Washington Watch

GAO Recommends TSCA Improvements, and a Senate Bill Responds with a Proposal

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In June, the Government Accountability Office (GAO) issued a report critical of the federal government's ability under the Toxic Substances Control Act (TSCA) to assess and prevent risks from new and existing chemical substances. Entitled *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program,*[1] the report is not the first (or likely the last) word from GAO on what it believes to be TSCA's inherent inability to identify and address risks posed by chemical substances.

Release of the GAO report coincided with the introduction by Senators Frank Lautenberg and James Jeffords of the Kid Safe Chemicals Act (S. 1391), a bill intended to improve children's health by reducing exposure to harmful toxic chemicals in everyday consumer products and otherwise address the deficiencies in TSCA outlined in the report.

Chemical manufacturers disagree with the premise of both the GAO report and the proposed Senate bill. They believe that legislative changes to TSCA are not needed to increase the law's effectiveness.

This "Washington Watch" column reviews the GAO report, the proposed Kid Safe Chemicals Act, and the outlook for both.

TSCA in Brief

TSCA is a federal law that regulates "chemical substances."[2] Although enacted almost 30 years ago, its core provisions have not been substantively amended.

TSCA defines the term "chemical substance" as "any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical."[3] EPA notes, "TSCA defines 'chemical substance' broadly and in terms which cover microorganisms as well as traditional chemicals."[4]

Congress provided EPA with broad regulatory tools to regulate the manufacture, production, and disposal of chemical substances. Key sections of the law are described below.

TSCA Section 4

This section provides authority to promulgate rules requiring manufacturers, importers, and processors to test certain new or existing chemical substances or mixtures for their effects on human health and the environment.

TSCA Section 5

Section 5 authorizes EPA to regulate new chemical substances prior to their manufacture, import, processing, or distribution for commercial purposes, and to regulate existing chemical substances for significant new uses.

TSCA Sections 6 and 7

These sections provide authority to regulate the manufacture, processing, distribution, use, or disposal of an existing chemical substance or mixture that EPA determines poses an unreasonable risk to human health or the environment.

In the case of chemical substances or mixtures that EPA determines will present an unreasonable risk of serious and widespread injury to health and the environment before a final TSCA Section 6 rule can be published, the Agency has authority to seize that imminently hazardous chemical substance or mixture.

TSCA Section 8

Under Section 8, EPA has authority to promulgate rules requiring manufacturers and processors to:

- collect, maintain, and submit data on certain chemical substances;
- maintain records on allegations of significant adverse reactions;
- submit health and safety data on certain chemical substances and mixtures; and
- report any information indicating that a chemical substance or mixture presents a substantial risk of injury to health and the environment.

TSCA Section 9

Section 9 sets forth TSCA's relationship to other laws. Under this section, if EPA determines that an unreasonable chemical risk may be prevented or sufficiently reduced by action under a federal law not administered by EPA, it must refer information on the chemical's risk to the agency administering the other law.

TSCA Sections 12(b) and 13

Section 12(b) authorizes EPA to require notification on the part of persons intending to export certain chemical substances.

Under section 13, EPA can promulgate rules regarding the importation of chemical substances.

TSCA Sections 11, 15, 16, and 17

These sections authorize EPA to:

- inspect facilities for TSCA compliance,
- issue civil and criminal penalties for TSCA violations, and
- seize any chemical substance or mixture manufactured, imported, processed, or distributed in commerce in violation of TSCA.

GAO Concerns with TSCA Authority

Despite the broad grants of authority outlined in the TSCA statutory language, GAO has identified what it believes are several deficiencies in the law. These concerns mirror similar issues identified in an earlier GAO report issued in 1994. The shortcomings cited by GAO are described briefly below.

New Chemical Review Deficiencies

GAO found that EPA lacks sufficient information to identify potential health and environmental risks associated with new chemicals. While TSCA authorizes EPA to promulgate rules compelling the development of test data on new chemical substances, it does not automatically require manufacturers to test new chemicals for their toxicity and exposures before they are submitted for Agency review.

EPA states that chemical companies typically do not voluntarily perform such testing. According to Agency estimates, most premanufacture notices (PMNs) do not include test data of any type; only about 15 percent of PMNs include health or safety test data.

GAO also expressed concern about EPA's reliance upon scientific models to screen new chemicals. While characterizing these models as useful "basic screening tools," GAO believes they do not always accurately determine the "chemicals' properties and the full extent of their adverse effects, especially with regard to their general health effects."[5]

GAO also indicated concern with the "limited information" manufacturers submit in PMNs, which EPA uses to assess potential exposures to new chemicals. According to GAO, PMN information does not always reflect accurately the use patterns of a chemical once it is approved, as this can vary greatly after a chemical has been approved for use.

