White Paper

TSCA Protects Confidential Chemical Identities in Health and Safety Studies From Disclosure

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Table of Contents

EXECUTIVE SUMMARY

Citing section 14(b) of the Toxic Substances Control Act (TSCA), the Environmental Protection Agency (EPA) has recently called for the disclosure of chemical identities in health and safety studies submitted under TSCA, notwithstanding objections by the study submitters that the chemical identities are trade secrets or confidential commercial information. EPA has developed a policy against confidential business information (CBI) protection for chemical identities in or underlying such studies. EPA should reconsider that CBI disclosure policy for both policy and legal reasons, and take specific steps to protect confidential chemical identities where appropriate. Under TSCA, EPA must balance the interest in disclosure against the interest in protecting trade secret and confidential chemical identities. It may do so by protecting that information while also providing the public with the information it needs to evaluate those studies, such as through a requirement for structurally-descriptive generic names.

There are strong policy reasons why EPA should reconsider its stance against CBI protection for chemical identities in health and safety studies. Trade secrets are crucial to U.S. leadership in innovation in a global economy, but the CBI disclosure policy may erode that leadership by reducing the protection for trade secrets. In the chemical industry, trade secret chemical identities are among the most valuable intellectual property, yet they often cannot be patented. The composition of formulations can be particularly valuable, especially for small businesses. Under the CBI disclosure policy, EPA would reveal those chemical identities when they are the subject of a health and safety study submitted under TSCA, notwithstanding CBI claims. This may have the effect of discouraging innovation and the jobs and greener chemicals that result from innovation, and driving jobs outside the U.S.

The CBI disclosure policy reflects EPA's legal perspective that section 14(b) requires disclosure of trade secret or confidential chemical identities in most studies submitted under TSCA. That perspective is flawed. The CBI disclosure policy runs counter to the text and legislative history of TSCA, as well to nearly 30 years of EPA policy and regulation. This paper establishes that in section 14 and the rest of TSCA, Congress intended for EPA to protect trade secret or confidential chemical identities in or underlying studies submitted under TSCA, while also providing the public with the information it needs to evaluate those studies.

The Congressional intention to protect trade secret or confidential chemical identities is reflected in the text of TSCA itself. Read as a whole, TSCA shows consistent concern for the protection of chemical identities that are trade secrets or confidential commercial information:

- Section 14(a) provides broad protection for trade secret or confidential commercial information. Section 14(b) cuts back on that protection for health and safety studies, but it requires health and environmental information, such as effects information, to be available for disclosure, not trade secret or confidential commercial information in those studies. Section 14(a) protects any trade secret or confidential commercial information in those studies other than health and environmental information.

- Both sections 5(b)(3) and 5(d)(2) mandate public disclosure of data from health and safety studies submitted under section 5, subject to protection for trade secret or

confidential chemical identities and other information in those studies under section 14. Section 5(d)(2) specifically endorses disclosure of generic names instead of confidential identities except where "required in the public interest."

- Section 4(d) similarly mandates public disclosure of data from health and safety studies submitted under section 4, subject to protection for trade secret or confidential chemical identities and other trade secret information in those studies under section 14.

- Section 8(a) authorizes EPA to require reporting of chemical identities and other information which is typically confidential without even mentioning section 14, indicating an expectation that section 14(a) protects such information when it is trade secret or confidential.

- Section 14(b) excludes trade secret or confidential chemical identities that, if disclosed, would result in disclosure of process information.

- Section 14(b) also excludes studies on R&D chemicals, for which the public interest in disclosure of trade secret or confidential commercial information is generally limited and the competitive interest in non-disclosure of such information is generally high.

This intention to protect trade secret or confidential chemical identities while disclosing health and safety studies is also manifest in the legislative history of TSCA. While considering TSCA, Congress recognized that its 1972 amendments to the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA), which also required the disclosure of health and safety studies, had raised a question of whether a study could be claimed as a whole to be a trade secret or confidential commercial information and thereby be protected from disclosure. EPA took the position that studies as a whole are not trade secrets or confidential commercial information.

With section 14(b), Congress intended to incorporate that position in TSCA. However, in the FIFRA debate, EPA carefully differentiated between studies as whole and chemical identities in or underlying those studies. EPA concluded that the trade secret or confidential identities in studies submitted under FIFRA are protected from disclosure. Stakeholders in the TSCA hearings similarly advocated for disclosure of studies, but recognized the need for continued protection of trade secret or confidential chemical identities. With section 14 of TSCA, Congress adopted EPA's viewpoint both that studies as a whole are not protected from disclosure, and that trade secret or confidential commercial information in or underlying them should be protected from disclosure.

TSCA is the second of six statutes enacted by Congress between 1972 and 1986 related to public disclosure of health and environmental information about chemicals. In all five of the other statutes, health and environmental information is required to be disclosed, but trade secret or confidential chemical identities are protected from disclosure. TSCA is not an exception, but rather should be recognized to be part of the same Congressional approach making health and environmental effects information public while protecting competitively sensitive information such as chemical identities.

EPA has long recognized that it has authority under section 14 to protect trade secret or confidential chemical identities in or underlying studies submitted under TSCA. In multiple rulemakings under section 5, it explicitly balanced the interest in disclosure of studies against the interest in protecting trade secret or confidential chemical identities in those studies by requiring disclosure except where disclosure is unnecessary to interpret the studies, such as by the provision of structurally-descriptive generic names. This longstanding legal interpretation by EPA is consistent with the text and legislative history of TSCA.

EPA should take several steps to balance transparency with protection of competitively sensitive information:

- Currently, EPA's regulations and guidance disallow confidentiality claims for chemical identities in or underlying studies, other than to a limited extent in its PMN and MCAN regulations. EPA should revise those regulations and guidance to allow such claims in appropriate circumstances. It should not proceed with its planned initiative to delete those provisions in its PMN and MCAN regulations.

- To address the need for public understanding of health and safety studies, EPA should consider requiring that structurally-descriptive generic names be provided in lieu of trade secret or confidential chemical identities for all studies submitted under TSCA. Generic names can provide important information to the public while still protecting competitively sensitive information important for innovation. EPA should also consider requiring up-front substantiation of CBI claims for chemical identities in studies.

- EPA should work with industry and NGOs to improve the process for determining appropriate generic names, both for the identities of chemical substances in studies and for names of PMN substances. The current process is unnecessarily resource-intensive. Industry representatives would volunteer to work with EPA and NGOs to streamline and otherwise improve the process.

- EPA should allow CBI claims for confidential identities of chemical substances in or underlying health and safety studies where appropriate. With structurally-descriptive generic names, an improved process for determining generic names, and an up-front substantiation requirement, the balance between transparency and protection of competitively sensitive information would be shifted to allow the disclosure of generic names rather than specific chemical identities where appropriate.

- EPA should not require disclosure of the components of R&D mixtures that are the subject of studies. Section 14(b) does not apply to mixtures which have not been offered for commercial distribution, such as R&D mixtures. Accordingly, EPA should protect confidential identities of components of R&D mixtures.

DISCUSSION

I. Policy Reasons Why EPA Should Reconsider Its Interpretation of Section 14

EPA has a policy of requiring disclosure of confidential chemical identities in or underlying health and safety studies submitted under TSCA. EPA should reconsider that CBI disclosure policy. It is based on a flawed interpretation of section 14 and may have serious adverse impacts on innovation and on small business. It may help drive chemical industry jobs overseas.

EPA must consider these impacts. In section 2(c) of TSCA, Congress expressed its intent that EPA "shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action" taken under TSCA. The CBI disclosure policy is neither reasonable nor prudent, and it may be having adverse economic and social impacts. Further, in section 2(b)(3), Congress found that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation." The CBI disclosure policy is such an unnecessary economic barrier to innovation.

Trade secret protection is crucial to U.S. competitiveness. According to the National Science Foundation's National Science Board, intellectual property in the form of trade secrets is a critical factor as the United States competes in a global marketplace:

> In most broad aspects of S&T [science and technology] activities, the United States continues to maintain a position of leadership but has experienced a gradual erosion of its position in many specific areas ....
>
> The United States runs a surplus with the rest of the world in trade of intangible assets, including patent licensing fees and use of trade secrets .... An important component of the surplus in U.S. intangible assets is generated by industrial processes ($19 billion), which include licensing fees for patents and use of trade secrets. U.S. exports in this category were $37 billion in 2007.[1]

The United States needs to protect its leadership in scientific and technological innovation. In the chemical industry, innovation often depends upon trade secret protection for trade secret or confidential chemical identities.

Trade secret protection also serves important public policy goals. As the Supreme Court has noted:

> Trade secret law encourages the development and exploitation of those items of lesser or different invention than might be accorded protection under the patent laws, but which items still have an important part to play in the technological and scientific advancement

[1] National Science Board, Science and Engineering Indicators 2010 (2010), http://www.nsf.gov/statistics/seind10/pdfstart.htm, at O-3, 6-5.

