

**AAIDD's Environmental Health Initiative * Alaska Community Action on Toxics
Association of Reproductive Health Professionals * American Nurses Association
Autism Society * BlueGreen Alliance * Breast Cancer Fund * Clean New York
Clean Water Action * Commonweal * Connecticut Coalition for Environmental Justice
Earthjustice * Environmental Defense Fund * Environmental Health Strategy Center
Environment California * The Green Science Policy Institute * Health Care Without Harm
Healthy Building Network * Kentucky Environmental Foundation
Learning Disabilities Association of America * Natural Resources Defense Council
New Jersey Work Environmental Council * Oregon Toxics Alliance * PODER
Science and Environmental Health Network * Women's Voices for the Earth**

August 25, 2010

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001
By Mail & Online
At <http://www.regulations.gov>

Docket ID No. EPA-HQ-OPPT-2010-0446

**RE: Comments on EPA's 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 Federal Register 29,754 (May 27, 2010).**

Dear Administrator Jackson:

Alaska Community Action on Toxics, AAIDD's Environmental Health Initiative, American Nurses Association, Association of Reproductive Health Professionals, Autism Society, BlueGreen Alliance, Breast Cancer Fund, Clean New York, Clean Water Action, Commonweal, Connecticut Coalition for Environmental Justice, Earthjustice, Environmental Defense Fund, Environment California, Environmental Health Strategy Center, The Green Science Policy Institute, Health Care Without Harm, Healthy Building Network, Kentucky Environmental Foundation, Learning Disabilities Association of America, New Jersey Work Environmental Council, NRDC, Oregon Toxics Alliance, PODER, Science Environmental Health Network, and Women's Voices for the Earth respectfully submit the following comments regarding the 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 (TSCA), published by the Environmental Protection Agency (EPA) at 75 Fed. Reg. 29,754 (May 27, 2010) (the Notice).¹

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 Inventory of TSCA (the Inventory) is confidential business information (CBI). 75 Fed. Reg. 3462 (January 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 will review the claim and “expects to find that the chemical identity clearly is not entitled to confidential treatment.” *Id.* This policy was a welcome step toward making more health and safety information available to the public but did not address the many unfounded CBI claims pertaining to the identity of such chemicals not listed on the public portion of the TSCA Inventory. The May 27 Notice takes this next step.

As discussed in more detail below, EPA’s announcement that it will 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 will help to bring agency action in line with the purposes and mandates of TSCA. 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. Although there remain a number of issues relating to disclosure of information under TSCA that continue to require the attention of Congress, EPA should exercise its authority to implement fully the mandates of current law, and this policy is an important step toward increasing the public’s access to information on chemicals to which they may be exposed. These comments are intended to support EPA’s new policy to review and reject both new and previously asserted CBI claims for the identity of chemicals in the context of health and safety information, and, also, to raise specific concerns and make recommendations about the implementation of the policy.

A. EPA’s Policy Is Long Overdue; If Fully Implemented, It Will Help to Bring Practice into Line with the Intent and Mandate of TSCA

Critical health and safety information has been shielded from public view because of both submitters’ assertion of excessive and often unfounded CBI claims and the failure of EPA routinely to review and reach determinations as to the legitimacy of those claims. Eighteen 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. Office of Pollution Prevention and Toxics, U.S. EPA, *Final Action Plan: TSCA Confidential*

¹ The signatories to these comments are non-profit public interest advocacy organizations that seek effective government regulation of chemicals. Please find a brief description of the signatory organizations in the appendix following these comments.

Business Information Reform 5 (1994) (Final Action Plan). The 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 intro (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.* 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 will begin 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.

1. Unfounded CBI Claims Have for Too Long Kept Health and Safety Information from the Public, Undermining the Mandate of TSCA

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(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). 15 U.S.C. §§ 2603, 2604, 2607(d)-(e).

Despite TSCA’s explicit language making clear that data from health and safety studies are not protected from disclosure by CBI claims, EPA has typically accepted CBI claims without review even as to health and safety data, thereby preventing disclosure of health and safety information, including chemical identity, for example 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. *Id.* § 2607(e).² 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 frequently assert that the names of the chemicals at issue constitute CBI, and EPA typically accepts these claims without question unless someone seeks the information through a request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552(a). Thus chemical names are 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*

<http://www.epa.gov/opptintr/tsca8e/pubs/8emonthlyreports/2009/8enov2009.html>; *see also infra* 3-4 identifying examples of improper CBI claims made in Section 8(e) notices. 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).

