March 1, 2012

Cass R. Sunstein
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
1650 Pennsylvania Avenue, N.W.
Washington, DC 20503

By Email & Hand Delivery

Re: CBI: PMN Amendments Claiming Chemical and Microorganism Identity as Confidential in Data From Health and Safety Studies Submitted Under TSCA Prior to the Commencement of Manufacture

Dear Administrator Sunstein:

The BlueGreen Alliance, Breast Cancer Fund, Clean Water Action/Clean Water Fund, Environmental Defense Fund, Earthjustice, National Medical Association, Science & Environmental Health Network, and Women's Voices for the Earth write to express support for the U.S. Environmental Protection Agency's (EPA's) 2010 policy and 2011 regulatory proposal for the review of confidentiality claims related to chemical or microorganism identity in data from health and safety studies submitted to the EPA under the Toxic Substances Control Act (TSCA). *See Regulatory Review Dashboard,* RIN 2070-AJ87, Office of Information and Regulatory Affairs, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201110&RIN=2070-AJ87 (last visited Feb. 28, 2012).[1] EPA's actions are intended to align review of confidential business information (CBI) claims with the statutory language of TSCA and bring long overdue daylight to health and safety studies, as intended by the statute.

Despite TSCA's explicit language making clear that data from health and safety studies are not protected from disclosure by claims of confidentiality, EPA historically accepted such claims without review even as to health and safety data, thereby preventing disclosure of health and safety information, including chemical identity. In January 2010, EPA announced a new general practice of reviewing submissions under TSCA Section 8(e) (substantial risk notices) for claims that the identity of a chemical listed on the public portion of the Chemical Substances

[1] Since the proposed rule has not yet been published for notice and comment, our information about this proposed rule is gleaned from the online description at www.reginfo.gov.

Inventory of TSCA (the Inventory) is CBI. *See* Claims of Confidentiality of Certain Chemical Identities Submitted under Section 8(e) of the Toxic Substances Control Act, 75 Fed. Reg. 3462 (Jan. 21, 2010). In accordance with the January announcement, where a health and safety study submitted under Section 8(e) involves a chemical identity listed on the public portion of the Inventory, EPA now reviews such claims and "expects to find that the chemical identity clearly is not entitled to confidential treatment." *Id*. In May, 2010, EPA announced that it would initiate a general practice of reviewing confidentiality claims for chemical identities in all health and safety studies, and in data from health and safety studies submitted under TSCA even if they are not listed on the public Inventory. *See* Notice of General Practice of Reviewing Confidentiality Claims for Chemical Identities in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the Toxic Substances Control Act, 75 Fed. Reg. 29,754 (May 27, 2010) (the May Notice). The current proposal to amend regulations related to disclosure of health and safety information submitted to EPA during the premanufacture notice (PMN) process would build upon EPA's prior efforts to evaluate CBI claims in the context of health and safety studies in a manner that is consistent with the language and intent of TSCA Section 14.

In a recent White Paper made public on January 19, 2012, the American Chemistry Council (ACC) makes sweeping assertions about the potential impact of EPA's policy, not only arguing against EPA's proposed regulations related to health and safety studies submitted during the PMN process, but launching a broadside attack on the policies announced by EPA in 2010. *See generally* ACC White Paper, TSCA Protects Confidential Chemical Identities in Health and Safety Studies from Disclosure (January 19, 2012) (ACC White Paper). As discussed below, ACC's argument has a number of searing flaws:

- Perhaps most significantly, ACC ignores the plain language of TSCA and substitutes a balancing test weighing interests against one another. Section 14 of TSCA, however, contains a general provision governing disclosure of data outside of the context of health and safety studies, 15 U.S.C. § 2613(a), which protects information that is exempt from disclosure under the Freedom of Information Act as a trade secret, and another explicit provision applicable to "Data from health and safety studies," 15 U.S.C. § 2613(b), which makes clear that any data reported to EPA from a health and safety study is not protected from disclosure unless it qualifies as CBI and reveals process or, in the case of a mixture, portion information. Information about chemical identity in health and safety studies, thus, is not protected unless it is CBI and would reveal process or portion information, a determination that should be made through the substantiation process as EPA reviews CBI claims.
- ACC mischaracterizes the legislative history of TSCA. The legislative record makes clear that Congress heard testimony about the protection of CBI and intended to allow the disclosure of chemical identity within health and safety studies. *See, e.g.*, H.R. Rep. No. 94-1341, at 51 (1976), Legis. Hist. at 458 ("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….") (emphasis added).

- ACC's proposal to substitute generic names for chemical identities – where those identities would not reveal process or portion information and, thus, would not fit under the exceptions allowed by Section 14(b) – is not consistent with the statutory mandate. As described below, the use of generic identifiers as a substitute for the disclosure of chemical identity is contemplated only for information published in the Federal Register in compliance with Section 5 but, even then, not in the context of health and safety studies. Moreover, the use of generic names is inadequate to make available health and safety information to the public.
- ACC states that disclosure of chemical identity data in health and safety studies "may have serious adverse impacts on innovation and on small business" and "may help drive chemical industry jobs overseas," but offers no quantification or meaningful analysis of such claims. ACC provides no evaluation of the direct or indirect costs and benefits and no evidence that in fact the economic and social costs of EPA's policy outweigh its benefits. Indeed, ACC completely ignores the benefits of transparency to innovation and stimulation of the economy. ACC's arguments are simply an attempt to cast aspersions on policy that furthers this Administration's commitments to greater transparency and open scientific inquiry.[2]

Below please find a more detailed discussion of EPA's proposal, the requirements of TSCA Section 14, Congressional intent to make information about chemical identity in the context of health and safety studies public, and other policy considerations. At the outset, though, we want to outline our agreement with some aspects of the ACC White Paper.

- First, where disclosure of confidential chemical identity would also reveal process or portion information, that chemical identity falls under the explicit exceptions in Section 14(b) and would be protected from disclosure.[3]

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[2] In a one page handout released on January 20, 2012 for a meeting with OMB, industry representatives offered one anecdotal example of the possible adverse impact on innovation, focusing on what disclosure might have meant for Proctor & Gamble, which delivered a PMN that included a significant number of health and safety studies to EPA. *TSCA: PMN Amendments Claiming Chemical Identity in Studies as CBI,* ACC/ACI/IFRA/OMB Meeting Talking Points (January 20, 2012), http://www.whitehouse.gov/sites/default/files/omb/assets/oira_2070/2070_01202012-2.pdf. The vast majority of PMNs, however, include no health and safety studies. E-mail from Greg Schweer, Chief, New Chemicals Management Branch, EPA, to Richard Denison, Senior Scientist, Environmental Defense Fund (Feb. 29, 2012) (on file with author) (more than 80% of PMNs include no health and safety study).

[3] *See* ACC White Paper at 2; however, the ACC White Paper conflates the exception with the rule. EPA's policies call for substantiation of CBI claims. EPA has not until now required substantiation of CBI claims for chemical identity made with the submission of PMNs. In order to maintain chemical identity as confidential, however, the submitter must reassert and substantiate claims with the Notice of Commencement to Manufacture (NoC). If disclosure of a chemical identity that otherwise qualifies as CBI would, in fact, reveal process or portion information, then the CBI claim would be substantiated. ACC inexplicably argues, though, that the fact that "some" chemical identities can reveal process

- Second, Section 14(b) does not cover R & D chemicals or mixtures, and thus excludes health and safety studies of R & D chemicals and R & D mixtures.[4]
- Third, EPA can and should require up-front substantiation of CBI claims.[5]
- Fourth, EPA can and should require reassertion and re-substantiation of CBI claims, allowing claims that are not reasserted and re-substantiated to expire.[6]

As discussed below, we urge OIRA to approve the publication of EPA's proposed PMN Amendments regarding claims of confidentiality related to data in health and safety studies submitted under TSCA. The proposal is an important step toward making health and safety information available to the public and will help to bring agency action in line with the mandates and purpose of TSCA.

