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# Bloomberg Environment Insights

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## Protecting the Value of Health, Safety Studies—Emerging TSCA Issues

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This article was originally published as a two part series on the importance of protecting confidential business information under the Toxic Substances Control Act.

Health and safety studies provide invaluable insights into the hazards posed by chemical substances. The cost of generating these studies is also considerable, and access to them should be commensurate with the intellectual property interests they reflect. This article explores two current challenges under the Toxic Substances Control Act (TSCA) and offers practical tips for managing these issues.

### **EPA Should Revise Its Safety Study Disclosure Policy**

TSCA Section 14(b)(2)(A)(i) provides that Section 14(a) of the act does not prohibit the disclosure of any health and safety study submitted under the law with respect to a chemical that has been offered for commercial distribution. The U.S. Environmental Protection Agency—based on its practice over the years—apparently interprets this provision to mean that all studies coming into its possession must be disclosed to the public in their entirety.

The cited language, however, does not support EPA’s apparent interpretation of what this provision means nor does it require EPA to disclose health and safety studies. It only states that EPA is not prohibited from doing so.

In fact, Section 14(b) explicitly addresses documents that include a mixture of confidential and nonconfidential information, and the provision states that confidential information in these “mixed” documents does not lose protection.

EPA’s construction of TSCA Section 14(b)(2)(A)(i) poses considerable challenges.

Many of the studies that will be relevant to EPA’s risk evaluations under TSCA Section 6 have significant monetary and competitive value, and data owners have every right to expect some protection from the disclosure of the study reports to preserve their value.

If the EPA as a matter of practice routinely posts entire study reports publicly, the reports would be rendered valueless for data compensation purposes.

Some organizations have considered approaches that include the selective claiming of certain information elements in the study report as confidential to protect the value of the research while providing relevant information on the general findings and health and safety effects observed in the study. It is unclear, however, if this practice provides other stakeholders with sufficient information or if this practice is entirely effective in preserving the monetary and competitive value of the study report.

### **Joint Ownership**

The EPA’s insistence that those who send in study reports accept the fact that the entire submission will be posted publicly also ignores the reality that many of these reports are jointly owned. Multiple entities often have title to the study as joint owners and its disclosure is generally subject to data sharing agreements that expressly prohibit its publication unless required by law.

If, for example, a data owner has entered into a data-sharing agreement under the European Union Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program, more often than not the data owner is prohibited by such agreements from distributing

the study reports to others, including the government, unless ordered to do so.

Under the applicable legal standard, voluntarily submitted data are generally entitled to confidential treatment “if it is of a kind that the provider would not customarily release to the public.” The case is *Critical Mass Energy Project v. Nuclear Regulatory Comm’n*, D.C. Cir. App., No. 90-5120, 1992.

Unfortunately, under EPA’s construction of TSCA Section 14(b)(2)(A)(i), EPA is required—rather than allowed—to override the protection that would otherwise apply to voluntarily submitted studies.

EPA’s practice of publishing full studies in their entirety means that a company must choose between either providing the information to EPA voluntarily without the protection otherwise available for voluntary submissions (in the case of assisting EPA in a Section 6 risk evaluation) or not sharing the information to abide by the terms of the data sharing agreement.

The consequences of this forced choice are extreme.

EPA would need to compel entities to develop potentially duplicative information, issue Section 11 subpoenas, exercise its new TSCA Section 4 authority, or initiate lengthy TSCA Section 8(d) rulemakings to mandate the disclosure of the information. In so doing, EPA is effectively denying interested groups the opportunity to voluntarily assist EPA in undertaking TSCA Section 6 risk evaluations without the benefit of receiving relevant and important existing information.

Companies spend millions of dollars in time and resources on health and safety studies that provide important information on the potential risks of chemical substances. The 2016 amendments to the Toxic Substances Control Act revise provisions on submitting critical information to the Environmental Protection Agency for evaluating these compounds.

Submitters need assurance and a process for ensuring their valuable data is protected. [...]

EPA’s reflexive practice of publishing full study reports resulting from research on new and existing chemicals is premised on a flawed reading of TSCA’s Section 14, which relates to the submission of confidential business information (CBI) in the course of submitting data. TSCA does not prohibit the disclosure of any health and safety study submitted under the law with respect to a chemical that has been offered for commercial distribution. But that doesn’t mean all studies coming into the EPA’s possession must be disclosed to the public in their entirety.

The EPA’s broad interpretation of the law should be reconsidered in light of a recent judicial decision and the pressing need to acknowledge the global relevance of health and safety studies in a changing world.