> of the Nation. Trade secret law promotes the sharing of knowledge, and the efficient operation of industry; it permits the individual inventor to reap the rewards of his labor by contracting with a company large enough to develop and exploit it. Congress, by its silence over these many years, has seen the wisdom of allowing the States to enforce trade secret protection. Until Congress takes affirmative action to the contrary, States should be free to grant protection to trade secrets.[2]

More particularly, confidential chemical identities in health and safety studies have recognized economic value, as a government report found:

> Further, specific identification of a product in a health and safety study may inform competitors that a product has commercial value or that it is used in a particular manufacturing process. This concern is particularly applicable to catalysts and intermediates that may not be detectable in the commercial product.
>
> Although the sensitivity of releasing confidential data is greatest at the beginning of a product's commercial life cycle, release of such data about an existing product may have some of the same economic consequences as disclosure of confidential data regarding a new product.[3]

The legislative history of TSCA includes the following plea for the recognition of the importance of trade secret chemical identities to their owners:

> Particularly in the chemical industry, the precise identification of ingredients ... may involve the results of research and development expenditures of considerable magnitude. Rights in trade secrets can be among the most valuable property rights owned by a company. Buildings and equipment can be replaced at predictable costs, but secrets once lost to competitors are gone forever, and with them the incalculable advantages their owners earned.[4]

New chemical substances and new mixtures of existing chemical substances usually take millions of dollars to develop. Public disclosure of their chemical identities would make the fruits of those investments readily available to others who do not have to make similar investments. EPA has acknowledged that "there is no doubt that the fact that certain substances are manufactured or processed for commercial purposes would be confidential under traditional trade secrets law and case law under the Freedom of Information Act fourth exemption (5 U.S.C. 552(b) (4))."[5] Yet information that is public knowledge cannot be a trade secret.[6]

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[2] Kewanee v. Bicron Corp., 416 U.S. 470, 492 (1974).

[3] "Toxic Chemicals and Public Protection: A Report to the President by the Toxic Substances Strategy Committee" (1980) at 48. The Committee consisted of representatives from the Council on Environmental Quality, eight executive branch departments, and other agencies.

[4] Statement by The Dow Chemical Company, "Toxic Substances Control Legislation – 1973: Hearings Before the Subcommittee on Commerce and Finance of the House Committee on Interstate and Foreign Commerce," 93d Cong., 1st Sess. (1973) at 355-56. Congressional materials cited in this paper are available in the LexisNexis Congressional Hearings Digital Collection.

[5] 42 Fed. Reg. 64572, 64590 (Dec. 23, 1977) (comment 93).

Forced disclosure of trade secret or confidential chemical identities under EPA's interpretation of section 14 means that innovators may have less incentive to invest the resources necessary to develop the new chemicals and mixtures that could promote the health and well-being of Americans and the environment. Increasingly, "greener" chemicals are being developed to replace those with greater possible risk to health or the environment. Without the potential for economic returns on investment made possible through CBI protection, those greener chemicals may never be introduced.

Lack of CBI protection may also drive innovation and jobs overseas. Companies may seek to manufacture chemicals in other countries where the confidentiality of their chemical identities is protected from disclosure.

Many businesses, and particularly small businesses, often innovate by combining existing chemical substances in new ways. Such combinations are typically not eligible for patent protection. Their combination creates considerable value, however, but only if protected from disclosure. EPA's CBI disclosure policy applies to the components of mixtures, and thus may inhibit innovation in development of new and improved formulations.

In light of these considerations, EPA should critically review its CBI disclosure policy. With some changes to that policy, it can still achieve its transparency goals without disclosing trade secret or confidential chemical identities. For example:

- Where chemical identities in or underlying a study are to be withheld, EPA can require the development of structurally-descriptive chemical names that will give context to the studies for the public, thus enabling both an evaluation of the studies themselves and searches of the toxicological literature for related compounds.[7]

- EPA can require up-front substantiation of claims that chemical identities in or underlying studies are trade secrets or confidential commercial information, thus discouraging inappropriate CBI claims.[8]

- EPA can require reassertion and resubstantiation of previous CBI claims so as to remove confidentiality protection for stale CBI claims, an idea already in development.[9]

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[6] Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1002 (1984) (citing the Restatement of Torts).

[7] EPA already requires development of generic names for chemical identities claimed as CBI in submissions under section 5 (40 C.F.R. §§ 720.80(a)(2), 721.1(c), 723.50(l)(2), 725.85(a)(3)). Its former Inventory regulations required submission of a generic name with a CBI claim for chemical identity. 40 C.F.R. § 710.7(e)(2)(ii), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977). EPA also requires submission of a generic name under the Emergency Planning and Community Right-to-Know Act of 1986 (40 C.F.R. § 370.64(a)).

[8] EPA already requires up-front substantiation for CBI claims for chemical identities submitted under section 5 (40 C.F.R. §§ 720.85(b)(3)(iv), 721.1(c), 725.94), section 4 (40 C.F.R. § 790.7(c)), and section 8(a)'s Chemical Data Reporting Rule (40 C.F.R § 711.30(b)(1)).

[9] According to the Spring 2011 Regulatory Agenda, RIN 2070-AJ90, "EPA is considering establishing regulations relating to claims for confidential business information (CBI) submitted under the Toxic Substances Control Act

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Moreover, as explained in the following sections, EPA's legal conclusion that it must disclose trade secret or confidential chemical identities in or underlying health and safety studies is simply incorrect. The information provided below, the legislative history in particular, may not have been considered fully by EPA in formulating its CBI disclosure policy.

II. Background on Section 14

With some exceptions, section 14(a) broadly prohibits EPA from disclosing to the public information which is exempt from mandatory disclosure to the public under the Freedom of Information Act (FOIA) exemption (b)(4), for "trade secrets and commercial or financial information obtained from a person and privileged or confidential."[10] Trade secret or confidential chemical identities are included within the protections of section 14(a).

Section 14(b) limits the scope of section 14(a) by providing that it "does not prohibit the disclosure of -- (A) any health and safety study which is submitted under this Act ...." Section 14(b) is itself limited by several qualifications. Not all studies submitted under TSCA are covered, only those with respect to:

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or
(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5 ….

In addition, section 14(b) contains the following exclusion from its coverage:

> This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

EPA has promulgated regulations under sections 5 and 8(d), in connection with definitions of the term "health and safety study," saying that chemical identity is always part of, or underlying data to, a health and safety study.[11] If the identity of the chemical being tested is not disclosed in the study itself (e.g., because a trade name is used instead), then the specific chemical identity is reasonably considered to be underlying data for the study. This conclusion, however, does not answer the question of whether the identity must be disclosed to the public when it is a trade secret or confidential commercial information.

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(TSCA) that would require the periodic reassertion and resubstantiation of such claims. Confidentiality claims which are not reasserted and resubstantiated would expire. EPA expects this action would increase transparency and availability of public health and environmental effects information on chemicals in commerce."

[10] 5 U.S.C. § 552(b)(4).

[11] 40 C.F.R. § 716.3 ("Chemical identity is part of, or underlying data to, a health and safety study."); § 720.3(k) ("Chemical identity is always part of a health and safety study."); § 725.3 ("Microorganism identity is always part of a health and safety study of a microorganism.").

Recently, EPA has taken the position that section 14(b) means that a trade secret chemical identity must be disclosed whenever it is part of, or underlying data for, a health and safety study submitted under TSCA. In May 2010, EPA declared:

> EPA believes that Congress generally intended for the public to be able to know the identities of chemical substances for which health and safety studies have been submitted. Congress did not specifically exempt chemical identities from TSCA section 14(b), and EPA believes that interpreting TSCA section 14(b) in such a manner would be inconsistent with the intent of Congress in enacting that provision.[12]

This interpretation of the statute is not correct. Congress intended for EPA to protect chemical identities in submitted health and safety studies while also providing the public with the health and environmental information it needs to evaluate those studies. In other words, EPA must balance the competing interests, as it has done for nearly 30 years.

III. The Text of TSCA Shows Intent to Protect Trade Secret or Confidential Chemical Identities in Submitted Health and Safety Studies

The text of TSCA itself establishes that Congress intended for EPA to balance the interest in disclosure of health and safety studies against the competing interest in non-disclosure of trade secret or confidential competitive information in or underlying those studies. The studies may be made public, but EPA must protect such information in those studies.

A. Section 14(a) Protects Trade Secret or Confidential Commercial Information in or Underlying Studies

Section 14(a) provides broad protection for trade secret or confidential commercial information submitted to EPA. It states in part:

> Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator ... under this Act, 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 [with certain enumerated exceptions].

That protection extends to trade secret or confidential chemical identities in appropriate cases, as demonstrated by court decisions interpreting FOIA exemption (b)(4).[13] As the EPA General Counsel has found with respect to FIFRA:

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[12] 75 Fed. Reg. 29754, 29756 (May 27, 2010).

[13] See, e.g., Appleton v. FDA, 451 F. Supp. 2d 129, 142 & n.7 (D.D.C. 2006) (drug chemical composition); Kennedy v. DHS, No. 03-6076, 2004 WL 2285058, at *7 (W.D.N.Y. Oct. 8, 2004) (protecting names and coding of inks) Center for Auto Safety v. NHTSA, 93 F. Supp. 2d 1, 40-41 (D.D.C. 2000) (identity of inflator gas used for air bags); Northwest Coalition for Alternatives to Pesticides v. Browner, 941 F. Supp. 197 (D.D.C. 1996) (reviewing individual chemical identities under FOIA exemption 4); Citizens Comm'n on Human Rights v. FDA, No. 92-5313,

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> Moreover, confidential ingredient statements often have been held by courts to be trade secrets. Thus, such information should not be disclosed routinely. If inquiry shows that the information is in fact confidential in the submitter's hands, and that its disclosure would be likely to cause substantial harm to the submitter's competitive position, the information is entitled to confidential treatment. Requests for disclosure of such information should be initially denied, citing 5 U.S.C. 552(b)(4), 5 U.S.C. 552(b)(3), and 7 U.S.C. 136h(b), and necessary further inquiry should be addressed to the data submitter.[14]

Congress emphasized the importance of protecting information subject to section 14(a) from disclosure. Section 14(d) authorizes criminal penalties for wrongful disclosure, and section 14(a)(3) limits EPA's discretion to disclose protected information outside of specified contexts to where EPA determines that disclosure "is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment."

Were it not for section 14(b), there would be no question that trade secret or confidential chemical identities in or underlying health and safety studies submitted under TSCA would be protected from disclosure. Accordingly, the real question is whether anything in section 14(b) undercuts that protection of trade secret or confidential chemical identities.

