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EXECUTIVE SUMMARY

The ABA SEER Pesticide, Chemical Regulation and Right-to-Know Committee, with the support of the section’s Special Committee on Congressional Relations, developed this paper outlining the provisions pertinent to the development and protection of confidential business information (CBI) to provide a frame of reference for underlying issues of policy. This paper is based upon a careful review of the Toxic Substances Control Act (TSCA), its implementing regulations, growth, and case law. In particular, this paper reviews the current CBI provisions in TSCA, compares them to CBI provisions in other federal environmental statutes, and then comments on the CBI provisions of TSCA legislation introduced in the 113th Congress, S. 696 and S. 1009.

The protection of CBI is commonly invoked under a host of federal statutes by those who are required by law, or are choosing voluntarily, to submit information to the government. Any time that a reporting obligation exists, a submitter must assess whether the information would compromise its position in the marketplace or provide a domestic or international business competitor with an advantage not otherwise accessible. These considerations often arise in the TSCA reporting arena, particularly in connection with new chemical innovations. Those entities that submit information to the U.S. Environmental Protection Agency (EPA) on a voluntary or mandatory basis commonly seek to obtain protection from public disclosure of sensitive commercial information.

In defining the scope of information that may be claimed CBI and thus withheld by EPA from disclosure to third parties, TSCA adopts the concept of “trade secrets, commercial and financial information obtained from a person and privileged and confidential” encompassed by section 552(b)(4) of the Freedom of Information Act (FOIA). In recent years, there has been heightened interest in TSCA CBI policies and practices. This interest stems from problems with handling and monitoring CBI, and in part from EPA’s desire to respond to criticism that entities make liberal use of CBI claims, sometimes without adequate justification. This creates a tension between informed public interest in EPA’s proceedings and the legitimate need to protect confidential information from being disclosed that could provide a commercial advantage.

An important consideration associated with the treatment of CBI is the extent to which TSCA CBI protection presents an impediment to state-federal cooperation and to EPA cooperation with its international agency counterparts. TSCA does not permit EPA to share CBI

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2 The ABA is a diverse, non-partisan nongovernmental organization that includes legal practitioners from private sector, public sector, non-profit world, and academia, reflecting a wide diversity of political and policy views. As such, the Section has not taken a formal position endorsing or opposing non-ABA policy proposals or legislation.

3 This report was prepared by Lynn L. Bergeson, Bergeson & Campbell, P.C., Group Leader; Lawrence E. Culleen, Arnold & Porter LLP; Mark N. Duvall, Beveridge & Diamond, P.C.; and Martha E. Marrapese, Keller and Heckman LLP with contributions from the SEER PCRRTK TSCA Briefing Paper Team, which the authors gratefully acknowledge.
with state governments for the purpose of assessing the safety of chemical substances, even when such governments can demonstrate that they have equivalent procedural safeguards to
protect the rights of CBI claimants to the same extent as EPA and have a legitimate interest in accessing the information. Neither does TSCA allow EPA to share information claimed CBI submitted by chemical companies with foreign governments.

In certain cases, TSCA submitters are required to substantiate their CBI claims. Specified expiration dates for CBI claims are not written into the statute and EPA does not require claimants to re-substantiate CBI claims. Neither does EPA require notification whenever a claimant becomes aware of circumstances that preclude maintenance of a CBI claim. While it has the authority to evaluate the appropriateness of CBI claims, EPA states that it does not have the resources to challenge large numbers of claims.⁴

There is a natural tension when addressing CBI protection in the context of TSCA, one goal of which -- essential to the central objective of chemical risk management -- is to collect and disseminate information about the properties and risks of thousands of chemical substances. Unless protected from disclosure as CBI under TSCA section 14, this information may be publicly available (in some form) and utilized by a host of regulatory bodies, including state agencies and foreign regulators. The CBI provisions of the existing law and the changes proposed by recent legislation must be understood in this context.

I. CURRENT TSCA PROVISION ON CONFIDENTIALITY

TSCA section 14 establishes a basic protection for confidential information submitted to EPA under TSCA, as well as a series of exceptions to that protection, as follows. The key controversy under this provision has related to EPA’s position that confidential chemical identities must be disclosed to the public if contained in health and safety studies submitted under TSCA, or in underlying data.

