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Toxic Substances

Volume of Chemical Information Required Stirs Unease on Protecting Proprietary Data

WASHINGTON, D.C.—As Asian governments join their Western counterparts in enhancing chemical regulations or developing new ones, chemical manufacturers have expressed concern about whether the volume of information governments are requiring globally will make it harder to protect proprietary information.

“There is a lot more confidential information entering the government sphere. That raises questions about how governments are protecting it, whether the disclosure will affect confidential business information claims that can be made, and whether CBI will be released,” Charles Franklin, senior counsel at Akin Gump Strauss Hauer & Feld LLP, told BNA.

Franklin chairs the American Bar Association’s Pesticides, Chemical Regulation, and Right-to-Know Committee, which held a panel discussion April 10 titled “Recent Developments in Confidentiality, Public Access, and Chemical Control Laws in Asia: Will East and West Finally Meet?”

Changes Afoot in Asia. Dan Newton, a government relations manager at the Society of Chemical Manufacturers and Affiliates (SOCMA), said helping small and medium U.S. chemical manufacturers increase their markets in Asia is among his group’s top priorities and that makes protecting confidential business information a key concern, because the regulatory systems are changing.

China, Japan, Taiwan, and South Korea have all either amended their existing chemical regulations or are developing new regulatory schemes, Tom Berger, a partner at Keller and Heckman LLP, told the ABA participants (35 INER 73, 1/18/12).

In 2009, the Japanese government amended its Chemical Substances Control Law to require the annual submission of extensive chemical production, use, and other data, he said. The Japanese requirement is similar to the U.S. Environmental Protection Agency’s Inventory Update Reporting rule (IUR), now called the Chemical Data Reporting (CDR) rule, Berger said.

More Chemical Regulations Coming. Indonesia, Malaysia, the Philippines, and Vietnam also are expected to develop their own regulatory systems over the next few years, Justine Freisleben, another SOCMA government relations manager, told BNA after the ABA meeting.

The trend among Asian and Pacific countries is to require chemical manufacturers to “tell us everything,” Karon Armstrong, international regulatory affairs manager at the 3M Co., told ABA participants.

She showed a list of questions that included: What do you make? Where do you make it? How much do you make? Where do you sell it? Who do you sell it to? and What do they use it for?

The answers to each of these questions raise potential confidential business information issues, Armstrong said.

Legal Procedures Still Maturing. Companies do not always get clear answers from governments because their institutions are in the midst of developing their new chemical management policies, Joanne Thelmo, vice president and general counsel for the American Cleaning Institute, told BNA.

Furthermore, the legal procedures and standards that parties would turn to in order to interpret these regulations and determine what specific chemical information should be protected as proprietary are still maturing in some countries, Thelmo said.

All of this leaves chemical manufacturers unclear about the extent to which critical confidential business information will be protected, she said.

That uncertainty cuts at least two ways, attorneys and trade association officials told BNA.

Companies are concerned that proprietary information will be disclosed and used by competitors, Franklin, Thelmo, and other attorneys told BNA.

Chemical Inventories Pose Problems. Companies also wonder whether the disclosure of information to other governments will make it more difficult to protect that same information as confidential in the United States, Franklin said.

China, Korea, and Japan have public websites that can be searched to identify the chemicals listed in their national inventories, and Taiwan is expected to publish its chemical inventory later this year, Sookie Hong, Asia Pacific regulatory analyst for the 3E Co., told BNA. 3E is a regulatory compliance consulting firm.

Berger told BNA a chemical’s presence on one public inventory of substances can be fatal to a confidential business information claim in another inventory.

For example, if a chemical is listed in the confidential portion of one of Canada’s chemical inventories and Environment Canada learns the compound was subsequently added to another public inventory (for example, the U.S. TSCA inventory), Environment Canada will transfer the chemical to the public portion of its inventory.

Yet a company may have a legitimate reason for allowing a chemical to be listed on one public inventory while wanting it to be confidential in another country, Mark Greenwood, an attorney with Ropes & Gray LLP and former director of EPA's Office of Pollution Prevention and Toxics, told BNA.

A company may be entering a market for the first time and not want other companies to know it is exploring that market, Greenwood said.

EPA Seeking More Public Access to Data. All of these concerns about confidentiality are increased because of EPA's goal of boosting public access to chemical information, the attorneys and trade association officials told BNA.

During the ABA meeting Scott Sherlock, attorney adviser in EPA's Office of Pollution, Prevention & Toxics, said disclosure of a chemical's identity on a foreign government's inventory of compounds being sold in that country would be one of several factors the agency would consider as it would determine whether the chemical's identity could be kept confidential on the TSCA inventory.

After the meeting, EPA sent BNA a statement saying that sometimes the agency faces situations where information on a chemical is publicly available in Europe, but similar information is claimed as CBI in the United States.

Determinations are made on specific facts and applicable law. Certainly if the information is available in another country that would be a factor in a U.S. determination, but it does not preclude the information being confidential in the United States, EPA said.

'There's Chaos.' "East has met West and there's chaos," Daryl Ditz, director of the chemical program at the Center for International Environmental Law, wryly told participants at the ABA committee's discussion.

He acknowledged that chemical manufacturers are dealing with "muddled" chemical management policies but asked for sympathy for the public health perspective.

Nongovernmental organizations are pushing governments to seek and make public more information about chemicals because they want to protect people's health and the environment, Ditz said.

Yet for a company, details about what it makes, how the chemical is made, and how the substance is used are often among its most valuable assets, Berger told BNA.

"That is their livelihood" and there is discomfort with increasing the number of parties requesting access to this information, he said.

Information Disclosure Laws Differ. During the ABA meeting Thelmo described information disclosure laws in China, Japan, South Korea, and the United States

that can be used to obtain government-held information.

U.S. chemical manufacturers increasingly are dealing with countries whose legal systems balance protecting the public interest and protecting confidential business information differently than does the U.S. Freedom of Information Act, she said.

Japan's Information Disclosure Act, for example does protect some proprietary information, but allows the government to disclose information when the public interest overrides the company's interest, Thelmo said.

Thelmo pointed to a 2002 case from the city of Takatsuki, in which the Osaka High Court ruled that a resident's concerns about safety warranted disclosure of floor plans from a biotechnology laboratory owned by Japan Tobacco Industries. The company unsuccessfully argued that disclosure of the information would cause significant harm to its competitive position.

In the United States, FOIA exempts confidential business information from disclosure by federal agencies.

Any company pursuing markets in Asia must have a well-thought-out marketing and intellectual property protection strategy, Thelmo said.

That IP strategy may include creating an attractive workplace environment so employees will not leave and go to work for competitors, Thelmo said.

Greenwood said protecting confidential business information in Asia was outside his expertise, but historically, as EPA determines whether information qualifies for confidential protection, the agency has focused on identifying how well a company has sought to protect that information with its own suppliers and customers.

EPA wants to see that a company has a history of guarding information it wants the agency to also keep confidential, he said.

Berger said companies should be very cautious and use nondisclosure agreements as appropriate with their customers.

Protecting chemical-related confidential business information is a growing and complex issue, Berger said.

Companies should proceed in an organized and methodical fashion, particularly given the growing number of international information-sharing treaties and agreements, he said.

Governmental agencies communicate with one another "more than you might think" about specific chemicals and companies that have submitted information, Berger said.

Governments have a legitimate interest in denying illegitimate assertions of confidential business information, Berger said, "but they also must recognize and balance the significant investment made by companies in their chemical products."

BY PAT RIZZUTO