Although EPA can require a chemical manufacturer to submit a "new" notice under certain circumstances, the Agency must first issue a significant new use rule (SNUR). This requires an entirely new rulemaking, which takes considerable time and effort.

Similarly, while TSCA Section 8 provides for the updating of information on chemical production, use, and exposure every four years pursuant to the Inventory Update Rule (IUR), this

follow-on information generally will be submitted and reviewed well after a chemical has begun to be distributed in commence.

Concerns With Existing Chemical Regulation

The GAO report notes that EPA has limited authority over existing chemicals. The Agency cannot, for example, require chemical companies "to test the safety of existing chemicals and provide the resulting test data to the agency unless EPA first determines on the basis of risk or production and exposure information that the chemicals warrant such testing."

By GAO's count, EPA has used its authority under TSCA to require testing "for fewer than 200 of the 62,000 chemicals in commerce." Additionally, EPA has performed internal reviews for only about two percent of the chemicals that were in the TSCA Inventory when the Agency began such reviews in 1979. Only five chemical substances or groups of chemical substances have been subject to TSCA Section 6 regulation, with the most recent action under this section occurring 15 years ago.

The paucity of EPA regulation on existing chemicals, according to GAO, stands in contrast to the action of other authorities, such as the European Union. In 2003, the European Commission proposed a new EU regulatory framework for chemicals called REACH (Registration, Evaluation, and Authorization of Chemicals).[6] The proposed REACH regulation would, among other things, authorize the production of new information on existing chemicals. REACH is currently undergoing review by the European Parliament, and is expected to be in place by 2007.

Similarly, in 1999 Canada enacted legislation under the Canadian Environmental Protection Act (CEPA) that requires the Ministers of the Environment and Health to compile and amend a Priority Substances List (PSL). The PSL identifies substances that are to be assessed on a priority basis to determine whether they pose a significant risk to human or environmental health. Pursuant to the legislation, chemical manufacturers may be required to provide information on some existing chemicals.

Although EPA has authority under TSCA to obtain toxicity and exposure data on existing chemicals, GAO notes that the power is "difficult to use." This difficulty is one of the reasons cited for EPA's alleged lack of progress in reviewing existing substances since the Agency began reviewing chemicals in 1979.

The GAO report makes much of the difficulty EPA has experienced in demonstrating that certain chemical substances may pose an unreasonable risk, and thus should be banned or have limits placed on their production and use.

TSCA Section 6 plainly provides EPA with such authority. Since 1976, however, the Agency has issued regulations to ban or limit production and use of only five existing chemicals or chemical classes: polychlorinated biphenyls (PCBs), fully halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavalent chromium.[7]

For an additional 169 chemicals, EPA has required companies to submit notice of any significant new uses of the chemical, which provides the Agency an opportunity to review potential risks posed by the substance.[8]

CBI Concerns

GAO also expressed concern regarding EPA's ability to make publicly available certain information collected under TSCA. Companies that submit data pursuant to the statute often claim that parts of it are confidential business information (CBI). Information so identified cannot be shared with third parties, and EPA is required to protect such data against unauthorized disclosures.

According to the GAO report, "about 95 percent of premanufacture notices contain some information that chemical companies claim as confidential." Much of the data identified as CBI is likely sensitive information that warrants special treatment. Given EPA's limited resources, however, the Agency cannot ensure that CBI claims are being appropriately asserted in all cases. According to the GAO report, EPA challenges about 14 CBI claims yearly, and chemical companies "withdraw nearly all of the claims challenged."

GAO Recommendations

GAO made two sets of recommendations aimed at enhancing EPA's ability to assess risks posed by chemicals. The first set recommends four executive actions:

- Develop and implement a methodology for using information collected through the High Production Volume (HPV) Challenge Program to prioritize chemicals for further review and to identify and obtain additional information needed to assess their risks.

- Promulgate a rule under TSCA Section 8 requiring chemical companies to submit to EPA copies of any health and safety studies, as well as other information concerning the environmental and health effects of chemicals, that they submit to foreign governments on chemicals that the companies manufacture, process, or import into the United States.

- Develop a strategy to improve and validate, for regulatory purposes, the models that EPA uses to assess and predict the risks of chemicals and to inform regulatory decisions on the production, use, and disposal of chemicals.

- Revise the regulations to require that companies reassert claims of confidentiality submitted to EPA under TSCA within a certain time period after the information is initially claimed as confidential.

The second set of recommendations urges Congress to consider amending TSCA to do the following:

- Provide explicit authority for EPA to enter into enforceable consent agreements under which chemical companies are required to conduct testing.