- **Section 14(a)** states in relevant part that “[e]xcept as provided by subsection (b) . . . any information reported to, or otherwise obtained by, the Administrator . . . which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States”;

- **Section 14(b)** generally provides that section 14(a) does not prohibit the disclosure of any health and safety study submitted under TSCA for a chemical substance or mixture that (as of the date of disclosure) has been offered for commercial distribution;

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Section 14(c) requires companies to designate what is claimed CBI and submit it separately to the agency. Information submitted without a CBI claim is deemed non-confidential;

Section 14(d) authorizes criminal penalties to attach when U.S. employees (including contractors and their employees) knowingly and willfully disclose CBI to any person not entitled to receive it; and

Section 14(e) authorizes the release of all information reported or obtained by EPA upon written request to Congress.

A. Interplay with FOIA

Section 14 operates in conjunction with FOIA and EPA’s FOI regulations to govern disclosure of information submitted voluntarily or by mandate under TSCA. Through cross-reference to FOIA, subject to certain exemptions, section 14 generally prohibits EPA from disclosing information designated as trade secret and commercial or financial information that is privileged or confidential pursuant exemption (b)(4) of FOIA.

Under FOIA, federal agencies must make available to the public information submitted to them unless it is exempt. Section 552(a)(6)(A) of FOIA gives the public the right to request access to federal agency records or information. Under FOIA, government agencies are required to disclose records upon receiving a written request for them, except for those records that are protected from disclosure by the nine exemptions and three exclusions of FOIA enumerated in sections 552(b) and (c), respectively. The exemption from this requirement for mandatory disclosure relevant to section 14 is paragraph (b)(4) for “trade secrets and commercial or financial information obtained from a person and privileged and confidential,” often referred to collectively as CBI. For purposes of this paper, CBI is equivalent in scope to section 552(b)(4).

For purposes of TSCA, section 552(b)(4) (Exemption 4) of FOIA offers protection from disclosure by government agencies, including EPA, to third parties for “trade secrets and commercial or financial information obtained from a person and privileged or confidential.” Therefore, if a company seeks confidential treatment for a trade secret or CBI, this exemption provides a government agency with the ability to deny public access to information that would otherwise be available through a FOIA request. Through this interaction with FOIA, section 14(a) of TSCA provides an affirmative, broad statement of protection from disclosure for trade

5 5 U.S.C. § 552.
6 40 C.F.R. Part 2.
7 Section 4 of TSCA also references the Agency’s FOI rules for purposes of disclosing information when providing chemical testing information to EPA. EPA has further addressed the submission and disclosure of health and safety data in several industry guidance documents.
secret and other commercial or financial information qualifying as exempt from mandatory disclosure under Exemption 4.

B. Exceptions That Require Disclosure

FOIA does not preclude discretionary disclosure of CBI, however. To limit EPA’s discretion to disclose, section 14(a) of TSCA provides that EPA shall not disclose CBI submitted under TSCA, subject to certain exemptions.

Some of the exceptions from the ban on disclosure are relatively standard. For example, EPA may disclose CBI to its contractors, for law enforcement purposes, in a proceeding under TSCA, or if necessary to protect against an unreasonable risk of injury to health or the environment. Also, EPA must disclose CBI to a Congressional committee upon request.

Although TSCA allows for disclosure of information relevant to a proceeding under the Act, 40 C.F.R. §2.306(i) specifically notes that “any such disclosure shall be made in a manner that preserves the confidentiality of the information to the extent practicable without impairing the proceeding.” With respect to the provision that allows for the disclosure of usually-protected confidential information in instances “when necessary to protect health or the environment against an unreasonable risk of injury,” the FOI regulations stipulate that “any disclosure shall be made in a manner that preserves the confidentiality of the information to the extent not inconsistent with protecting health or the environment.”

The exemption that has attracted the most attention appears in section 14(b). It generally provides that section 14(a) does not prohibit the disclosure of any health and safety study submitted under TSCA for a chemical substance or mixture that (as of the date of disclosure) has been offered for commercial distribution. The phrase “offered for commercial distribution” was intended to exclude chemical substances that are not listed on the TSCA Inventory, nor are subject to a marketing authorization such as a low volume exemption; an example is a new chemical substance undergoing research and development (R&D). Section 14(b) also exempts from the disclosure ban in section 14(a), any health and safety studies submitted under TSCA on chemical substances subject to testing requirements under section 4 or to notification under section 5 (i.e., new chemical substances undergoing premanufacture notification (PMN) or chemical substances subject to significant new use rules). Finally, section 14(b) exempts from section 14(a) any data reported to, or otherwise obtained by EPA (e.g., through a subpoena) that relates to a chemical substance or mixture described above (i.e., underlying data).

