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August 21, 2014

The Hon. Gina McCarthy, Administrator
EPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington, DC 20460

Re: Petition for rulemaking to establish time limits for confidentiality claims applicable to information received under Toxic Substances Control Act.

Dear Administrator McCarthy:

Pursuant to Section 4 of the Administrative Procedure Act, 5 U.S.C. § 553(e), BlueGreen Alliance, Breast Cancer Fund, Connecticut Coalition for Environmental Justice, Environmental Defense Fund, and New Jersey Work Environment Council ("Petitioners") request that EPA exercise its authority under Section 14(c) of the Toxic Substances Control Act ("TSCA"),[1] to propose a rule defining and delimiting the duration and terms for reassertion of the protective treatment afforded confidential business information submitted under TSCA ("TSCA CBI"). The adoption of such a TSCA CBI "sunset" rule would be a highly efficient and effective step toward the realization of EPA's goal to "increase access to and transparency in TSCA-related chemical information."[2]

I. BACKGROUND

Congress enacted TSCA in 1976, after it had become all too clear that "human beings and the environment [were] being exposed each year to a large number of chemical substances and mixtures . . . some whose . . . distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment."[3] TSCA's authors intended to stem the toxic tide by giving EPA "adequate authority" to safeguard against such risks, and, more fundamentally, to ensure that "adequate data [w]ould be developed with respect to the effect of

[1] 15 U.S.C. § 2613(c). The text of this Petition will refer to the popular name sections of TSCA, with codified citations provided in the footnotes, as here.
[2] OPPT, EPA, Increasing Transparency in TSCA, http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html, (last visited Aug. 4, 2014).
[3] 15 U.S.C. § 2601(a)(1).

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chemical substances and mixtures on health and the environment."[4] The Act therefore includes a wide range of information gathering provisions. Section 4 allows EPA to fill gaps in the scientific understanding of health and environmental effects, by issuing necessary test rules for any chemical at any stage in its commercial life cycle.[5] Section 5 establishes a Pre-manufacture Notification process by which manufacturers and importers must notify EPA of their intent to produce or introduce into commerce any new chemical substance, and provide available information on the substance, at least 90 days prior to commencing such activity.[6] Section 8 requires EPA to develop and maintain an inventory of all chemicals used commercially in the United States, and to promulgate rules under which chemical companies must maintain records and submit such information as EPA reasonably requests.[7] The Agency may, by rulemaking initiated under the same section, require companies to submit lists or copies of available health and safety studies.[8] Finally, § 8 obligates chemical companies to notify EPA whenever they obtain data indicating that a chemical presents a substantial environmental or human health risk.[9]

That Congress specifically contemplated and promoted the use of collected information outside the Office of Pollution Prevention and Toxics ("OPPT"), the EPA office responsible for administering TSCA, is evidenced by explicit legislative statements pronouncing Americans' "right to know what is in store as far as the toxicity of chemicals is concerned."[10] It can also be seen within the text of the Act itself. For instance, TSCA § 14(b) narrowly limits the circumstances in which "data from health and safety studies" may be claimed as CBI.[11] Moreover, the unambiguously pro-disclosure language of the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), which aims to "pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny," *Rose v. Dep't of Air Force*, 495 F.2d 261, 263 (2d Cir. 1974) *aff'd*, 425 U.S. 352 (1976), fully applies to information collected under TSCA.

Yet despite efforts by the present Administration to remind the regulated community that transparency is an "essential element" of TSCA, chemical importers and manufacturers continue to be able to assert CBI claims unnecessarily and excessively, to the detriment of EPA, other governmental entities, and the general public.[12] One major contributing factor is the sheer number of industry submissions received under the heading "CBI," which must be protected by EPA from disclosure until and unless challenged by EPA on a case-by-case basis and found not to warrant such protection. But even as EPA and others focus on reducing the influx of new and unwarranted or unnecessary claims, in the vast majority of cases the confidential status already granted continues

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[4] *Id.* § 2601(b).
[5] *Id.* § 2603.
[6] *Id.* § 2604.
[7] *Id.* § 2607(a), (b).
[8] *Id.* § 2607(d).
[9] *Id.* § 2607(e).
[10] 122 Cong. Rec. S4,397 (daily ed. Mar. 26, 1976) (statement of Sen. Vance Hartke), *reprinted in* U.S. CONGRESS, LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT 218 (1976).
[11] 15 U.S.C. § 2613(b).
[12] 122 Cong. Rec. at S4,397, *reprinted in* U.S. CONGRESS, *supra* note 10, at 218.

indefinitely, even after the legitimacy of the claim has eroded due to the passage of time and the operation of market forces.

As discussed below, the accumulation of excessive CBI claims is fed in part by a loophole in EPA's regulations, which makes practically all confidentiality protection indefinite by default. EPA should close this loophole by amending its rules to attach presumptive time limits – or "sunsets" – on all TSCA CBI claims. By allowing CBI submitters to seek to renew confidentiality protections for eligible submissions, a sunset rule would avoid compromising legitimate trade secrets while imposing minimal burdens on the regulated community, just as it would conserve agency resources and expand the body of risk-relevant data available to the concerned public.

II. EXCESSIVE CBI CLAIMS: EPA GRANTS CBI STATUS TO MORE DATA THAN IS REASONABLY LIKELY TO BE CBI, AND MAINTAINS CBI STATUS FOR LONGER THAN SUCH DATA IS REASONABLY LIKELY TO REMAIN CBI.

Two decades have passed since an independent review of OPPT's practices revealed that "CBI claims under TSCA are far in excess of what is needed to protect true trade secrets."[13] EPA commissioned the 1992 Report – the first and still most comprehensive investigation into OPPT's handling of TSCA CBI – to "examine[] whether the CBI provisions of TSCA, either as explicitly mandated by the statute or as put into practice by EPA, have had a deleterious effect on the implementation and impact of the law."[14] The Report based its unambiguous conclusion – that "CBI claims under TSCA are far in excess of what is needed to protect true trade secrets"[15] – on several observations, including: "increases in the proportion of CBI claims for [all] submission types" over the time period studied;[16] the inability of submitters "to substantiate their claims" for "nearly all" of the "limited number of submissions that EPA . . . had the resources to challenge";[17] and the high rate of TSCA CBI claims, in relation to "a comparable set of information" received under the Emergency Planning and Community Right-to-Know Act ("EPCRA"), for which CBI claims are much less common.[18]

By 1994 EPA had responded with plans (1) to "limit" the total resources devoted to CBI protection, so as "to operate in a fiscally responsible manner" and (2) to "increas[e] the availability of information on toxics and OPPT's toxics programs," so as to empower the public "to participate in chemical management and pollution prevention efforts."[19] Unfortunately, while the Agency

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[13] SHEILA A. FERGUSON ET AL., EPA, INFLUENCE OF CBI REQUIREMENTS ON TSCA IMPLEMENTATION 20 (1992) ["1992 Report"], *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2002-0054-0074.
[14] 1992 Report, *supra* note 13, at 5.
[15] *Id.* at 20.
[16] *Id.* at 7.
[17] *Id.* at iv.
[18] *Id.*
[19] OPPT, EPA, FINAL ACTION PLAN: TSCA CONFIDENTIAL BUSINESS INFORMATION REFORM, at Executive Summary (1994) ["Final Action Plan"], *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2002-0054-0075.

stands by these promises, its attempts to increase dissemination of TSCA data "have been thwarted by pervasive CBI claims" – even where such claims are "legally inappropriate."[20]

To be valid, CBI claims must comply with TSCA § 14.[21] Section 14(a) first requires that they meet the substantive criteria for FOIA's trade secret/CBI exemption.[22] But this is not enough, as TSCA strongly favors disclosure above and beyond that required under FOIA. TSCA § 14(b) states that "[s]ubsection (a) does not prohibit the disclosure of any health and safety study" unless disclosure would reveal "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."[23]

