Decades of out-of-control CBI

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I recently obtained – not without some effort on both EPA's and my part – a scanned copy of a 1992 report commissioned by EPA innocuously titled "Influence of CBI Requirements on TSCA Implementation," authored by the now-defunct Hampshire Research Associates. I subsequently found a copy in an old EPA docket, located here (6 MB PDF file).

This understated yet remarkable report is a veritable treasure trove of information that painstakingly documents the rampant rise in illegitimate confidential business information (CBI) claims made by the chemical industry in the first decade after passage of the Toxic Substances Control Act (TSCA) – and the very limited options available to EPA to stop such activity (despite recent admirable efforts on its part).

Now, some of you may be saying: "Wow, that report is old, surely things have improved since then." To which I respond there is absolutely no reason to believe that is the case (see this earlier blog post for just one indication of the continuing excess of CBI claims under TSCA). I would welcome any evidence to the contrary, but as you'll see, the underlying reasons for this problem are ***structural to TSCA*** and EPA's implementing regulations.

nature and extent of the problem. And it documents them: Because the authors were contracted by EPA, they had access to internal databases and records of submissions EPA had received under TSCA during the period of 1979-1990.

In this post, I'll summarize 10 key findings from the report that document the problem. In a subsequent post, I'll look at what the report had to say about solutions.

Key findings (I'll list them all here so you can take them in all at once, and then elaborate on each one below)**:**

1. Half or more of all information submitted to EPA under TSCA was claimed as CBI.
2. The fraction of information claimed CBI under TSCA was initially low and then rose, often dramatically, over time.
3. When EPA reversed a policy it had in place until 1982 that required up-front substantiation of CBI claims for new chemicals, the number of such claims shot up.
4. When examined by EPA, a large fraction of CBI claims were found to be illegitimate – the information so claimed was not eligible under TSCA or EPA regulations.
5. However, the vast majority of CBI claims have never been reviewed by EPA. And EPA has accepted without challenge CBI claims for information which TSCA does not allow to be so claimed.

penalties for wrongful disclosure of CBI – even if the information is not eligible for CBI protection.

7. Claiming information CBI under TSCA is simple and facilitated by EPA procedures; in contrast, challenging such claims is highly cumbersome and resource-intensive.
8. Processing and protecting CBI imposes heavy direct and indirect costs on EPA; in contrast, there is virtually no cost to industry to assert a CBI claim.
9. EPA has routinely failed to disclose the extent of CBI claims asserted overall, or what types of information it receives have been claimed CBI, to what extent and by whom.
0. The extent of CBI claims asserted under TSCA exceeds by orders of magnitude that under other federal laws – most notably the Toxics Release Inventory (TRI) – even for very similar types of information submitted by companies.

Elaboration of findings (quotes below are taken from the report)**:**

1. Half or more of all information submitted to EPA under TSCA was claimed as CBI.

While the extent varies by submission type and information element, CBI claims were made for:

CBI);

- more than 20% of all health and safety studies;
- about half of all EPA-requested records of significant adverse reactions (required to be kept under TSCA Section 8(c)); and
- more than 90% of all new chemical notices.

Submissions for all of the first three categories, and for quite a few of the fourth category, constitute or contain what EPA defines to be "health and safety studies." These CBI claims were made, therefore, in direct contravention of the plain language of TSCA, which expressly precludes such studies from CBI protection (see discussion of this issue in earlier posts).

2. The fraction of information claimed CBI was initially low and then rose, often dramatically, over time.

The report examined trends over time in CBI claims, and revealed a "learning curve" that appears to have been followed: companies increased the frequency of such claims as they learned there was little or no consequence to their asserting them, even for information clearly off-limits for CBI protection under TSCA or EPA regulations. For example:

- About 70% of premanufacture notification (PMN) submissions for new chemicals submitted to EPA during the first 4 years of the PMN program (1979-1982) claimed the chemical identity as CBI.

rate of CBI claims for PMNs has if anything increased further since 1990: EPA indicated in 2007 that about 95% of PMNs contain information, including chemical identity, designated by the submitter as CBI; see p. 10 of this report).

- Very few "substantial risk" notices were submitted until 1983 (fewer than 15 per year). From that year onward, the number of such submissions increased – but so did the fraction of them claiming CBI, rising from a mere 15-18% in 1983-85 to a whopping 48% by 1990.

3. When EPA reversed a policy it had in place until 1982 that required up-front substantiation of CBI claims for new chemicals, the number of such claims shot up.

