

CSPA Position Statement on

Continued Protection of Trade Secret and Confidential Business Information under TSCA

Introduction / Summary

The recommendations presented in this white paper reflect what CSPA member companies of the formulated consumer and commercial products industry believe to be a reasonable framework for continued protection of trade secret¹ and confidential business information under the Toxic Substances Control Act (TSCA) balanced with the U.S. Environmental Protection Agency (EPA) and the public interest for increased disclosure of information related to TSCA-regulated chemicals used in our products.

Intellectual property is a company's most valuable intangible asset, and represents a substantial R&D resource and financial investment that results in the introduction of sustainable and innovative products into the US market. Trade secrets and other confidential business information (CBI) must be carefully safeguarded from competitors to ensure a financial return on the significant R&D investment and preserve brand integrity and distinction. Any valid trade secret protected under state laws (a majority of which are based on the Uniform Trade Secrets Act) and the Federal Freedom of Information Act and/or Federal Economic Espionage Act of 1996 shall *always* be considered confidential under the envisioned approach.

CSPA's supports updates to TSCA to: (1) require upfront substantiation of confidentiality claims and; (2) provide statutory authority for EPA to share CBI with state governments (upon assurances of appropriate safeguards comparable with EPA's CBI safeguards). These two provisions are reasonable improvements to current practices that will ensure continued protection of legitimate CBI under TSCA while providing the Agency with expanded authority to disclose chemical information to federal and state government authorities state are working toward the common goal of robust chemical management.

Definitions and Background

Section 14(a) of TSCA provides authority to EPA pursuant to the Freedom of Information Act (FOIA)² to protect the confidentiality of data obtained under TSCA. Under currently applicable law, FOIA specifically prohibits disclosure if the subject information consists of "trade secrets and commercial or financial information obtained from a person and is privileged or confidential."³

Section 14(a) of TSCA expressly prohibits EPA from disclosing trade secrets and commercial or financial information that is privileged or confidential.⁴ However, there are limited exceptions to the protections provided by Section 14(a); specifically, EPA is allowed to disclose confidential information if the Agency determines that disclosure is necessary to protect against "unreasonable

risk of injury to health or the environment.”⁵ In addition, Section 14(b) of TSCA creates a limited exception that allows EPA to disclose trade secret-type information if the information consists of “health and safety studies.”⁶ Notwithstanding these limited exemptions, Congress clearly recognized the importance of protecting trade secrets and CBI by including significant criminal penalties for wrongful disclosure in Section 15 of TSCA.⁷

Proprietary chemical identities for which downstream formulated companies seek protection under TSCA represent significant economic value to individual companies and would inflict serious business harm should this information become prematurely disclosed. Such information can serve as a prime example of trade secret information.

There are increasing demands from the general public, legislators at both the state and federal level, and EPA to significantly limit confidentiality claims and to disclose chemical information previously designated as CBI in historical case files. EPA Administrator Lisa Jackson has embraced this new “transparency” vision as an integral part of ensuring chemical safety in commerce, which she has identified as a priority focus for the Agency in her public addresses. The Agency has taken several chemical management actions in advance of Congressional action. Restricting CBI claims, under the Agency goal of increasing public accessibility to health and safety information for chemicals in US commerce, has been a notable and key component of the Agency’s efforts.

Through this set of recommendations, CSPA member companies have sought to carefully balance the need for continued CBI protection that will drive American innovation, domestic jobs and competition in a global marketplace with the public demand for increased disclosure.

Aligned Positions

The recommendations outlined here are solely presented as positions supported by CSPA. The following shared principles, developed in collaboration with affiliated trade associations, have guided CSPA member company discussions on CBI:

- The U.S. chemical management system must protect public health and the environment while also protecting confidential business information, thereby preserving the ability of American companies to drive innovation, create jobs and compete in the global marketplace.
- The EPA regulatory framework for TSCA must include a means by which EPA can obtain reasonable and appropriate use and exposure information from “downstream” formulated companies like those CSPA represents to better inform EPA’s prioritization decision-making and subsequent safety assessment work.
- EPA must have adequate resources to successfully manage and meet deadlines and responsibilities under TSCA.

1. “Three Bucket” Approach to CBI

CSPA can support the following conceptual “three bucket” approach to CBI, which is based upon REACH Articles 118-119. Currently the EPA requires upfront substantiation of certain confidential information under TSCA (i.e., reporting under TSCA sections 4, 5 and 8); and this section will not supersede those requirements.