Thus, CBI claims are "inappropriate" whenever the relevant information is from a health and safety study and would not reveal process or portion details or fails to meet EPA's "[s]ubstantive criteria for use in confidentiality determinations," located at 40 CFR § 2.208.[24] The most important criterion is typically the submitter's ability to "satisfactorily show[] that disclosure of the information is likely to cause substantial harm to the business's competitive position."[25] For "voluntarily submitted information," submitters may instead show that "disclosure would be likely to impair the Government's ability to obtain necessary information in the future."[26]

As a practical matter, the "inappropriate" CBI claims addressed in the 1992 Report and later documents refer to two sorts of information: (1) that which failed to meet the § 2.208 criteria when CBI status was initially claimed; or (2) that which did meet the § 2.208 criteria when CBI status was initially claimed, but does not any longer. This latter category exists because "information that at one time may have qualified under the legal requirements as CBI may no longer qualify, or the circumstances that caused the information to be claimed as CBI, may change over time."[27]

Although industry attempted at first to downplay the findings contained in the 1992 Report, the fact that TSCA CBI claims are excessive has never been refuted with contrary evidence. Instead,

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[20] *Id.*

[21] 15 U.S.C. § 2613.

[22] *Id.* § 2613(a) (citing 5 U.S.C. § 552(b)(4)).

[23] *Id.* § 2613(b).

[24] *See also* OPPT, EPA, PROPOSED ACTIONS TO REFORM TSCA CONFIDENTIAL BUSINESS INFORMATION 2 n.1 (May 20, 1993) ["Proposed Actions"], *available at* http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=91014AC3.txt (CBI claims "made on information which is not eligible for confidential treatment by the standards established in TSCA and its implementing regulations, including 40 CFR Part 2" are inappropriate). *Cf. Nw. Coal. for Alternatives to Pesticides v. EPA*, 254 F. Supp. 2d 125, 130 (D.D.C. 2003) (accepting, without discussion, EPA's position that information qualifies as CBI when it meets § 2.208 criteria).

[25] 40 C.F.R. § 2.208(e)(1).

[26] *Id.* § 2.208(e)(2). These are parallel to the standards in federal case law interpreting FOIA's statutory CBI exemption. *See also Nat'l Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974) (holding that records are "'confidential' for purposes of [5 U.S.C. § 552(b)(4)] if disclosure" is likely "(1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the [claimant's] competitive position").

[27] EPA, Summary of EPA's Responses to Public Comments Submitted for the Proposed TSCA Inventory Update Rule Amendments (64 FR 46772), at 137 (Nov. 20, 2002) [hereinafter 2002 Comment Response], *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2002-0054-0271.

all authoritative reviews of the matter – including those found in OPPT's 1993 draft guidance[28] and 1994 final action plan;[29] EPA's 1994 proposed rulemaking,[30] 1999 proposed rulemaking,[31] 2000 Advanced Notice of Proposed Rulemaking,[32] and 2003 final rulemaking publications;[33] the Government Accountability Office's ("GAO's") 2005 Report;[34] and the EPA Office of Inspector General's ("OIG's") 2010 Report[35] – have recognized the severity of the problem, and urged EPA regulators to "limit CBI claims to the extent permitted by law."[36] For example, the GAO Report pointed to the administrative history of TSCA § 8(e), which requires the submission of any information "reasonably support[ing] the conclusion that [a] substance or mixture presents a substantial risk of injury to health or the environment."[37] Although EPA has received 25,000 § 8(e) notices since 1977, the author noted that "the value of the [included] studies… is greatly reduced by the confidentiality claims of the submitters: *in most cases, the identity of the chemical is concealed*."[38]

Additionally, available data proves that the troubling patterns observed in the 1992 Report have not been significantly abated by voluntary industry responses. As of January 2014, the public TSCA Inventory lists approximately 84,000 chemicals, divided across two separate data sets: one providing Chemical Abstract Service ("CAS") Registration Numbers and names; the other, only PMN or Agency-assigned accession numbers.[39] The latter (confidential) set includes nearly 17,000 chemicals. The 1982 Inventory, in contrast, listed approximately 60,000 chemicals, with some 2,000

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[28] *See* Proposed Actions, *supra* note 24.

[29] *See* Final Action Plan, *supra* note 19.

[30] EPA, Public Information and Confidentiality Regulations, 59 Fed. Reg. 60,446 (proposed Nov. 23, 1994). It also noted that: "Information submitted to the Agency under a claim of confidentiality interferes with EPA's ability to inform the public. EPA recognizes its duty to safeguard [CBI], but believes there are confidentiality claims that are no longer valid. Where there is no longer a reason for a confidentiality claim, the subject information should be declassified to maximize the amount of information publicly available to facilitate public participation in the regulatory process." *Id.* at 60,450.

[31] EPA, TSCA Inventory Update Rule Amendments, 64 Fed. Reg. 46,772 (proposed Aug. 26, 1999).

[32] EPA, Public Information and Confidentiality: Advance Notice of Proposed Rulemaking; Withdrawal of 1994 Proposed Rule, 65 Fed. Reg. 80,394 (proposed Dec. 21, 2000).

[33] EPA, TSCA Inventory Update Rule Amendments, 68 Fed. Reg. 848 (Jan. 7, 2003).

[34] GAO, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM (June, 2005), *available at* http://www.gao.gov/assets/250/246667.pdf.

[35] EPA OFFICE OF INSPECTOR GENERAL, EPA NEEDS A COORDINATED PLAN TO OVERSEE ITS TOXIC SUBSTANCES CONTROL ACT RESPONSIBILITIES (Feb. 17, 2010), *available at* http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf.

[36] Final Action Plan, *supra* note 19, at 2.

[37] 15 U.S.C. § 2607(e).

[38] LINDA-JO SCHIEROW, CONGRESSIONAL RESEARCH SERVICE, THE TOXIC SUBSTANCES CONTROL ACT (TSCA): IMPLEMENTATION AND NEW CHALLENGES 11-12 (July 28, 2009) (emphasis added), *available at* https://www.acs.org/content/dam/acsorg/policy/acsonthehill/briefings/toxicitytesting/crs-rl34118.pdf. For example, 90% of all PMN submissions assert (and receive) CBI claims for chemical identity. Even after PMN chemicals are introduced to the market, their identities remain secret 65% of the time. *Id.* at 9.

[39] Inventory data is available as downloadable Excel files at https://explore.data.gov/Geography-and-Environment/TSCA-Inventory/pkhi-wvjh.

appearing under generic names only.[40] This means that roughly 15,000 – 62.5% – of the 24,000 chemicals introduced to commerce since 1982 cannot be meaningfully identified by the public. To be sure, these figures are only estimates – the Inventory is constantly expanding. What is clear is that "chemicals with confidential identities now represent a much greater portion of the most widely used chemicals than they did 15 years ago."[41]

Nor does EPA claim to have resolved the TSCA CBI problem. Indeed, the Agency admits to having "information indicating the existence of inappropriate or no longer valid CBI claims."[42] In 2010, not long after the OIG found "that EPA's current process for handling CBI requests is weighted toward the protection of industry information rather than public access,"[43] former OPPT Assistant Administrator, Stephen Owens, circulated a letter in which he "urged the chemical industry to reduce the voluminous [CBI] claims . . . made for [TSCA] materials submitted to EPA."[44] While EPA has adopted some corrective measures to "tighten[] CBI policy" and "ensur[e] [that] CBI claims are necessary,"[45] it has not to date adopted the one specific "tightening" measure that is

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[40] *See* OPPT, EPA, TOXIC SUBSTANCES CONTROL ACT CHEMICAL SUBSTANCES INVENTORY: CUMULATIVE SUPPLEMENT II (May 1982). The numbers of chemicals appearing in the printed Inventory as of 1982 were 58,000 (total); 1,800 (generic). According to OPPT, however, the listings of total chemicals and generically-named chemicals were then only 97% and 90% complete, respectively. *Id.*

[41] DAVID ANDREWS & RICHARD WILES, ENVIRONMENTAL WORKING GROUP, OFF THE BOOKS: INDUSTRY'S SECRET CHEMICALS 7 (2009), *available at* http://www.ewg.org/sites/default/files/report/secret-chemicals.pdf. *See also id.* at 2 (observing that "nearly two-thirds of the 20,403 chemicals added to the list" between 1976 and 2009 had their identities concealed by CBI claims).