One contributing factor to the jump in CBI claims accompanying PMNs starting in 1983 appears to have been EPA's reversal of a policy in place prior to that year that required up-front substantiation of CBI claims to be provided at the time the claims were asserted. This is one of several factors the report identifies clearly indicating that ***the lower the "cost" or effort required to assert CBI claims, the more claims are made*** – regardless of whether or not the claims are warranted.

4. When examined by EPA, a large fraction of CBI claims were found to be illegitimate – the information so claimed was not eligible under TSCA or EPA regulations.

program to review and challenge CBI claims. Specifically, EPA challenged all CBI claims made in association with a significant number of the submissions of health and safety data it received over a limited period under either Section 8(d) or 8(e) of TSCA. Remember that TSCA expressly excludes health and safety studies from eligibility for CBI protection, and EPA regulations expressly define chemical identity as an integral part of a health and safety study; for a refresher on these points, click here).

So what happened?

In every case in which EPA challenged a claim, the submitter agreed to remove or reduce the scope of the claim. The report states that this result "indicates that EPA is correct in challenging the validity of these CBI claims." This high frequency of questionable or invalid claims appears to have continued: It was reconfirmed by an EPA official cited in a 2005 report by the Government Accountability Office (see page 33), who indicated that, while only about 14 CBI claims are reviewed per year, nearly all challenged claims were withdrawn.

The report provides numerous examples of spurious claims and justifications uncovered by this review, concluding that "they illustrate an apparent reliance on CBI claims to avoid embarrassment or adverse public reaction, rather than to protect trade secret information," and "an effort to prevent disclosure of precisely the sort of information that the framers of TSCA sought to make available to the public."

and the identity of the chemical in question as CBI. When asked to justify the claim, the submitter said the health effect identified in the study was "highly unusual" and that it sought to avoid public release of this information until it could conduct further research, so as to avoid "premature and possibly unnecessary concern" about its chemical.

Seeking in this manner to use TSCA's CBI provisions for a purpose for which a company might otherwise hire a public relations firm is not, of course, what Congress had in mind when it mandated immediate disclosure of such information. Nor does it come close to a justification that the information constitutes a trade secret, which is the sole legitimate basis for CBI assertions.

Unfortunately, to the best of my knowledge, that review program at EPA was short-lived and has not been repeated.

5. The vast majority of CBI claims have never been reviewed by EPA. And EPA has accepted without challenge CBI claims for information which TSCA does not allow to be so claimed.

TSCA allows companies submitting information to claim any information they want confidential, whether or not it actually meets statutory or regulatory descriptions of eligible information. The onus then shifts to EPA to challenge a claim it considers invalid (more on the process EPA must follow is below).

Because the resources required to conduct such case-by-case challenges are lacking, the report found that "the vast majority of

typically only when a Freedom of Information Act (FOIA) request is filed for the information (but see finding 8 below on the limitations of this as a trigger for review).

Lest you think things might have improved, all indications are that this minute rate of review of CBI claims continues to the present day. As noted earlier, EPA confirmed in the 2005 GAO report (see page 33) that only about 14 CBI claims are reviewed per year.

Another key conclusion of the Hampshire report is that "Agency practice in accepting CBI claims has, in fact, been more lenient than the statute (or its implementing regulations) requires."

For example, EPA routinely allows PMN submissions to be claimed CBI in their entirety – even when they contain health and safety studies. (Elsewhere I have noted how few PMNs actually contain any such studies; for example, 85% of PMNs contain no health data. But 15% of the roughly 1,500 PMNs filed annually is still a good number of PMNs with health data – which should, but are not being, released by EPA.)

All of this contributes to quite a vicious circle: The more CBI claims are made, the fewer EPA can review; the fewer EPA reviews, the greater the incentive to make unwarranted claims.

Ah, but we're not nearly done yet: There are still more factors that contribute to this perverse downward spiral that serves to reduce disclosure of chemical information that Congress meant for the public to see; read on.

penalties for wrongful disclosure of CBI – even if the information is not eligible for CBI protection.

The report calls out this remarkable imbalance, noting that it has contributed to the proliferation of CBI claims. It has also led EPA to create a level of protection for CBI equivalent to that granted top-secret national security information elsewhere in government, and has engendered an "institutional culture" at EPA that invariably tilts far to the side of nondisclosure over public right to know.

7. Claiming information CBI under TSCA is simple and facilitated by EPA procedures; in contrast, challenging such claims is highly cumbersome and resource-intensive.