## I. EPA's Proposed Regulation is a Long Overdue Step Toward Bringing Practice into Line with the Intent and Mandate of TSCA and with This Administration's Commitment to Transparency and Scientific Inquiry

Health and safety studies are submitted to EPA under various sections of TSCA, including Section 4 (testing requirements), Section 5 (pre-manufacture notices), Section 8(a)(2)(E) (report of existing data on environmental and health effects), Section 8(d) (submission of health and safety studies by manufacturers, processors, and distributors of chemical substances or mixtures in commerce or those who propose to manufacture, process or distribute chemical substances or mixtures) and Section 8(e) (substantial risk notices). *See* 15 U.S.C. §§ 2603, 2604, 2607(a), (d)-(e). For too long, health and safety information, even including information indicating that chemical substances or mixtures present a substantial risk of injury to health or the environment, has been shielded from the public by EPA's passive acceptance of CBI claims. For too long key health and safety information about chemicals that are planned for use in the marketplace has been kept secret. EPA's 2010 policies and the current proposal regarding health and safety information submitted to EPA as part of the PMN process are welcome steps toward making more health and safety information available to the public in accordance with TSCA Section 14(b).

Historically, critical health and safety information has been shielded from public view because of both submitters' assertions of excessive and often unfounded CBI claims and the failure of EPA to routinely review and reach determinations as to the legitimacy of those claims.

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information somehow supports its argument that, more broadly, TSCA protects chemical identity. *See* ACC White Paper at 13.

[4] *See* ACC White Paper at 2. Section 14(b) applies to any health and safety study with respect to any chemical substance or mixture that "has been offered for commercial distribution," for which testing is required under Section 4, or for which a PMN or Significant New Use Notice (SNUN) is required under Section 5. 15 U.S.C § 2613(b)(1)(A). By its terms, Section 14(b) does not apply to R & D chemicals and mixtures, and is triggered at the point of the premanufacture notice. *See id., see also* 15 U.S.C. § 2604.

[5] *See* ACC White Paper at 6.

[6] *Id.*

*See* Sheila A. Ferguson, et al., EPA-HQ-OPPT-2002-0054-0074, Influence of CBI Requirements on TSCA Implementation, Hampshire Research Assocs. (Mar. 1992), at iii ("While there are several circumstances under which data submitted by companies are and should be handled as legitimate trade secrets, the majority of the confidentiality claims affecting data submitted under TSCA have not been substantiated, and a significant fraction of these claims would appear not to be supportable under the statute."). Nineteen years ago, EPA identified "inappropriate confidentiality claims" as impairing "the dual goals of public education about chemical substances and public participation" that were enshrined in TSCA. *See* EPA Office of Pollution Prevention and Toxics, Final Action Plan: TSCA Confidential Business Information Reform 5 (Jun. 20, 1994) (Final Action Plan). EPA's Final Action Plan stated, "The unmistakable purpose behind the participatory opportunities provided in TSCA is to afford the public the chance to contribute meaningfully to the regulatory process" and indicated that inappropriate CBI claims were thwarting the legislative purpose of TSCA. *Id.* at 3, 5. Nonetheless, industry claims of CBI protection for health and safety information and, in particular, for chemical identity, have continued unabated and virtually unchecked.

A study undertaken by the U.S. Governmental Accountability Office (GAO) in 2005 acknowledged the problem, recognizing that under TSCA "chemical companies claim much of the data submitted as confidential." GAO, GAO-05-458, Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program, at introduction (2005). The GAO noted the relevance of information provided under TSCA to the general public:

> Individual citizens or community groups may have a specific interest in information on the risks of chemicals that are produced or used in nearby facilities. For example, neighborhood organizations can use such information to engage in dialogues with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures.

*Id.* at 32. At the time of its study, the GAO reported that although "EPA has the authority to evaluate the appropriateness of these confidentiality claims," the agency stated that it lacked the resources to challenge large numbers of claims. *Id.* at introduction. Indeed, EPA's reluctance to review claims was related to the scale of the problem. *Id.* at 32-33 (noting that a 1992 EPA study "indicated that problems with inappropriate claims were extensive"). If fully implemented, EPA's new policy, under which it engages in a general practice of reviewing confidentiality claims for chemical identities in health and safety studies and data from those studies, and by which it announced that it does not expect such chemical identities to be entitled to confidential treatment unless they explicitly contain process information or reveal portions of a mixture, will begin to bring practice into line with the statute.

Notably, absent specific chemical names, the information in health and safety studies can be rendered all but useless to the scientific community, chemical users, state, Tribal and

local government officials, and the public. Consider, for example, the health and environmental risk information provided in Section 8(e) substantial risk notices. These notices describe health and safety studies or data that reasonably support the conclusion that certain chemical substances or mixtures present a substantial risk of injury to health or the environment. 15 U.S.C. § 2607(e).[7] Among other health and environmental risks, Section 8(e) notices describe studies and other evidence linking particular chemicals with cancer, reproductive and developmental abnormalities, mutagenesis, and neurotoxicity. Though all Section 8(e) notices are posted on EPA's website, companies have frequently asserted that the names of the chemicals at issue constituted CBI, and EPA historically accepted these claims without question unless someone sought information through a request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552(a). Thus chemical names were – and continue to be – redacted from a significant number of Section 8(e) notices posted on EPA's website, including a majority of the chemicals covered by the notices received during some months. *See, e.g., TSCA Section 8(e) Notices*, EPA, http://www.epa.gov/opptintr/tsca8e/pubs/8emonthlyreports/2009/8enov2009.html (last visited Feb. 28, 2012). EPA statistics indicate that for fiscal years 2006 through 2009, nearly 70% of Section 8(e) notices submitted to EPA contained CBI claims, and for more than 40% of them the chemical identity was specifically claimed as CBI. EPA, TSCA Statistics for Congressional Briefing (Documents Received from FY 06 through FY 09)(received from EPA by OMB Watch pursuant to FOIA request) (undated).

As a report by the Congressional Research Service stated, the value of 8(e) submissions and EPA's website making the studies available to the public "is greatly reduced by the confidentiality claims of the submitters: in most cases, the identity of the chemical is concealed." Linda-Jo Schierow, Cong. Research Serv., CRS RL 34118, The Toxic Substances Control Act (TSCA): Implementation and New Challenges 13 (Jul. 28, 2009).

Consider, for example, the information provided in a "Company Sanitized" Section 8(e) notice about an "Optionally Substituted Aromatic Substance." *See Notice in Accordance with Section 8(e): Results of a Developmental Toxicity Screening Study in Wistar Rats with Optionally Substituted Aromatic Substance*, BASF, 8EHQ-09-17748, at 1 (Nov. 25, 2009), http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2009/nov09/8ehq_1109_17748a.pdf. This notice reported on toxicity findings relevant to fetal development, including the following:

- Statistically significantly reduced mean fetal weights (70%), i.e. males (71%), females (69%), compared to the control group (set to 100%)

[7] 15 U.S.C. § 2607(e) provides:

> Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

- Two fetuses with cleft palate
- Four fetuses with anasarca
- Fourteen fetuses with malrotated limbs

*Id.* at 2. Despite the disconcerting information about the effects associated with the "Optionally Substituted Aromatic Substance," this notice is useless because the chemical identity of the substance has been redacted.

Similarly, consider another self-titled "Sanitized Version" of a Section 8(e) notice dated November 23, 2009, which does not disclose the identity of the chemical that is the subject of the notice. The filing reports on the results of an acute eye irritation test in rabbits with "a Formulation Containing Two Active Ingredients; (1) Substituted Nitrogen Containing Heterocycle and (2) Substituted Epoxide," and indicates that "[t]he test substance is a crop protection formulation." *Notice in Accordance with Section 8(e): Results of an Acute Eye Irritation Test in Rabbits with a Formulation Containing Two Active Ingredients; (1) Substituted Nitrogen Containing Heterocycle, and (2) Substituted Epoxide*, BASF, 8 EHQ-1109-17747A, at 1 (Nov. 23, 2009), http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2009/nov09/8ehq_1109_17747a.pdf. Among other things, the notice reports the following:

> Slight to moderate corneal opacity, moderate iritis, slight to severe conjunctival redness, slight to moderate conjunctival chemosis and slight to severe discharge were observed in the animals during the course of the study. Additional findings like contracted pupil, marginal vascularization of the cornea in a circumscribed area or circular as well as vascularization into the central part of the cornea in a circumscribed area and injected scleral vessels in a circumscribed area or circular were noted in the animals during the observation period.