[42] 68 Fed. Reg. 848, 879 (Jan. 7, 2003).

[43] EPA OFFICE OF INSPECTOR GENERAL, EPA NEEDS A COORDINATED PLAN TO OVERSEE ITS TOXIC SUBSTANCES CONTROL ACT RESPONSIBILITIES 11 (Feb. 17, 2010), *available at* http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf. *See also id.* (concluding that EPA had failed to fulfill Congress's objective "for chemical health and safety data to be made available to the public").

[44] Letter from Stephen A. Owens, Ass't Adm'r, EPA Office of Chem. Safety and Pollution Prevention, to Jennifer Abril, Exec. Dir., Fragrance Materials Ass'n, et al. 1 (June 4, 2010), *available at* http://www.epa.gov/oppt/existingchemicals/pubs/declassify_cbi.pdf.

[45] OPPT, EPA, *supra* note 2. Two "tighten[ing]" policy shifts announced in 2010 merit attention here. *Id.* Both arise out of EPA's "general practice of reviewing confidentiality claims for chemical identities in health and safety studies, and in data from health and safety studies, submitted under [TSCA]." 75 Fed. Reg. 29,754, 29,754 (May 27, 2010). The Agency indicated, first, that it would reject such claims "[w]here a health and safety study submitted under section 8(e) of TSCA involves a chemical identity that is already listed on the public portion of the TSCA Chemical Substances Inventory." 75 Fed. Reg. 3,462, 3,462 (Jan. 21, 2010). EPA later added that it would also reject such claims "[w]here a chemical identity does not explicitly contain process information or reveal portions of a mixture." 75 Fed. Reg. 29,754, 29,754 (May 27, 2010).

perhaps more easily attainable, explainable and implementable than any other: a TSCA CBI sunset rule.[46]

III. CURRENT RULES GOVERNING THE SUBMISSION OF RECORDS UNDER TSCA INVITE CBI CLAIMS THAT CONTINUE INDEFINITELY, IMPOSING COSTS ON THE AGENCY AND THE PUBLIC.

As discussed below, the unnecessary protection given to stale TSCA CBI claims can be avoided through revised rulemaking.

A. EPA rules exacerbate the CBI overload by automatically offering indefinite protection to every TSCA CBI claim.

EPA's rules for designating and handling – as well as resolving conflicts over – CBI are set out according to the two-tiered regulatory scheme found in Title 40, Part 2, of the Code of Federal Regulations. The "Part 2 Regulations" consists of a series of basic, generally-applicable rules, which are supplemented or supplanted by statute-specific rules. *See* 40 C.F.R. § 2.202 (describing the two-tiered scheme); *id.* § 2.306 (providing specific rules for TSCA submissions). The generally-applicable "[m]ethod of asserting business confidentiality claim[s]" requires each claimant to include "a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as *trade secret*, *proprietary*, or *company confidential*." *Id.* § 2.203(b) (emphasis added).[47] Significantly, further language in the same paragraph states that "[i]f the business desires confidential treatment only until a certain date or until the occurrence of a certain event, the notice should so state." *Id.* Otherwise, "[a] determination that information is entitled to confidential treatment for the benefit of a business . . . shall continue in effect in accordance with its terms until an EPA legal office . . . issues a final determination" that such treatment is no longer warranted. *Id.* § 2.205(h). EPA's TSCA-specific regulation incorporates § 2.203(b), one of the "[b]asic rules which apply without change." *Id.* § 2.306(c).

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[46] Since the fall of 2011, EPA has listed an entry in its regulatory agenda, *see* Office of Info. & Reg. Affars, Office of Mgmt. & Budget, Unified Agenda And Regulatory Plan Search Results, http://www.reginfo.gov/public/Forward?SearchTarget =Agenda&textfield=2070-AJ90 (last visited Aug. 5, 2014), indicating that it is "considering proposing to establish regulations relating to claims for confidential business information (CBI) submitted under the Toxic Substances Control Act (TSCA) that would require the periodic reassertion and resubstantiation of such claims. Confidentiality claims which are not reasserted and resubstantiated would expire. EPA expects this action would increase transparency and the availability of public health and environmental effects information on chemicals in commerce," OIRA, OMB, View Rule, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201404&RIN=2070-AJ90 (last visited Aug. 5, 2014). The most recent such posting, in spring 2014, lists an estimated date of August 2014 for publication of a notice of proposed rulemaking. Petitioners urge EPA to move forward with rulemaking without further delay.

[47] *See also* 1992 Report, *supra* note 13, at 6 ("Claiming information as confidential is a simple procedure under TSCA. . . . Under some sections of TSCA, EPA has provided for information to be claimed as confidential by simply checking a box on the appropriate form (*e.g.*, new chemicals under section 5).").

The import of the Part 2 Regulations cited above is clear: they establish that initial CBI determinations – even if made by default – will last indefinitely, and they place the entire burden of determining whether a claim is initially or remains valid over time on EPA. By leaving it to submitters to decide when, if ever, their claims will expire,[48] EPA's current rules validate the concern that the "only meaningful check on [the duration of] CBI claims is the goodwill of the submitters."[49] If industry declines to take the affirmative step of assigning termination dates to each CBI claim, the critical data it submits is thus "withheld by EPA from the public for long periods, at additional cost to the Agency and with no appreciable advantage to the submitter."[50] In other words, by failing to revise its rules, EPA obliges itself to "protect[] indefinitely, and at taxpayer expense, information claimed as CBI" even though the information "may no longer qualify for such protection."[51]

B. Federal authorities have repeatedly urged EPA to adopt a TSCA CBI sunset rule, and EPA has failed to act each and every time.

Petitioners are the latest in a steadily growing line of interested actors to recognize the harmful consequences of granting TSCA CBI protection for claims without expiration dates. In fact, each of the federally-authorized studies discussed below has explicitly endorsed a sunset rule as the logical solution to the problem.

1. OPPT's 1994 Final Action Report and Proposed Regulations

In its 1994 Final Action Plan, prepared as a response to the 1992 Report, OPPT expressly concluded "that submitters should justify the continuing need for protection, by reasserting a claim or substantiating the existing claim at some specific time after the claims are initially made."[52] The Agency even identified "certain TSCA §§ 5 and 8 submissions," as "appropriate for such a [sunset] provision."[53]

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[48] New chemicals entering commerce are an exception of sorts. Attempts to protect the identity of such chemicals must, at the time of introduction into commerce, be accompanied by substantiating documents and will succeed only if the applicant had previously asserted its claim at the time of the initial pre-manufacture notice. *See* 40 C.F.R. § 720.85(b)(3)(iv)(B). The Agency's actual practice in this regard is unclear.

[49] 1992 Report, *supra* note 13, at 35. When EPA offers indefinite CBI protection as a matter of course, there is no reason to expect the submitting companies will refuse the offer, especially since the actual costs of safeguards and restricted access to information are borne by EPA and the public, but not the submitting companies. According to the GAO study, "[c]hemical company representatives said that companies sometimes choose to inform EPA that the information is no longer confidential, *but neither TSCA nor EPA regulations require them to do so*." GAO, *supra* note 34, at 34 (emphasis added). Even assuming that companies "may be willing to take action" to cabin their own CBI claiming practices, "the industry is nonetheless large and diverse, and it is uncertain that all companies will always take action voluntarily." *Id.* at 35.