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10 TSCA § 14(a).
11 TSCA § 14(e).
12 40 C.F.R. § 2.306(k).
13 Health and safety studies on R&D chemical substances are often submitted to EPA under section 8(e).
Section 14(b) itself contains exemptions for “any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture” or, in the case of a mixture, “data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.”

Problems have arisen regarding the interpretation of section 14(b) and its relationship to section 14(a), as the degree of protection to be accorded confidential chemical identity in a health and safety study is not clear from the text of section 14(b). Some have interpreted these provisions to mean that chemical identity is only allowed CBI protection when its disclosure would reveal processing information or portion in a mixture. EPA’s practice for more than 30 years was to interpret these provisions to mean that EPA is not prohibited from disclosing the health and safety effects information within health and safety studies, but the legitimate CBI contained within a study can and must be protected.

Most recently, EPA has interpreted TSCA section 14(b) as extending to confidential chemical identities revealed by health and safety studies submitted under TSCA or in underlying data. Nevertheless, its regulations for PMN under section 5 allow submitters of health and safety studies for PMN chemical substances to claim the chemical identities as confidential if they substantiate the claims and provide chemically-descriptive generic names.

In 2010, EPA published a notice indicating that it planned to reject CBI claims for chemical identities appearing on the public portion of the TSCA Inventory in reports that have been submitted under TSCA section 8(e). It also published a notice indicating more broadly that it generally planned to deny CBI claims for the identities of chemical substances in studies submitted under TSCA. The notice suggested, however, that some chemical names, such as those for polymers, may reveal process information and thus may not be subject to the section 14(b) exemption from section 14(a).

As part of an ongoing transparency initiative, EPA has been reviewing past CBI claims for chemical identities made in studies submitted under TSCA and, in some cases, releasing the chemical identities publicly. EPA has also been encouraging industry to review past submissions made with CBI claims and voluntarily relinquish those claims in appropriate cases.

C. What Kind of Information Is CBI or a Trade Secret?

Definitions for what is a “trade secret” or “CBI” are not found in TSCA or FOIA. Rather

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14 Its regulatory definitions of “health and safety study” state that chemical identity is always part of, or underlying data to, a health and safety study. 40 C.F.R. §§ 716.3, 720.3(k).

15 40 C.F.R. §§ 720.85(b)(5), 720.90(c), (d). EPA had considered amending this provision to revoke the generic name option to disclosure, e.g., EPA Regulatory Agenda (Spring 2011), RIN 2070-AJ87, but has since dropped this proposal.


than an enumerated list, EPA’s regulations generally characterize “business information” as “any information which pertains to the interests of any business, which was developed or acquired by that business, and (except where the context otherwise requires) which is possessed by EPA in recorded form.” 18 “Reasons of business confidentiality” is a defined term to include “the concept of trade secrecy and other related legal concepts which give (or may give) a business the right to preserve the confidentiality of business information and to limit its use or disclosure by others in order that the business may obtain or retain business advantages it derives from its rights in the information.” 19 EPA’s general FOI regulations at 40 C.F.R. Part 2.208 have worked well over many years and define CBI as any information that pertains to business interests that have been developed or acquired by a business where:

- The business has asserted a CBI claim that has not expired, been waived, or withdrawn;
- The business has taken reasonable measures to protect the confidentiality;
- The information is not reasonably obtainable without the business’ consent by use of legitimate means;
- No statute specifically requires its disclosure; and
- Either --
  (a) The business demonstrates disclosure if likely to cause substantial competitive harm; or
  (b) The information is voluntarily submitted to the government and its disclosure is likely to impair the government’s ability to obtain the necessary information in the future.

Courts usually focus on (a) above when evaluating this final factor.

For the interpretation of what is intended as a trade secret, in the past EPA has turned to the commonly-recognized Restatement of Torts, section 757.20

Any formula, pattern, device, or compilation of information which is used in one’s business, and which gives the [employer] an

18 40 C.F.R. § 2.201(c).
19 40 C.F.R. § 2.201(e).
opportunity to obtain an advantage over competitors who do not know or use it.

Comment b to the Restatement further explains that a trade secret: “. . . may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. . . . Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article.”