<p><i>Always allowed as confidential</i></p> <p>Represents Intellectual Property of Owner</p> <p>No Up-front Substantiation</p> <p>No Requirement for Re-substantiation</p>	<ul style="list-style-type: none"> • Detailed information about manufacturing and/or marketing processes • Sales, production, or other commercial/financial information • Detailed information about processing • Customer lists: links between manufacturer and distributors and downstream users • Precise use, function and application of a chemical or mixture, including information about its precise use as an intermediate • Precise production (including batch production) or import volumes • Compositional details (% of ingredients in mixtures or formulations) • Any valid trade secret protected under state laws (a majority of which are based on the Uniform Trade Secrets Act) and the Federal Economic Espionage Act of 1996 and/or Freedom of Information Act.
<p><i>Never CBI</i></p> <p>No Up-front Substantiation</p>	<ul style="list-style-type: none"> • Health and safety data for commercial chemicals (NB: CSPA excludes confidential chemical identities from the designation of “Never CBI” for health and safety data) • Physical/chemical information already publicly disclosed (e.g., listed on Material Safety Data Sheet) • General category information/descriptions of a chemical’s use and function (e.g., “surfactant”) • Production volume ranges, when EPA aggregates using a validated and publicly available statistical method of aggregation • Classification, labeling, guidance on safe use of the chemical
<p>Eligible for protection when appropriately substantiated for CBI protection</p>	<ul style="list-style-type: none"> • Precise chemical identity (e.g., CAS name) for proprietary chemical substances. • Degree of purity • Production/import volume ranges linked to an individual company

2. Going forward, claimants should provide an upfront justification for information eligible for CBI protection (third bucket), including a description of the competitive harm likely to result from disclosure.

Under current EPA regulations that have been in effect since the mid-1970s, substantiation of CBI requires a showing that: (1) the company has taken and intends to continue to take reasonable measures to protect the confidentiality of the information; (2) no statute specifically requires disclosure of the information; (3) the information is not reasonably obtainable through reverse engineering; and (4) disclosure of the information is likely to cause substantial harm to the company's competitive position. See 40 C.F.R. § 2-208. CBI information that has been substantiated would be protected from public disclosure pursuant to a FOIA request, except in very limited circumstances.

3. EPA may require re-substantiation of certain claims. The same criteria that apply to upfront substantiation should apply to re-substantiation of CBI claims.

Opportunities for subsequent renewals would not be limited provided that continued CBI protection is justified in a re-substantiation. Re-substantiation does not mean that companies will be held to a higher burden of proof as compared to the data required to substantiate the original CBI claim; however, the re-substantiation will require an explanation of why the original CBI substantiation is still relevant. CBI owners could also choose to provide additional data as needed to support the re-substantiated CBI claim.

4. CBI claims that have been approved by EPA should continue to be CBI until either: (1) the claimant withdraws CBI claim, or (2) EPA rejects the CBI claim.

CBI claims that have been approved by EPA should not be subject to arbitrary time limits; however, re-substantiation of certain claims (i.e., "may be considered for CBI") may be required. So long as the data qualifies as a trade secret or CBI, it should be protected from disclosure, subject to appropriate substantiation and re-substantiation.

5. Allowing EPA to share CBI data with other government authorities

CSPA can support EPA sharing data with other U.S. federal and state agencies for the purposes of protecting public health and the environment. The Agency would be required to verify that the other government(s) has adequate and equivalent systems in place to protect CBI from disclosure.

TSCA does not currently allow EPA to disclose CBI data to other federal, state or foreign governmental entities. Under a modernized TSCA, sharing of CBI with other U.S. (federal and state) government authorities should be allowed for the purposes of protecting public health and the environment as long as the EPA has a binding data sharing agreement to ensure that adequate safeguards are in place to protect the confidential information.

This type of data sharing among regulatory authorities is supported to maximize the use of existing data and centralize chemical management at the federal level. As part of this, we believe it is also necessary to look closely at the preemption provisions under TSCA. Many state authorities have acknowledged that they do not have the capacity or resources to manage duplicate regulatory systems and would strongly prefer an effective and reliable Federal role for chemical regulation and management. We believe an appropriately modernized federal TSCA statute would serve to reduce the need for regulation of chemicals on a state-by-state basis. Any requests for confidential information by municipal governments should be worked through their respective states – eliminating the need for EPA to share CBI directly with local governments.

Recognizing that it is essential for the CBI owner to track and maintain control of confidential information, the EPA should be required to notify the owner of the CBI when their data is shared with another government with whom the EPA has a data sharing agreement in place. Under this approach, EPA would be required to notify the data owner of its decision to share CBI data with another government authority, and identify: (1) the purpose for which the data are intended to be used; and (2) provide information regarding the CBI protection provisions the receiving government authority has in place to protect CBI from being disclosed.