[50] 64 Fed. Reg. 46,772, 46,793 (Aug. 26, 1999).

[51] 2002 Comment Response, *supra* note 27, at 133.

[52] Final Action Plan, *supra* note 19, at 10.

[53] *Id.*

The Final Action Plan was incorporated into a broader agency-wide initiative to amend the confidentiality procedures set out at Part 2. By 1994, EPA had come to realize that criticism of the sort the 1992 Report leveled against TSCA CBI was reflective of an underlying problem. It stated:

> Information submitted to the Agency under a claim of confidentiality interferes with EPA's ability to inform the public. EPA recognizes its duty to safeguard [CBI], but believes there are confidentiality claims that are no longer valid. Where there is no longer a reason for a confidentiality claim, the subject information should be declassified to maximize the amount of information publicly available to facilitate public participation in the regulatory process.[54]

EPA thus proposed, in relevant part, "to add a new [provision], which would allow selected CBI claims to expire unless reasserted."[55] But then the Agency failed to "select[]" *any* TSCA CBI claims for coverage under a sunset provisions, choosing instead to "defer proposal of a TSCA sunset provision."[56]

2. 1999 Proposed Rule and Subsequent Withdrawal

In 1999, EPA proposed a sunset rule for CBI claims on records submitted pursuant to the TSCA Inventory Update Rule ("IUR").[57] This rule would have required manufacturers and importers "to affirmatively represent the need for the continued CBI protection of the claims made in previous IUR reporting periods" during each subsequent quadrennial reporting period.[58]

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[54] 59 Fed. Reg. 60,446, 60,450 (Nov. 23, 1994).

[55] *Id.*

[56] *Id.* at 60,460. In many ways EPA's rationale was more puzzling than its decision. EPA stated that "a sunset provision [would be] appropriate only with respect to those data collections where there is an identified need for information to be publicly available after the passage of time (or occurrence of an event)," *Id.* Such an explanation completely misunderstands the purpose and function of a sunset provision. As the 1992 Report stated, a central problem with EPA's system for TSCA CBI is that it relies on "persistent requestor[s] insist[ing] upon release of [specific] data," often merely to discover that such data should never have been classified as CBI in the first place. 1992 Report, *supra* note 13, at 17. More fundamentally, however, it is absurd to expect that information, which is not specifically requested, is therefore useless to the public. "To learn whether a chemical is on the TSCA Inventory, . . . a person first must know the unambiguous identity of the chemical substance in question." Comments of the Electronic Industry Association on the Confidential Business Information Process Under TSCA (Docket No. OPPTS-00125), at 2 (May 5, 1993), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2002-0054-0030. Because chemical identity itself is so frequently claimed as CBI, "it is extremely difficult, if not impossible, for chemical processors and users to determine whether chemicals they intend to use are on the TSCA Inventory." *Id.* at 3. In sum, EPA completely disregarded the 1992 Report's unmistakable conclusion that, "[i]n addition to the costs imposed by invalid CBI claims on OPPT internal functioning, the data covered by invalid CBI claims represent a valuable resource that could further the purposes of TSCA if they could be more widely disseminated." 1992 Report, *supra* note 13, at 41.

[57] 64 Fed. Reg. 46,772 (Aug. 26, 1999). In 2011, EPA finalized modifications to and changed the name of this program to the Chemical Data Reporting rule, "to better reflect the distinction between this data collection (which includes exposure-related data) and the TSCA Inventory itself (which only involves chemical identification information)." 76 Fed. Reg. 50,816, 50,819 (Aug. 16, 2011).

[58] *Id.* at 46,793.

Reassertion statements would be included in the reporting forms themselves, and companies seeking renewed CBI protection would be required to provide such statements "even if the submitter [was] not required to report in the present reporting period."[59]

The IUR reassertion rule proposed in 1999 was never finalized, however. By 2003, EPA had received "a number of comments . . . opposed to the proposed new requirement," and decided to withdraw the rule "in an effort to reduce the overall burden of" the IUR regulations.[60] This explanation, however, was directly contradicted by the Agency's simultaneous conclusion that the reassertion requirement was "justified as a practical measure" and that industry's objections were "the result of a misunderstanding of the practical aspects of the proposed reassertion requirement."[61] In its comment response document, EPA continued to argue vigorously in support of the sunset rule and strongly implied that the rule's abandonment resulted from undisclosed calculations "made during interagency review."[62]

3. 2005 GAO Report and Recommendation

In 2005, as part of its report on the Agency's performance of its TSCA-related duties, the GAO "reviewed EPA's efforts to . . . publicly disclose information provided by chemical companies under TSCA."[63] Noting that EPA had done little to fix the problems identified in previous studies, GAO joined the chorus of support for a TSCA CBI sunset rule, recommending that

> [t]o improve EPA's management of its chemical review program, the EPA Administrator should revise its regulations to require that companies reassert claims of confidentiality submitted to EPA under TSCA within a certain time period after the information is initially claimed as confidential.[64]

EPA's response to this suggestion remains unclear.[65]

4. EPA Office of Inspector General's 2010 Evaluation Report

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[59] *Id.* at 46,794.
[60] 68 Fed. Reg. 848, 880-81 (Jan. 7, 2003).
[61] *Id.*
[62] 2002 Comment Response, *supra* note 27, at 133.
[63] GAO, *supra* note 34, at 2.
[64] *Id.*, Highlights Page, *available at* http://www.gao.gov/assets/250/246669.pdf.
[65] The Highlights Page erroneously describes the "status" of the GAO sunset recommendation as "closed – implemented." *Id.* A "comment" states that "EPA is exploring ways to reduce the number of inappropriate and overbroad claims," but fails to indicate that EPA has never taken any action on the Report's *actual* recommendation. *Id.*

Ironically, one cited example of EPA "actions" responsive to the 2005 recommendation – EPA's declassification of "530 substances, previously treated as confidential on the public portion of the master inventory list" –, *id.*, was discussed in the 2010 OIG Report, *see infra* Section III.B.4., in relation to the point that EPA's *failure* to carry out any "systematic verification or validation" of CBI requests had made such cost-intensive challenges necessary, *see supra* note 35, at 12.

The 2010 EPA OIG's Evaluation Report represents the most recent exhortation upon EPA to adopt a TSCA CBI sunset rule. Like the aforementioned reviewers, OIG took specific issue with "the current procedures for submitting PMNs and Section 8(e) notices [that] allow manufacturers and importers to make the determination with regard to the length of time they would like CBI protection."[66] The "common[]" product of EPA's regulations is CBI designations with "no expiration date," that "potentially remain in effect indefinitely and, in some cases, incorrectly."[67] OIG concluded by offering a recommendation nearly identical to that of the GAO – that EPA "establish[] a time limit for all CBI requests to allow for eventual public access to health and safety data for chemicals."[68]

In its response to a draft version of the OIG Report, OPPT purportedly "accept[ed] this recommendation," but gave no indication as to when or how the prescribed "time limit for all CBI requests" would be promulgated.[69] In the meantime, however, the sunset rule suggested by the 2010 Evaluation Report has become a constant presence in the OIG's Compendium of Unimplemented Recommendations.[70]

IV. PETITIONERS REQUEST THAT EPA PROPOSE A RULE TO ATTACH "SUNSETS" ON TSCA CBI CLAIMS WITHOUT FURTHER DELAY.

A. Proposal

Petitioners hereby request that EPA take the following actions pursuant to TSCA § 14(c), 15 U.S.C. § 2613(c):

1. Propose a rule that would attach an automatic expiration date ("sunset") on all affirmative CBI determinations made with respect to any submission of information covered by 40 CFR § 2.306(b). The expiration date should be