*Id.* Indeed, findings were significant; the notice concludes: "Considering the described ocular reactions as well as the average score for irritation, the formulation substance causes serious eye damage under the test conditions chosen." *Id.* at 2. The public was thus on notice of danger from an unspecified "crop protection formulation," but the notice was otherwise of severely limited utility. *See id.* at 1; *see also* Richard A. Denison, *Hiding a Toxic Nanomaterial's Identity: TSCA's Disappearing Act* (July 14, 2009), http://blogs.edf.org/nanotechnology/2009/07/14/hiding-a-toxic-nanomaterials-identity-tscas-disappearing-act/ (discussing CBI claim for a material generically named "Carbon Nano Tube").[8]

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[8] In another Section 8(e) notice dated April 15, 2010, the identity of the company submitting the notice, the "subject chemical," and "alternative name" were all redacted. *TSCA Section 8(e) Substantial Risk Notification*, 8 EHQ 0410-17890A, at 1 (Apr. 15, 2010), http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2010/apr10/8ehq_0410_17890a.pdf (company name and identification of chemical omitted). The text of the letter is replete with deletions, rendering the notice essentially useless as a means of informing the public of health and safety concerns:

The identity of the chemicals in health and safety studies submitted to EPA pursuant to Section 5 PMN requirements is similarly crucial information necessary for the interpretation of the studies and of great interest to the public.[9] For example, even before distribution for commercial purposes, workers may well be exposed to a new chemical. If a labor union is concerned about exposure and takes the step of arranging for biomonitoring of workers in a facility making a new chemical, the ability to determine whether there is – and prove the origin of – exposure to the chemical requires knowledge of its specific chemical identity. To present evidence that workers are being exposed to a chemical that belongs to the class of chemicals identified by reference to a generic name would likely lead to disputes, especially if the company also produces other structurally related chemicals. More generally, workers should not have to rely exclusively on their employers' or EPA's knowledge of specific chemical identity, and should have the ability independently to assess their potential exposure to a new chemical.

In addition, there may be environmental releases of a chemical even before commercial production begins. If concerned citizen groups or environmental researchers arrange for environmental monitoring, for example, in the vicinity of a facility making a chemical, they would similarly need to know specific chemical identity in order to monitor for it, and the same concerns would arise if only access to a generic name were provided.

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> [ ] has been made aware of preliminary findings from a second 28-day inhalation study in the rat. The dose levels of [] employed were 0,500, 1500, 5000, and 15000 ppm. These dose levels were selected on the basis of the first 28-day inhalation study reported to the EPA under Section 8(e) of TSCA in a letter dated August 26, 2009. [ ] believes the results of the second 28-day study to be reportable under the established criteria for notification of substantial risk under TSCA Section 8(e).
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> Groups of 10 male and 10 female Wistar rats were exposed to [ ] by inhalation(nose only) at levels of 0, 500, 1500, 5000 and 15000 ppm for 6 hours per day, 5 days per week for four weeks.
>
> An incidence of minimal to moderate myocardial focal/multifocal inflammation, accompanied by minimal to moderate vacuolation and/or myofibre degeneration was observed in all groups of exposed rats….

*Id.* at 1. Again, absent chemical identity, significant findings are rendered of limited or no utility for the public.

[9] Concerns about the impact of revealing chemical identities along with the name of the manufacturer or distributor on the competitive position of a manufacturer or distributor can be reduced through the mechanics of disclosure. If releasing chemical identity together with the name of the company would affect the manufacturer or processor's competitive position, EPA can disclose chemical identity in the study but redact company identifying information.

Test marketing of products containing chemicals also presents the possibility of exposures even if only on a limited scale. While the manufacturer would have to apply for a test marketing exemption (TME) pursuant to 40 C.F.R. § 720.38, it may well be granted on the basis of a limited review by EPA. All of the same rationales discussed above for the need to know specific chemical identity, and the same concerns would arise if only access to a generic name were provided.

Finally, new chemicals are frequently developed to replace existing ones that have been shown to be risky. Recent examples include the introduction of substitute flame retardants to replace polybrominated diphenyl ethers (PBDEs) and substitute fluorotelomers to replace those that break down into perfluorooctanoic acid (PFOA). Often in such cases, structurally similar chemicals are used as the substitutes. *See, e.g.*, Press Release, DuPont, New DuPont™ Capstone™ for Repellents and Surfactants Deliver Maximum Performance, Minimal Environmental Footprint (Mar. 31, 2008), http://www2.dupont.com/Capstone/en_US/assets/downloads/final_press_release_english_3_20_2008.pdf. This creates more than a theoretical concern that the substitutes could pose the same or similar risks. There is a strong, legitimate public interest in having access to robust health and safety information for such chemicals *before* they enter widespread use.

EPA's 2010 CBI policies and the Proposed Regulation are also consistent with this Administration's commitment to transparency and scientific inquiry. Executive Order 13563 directs agencies "[w]here relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law" to "identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include warnings, appropriate default rules, and disclosure requirements as well as provision of information to the public in a form that is clear and intelligible."[10] Enforcement of TSCA Section 14(b), providing for the disclosure of chemical identity in the context of health and safety studies unless the information would reveal process or portion information, promotes informed consumer choice and makes information accessible to the public.

Disclosure also serves to ensure that health and safety studies are made available to the scientific community and furthers scientific inquiry and the goal of scientific integrity. At a 2009 National Academy of Sciences Annual Meeting, President Obama affirmed this Administration's interest in "restoring science to its rightful place." He stated,

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[10] Exec. Order No. 13563, 76 Fed. Reg. 14, Sec. 4 (Jan. 21, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf; *see also* Executive Office of the President, Memorandum for the Heads of Executive Departments and Agencies: Informing Consumers Through Smart Disclosure (Sept. 8, 2011), http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/informing-consumers-through-smart-disclosure.pdf.

> Under my administration, the days of science taking a back seat to ideology are over. Our progress as a nation –- and our values as a nation –- are rooted in free and open inquiry. To undermine scientific integrity is to undermine our democracy. It is contrary to our way of life.

Office of the Press Secretary, Remarks by the President at the National Academy of Sciences Annual Meeting (Apr. 27, 2009), http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-at-the-National-Academy-of-Sciences-Annual-Meeting.[11] Shielding chemical identity in health and safety studies from public disclosure is in conflict with both the terms of TSCA Section 14(b) and the affirmation of free and open inquiry.

## II. Disclosure of Chemical Identity Information in Health and Safety Studies is Consistent with TSCA Section 14(b)

ACC argues that EPA incorporates a balancing test, and that the interest in disclosure should be weighed against the interest in protecting trade secrets. *See* ACC White Paper at 26-28. Indeed, Section 2 of TSCA does require that, in implementing the provisions of TSCA, the Administrator "shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take." 15 U.S.C. § 2601(c). However, Section 14 of TSCA does not call for a balancing test and contains explicit language governing the disclosure of information reported to EPA pursuant to the provisions of TSCA.

Section 14(a) contains a general provision governing disclosure of data outside of the context of health and safety studies, which protects information that is exempt from disclosure under the Freedom of Information Act as a trade secret. *See* 15 U.S.C. § 2613(a). TSCA Section 14(b)(1) specifically provides that health and safety studies *and data* from health and safety

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[11] *See also* EPA, Scientific Integrity Policy, at 5, http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf (last visited Feb. 28, 2012), which states:

> Scientific research and analysis comprise the foundation of all major EPA policy decisions. Therefore, the Agency should maintain vigilance toward ensuring that scientific research and results are presented openly and with integrity, accuracy, timeliness, and the full public scrutiny demanded when developing sound, high-quality environmental science. This policy [EPA's Scientific Integrity Policy] is intended to outline the Agency's expectations for developing and communicating scientific information to the public, to the scientific community, to Congress, and to the news media by further providing for and protecting the EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information – uncompromised by political or other interference. This policy recognizes the importance of, and the need to foster a culture of, openness regarding the results of research, scientific activities, and technical findings. To that end, the EPA strongly encourages and supports transparency and active, open communications through various forms....

studies are not entitled to confidential treatment, with two significant and explicit exceptions for process and portion information. *See* 15 U.S.C. § 2613(b)(1) (emphasis added). Section 14(b)(1) provides:

> (b) Data from health and safety studies
> (1) Subsection (a) does not prohibit the disclosure of –
> (A) any health and safety study which is submitted under this chapter 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 2603 of this title or for which notification is required under section 2604 of this title, and
> (B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

15 U.S.C. § 2613(b)(1). The process or portion exceptions are explicit:

> 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.