One obvious point to make is that section 14(b) nowhere refers to chemical identities; instead, it refers to health and safety studies. Section 14(b) provides that section 14(a) "does not prohibit the disclosure of" studies submitted under TSCA, but it specifically does not require that otherwise protected information in or underlying those studies be made public. By explicitly prohibiting disclosure of process and portion of mixture information, section 14(b) clearly contemplates that EPA must protect from disclosure at least some trade secret or confidential information in or underlying submitted studies.

The exclusions from section 14(b) are not exhaustive. For example, EPA has declared in its section 8(d) rules that section 14(b) does not extend, in appropriate cases, to information such as "company name or address, financial statistics, and product codes used by a company, which is contained in a study."[15] Section 14(b) has no explicit exemption for such information.

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1993 WL 1610471, at *7 (C.D. Cal. May 10, 1993) (information about how a pioneer drug product is formulated and chemically composed), *aff'd in part & remanded in part on other grounds*, 45 F.3d 1325 (9th Cir. 1995).

[14] Opinion No. 76-8 (Mar. 5, 1976), 1976 WL 25230 (E.P.A.G.C.) (emphasis added).

[15] "Any respondent may assert a confidentiality claim for company name or address, financial statistics, and product codes used by a company [in a study]. This information will not be subject to the disclosure requirements of section 14(b) of TSCA." 40 C.F.R. § 716.55(a)(4). When adopting the predecessor provision in 1982, EPA asserted that it was justified by exemption 6 of FOIA, for "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 47 Fed. 38780, 38788 (Sept. 2, 1982). In adopting the current provision, EPA wisely no longer relied on exemption 6, which the Supreme Court has held applies only to individuals, not to companies. *See*, *e.g.*, FCC v. AT&T, Inc., No 09-1279 (S. Ct. Mar. 1, 2011) (interpreting exemption 7(C) consistently with exemption 6 to apply only to the privacy interests of individuals). Thus, the provision relies on exemption 4, the same exemption that applies to confidential chemical identities.

However, as confidential financial statistics and product codes are both kinds of information protected by section 14(a) and are not themselves health or environmental effects information, section 14(b) should not be read to preclude the application of section 14(a) to such information. More generally, section 14(a) continues to apply to other trade secret or confidential commercial information in or underlying those studies that is not health or environmental effects information, including confidential chemical identities.

B. Protection of Trade Secret or Confidential Chemical Identities in Studies Submitted Under Section 5

One situation in which section 14(b) applies is where studies have been submitted under section 5, in connection with either a premanufacture notice (PMN) or a significant new use notice (SNUN). In some situations, the submitter of a PMN or SNUN must submit health and safety data to EPA. Section 5(b)(3) provides that such data "shall be available, **subject to section 14**, for examination by interested persons." (Emphasis added.) The reference to section 14 reflects Congressional concern for confidential competitive information; otherwise, section 5(b)(3) could simply require disclosure.

In all situations, section 5(d)(1) requires the submitter of a PMN or SNUN to submit "any test data in the possession or control" of the submitter. Section 5(d)(2) requires public release (in the form of a Federal Register notice) of a summary of that test data and any data submitted under section 5(b) or 4:

> **Subject to section 14** …, the Administrator shall publish in the Federal Register a notice which—
> (A) identifies the chemical substance for which notice or data has been received;
> (B) lists the uses or intended uses of such substance; and
> (C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substances and any data which was developed pursuant to subsection (b) or a rule under section 4.

(Emphasis added.) Again, Congress felt the need to invoke section 14 so as to protect competitively sensitive information. In addition, section 5(d)(2) specifically addresses chemical identities:

> A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

Thus, trade secret or confidential chemical identities in health and safety studies submitted under section 5 are to be protected by use of generic names unless, in balancing the respective interests at stake, EPA determines that disclosure is necessary.

A provision requiring disclosure of chemical identities of PMN chemicals in Federal Register notices appeared in the 1972 TSCA bill.[16] The accompanying Senate report expressed support for the use of generic names in lieu of specific chemical identities in those Federal Register notices, as now appears in section 5(d)(2):

> It is anticipated that a limited amount of data will be published in the Federal Register, since a disclosure of the identity of the chemical substance and intended uses prior to its commercial production would, in many cases, result in the disclosure of trade secrets that would be protected by section 115. However …, it may be possible to identify a chemical as a member of a family of chemical substances without disclosing trade secret information. This information, coupled with the test results that are made available would be valuable to independent scientists who have knowledge of similar chemical substances and the toxicity characteristics that might be expected of a member of that same family. If the test results published vary significantly from the known toxicity of similar substances, then the independent scientist could have good reason to question the published results.[17]

Section 5(d)(2) may be seen as a response to an industry letter calling for complete protection of chemical identity and use information in Federal Register notices:

> Member firms have continually objected to the release of unnecessary information via Federal Register publication. Publication of such information has the very definite effect of discouraging product innovation and the release of new and valuable chemical specialty products. We suggest, therefore, that any requirement for Federal Register publication in any toxic substances legislation exclude information pertaining to proposed uses and composition because such data constitutes confidential commercial and trade secret information.[18]

Congress did not categorically exclude composition and use information from Federal Register notice requirements, as requested. In section 5(d)(2) it did, however, protect composition information through the use of generic names except where EPA's balancing of interests indicates otherwise.

It would make no sense for EPA to be required by section 14(b) to disclose those same trade secret identities protected by section 5(d)(2) when it makes the studies themselves available for disclosure. Thus, while section 14(b) means that public disclosure of studies submitted in connection with a PMN or SNUR is not prohibited, TSCA protects any trade secret or confidential chemical identities in or underlying those studies from disclosure.

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[16] S. 1478 (1972), § 104(a), S. Rep. No. 92-783 at 3 (1972) ("Subject to section 115 of this title [captioned "Confidentiality"], the Administrator shall promptly publish in the Federal Register the identity of such chemical substance, the uses intended, and a statement of availability of test data.").

[17] S. Rep. No. 92-783 at 19-20 (1972) (emphasis added).

[18] Letter submitted by the Chemical Specialty Manufacturers Association, "Toxic Substances Control Act: Hearings Before the Subcommittee on Consumer Protection and Finance of the House Committee on Interstate and Foreign Commerce," 94th Cong., 1st Sess. (1975) (1975 House Hearings) at 450.

C. Protection of Trade Secret or Confidential Chemical Identities in Studies Submitted Under Section 4

A second situation in which section 14(b) applies is where a chemical substance or mixture is the subject of testing requirements under section 4.[19] As with studies submitted under section 5, this means that the resulting studies themselves are not prohibited from disclosure. However, the trade secret or confidential identity of the tested chemical substance or mixture is subject to protection from disclosure under section 14(a). This may be seen in section 4(d), which provides (emphasis added):

> Upon the receipt of any test data pursuant to a rule under subsection (a), the Administrator shall publish a notice of the receipt of such data in the Federal Register. within 15 days of its receipt. **Subject to section 14**, each such notice shall (1) identify the chemical substance or mixture for which data has been received …. **Except as otherwise provided by section 14**, such data shall be made available by the Administrator for examination by any person.

That section 4(d) was intended to protect trade secret or confidential identities from disclosure is apparent from the corresponding provision of a 1975 House bill, H.R. 7664, which included at the end the following additional sentence not included the final version of TSCA:

> Notice under this subsection shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.[20]

This is virtually the same language that appears in section 5(d)(2). Congress ultimately decided not to require disclosure of generic names in the Federal Register notice for reports on studies submitted under section 4, as it did with section 5, but it clearly intended for EPA to balance the competing interests in making disclosure decisions for studies submitted under section 4, including with respect to trade secret or confidential chemical identities. Thus, section 4(d) protects such chemical identities in the Federal Register notice announcing receipt of studies submitted under section 4.

It would make no sense for EPA to be required by section 14(b) to disclose those same trade secret identities when it makes the studies themselves available for disclosure. Accordingly, section 14(b) does not mandate disclosure of trade secret chemical identities in studies submitted under section 4.

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[19] It is unlikely that health and safety studies submitted under section 4 would involve confidentiality claims for chemical identities. The point here, however, is that Congress anticipated that in some cases there could be a need for confidentiality in section 4 submissions as well as section 5 and other submissions under TSCA.

[20] H.R. 7664 § 4(f), 1975 House Hearings at 42. The same language appeared in the 1973 House bill, H.R. 5356, § 4(f), H.R. Rep. No. 93-360 at 4 (1973).

D. Section 8(a) Illustrates How Section 14 Protects Chemical Identities

Under section 8(a), EPA may require manufacturers and processors to report chemical identity information. It specifically mentions "the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required." It restricts EPA's ability to require reporting of "changes in the proportions of the components of a mixture" except in defined circumstances.

Such detailed chemical information is subject to reporting to EPA; but, key to this discussion, it is protected from disclosure to the public. This information is clearly covered by section 14(a). In the Inventory Update Reporting (IUR) rule, now the Chemical Data Reporting (CDR) rule, EPA has allowed CBI claims under section 14(a) for such information.[21]

With section 8(a), Congress again recognized that chemical identity information should be protected from disclosure when it is trade secret or confidential. In contrast, section 14(b) is limited to health and safety studies themselves, not to trade secret or confidential information in or underlying them, such as chemical identities.

E. Protection of Trade Secret or Confidential Chemical Identities in Studies Where Disclosure Would Reveal Process Information

Section 14(b) does not apply to process information, even when that information is in the form of a trade secret or confidential chemical identity related to a study submitted under TSCA:

> This paragraph does not authorize the release of any data which discloses process used in the manufacturing or processing of a chemical substance or mixture ….