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[66] EPA OIG, *supra* note 43, at 11.
[67] *Id.* at 11-12.
[68] *Id.* at 15.
[69] *Id.* at 23.
[70] Recent issues of the biannual Compendium of Unimplemented Recommendations (the "Compendium") are available at http://www.epa.gov/oig/reports/specialReportsByType/compendium_of_unimplemented_recommendations.html. Recommendation 2-5 first appeared on September 30, 2011, with a "planned completion date" of January 31, 2012. EPA OIG, COMPENDIUM OF UNIMPLEMENTED RECOMMENDATIONS AS OF SEPTEMBER 30, 2011, at 39 (Oct. 31, 2011). But by the release of the next issue, this date had passed without any action. *See* EPA OIG, COMPENDIUM OF UNIMPLEMENTED RECOMMENDATIONS AS OF MARCH 31, 2012, at 67 (Apr. 30, 2012) (noting that "corrective actions [would] be considered past due as of January 31, 2013"). An accompanying note explained that the regulations would be proposed "[i]f legal authority is determined to exist." *Id.* An identical listing appeared six months later. *See* EPA OIG, COMPENDIUM OF UNIMPLEMENTED RECOMMENDATIONS AS OF SEPTEMBER 30, 2012, at 78-79 (Oct. 31, 2012). Recommendation 2-5 most recently appeared in the March 31, 2014 Compendium, this time with a note that "OCSPP expects the publication of the proposed rule by September 30, 2014." EPA OIG, COMPENDIUM OF UNIMPLEMENTED RECOMMENDATIONS AS OF MARCH 31, 2014, at 27 (Apr. 30, 2014) (emphasis added).

set at no longer than five years from the date on which such submission was originally made.[71]

2. Propose, in conjunction with the sunset provision described in paragraph 1, procedures, by which any submitter of information subject to automatic expiration would be permitted to seek, prior to the date of expiration, a renewed CBI determination ("reassertion"), under the same terms as the previous assertion and determination, upon a showing that the information continues to meet the relevant criteria described at 40 CFR § 2.208. A renewed determination would, if granted, run consecutively, so that eligible records would continue to enjoy CBI protection until the subsequent expiration date, and so on.

3. Make any necessary amendments to Title 40 of the Code of Federal Regulations necessary to implement the actions indicated in paragraphs 1 and 2.[72]

B. Explanation and authority

EPA possesses sufficient authority to promulgate the CBI sunset rule proposed above. First, EPA's general "authority to promulgate requirements for maintaining confidentiality claims is inherent in the environmental statutes administered by the Agency, which provide that information may be protected upon a showing made to the Administrator that the information is entitled to confidentiality."[73] Second, TSCA § 14(c)(1) specifically provides that "[a] designation [of confidentiality] under this paragraph shall be made in writing and in such manner as the Administrator may prescribe."[74] This language endows EPA "with the authority to prescribe the manner in which CBI shall be designated," and the Agency has asserted that the promulgation of

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[71] By proposing the operative phrase "affirmative CBI determinations," Petitioners intend only to incorporate the clear language of the regulations, which is necessary to make the proposed amendments effective. Petitioners do not, at present, express an opinion as to whether EPA actually engages in meaningful substantive review of all claims.

[72] These include: 40 CFR § 704.7 (Reporting and Recordkeeping Requirements – General Reporting and Recordkeeping Provisions for Section 8(a) Information-Gathering Rules); *id.* § 707.75 D (Chemical Imports and Exports – Notices of Export Under Section 12(b)); *id.* § 712.15 (Chemical Information Rules); *id.* § 716.55 (Health and Safety Data Reporting); *id.* § 717.19 (Records and Reports of Allegations that Chemical Substances Cause Significant Adverse Reactions to Health or the Environment); *id.* §§ 720.80-.95 (Premanufacture Notification – Confidentiality and Public Access to Information); *id.* §§ 723.50(*l*) & 723.175(k) (Premanufacture Notification – Specific Exemptions); *id.* § 750.16 (Procedures for Rulemaking Under TSCA § 6 – Interim Procedural Rules for Manufacturing Exemptions); *id.* § 750.36 (Procedures for Rulemaking Under TSCA § 6 – Interim Procedural Rules for Processing & Distribution in Commerce Exemptions); *id.* § 790.7 (Procedures Governing Testing Consent Agreements and Test Rules – General Provisions).

[73] EPA, Public Information and Confidentiality Regulations, 59 Fed. Reg. 60,446, 60,450 (proposed Nov. 23, 1994)

[74] 15 U.S.C. § 2613(c)(1)(B).

"reassertion requirements" is well within the scope of such authority.[75] Finally, Executive Order 12,600, sec. 3(b), removes any trace of uncertainty by stating that "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."[76]

V. A TSCA CBI SUNSET RULE WOULD MITIGATE THE COSTS OF EXCESSIVE CBI CLAIMS WITHOUT HARMING INDUSTRY COMPETITIVENESS.

A CBI sunset rule would reduce OPPT's CBI budget without imposing any substantial burden on the regulated community. The rule furthers the goal of efficiency, although Petitioners see their recommendation as much more than a typical housekeeping measure. By providing access to long-hidden chemical data to the innovative, interested, and proactive American public, a TSCA CBI sunset rule presents informational benefits that, while defying easy description, are significant.

A. Adopting the proposed sunset rule would have internal and external benefits.

As explained in the 1992 Report,

> [m]aintaining large volumes of data as CBI not only denies access to interested outside users, it also leads to high costs for . . . [OPPT] . . . to keep the data secure, impedes the program's ability to develop regulations openly, and makes it difficult for other federal officials to use the data. It also prevents OPPT from sharing the knowledge it gains from reviewing such data about the chemical attributes that give rise to significant health and environmental risks. Thus, TSCA CBI is impeding government regulatory programs, scientific research, industrial chemical stewardship programs, worker and community right-to-know, and industrial accountability.[77]

This passage serves as a reminder that the "high costs" imposed by excessive confidentiality are borne internally (by OPPT) and externally (by "interested outside users"). These thematic points, elaborated below, remain as vital today as when they were first identified 20 years ago.

1. Internal benefits

The following discussion considers the benefits that will accrue to EPA generally and OPPT specifically if the proposed rule is adopted.

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[75] 2002 Comment Response, *supra* note 27, at 134. As proof of this assertion, EPA has rightly pointed to current regulatory provisions "caus[ing] certain confidentiality claims associated with Premanufacture Notifications to expire upon submission of a Notice of Commencement, unless the claim is reasserted at that time." 59 Fed. Reg. at 60,450 (citing 40 CFR § 720.85). In promulgating the PMN sunset rule, which is operatively analogous to the instant proposal, EPA relied directly on TSCA § 14(c)(1)(B) for the needed authority, a determination that was never challenged.

[76] Predisclosure Notification Procedures for Confidential Commercial Information, 52 Fed. Reg. 23,781, 23,781 (June 23, 1987).

[77] 1992 Report, *supra* note 13, at iii.

a. Reducing operational costs

Simply put, the recommended sunset rule will save EPA and taxpayers money. The responsibility to protect thousands upon thousands of confidential records is a huge burden for an office like OPPT, staffed by "325 to 350 employees, including secretarial assistants."[78] Thus, as Agency staff noted in connection with the 1999 proposal, putting presumptive durational limits on CBI claims is "in the interest of maintaining the integrity and accuracy of the CBI files on which EPA expends considerable taxpayer resources."[79]

Of course, just *how* expensive it is for EPA to protect old CBI claims remains anyone's guess. "It is difficult to quantify the costs to EPA of CBI security provisions, as many of the expenses entailed in maintaining CBI security are not accounted separately by OPPT."[80] As an overview of the TSCA CBI Protection Manual ("CBI Manual") makes clear though, such costs exist and they are significant.[81] The CBI Manual is an internal guidance document requiring OPPT to "establish a controlled environment for TSCA CBI material to ensure that a complete audit trail remains as to the location of any document at all times."[82] Under its terms, OPPT staff members are variously responsible for:

- Performing annual transaction audits of all documents received or logged out and quadrennial comprehensive audits of the entire CBI Center collection;[83]
- implementing an enhanced Document Tracking System and bar coding for CBI;[84]
- obtaining office space for use as Secure Storage Areas ("SSAs"), which must meet specified physical requirements and maintain strict operational controls;[85]
- purchasing and updating specified door locks and electronic access systems,[86] and "GSA-approved Class 6 security containers";[87]
- personally inspecting contractor sites for approval as alternative secure locations,[88] and approving each "employee's plan for home use of TSCA CBI" "in every case where home use is requested";[89]

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[78] Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 IND. L.J. 629, 632 n.14 (2008), *available at* http://www.repository.law.indiana.edu/cgi/viewcontent.cgi?article=1213&context=ilj.