*Id*. By its very terms, Section 14(b) protects data revealing process or portion information but does not provide similar protection for chemical identity outside of those contexts. Had Congress intended to exempt chemical identity from disclosure, Section 14(b) could have included this exemption along with the process and portion exceptions, but such language is noticeably absent.[12] Indeed, the process and portion exceptions are premised on an understanding that, more generally, chemical identity is not shielded from disclosure.

TSCA Section 3(6) broadly defines the phrase "health and safety study" to mean:

> Any study of any effect of a chemical substance or mixture on health or the environment or on both, *including underlying data* and epidemiological

[12] Had Congress intended to carve out a larger exception to the disclosure of information in health and safety studies, it could have done so clearly and expressly. *See Meghrig v. KFC Western, Inc.*, 516 U.S. 479, 485 (1996) (finding omission of language by Congress in CERCLA significant); *FCC v. NextWave Pers. Commc'ns, Inc.*, 537 U.S. 293, 302 (2003) (finding that when Congress intended to create exceptions to the requirements of bankruptcy law, "it had done so clearly and expressly").

> studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

15 U.S.C. § 2602(6) (emphasis added).[13] Consistent with that broad definition, EPA's regulations define "health and safety study" as including "[a]ny data that bear on the effects of a chemical substance on health or the environment" and specifically confirm that "[c]hemical identity is part of, or underlying data to, a health and safety study." 40 C.F.R. § 716.3; *see also id.* § 720.3(k) ("Chemical identity is always part of a health and safety study.") Clearly, the identities of the chemicals in health and safety studies are part of the data that give meaning to the results. As such, chemical identity associated with a health and safety study is not entitled to confidentiality unless disclosure would reveal process or portion information.

A. Section 5 PMN Disclosure Provisions are "Subject to" the Provisions of Section 14 and, Thus, Chemical Identity Information in the Context of Health and Safety Studies Submitted to EPA Pursuant to Section 5 is Subject to Disclosure

ACC asserts that data from health and safety studies submitted to EPA pursuant to Section 5 of TSCA is subject to protection as trade secrets or CBI and that Section 5(d)(2) "specifically endorses disclosure of generic names" in the context of PMNs. ACC White Paper at 1-2. These arguments are mistaken.

TSCA Section 5 requires manufacturers, importers, and processors to notify EPA at least 90 days prior to producing or otherwise moving a new chemical into commerce into the United States or when planning a significant new use of the chemical. 15 U.S.C. § 2604(a)(1)((B). Such manufacturers, importers, and processors are required to submit to EPA any information or test data that is known to or reasonably ascertainable by them, or in their possession, that might be useful to EPA in evaluating the risks of the chemical for human health and the environment. 15 U.S.C. § 2604; *see also* Linda-Jo Schierow, Cong. Research Serv., CRS RL 31905, The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements 3-4 (February 2, 2010). ACC relies on two provisions, Sections 5(b)(3) and 5(d)(2), which it claims limit disclosure of chemical identity based on trade secrets or CBI claims and, in the case of Section 5(d)(2), "endorses disclosure of generic names instead of confidential identities where `required in the public interest.'" ACC White Paper at 2. The text of both of these provisions,

[13] The definition of "health and safety study" provided by TSCA Section 3(6) encompasses outcomes and underlying data that bear on the content of the study, including chemical identity. As a study prepared for EPA back in 1992 noted, "It is unlikely that any reputable health or environmental scientist could be found who would argue that it is ever the case that chemical identity is unnecessary to interpret health and safety data." Sheila Ferguson, et al., EPA-HQ-OPPT-2002-0054-0074, Influence of CBI Requirements on TSCA Implementation, Hampshire Research Assocs. (Mar. 1992), at 24. Chemical identity is thus distinguishable from information about the manufacturer or distributor, such as its finances, which arguably would not usually be considered "data" and may be extraneous to interpretation of the health and safety study.

however, contains explicit language clarifying that disclosure requirements are "subject to section 2613" – in other words, subject to the protection of Section 14(a) and subject to the disclosure requirements for health and safety studies in Section 14(b). Specifically, the relevant portions of Section 5 provide:

> (b)(3) Data submitted under paragraph (1) or (2) shall be made available, *subject to section 2613, of this title,* for examination by interested persons.
>
> (d)(2) *Subject to section 2613 of this title*, … 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) of this section, describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (b) of this section or a rule under section 2603 of this title.
>
> 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.

15 U.S.C. § 2604(b)(3), (d)(2) (emphasis added). Thus, Section 5(b)(3) mandates that the EPA make available data submitted pursuant to Section 5(b)(1) and (2), *subject to* the disclosure requirements of Section 14. Similarly, Section 5(d)(2) mandates that EPA publish information in the Federal Register *subject to* the disclosure requirements of Section 14. As discussed above, Section 14(b) provides for the disclosure of chemical identity and other data in health and safety studies unless such disclosure would reveal process or portion information.

Although Section 5(d)(2) does contain language endorsing the disclosure of generic names in PMNs published in the Federal Register, generally, this provision is explicitly *subject to* the more specific mandate in Section 14(b) *if the information is part of a health and safety study*.

Assuming for the sake of argument that we can ignore the language subjecting Section 5(d)(2) to the disclosure requirements of Section 14 and that it is plausible to interpret the specific language requiring EPA to identify chemical substances by generic class as carving out an exception to Section 14(b), this exception would apply only to the disclosure of chemical identity in health and safety studies received pursuant to Section 5 required to be made public

by EPA.[14] By its own terms, the provision only applies to the identification of chemical substances in a Section 5 notice. 15 U.S.C. § 2604(d)(2) ("*A notice under this paragraph* respecting a chemical substance shall identify the chemical substance by generic class….") (emphasis added). Moreover, similar language does not appear in Sections 4 or 8 of TSCA, and the provision cannot be read as a broad amendment to Section 14(b).

B. Section 4's Test Data Notice Provisions are also "Subject to" the Provisions of Section 14 and, Thus, Chemical Identity Information in the Context of Health and Safety Studies is Subject to Disclosure

ACC inexplicably argues that disclosure of data in health and safety studies pursuant to Section 4(d), which sets forth the requirements for providing notice of the receipt of test data, is also subject to protection as trade secrets or CBI. ACC White Paper at 2. This interpretation defies the language of Section 4(d) and canons of statutory construction.