In connection with enforcing Exemption 4, some courts have adopted the following, more narrow definition of trade secret -- “a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.” Commercial or financial information is broadly accepted as such by the courts under the FOIA exemption if it relates in some way to business or trade. Generally, courts have held that if the submitter has commercial interest in the information, then it can be considered commercial. For information that is not clearly a trade secret to be protected from disclosure by Exemption 4, however, it must also be obtained from a “person” and be “privileged or confidential.”

D. Process for Claiming Confidentiality and for Disclosure

TSCA section 14, cross-referencing FOIA, protects from disclosure information reported to, or otherwise obtained by EPA, that is exempt from disclosure under FOIA section 552(b)(4). The latter provision exempts “trade secrets and commercial or financial information obtained from a person and privileged or confidential.” Manufacturers, processors, or distributors in commerce may designate such information as confidential in submitting or otherwise making it available to EPA, in which case it may be shared only narrowly, generally disclosed only to federal employees undertaking health or environment-related duties under TSCA, or when relevant in a proceeding under TSCA. Such CBI also may be disclosed -- i.e., EPA may override the applicable FOIA exemption -- “if the [EPA] Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment.” If EPA intends to release otherwise exempt CBI to the public, TSCA requires prior notice to the manufacturer, distributor, or processor.

EPA’s FOIA regulations at Part 2, Subpart B establish “basic rules governing business confidentiality claims . . . and determinations by EPA of whether information is entitled to confidential treatment for reasons of business confidentiality.”21 In order to assert a claim of confidentiality under Part 2, one must provide the agency with a “suitable form of notice.

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21 40 C.F.R. § 2.202(a).
employing language such as *trade secret*, *proprietary*, or *company confidential.*”\(^{22}\) PMN submitters may assert CBI claims for information supplied in a PMN for the period prior to the commencement of manufacture or import. If any information is claimed as CBI in a PMN, a “sanitized” copy of the PMN form, i.e., a version from which all CBI has been removed, must be submitted to EPA. Subsequently, to maintain confidentiality, CBI must be substantiated at the time that a notice of commencement of manufacture or import (NOC) is filed. A similar substantiation must accompany the submission of substantial risk information under section 8(e) of TSCA to claim such information as CBI. Other TSCA reporting requirements (*e.g.*, the Chemical Data Reporting rule (CDR)) also have specified CBI provisions.

Generally, EPA cannot disclose CBI without following certain procedures designed to protect the submitter’s rights, including advance written notice to the submitter. Specifically, EPA notifies the data submitter and gives the data submitter an opportunity to submit comments on, among other things: (1) measures taken by the company to guard against the undesired disclosure of the information to others; (2) the extent to which the information has been disclosed to others; and (3) whether the business claims that disclosure will likely result in substantial harmful effects on the company’s competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial, and an explanation of the causal relationship between disclosure and such harmful effects.\(^{23}\) EPA must give the business at least 15 working days after such notification to submit comments.\(^{24}\)

If EPA determines that the data are entitled to confidential treatment, it will maintain the information as confidential, and notify the data submitter of its determination.\(^{25}\) If EPA denies the claim of confidentiality, it must notify the data submitter of its denial and state the basis for its determination. A denial of a claim of confidentiality is a final agency action subject to judicial review.\(^{26}\) The denial notice must state that EPA will make the information public on the 31st day after the data submitter’s receipt of the notice, unless the data submitter has notified EPA’s legal office within that time that the company has initiated a legal action seeking judicial review of the disclosure determination or an injunction prohibiting disclosure.\(^{27}\)

E. Interpretations of Note

In interpreting when information is “privileged or confidential,” the court in *National Parks and Conservation Ass’n v. Morton* held that “commercial or financial matter is ‘confidential’ for purposes of [Exemption 4] if disclosure of the information is likely to have

\(^{22}\) *Id.* § 2.203(b) (emphasis in original).

\(^{23}\) *Id.* § 2.204(e)(4).

\(^{24}\) *Id.* § 2.204(e)(2).

\(^{25}\) See *id.* § 2.205(e).

\(^{26}\) *Id.* §§ 2.205(f)(1),(2).