EPA has acknowledged that some chemical identities can reveal process information. Its May 2010 policy statement identified polymers and UVCB chemicals as examples of such chemical identities.[22] This is another way in which TSCA protects trade secret or confidential chemical identities in submitted studies.

F. Protection of Trade Secret or Confidential Chemical Identities in Studies on R&D Chemicals and Mixtures

TSCA protects trade secret or confidential identities in studies on R&D chemicals and mixtures by exempting such studies from the provisions of section 14(b) altogether.

Section 14(b) applies to a health and safety study submitted under TSCA that relates to "any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution." The key phrase "offered for commercial

[21] EPA has limited CBI claims for chemical identities to those on the confidential portion of the TSCA Inventory, but it has allowed CBI claims for the connection of the manufacturer to the chemical where the chemical identity is not protected from disclosure. 40 C.F.R. § 710.58(b), now 40 C.F.R. § 711.30(b).
[22] 75 Fed. Reg. 29754, 29756 (May 27, 2010).

distribution" excludes studies of R&D chemicals and R&D mixtures. It has a different meaning than the phrase "for commercial purposes," which EPA has interpreted to include R&D.[23]

EPA has noted that "Congress, accordingly, seemed to recognize the importance of confidentiality prior to manufacture of a chemical for commercial purposes."[24] More recently, EPA has acknowledged this exclusion for studies of R&D chemical substances in its January 2010 policy statement regarding CBI claims for studies submitted under section 8(e), many of which relate to R&D chemical substances. That policy statement is limited to studies on chemical substances on the public Inventory, i.e., which are no longer R&D.[25]

This R&D exclusion also applies to mixtures which are themselves the subject of R&D, since section 14(b) refers to "any chemical substance **or mixture** which … has been offered for commercial distribution" (emphasis added). For example, a processor may be conducting R&D on a mixture of existing chemicals. A submitted study on such an R&D mixture would be excluded from section 14(b), even if its components were entirely on the Inventory. The mixture itself must have been offered for commercial distribution for section 14(b) to apply to submitted studies on the mixture.[26]

G. Implications for Other Studies Submitted Under TSCA

Some studies submitted to EPA under TSCA are not submitted under either section 4 or 5, nor do the identities of the chemicals tested reveal process information, nor do the studies concern R&D chemical substances or mixtures. But the concern expressed throughout TSCA for balancing the interest in disclosure of health and safety studies with the interest in non-disclosure of competitively sensitive information in or underlying those studies is implicit in section 14 with respect to these other studies as well.[27]

Section 14(a) protects from disclosure trade secret or confidential commercial information, such as confidential chemical identities. Section 14(b) provides an exception for health and safety studies, but not for trade secret or confidential commercial information contained in those studies. As discussed above, Congress repeatedly distinguished trade secret or confidential commercial information in or underlying those studies from the studies themselves. Accordingly, while section 14(b) does not prohibit the disclosure of many studies submitted under TSCA, EPA must still balance the competing interests with respect to

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[23] *See* 40 C.F.R. § 720.3(r)(1)(ii) (defining the term "manufacture or import for commercial purposes" to include R&D); 44 Fed. Reg. 17673-74 (Mar. 23, 1979); Dow Chemical Co. v. EPA, 605 F.2d 673, 689 (3d Cir. 1979).

[24] 44 Fed. Reg. 2242, 2256 (Jan. 10, 1979).

[25] 75 Fed. Reg. 3462 (Jan. 21, 2010).

[26] Accordingly, EPA should deny FOIA requests for the release of chemical identities of mixtures that are the subject of submitted health and safety studies where the mixture itself is not, on the date of proposed disclosure, offered for commercial distribution.

[27] To resolve questions arising from the text of a statute, it is well established that legislative intent must be ascertained by looking to the entire statute, read comprehensively as a whole. See, e.g., Samantar v. Yousuf, 130 S. Ct. 2278, 2289 (2010) ("'[w]e do not . . . construe statutory phrases in isolation; we read statutes as a whole.'") (citation omitted).

competitively sensitive information in or underlying such studies. This conclusion finds additional support in the legislative history of section 14, discussed below.

IV. The Legislative History Demonstrates That Congress Wanted EPA to Protect Trade Secret or Confidential Chemical Identities When Disclosing Health and Safety Studies

Several TSCA bills were introduced from 1971 to 1976, and all had provisions protecting trade secrets, counterparts to what became section 14(a). A counterpart to section 14(b) did not appear until the 1976 House bill, however. Section 14(b) was added to resolve for TSCA an issue which for FIFRA was then under active debate, and which came to the forefront in 1975: whether health and safety data submitted to EPA qualified as trade secrets or confidential commercial information. That issue did not relate to proprietary data in studies, such as trade secret or confidential chemical identities, which under FIFRA were protected.

Accordingly, to understand section 14(b) properly, it is important to review the history of the debate on confidentiality of health and safety studies under FIFRA that led to section 14(b).[28] That history is summarized below, followed by additional TSCA legislative history that refers to this FIFRA debate.

A. 1972 FIFRA Amendments

In 1972, Congress extensively revised FIFRA with enactment of the Federal Environmental Pesticide Control Act of 1972 (FEPCA).[29] Among many other changes to FIFRA, FEPCA required public disclosure of studies submitted in connection with applications:

> Except as provided by subsection (c) (1) (D) of this section **and section 10**, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.[30]

While FEPCA called for disclosure of studies, it also protected trade secret or confidential information in or underlying those studies. FIFRA § 10(b) protected trade secrets and confidential information from disclosure. It specifically included, "formulas of products," i.e., chemical identities and their percentages, within this protection from public disclosure:

> Notwithstanding any other provision of this Act, the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, **information relating to formulas**

[28] See, e.g., National Treas. Employees Union v. Federal Labor Relations Auth., 691 F.2d 553, 559 (D.C. Cir. 1982) ("[T]he intent of Congress is paramount, and this intent may appropriately be ascertained from relevant legislative history.").
[29] Pub. L. 92-516 (1972).
[30] FIFRA § 3(c)(2), as added by FEPCA (emphasis added).

> **of products** acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.[31]

The exception beginning "when necessary to carry out the provisions of this Act" has its counterpart in section 14(a) of TSCA, which enumerates four exceptions to protection of CBI related to administration of that act, including disclosure to other federal agencies and in proceedings. Such exceptions are common in statutory guarantees of CBI protection. The exception is not a broad license for EPA to ignore the mandate to protect CBI, but rather a prudential limitation on the extent of protection.

Other aspects of FEPCA also protected confidential identities of inert ingredients from disclosure. Active ingredients and their percentage in formulated products had to appear on the pesticide label, but confidential inerts only had to be reported on the label as a total percentage.[32] FIFRA § 12(a)(2)(D) made it unlawful for any person to reveal "any information acquired by authority of this Act which is confidential under this Act," and FIFRA § 14(b) made disclosure of "formulas" in some cases a criminal act.

In addition, FIFRA § 3(c)(1)(D) provided an opportunity for data compensation for submitters of studies relied on by EPA in reviewing the application of a second applicant.

A Senate report on the FEPCA legislation commented that disclosure of health and safety studies without disclosure of trade secret identity information would serve the public need for information about the effects of pesticides under review by EPA: "Merely disclosing test results without identifying the pesticide will enable toxicologists and other scientists to evaluate the results that are claimed."[33]

B. Debate About Disclosure of Health and Safety Studies Under FIFRA

An issue arose under FEPCA about whether the health and safety studies submitted by applicants and registrants were also covered by FIFRA § 10(b). That issue had immediate relevance to pesticide applicants and registrants, since FIFRA § 3(c)(1)(D), which allowed EPA to use a previous applicant's studies in assessing the registration application of a second applicant, subject to data compensation, only applied if "such data is not protected from disclosure by section 10(b)." In other words, if those studies qualified as trade secrets, EPA could neither use them for registering competitive pesticides nor disclose them publicly.

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[31] Emphasis added. Note that "trade secrets or commercial or financial information obtained from a person and privileged or confidential" is a reference to exemption (b)(4) of FOIA. TSCA § 14(a) also relies on exemption (b)(4) of FOIA as the basis for protecting trade secret information from disclosure.

[32] As amended by FEPCA, FIFRA § 2(q)(2)(A) provides that a pesticide is misbranded if its label does not bear an "ingredient statement," a term defined in § 2(n) to include "the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticides ...." Thus, Congress did not require disclosure of the identity of inert ingredients.

[33] S. Rep. No. 92-270 at 20 (1972), 1972 U.S.C.C.A.N. 4092, 4104-05.