Specifically, TSCA Section 4(d) provides:

> (d) Notice
> Upon the receipt of any test data pursuant to a rule under subsection (a) of this section, the Administrator shall publish a notice…. *Subject to section 2613 of this title*, each such notice shall (1) *identify the chemical substance or mixture for which data have been received*; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. *Except as otherwise provided in section 2613 of this title, such data shall be made available by the Administrator for examination by any person.*

15 U.S.C. § 2603(d) (emphasis added).

Notably, this provision states explicitly that it is subject to the mandates of TSCA Section 14, both the protections afforded and the disclosure requirements of Section 14 (a) and (b). Section 4(d) refers to Section 14 twice: first, to establish that the notice requirement, generally, is subject to Section 14, and then subsequently, as a limitation on data to be made available for examination. *See id.*

Moreover, Section 4(d) explicitly requires that each notice "shall" "identify the chemical substance or mixture for which data have been received." 15 U.S.C. § 2603(d). Finally, to the

[14] To ignore the "subject to" clause, however, would be to violate the basic principle of statutory construction that calls for giving effect, where possible, to every clause and word of a statute and to avoid rendering statutory language superfluous. *See Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002).

extent that ACC has argued that the language in Section 5 regarding generics is relevant to data in health and safety studies, it is significant that Section 4(d) contains no such provision.[15] ACC suggests that rejected language in a 1975 House bill, H.R. 7664, which mirrored the language that ultimately appeared in Section 5(d)(2) demonstrates that Section 4(d) "was intended to protect trade secret or confidential identities from disclosure." ACC White Paper at 12. To the contrary, "'[W]here Congress includes particular language in one section of a statute but omits it in another . . . it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'" *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (citting Russello v. United States, 464 U.S. 16, 23 (1983)).[16]

## III. Disclosure of Chemical Identity Information in Health and Safety Studies is Consistent with Congressional Intent

TSCA was enacted in 1976, in an era when policy makers were paying increasing attention to the risks that toxic substances posed to human health and the environment. *See* David Markell, *An Overview of TSCA, its History and Key Underlying Assumptions, and its Place in Environmental Regulation*, 32 Journal of Law & Policy 333, 338-340 (2010). Other laws in place at the time that addressed the dangers of chemical substances included the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act. *See* S. Rep. No. 94-698, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4491. Yet the statutes in place prior to TSCA's enactment left a number of regulatory gaps.

Prior to TSCA, the law failed to provide a way to discover the adverse health and environmental effects of chemical substances before they were manufactured. *See id.* The government's only response to chemical dangers was to regulate after manufacturing began. *See id.* at 5. The 1971 Council on Environmental Quality (CEQ) Report, Toxic Substances, which set the foundation for TSCA legislation, noted that then current laws were inadequate to control the dangers of toxic substances and that media-based pollution laws did not adequately account for a person's total exposure to chemicals. *See* U.S. Council on Environmental Quality, Toxic Substances at *v (Apr. 1971); Markell, *An Overview of TSCA*, at 346. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which was essentially rewritten in 1972 by the Federal Environmental Pesticide Control Act (FEPCA), addressed chemical dangers prior to the manufacturing process, but covered only a small portion of the total number of potentially toxic

[15] If, however, test data developed pursuant to a Section 4 rule is received by EPA in connection with a PMN or SNUN requirement under Section 5, such data would also be subject to Section 5(d)(2) disclosure requirements.

[16] *See also Pacific Gas & Elec. Co. v. Energy Res. Conserv. & Dev. Comm'n*, 461 U.S. 190, 220 (1983) ("While we are correctly reluctant to draw inferences from the failure of Congress to act, it would, in this case, appear improper for us to give a reading to the Act that Congress considered and rejected"); *Doe v. Chao*, 540 U.S. 614, 622 (2004) (finding significant evidence "that Congress cut out the very language in the bill" that would have authorized the presumed damages being urged on the Court).

substances and did not deal with all uses of a substance that may produce toxic effects. *See* U.S. Council on Environmental Quality, Toxic Substances at *v (Apr. 1971); 7 U.S.C. § 136 *et seq*.

TSCA was enacted to close these regulatory and information gaps. *See* S. Rep. No. 94-698, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4491. Its primary purpose is to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." *Id.* at 1; *see also* Markell, *An Overview of TSCA*, at 346. The 1977 CEQ Annual Report stated that the major accomplishment of TSCA "is that it gives the government broad authority to control the production, distribution, and use of all potentially hazardous chemicals. It provides for testing of suspect chemicals before they become widely used and economically important. It emphasizes collection of information and freedom of access to research data so that the scientific community can note and assess potential problems." Council on Environmental Quality, Eighth Annual Report of the Council on Environmental Quality 1-3 (1977). The 1978 CEQ Report summarized TSCA's role as giving the government "a new mandate and broad new authority to gather information on the potential of chemicals to damage human health and the environment . . . The result is more awareness on the part of government, industry, scientists, and the public of the problems of toxic chemicals . . . ." Council on Environmental Quality, Ninth Annual Report of the Council on Environmental Quality 178 (1978).

ACC's argument that statements made during the legislative process leading to TSCA in 1975-1976 support continued protection of chemical identity information relies on imprecise readings of the legislative record. In fact, the legislative record makes clear that Congress heard testimony regarding CBI issues, and that TSCA was intended to provide for the disclosure of chemical identity within the context of health and safety studies unless such disclosure would reveal process or portion information.

ACC often conflates arguments made for the protection of formulae, process, or portion information with the question whether chemical identity should be disclosed. For example, ACC quotes the Statement of Anita Johnson from the Public Citizen Health Research Group (ACC White Paper at 19), who expressed support for protecting secret formulas and secret manufacturing methods as trade secrets, but advocated for disclosure of health and safety data. *See Hearing on H.R. 7229, H.R. 7548, and H.R. 7664 before the House Subcomm. on Consumer Protection and Finance of the Comm. on Interstate and Foreign Commerce,* 94th Cong. 355 (1975) (statement of Anita Johnson, Public Citizen Health Research Group). Yet nothing about that statement is inconsistent with allowing the disclosure of chemical identities, since it only speaks to protecting formulas and manufacturing methods. Read in its entirety, Ms. Johnson's statement expresses deep concern for public health and the desire for complete disclosure of health and safety data, other than information disclosing processes and formulas, reflecting the language of TSCA §14. *See id.;* 15 U.S.C. §2613(b)(1)(B). ACC also quotes Dr. Sidney Wolfe who stated that legitimate trade secrets should not be disclosed, but who also testified that health and safety studies are not trade secrets. ACC White Paper at 19; *Hearing on S. 776 Before the Senate Subcomm. on the Environment of the Comm. on Commerce,* 94th Cong. 168-169 (1975)

(statement of Dr. Sidney Wolfe, Health Research Group). Dr. Wolfe's testimony is an example of testimony before Congress in support of disclosure of chemical identity in the context of health and safety information. Similarly, ACC quotes Jacqueline Warren from the Environmental Defense Fund as suggesting that detailed information about chemical identity might qualify as trade secrets. ACC White Paper at 19; *Hearing on S. 776 Before the Senate Subcomm. on the Environment of the Comm. on Commerce*, 94th Cong. 171 (1975) (statement of Jacqueline Warren, Environmental Defense Fund). A full reading of the testimony, however, makes clear that the discussion distinguished between "detailed" information that would disclose information about the manufacture of chemicals and the importance of disclosing chemical identity to the public. *Hearing on S. 776 Before the Senate Subcomm. on the Environment of the Comm. on Commerce*, 94th Cong. 171 (1975) (statements of Jacqueline Warren, Environmental Defense Fund, and Dr. Albert Fritsch, Center for Science in the Public Interest).[17]

ACC states that a 1975 report released by the National Academy of Sciences recommended that proprietary data be protected from disclosure unless essential to evaluating a hazard of the chemical. ACC White Paper at 19; National Academy of Sciences, Decision Making for Regulating Chemicals in the Environment 28 (1975), *available at* 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. Yet ACC fails to mention that proprietary data in the report are defined as use data, such as to whom the chemical is sold, and not chemical identity. *See id.* The report specifically states that intrinsic toxicological properties of a given substance are non-proprietary data, a definition that would support the disclosure of chemical identity in health and safety studies. *See id.*

More significantly, TSCA's legislative history demonstrates Congressional intent to require disclosure of chemical identity in the context of health and safety studies, while protecting CBI that contains portion and process information. In House Conference report 94-1679, the conference substitute for the House and Senate bill language specifically provided that "disclosure of any health and safety study or information from such a study on any substance or mixture which is already being distributed or for which testing is required under section 4 or

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[17] ACC also quotes Orin Smith from M&T Chemical Co., who states that the "chemical entity's molecular structure, proposed usage and amounts to be manufactured should not be published for all to see." ACC White Paper at 19; *Hearing on* S. 776 *Before the Senate Subcomm. on the Environment of the Comm. on Commerce*, 94th Cong. 121 (1975) (statement of Orin Smith, M&T Chemical Co.). It is unsurprising that a representative from a chemical company argued for protection of chemical identities in health and safety studies. Such isolated statements at the particular Hearings should be examined cautiously, as they are merely arguments before the House and Senate committees and do not reflect the committees' opinions. Although reference to legislative history for background and context can be helpful, isolated statements by individual members of Congress or even committees, much less lobbyists, "cannot substitute for a clear expression of legislative intent at the time of enactment." *See Southeastern Community College v. Davis*, 442 U.S. 397, 411 n.11 (1979).

for which notification is required under section 5, is not prohibited. Data in such a study which disclosed manufacturing *processes* or the *proportions* of a mixture may not be disclosed if such *processes* or *proportions* would otherwise be entitled to protection from disclosure." H.R. Rep. No. 94-1679, at 36 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4539,4576 (emphasis added). The report specifies that manufacturing processes and the proportions of chemicals in a mixture may not be disclosed, consistent with the language of TSCA section 14(b)(1)(B). *See id.; see also* 15 U.S.C. § 2613(b)(1)(B).