\(^{27}\) *Id.* § 2.307(e)(3).
either of the following effects: (1) to impair the Government’s ability to obtain necessary information in the future, or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.\textsuperscript{28} The second prong has been generally interpreted by the courts as posing a threat to the competitive position of the submitter.\textsuperscript{29} In one case, an intervening drug manufacturing company successfully argued that the release of investigator names and article titles under FOIA should not be permitted since the information had commercial value and provided evidence that would otherwise be costly for competitors to figure out.\textsuperscript{30}

Relatively greater protection is usually afforded for information that is submitted “voluntarily” to an agency as compared to when it is “required.” The longstanding test of \textit{National Parks} applies for the submission of required information. \textit{Critical Mass Energy Project v. NRC}, in contrast, considers “information provided to the government on a voluntary basis.” Such information is “confidential” for the purposes of the FOIA Exemption 4 if it is the type of information that would customarily not be released to the public by the person from whom it is obtained.\textsuperscript{31}

To determine whether information was submitted on a voluntary basis, U.S. Department of Justice (DOJ) guidance suggests that two questions be asked: (1) Did the agency hold the legal authority to require that information submission, and, if so, (2) Did it in fact exercise that authority in obtaining that information. “Legal authority” can be through a statute, executive order, or regulation, as well as a “less formal mandate” that is issued by an agency that make the submission of information a condition of participating in an administrative process or of doing business with the government. The mere existence of an agency’s power to compel information is not enough to consider it required; the agency must also exercise its authority. “This could occur, for example, where an agency holds the authority to enact an information-submission

\textsuperscript{28} 498 F.2d 765, 770 (D.C. Cir. 1974).

\textsuperscript{29} \textit{National Parks and Conservation Ass’n v.Kleppe}, 547 F.2d 673, 684 (D.C. Cir. 1976) (“[T]he likelihood of substantial harm to [the applicants’] competitive positions . . . [is] virtually axiomatic . . . [where] [d]isclosure would provide competitors with valuable insights into the operational strengths and weaknesses of [an applicant], while the [competitors] could continue in the customary manner of ‘playing their cards close to their chest.’” “The documents which have been identified by courts as properly cognizable under the competitive harm prong of the \textit{National Parks} test include: detailed financial information . . . technical and commercial data; information constituting the ‘bread and butter’ of a manufacturing company; currently unannounced and future products, proprietary technical information . . . .” 66 Fed. Reg. 19798, 19799 (Apr. 17, 2001) (emphasis added).


\textsuperscript{31} 975 F.2d 871, 878 (D.C. Cir. 1992) (\textit{en banc}).
regulation, but has not yet done so, or where it has the power to subpoena business records, but
does not do so.”

For example, in *Critical Mass*, the plaintiff was seeking safety reports that were
voluntarily submitted by the Institute of Nuclear Power Operations (INPO) (on behalf of several
nuclear power facilities) with the understanding that the Nuclear Regulatory Commission (NRC)
would not release them to third parties without INPO’s consent. The court agreed with the NRC
that the documents should be protected under Exemption 4 of FOIA and stated, “where . . . the
information is provided to the Government voluntarily, the presumption is that its interest will be
threatened by disclosure as the persons whose confidences have been betrayed will, in all
likelihood, refuse further cooperation.”

Other cases specifically acknowledge the redaction of “identifying” information as an
acceptable means to maintain confidentiality. In *National Cable Television Ass’n, Inc. v. F.C.C.*,
the court held that Exemption 4 of FOIA does not protect all data contained in such filings but
only that information which cannot be rendered sufficiently anonymous by deletion of filing
party’s name and other identifying information. In another example, the court found that
identifying details or secret matters can be deleted to render the material subject to disclosure
where portions of a requested document are privileged or confidential.

TSCA CBI is perhaps most frequently encountered in the context of TSCA Inventory
chemical names. As noted above, the TSCA Inventory has a non-confidential portion and a
confidential portion. If the specific chemical name of a substance is claimed as CBI in a PMN
and NOC, the substance will become listed on the confidential portion of the Inventory. In this
case, a generic name that masks the specific chemical identity of the substance and an accession
number are placed on the non-confidential portion of the Inventory, and the specific chemical
name is placed only on the confidential portion of the Inventory. The confidential Inventory is
not directly accessible to the public, but EPA will search the confidential portion of the Inventory
in response to a notification (commonly called a *bona fide* inquiry) that establishes that a person
has a *bona fide* intent to manufacture or import the substance. If the specific chemical name for
a reported chemical substance is not claimed as CBI, the specific chemical name will appear on
the publicly accessible non-confidential portion of the TSCA Inventory.

