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Leveraging Chemical Data More Efficiently

Some truths transcend politics, one being that chemical data holds enduring value and is becoming increasingly essential. In the United States, regardless of which party federally controls the levers of power, it's clear that chemical manufacturers and their customers must develop and curate robust data portfolios for their chemical inventories. The commercial imperatives driving this are undeniable and gaining traction.

Data Are Intellectual Property Assets

Data in this context includes health and safety studies, physical property information, environmental fate and transport studies, release and exposure information, and similar information beyond commercial information like financial data, product formulations, and customer lists. A key tenet of the U.S. Environmental Protection Agency's (EPA) regulatory authority under the Toxic Substances Control Act (TSCA) is the principle that manufacturers and processors are responsible for developing adequate information regarding their chemical products. Like any valuable commodity, data needs to be protected from disclosure and managed carefully to retain its value.

The industrial chemical community has not always been as protective of its health and safety chemical data, unlike their

counterparts in the agricultural chemical space. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), data supporting a registered active ingredient or pesticide product and relied upon by the EPA to maintain a registration are, for 15 years, "compensable" when cited or relied upon by third parties to support follow-on FIFRA registrations.


Lynn Bergeson

These data are bought, sold, and valued based on a complicated calculus reflecting the study costs (e.g., laboratory invoices), risk avoidance, interest, the time value of money, and other financial variables. In disputed cases, American Arbitration Association panels decide valuation decisions in trial-like arbitrations. This process has existed for decades.

FIFRA data, like Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) data, will remain undisclosed unless they satisfy certain conditions, including provisions in FIFRA Section 10(g) that prohibit the release of data to foreign or multinational corporations. Companies cannot claim TSCA health and safety data as confidential. Although TSCA Section 4 includes a data cost reimbursement mechanism, regulators have largely ignored it. REACH helped strengthen the concept of monetizing chemical data, and the recognition of data as a currency in the industrial chemical community is now a more prevailing view.

The Essentiality of Data

A company's freedom to operate is increasingly tied to its ability to prove the safety of its products. Regulatory trends demonstrate this. The EPA's enhanced authority under new TSCA Section 4 to compel chemical data production reflects

Congress's recognition that the public has a right to know more about chemicals in products. The availability of high-quality studies impacts EPA's evaluation of chemical substances under TSCA Section 6 and consequent risk management regulations.

Innovators seeking to commercialize new chemicals under TSCA Section 5 are at a severe disadvantage if they lack chemical and exposure data. The absence of these data results in the imposition of conservative risk assumptions and multiple safety factors during new chemical review that make operating conditions less competitive.

REACH is premised on similar principles. Under REACH, the greater the production volume, the greater the data burden as a regulatory predicate to marketing the chemical. REACH-like laws around the globe are premised on the same principles, creating a regulatory imperative to know more about a chemical's hazard and risk profile as a prerequisite to commercialization. Generating new data is not always necessary, as it's possible to leverage read-across and chemical analogue analysis to fill data gaps. What is no longer acceptable is the adage "What you don't know can't hurt you."

Emerging product stewardship principles require manufacturers of industrial chemicals and articles alike to understand the toxicological, environmental fate, and exposure implications of their products. Incomplete product profiles translate into product liability, commercially adverse inferences regarding risk potential, and mistrust in commercially significant constituencies like customers, workers, regulators, and neighbors.

Savvy companies are conducting data gap analyses for critical products and key chemical components in them and voluntarily generating defensive data. The availability of these data fortifies advocacy opportunities in product liability disputes, fulfills product stewardship commitments, and holds entities accountable to answer questions key stakeholders are likely to ask if things go south. This is smart. While facts and science may not always win over juries, defendants have a much stronger case when they support their arguments with data.

What to Do Now

Smart businesspeople are taking stock of their chemical product inventories and critically assessing their options. Here are a few to consider:

Conduct a data call-in: Companies need to know what data they own or have access to through data sharing agreements. Trade associations can assist by managing these efforts to ensure they efficiently identify unpublished studies to present a comprehensive composite overview of a chemical's data, use, and exposure information unique to a commercial sector. Use a lawyer in this exercise to carefully navigate confidentiality claims, competition issues, and related legal sensitivities.

Curate data prudently: Companies and trade associations must carefully curate existing data to preserve confidentiality and maximize value. Develop standard operating procedures to routinize these protections and observe them.

Prepare data sharing agreements to leverage data: To monetize data effectively, entities that need to rely on it must be able to access the data and pay fair data compensation. Data sharing agreements should spell out the rights, duties, and obligations of the contracting parties. Compensation mechanisms need to be standardized.

Develop data smartly and carefully: There are many reasons to generate chemical data. It is critical that a decision to do so, whether by a company or jointly by a consortium, is based on a review of global regulatory and testing protocol requirements. Satisfying Good Laboratory Practice (GLP), Organization for Economic Co-operation and Development (OECD), and other testing requirements is challenging but essential.

It is a brave new world, fueled increasingly by chemical data. Like any asset, it's essential to manage these data smartly and generate new data carefully. These politically agnostic facts are true globally. Start now to embrace them and plan accordingly. **PCB007**

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