EPA took the position that it could use previously submitted studies for reviewing applications by other companies and could disclose health and safety studies, notwithstanding trade secret claims under section 10(b). In 1973, EPA issued a policy statement saying it planned to use the health and safety studies submitted by others in reviewing new applications under section 3(c)(1)(D) (i.e., notwithstanding its reference to section 10(b)).[34] In a 1975 proposal under FOIA, EPA proposed to exclude health and safety studies from confidentiality review procedures because "EPA believes as a matter of public policy, data concerning the effects of such pesticides on humans cannot qualify for confidential treatment," and because FIFRA suggested that "safety, toxicity, and efficacy test data should be available for public inspection."[35] However, information "[w]hich relates to formulas of products" would only be disclosable under limited circumstances.[36]

A key development occurred in March 1976, when the EPA General Counsel issued an opinion on the meaning of FIFRA § 10(b), saying that with certain exceptions, "I conclude that none of the test data in the categories listed above [including hazard data] are entitled to confidential treatment under §10(b)." Significantly, while finding that health and safety studies generally are subject to public disclosure, the EPA General Counsel held that disclosure of confidential chemical identities was both prohibited by FIFRA § 10(b) and not required by the public interest in disclosure:

> **Disclosure of the confidential formula of a pesticide, as defined above, would further neither the § 3(c)(1)(D) mandatory licensing scheme nor the § 3(c)(2) policy favoring data scrutiny.** However, disclosure would often reveal a firm's manufacturing process. Moreover, **confidential ingredient statements often have been held by courts to be trade secrets. Thus, such information should not be disclosed routinely.** If inquiry shows that the information is in fact confidential in the submitter's hands, and that its disclosure would be likely to cause substantial harm to the submitter's competitive position, the information is entitled to confidential treatment. Requests for disclosure of such information should be initially denied, citing 5 U.S.C. 552(b)(4), 5 U.S.C. 552(b)(3), and 7 U.S.C. 136h(b), and necessary further inquiry should be addressed to the data submitter.[37]

The General Counsel also found manufacturing and quality control information to be protected from disclosure under section 10(b), even when found in a health and safety study, as well as information supporting applications not yet approved. EPA cited this opinion in September 1976 in finalizing its 1975 FIFRA FOIA proposal.[38]

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[34] 38 Fed. Reg. 31862 (Nov. 19, 1973).
[35] 40 Fed. Reg. 21987, 21991 (May 20, 1975).
[36] Id. at 22001.
[37] Opinion No. 76-8 (Mar. 5, 1976), 1976 WL 25230 (E.P.A.G.C.) (emphasis added).
[38] 41 Fed. Reg. 36902, 36924 (Sept. 1, 1976). The final regulation, unamended since 1976, reads, "Information to which this section applies, and which relates to formulas of products, may be disclosed at any public hearing or in findings of fact issued by the Administrator, to the extent and in the manner authorized by the Administrator or his designee." 40 C.F.R. § 2.307(g)(4). This language is adapted from FIFRA § 10(a), as added by FEPCA.

Once the General Counsel issued his opinion, EPA began issuing notices informing registrants of its intention to make their studies available to the public. Several registrants sought to prevent disclosure by initiating lawsuits that challenged the General Counsel's opinion that health and safety studies were not confidential. The first such suit was filed in June 1976,[39] while the House bill with a provision that became section 14(b) was still in committee.[40]

C. Congressional Consideration of TSCA in 1975-1976

This debate under FIFRA figured significantly in the 1975 hearings, the 1976 House bill, and the enactment of TSCA § 14(b).

1. Stakeholder Comments on Disclosure of Health and Safety Studies

The issue of making health and safety studies public was raised numerous times by NGOs in their testimony to EPA in 1975. See, for example, the following statements:

> If science is to flourish the findings must be public. Since the dawn of the scientific revolution any suppression of scientific information has been regarded as antiscientific and repressive. Yet the walls of trade secrecy and corporate confidentiality restrict the dissemination of knowledge about the nature and properties of chemicals.[41]

> In particular, the final Subcommittee bill should specify that data from health and safety studies reported to the Administrator pursuant to sections 5 and 8 ... are not to be considered proprietary information or subject to protection as trade secrets. The effective implementation of a Toxic Substances Control Act requires that information concerning the hazardous nature of substance be available to the public.[42]

An NGO representative explicitly referenced the ongoing debate under FIFRA about whether health and safety studies were protected from disclosure as trade secrets:

> Under the Pest Control Act, reported out of this committee in 1972, toxicology data on pesticides is not a trade secret. Under the current bill, toxicology appears to be a trade secret, since there is no explicit provision for release ....[43]

Even as they advocated for disclosure of health and safety studies submitted under TSCA, however, several NGO representatives acknowledged that trade secret chemical identities

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[39] *See* A. Gabbay, The Confidentiality of Test Data Under FIFRA, 2 Harvard Environmental L. Rev. 378, 388 (1978) (citing cases).
[40] H.R. 14032, introduced May 26, 1976, reported with an amendment July 14, 1976, § 14(b), Legis. Hist. at 371-72.
[41] Statement of Alfred J. Fritsch, Center for Science in the Public Interest, 1975 House Hearings at 172.
[42] Statement of Jacqueline M. Warren, Environmental Defense Fund, 1975 House Hearings at 185.
[43] Statement of Peters D. Willson, National Wildlife Foundation, "Toxic Substances Control Act: Hearings Before the Subcommittee on the Environment of the Senate Committee on Commerce," 94th Cong., 1st Sess. (1975) (1975 Senate Hearings) at 158.

should remain confidential. One said that "secret formulas" should remain confidential, so long as effects information is made public:

> In summary, we support the language in the Brodhead Bill, which would withhold bona fide trade secrets such as secret formulas and secret manufacturing methods, but which would disclose health and safety data or publicly-known manufacturing methods.[44]

Another stated, "Well, we are certainly not advocating that legitimate trade secret information be turned over." However, he maintained that health and safety studies were not trade secrets.[45] A third said, "If there are studies which give you detailed information on the chemical itself, I think the companies might have a legitimate [trade secret] claim."[46]

Industry also emphasized the importance of protecting trade secrets, particularly confidential chemical identities. For example, one industry represented stated:

> Legislation should offer strict control of manufacturers' trade secrets. The chemical entity's molecular structure, proposed usage and amounts to be manufactured should not be published for all to see and use. Similarly, disclosure of detailed information on formulations, that is, a mixture of materials, should be avoided. Disclosure of all such information can have particularly severe competitive repercussions abroad, in those foreign countries whose manufacturers are not or do not feel restricted by patents or other agreements.[47]

A significant development occurred in September 1975 with the release of a report by the National Academy of Sciences, which EPA had commissioned so as to influence the drafting of TSCA. The report recommended that health and safety studies be made publicly available, but not proprietary information in those studies:

> *Any information available to an agency on the hazards of a chemical that is regulated by that agency should not be considered proprietary and should be available for public inspection in a timely fashion during and after the decision-making process.*

The report focused on effects and exposure data such as "data on the intrinsic toxicological properties of a given substance" and "data on patterns and quantities of use." The report agreed, however, that "proprietary" data should be protected from disclosure unless essential to evaluation of the hazard.[48] While the report did not refer specifically to proprietary chemical identities, EPA subsequently addressed that issue, finding that a structurally-descriptive generic

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[44] Statement of Anita Johnson, Public Citizen Health Research Group, 1975 House Hearings at 355.
[45] Statement of Dr. Sidney Wolfe, Health Research Group, 1975 Senate Hearings at 168-69.
[46] Statement of Jacqueline Warren, Environmental Defense Fund, 1975 Senate Hearings at 171.
[47] Statement of Orin Smith, M. & T. Chemical Co., 1975 Senate Hearings (Part 2) at 121.
[48] National Academy of Sciences, Decision Making for Regulating Chemicals in the Environment (1975), http://books.google.com/books?id=1zArAAAAYAAJ&printsec=frontcover&dq=%22Decision+Making+for+Regulating+Chemicals+in+the+Environment+%22&source=bl&ots=0KpnIvNpTP&sig=-pNWX4LW5HFJCqxwSvUYPUrKiHY&hl=en&ei=gfexTZTZOKbf0QHxtqGKCQ&sa=X&oi=book_result&ct=result&resnum=1&ved=0CBoQ6AEwAA, at 28 (italics in original).

name can mean that disclosure of the specific chemical identity "is not necessary to interpret a health and safety study."[49] See section VI of this paper. The report's recommendation was quoted in the TSCA hearing statements of two NGO representatives.[50]

2. The 1976 Provision on Disclosure of Health and Safety Studies

In May 1976, two months after issuance of the General Counsel's opinion, the House responded to these comments by including in a new TSCA bill a provision that would explicitly exclude health and safety studies from confidentiality protection, H.R. 14032.[51] With minor editing, that provision became TSCA § 14(b). The House report accompanying H.R. 14032 explained:

> The purpose of subsection (b) is to clarify that health and safety information is not entitled to confidential treatment either under subsection (a) or the Freedom of Information Act. The subsection should not be construed to imply that in the absence of such a provision, health and safety information would be entitled to such confidential treatment.[52]

This statement is a clear reference to the then-ongoing debate under FIFRA of whether health and safety studies were protected from disclosure as trade secrets, and reflected the opinion of the EPA General Counsel that they were not so protected.

The House bill and report did not, however, endorse public disclosure of confidential information of competitive value that might be contained in the health and safety studies. Notwithstanding section 14(b), the House report provided assurance that section 14 would protect the "competitive position" of submitters of information to EPA:

> However, the Committee recognizes that some information which the Administrator may obtain will be of tremendous competitive value to the person providing it. Accordingly, section 14 contains specific prohibitions against release of such information so that the competitive position of those supplying the information will be protected.[53]

It would be inconsistent with this statement that "section 14" protects "the competitive position of those supplying the information" to consider that the exemption from confidentiality protection for health and safety studies mandates disclosure of competitively sensitive composition information. While section 14(b) does not list composition information specifically as exempt, neither does it specifically mandate disclosure of composition information. Indeed, in

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[49] 40 C.F.R. §§ 720.90(c)(3), 725.92(c)(2).
[50] Statement of Linda M. Billings, Sierra Club, in 1975 House Hearings at 165, and statement of Jacqueline M. Warren, Environmental Defense Fund, 1975 House Hearings at 178.
[51] H.R. 14032, introduced May 26, 1976, reported with an amendment July 14, 1976, § 14(b), H.R. Rep. No. 94-1341 at 176-77 (1976), Legislative History of the Toxic Substances Control Act (1976) (Legis. Hist.) at 371-72.
[52] H.R. Rep. No. 94-1341 at 51, Legis. Hist. at 458.
[53] H.R. Rep. No. 94-1341 at 50 (1976), Legis. Hist. at 457.

describing what a health and safety study is, the Conference Committee emphasized information related to effects, saying nothing about composition information:

> It is intended that the term be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included but other information relating to the **effects** of a chemical substance or mixture on health and the environment is also included. Any data which bears on **the effects** of a chemical substance on health or the environment would be included.[54]

The EPA General Counsel opinion specifically found in the FIFRA context that non-disclosure of confidential composition information would not impact the purposes of public disclosure of health and safety studies; the same reasoning applies to the TSCA context as well.