[79] 2002 Comment Response, *supra* note 27, at 137. *See also* 1992 Report, *supra* note 13, at 36 ("In order to issue and sustain . . . challenges, EPA must go through a series of time consuming and labor intensive steps.")

[80] 1992 Report, *supra* note 13, at 26

[81] OPPT, EPA, TSCA CBI PROTECTION MANUAL (Oct. 20, 2003), ["CBI Manual"] *available at* http://www.epa.gov/opptintr/pubs/tsca-cbi-protection-manual.pdf.

[82] 1992 Report, *supra* note 13, at 25.

[83] CBI Manual, *supra* note 81, at 38-40.

[84] *Id.* at 49.

[85] *Id.* at 53-55. For example, any "[c]ustodial, maintenance, mail or other delivery personnel" who are not "known generally to EPA staff . . . must be escorted" while inside the SSAs. *Id.* at 55.

[86] *Id.* at 53.

[87] *Id.* at 56.

[88] *Id.*

- logging and tracking "working papers" containing references to CBI (*e.g.*, "such documents as notes, outlines, and drafts");[90]
- observing detailed copying procedures, such as restricting use of "non-secured machines" to those which are "dedicated to the task and located in a manner that makes copying activity secure" and "approved by the OPPT [Document Control Officer]";[91]
- purchasing security software and maintaining secure electronic communication networks (*e.g.*, fax, voicemail, email and video conference);[92]

Restrictions on personnel resources are similarly severe. Volunteer staff, students, student interns, grantees, and others are strictly forbidden to view CBI, regardless of the nature of their work or level of supervision.[93]

A sunset rule would have several salutary effects on the budgetary and logistical aspects of CBI protection. Not only would it reduce the total amount of CBI charged to OPPT, it would do so in a maximally effective manner. The 1992 Report, for example, noted that "internal cost savings" of regulatory reform will "depend critically not only on the extent of any reduction in claims, but also on the patterns of reduction."[94] Patterns of reduction under a case-by-case agency review process are likely to be less than optimal, since a submission might contain several CBI claims, each of which would need to be reviewed separately. By contrast, a sunset mechanism would resolve the status of all CBI claims records submitted on a given date. A claimant's failure to reassert would leave a contemporaneous body of submitted material "*entirely* free of CBI claims," which, according to the authors of the 1992, is the only scenario offering "a reasonable possibility . . . [of] freeing staff and resources from CBI procedures."[95]

Relatedly, the automatic operation of a proposed sunset rule offers a far more cost-effective means of realizing EPA's transparency objectives than the laborious mechanisms currently in use. While petitioners strongly approve of the pro-disclosure stance taken by the Agency in its 2010 policy clarifications (regarding CBI claims on chemical identity in health and safety studies),[96] the effectiveness of the resultant policies will ultimately turn on the resources OPPT muster for review of individual CBI claims. This is a serious limitation, as tracking down the assertors of stale claims

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[89] *Id.* at 57-58.
[90] *Id.* at 60-61.
[91] *Id.* at 64.
[92] *Id.* at 68-71
[93] *Id.* at 9. EPA is bound to these expensive security procedures by a Consent Order entered in 1985, requiring that "adequate public notice be given by the Agency prior to implementing any significant changes in security procedures, and contemporaneously with the implementation of any substantive changes." 1992 Report, *supra* note 13, at 25. *See also* EPA, INFORMATION SENSITIVITY COMPENDIUM 24 (July 2002), *available at* http://semanticommunity.info/@api/deki/files/2555/=InformationSensitivity.pdf.
[94] 1992 Report, *supra* note 13, at 26.
[95] *Id.* (emphasis in original).
[96] *See supra* note 45.

from years gone by is time consuming and confrontational approaches "are time and resource-intensive, and the agency does not have the resources to challenge a significant [sic] large number of claims."[97] In contrast, a sunset rule for TSCA CBI would put the initial burden on the claimants themselves, who are in the best position to determine the necessity of continued confidentiality. Where claims are not reasserted, they would expire automatically. The marginal cost to the Agency would be the preparation and mailing of any requisite notification letters.

b. Facilitating open and efficient regulatory decisions

Removing unnecessary CBI protection will help EPA carry out its obligations in numerous ways besides just saving taxpayers money. Agency staff have reportedly experienced "difficulty explaining how [regulatory] priorities were established when it can not reveal essential, underlying, yet confidential, data."[98] This retrogressive pattern – "agency isolation," according to a seminal Harvard Law Review article –"has a deleterious impact on public confidence and agency morale," ultimately "slowing" the regulatory process itself.[99]

For example, when performing a risk assessment, EPA employs "a 'weight-of-evidence' approach that considers all relevant information and its quality."[100] This methodology is wholly predicated on a "transparent process and products that are clear, consistent and reasonable."[101] In other words, "public participation is an essential aspect of EPA's process for making decisions to achieve the Agency's mission of protecting human health and the environment."[102] When significant parts of the evidence being weighed are claimed as CBI, "[t]here is no way for the outside scientific community to review the risk assessment decisions made within OPPT."[103]

On the other hand, "EPA's own efforts to make its decisions more comprehensible to the public would . . . be considerably facilitated by the removal of invalid CBI claims that obscure the reasoning underlying Agency actions."[104] Further benefits of enhanced citizen participation – which remain likely even if the associated regulatory decisions do not prove optimal – are discussed at Section V.A.2.b, *infra*.

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[97] GAO, *supra* note 34, at 5.

[98] DISCUSSION PAPER: AMENDMENTS TO THE TSCA INVENTORY UPDATE RULE NEEDED TO CREATE A CHEMICAL USE INVENTORY (EPA-HQ-OPPT-2002-0054-0027) at 4 (paragraph describing 1 of 3 components of "project implementation strategy").

[99] Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Practices*, 93 HARV. L. REV. 837, 844 (1980) (footnotes omitted). The authors also referred to similar "secrecy policies" at another federal agency (the Food and Drug Administration), which "prevent [FDA] from satisfactorily answering its critics, limiting public confidence in its judgments and causing deep resentment among FDA staff." *Id.*

[100] EPA, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY 21 (Oct. 2002), *available at* http://www.epa.gov/QUALITY/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

[101] *Id.* at 13.

[102] EPA, FRAMEWORK FOR HUMAN HEALTH RISK ASSESSMENT TO INFORM DECISION MAKING 35 (Apr. 5, 2014), *available at* http://www.epa.gov/raf/files/hhra-framework-final-2014.pdf.

[103] 1992 Report, *supra* note 13, at 35.

[104] 1992 Report, *supra* note 13, at 41.