Absent specific chemical names, the health and environmental risk information provided in Section 8(e) notices is of little or no public value. As a recent 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* 12 (July 28, 2009).

Consider, for example, the information provided in a "Company Sanitized" Section 8(e) notice about an "Optionally Substituted Aromatic Substance." *See* BASF, Notice in Accordance with Section 8(e): Results of a Developmental Toxicity Screening Study in Wistar Rats with Optionally Substituted Aromatic Substance, 8EHQ-09-17748, at 1 (Nov. 25, 2009), at 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%)

Two fetuses with cleft palate

Four fetuses with anasarca

Fourteen fetuses with malrotated limbs

² 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.

Id. at 2. Despite including 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.” BASF, 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, 8 EHQ-1109-17747A, at 1 (Nov. 25, 2009), at http://www.epa.gov/opptintr/tscas8e/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 is thus on notice of danger from an unspecified “crop protection formulation,” but the notice is otherwise of severely limited utility.

In another recent 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. 16, 2010), at http://www.epa.gov/opptintr/tscas8e/pubs/8ehq/2010/apr10/8ehq_0410_17890a.pdf (company name and identification of study 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:

[] 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).

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. *See also* Richard A. Denison, Hiding a Toxic Nanomaterial's Identity: TSCA's Disappearing Act (July 14, 2009), at <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").

2. EPA's New Policy Is Consistent with Its Statutory Authority and the Mandates of TSCA

EPA's newly announced policy more accurately reflects the language and intent of the statute. TSCA Section 14(b)(1) places strict limits on CBI protection in association with health and safety information. Specifically, TSCA Section 14(b)(1) explicitly authorizes disclosure, barring CBI protection, for "health and safety" studies and data under the following circumstances:

- (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 only exception from these limits on CBI protection of health and safety studies and data is for 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 chemical substances in the mixture." *Id.* § 2613(b)(1)(B). The statute makes clear that, in response to requests made under the FOIA for health and safety information that does not qualify for this limited exception, EPA "may not deny such request on the basis of subsection (b)(4) of FOIA, which is the subsection of FOIA governing confidential treatment of "trade secrets and commercial or financial information." *See* 5 U.S.C. § 552(b)(4).

By its very terms, therefore, TSCA bars CBI claims for health and safety studies, except in the limited instances where, if made public, information would disclose processes used in the manufacturing or processing of a substance or mixture, or, in the case of a mixture, the portions of the mixture. *See id.* § 2613(b). 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 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). 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.”). In the context of a health and safety study, therefore, chemical identity is not entitled to CBI protection unless it would directly reveal process information or portions of a mixture.

The Notice correctly dismisses what would be an overly broad interpretation of the exception from disclosure for process information and portions of a mixture. *See* 75 Fed. Reg. at 29756 (“Disclosing the end product of a process (i.e., a chemical identity) is not the same thing as disclosing the process to make that end product” and “as a general matter disclosure of a chemical identity does not disclose process information except where the identity explicitly contains process information.”). EPA appropriately rejects the argument that chemical identity should be eligible for CBI protection on the grounds that disclosure could assist a competitor to glean information about a process.

EPA has itself consistently taken this view, although until now its practices have not followed suit. *See* Sheila A. Ferguson, *et al.*, *Influence of CBI Requirements on TSCA Implementation* 23-24 (March 1992) (“[A]s OPPT attorneys have pointed out, chemical identity can only be claimed confidential in a health and safety study when the submitter can demonstrate that knowledge of identity *per se* is sufficient to disclose a process of manufacture or portions of a mixture, a condition that would almost never be true.”). Simply put, chemical identity must be disclosed unless the submitter affirmatively demonstrates that such identity *explicitly* contains process or mixture information.

As recognized by EPA back in 1994, the dissemination of meaningful information about chemicals is not only consistent with the language of the statute, but also with congressional intent. *See* Final Action Plan at 3-4 (citing Legislative History of the Toxic Substances Control Act, 218 (1976) (quoting statement of Senator Pearson (“[T]he essential element of this legislation is that it has attempted to provide the individual ... the right to know what is in store as far as the toxicity of chemicals is concerned”); Senator Hartke (stating that “there are thousands and thousands of items at this moment which are going undetected and unknown by

millions of Americans and it is high time we recognized that they are entitled not alone to the right to know” but also to have EPA act effectively)).