As proposed and adopted, section 14(b) has an exemption for "portion of mixture" information. The House report commented on this provision:

> In referring to data "disclosing the portion of the mixture comprised by any of the chemical substances in the mixture," the Committee **intends to protect confidential trade secret information respecting the specific formulation of a mixture**. However, the Committee does not intend to prohibit the Administrator from disclosing the chemical substances comprising the mixture **by their order of quantity in the mixture**.[55]

The "specific formulation of a mixture" clearly refers to both the names of the ingredients as well as their percentages, as seen in the FEPCA references to protecting "information relating to formulas of products"[56] and "information relative to formulas of products,"[57] where those provisions have always been interpreted to include the identities of confidential inerts as well as their respective percentages.

The reference to "order of quantity in the mixture" is a reference to the Fair Packaging and Labeling Act (FPLA), enacted ten years earlier, which mandates that ingredients in consumer products be disclosed on labels "in order of decreasing predominance" while protecting trade secrets. It provides that the Federal Trade Commission (FTC) or Food and Drug Administration (FDA) may promulgate regulations to:

> require that the label on each package of a consumer commodity …. bear … in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed **in order of decreasing predominance**, but nothing in this paragraph shall be deemed to require that any trade secret be divulged ….[58]

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[54] H.R. Rep. No. 94-1679 at 58 (1976), Legis. Hist. at 671 (emphasis added).
[55] H.R. Rep. No. 94-1341 at 51 (1976), Legis. Hist. at 458 (emphasis added).
[56] FIFRA § 10(b).
[57] FIFRA § 14(b)(3)/
[58] Fair Packaging and Labeling Act, Pub. L. 89-755 (1966), § 5(c)(3), 15 U.S.C. § 1454(c)(3) (emphasis added).

In other words, the order of ingredients by decreasing predominance was not considered a trade secret, but such mandated disclosure was coupled with a prohibition on disclosure of trade secrets (both ingredient names if trade secret and portion of mixture information). In 1973, FDA adopted regulations for cosmetic labeling under the FPLA which required disclosure of intentionally added ingredients "in descending order of predominance," but with a mechanism whereby FDA could rule on claims that ingredient identities were trade secrets, in which case they would be identified as "other ingredients."[59] In 1975, FDA amended those regulations[60] and made them effective starting in 1976.[61] Thus, the issue of ingredient disclosure in descending order was a current topic when the provision that became section 14(b) was introduced and considered.

In short, the reference to disclosure of mixture components "by their order of quantity in the mixture" is not an implicit call for public disclosure of trade secret chemical identities, as EPA has suggested.[62] Rather, it is a repetition of a decade-old legislative determination that order of predominance is not a trade secret. Since that determination from the FPLA contained, within the same sentence, a prohibition on disclosure of trade secret ingredient names, the reference in section 14(b) to "order of quantity" actually strengthens the conclusion that TSCA protects trade secret chemical identities.

During Senate consideration of the conference-approved bill, Senator Magnuson referred to "mixture composition" information as an exception to section 14(b).[63] This statement by a member of the Conference Committee, one of the leading proponents of TSCA in the Senate, indicates the expectation that information in health and safety studies on "mixture composition," not just portion of mixture information, would not be disclosed as part of health and safety studies.

In summary, the legislative history of TSCA demonstrates continued Congressional concern for protecting critical competitive information from public disclosure, specifically including trade secret or confidential chemical identity information.

V. TSCA as Part of a Series of Statutes Mandating Disclosure of Health and Environmental Information on Chemicals But Not Confidential Chemical Identities

TSCA was the second of six chemical-related statutes that Congress enacted within a fifteen-year period to mandate that health and environmental information submitted to EPA be made public. Besides TSCA, the statutes include the Federal Environmental Pesticide Control Act of 1972 (FEPCA); the Federal Pesticide Act of 1978 (FPA); the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA); the Emergency

[59] 21 C.F.R. § 1.205(a), 38 Fed. Reg. 28912, 28913 (Oct. 17, 1973). FTC has not adopted implementing regulations. See 36 Fed. Reg. 12284, 12286 (June 30, 1971), which reserved 16 C.F.R. §§ 502.200-502.299 ("Common Name and Ingredient Listing").
[60] 40 Fed. Reg. 8918 (Mar. 3, 1975). The current provision is codified at 21 C.F.R. § 701.3.
[61] 40 Fed. Reg. 8924 (Mar. 3, 1975).
[62] 44 Fed. Reg. 2242, 2256 (Jan. 10, 1979); EPA, Comment and Response Document for Revised Policy Statement of Section 8(e) of TSCA (2003), OPPT-2002-0067-0002, Docket No. OPPT-2002-0067, at 35-36.
[63] Cong. Rec., Sept. 28, 1976, Legis. Hist. at 730.

Planning and Community Right-to-Know Act of 1986 (EPCRA); and the Superfund Amendments and Reauthorization Act of 1986 (SARA), Title I. These other statutes all protect confidential competitive information in or underlying the health and environmental information from disclosure. In light of these statutes, it is even clearer that TSCA does so also.

A. Federal Environmental Pesticide Control Act of 1972

As noted in Section III.A. above, FEPCA required disclosure of health and safety studies submitted to EPA under FIFRA, but it protected confidential competitive information from disclosure, using the standards of FOIA exemption 4. Several provisions explicitly protected confidential formula information, including the identity of confidential inerts, from disclosure.

B. Federal Pesticide Act of 1978

The controversy under FEPCA about whether health and safety studies were protected from disclosure continued past the enactment of TSCA. In 1978 with FPA, Congress applied the solution adopted in TSCA § 14(b) to FIFRA, saying that health and safety studies were not protected from disclosure, but proprietary information in those studies, including trade secret identities of inerts, were protected from disclosure, except under unusual circumstances.

Twelve months after enactment of TSCA, a House committee reported a FIFRA bill which would:

> Clarify the prohibition against public disclosure of "trade secret" information obtained by the Environmental Protection Agency through the registration process. Data showing test results would not be considered "trade secrets." Data relating to the manufacturing process or quality control process, **or to the identity or percentage quantity of inert ingredients** ... could not be made public unless the Administrator determined it necessary to protect against an unreasonable risk of injury to health or the environment subject to prescribed procedures ....
>
> H.R. 8681 also clarifies the trade secret provisions of the Act by **balancing the legitimate right of the public to know the basis for agency decisions and the right of a business to see that the manufacturing process and other trade secret information controlled by the Act are not disclosed to the commercial advantage of competing business owners** ....
>
> This provision is intended to protect the secrecy of manufacturing methodology, the **confidential formula of a formulated product**, and the means of analysis of a formulated product to determine its inert ingredients.[64]

In 1978, Congress accepted the House language and added a new FIFRA § 10(d) that declared that health and safety studies submitted under FIFRA in connection with registered

[64] H. Rep. No. 95-663, at 16, 18 (1977), 1978 U.S.C.C.A.N. 1989, 1991-92, 2005-06 (emphasis added).

pesticides "shall be available for disclosure to the public." However, that provision was limited to include the limitations on disclosure identified in the General Counsel's 1976 opinion:

> *Provided further*, That **this paragraph does not authorize the disclosure of information that--**
>
> (A) discloses manufacturing or quality control processes, ...
> (C) **discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide**,
>
> unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.[65]

In other words, Congress required disclosure of health and safety studies, but not the trade secret or confidential identities of the chemicals tested, except where EPA's balancing of the competing interests required a different outcome. This is the same resolution that Congress provided in TSCA § 14, two years earlier, only somewhat less explicitly.

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

Two years later, in 1980, Congress enacted CERCLA. Section 104(e)(2)(A) provided 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.[66] This provision provided broad protection for trade secret chemical identities, similar to that in FEPCA and in TSCA bills prior to the introduction of the 1976 House bill.

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.[67] The provision on trade secrets, section 322, protects from public disclosure only "specific chemical identities (including chemical name and other specific identification)."[68] Where the identity of a chemical is withheld from the public, information about the adverse effects of the chemical must be disclosed.[69]

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 chemicals whose identities are withheld, section 322

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[65] Federal Pesticide Act of 1978, Pub. L. 95-396 (1978), § 15(2), 7 U.S.C. § 136h(d) (emphasis added).
[66] Pub. L. 96-510 (1980), § 104(e)(2)(A), 42 U.S.C. § 9604(e)(7)(A).
[67] EPCRA is Title III of SARA, Pub. L. 99-499, 42 U.SC. § 11001 et seq.
[68] EPCRA § 322(a)(1), 42 U.S.C. § 11042(a)(1).
[69] EPCRA § 322(h), 42 U.S.C. § 11042(h).

requires that the submitter identify "the generic class or category" of the chemical.[70] An up-front substantiation of trade secrecy is required, including a showing that the chemical identity "is not readily discoverable through reverse engineering,"[71] 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 § 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.[72]

More than FIFRA or TSCA, EPCRA is intended to provide the public with information about chemicals. 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 reached in TSCA § 5(d)(2).

E. Superfund Amendments and Reauthorization Act of 1986, Title I

EPCRA is Title III of SARA and essentially a stand-alone statute. Title I amended CERCLA to cut back on the broad protection from disclosure granted by simple reliance on the Trade Secrets Act. 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.[73] 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."[74] Specific chemical identities, however, could be protected from disclosure.