II. MANAGEMENT OF CONFIDENTIAL BUSINESS INFORMATION UNDER
OTHER FEDERAL ENVIRONMENTAL LAWS

TSCA is one of several federal laws that contains carefully crafted provisions compelling
the release of certain information, including health and safety information, while protecting

32 FOIA Counselor, Exemption 44 Under Critical Mass: Step-By-Step Decisionmaking, FOIA Update, Vol. XIV,

33 975 F.2d at 878.

34 479 F.2d 183 (D.C. Cir. 1973).
information deemed confidential and/or trade secret. A brief review of other federal statutory schemes reveals common themes in each law.

A. The Trade Secrets Act

The Trade Secrets Act prohibits agency employees from disclosing, unless otherwise "authorized by law," any information which “concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association.”\(^\text{35}\) In a challenge to an unauthorized agency disclosure, often called a “reverse FOIA” suit, courts have held that the Trade Secrets Act, a criminal statute, does not contain a private right of action. Therefore, reverse FOIA plaintiffs typically allege that an agency’s decision to disclose confidential information under a FOIA exemption that is unauthorized by law would violate the Trade Secrets Act and would be arbitrary and capricious under the Administrative Procedure Act.\(^\text{36}\) The Trade Secrets Act does not apply to TSCA, but an analogous provision, section 14(d), provides similar protection.

B. Comprehensive Environmental Response, Compensation, and Liability Act of 1980

As originally enacted in 1980, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) provided in section 104(e)(2)(A) that all information obtained under the response authority “shall be made public” unless the person providing the information establishes that disclosure would “divulge information entitled to protection under section 1905 of title 18 of the United States Code” (i.e., the Trade Secrets Act). There is an exception for “health or safety effects data,” which are not protected from disclosure, a provision closely aligned with TSCA’s health and safety studies exception. Title I of the Superfund Amendments and Reauthorization Act (SARA) amended CERCLA in 1986 to cut back on the broad protection from disclosure granted by simple reliance on the Trade Secrets Act, however. It added several restrictions, including that the person submitting the information establish that “[t]he specific chemical identity, if sought to be protected, is not readily discoverable through reverse engineering,” thereby conforming CERCLA to the trade secret provisions of EPCRA discussed below. It also prohibited confidentiality protection for information on the physical properties and health and environmental hazards of the hazardous substances, as well as “[t]he trade name, common name, or generic class or category of the hazardous substance.” Specific chemical identities, however, may be protected from disclosure.

C. FIFRA

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is the federal law regulating pesticides. FIFRA section 10(b) protects trade secret or commercial or financial


\(^{36}\) See, e.g., McDonnell Douglas Corp. v. Widnall, 57 F.3d 1162, 1164 (D.C. Cir. 1995).
information submitted by an applicant from public release, with a number of exceptions. FIFRA section 10(d) allows EPA to make health and safety data publicly available, with three exceptions. These exceptions are: (1) data concerning pesticide manufacturing or quality control processes; (2) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient in a pesticide product; and (3) the identity or percentage quantity of any deliberately added pesticide inert ingredient. Disclosure of such protected information can only occur if EPA determines that its release is necessary to protect against an unreasonable risk of injury to health or the environment. Before it can release any protected information, EPA must notify the data submitter by certified mail of its intent to release the data and provide the data submitter with a 30-day period in which to take action in district court to enjoin the release of the information.

FIFRA section 10(g) prohibits EPA from knowingly disclosing information submitted by an applicant or registrant to any employee or agent of a foreign or multinational business without the consent of the registrant or applicant. The statute requires EPA to obtain an affirmation from any person who intends to inspect health and safety data that such person will not deliver the information, or offer it for sale to a foreign or multinational business. In effect, the provisions of section 10(g), prohibiting the release of data to foreign or multinational corporations, often override the section 10(b) disclosure authorization for health and safety data, and protect data from release.

In responding to FOIA requests for information claimed as confidential, EPA follows the procedures in its general FOIA rules.

**D. Emergency Planning and Community Right-to-Know Act of 1986**

In 1986, Congress enacted EPCRA to require disclosure of chemical-related information to EPA, state and local authorities, and the public. In particular, EPCRA created TRI. Under TRI, chemical-using industries report to EPA their toxic emissions to the air, water, and land. EPA makes the data available through computer telecommunications and other means to any person on a cost-reimbursable basis. Numerous reports cite the TRI program as a model for providing environmental information to the public.