Increasingly, chemical notification programs are standard practice in a growing number of jurisdictions.

This inconvenient reality has significantly amped up the need to generate or rely upon others’ chemical data to gain market entry. It also highlights the inherent monetary and competitive value in these data.

The U.S. Court of Appeals for the District of Columbia Circuit on July 5 considered a TSCA Section 8(e) (substantial risk information) case and whether the obligation under that provision to inform EPA immediately of substantial risk information constitutes an obligation to transmit property.

In [\*USA ex rel. Kasowitz, Benson v. BASF Corp.\*](#), the court concluded that “TSCA does not require the transmission of a property interest. TSCA gives the EPA one—and only one—interest in substantial risk information: the right to be informed of it.”

The decision involved the application of the so-called reverse false claim provision of the federal False Claims Act in the context of TSCA Section 8(e) reporting. Because the court concluded that EPA has no property interest in the submitted information and is entitled only to being informed of the information, this supports a construction of TSCA under which EPA will exercise its authority to disclose otherwise confidential health and safety studies information only through procedures that will not vitiate the data owner's property interest.

### **Possible Options to Protect CBI**

EPA should work with groups to identify approaches in which data owners can protect their intellectual property, perhaps through claiming certain pieces of information that are not critical to the interpretation of the overall study as confidential business information.

Such an approach would provide the EPA with the entire study report, enabling it to do its job under TSCA, as well as a redacted version for public access that contains relevant results and conclusions. In this instance, the needs of the various interest groups can be balanced appropriately.

An alternative option would be for the EPA to take a page from the Federal Insecticide, Fungicide, and Rodenticide Act playbook and prepare a data evaluation report (DER) for submitted studies.

DERs provide detailed summaries of studies but withhold sufficient information to preserve data compensation, an integral and well-developed part of the FIFRA pesticide registration process. This approach would also ensure the EPA has the full study reports and can provide the public with relevant safety information and the intellectual property of study report sponsor.

### **Reading Rooms for Reports**

Alternatively, the EPA could provide access to entire study reports through reading rooms in which reports are available for public review but cannot be copied. The EPA also could require outside groups seeking access to full study reports to execute enforceable nondisclosure agreements with data owners as a predicate to access full study reports.

Other options exist that the EPA needs to consider and decide with outside input on how best to proceed.

While there are more questions than answers at this point, what is clear is that the EPA must modernize its policies and practices to reflect the intellectual property interest in chemical data and the availability of, and the EPA's need to embrace, reasonable measures to protect data owners' rights to data compensation.

Failure to do so will unnecessarily compromise the EPA's access to critical data in discharging its TSCA Section 6 obligations and de-incentivize data owners from participating in rulemakings in which they may have a significant stake in the outcome.

Indeed, the choice hoisted upon data owners in this regard reflects an impermissible interpretation of TSCA and a violation of a data owner's constitutional interest in equal protection under the law.

### **Submitter's Assert CBI: The Training Wheels Are Off**

The 2016 TSCA amendments place a significantly greater burden on submitters to protect information that is eligible to be exempt from disclosure. TSCA recognizes the need to protect information that would, if released, result in potential substantial commercial harm.

Section 14(c)(2) includes categories of information that are presumptively eligible for protection and do not require the submitter to substantiate claims for protection.

Importantly, the EPA announced July 15 that it would cease providing notices of deficient CBI claims. Now, if the EPA receives a document containing CBI without accompanying substantiation and a certification statement, it will invalidate the claim and consider the entire document nonconfidential.

This does not mean that if the EPA disagrees with an asserted claim of confidentiality it will disclose the information without notice. The agency is required to provide the submitter notice that it disagrees with the CBI claim or substantiation and intends to release information that was properly claimed, substantiated, and submitted with an accompanying certification statement.

Rather, the EPA will only disclose information claimed without the other elements required by the statute.

Similarly, the EPA will not seek to correct obvious mistakes a submitter may have made as it has in the past. The agency also announced that it will begin to post publicly the redacted copies of documents submitted in real time without prior review of those documents.

This means that if a submitter inadvertently neglected to protect all instances of CBI, that information may well be disclosed without notice.

In both cases, the EPA is putting the burden back on the submitter to ensure that CBI claims are properly claimed and properly protected. This is where the burden belongs, after all, and the EPA cannot reasonably be expected to do a submitter's work for it.

This means, however, that submitters need to step up and do a better job of ensuring that CBI claims meet the statutory requirements and up their game, as it were, in identifying CBI and certifying that release of such information would pose "substantial commercial harm."

Failure in this regard just got more consequential.