



**Supplemental Testimony of the American Chemistry Council's
Opposition to
LD 1181
An Act to Further Strengthen the Protection of Pregnant Women and
Children from Toxic Chemicals
Environmental & Natural Resources Committee
Maine State Legislature
Augusta, Maine
April 12, 2013**

Introduction

The American Chemistry Council is pleased to submit this supplemental testimony on LD 1181, as requested by the Senator Gratwick during the Committee hearing on the bill on April 11, 2013. Specifically requested was additional information on the U.S. Environmental Protection Agency's (EPA's) implementation of the New Chemicals program under the federal Toxic Substances Control Act (TSCA), 15 U.S.C.2601-2692.

Overview

- Chemicals are developed, manufactured, distributed and used under a strict and comprehensive set of government rules found in more than a dozen separate federal laws.
- TSCA is the central law governing basic chemicals in commerce that have broad industrial, commercial and consumer uses.
- Passed in 1976, TSCA gives the EPA broad authority to require manufacturers to report information about the chemicals they make, to screen and test their chemicals, and to regulate both new and existing chemicals. TSCA does not address chemicals that are pesticides, tobacco products, nuclear material or food, food additives, drugs, cosmetics or medical devices when manufactured



for these purposes. These are addressed under other federal laws and regulations.

- Under TSCA, EPA has the authority to limit or prohibit the manufacture and distribution of a chemical substance if it is found to pose an unreasonable risk.
- **Under TSCA, chemical product makers are required to submit information on all newly developed chemicals to EPA. The agency evaluates this information before any new chemical can be used in commerce.**
- **In addition, EPA maintains a TSCA inventory of both “new” and “existing” chemicals, allowing the agency to identify, evaluate and monitor any chemical that has ever been in U.S. commerce. If EPA has questions or concerns about the risks associated with a chemical, it may propose a rule requiring manufacturers to provide additional information or to perform testing.**
- The laboratory practices for conducting chemical testing are also federally regulated. Toxicological test methods required by federal agencies are reviewed to assure that results are reproducible, accurate and meaningful.
- In addition, TSCA has automatic reporting requirements under which chemical makers and importers must submit to EPA within 30 days *any* information (not already known to EPA) that reasonably supports the conclusion that a chemical poses a substantial risk of injury to human health or the environment.

TSCA Inventory: EPA Maintains Information on Chemicals in Commerce

EPA maintains an information inventory that enables the agency to identify, evaluate and monitor chemicals in commerce. A chemical product must be listed on EPA’s TSCA inventory in order to be legally produced for commercial purposes or imported into the United States.

At the inventory’s inception in 1979, manufacturers were required to submit information on all chemicals produced, imported or used for commercial purposes between 1975 and 1979. The initial inventory contained information on approximately 61,000 “existing” substances. Since that time, manufacturers have been required to submit all available health- and safety-related information for EPA review prior to bringing any “new” chemical into commerce. In other words,



every chemical that has been added to the inventory since 1979 has been subject to EPA's New Chemical Review Program.¹

Since the inventory's inception, information on new and existing chemicals produced or imported in specific quantities has been updated every four years. The inventory was last updated in 2012 and will be updated again in 2016 under EPA's Chemical Data Reporting Rule (CDR), which ACC discussed in its initial April 11, 2013, testimony which is already on the record concerning this bill.

EPA New Chemicals Program: Adding "New Chemicals" to the TSCA Inventory

Under EPA's New Chemical Review Program, a manufacturer must notify the agency prior to bringing any newly developed chemical into the market. Manufacturers or importers of new chemicals must submit a Pre-manufacture Notice (PMN) Form to EPA, which provides the agency with information on new chemicals:

- Chemical identity
- Physical chemical properties
- Available test data
- Anticipated production volume
- Byproducts
- Anticipated use(s)
- Environmental release
- Disposal practices
- Human exposure

¹The TSCA inventory, which today contains more than 80,000 chemicals, is not a current list of chemicals in commerce. The TSCA inventory lists all 61,000 existing chemicals (reported to the inventory in 1979) and approximately 19,000 new chemicals that have been commercialized since 1979. It is important to note that many of the original 61,000 chemicals listed in the inventory are no longer in commercial production and that many chemicals for which PMNs have been filed were never fully commercialized or have not remained in commercial production.