EPA’s regulations governing *new* chemicals (i.e., chemicals for which notice is required under TSCA Section 5) refer to the statutory allowance for confidentiality treatment for a chemical identity that would disclose process or portion information. EPA’s regulations state further that confidentiality of chemical identity might be granted if “[t]he specific chemical identity is not necessary to interpret a health and safety study.” 40 C.F.R. § 720.90(b). This additional exclusion appears to be in direct conflict with the statutory and regulatory language described above. In any event, EPA’s own reports indicate that it would be highly unusual for the agency to conclude that the specific chemical identity is not necessary to interpret a health and safety study. In particular, a 1992 report commissioned by EPA’s Office of Pollution Prevention and Toxics (OPPT) summarized the low likelihood that chemical identity would *not* be necessary to interpret a health and safety study as follows:

OPPT attorneys have argued that it is *rarely* the case that chemical identity information could legitimately be covered by such an exemption. 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 A. Ferguson, *et al.*, *Influence of CBI Requirements on TSCA Implementation* 24 (March 1992) (emphasis in original).

Likewise, the CBI Final Action Plan developed by OPPT in 1994 declares that “[t]he utility of a health and safety study, particularly for chemicals in commercial distribution, is greatly enhanced by connection to a specific chemical identity.” *Response to Comments Received on the Proposed Actions to Reform TSCA Confidential Business Information Working Paper*, Appendix to the Final Action Plan, at 3. Specifically, OPPT explains: “This connection allows for risk analysis by all segments of the interested public, including the chemical industry. In many instances, a broad spectrum [of] industry has taken immediate voluntary protective actions when new, readily identifiable hazards are reported to OPPT under TSCA §8(e).” OPPT emphasizes: “Such actions cannot take place when a hazard cannot be associated with a specific chemical.” *Id.*

B. EPA Should Take Concrete Steps to Ensure Transparency and Accountability in the CBI Review Process

This administration has emphasized a commitment to transparency in carrying out its duties. The Administrator’s Opening Memo to EPA Employees strongly expressed this principle:

Public trust in the Agency demands that we reach out to all stakeholders fairly and impartially, that we consider the views and data presented carefully and objectively, and that we fully disclose the information that forms the bases for our decisions. I pledge that we will carry out the work of the Agency in public view so that the door is open to all

interested parties and that there is no doubt why we are acting and how we arrived at our decisions.

Lisa P. Jackson, Opening Memo to EPA Employees, (January 23, 2009), <http://blog.epa.gov/administrator/2009/01/26/opening-memo-to-epa-employees/#more-174>. Given the long history of EPA's permissiveness in allowing CBI claims, transparency in the review process will be critical to re-establishing public trust and credibility.

The Notice indicates that the agency will respond to CBI claims regarding chemical identity in health and safety studies and in data from these studies with determination letters pursuant to 40 CFR §§ 2.306(d), 2.204(d)(2), and 2.205(f) and will provide a contact within EPA whom the recipient of the letter can contact with questions or concerns about the determination. *See* 75 Fed. Reg. at 29,755. Yet the Notice is silent as to any method that the agency will use to track or report on the status of its review process. *See id.* at 29,754-55.

At a minimum, EPA should implement a system for tracking and publicly reporting the status of all reviewed and challenged claims, both pre-existing and new, so that the public will have accurate and up to date information about the number of CBI claims; the status of Agency claim reviews and determinations, including whether claims are pending, approved or denied; whether claims are withdrawn; the timeline for review of claims; whether determinations are being challenged; and the status of any such challenges.

The agency should track claims using identification numbers (for example, Section 8(e) notices are assigned numbers) and, will in this way be able to disclose information about the process and its status and progress to the public without releasing chemical identity or other data claimed to be confidential during the pendency of the review process and any appeal.

The status of CBI claims and EPA determinations upon review of such claims are matters of public interest and should be made available on EPA's website in a timely manner.