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38 FIFRA § 10(c), 7 U.S.C. § 136h(c); FIFRA § 10(d)(3), 7 U.S.C. § 136h(d)(3).

39 FIFRA § 10(g), 7 U.S.C. § 136h(g).

40 EPA can disclose information otherwise protected by FIFRA section 10(g) in connection with a cancellation hearing if such information is relevant to whether the pesticide or its ingredients cause unreasonable adverse effects on health or the environment.


42 EPCRA is Title III of SARA, Pub. L. 999-499, 42 U.S.C. § 11001 et seq.
The provision on trade secrets, section 322, protects from public disclosure only “specific chemical identity (including the chemical name and other specific identification).”43 Where the identity of a chemical substance is withheld from the public, information about the “adverse effects of the chemical” must be disclosed.44 This provision reflects congressional balancing of the competing interests in disclosure and non-disclosure. Information other than chemical identity is not protected. To provide the public with some information about chemical substances whose identities are withheld, section 322 requires that the submitter identify “the generic class or category” of the chemical substance.45 An up-front substantiation of trade secrecy is required, including a showing that the chemical identity “is not readily discoverable through reverse engineering”46 (i.e., that it actually is a trade secret). The legislative history refers to EPA’s experience with generic names under TSCA, as required under TSCA section 5(d)(2):

The Administrator may give guidance for choosing such [generic] classes or categories in implementing regulations, drawing upon experience under the Toxic Substances Control Act.47

More than FIFRA or TSCA, EPCRA is intended to provide the public with information about chemical substances. That Congress chose to protect trade secret chemical identities even under this statute shows the continuing Congressional concern with balancing the interest in disclosure of health and safety information with the interest in protecting confidential competitive information, a balancing also present in TSCA. Congress mandated non-disclosure of trade secret chemical identities if certain requirements are met, but disclosure of structurally descriptive generic names (i.e., the same resolution in TSCA section 5(d)(2)).

III. CBI PROPOSALS IN S. 696 AND S. 1009

The CBI provisions of the existing law and the changes proposed by the Safe Chemicals Act (SCA or S. 696) and the Chemical Safety Improvement Act of 2013 (CSIA or S. 1009), respectively, must be understood in the context as discussed above in the Executive Summary.

44 EPCRA § 322(h), 42 U.S.C. § 11042(h).
46 EPCRA § 322(b), 42 U.S.C. § 11042(b).
Neither proposal abandons the basic principle that entities submitting information to EPA that would be subject to protection under FOIA Exemption 4 may assert claims with respect to its confidentiality for TSCA purposes, while both take a more prescriptive approach to describing the types of information that will be presumed to be eligible for such claims. Existing confidentiality claims would presumably remain in place unless EPA specifically challenges them.

A. The Safe Chemicals Act (S. 696)

The amendments to current TSCA section 14 proposed under section 14 of the SCA, S. 696, would limit the current latitude of commercial entities who seek to safeguard CBI, tipping the balance more decidedly in favor of providing information to the public. As in the current statute, FOIA and its exemptions would underpin the potential exemptions.

Notably, the SCA proposes a three-category system for classifying CBI as (1) always eligible for protection from disclosure; (2) possibly eligible for protection; or (3) never eligible for protection. Information deemed always eligible for protection would include the following:

- Precise information describing the manufacture, processing, or distribution of a chemical substance or mixture;
- Marketing and sales information; information that identifies the customers of a manufacturer, processor, or distributor; details of the full composition of a mixture of a particular manufacturer or processor; and
- Precise information about the use, function, or application of a chemical substance or mixture within a process, mixture, or product of a particular manufacturer or processor; or
- Precise production or import volumes of a particular manufacturer, processor, or distributor.

Information deemed never eligible for confidential treatment includes the following:

- The identity of a chemical substance;
- An EPA safety standard determination and supporting analysis under TSCA section 6;
- Any health and safety study submitted under TSCA with respect to any chemical substance or mixture (1) that has been offered for commercial distribution as of the date on which the study is to be disclosed, or (2) for which testing under TSCA section 4 or notification under TSCA section 5 is required, and (3) any data reported to, or otherwise obtained by, EPA from a health and safety study that relates to such chemical substance or mixture;
• Health and safety data in notices of substantial risk submitted pursuant to TSCA section 8(l) (current section 8(e)) and in the underlying studies; general information describing manufacturing volumes, expressed in ranges, and industrial, commercial, or consumer functions and uses of a chemical substance or mixture; or

• Any information indicating the presence of a chemical substance in consumer products intended for use, or reasonably expected to be used, by children aged 14 years or younger, if EPA or another authoritative body has determined that the substance (1) is a known or probably reproductive, developmental, neurological, or immunological toxicant, carcinogen, or mutagen, or (2) is persistent, bioaccumulative, and toxic, or (3) in the case of a substance for which a safety standard determination has been made, EPA has not found that the chemical substance meets the safety standard.