2. External benefits

The chemical data that EPA has collected through its various TSCA programs represent important sources of information that are withheld from the interested public and other governmental entities only at considerable societal cost. Despite the relative ease of communication in the digital age, "[i]nformation gaps plague environmental decisionmaking from the household level to the global scale,"[105] and "we still operate under the burden of a great deal of 'toxic ignorance.'"[106]

To be sure, Petitioners are unable – and thus do not attempt – to predict the extent to which society would benefit from bridging the information gap or even, more modestly, the incremental bridging that a TSCA CBI sunset rule would itself accomplish. The truth is that information economies are highly dynamic and interactive. This, however, is precisely the point. "Excessive private control over health and environmental information creates pockets of static information within a system that needs to be dynamic." [107] As such, excessive CBI claims inhibit progress in the fields of risk assessment and management just as they stymie attempts to predict where, when and how such progress will occur.

a. Assisting state regulators, foreign governments and other federal agencies

Confidentiality prevents communication and collaboration with other governmental actors. State regulators have no access to CBI.[108] The same is true for foreign governments,[109] and even most members of Congress.[110] Other federal agencies are granted access to CBI only when "necessary" for a short list of specific purposes, and only after compliance with strict procedural requirements, such as notification to the affected business "published in the Federal Register at least 10 days prior to disclosure,"[111] and submission of "a written request to the [Information Management Division] Director . . . at least one month before access is to begin."[112] Naturally, these restrictions "make[] it difficult for other federal officials to use the data" and "imped[e] government

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[105] Daniel C. Esty, *Environmental Protection in the Information Age*, 79 N.Y.U. L. REV. 115, 140 (2004)
[106] Bradley C. Karkkainen, *Bottlenecks and Baselines: Tackling Information Deficits in Environmental Regulation*, 86 TEX. L. REV. 1409, 1425 (2008) (footnote omitted).
[107] Mary L. Lyndon, *Secrecy and Access in an Innovation Intensive Economy: Reordering Information Privileges in Environmental, Health, and Safety Law*, 78 U. COLO. L. REV. 465, 467-68 (2007).
[108] *See, e.g.*, GAO, *supra* note 34, at 31.
[109] *See, e.g.*, *id.*
[110] *See* 15 U.S.C. § 2613(e); 40 CFR § 2.209(b) (allowing limited access to "the Speaker of the House, President of the Senate, chairman of a committee or subcommittee, or the Comptroller General [*i.e.*, the GAO], as appropriate").
[111] *Id.* § 2.209(c).
[112] CBI Manual, *supra* note 81, at 26.

regulatory programs."[113] Indeed, "[t]he lack of data can inhibit sound policy formation at all levels of government."[114]

As an example of how TSCA data could help other government entities "reliably predict risks from specific exposures" of toxic chemicals, but for excessive CBI claims, the 1992 Report discussed the National Toxicology Program's ("NTP's") Fifth Annual Report on Carcinogens. The NTP authors sought §§ 8(d) and 8(e) submissions for eleven chemicals that, despite being "known to cause cancer in humans" were still not "adequately characterized for health risks."[115] Even though the request "only addresse[d] a small subset of the data collected by OPPT" and "any information that was identified" as responsive "would be critical to assessing the risks posed by these chemicals," the Agency withheld "nearly a fifth" of the responsive data as CBI.[116] One chemical in particular, benzidine, a dye ingredient that "can cause bladder cancer,"[117] was the subject of "three 8(d) submissions, *all* of which had *all* key data fields flagged as CBI."[118] While it is impossible to know for sure what use the NTP might have made of the withheld data, it bears pointing out that EPA's own attempts to regulate benzidine under TSCA have done little to suggest the public benefits of confidentiality.[119]

b. Enabling active citizen participation

Citizens can neither effectively participate nor have confidence in the administrative process if EPA continues to make regulatory decisions based on evaluations of secret facts. Unveiling the bases of Agency deliberations will bring more stakeholders to the table, resulting in benefits that are both intrinsic and instrumental. "Broad participation," in the words of one scholar, "has an independent democratic value."[120] Indeed, as FOIA and other congressional enactments make clear, the diffusion of information is, in and of itself, a sort of "baseline equal endowment, available for all to use in pursuit of their goals."[121]

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[113] 1992 Report, *supra* note 13, at iii.

[114] Jonathan H. Adler, *Jurisdictional Mismatch in Environmental Federalism*, 14 N.Y.U. ENVTL. L.J. 130, 168 (2005). *See also* OPPT, EPA, EPA NEEDS EXPOSURE-RELATED DATA: A DISCUSSION OF THE JUSTIFICATION FOR COLLECTING EXPOSURE-RELATED DATA THROUGH THE IUR AMENDMENTS 5 (Sep. 1, 1998), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2002-0054-0077 ("Other national and international organizations recognize that exposure-related data is useful for screening chemical risks.")

[115] 1992 Report, *supra* note 13, at 34.

[116] *Id.*

[117] American Cancer Society, What Are the Risk Factors for Bladder Cancer?, http://www.cancer.org/cancer/bladdercancer/detailedguide/bladder-cancer-risk-factors (last revised Feb. 26, 2014).

[118] 1992 Report, *supra* note 13, at 34 (emphasis in original).

[119] In 2012, EPA proposed a Significant New Use Rule ("SNUR") for certain benzidine-based dyes, to allow the Agency the opportunity to review the health and safety effects of benzidine in its various commercial applications and determine whether regulatory controls are justified from a risk-benefit perspective. *See* EPA, Benzidine-Based Chemical Substances, 77 Fed. Reg. 18,752 (prop. Mar. 28, 2012). This rule has never been finalized. *See* OIRA, OMB, View Rule: RIN: 2070-AJ73, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201110&RIN=2070-AJ73 (last viewed Aug. 4, 2014) (showing "To Be Determined" as the date for Final Action).

[120] Jody Freeman, *Collaborative Governance in the Administrative State*, 45 UCLA L. REV. 1, 22 (1997).

[121] Yochai Benkler, *Freedom in the Commons: Towards A Political Economy of Information*, 52 DUKE L.J. 1245, 1270 (2003)

In addition to information's naturally democratizing effect, the participation that it spawns "may take different forms in different contexts," any of which may in turn "facilitate effective problem solving."[122] For example, non-industry stakeholders might use their resources and expertise to check industry submissions and thus "limit a manufacturer's discretion in how it chooses to conduct, analyze and report its toxicity testing."[123] When information is presented to the Agency in a distorted or overly self-interested manner, "the only way for regulators to detect distorted research" may be "to replicate the study themselves."[124] Since EPA has limited resources to devote to such policing efforts, it is all the more vital that interested citizen groups possess the information they need to fill the gap. Prior experience with the toxic chemical heptachlor is a fitting illustration:

> After a product is approved, agencies rarely have the time and resources to reevaluate the original test data in light of changing scientific evaluational criteria. Thus, questionable industry interpretations can remain undetected for years. In one case, fifteen years elapsed between the original regulatory decision to accept the manufacturer's interpretation that the pesticide "heptachlor" did not cause cancer in rats and later evaluation of the same data, buttressed by independent experimentation, finding strong evidence which indicated that "heptachlor" was very likely carcinogenic.[125]

c. Keeping industry accountable and innovative

Experts have long understood that, in addition to spurring "active" intervention from public and private sources, information disclosure plays another valuable, albeit "more passive[,] role" – preventing industry from using confidentiality as a permanent shield for incomplete, misleading, manipulated, or fraudulent data.[126] One of the most troubling aspects of TSCA CBI practices was revealed by the 1992 Report's finding that "[i]n many cases, the invalid CBI claims appear to cover information that is potentially embarrassing to the submitter, but not [legally] entitled to protection."[127] Even in the rare situation where the public is simply unable to interpret disclosed chemical data in a useful manner, the mere "threat of scrutiny by critical outsiders may motivate industry and agency scientific personnel to analyze health and safety data more carefully."[128]

There are many instances of information disclosure increasing the responsiveness and accountability of market participants. The Toxics Release Inventory ("TRI"), a reporting program that requires facilities handling specified toxic chemicals to document their releases of those chemicals to the environment, is a noteworthy example. As noted above, TRI, and the information