Discussion Issues

1. Allowing EPA to share CBI with foreign governments.

The sharing of CBI with foreign government authorities is more challenging because it raises the issue of how EPA can ensure that equivalent protection is not only in place but enforced to prevent disclosures of proprietary information of U.S. companies. While CSPA member companies would consider supporting an approach for data sharing, along the lines of the Four Corners Agreement between the U.S. and Canada for working with “favored” foreign governments, in an effort to achieve joint chemical management objectives, we believe that this is a very difficult process to implement. Currently, there is no reliable legal means at the international level to enforce a right to compensation for damages that arise from the loss of intellectual property if a trade secret is disclosed in a way that destroys its secrecy.

2. Chemical Identity

Protecting confidential information is critical to maintaining an economic environment that (1) supports U.S. competitiveness and (2) encourages continued sustainable innovation. New chemicals and new uses and mixtures of existing chemicals often require millions of dollars to research and develop. Public disclosure of proprietary chemical identities could serve to disadvantage U.S. companies by allowing competitors—both in the U.S. and abroad—access to trade secret information.

Any disclosure of chemical identity must balance the need for manufacturers to retain exclusive use of the new substance once in commerce. Perhaps the most compelling reason for the ability to

claim chemical identity as CBI under TSCA is the need to protect proprietary chemical technologies while navigating the New Chemicals Program for addition to the TSCA Inventory. However, we also strongly assert the need to allow a company to substantiate a claim of confidentiality for proprietary chemical identities for existing chemicals under TSCA.

CSPA, along with other trade associations, believe that there is a compelling need to develop a comprehensive reference to define and use chemically descriptive names for disclosure of information on proprietary chemical substances under TSCA. CSPA's experiences in developing the *CSPA Consumer Products Ingredients Dictionary* has provided us assurance that generic nomenclature can serve as a means by which the industry could share meaningful information with the public about the chemical substance while also maintaining confidential chemical identity that is critical to competitiveness and innovation. The *CSPA Consumer Products Ingredients Dictionary* ingredient monographs provide ingredient nomenclature and definitions that are fully consistent with our industry's transparency goals, as well as those of the EPA Design for the Environment, which now requires that its partner products provide chemically descriptive names for proprietary ingredients.

CSPA recognizes that some agreement has been reached among companies and NGOs around the concept of allowing self-specified CBI time limits for the protection of chemical identity in PMN applications. CSPA could also consider an approach that would allow for a self-specified time period for the protection of chemical identity as long as the CBI time period would be the reasonable length of time needed to protect proprietary information, and retain exclusive use and competitive advantage, subject to appropriate substantiation and EPA approval.

3. Length of CBI protection

As a threshold matter, CSPA supports an aligned position that a valid CBI claim does not expire if the claimant appropriately substantiates the claim at the time of submission to EPA. CSPA also supports an aligned position that the EPA could seek re-substantiation of certain claims, and that the same criteria that apply to upfront substantiation should apply to re-substantiation of CBI claims.

Legislative recommendations that set an automatic expiration for CBI based on a time period to ensure return on investment would be extremely difficult to calculate. Moreover, there is no known provision in law for terminating a data owner's trade secret rights in such an arbitrary manner. CSPA supports an aligned position that EPA should determine legitimate CBI claims based on initial substantiation requests and that, if CBI timelines are imposed, EPA must provide an opportunity for CBI owners to re-substantiate the claim(s).

As part of a supported position, we have outlined some options for time limits on CBI claims, each contingent upon the understanding that the opportunity for re-substantiation will be provided:

- **Allow protections to continue until a trigger occurs** (i.e., as new information becomes available or EPA prioritizes the substance for further assessment, etc.). Re-substantiation would be allowed for certain CBI claims (i.e., “3rd Bucket” -- CBI with substantiation). EPA would be required to contact the CBI owner to request a re-substantiation of the CBI claim.
- **Self-Imposed CBI Time Limit.** Rather than an arbitrary or “triggered” timeline for CBI expiration in the statute (e.g., five years), accept the premise that CBI claims should not exist in perpetuity and should be subject to a periodic review requirement. Under this option, the claimant would include a self-specified length of CBI protection in the original CBI claim, provided that the length of time is reasonable and justified (subject to EPA review). At the end of the specified timeframe, the CBI owner could choose to extend CBI protection for a specified time period provided that they submit an appropriate re-substantiation.

In any case of an expiring claim or “triggered” renewal, CSPA supports a position that the EPA should provide some reasonable notification to the CBI owner to allow them to re-substantiate the claim prior to taking any action that would disclose trade secret information.

Endnotes

¹ The Uniform Trade Secrets Act defines the term “trade secret” as: “...information, including a formula, pattern, compilation, program device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. *See* Section 1(4) of the Uniform Trade Secret Act.

² 5 U.S.C. § 552.

³ *Id.* at § 552(b)(4).

⁴ 15 U.S.C. § 2613(a).

⁵ *Id.* at § 2613(a)(3).

⁶ *Id.* at § 2613(b).

⁷ *Id.* at § 2614(d).