Furthermore, TSCA House Committee Report 94-1341 stated "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." H.R. Rep. No. 94-1341, at 51 (1976), Legis. Hist. at 458 (emphasis added).

A. ACC's Reliance on FIFRA is a Red Herring: FIFRA's Disclosure Terms are Inapposite

ACC's argument about the relevance of FIFRA to an understanding of TSCA suffers from some of the same obfuscation found elsewhere in the White Paper: perhaps most fundamentally, ACC conflates chemical identity with formulae, process or portion information. *See, e.g.,* ACC White Paper at 23 ("Several provisions explicitly protected confidential *formula* information, including the *identity* of confidential inerts….") (emphasis added). The White Paper's core argument, though, is that TSCA's treatment of trade secrets was modeled after FIFRA. ACC White Paper at 15-22. ACC contends that the disclosure requirement in TSCA Section 14(b) "did not relate to proprietary data" in health and safety studies, "such as trade secret or confidential chemical identities, which under FIFRA were protected." ACC White Paper at 15. This argument is patently misguided: Section 14(b) clearly relates to information that would otherwise have been considered a trade secret or CBI. This was the very reason for Section 14(b). Moreover, FIFRA itself provides for the release of the identity of active ingredients. 7 U.S.C. §§ 136(n)(defining "ingredient statement" to include the name and percentage of each active ingredient), (q)(2)(establishing that a "pesticide is misbranded if – (A) the label does not bear an ingredient statement…."). Indeed, nothing in the legislative history of TSCA suggests that TSCA's disclosure requirements concerning health and safety studies should be read in light of FIFRA, and a comparison of the language in the two statutes reflects significant and material distinctions. ACC's focus on FIFRA is a red herring.

FIFRA and TSCA reflect different approaches to questions of confidentiality. The statutes were each intended to address different circumstances and, with each, Congress offered solutions tailored to the purpose of the statute. For example, TSCA does not differentiate between active and inert chemicals, and specifies that information in health and safety studies regarding the "portion of the mixture" or the manufacturing process of the chemical may not be

revealed. *See* 15 U.S.C. § 2613(b)(1)(B). FIFRA, on the other hand, requires that active ingredients be disclosed on product labels, together with their percentage by weight, and only protects from disclosure the identity of inert ingredients. *See* 7 U.S.C. §§ 136(q), h(d)(1)(A)-(C); 40 C.F.R. § 156.10(g). Since under FIFRA the active ingredients of pesticides are already revealed to the public, they face no confidentiality or trade secret issues. For inert ingredients, FIFRA labeling regulations require a listing of the total percentage by weight of all inert ingredients. *See id.*

Moreover, a comparison of the language in FIFRA and TSCA shows that Congress knew how to use explicit language to protect chemical identities from being disclosed, and chose not to do so in the context of data submitted to EPA under TSCA as part of health and safety studies. TSCA was enacted a few years after the FEPCA amended FIFRA, although the first TSCA bill was introduced in 1971 while the FIFRA amendments were still being considered. *See* S. Rep. No. 92-970 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4092; *Toxic Substances Control Act of 1971 and Amendment. Part 1: Toxic Substances*, *Hearing Before the Senate Committee on Commerce, Science, and Transportation*, 92nd Cong. (1971). FIFRA was subsequently amended by the Federal Pesticide Act of 1978, which provided that health and safety studies submitted under FIFRA should be publicly disclosed unless information in the study revealed the "manufacturing or quality control processes," methods for testing the quantity of deliberately added inert ingredients, or the "identity or percentage quantity of any deliberately added inert ingredient of a pesticide." *See* Federal Pesticide Act of 1978, Pub. L. No. 95-396 (1978) § 15(2); 7 U.S.C. § 136h(d). Section 10(d)(1)(C) of FIFRA specifically protects from disclosure any information that discloses the *identity* or percentage quantity of any deliberately added inert ingredient. The word "identity" was used to specify that not only was the percentage quantity of the inert ingredient a trade secret but also the inert ingredient's identity. TSCA section 14(b)(1)(B) notably leaves out the word "identity" and only specifies that information revealing manufacturing "processes" and "portion" of a mixture be protected from disclosure. The difference in the wording as to trade secret protection for health and safety studies is especially revealing given the relatively concurrent consideration and passage of amendments to FIFRA and TSCA. Congress evidently knew full well how to protect chemical identities from disclosure. It chose to do so with inert ingredients in FIFRA Section 10, and it chose not to do so with chemical identity of substances in health and safety studies in TSCA Section 14. *See* 7 U.S.C. § 136h(d)(1)(A)-(C); 15 U.S.C. § 2613(b)(1)(B).

B. ACC's Reliance on a Range of Provisions in Other Environmental Laws is Misplaced and Unpersuasive

Grasping at straws, ACC argues further that TSCA should also be read in light of the Emergency Planning and Community Right-to-Know Act (EPCRA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and the Superfund Amendments and Reauthorization Act (SARA). ACC White Paper at 22-26. Yet EPCRA was enacted in October of 1986, CERCLA, commonly known as Superfund, was enacted in December of 1980, and SARA amended CERCLA in October of 1986. *See* 42 U.S.C. § 11001 *et*

*seq*. (1986); 42 U.S.C. § 9601 *et seq*. (1980). All of these statutes were enacted significantly later than TSCA and focus on the release of chemicals into the environment from individual facilities rather than manufactured products entering into commerce. *See id.* They do not shed light on Congressional intent in 1976 and should not be used as guidance for interpreting TSCA provisions.

## IV. Generic Names Are Neither a Permissible Substitute for Disclosure Required by TSCA Section 14(b) Nor Do They Provide Sufficient Information to the Public

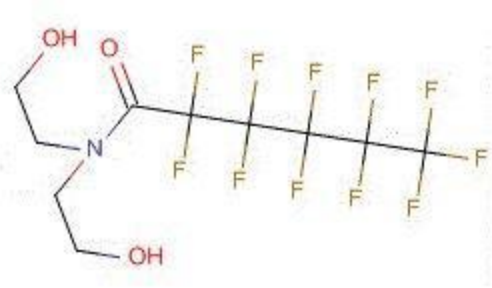
Section 14(b) does not contemplate the substitution of generic names for chemical identity in health and safety studies unless otherwise confidential chemical identity would reveal process or portion information. Neither do generic names provide sufficient information to the public. Incredibly, ACC seems to argue that using generic names will enhance access to information, suggesting that a search using a generic name will produce more information about the toxicology of a chemical than one using a CAS number or name. ACC White Paper at 30. Of course, nothing precludes a researcher from searching for the generic as well as the chemical name, though the reverse is not true. By definition, having only the generic name does not allow the researcher to identify and search for information about the specific chemical. Even with a generic name policy in place, the substitution of generic names creates a barrier to the flow of information and limits the possibility of understanding available health and safety studies.

To illustrate how the use of generic names obscures rather than illuminates information essential to the public's ability to understand and use health and safety information, we will examine: A) EPA's current guidance on selection of generic names; B) examples of actual generic names chemical manufacturers have provided when submitting "substantial risk" notices to EPA as required under TSCA Section 8(e) and PMNs, and that EPA has in turn provided to the public; and C) an example of a generic name of a chemical for which a PMN was filed in the past that included health and safety studies, the specific chemical identity of which EPA has recently declassified pursuant to its 2010 policies.