Further lowering the transaction costs for asserting CBI claims and raising those for challenging them are the procedures EPA has developed.

In many cases, merely checking a box is all that is required to designate part or all of a submission as CBI. Until and unless a specific claim is challenged, the confidentiality of that information must be protected by EPA.

In contrast, EPA policy specifies that, for each CBI claim it wishes to scrutinize, it must typically first contact the submitter to request substantiation of a CBI claim, then review the substantiation, then again contact the submitter if it believes the claim is unwarranted to seek its consent to release the information. If unsuccessful, EPA must then convince its Office of General Counsel the case warrants

submitter can challenge the impending disclosure in court and halt it pending judicial review and decision.

8. Processing and protecting CBI imposes heavy direct and indirect costs on EPA; in contrast, there is virtually no cost to industry to assert a CBI claim.

The report describes a range of substantial costs CBI protection imposes on EPA, ranging from direct costs to establish and maintain the needed security infrastructure, to indirect costs associated with limiting or complicating the ability of EPA staff to access information critical to performance of their jobs. While these costs may be legitimate for information that truly warrants CBI protection, they clearly are excessive in light of the large number of unwarranted claims made.

In contrast, under TSCA there is not even a processing fee associated making a CBI claim. The report points out that such a fee would serve a dual function, based on experience under other laws: It could reduce the number of claims made merely by imposing a cost on doing so. And it would provide EPA with resources sufficient to cover its costs of processing, reviewing, and where necessary challenging such claims.

9. EPA has routinely failed to disclose the extent of CBI claims asserted overall, or what types of information it receives have been claimed CBI, to what extent and by whom.

public even the fact that such information was claimed CBI. As a result, the report concludes, “there is no way for outside users to know whether or not EPA is in possession of data relevant to their interests.”

Yet TSCA provides no basis for EPA to hide from the public the fact that a company has claimed certain information to be CBI. Nor can EPA legitimately hide the extent to which certain types of data are claimed CBI.

Surely the public has a right to know that a certain company claims all of the information it submits to be CBI, while another company claims little or none of what it submits. And the public should be able to know how often companies claim health and safety data they submit to be CBI – despite and in direct contravention to TSCA’s prohibition on doing so.

How else can we know what we don’t know?

One bright spot of late was EPA’s effort to tally and publicize the extent of CBI claims made for data elements required to be reported under its most recent TSCA Inventory Update Reporting (IUR) cycle. EPA’s summary report of the information submitted under the 2006 IUR has a nifty table (see Exhibit 3 in that report) indicating the – often large – extent to which certain types of information were claimed CBI by companies.

But it needs to go the next step: For each submission it receives, it should either make public each information element in the

latest IUR report) aggregated statistics characterizing the frequency and extent of CBI claims both for individual information elements and overall for a given submission type.

10. The extent of CBI claims asserted under TSCA exceeds by orders of magnitude that under other federal laws – most notably the Toxics Release Inventory (TRI) – even for very similar types of information submitted by companies.

This finding falls under the category of "clearly, there is a better way." The report highlights CBI policy and practice under the Emergency Planning and Community Right-to-Know Act (EPCRA), which established the Toxics Release Inventory (TRI).

The report notes that, in 1988, only 23 trade secret claims were made under TRI – out of more than 70,000 forms submitted. ***That's 0.03%.*** Contrast that with TSCA, under which the report estimates ***50% or more*** of the submitted information was subject to CBI claims.

The report's conclusion: "CBI claims under TSCA are far in excess of what is needed to protect true trade secrets."

What accounts for the radical disparity in the CBI experience under these two laws? The report identifies five key differences. EPCRA (Section 322) and its associated regulations:

- require up-front substantiation of all CBI claims at the time they are made;

- limit CBI claims to a narrow set of information elements; and
- require that each submission be made available – with each information element claimed CBI clearly identified so the public understands what is being withheld.

These EPCRA provisions help to inform the report's excellent assessment of solutions to excessive CBI claims under TSCA – which I will delve into in another post in the near future. So stay tuned – or just read the report!

2 Comments

Tim Hayes
Posted February 12, 2010 at 2:19 pm | *Permalink*

We are a nation controlled by corporate oligarchs. Until we get off our butts and take to the streets and demand changes it's only going to get worse. Time to bridle the Big Chem., Ag., Pharm., Defense, Bank, "to big to fail," industrial complexes and the lobbyist controlled system of big budget elections that keeps it fueled.

Kavita Hardy
Posted February 19, 2010 at 2:35 pm | *Permalink*