

ACC/ACI/IFRA/OMB Meeting
TSCA: PMN Amendments Claiming Chemical Identity in Studies as CBI
January 20, 2012

EPA Proposed Action: To amend the PMN regulations to delete the longstanding opportunity of submitters to protect the confidentiality of chemical identities in health and safety studies from disclosure by providing generic names.

What's the Issue: EPA now believes that its 1983 regulation allowing use of generic names in lieu of disclosing specific chemical identities in studies violates TSCA § 14(b). Section 14(b) says health and safety studies are not protected from disclosure, with minor exceptions. The text of TSCA and its legislative history show that EPA's new interpretation is wrong. EPA may disclose health and safety studies, but when it does so, it must delete confidential information in those studies, such as trade secret chemical identities. TSCA is one of six federal environmental statutes enacted during 1972 - 1986 mandating disclosure of health and safety information *but not* confidential chemical identities.

What's at Risk: Trade secret protection is crucial to U.S. competitiveness. Much of the innovation in chemistry depends on protection for trade secret identities. In the chemical industry, trade secret chemical identities are among the most valuable intellectual property, yet they often cannot be patented. EPA is proposing to restrict confidentiality claims for chemical identities in health and safety studies for new chemicals, which will **hurt innovation, jobs, and the economy.**

Chemical Identity versus Generic Names: Studies can be meaningful to the public even without disclosing chemical identities. Structurally-descriptive generic names can provide sufficient information to make studies useful while still protecting trade secret identities. Generic names can provide the public with detailed information about the structure of the chemical, thus allowing linkage to the scientific literature on similar chemicals and permitting an assessment of the suitability of study methods. In contrast, specific chemical names are sometimes of little value to the public, since there may be no published scientific literature on the specific chemical, particularly with new or recently developed chemicals.

Individual Company Example of Adverse Impact on Innovation: P&G discovered innovative surfactants that led to introduction of Tide ColdWater in the U.S. This technological breakthrough enables consumers to obtain strong performance benefits from washing in cold water as expected from washing with standard detergents in warm or hot water. The product is a sustainable innovation, allowing consumers to save money on energy bills and reducing CO₂ emissions from the energy-intensive process of heating water in the laundry wash cycle. P&G submitted two PMNs to EPA to create Tide ColdWater. Both claimed the chemical identity as confidential, to prevent competitors from piecing together the required chain lengths, isomeric structures, and salt derivatives of the sulfated alcohols needed for optimal surfactancy in cold water wash. PMN #1 development costs were about \$55.5 million and those for PMN #2 were about \$94.5 million. The PMNs weighed 150 lbs., mostly due to the studies provided by P&G. EPA's new interpretation of section 14(b) would have meant disclosing to competitors those chemical identities because of the submitted studies.

Adverse Impact on Chemical Industry Innovation and Jobs: In 2010, the chemical sector (excluding pharmaceuticals) invested \$13.4 billion in R&D. This translates to more than 70,000 jobs in scientific R&D services in both the private sector and at universities. Every dollar invested in chemical R&D produces \$2 in operating income over six years, which is a 17% return on investment in R&D by chemical companies. In 2010, nearly \$43 billion revenue was from sales of new products. In the chemical industry, this translates to ~ 40,000 jobs. **If this NPRM is implemented, why would chemical and consumer product manufacturing companies continue to manufacture in the U.S.? Why not move manufacturing to countries with more favorable protections for confidential chemical identities?**

U.S. Is Losing High-Tech Manufacturing to Asia, With an Adverse Impact on U.S. Economy: The National Science Board reported this month that the U.S. lost more than a quarter of its high-tech manufacturing jobs in the last decade as U.S.-based multinational companies placed a growing percentage of their R&D overseas. The number of high-tech manufacturing jobs in the U.S. has declined by 687,000 (28%) between 2000 and 2010. This is not due solely to low-wage competition, according to the report.

Proposed Solution: Our members are committed to enhancing the health and safety information provided to EPA on chemicals in commerce. We support requiring up-front substantiation of confidential chemical identities; requiring structurally-descriptive generic names (which can provide **greater access to relevant health and safety studies** than the specific chemical name or CAS number); providing the public with health and safety information; and protecting trade secrets such as confidential chemical identities so we can promote U.S. innovation, jobs, and the economy.