C. Claim Reviews Should Be Completed by a Date Certain and Prioritized Using Section 8(e) Triage Criteria and Other Indicators of Risk, Use, and High Production Volume, and the Criteria Should Be Made Public

The Notice made clear that reviews will include both newly submitted and pre-existing CBI claims. We presume and expect that EPA will review all newly submitted CBI claims in association with health and safety information as they are submitted. With respect to pre-existing claims, the large number of such claims poses challenges with respect to how, with limitations on resources, the review process can be prioritized and ultimately completed in a timely way, and whether particular types or subsets of claims should be prioritized. The undersigned urge the Administrator to establish a firm deadline on the order of two years for the completion of all retroactive reviews and to allocate sufficient resources to complete reviews of both retroactive and new CBI claims in a timely way. We offer the following recommendations for prioritizing which CBI claims regarding chemical identity in health and safety studies and data should be reviewed and challenged first:

1. Any chemicals for which the submitted data trigger EPA's Section 8(e) "triage" criteria for chemicals of concern: for the purpose of reviewing 8(e) notices, EPA has developed explicit cutoff values for various health and environmental endpoints to flag chemicals that present evidence of serious concern.³ CBI claims for those chemicals that have met the triage criteria should clearly be reviewed early.
2. Chemicals that have commercial or consumer product uses (especially in products to which children or other vulnerable populations may be exposed) as reported in the last cycle of the Inventory Update Rule (IUR) reporting (2006).
3. Chemicals classified or identified as carcinogens, mutagens, reproductive toxicants or PBTs by EPA, NTP, IARC, California's Proposition 65, or the European Union.
4. Chemicals detected in biomonitoring, based on sampling and analysis of tissues and body fluids.
5. Chemicals listed on the Toxics Release Inventory or regulated by EPA under various federal laws, i.e., the Clean Air Act, the Clean Water Act, etc.
6. High production volume (HPV) chemicals.

Criteria for prioritizing EPA's CBI reviews should be clearly articulated and made available to the public.

D. Agency Review of CBI Claims Should Include Review of Claims Related to Disclosure of Chemical Identity on the TSCA Inventory

TSCA Section 8(b) establishes the Inventory and requires EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States." 15 U.S.C. § 2607(b) (emphasis added). As an Environmental Working Group analysis reported, however, "[t]he public has no access to any information about approximately 17,000 of the more than 83,000 chemicals on the master inventory compiled by the EPA." Indeed, "[i]ndustry has placed 'confidential business information' (CBI) claims on the identity of 13,596 new chemicals produced since 1976 – nearly two-thirds of the 20,403 chemicals added to the list in the past 33 years." David Andrews & Richard Wiles, *Off The Books: Industry's Secret Chemicals*, Environmental Working Group 2 (December, 2009), <http://www.ewg.org/files/secretchemicals.pdf> (emphasis in original).

The Notice appropriately indicates that EPA expects to review industry CBI claims related to the disclosure of chemical identity on the Inventory in connection with its review and determination under TSCA Section 14(b).

EPA considers confidentiality claims related to the disclosure of chemical identity on the public Inventory in accordance with the "Substantive Criteria for Use in Confidentiality

³ EPA's Frequent Questions for Section 8(e) Notices, www.epa.gov/opptintr/tscas8e/pubs/frequentlyaskedquestionsfaqs.html (last updated April 29, 2010), refers to criteria in the "1996 EPA hazard ranking system for TSCA §8(e) triage evaluation."

Determinations” set forth in 40 C.F.R. § 2.208, rather than in accordance with the CBI standard for health and safety studies in TSCA Section 14(b). The Inventory “is a listing of all chemical substances manufactured, imported, or processed for a commercial purpose, which EPA was directed to establish and maintain pursuant to TSCA section 8,” 74 Fed. Reg. 37,224 (June 28, 2009), and contains no health and safety information. Disclosure of chemical identity for this purpose is not governed by TSCA Section 14(b), 15 U.S.C. 2613(b) (disclosure of data from health and safety studies), and is not, therefore, subject to 14(b)’s exception to disclosure for information that discloses processes or portions. *See* 15 U.S.C. §§ 2607(b), 2613(b); 40 C.F.R. § 2.208. Instead, information reported to EPA for purposes of placement on the Inventory falls within the scope of TSCA Section 14(a), 15 U.S.C. § 2613(a), which relies on standards set forth by the Freedom of Information Act, 5 U.S.C. § 552 (a), (b)(4), with exceptions allowing disclosure in specific circumstances. *See, e.g.*, 15 U.S.C. § 2613(a)(3) (information “shall be disclosed if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment”).