### A. EPA's Current Guidance on Selection of Generic Names

EPA's current guidance document, "Generic Names for Confidential Chemical Substance Identity," issued in 1985, provides examples of "acceptable" generic names to be used in lieu of a specific chemical identity.[18] One example is a set of "acceptable" generic names for the specific chemical depicted below: 2,2,3,3,4,4,5,5,6,6,6—Undecafluoro—N,N—bis(2—hydroxyethyl)hexanamide.

[18] EPA, TSCA Inventory, 1985 Edition, Appendix B: Generic Names for Confidential Chemical Substance Identities, http://www.epa.gov/oppt/newchems/pubs/genericnames.pdf (last visited Feb. 29, 2010).




Each of the "acceptable" generic names EPA allows for this chemical would encompass an exceedingly high number of potential chemical substances. For example, EPA suggests using a generic name that masks the fluorine (F) atoms in this substance (*i.e.*, N,N—Bis(2—hydroxyethyl), 2,2,3,3,4,4,5,5,6,6,6-undecasubstituted hexanamide). Such a generic name would include chemical substances with any possible combination of halogen atoms – bromine, chlorine, etc., replacing the fluorine atoms in each of the 11 positions shown above. This would theoretically include millions of distinct chemical compounds. Research has clearly shown that different forms of a chemical substance containing different types of halogen atoms can have very different toxicological profiles and environmental and biological fate. *See, e.g.*, EPA, Polybrominated Diphenyl Ethers (PBDEs) Action Plan (Dec. 30, 2009), http://www.epa.gov/oppt/existingchemicals/pubs/pbdes_ap_2009_1230_final.pdf (variation in toxicity and environmental fate among PBDEs based on extent of bromination). In order to have a clear understanding of the potential toxicity of a chemical substance it is essential to know the types of halogen atoms present.

Another generic name EPA allows for this chemical masks the number of fluorine atoms contained in the substance (*i.e.*, Polyfluoro—N,N—bis(2—hydroxyethyl) hexanamide). In this case, the generic name would include chemical substances containing anywhere from 2 to 11 fluorine atoms, at any combination of positions in hexanamide portion of the chemical substance. Again, such a generic chemical name would literally include hundreds or thousands of distinct chemical substances. Studies have clearly indicated that the extent of halogenation of a chemical (i.e., the degree to which hydrogen atoms bound to carbon atoms have been replaced with halogen atoms) dramatically impacts its toxicity and environmental and biological fate. *See*, e.g., *id.* It is absolutely pertinent to know the extent to which it is halogenated in order to understand the potential risk of a chemical substance.

The generic names EPA's guidance allows to be substituted for specific chemical identities are far from capable of narrowing, to any manageable number, the universe of compounds to which a health and safety study relates, nor do they foster an understanding of the underlying chemistry that determines a chemical's toxicity.

B. Examples of Actual Generic Names Chemical Manufacturers have Provided When Submitting "Substantial Risk" Notices to EPA under TSCA Section 8(e) and PMNs

Even with the existence of EPA guidance on the generation of generic chemical names, chemical companies have often chosen generic names that diverge completely from that guidance. For example, in the most recent monthly batch of Section 8(e) substantial risk notices received by the agency (January 2012) there are:

- four notices for chemicals whose identities have been masked and instead identified as "Confidential *2,"
- four notices for chemicals whose identities have been masked and instead identified as "Substance A *2,"
- four notices for chemicals whose identities have been masked and instead identified as "Substance B *2," and
- a notice for a chemical merely identified by the generic name "hydrofluorocarbon."[19]

These substantial risk notices could refer to any of a virtually infinite number of chemicals.

The same derisory approach to selection of generic names by chemical companies occurs in the context of PMN notifications. The most recent posting of PMNs received by EPA in the Federal Register (February 22, 2012) includes chemicals with specific identities that have been masked and replaced instead with generic names such as "Acrylic copolymer" and "Aromatic diazo compound."[20] While these PMN notifications are not notifications of health and safety studies (see next section), the selection of generic names, wholly at odds with EPA's 1985 guidance, is frequent and ongoing in PMN submissions as well as in section 8(e) notices.

C. Example of a Generic Name of a Chemical for Which a PMN was Filed in the Past that Included Health and Safety Studies

In recent months, pursuant to its 2010 policies, EPA has begun declassifying health and safety studies and disclosing the associated specific chemical identities. *See* EPA, Increasing Transparency in TSCA, http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html (last visited Feb. 29, 2012). Some of these health and safety studies were submitted with PMNs filed in the past. We have examined a number of these. For example:

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[19] EPA, 8(e) and FYI Submissions Received January 2012, http://www.epa.gov/oppt/tsca8e/pubs/8emonthlyreports/2012/8ejan2012.html (last visited Feb. 29, 2012).

[20] Certain New Chemicals; Receipt and Status Information, 77 Fed.Reg. 35, 10512-10515 (Feb. 22, 2012), http://www.gpo.gov/fdsys/pkg/FR-2012-02-22/pdf/2012-4069.pdf

- A PMN filed in 1999, for which a Notice of Commencement of manufacture was filed in 2002, was originally identified in the PMN merely as a "Halogenated Alkane." EPA recently posted a declassified copy of this PMN, which discloses the specific chemical identity as Propane, 1,1,1,3,3-pentachloro-.[21] Relative to the examples provided earlier, this generic name is more consistent with the 1985 guidance.

- Attached to the PMN were a Material Safety Data Sheet (MSDS) and a number of health and safety studies. These documents reveal the chemical to have considerable toxicity. The MSDS states, among other warnings:

    - POSSIBLE REPRODUCTIVE HAZARD May cause birth defects or other reproductive harm based on animal data.
    - INHALATION - TOXIC. Exposure to high concentrations of vapor or mist can cause central nervous system depression with symptoms of headache, dizziness, stupor, loss of consciousness or death, depending on concentration and duration of exposure. Overexposure to vapors has been associated with severe adverse effects on the liver, kidney, and nasal epithelium. Exposure to high concentrations of similar materials can cause irregular heartbeat, cardiac arrest and death.
    - CHRONIC EFFECTS - Studies in laboratory animals indicate that exposure to vapors of this material can cause adverse effects on the liver, kidney, and nasal epithelium. Overexposure to similar materials has been shown to cause adverse effects on the fetus, such as birth defects.[22]

Until EPA's recent declassification,[23] none of these disturbing effects could have been linked to this chemical – not by any member of the public, workers handling this chemical, health or environmental researchers or other professionals, state, Tribal or local government officials, or companies using or contemplating using this chemical. None of these stakeholders would have been able to search for this information even had they somehow known the specific chemical identity, because only the generic name had been disclosed. All they would have known would be that some mystery "Halogenated Alkane" now on the market had these toxic properties.

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[21] A copy of the original PMN, declassified chemical identity and associated health and safety studies is *available at* http://java.epa.gov/oppt_chemical_search/download?filename=09022526800b411d_P-99-1327_10-12-2011_PMN_PHCS_Original - 51990001327.pdf.

[22] *See id.*

[23] Unfortunately, EPA inadvertently kept the specific chemical identity of this "halogenated alkane" confidential well past the time of its receipt of the NOC in 2002, in which the submitter relinquished its CBI claim on chemical identity that it had made in its PMN submission. Nevertheless, even had EPA promptly disclosed this chemical's identity at the time of the NOC filing, three years would have passed during which abundant, critical toxicity data for the chemical would have been kept secret from key public, governmental, and market constituencies mentioned above.

ACC's proposed approach would allow the indefinite masking of the specific identity of such a chemical and its replacement by a useless generic name that could refer to any of hundreds or thousands of chemicals.

