

Disclosure Protection May Narrow

EPA targets confidential business information claims.

Chemical Processing, February 2010

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A business' ability to claim information as confidential when submitted to the U.S. Environmental Protection Agency (EPA) may soon be at risk, based on several EPA initiatives rolled out over the past year. As Congress gears up for Toxic Substances Control Act (TSCA) legislative reform, stakeholders are preparing for changes in the scope of confidential business information (CBI) protection under TSCA.

Message of Change Resonates

Lisa Jackson, EPA administrator, has repeatedly sought to ensure EPA's operations are transparent and accessible, particularly in assessing potential risks from chemicals. Her much publicized revisions to the EPA Office of Research and Development Integrated Risk Information System chemical risk assessment process last May were expressly intended to improve as well as make the review process more transparent.

That change is in the air should come as no surprise. Over the years, CBI has been on a collision course with the right-to-know movement. Competing interests of CBI protection and chemical identity and risk information are no place more at odds than under TSCA's confidential information provisions and EPA's implementing regulations. EPA's TSCA and Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) programs have been under intense pressure from public interest groups, consumer groups and even state and local government authorities to share information now claimed as CBI and thus shielded from public review. These interests have long pushed for reviewing and perhaps narrowing the scope of information under CBI protection, particularly chemicals and chemical risk assessments information. Several recent developments confirm that this message of change resonates with the current Administration. "Businesses should ensure that safeguards protecting information from disclosure aren't inadvertently eroded."

First, EPA is seeking ideas for greater disclosure of inert ingredient identities in FIFRA pesticide formulations.. EPA issued an Advance Notice of Proposed Rulemaking on December 23, 2009, stating that it's considering two approaches to increasing public availability. One mandates disclosure only of potentially hazardous ingredients and the other promotes or mandates public availability of most or all inert ingredient identities, regardless of hazard.

Second, EPA on January 21, clarified that if a chemical substance is listed on the public portion of the TSCA Inventory, EPA expects a company submitting a health and safety study for that substance under TSCA Section 8(e) won't claim the chemical identity as confidential. EPA says, "[t]his action is part of a broader effort to increase transparency and provide more valuable information to the public by identifying programs where non-CBI may have been claimed and

treated as CBI in the past." EPA also states that this general practice notice isn't a final Agency action, but instead, any EPA issued determination letter for a specific TSCA Section 8(e) submission finding that the chemical identity isn't entitled to confidential treatment would be. If EPA is correct, judicial review of the new policy can't be sought until EPA denies a submitter's CBI claims. While EPA didn't specifically solicit comments on its announcement, it opened docket number EPA-HQ-OPPT-2009-1013, available at www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a80fe4.

Third, EPA also is expected to issue proposed TSCA Inventory Update Rule (IUR) revisions. According to the December 2009 Regulatory Agenda, revisions could include eliminating the upper threshold to collect processing and use data for all reported chemicals; collecting multi-year production volume information; returning reporting frequency to every four years from every five, triggering reporting based on annual production volume since the last IUR; and requiring electronic reporting. Other possible changes include CBI claims modifications. EPA reportedly may issue a proposed rule this spring.

Finally, TSCA reauthorization legislation likely will be introduced soon. It's widely believed that CBI provisions will be revised. The ability to claim information as CBI may be diminished, and opportunities to share CBI information with foreign and state government entities may be expanded.

Public Disclosure Gains Momentum

Government interests are keenly aware of the need to protect innovations and other information that qualifies as CBI. At the same time, pressures to revisit the scope of CBI protections that have historically been available to shield broad categories of information from public disclosure are strong and gaining significant momentum. Businesses should track regulatory and legislative initiatives and seek to ensure that safeguards protecting information from disclosure aren't inadvertently eroded.

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