



Highlights of [GAO-07-825](#), a report to congressional requesters

## Why GAO Did This Study

Chemicals play an important role in everyday life. However, some chemicals are highly toxic and need to be regulated. In 1976, the Congress passed the Toxic Substances Control Act (TSCA) to authorize the Environmental Protection Agency (EPA) to control chemicals that pose an unreasonable risk to human health or the environment, but some have questioned whether TSCA provides EPA with enough tools to protect against chemical risks. Like the United States, the European Union (EU) has laws governing the production and use of chemicals. The EU has recently revised its chemical control policy through legislation known as Registration, Evaluation and Authorization of Chemicals (REACH) in order to better identify and mitigate risks from chemicals.

GAO was asked to review the approaches used under TSCA and REACH for (1) requiring chemical companies to develop information on chemicals' effects, (2) controlling risks from chemicals, and (3) making information on chemicals available to the public. To review these issues, GAO analyzed applicable U.S. and EU laws and regulations and interviewed U.S. and EU officials, industry representatives, and environmental advocacy organizations.

GAO is making no recommendations.

[www.gao.gov/cgi-bin/getrpt?GAO-07-825](http://www.gao.gov/cgi-bin/getrpt?GAO-07-825).

To view the full product, including the scope and methodology, click on the link above. For more information, contact John Stephenson at (202) 512-3841 or [stephensonj@gao.gov](mailto:stephensonj@gao.gov).

## CHEMICAL REGULATION

# Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals

## What GAO Found

REACH requires companies to develop information on chemicals' effects on human health and the environment, while TSCA does not require companies to develop such information absent EPA rule-making requiring them to do so. While TSCA does not require companies to develop information on chemicals before they enter commerce (new chemicals), companies are required to provide EPA any information that may already exist on a chemical's impact on human health or the environment. Companies do not have to develop information on the health or environmental impacts of chemicals already in commerce (existing chemicals) unless EPA formally promulgates a rule requiring them to do so. Partly because of the resources and difficulties the agency faces in order to require testing to develop information on existing chemicals, EPA has moved toward using voluntary programs as an alternative means of gathering information from chemical companies in order to assess and control the chemicals under TSCA. While these programs are noteworthy, data collection has been slow in some cases, and it is unclear if the programs will provide EPA enough information to identify and control chemical risks.

TSCA places the burden of proof on EPA to demonstrate that a chemical poses a risk to human health or the environment before EPA can regulate its production or use, while REACH generally places a burden on chemical companies to ensure that chemicals do not pose such risks or that measures are identified for handling chemicals safely. In addition, TSCA provides EPA with differing authorities for controlling risks, depending on whether the risks are posed by new or existing chemicals. For new chemicals, EPA can restrict a chemical's production or use if the agency determines that insufficient information exists to permit a reasoned evaluation of the health and environmental effects of the chemical and that, in the absence of such information, the chemical may present an unreasonable risk. For existing chemicals, EPA may regulate a chemical for which it finds a reasonable basis exists to conclude that it presents or will present an unreasonable risk. Further, TSCA requires EPA to choose the regulatory action that is least burdensome in mitigating the unreasonable risk. However, EPA has found it difficult to promulgate rules under this standard. Under REACH, chemical companies must obtain authorization to use chemicals that are listed as chemicals of very high concern. Generally, to obtain such authorization, chemical companies need to demonstrate that they can adequately control risks posed by the chemical or otherwise ensure that the chemical is used safely.

TSCA and REACH both have provisions to protect information claimed by chemical companies as confidential or sensitive business information but REACH requires greater public disclosure of certain information, such as basic chemical properties, including melting and boiling points. In addition, REACH places greater restrictions on the kinds of information chemical companies may claim as confidential.