Criteria for evaluating CBI claims related to the disclosure of chemical identity on the Inventory are thus not identical to those governing the analysis of CBI claims shielding chemical identity that is part of health and safety information submitted pursuant to other sections of TSCA. Most notably, the statute explicitly directs EPA to “publish” each chemical substance that is manufactured or processed within the United States. Even assuming, *arguendo*, the legality of keeping the identity of chemicals listed on the Inventory secret, public disclosure of chemical identity in the context of health and safety information will nonetheless affect CBI claims relevant to the Inventory. Regulations establishing the criteria for determining confidentiality under TSCA outside of the context of health and safety studies and data require an evaluation of whether the company has asserted a valid CBI claim. 40 C.F.R. 2.208.⁴ Therefore, a determination under TSCA Section 14(b) that chemical identity should be disclosed in the context of a health and safety study should inherently limit claims to confidentiality on the Inventory. That is, if the identity of a chemical is determined not to be eligible for protection in association with health and safety information and is thus made public, then by virtue of its identity becoming public it is no longer eligible for CBI protection in other contexts, including

⁴ Regulations setting forth criteria for use in confidentiality determinations provide that information is entitled to confidential treatment if:

- (a) The business has asserted a business confidentiality claim which has not expired by its terms, nor been waived nor withdrawn;
- (b) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures;
- (c) 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 ...
- (d) No statute specifically requires disclosure of the information; and
- (e) either
 - (1) The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business’s competitive position; or
 - (2) The information is voluntarily submitted information ... and its disclosure would be likely to impair the Government’s ability to obtain necessary information in the future.

its listing on the Inventory. Review of CBI claims for chemicals on the Inventory is critical to enhancing public awareness and to fulfilling the intent of TSCA.

E. EPA Should Require the Recertification of Claims for the Confidentiality of Chemical Identity After a Certain Period of Time and Not Allow Information to Be Withheld from the Public Indefinitely Without Substantiation

Finally, EPA should further strengthen its policy for reviewing confidentiality claims for chemical identity pursuant to both TSCA Section 14(b)(health and safety studies) and TSCA Section 8(b) (the Inventory) by requiring submitters to reassert and justify any new CBI claims, or any previous claims that EPA reviews under the new policy and determines are valid, after a certain period of time. Any claim that has not been reasserted and justified should be deemed waived after this time. Confidentiality claims are more likely to be legitimate early in the life of a chemical, and may no longer qualify after the chemical has entered and become established in the market. Taking this into account, an expiration date of no more than five years would balance the interests of the chemical industry, concern for EPA's workload, and the goal of maximizing public access to chemical information.⁵

A recertification requirement is consistent with federal law governing the release of confidential commercial information, *see, e.g.*, Executive Order 12600 ("agency procedures may provide for the expiration, after a specified period of time or changes in circumstances, of designations of competitive harm made by submitters"), and with EPA's recognition that the institutionalization of periodic review of claims would be beneficial in weeding out "unnecessary expired CBI claims." Final Action Plan, at 9. The Final Action Plan explained, "By 'expired CBI claims,' we mean those claims [for which] the need for confidentiality has ended over time." *Id.* EPA's notice of a recertification policy should make clear that CBI claims expire unless reasserted. As Linda Fisher, Chief Sustainability Office at DuPont recently testified, the need to recertify would "drive more rigor that would help ensure only truly CBI info gets claimed for protection." Linda Fisher, Statement before the Sen. Subcomm. on Superfund, Toxics and Env. Health, Comm. on Env. and Public Works at 5 (March 9, 2010), at http://epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=e4eab882-a990-4dac-869a-899886626fe5.

⁵ See GAO, at 34 ("Chemical industry representatives said that a requirement to reassert claims of confidentially [sic] at some later date would not be disruptive to the industry if the effective date of the requirement occurred after a considerable period had passed, such as 5 years or more after the information was initially claimed as confidential.")

We appreciate your solicitation of comments on these important issues. Thank you in advance for your consideration of our comments.