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[122] Freeman, *supra* note 120, at 22.
[123] Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 IND. L. J. 629, 633 (2008).
[124] *Id.*
[125] McGarity & Shapiro, *supra* note 99, at 841.
[126] W. Thomas Jacks, *The Public and the Peaceful Atom: Participation in AEC Regulatory Proceedings*, 52 TEX. L. REV. 466, 502-03 (1974).
[127] 1992 Report, *supra* note 13, at 18.
[128] Jacks, *supra* note 126, at 503.

it generates, has a range of synergies with other EPA regulatory programs.[129] But even where the actual use of TRI data has been limited, their mere existence has proven remarkably beneficial: "the overall volume of reported TRI emissions has fallen by roughly half since the program was inaugurated, despite substantial economic growth over that period.[130] For this reason, "the TRI program has frequently been identified as a successful example" of "the incentives openness creates for 'regulated parties' to bolster protective practices."[131] California's consumer products labeling statute, Proposition 65, is another example. While at least one scholar has questioned the merit of Proposition 65 "under an information economics analysis," that same author heralded the law's "consciousness-raising" aspect as a considerable success.[132]

Industry groups have often contended, without meaningful corroboration or supporting analysis, that TSCA transparency "may have serious adverse impacts on innovation and small business."[133] In fact, the opposite is often true: protection of intellectual property and robust risk management are not only "consistent" – "they are symbiotic in an important sense."[134] Whereas trade secrecy regimes "encourage[] investment in whatever improvements will sell," disclosure of chemical risk data "supplements intellectual property by limiting investment incentives to products and processes that will not be too costly to society."[135] Meanwhile, for every anecdotal argument suggesting that nondisclosure fosters innovation, there is an equally strong argument that nondisclosure "constitute[s] a 'failure' in the chemicals market economy,"[136] which hampers innovation by preventing third-party improvements to confidential designs.[137]

Scholars focusing on the social consequences of TSCA CBI have also pointed to "general agreement among economists that secrecy as such is costly[,] [and] encourages wasteful duplication and lack of coordination."[138] This consensus includes governmental actors, namely the U.S. Council

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[129] *See* EPA, Learn about the Toxics Release Inventory, http://www2.epa.gov/toxics-release-inventory-tri-program/learn-about-toxics-release-inventory (last visited Apr. 29, 2014) (diagram showing "TRI Overlap for Air, Water, and Waste Programs at EPA").

[130] Karkkainen, *supra* note 106, at 1436-37.

[131] David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 WASH. U. J.L. & POL'Y 333, 372 (2010)

[132] Michael Barsa, *California's Proposition 65 and the Limits of Information Economics*, 49 STAN. L. REV. 1223 (1997).

[133] Am. Chem. Council, ACC White Paper: TSCA Protects Confidential Chemical Identities in Health and Safety Studies from Disclosure 4 (Jan. 19, 2012), *available at* http://www.whitehouse.gov/sites/default/files/omb/assets/oira_2070/2070_01202012-1.pdf. *But see* U.S. Council on Envtl. Qual., Toxic Substances Strategy Comm., Toxic Chemicals and Public Protection: A Report to the President 47 (1980) ("[I]t is unclear . . . how much th[e] [innovation] incentive is affected by disclosure of confidential health, safety, and efficacy data.").

[134] Lyndon, *supra* note 107, at 475. *See also id.* ("Successful and sustainable technology depends upon robust risk evaluation and feedback, which is impossible without disclosure of relevant data.").

[135] *Id.*

[136] Joseph H. Guth, et al., *Require Comprehensive Safety Data for All Chemicals*, 17 NEW SOLUTIONS 233, 234 (2007).

[137] *See, e.g.*, Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CAL. L. REV. 241, 266-67 (1998).

[138] Mary L. Lyndon, *Secrecy and Innovation in Tort Law and Regulation*, 23 N.M. L. REV. 1, 14 (1993).

on Environmental Quality, which has long recognized that nondisclosure is likely to result in duplicative testing and "the attendant waste of scare scientific resources."[139]

d. Facilitating non-governmental risk management strategies

Nongovernmental actors, particularly those that hold special relationships with vulnerable sub-populations, also use chemical data to foster healthier and safer societal practices. Labor unions, for example, can use "toxic-related information . . . to assess whether the information supplied by employers adequately reflects known dangers," and "to monitor both employer safety procedures and actual exposure levels."[140] The GAO provided the further example of "neighborhood organizations," which "can use such information to engage in dialogues with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures."[141] Professional organizations are another example. Perhaps no group within society is better situated to formulate and convey individually-tailored risk-avoidance strategies based on safety and exposure data than physicians, especially those with specialized practices, such as pediatricians advising patients who are nursing or pregnant.[142]

B. The proposed sunset rule would impose only negligible costs, if any.

As public awareness of the risks of toxic chemical exposures has grown in recent years, industry has responded by softening its position on new disclosure mechanisms, from hostility to skepticism, and most recently, to assent. According to the 2005 GAO Report, "EPA and the chemical industry agree that the need to protect industry data often diminishes over time, and thus it would be appropriate to revise TSCA regulations to require companies to periodically reassert the confidentiality of business information."[143]

As the industry representative paraphrased in the GAO Report recognized, sunset mechanisms do not redefine the substantive criteria for CBI protection, and there is thus no foreseeable likelihood that they will give rise to any competitive harm. The proposed sunset rule is simply a procedure allowing CBI claims to lapse whenever such claims are no longer actively sought or OPPT has determined that they are not sufficiently supported by their submitters (or submitters' successors-in-interest). OPPT would reach such a determination as a matter of course, where the submitter does not reassert its claim in a timely manner, or by applying substantive legal criteria, where adequate substantiation is not provided. Such an approach is clearly justified by the pre-existing duty for each CBI claimant to "satisfactorily show[] that it has taken reasonable measures to

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[139] CEQ, *supra* note 133, at 50.

[140] John N. Gevertz, *Workplace Exposure to Toxic Chemicals: Information Disclosure Versus Trade Secret Protection*, 13 N.Y.U. REV. L. & SOC. CHANGE 149, 154-55 (1985).

[141] GAO, *supra* note 34, at 32.

[142] *See, e.g.*, Kate E. Bloch, *Creating A Clearinghouse to Evaluate Environmental Risks to Fetal Development*, 63 HASTINGS L.J. 1571, 1582 (2012) (discussing 2011 Report by American Academy of Pediatrics bemoaning lack of access to risk information relevant to practitioners' treatment of pregnant patients).

[143] GAO Report, *supra* note 34, at 36.

protect the confidentiality of the information, *and that it intends to continue to take such measures*." 40 CFR § 2.208(c) (emphasis added). A sunset rule would, by its own terms, only release data that is no longer CBI, and thus does not raise the same difficult interest balancing questions that arise in broader policy debates over disclosure of CBI.

VI. CONCLUSION

The Petitioners submit their Petition in furtherance of the belief, in OPPT's own words, "that the benefits of maintaining only claims for CBI which have legal, contemporaneous merit, and clearing all other information for public release outweigh the comparatively minor burden of completing the simple reassertion requirement." [144] Of course, Petitioners appreciate EPA's recent efforts to make its TSCA programs more transparent. To this end, they acknowledge that some of the broader regulatory limitations EPA faces are the direct consequences of a badly outdated statute. And they recognize that when the public right to know is pitted against interests in competitive secrecy, EPA is often required to make difficult decisions.

This Petition does not ask EPA to make a close call. Indeed, one cannot reasonably dispute that the benefits of the proposed rule outweigh its costs, or that TSCA § 14 unambiguously gives EPA the discretion to "prescribe" the "manner" in which CBI protection will be afforded. Since Congress has granted EPA the authority to implement sound, environmentally protective policy, all that remains is for the Agency to act. We urge EPA to commence a TSCA CBI rulemaking without delay.

Respectfully submitted,

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[144] 2002 Comment Response, *supra* note 27, at 133.

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