confidential Business Information (CBI) under TSCA.² AFPM has significant concerns with the considerable changes this proposed rule seeks and how those changes could affect American manufacturing competitiveness.

1.1 AFPM’s Interest in the Proceeding

AFPM is the leading trade association representing the makers of the fuels that keep us moving, the petrochemicals that are the essential building blocks for modern life, and the midstream companies that get our feedstocks and products where they need to go. AFPM members are dedicated to sustainably and efficiently manufacture the petrochemicals and derivatives that growing global populations and economies need to thrive.

AFPM members are committed to collaborating with policymakers and other stakeholders to develop sound, risk- and science-based policies to address chemicals management issues, including the protection from disclosure of CBI. Since the enactment of TSCA, AFPM members have been able to claim certain sensitive business information as confidential to protect American business interests here and abroad. CBI protection has always been an integral part of TSCA because Congress acknowledged the importance of protecting sensitive business information from disclosure to competitors. Chemistry processes, reactants, and even chemical identities of novel molecules can give an American chemical manufacturer a distinct advantage

¹ See 87 *Fed. Reg.* 29078, “Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA)”, EPA-HQ-OPPT-2021-0419, published May 12, 2022, at <https://www.federalregister.gov/documents/2022/05/12/2022-09629/confidential-business-information-claims-under-the-toxic-substances-control-act-tsca>.

² See the Frank R. Lautenberg Chemical Safety for the 21st Century Act at <https://www.congress.gov/114/plaws/publ182/PLAW-114publ182.pdf>.

in the marketplace. Disclosure of sensitive information can quickly diminish or remove that advantage, allowing overseas competitors without robust regulatory regimes to undercut American companies.

TSCA Section 14, introduced in the original TSCA statute, explicitly directs EPA to allow chemical manufacturers to claim sensitive business information as confidential and to protect that information from disclosure. From the inception of TSCA, Congress clearly intended to strike a balance between the public's right to know about the hazards and risks of chemicals and manufacturers' ability to keep sensitive business information confidential.

1.2 General Comments

The LCSA does not require or even suggest that EPA has authority to diminish Section 14 CBI protections. Protection of CBI is, and has always been, a cornerstone of TSCA to keep sensitive business information such as proprietary formulations, supplier/customer relationships, novel processes, and other innovations from being disclosed to competitors. Failure to protect this information could directly affect the competitive advantage enjoyed by many American manufacturing businesses.

EPA's interpretation of subtleties found in the LCSA, the original statute and even Merriam-Webster often ignores the context from which that language was taken. For example, in the preamble, EPA says it interprets the phrase "otherwise obtained by" to mean that Congress gives the Agency broad authority over information received outside of TSCA regulations. That phrase appears in the original TSCA statute from 1976. AFPM finds it disconcerting that after 40 years EPA would interpret this simple phrase in such a way. If Congress had intended to give EPA broader authority under Sec. 14, it would have made it explicit in the LCSA – which it did not. EPA also attempts to use TSCA Sec. 4(h)(3)(A) to justify its treatment of information submitted under voluntary agreements. This ignores the fact that the provisions of Sec. 4(h) only pertain to reducing the impact of testing on vertebrate animals. Those provisions have nothing to do with treatment of CBI. EPA is trying to use this faulty reasoning to broaden its authority so it can release information that should otherwise be protected.

EPA needs to maintain the balance between the public's right to know about chemicals in commerce and protecting against disclosure of sensitive business information. Over time, EPA has significantly increased the burden for substantiation of CBI claims to ensure claims are legitimate and to allow greater disclosure of information that would not jeopardize a company's competitiveness. In this proposal, however, it appears EPA is attempting to narrow what can be claimed as CBI and trying to shortcut the disclosure process altogether by reducing the amount of time for which a company can respond to a potential disclosure and narrowing the mode of communication to an unreliable web-based system. These proposed changes clearly tip the balance more toward disclosure than protection.

2.0 AFPM'S COMMENTS ON SPECIFIC PROPOSED CHANGES

2.1 EPA should notify original CBI claimants of all disclosures and allow sufficient time to respond to inquiries or threats of disclosure.

Although EPA acknowledges that CBI can now be shared with other agencies, states and tribes under certain conditions, there is nothing in the proposal that discusses notification of the CBI disclosure to the claimant. Sec. 14(g)(A) is clear that if the Agency discloses information under Sec. 14 (d), it is required to notify claimants via certified mail or through another method that ensures that the notification is received and the date of receipt. Due to consistent technical problems and reliability issues, the Central Data Exchange (CDX) does not meet the requirement for ensuring receipt. AFPM urges EPA to include provisions for notification of the CBI claimant prior to release of CBI in non-emergency situations and notification in a reasonable time frame after disclosure during an emergency. This will allow companies to monitor for further disclosures after EPA releases the information to a particular party.