EPA scientists then determine if the chemical presents an unreasonable risk of injury to health or the environment for the uses proposed. In some cases, EPA can and does require manufacturers to provide additional information or conduct further testing prior to making this determination. If the EPA scientists believe a chemical presents an unreasonable risk², EPA has the legal authority to prohibit or limit the manufacture or distribution of the new substance. Only about 50 percent of the PMNs submitted to the agency were ultimately commercialized, based on the statistics for Notices of Commencement (NOCs) which must be submitted to the EPA at the time that commercial production or import begins. A new chemical is added to the TSCA inventory upon EPA's receipt of the NOC.

Over the years, EPA has required manufacturers to conduct testing on approximately 200 existing chemicals, report specific information for approximately 1,100 chemicals, and submit health and safety studies for approximately 1,000 chemicals, resulting in more than 50,000 studies covering a broad range of health and ecological endpoints.³ In 2005, EPA announced plans to conduct a significant information and data call-in on an additional 275 chemicals.

Results of EPA's New Chemical Review Under TSCA⁴

According to EPA, between 1979 and 2003, the agency had reviewed more than 36,600 PMNs for new chemicals since the TSCA inventory was established in 1979. Approximately 10 percent of the 36,600 PMN submissions have resulted in restrictions, additional testing requirements, withdrawn submissions, or denial:

- More than 1,200 chemicals are subject to consent orders, the terms of which are legally imposed upon manufacturers by EPA. Such consent orders typically prescribe limitations on use, workplace practices, labeling requirements, and release and disposal restrictions.

² For EPA's definition of "unreasonable risk," see:
<http://www.epa.gov/oppt/newchems/unrerisk.htm>.

³ Overview: Office of Pollution Prevention and Toxics Programs, December 24, 2003 (Draft)

⁴ *Id.*



- EPA has prohibited certain uses of more than 900 additional substances, using tools such as "significant new use rules," "consent orders" and other TSCA authorities, which have been effectively tailored to a variety of situations.
- In more than 300 other cases, PMN submitters voluntarily agreed to conduct additional testing in response to EPA's informal requests.
- In more than 1,500 cases, companies have withdrawn PMNs in the face of EPA concerns and likely regulatory requirements.

In sum, TSCA's New Chemicals program is considered one of TSCA's major regulatory successes. Several former EPA officials have expressed this perspective in public hearings and in published articles.⁵ The TSCA New Chemicals program is considered scientifically rigorous, efficient and very successful at promoting the innovation of new and better products and technologies from which all Americans have benefitted. It has helped assure the introduction of new chemicals onto the U.S. market that are designed to avoid EPA identified health concerns (including to children) and environmental concerns as well as to serve useful functions in the products and technologies of modern life.

Conclusion

ACC hopes this information is helpful to the Committee's understanding of the EPA's New Chemicals Program, which effectively evaluates substances before they are permitted to enter the marketplace.

ACC urges this committee to consider this information and ACC's initial testimony, and, in light of it, to ask itself whether LD 1181 is even necessary and whether it would have any public health benefit to the children of Maine.

⁵ See, *Practical Advice for TSCA Reform: An Insider Perspective*, James V. Aidala, Jr., Charles M. Auer, Lynn R. Goldman, M.D., and James B. Gulliford, June 2010, pages 6-7; See, Written and Oral Testimony of Dr. Lynn R. Goldman, MD, MPH, http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_id=cd4fd6b9-802a-23ad-4d18-eac94d1414b3