## V. Even Under TSCA Section 14(a), Chemical Identity is Not Shielded from Disclosure Unless it is CBI

Pursuant to TSCA Section 14, even outside of the context of health and safety studies, chemical identity is not shielded from disclosure unless it qualifies as a trade secret under the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4). EPA regulations implementing the requirements of FOIA set forth the substantive criteria to be applied in making confidentiality determinations, which include, among other things, that "the information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means . . ." and either "the business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position" or the information is voluntarily submitted to the government and disclosure would likely impair the government's ability to obtain necessary information in the future. 40 C.F.R. § 2.208(c), (e)(1)-(2). Although the release of trade secrets is associated with some costs, changes in technology and, particularly, the ability of competitors to "deformulate" or reverse engineer the ingredients of products has an impact on whether chemical identity is in fact reasonably obtainable and, also, whether disclosure is likely to cause competitive harm. *See Kewanee Oil Co. v. Bicron Corp*., 416 U.S. 470, 476 (1974) ("[T]rade secret law . . . does not offer protection against discovery by fair and honest means, such as by independent invention, accidental disclosure, or by so-called reverse engineering . . . ."); *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 93 F. Supp. 2d 1, 10-11 (D.D.C. 2000) ("No competitive harm can result if the information is publicly available through other sources.").[24] Any cost-benefit analysis of EPA's proposal should take into account that, even in the absence of the provisions of TSCA Section 14(b), chemical identity may not be considered CBI given increasing transparency worldwide as well as advances in the technology available to reverse engineer chemicals.

*Worthington Compressors, Inc. v. Costle,* 662 F.2d 45 (D.C. Cir.1981), sets forth the *cost* considerations in assessing whether reverse engineering makes information publicly available and hence not protected from disclosure. In *Worthington*, a manufacturer of air compressors requested all production verification and quality control reports submitted by other air compressor manufacturers. *Id.* at 48. The district court granted summary judgment for the EPA, which had disclosed the requested information. *Id.* at 52-53. The district court reasoned that the requested information was public because noise level information could be ascertained

[24] The party requesting the information "bears the initial burden of producing evidence to show that the information is available through public sources, but the burden of persuasion remains with the party opposing disclosure." *Id.* (citing *NW Coal. for Alts. to Pesticides v. Browner,* 941 F.Supp. 197, 202 (D.D.C.1996)).

through private testing (by purchasing a compressor and duplicating standard noise test procedures) and design and engineering specifications could be reverse engineered. *Id.* The D.C. Circuit reversed, finding that summary judgment was precluded, but recognized that the ability to reverse engineer raised factual questions about whether information was publicly available:

> In this case, . . . the requested information is available, at some cost, from an additional source. In our view, this requires that the inquiry be expanded to include two considerations: (1) the commercial value of the requested information, and (2) the cost of acquiring the information through other means.
>
> The first consideration is based on the obvious fact that a submitter can suffer competitive harm only if the requested information has commercial value to competitors. When the information does have commercial value, the second consideration comes into play. If the information is freely or cheaply available from other sources, such as reverse engineering, it can hardly be called confidential and agency disclosure is unlikely to cause competitive harm to the submitter.

*Id.* at 51. Because material factual issues existed as to the cost of seeking the requested information, the commercial value of such information, and the practicality of reverse engineering, the D.C. Circuit found that summary judgment was inappropriate.

In *NW Coalition for Alternatives to Pesticides v. Browner*, plaintiffs sought the common names and CAS numbers of inert ingredients in certain pesticides. 941 F. Supp. 197 (D.D.C. 1996). The court determined that the common names and CAS numbers of the ingredients were not trade secrets, but nevertheless found that some of the information was protected as CBI. *See id.* at 202-205. The court noted that:

> There is no genuine issue of material fact as to the economic feasibility of identifying the common names and CAS numbers of inert ingredients through 'reverse engineering.' Plaintiffs state that reverse engineering to identify *ingredients* is common practice in the pesticide industry. . . . Defendants state that it is costly and impracticable to reverse engineer pesticide *formulas*. Neither factual proposition is challenged, and both are accepted as true. Lying between those two propositions, however, and unexplained on this record, is the question of how difficult and costly it is or would be to learn the identity of the inert ingredients of the six pesticides in question by reverse engineering.

*Id.* at 202. The court found that EPA failed to meet its "burden of both production and persuasion" on this point. *Id.*

## VI. Disclosure is Associated with Social and Economic Benefits, Which Were Ignored by ACC

ACC quotes a Council on Environmental Quality report to show that chemical identities in health and safety studies have recognized economic value. Specifically, ACC points to language in the report stating that "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," and that "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 the same economic consequences as disclosure of confidential data regarding a new product." ACC White Paper at 5; *see also* U.S. Council on Environmental Quality, Toxic Substances Strategy Committee, Toxic Chemicals and Public Protection: A Report to the President 48 (1980). ACC, however, fails to mention that these statements are selectively taken from the first half of a section in the CEQ report that first assesses the drawbacks of routine disclosure of confidential health and safety data, and then goes on to consider the benefits of routine disclosure. *See* CEQ Toxic Substances Strategy Committee, Toxic Chemicals and Public Protection at 49-54. The report points out, "the need for assessing risks from the increasing number of potentially toxic chemicals in the environment and the well-recognized right of citizens to be informed about their health and well-being are strong arguments for public access to data reflecting on the safety or health effects of a chemical to which they may be exposed." *See id.* at 49. The report further notes the following consequences of nondisclosure:

> First, the value of scientific peer review is lost, and errors in test methods or data may not be detected. Failure to identify potential dangers because of faulty data may have serious health or environmental consequences. Second, the possibility of needless duplication of tests, with the attendant waste of scarce scientific resources, is enhanced. Third, advancement of scientific knowledge can be hindered by one researcher's lack of access to the experience and insights of another.

*Id.* at 50. The CEQ report concluded that not all health and safety data was confidential, and that "the trend in recent legislation, particularly TSCA and FIFRA, is to accord confidential health, safety, and efficacy data less protection from disclosure than general confidential information on the ground that the public has an especially strong interest in access to these data." *Id.* at 47.

Undoubtedly, there are costs associated with disclosure of previously confidential chemical identities. Yet, when information is withheld from the public and the scientific community, there are also adverse consequences. The empirical relationship between confidentiality of business information on the one hand and innovation and economic growth

on the other, assumed by ACC, is inconclusive.[25] For example, confidentiality can hamper productive innovation in a way that may offset any innovation incentive provided by the prospect of maintaining trade secrets. When an inventor maintains a trade secret, innovators will not be able to learn from the scientific and technological insights that led to the original invention, slowing the overall rate of innovation.[26] To make matters worse, under trade secret laws, firms are likely to waste scarce resources pursuing an invention that has already been made rather than investing in socially productive innovation.[27]

The lack of publicly available information also impedes the market from responding to the demand for safer chemicals because sufficient information is not available to help the market, generally, and consumers, in particular, distinguish safe from unsafe chemicals. Secrecy has an impact on all players in the market: consumers, workers, downstream industrial users of chemicals, and others. As the Final Report of California's Green Chemistry Initiative stated, "There are tens of thousands of chemicals in use today, but we know very little about how they effect people or the environment. This information gap prevents the free market from working properly to stimulate the innovation of safer, healthier substitutions." California Green Chemistry Initiative, Final Report at 1 (December, 2008); *see also* Joseph H. Guth, et al., *Require Comprehensive Safety Data for All Chemicals*, 17 New Solutions 233, 234 (2007) (data gaps "constitute a `failure' in the chemicals market economy that prevents buyers of chemicals from choosing safer alternatives and reduces market incentives for the chemical industry to innovate safer chemicals").

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[25] *See* U.S. Council on Environmental Quality, Toxic Substances Strategy Committee, Toxic Chemicals and Public Protection: A Report to the President 47 (1980) ("it is unclear today how much that incentive [to innovate] is affected by disclosure of confidential health, safety, and efficacy data").

[26] Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 Cal. L. Rev. 241, 266-267 (1998).

[27] *Id.*; *see also* Thomas O. McGarity and Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 Harv. L. Rev., 837, 845 (1980).

We appreciate your consideration.

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On behalf of the Signatory Organizations

BlueGreen Alliance
Breast Cancer Fund
Clean Water Action/Clean Water Fund
Earthjustice
Environmental Defense Fund
National Medical Association
Science Environmental Health Network
Women's Voices for the Earth

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Joseph H. Guth, Science & Environmental Health Network
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Jamie Silberberger, Women's Voices for the Earth
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