The Lautenberg Chemical Safety Act
By Nelson E. Lawson

After eight years of effort by many stakeholders, the venerable Toxic Substances Control Act (TSCA) was finally updated for the first time since it was passed in 1976. The result is the Lautenberg Chemical Safety Act (LCSA), signed into law on June 22nd, 2016.

This brief article can't do justice to all the complexities and implications of LCSA, but it may give the reader a sense of what LSCA covers. Overall, the new law is closer to the Canadian system, which involves an agency-driven, risk based process and is less onerous than REACH.

Under the new law the U.S. Environmental Protection Agency (EPA) will conduct risk-based reviews of *existing chemicals* in commerce, prioritizing them into low and high risk. However, the EPA's Chemical Substance Inventory contains many substances no longer used in commerce, so one of the first things to do is to "reset the inventory" eliminating them from further consideration. The PCA intends to weigh in on this issue to be sure that substances with an approved PMN are not eliminated so they can be quickly activated. Of the remaining entries the low priority substances can continue to be used unless new information causes the priority to be raised. The high priority substances will receive a thorough analysis based on science-based health and environmental data and consideration of the conditions of use.

The EPA must rely on the best data available and a weight of scientific evidence. If data is missing, EPA can request further test studies and more complete exposure data. Exposure to vulnerable groups and avoidance of animal testing will be emphasized. The risk assessment will lead to an evaluation of whether the substance meets the law's safety standards and a risk management program will result, including labeling and use restrictions up to and including an outright ban. States are pre-empted from evaluations while the EPA is progressing its review. Ten risk assessments must be started immediately with twenty underway within the first 3.5 years. New fees will fall on industry, of course.

New chemicals are supposed to be evaluated more or less as usual to preserve the excellent record of new product generation in the U.S. EPA can request additional studies but in the end, it must affirm that the new chemical "will not present an unreasonable risk in its foreseeable uses."

How will the EPA know what the foreseeable uses are? To protect itself, the EPA is giving only narrow approvals for specified uses through the use of consent orders. This is slowing down the rate of new product introduction. If, at the end of 180 days after Pre-manufacture Notice (PMN) submission, the EPA can't state that the new substance presents no unreasonable risk, it may demand additional tests and information, further slowing the process. The EPA also has to approve the Confidential Business Information part of the application. Lacking the staff, it is simply returning every fourth PMN with a form letter requesting more substantiation. Again,

this causes a dramatic slowdown in new product introduction and two PCA members have already experienced significant delays in processing PMN's.

The EPA has a huge job ahead of itself. It must write and rewrite the many rules and procedures that cover all aspects of chemical control, while reflecting the intent of the new law. Much public input will be needed. The industry is ably represented by the American Alliance for Innovation (AAI), and in particular, its Technical Committee, of which the PCA is a member. The new administration will surely have something to say, as well.