Sincerely,



Richard A. Denison, Ph.D.
Senior Scientist
Environmental Defense Fund
1875 Connecticut Avenue, NW #600
Washington, DC 20009
tel: 202/387-3500, x3348
fax: 202/234-6049
rdenison@edf.org



Marianne L. Engelman Lado
Staff Attorney
Earthjustice
156 William Street, Suite 800
New York, NY 10038
tel: 212/719-1881 x228
fax: 212/918-1556
mengelmanlado@earthjustice.org

On behalf of the Signatory Organizations

Appendix Signatory Organizations

Alaska Community Action on Toxics

Alaska Community Action on Toxics (ACAT) is a statewide organization established in 1997 and dedicated to achieving environmental health and justice. *See* <http://www.akaction.org/favicon.ico>. The mission of ACAT is to assure justice by advocating for environmental and community health. ACAT protects the rights to clean air, clean water, and toxic-free food. ACAT works to eliminate the production and release of harmful chemicals by industry and military sources; ensure the community's right-to-know; achieve policies based on the precautionary principle; and support the rights and sovereignty of Indigenous peoples.

American Association on Intellectual and Developmental Disabilities' (AAIDD's) Environmental Health Initiative

AAIDD's Environmental Health Initiative (EHI) represents people with intellectual and developmental disabilities who have the right to live, work, learn, worship and play in environments that are healthy and safe. For over 30 years TSCA has allowed industry to use confidential business information (CBI) not only to protect "trade secrets" but also to hide the health dangers in the chemical make-up of the products being introduced into commerce. EHI's constituency is particularly vulnerable to chemical exposure and, without accurate and complete knowledge of the chemicals in the products they use, those with disabilities and their advocates are unable to protect them from the health effects from chemicals in thousands of products. EHI applauds EPA's new policy of reviewing confidentiality claims in health and safety studies and believes it will increase the access of all citizens, including those with intellectual, developmental and learning disabilities, to information critical to their health. *See* http://www.aamr.org/ehi/content_323.cfm?navID=105.

American Nurses Association

The American Nurses Association (ANA) is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses through its constituent member nurses associations, its organizational affiliates, and its workforce advocacy affiliate, the Center for American Nurses. The ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and by lobbying Congress and regulatory agencies on health care issues affecting nurses and the public. *See* <http://www.nursingworld.org>.

Association of Reproductive Health Professionals

The Association of Reproductive Health Professionals (ARHP) is the leading source for trusted medical education and information on reproductive and sexual health. ARHP educates health care providers, informs consumers, and impacts public policy. Through convening teams of organizational colleagues and respected experts, ARHP advocates for reproductive health

advances and educates professionals across specialties. ARHP is well positioned as the leader in providing credible, evidence-based programs on all that is current and urgent in reproductive health. ARHP has served a leadership role in educating professionals and the public about the impact of environmental toxicants on reproductive health. See <http://www.arhp.org/>.

Autism Society

The mission of the Autism Society Environmental Health Initiative is to improve the lives of individuals with autism spectrum disorders (ASD) by fostering an understanding of environmental contributors to the onset and severity of neurodevelopmental disabilities and other health issues. See <http://www.autism-society.org>.

BlueGreen Alliance

The BlueGreen Alliance is a national, strategic partnership between nine labor unions and two environmental organizations, which unites more than eight and a half million people in pursuit of good jobs, a clean environment and a green economy. See <http://www.bluegreenalliance.org>. One of the Alliance's priorities is to create an informed 21st century policy on toxic chemicals that protects workers and communities from dangerous chemicals, enhances public health, and promotes safer alternatives. The BlueGreen Alliance works with eight unions and two environmental partner organizations to achieve its goals.

Breast Cancer Fund

The Breast Cancer Fund is a national non-profit organization whose mission is to prevent breast cancer by identifying and working to eliminate the environmental causes of the disease. See <http://www.breastcancerfund.org>. The Breast Cancer Fund has a strong track record of raising awareness and educating the public through traditional media outreach and social networking outlets. The Breast Cancer Fund is a member of numerous and extensive coalitions, which connect it with millions of individuals who care about health and the environment.

Clean New York

Clean New York advances broad policy and market changes to protect people and communities from toxic chemicals. See <http://clean-ny.org>. Each of Clean New York's efforts focuses on comprehensive chemical policy reform, including engaging New Yorkers at the grassroots level through such gateway issues as cleaners, cosmetics, and children's products, and documenting the problems posed by our failed system through biomonitoring and product testing. Our top priority is an infrastructure policy within New York State and the federal government that categorizes chemicals of concern, determines where they are used, and moves manufacturers to safer solutions to toxic chemicals, especially in children's products.

