



EPA regulations change, limiting trade secret protection of chemicals

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USA

October 19 2010



The United States Environmental Protection Agency (EPA) recently took several actions to increase transparency regarding chemicals and their potential environmental and health risks. These changes will reduce the trade secret protection previously available to chemical manufacturers.

The regulatory changes involve the 1976 Toxic Substance and Control Act (TSCA), which prohibits manufacture of chemicals that are not on the TSCA chemical inventory. The EPA reviews new chemicals for possible addition to the inventory, and can regulate or refuse approval to manufacture chemicals found to have unreasonable environmental or health risks. The TSCA also requires public access to chemical health/safety information, including certain health studies involving inventory chemicals. However, manufacturers can claim the actual identities of chemicals as Confidential Business Information (CBI) to protect legitimate commercial interests. As a result, companies have routinely claimed chemical identities as CBI, arguing that competitors could use a disclosed chemical identity to learn trade-secret manufacturing processes for that chemical. This practice has led to much criticism that companies abuse CBI protections to the detriment of the public and the environment.

The EPA responded to that criticism this year with a series of actions limiting protection of chemical identities. In January 2010, the EPA announced in the Federal Register (75 Fed. Reg. 3462) its plan to begin rejecting CBI claims on chemicals listed on the public portion of the TSCA inventory when those chemicals were submitted to the EPA with studies showing a substantial health and environmental risk. This change imposes a surprising limit on what previously were routine CBI claims permitted with few limitations.

More recently, the EPA took this new policy even further. In May 2010, the EPA published another notice (75 Fed. Reg. 29754) indicating that it would begin routinely reviewing CBI claims regarding all chemical entities that are part of a health/safety study. The EPA explained that, where a chemical identity does not explicitly contain manufacturing process information or reveal portions of a chemical mixture, the chemical identity will not receive confidential treatment. The EPA further proposed amendments to the TSCA in August (75 Fed. Reg. 49658) to require CBI claims to be accompanied by an upfront, detailed, written explanation of why the chemical identity should be confidential.

The EPA's revised take on chemical identity confidentiality seems timely in view of current concerns about the identity of chemical dispersants used in the British Petroleum (BP) oil spill. These dispersants are intended to break down oil in the ocean before it can reach the shore,

but scientists have raised toxicity concerns about the dispersants' potential short- and long-term environmental effects. Yet, CBI claims have limited what information the EPA can release about these chemicals. The EPA's recent policy changes will likely increase future public availability of data regarding chemicals used by oil companies.

Going forward, chemical manufacturers may still protect well-justified chemical trade secrets under the TSCA. However, given the EPA's current stated goal to increase transparency, companies should plan for a continued trend toward reducing trade secret protection and increasing public access to information.

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