F. Implications for TSCA

Each of these five statutes regulating chemicals mandated disclosure of health and safety information, but protected confidential chemical identities from disclosure, either explicitly or by implication, with provisions similar to what appears in TSCA § 14. None prohibited trade secret claims for chemical identities, although some imposed criteria for those claims.

TSCA similarly provides broad protection for trade secrets and confidential information in section 14(a). Its main reservation from that protection, in section 14(b), is for health and

[70] EPCRA § 322(a)(2), 42 U.S.C. § 11042(a)(2).
[71] EPCRA § 322(b), 42 U.S.C. § 11042(b).
[72] H. Conf. Rep. No. 99-962 (1986) at 303, 1986 U.S.C.C.A.N. 3276, 3396.
[73] Id. at 197, 1986 U.S.C.C.A.N. at 3290.
[74] Pub. L. No. 99-499 (1986), § 104(n), amending CERCLA § 104(e) (adding CERCLA § 104(e)(7)(E) and (F)).

safety studies, which are not protected from disclosure. This limitation is similar to the requirement in several of these statutes that health and environmental effects data must be made public. Just as none of those statutes required disclosure of confidential chemical identities, so TSCA does not do so either.

VI. EPA Recognition of Its Need to Balance Disclosure of Health and Safety Studies With Protection of Trade Secret or Confidential Chemical Identities

Early in its implementation of TSCA, EPA recognized that "Congress was clear in section 14 that confidentiality should be preserved to the maximum extent practicable without impairing the regulatory scheme of TSCA."[75] Despite the language of section 14(b), it concluded:

> Accordingly, EPA is not persuaded that Congress intended the Agency to take a mechanical approach to disclosure of a specific chemical identity as part of a health and safety study.[76]

The 1983 final PMN rule developed the idea that, consistent with section 14(b), EPA could balance the public's interest in access to health and safety information with industry's competitive interest in protecting trade secret chemical identities. This balancing was to be achieved through disclosure of structurally-descriptive generic names, an approach endorsed by TSCA § 5(d)(2) and proposed in the 1972 Senate report.[77] The preamble stated:

> As EPA stated in the January 1979 proposal, the Agency considers the specific chemical identity always to be part of a health and safety study even when it does not appear in the study. Consequently, the chemical identity would be subject to the disclosure requirements of section 14(b). However, in many cases the chemical identity is one of the most commercially sensitive pieces of information in the section 5 notice. Because of the substantial concern expressed by industry about the harm of disclosing confidential chemical identities, **EPA explored ways of limiting the commercial harm of such disclosure while still meeting the requirements of section 14(b) of TSCA and providing the public with adequate information about health and safety studies** ....
>
> This issue generated a great deal of comment. Industry has expressed its concerns about disclosure of confidential chemical identities at any time, while public interest groups and others are concerned that health and safety studies would be meaningless without knowledge of the specific chemical identity involved. In an attempt to meet both these concerns, **EPA has chosen an approach that balances the need for confidentiality, the need to understand health and safety studies, and the provisions of TSCA** ....

[75] 42 Fed. Reg. 64572, 64591 (Dec. 23, 1977).
[76] 44 Fed. Reg. 2242, 2256 (Jan. 10, 1979).
[77] S. Rep. No. 92-783 at 19-20 (1972).

> Under § 720.90(c) of the rule, if any health and safety studies have been submitted for the chemical substance in question, the specific chemical identity will be held confidential only if disclosure would reveal confidential manufacturing or processing processes or the confidential proportions of substances in a mixture, or if the specific chemical identity is not necessary to interpret any of the studies.
>
> This solution will result in disclosure of a confidential chemical identity only when it is necessary to interpret a health and safety study, unless disclosure would reveal confidential process or mixture information that is protected under section 14(b). This meets concerns expressed by both industry and public interest groups. Industry was concerned that a rule mandating disclosure even when disclosure would not serve any public interest would unnecessarily penalize companies conducting health and safety studies. On the other hand, **public interest groups were concerned that disclosure of health and safety studies without the identity of the substance involved would be meaningless if knowledge of the specific identity were necessary to understand the study.** Under this approach, companies will be able to present arguments that disclosure of the specific chemical identity is not necessary to interpret a study and, at the same time, members of the public requesting access to studies will be able to argue why disclosure of the specific identity is necessary.
>
> This solution to the issue of confidential chemical identities also has an impact on development of generic chemical names. Companies that claim specific chemical identity confidential in their notices who wish to argue that knowledge of the specific identity is not necessary to interpret their health and safety studies are encouraged to choose generic names which are sufficiently specific to interpret their health and safety studies. **Sufficiently specific generic names will tend to support arguments that disclosure of the specific chemical identity is not necessary to understand the study.**[78]

In other words, EPA recognized that, like other proprietary commercial information, confidential chemical identities (including those that do not reveal process or portion of mixture information) in a health and safety study fall within the protection of section 14(a). That protection mandate must be balanced against the disclosure mandate of section 14(b). The competing interests can and should be balanced through disclosure of appropriate generic names.

A decade later, EPA reaffirmed this approach in the preamble to 1993 proposed amendments to the PMN rules[79] and in the preamble to the 1994 proposed rule on microbial products of biotechnology.[80]

EPA has announced that it plans to initiate rulemaking to delete these generic name provisions in its regulations, apparently on the basis that under section 14(b) it had no authority

[78] 48 Fed. Reg. 21722, 21739-40 (May 13, 1983) (emphasis added).
[79] 58 Fed. Reg. 7661, 7666 (Feb. 8, 1993).
[80] 59 Fed. Reg. 45526, 45553-54 (Sept. 1, 1994).

to adopt them.[81] EPA certainly had authority to adopt those provisions, just at it had authority under section 8(d) to exclude proprietary information such as company name, financial statistics, and product codes from studies otherwise disclosed to the public.[82] EPA's authority for all these provisions is section 14(a). All this information may be a part of a study submitted under TSCA, but it is nevertheless protected from disclosure. Because chemical identity can also impact public understanding of the study, however, EPA properly adopted provisions for disclosure of appropriate generic names so as to balance the competing interests.

VII. Steps EPA Should Take to Protect Confidential Chemical Identities

In light of the information provided in this paper, EPA should take the following specific steps to provide appropriate protection for confidential chemical identities in submitted health and safety studies and in other contexts.

A. EPA Should Revise Its Regulations and Guidance to Allow Confidentiality Claims for Confidential Chemical Identities in Studies Where Appropriate

EPA's regulations and guidance currently preclude all or most confidentiality claims for chemical identities in or underlying studies.[83] In light of the foregoing discussion, EPA should amend those regulations and revise that guidance to allow CBI claims for chemical identities where appropriate.

EPA's Spring 2011 Regulatory Agenda identifies a planned initiative, RIN 2070-AJ87, to adopt amendments to its PMN and MCAN rules to delete provisions allowing CBI claims for confidential chemical and microorganism identities in data from health and safety studies submitted under TSCA prior to the commencement of manufacture. It targets 40 C.F.R. §§ 720.90(c) and 725.92(c). EPA submitted this proposal to the Office of Management and Budget on December 27, 2011. EPA should not proceed with this initiative.

Section VI of this paper discusses EPA's reasoning for adopting those requirements in the 1980s and 1990s. At the time, EPA took extensive comments and thoroughly considered the scope of section 14 and its legal authority. Nothing has occurred since then that should cause EPA to conclude now, 35 years after enactment of TSCA, that its longstanding interpretation of section 14 allowing confidentiality claims under strictly limited conditions is inconsistent with TSCA and that section 14 necessitates deleting those regulatory provisions.

[81] EPA, Spring 2011 Regulatory Agenda (July 7, 2011) at 277.
[82] See 40 C.F.R. § 716.55(a)(3).
[83] See 40 C.F.R. § 716.55 (section 8(d) regulations); 40 C.F.R. § 720.90(b) (PMN regulations); 40 C.F.R. § 725.92(b) (MCAN regulations); 68 Fed. Reg. 33129, 33136 (June 3, 2003) and 75 Fed. Reg. 3462 (Jan. 31, 2010) (section 8(e) guidance); 75 Fed. Reg. 29754 (May 27, 2010) (general guidance).

B. EPA Should Consider Requiring Generic Names for Trade Secret or Confidential Chemical Identities in Health and Safety Studies and Requiring Up-Front Substantiation of CBI Claims for Studies

EPA already requires up-front substantiation for CBI claims in studies submitted under sections 4, 5, and section 8(e).[84] EPA does not require up-front substantiation for CBI claims for submissions under section 8(d)[85] or section 5(h)(4).[86] It should require up-front submission of all CBI claims for chemical identities.

A key reason for EPA's current position that it must disclose trade secret or confidential chemical identities in studies is its belief that without some knowledge of what chemicals were studied, the public has no way to evaluate the study. Steve Owens, then Assistant Administrator for Office of Chemical Safety and Pollution Prevention, has said, "[a] health and safety study with the chemical name kept secret is completely useless to the public."[87] This position is contradicted by EPA's findings in 1983, 1993, and 1994 that in some circumstances "[t]he specific chemical identity is not necessary to interpret a health and safety study," as explained in Section VI above.

As EPA previously recognized, in order to make studies meaningful to the public, it is not necessary to require disclosure of chemical identities in every case. Instead, requiring submission of structurally-descriptive generic names can provide sufficient information to make studies useful while still protecting trade secret or confidential identities. Such generic names can provide the public with detailed information about the structure of the chemical, thus allowing linkage to the scientific literature on similar chemicals and permitting an assessment of the suitability of study methods. In contrast, specific chemical names are sometimes of little value to the public, since there may be no published scientific literature on the specific chemical, particularly in the case of new or recently developed chemicals.