Clean Water Action

Clean Water Action, a national nonprofit environmental organization with 1.4 million members, operates programs across four main areas: Protecting America's Waters; Global Warming & a

New Energy Economy; Healthy, Safer Families and Communities; and Making Democracy Work. See <http://www.cleanwateraction.org/issues>. Clean Water Action employs professional door-to-door and telephone canvassers who conduct person-to-person education campaigns reaching hundreds of thousands of additional households each year, which have proven highly effective at communicating complex information on toxics and environmental health to diverse communities in all parts of the U.S.

Commonweal

Commonweal is a nonprofit health and environmental research institute in Bolinas, California. Founded in 1976, Commonweal conducts programs that contribute to human and ecosystem health — to a safer world for people and for all life. We support local, national and international initiatives that contribute to human health and a healthy environment, including the Collaborative on Health and the Environment, Health Care Without Harm, Safe Cosmetics Campaign, the Commonweal Biomonitoring Resource Center, Women's Health & the Environment, the Commonweal Garden, the Commonweal Fair Growth Program, and the Commonweal Ocean Policy Program. See <http://www.commonweal.org/>.

Connecticut Coalition for Environmental Justice

Connecticut Coalition for Environmental Justice (CCEJ) strives to reduce the burden of environmental toxins in the urban areas and communities of color in Connecticut. By doing so, CCEJ aims to prevent and reduce environmentally associated harmful health effects such as asthma and other respiratory conditions, lead poisoning, cancer, and adverse developmental effects including physical, mental and emotional development, and learning disabilities. See <http://www.environmental-justice.org/>.

Earthjustice

Earthjustice, a national nonprofit environmental law firm, has made safeguarding public health against toxic chemicals one of its top priorities and has developed expertise in this area. See http://www.earthjustice.org/our_work/health_and_toxics/. For more than three decades, Earthjustice has been at the forefront of safeguarding the fundamentals of human health — the air we breathe, the food we eat, and the water we drink. Earthjustice works to ensure that right-to-know laws are enforced so that people have access to information about the health risks posed by chemicals.

Environment California

Environment California is a statewide, citizen-based environmental advocacy organization. See <http://www.environmentcalifornia.org/>. Our professional staff combines independent research, practical ideas and tough-minded advocacy to overcome the opposition of powerful special interests and win real results for California's environment. Our Toxics and Environmental Health Program aims to protect human health and the environment from toxic chemicals by educating the public and decision-makers about the effects of toxics on our health and

advocating for policy reform that will reduce our exposure in the short term and eliminate the root causes in the long term.

Environmental Defense Fund

Environmental Defense Fund (EDF) is a leading national nonprofit organization representing more than 700,000 members. Since 1967, EDF has linked science, economics, law and innovative private-sector partnerships to create breakthrough solutions to the most serious environmental problems. For many years, EDF has been actively engaged in the public debate over the safety of industrial chemicals. EDF staff members have published numerous papers and reports, and have commented extensively on EPA's proposals and decisions relating to such chemicals. See <http://www.edf.org/page.cfm?tagID=90>.

Environmental Health Strategy Center

Environmental Health Strategy Center (EHSC) is a Maine-based environmental public health organization with offices in Portland and Bangor, Maine. The EHSC promotes human health and safer chemicals in a sustainable economy. We believe that every person has the right to a clean and healthful environment wherever they live, work, learn or play. We envision a future in which an environmentally sustainable economy provides good jobs, healthy communities and social justice for all. See <http://www.preventharm.org>.

Green Science Policy Institute

The Green Science Policy Institute (GSP) provides unbiased scientific information to government, industry, and non-governmental organizations to facilitate more informed decision-making about chemicals used in consumer products in order to protect health and environment world-wide. See <http://www.greensciencepolicy.org/>. The Green Science Policy Institute provides unbiased scientific data to government, industry, and non-governmental organizations to facilitate more informed decision-making about chemicals used in consumer products.

Health Care Without Harm

Together with our partners around the world, Health Care Without Harm (HCWH) shares a vision of a health care sector that does no harm, and instead promotes the health of people and the environment. To that end, HCWH works to implement ecologically sound and healthy alternatives to health care practices that pollute the environment and contribute to disease. The organization is an international coalition of hospitals and health care systems, medical professionals, community groups, health-affected constituencies, labor unions, environmental and environmental health organizations and religious groups. HCWH works to ensure patients, workers and communities have full access to information about chemicals used in health care and can participate in decisions about exposures to chemicals. See <http://www.noharm.org/>.