The intermediate “may be eligible for protection” category addresses identities of certain chemical substances for which the submitter provides supporting documentation sufficient to establish to EPA that a number of criteria set out in section 14(b)(2) of TSCA as it would be amended by the SCA have been satisfied. The SCA would direct EPA, within one year of its enactment, to promulgate rules that specify the acceptable bases for approval of written requests to maintain the confidentiality of particular information; the nature of the documentation and justification that must accompany such a request; the types of information that warrant protection indefinitely, rather than for an EPA-determined period not to exceed five years (subject to a renewal period not exceeding five years if the submitter can show that an extension of protection is justified). EPA would have to review and respond to requests for confidential treatment within 90 days after receiving the information.

B. The Chemical Safety Improvement Act (S. 1009)

The CSIA would amend section 14 of TSCA somewhat similar ways. Like the SCA, it would afford a presumption of confidentiality to certain types of information submitted by a manufacturer, processor, or distributor. These would include the following:

• Specific information describing the manufacture, processing, or distribution in commerce of a chemical substance, mixture, or article;

• Marketing and sales information;

• Information identifying suppliers or customers;

• The identity of constituents in a mixture and their respective percentages;

• Specific information about use, function, or application in a chemical substance or mixture in a process, mixture, or product;
- A manufacturer’s specific production or import volumes and specific volumes aggregated across manufacturers if EPA determines that disclosing the latter could reveal CBI; or

- The specific identity of a chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service (CAS) number, and other information that would identify a specific chemical substance if (1) the specific identity was claimed as CBI when submitted; and (2) the claim was not subsequently withdrawn or determined by EPA not to warrant confidential treatment.

In addition to setting out those types of information to which a presumption of confidentiality attaches, the CSIA would identify information that would not be protected from disclosure:

- Information submitted after enactment of the CSIA for which the submitter fails to meet the supporting requirements in section 14(d);

- A safety assessment developed or a safety determination made under TSCA section 6;

- Health and safety data submitted under TSCA for a chemical substance or mixture that has been offered for commercial distribution as of the date on which the study is to be disclosed or for which testing is required under TSCA section 4;

- Health and safety data in notices of substantial risk submitted under TSCA section 8(e) and in the underlying studies;

- General information describing manufacturing volumes expressed in ranges that would not reveal confidential information; and

- General descriptions of industrial, commercial, or consumer functions and uses of a chemical substance or mixture.

Applicable to any of these is an exception for information elements contained in submissions that are otherwise eligible for protection, if the submitter meets the requirements for support and substantiation.

CSIA would set out requirements for a submitter to designate information as warranting confidential treatment, including documentation and certification of its claim and to demonstrate that the submitter had protected the identity of the information, and that its disclosure likely would cause substantial competitive harm to the submitter. The submitter additionally would have to identify a time period for which protecting the confidentiality of the information would be necessary, as well as a generic name for the chemical involved that would disclose as much information to the public as possible consistent with safeguarding what is claimed as confidential. If EPA were to determine that the information is eligible for protection, it could
allow confidential treatment for the time period requested by the submitter, or for such other period of time as EPA determines is reasonable. EPA also may request “redocumentation” of a confidentiality claim, if the chemical substance involved were to be identified as a high-priority substance, or for other reasons. EPA could deny a request for confidentiality protection for a substance only if the submitter were to fail to meet the requirements, described above, in support of the request. Where a request is denied or modified, EPA would have to provide a written statement of the reasons why. The bill would provide a pathway for a submitter to appeal in the event that EPA determines to release the information involved.

IV. CONCLUSION

TSCA’s long standing protection of information submitted to EPA and claimed CBI is a critically important component of the law. Innovators rely upon the protections offered under TSCA to ensure competitiveness and protect innovations without compromising EPA’s obligation to protect health and the environment. TSCA reform can be expected to tighten up the CBI claims process, possibly require up-front corroboration, and potentially enable EPA to share CBI with federal and state entities provided comparable protections are in place.