There is ample Congressional precedent for the disclosure of structurally-descriptive generic names instead of specific chemical identities. The use of such generic names is called for in section 5(d)(2), in EPCRA, and in SARA Title I. As noted above, the legislative history of the EPCRA generic name provision cited EPA's experience with generic names under TSCA with approval.

Aside from the examples cited above, EPA has numerous times required disclosure of generic names instead of specific chemical identities as a way of balancing the competing interests. EPA chose to require the use of generic names for entries in the confidential TSCA

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[84] 40 C.F.R. §§ 720.85(b)(3)(iv) (PMNs), 725.94 (MCANs), 790.7(c) (section 4 submissions), and 68 Fed. Reg. 33129, 33140 (June 3, 2003) (section 8(e) submissions).
[85] See 40 C.F.R. § 716.55.
[86] See 40 C.F.R.§ 723.50(l), 723.175(k).
[87] EPA press release, "EPA Removes Confidentiality Claims for More Than 150 Chemicals / Part of continuing effort to protect Americans' health by increasing access to chemical information" (June 8, 2011), available at http://yosemite.epa.gov/opa/admpress.nsf/a543211f64e4d199852573590040442/9f7964fcbca3824a852578a900574cea!OpenDocument.

Inventory,[88] even though "Congress did not seem to contemplate that the fact that certain chemical substances are manufactured or processed for commercial purposes would be claimed as confidential." EPA explained that in deciding to require the use of generic names it "had to balance the competing concerns of section 14 and sections 8(a) and 5(b)."[89] EPA has adopted generic name requirements in its regulations implementing section 5,[90] section 8(b),[91] and EPCRA § 322.[92]

As articulated in the PMN and MCAN regulations, EPA has identified the key question as whether the specific chemical identity is "necessary to interpret a health and safety study." This is a different question than whether the public must have the chemical substance's CAS number in order to access the published toxicological literature of other studies on the same chemical substance. That makes sense, particularly with respect to recent PMN substances, which are highly unlikely to be the subject of published toxicological literature. In that context, a generic name can provide sufficient information to interpret that study.

Moreover, a generic name may be used to access the toxicological literature on structurally-related compounds. In many cases, a search on Toxline, a common tool for searching the toxicological literature, using a CAS number or CAS name will identify few, if any, studies. In contrast, searching on a generic name for the same chemical substance may identify a significant number of studies. This may be seen by searching on Toxline using specific chemical names, CAS numbers, and generic names for the same chemicals.

In 2009, EPA changed 530 chemical identities on the TSCA Inventory from confidential to non-confidential.[93] EPA had previously associated generic names with those chemical substances. In many cases, a Toxline search for a generic name for a declassified substance identified more studies than did Toxline searches for the corresponding CAS number and CAS name. For example:

- EPA associated the generic name "alkyl salicylaldehyde" with benzaldehyde, 5-dodecyl-2-hydroxy-, CAS No. 77635-21-3.
    - A Toxline search on "salicylaldehyde" identified 279 studies.
    - Toxline searches on the CAS name and on the CAS number identified no studies.
- EPA associated the generic name "silane, dichloro(chloralkyl)alkyl-" with silane, dichloro(3-chloro-2-methylpropyl)methyl-, CAS No. 1628-11-1.
    - A Toxline search on "dichlorosilane" identified 27 studies.
    - Toxline searches on the CAS name and on the CAS number identified no studies.

[88] 40 C.F.R. § 710.7(f), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977).
[89] Id. at 64590. See 44 Fed. Reg. 2242, 2255 (Jan. 10, 1979) (similar language in proposed PMN provision on generic names).
[90] 40 C.F.R. §§ 720.80(a)(2), 721.1(c), 723.50(l)(2), 725.85(a)(3),); former 40 C.F.R. § 723.250(f)(2)(x), 49 Fed. Reg. 46066, 46088 (Nov. 21, 1984).
[91] Former 40 C.F.R. § 710.7(e)(ii), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977).
[92] 40 C.F.R. § 350.5(f).
[93] 74 Fed. Reg. 37224 (July 28, 2009).

- EPA associated the generic name "disubstituted quinolone" with 2,3-quinolinedicarboxylic acid, CAS No. 643-38-9.
    - A Toxline search on the generic name identified 21 studies.
    - Toxline searches on the CAS name and on the CAS number identified one study.
- EPA associated the generic name "alkylpridinium halide" with pyridinium, 1-dodecyl-, bromide (1:1), CAS No. 104-73-4.
    - A Toxline search on "alkylpridinium" identified 38 studies.
    - Toxline searches on the CAS name and CAS number identified 13 studies.
- EPA associated the generic name "pyrimidinamine, disubstituted" for two of the declassified identities.
    - A Toxline search on "pyrimidinamine" identified 118 studies.
    - One of the declassified chemical substances with that generic name was 2-pyrimidinamine, 4,6-dimethoxy-, CAS No. 36315-01-2. Toxline searches on the CAS name and on the CAS number identified one study.
    - The other declassified chemical substance with that generic name was 2-pyrimidinamine, 4-chloro-6-methoxy-, CAS No. 5734-64-5. Toxline searches on the CAS name and on the CAS number identified two studies.

In short, generally, a structurally-descriptive generic name is sufficient for interpreting a submitted health and safety study, and that same generic name can be more effective than the specific chemical name or CAS number for identifying studies on the same or related compounds in the toxicological literature.

C. EPA Should Work With Industry and NGOs to Improve Development of Generic Names

EPA has complained that "CBI procedures consume an inordinately large amount of Agency resources that may not be justified."[94] In particular, negotiations between EPA and a submitter about appropriate generic names may be onerous. The solution is for EPA, industry, and NGOs to work together to improve the process for identifying appropriate generic names and thereby expedite those negotiations.

EPA has provided some guidance on how to develop generic names,[95] but that guidance has not been updated in over 25 years. As EPA has recognized, the guiding principle should be that "[t]he proposed generic name must be only as generic as necessary to protect the identity of the particular chemical substance."[96] Congress endorsed that principle in EPCRA and SARA Title I, where it called for disclosure of "the generic class or category" rather than a highly-detailed generic name. The legislative history of that provision in EPCRA states:

> The generic class or category of chemical may be defined as broadly as is needed to protect the specific chemical identity from disclosure, but, consistent with the purpose of

[94] 58 Fed. Reg. 7661, 7666 (Feb. 8, 1993).
[95] "Generic Names for Confidential Chemical Substance Identities," Appendix B to Vol. 1 of the Toxic Substances Control Act Chemical Substance Inventory (1985), http://www.epa.gov/opptintr/newchems/pubs/genericnames.pdf.
[96] Id. at 64591.

this title to provide information to the community and the public, it should be defined no more broadly than necessary to afford such protection.[97]

EPA now has decades of experience in developing generic names. It should work with industry and NGOs to memorialize that experience in the form of detailed guidance. Such guidance, reflecting the input of industry, will go a long way toward reducing the resources needed for determining appropriate generic names.

D. EPA Should Allow CBI Claims for Chemical Identities in Studies Where Appropriate

EPA has announced that "[w]here a chemical identity [in or underlying a study] does not explicitly contain process information or reveal portions of a mixture, EPA expects to find that the information would clearly not be entitled to confidential treatment."[98] As explained above, EPA should follow the requirements of section 14(a) and in appropriate cases accord CBI protection for those chemical identities. As it reviews studies with CBI claims for chemical identities (e.g., in its ongoing review of historical CBI claims), EPA should allow those claims, at least where substantiation of continuing CBI status is provided. EPA should consider requiring disclosure of an appropriate generic name as a condition for non-disclosure.

E. EPA Should Allow CBI Claims for Chemical Identities in R&D Mixtures Where Appropriate

Of particular concern to much of industry is the situation where product formulations under development are tested, then those studies are submitted under TSCA. In almost all cases, the formulations contain only existing chemical substances, but the combination of the particular components may be highly innovative. EPA has indicated that it expects to release to the public chemical identities in or underlying studies submitted under section 8(e) where the chemical identities appear on the public TSCA Inventory. Presumably, this includes mixtures of chemical substances, all of whose identities appear on the public Inventory. Where those mixtures are for R&D products, however, EPA should not require disclosure.

As explained in section III.F of this paper, section 14(b) of TSCA applies to a submitted study with respect to "any chemical substance **or mixture** which, on the date on which such study is to be disclosed has been offered for commercial distribution." A mixture that has not "been offered for commercial distribution" at the time of disclosure because it is R&D or has otherwise never been commercialized is not covered by that provision, even if its components are on the public Inventory. Accordingly, EPA should not disclose its components just because a study on that mixture has been submitted. EPA did disclose the components of such a mixture recently in connection with a section 8(e) submission by Proctor & Gamble, 8EHQ-94-13020.[99] There the original submission indicated that the mixture was the subject of R&D.

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[97] H. Conf. Rep. No. 99-962 (1986) at 303, 1978 U.S.C.C.A.N. 3276, 3396.
[98] 75 Fed. Reg. 29754 (May 27, 2010).
[99] Available at http://www.epa.gov/oppt/existingchemicals/pubs/declassified/actions/6-8-2011/8EHQ-94-13020_89110000315.pdf.

CONCLUSION

EPA is incorrect in interpreting section 14(b) to require disclosure of trade secret or confidential chemical identities in or underlying most health and safety studies except where their disclosure would also reveal process or portion of mixture information. Instead, section 14(a) protects trade secret chemical identities, even in or underlying studies. Section 14(b) is directed at health and safety information, not trade secret or confidential chemical identities.

EPA should continue to balance the interest in disclosure of health and safety information with the interest in protecting trade secrets and confidential information. One way favored by Congress to do this balancing is to require development of generic names, which would be disclosed in lieu of specific chemical identities.