Healthy Building Network

The Healthy Building Network is a non-profit organization whose mission is to transform the building materials market in order to advance best environmental, health and social equity practices over the lifecycle of building materials. See <http://www.healthybuilding.net/>. Our Pharos Project is an on-line tool that helps green building professionals identify, evaluate and compare building materials against multiple attributes, including the willingness of manufacturers to disclose the ingredients in their products. In our own investigations of confidentiality claims, we often find the requested information available elsewhere on the internet.

Kentucky Environmental Foundation

The Kentucky Environmental Foundation (KEF) is a nonprofit organization dedicated to securing solutions to environmental problems in a manner that safeguards human health, promotes environmental justice, preserves ecological systems and encourages sustainability. See <http://www.kyenvironmentalfoundation.org/>. KEF's experience finding and implementing solutions for chemical weapons disposal through the work of our Chemical Weapons Working Group coalition, is that transparency and information sharing between companies, community members and policy makers is not only feasible, but necessary to establish win-win scenarios for all parties and ultimately the prevention of harmful toxic exposures.

Learning Disabilities Association of America

Learning Disabilities Association of America (LDA) is the oldest national organization advocating for people with learning disabilities and their families, with several hundred state and local affiliates. See <http://www.ldanatl.org/>. LDA seeks to raise awareness of toxic chemicals linked to problems with brain development and to prevent toxic chemical exposures, especially among pregnant women and children.

Natural Resources Defense Council

The Natural Resources Defense Council (NRDC) uses law, science and the support of 1.3 million members and online activists to protect the planet's wildlife and wild places and to ensure a safe and healthy environment for all living things. NRDC has a long-standing interest in protecting the public from toxic chemicals, and ensuring the public has access to information about their hazards and uses. See <http://www.nrdc.org>.

New Jersey Work Environment Council

The New Jersey Work Environment Council (WEC) is a non-profit alliance of 70 labor, environmental and community organizations working for safe, secure jobs and a healthy, sustainable environment and has significant expertise and experience concerning preventing exposures to toxic chemicals. See <http://www.njwec.org>. WEC connects with many thousands of members of WEC-affiliated organizations throughout New Jersey.

Oregon Toxics Alliance

The mission of the Oregon Toxics Alliance (OTA) is to work for all Oregonians to expose the root causes of toxic pollution and help communities find solutions that protect human and environmental health. See <http://www.oregontoxics.org/>. OTA adheres to two proactive commitments. Our first goal is to challenge the root causes of toxic pollution in Oregon by changing policies and laws, and our second is to provide grassroots, direct-action on local projects to preserve the environment and protect public health. OTA believes that communities should have the right to clean air, land and water. Our organization was founded on the underlying principle that communities have a right to participate with informed consent about the decisions that affect their own health.

People Organized in Defense of Earth and Her Resources

People Organized in the Defense of the Earth and her Resources (PODER) redefines environmental issues as social and economic justice issues, and promotes collective agenda setting to address these concerns as basic human rights. See <http://www.poder-texas.org>. PODER seeks to empower our communities through education, advocacy and action. The organization's aim is to increase the participation of communities of color in corporate and government decision making related to toxic pollution, economic development and their impact on our neighborhoods. PODER undertakes community education projects and sustains programs that focus on transportation, quality of life and public health in relation to land use issues.

Science and Environmental Health Network

The Science and Environmental Health Network engages communities and governments in the effective application of science to protect and restore public and ecosystem health. The Network encourages the practice of science in the public interest and the accurate interpretation of scientific information. The Network identifies information, ethical concepts, and logic that have the potential to provoke essential change and helps communities, organizations, and governments develop and implement sound environmental policies. See <http://www.sehn.org/>.

Women's Voices for the Earth

Women's Voices for the Earth (WVE) is a national organization that seeks to educate the public about the harmful effects of chemicals, particularly those that affect women, and provide them with the tools they need to protect themselves and effectively advocate for a healthy environment. WVE has a strong record of educating the public about chemical risks through its website, issue reports, newsletters, electronic mail alerts, and green cleaning parties, and other campaign outreach and activities. See <http://www.womenandenvironment.org/>.