In cases where a TSCA inspection took place or when EPA notifies a submitter that a substantiation is incomplete or a clarification or some other response is needed, the proposal only provides for a response time of 10 days. There are a variety of situations, such as vacations, extended sick leave, maternity/paternity leave, etc., that could make that time frame unrealistic. AFPM strongly urges EPA to adopt a 45-day response period, which should sufficiently account for the availability of key personnel.

2.2 EPA should notify original CBI claimants of potential disclosures when information is obtained through another statute or program.

In all cases involving disclosure of information that was previously submitted to the Agency under a different statute or program, EPA should notify the original submitter of the information as to why and how the Agency is using the information and allow the original submitter to provide additional information. In cases where there are conflicting provisions on the protection of confidential information, EPA should use the provisions for the statute under which the information was originally submitted. In cases where information was submitted under a program that does not explicitly provide for protection of confidential information, EPA should protect the confidentiality of the information like it would any other CBI submitted for TSCA purposes.

2.3 CBI from an original claimant should be protected from disclosure even if a chemical name or other confidential information has been submitted later without a CBI claim.

A legitimate CBI claim under TSCA should be treated as an agreement between the original submitter (claimant) and the Agency. Other actors, such as those reporting under the Chemical Data Reporting (CDR) rules or submitting bona fide requests to check the confidential inventory should not affect that agreement. For instance, EPA points to an example where a customer discloses the generic name and accession number for a chemical supplied by another company but does not substantiate a claim for the specific confidential chemical substance. The customer

is not going to know the specific identity, nor will it be able to assert or substantiate a claim for confidentiality of that specific chemical identity. Under this proposed rule, EPA could take away the confidentiality claim of the supplier and disclose the specific chemical identity.

In cases where CBI is either inadvertently disclosed by another party or included in a future submission under Section 5 (Bona Fide Intent Notices and Premanufacture Notices) or Section 8 (chemical reporting) but not claimed as confidential, EPA must still honor the CBI claim with the original claimant.

2.4 Information provided in patents should not affect any CBI claim.

In the Preamble and at 40 CFR 703.5(b)(3), EPA proposes to disclose CBI in certain cases where patent information may make similar information available. EPA has no jurisdiction over patents, including how they are written and protected, and should not attempt to use any patent as a justification to disclose CBI. Patents fall under different laws that have nothing to do with TSCA, nor are patents written for TSCA purposes. The protections afforded under both laws are also different.

Eliciting information from a patent is challenging and time-consuming. Specific chemical identities are often buried in layers of redundant information on general chemical families and functional groups, if it is available at all. EPA's proposal will likely serve as a disincentive to file for chemistry patent protection, which is clearly not what Congress intended under Section 14 of TSCA.

2.5 EPA should require a robust summary template only when a full health and safety study is not available.

In 40 CFR 703.5(g), EPA is proposing to require the submission of a robust summary template using the Organization for Economic Cooperation and Development (OECD) Harmonized Templates in addition to copies of full studies. This proposal is duplicative, in that EPA already receives the full study report. Preparation of robust summaries is expensive, requiring a toxicologist to cull and organize pertinent information from the full study report. Furthermore, AFPM does not see the connection between the proposed requirement for a summary template and Section 14, which applies to protection of CBI.

2.6 EPA should use normal communications methods in addition to the Central Data Exchange (CDX) to notify claimants of potential disclosures, clarifications, deficiencies, denials of protection and disclosures.

EPA proposes in 40 CFR 703.5(h) to use the CDX system as a primary means of communication. It has been the experience of AFPM members that the CDX is not very reliable and inconsistent in its performance. EPA should not rely solely on CDX and should contact submitters via certified mail at the physical address the Agency has on file and the submitter's email address (also on file).

2.7 The provisions of the final rule should take effect upon publication in the Federal Register and should not be retroactive.

EPA asks throughout the notice whether certain provisions should be retroactive. AFPM strongly urges the Agency to disregard retroactivity and make any changes applicable after publication in the *Federal Register*. Reviewing all previous CBI submissions, most of which were on paper, would be a significant burden on both companies and the Agency, and yield little to no benefit in protection of health and the environment.

3.0 CONCLUSION

AFPM appreciates the opportunity to comment on this proposal and is committed to working constructively with EPA and other stakeholders to realize the goals and objectives of a modernized TSCA.

Sincerely,

A handwritten signature in black ink, appearing to read "James Cooper". The signature is fluid and cursive, with a large initial "J" and "C".

James Cooper
Senior Petrochemical Advisor
American Fuel & Petrochemical Manufacturers