- Give EPA, in addition to its current authorities under TSCA Section 4, power to require chemical substance manufacturers and processors to develop test data based on substantial production volume and the necessity for testing.

- Authorize EPA to share with the states and with foreign governments the CBI that chemical companies provide to the Agency, subject to regulations to be established by EPA (in consultation with the chemical industry and other interested parties) that would establish the procedures to be followed by all recipients of the information to protect the information from unauthorized disclosures.

Chemical Industry Response to the GAO Report

Many of the issues identified in the GAO report are similar to concerns expressed previously by both GAO and others. The American Chemistry Council (ACC), the largest trade association representing the interests of the domestic chemical production community, was quick to respond.

In general, ACC believes that "TSCA provides EPA with appropriate regulatory authority to manage risks of chemicals and therefore does not require a fundamental overhaul."[9] ACC cites, for example, the Agency's broad authority to evaluate potential risks posed by chemicals through the PMN process.

ACC notes that, according to EPA, between 1979 and 2003, the Agency reviewed over 36,600 PMNs. More than 3,500 PMNs submitted to EPA have been subject to some form of regulation as a result of the Agency's review.

ACC also notes the vast amount of information that has been submitted to EPA through voluntary programs, including the HPV Challenge and the Voluntary Children's Chemical Evaluation Program (VCCEP). Under the HPV Challenge Program, complete hazard screening data sets on almost 2,200 chemicals have been submitted to EPA. For approximately 700 of these chemicals, the Agency also received use and exposure information. Thirty-five companies and ten consortia have volunteered to sponsor 20 chemicals under the VCCEP.

ACC also reminds critics that EPA has obtained a great deal of information under the Preliminary Assessment Information Reporting rules issued under TSCA Section 8(a). In addition, pursuant to over 50 TSCA Section 8(d) rules covering approximately 1,000 chemicals, EPA has received more than 50,000 studies covering a wide range of health and ecological endpoints.

ACC also points to substantial information submitted to EPA under TSCA Section 8(e). This section requires chemical manufacturers and importers to submit to EPA within 30 days information that reasonably supports the conclusion that a chemical poses a substantial risk of injury to human health or the environment. EPA has received and reviewed more than 15,000 TSCA Section 8(e) notices covering a wide range of chemical substances and mixtures.

On CBI issues, the chemical industry believes strongly that Congress clearly understood what types of data would be covered by TSCA and intentionally built in strong protections for CBI. ACC thus believes that looking at the number of TSCA submissions with confidentiality claims is not an indicator of improper actions by data submitters, but rather a validation of the protections Congress intended to provide.

Proposed Kid Safe Chemicals Act

In should come as no surprise that introduction of the Kid Safe Chemicals Act was timed to coincide with publication of the GAO report. The bill is premised on the view that EPA does not routinely assess the human health and environmental risks of existing chemicals, and that new legislation is required to ensure this result.

In brief, the bill would set safety standards for chemicals that are on the market or coming onto the market; ensure that EPA obtains the data it needs to make decisions on chemicals; and strengthen EPA's authority to restrict certain chemicals. More specifically, the bill would:

- Require manufacturers to certify either that their new and existing chemicals meet the safety standard established under the Act, or that there are insufficient data to determine whether the chemicals meet the standard, and to submit all reasonably available information that has not been submitted previously to EPA. Manufacturers would be required to update this information every three years, or whenever significant new information becomes available.

- Create a priority list of at least 300 chemicals on which safety determinations would be made first; chemical substances that pose the greatest risk to humans would be ranked as highest priority. Criteria for identifying priority substances would include whether the chemical:

  - is found in human blood, fluids, or tissue (unless the chemical is not synthetic and is naturally present at the level found in blood, fluids, or tissue);

  - is found in food or drinking water, unless the chemical substance is not synthetic and is naturally present at the level found in food or drinking water;

- is manufactured or discharged into the environment at a volume of more than 1,000,000 pounds annually;

- is a known or suspected reproductive, neurological, or immunological toxicant, carcinogen, mutagen, or endocrine disruptor, or causes negative developmental effects; or

- is persistent or bioaccumulative.

EPA would have three years to determine the safety of priority-list chemicals. If the Agency failed to meet the deadline, manufacturers would be required to issue to EPA, the public, and "each known customer" a written notice that a determination of safety is pending. If the Agency failed to determine the safety of a chemical five years after it was placed on the priority list, distribution in commerce would be prohibited.

- Establish a safety standard that provides a reasonable certainty that no harm will be caused by aggregate exposure of a fetus, infant, child, worker, or member of another sensitive subgroup. In the case of a fetus, infant, or child, the standard would account for their special vulnerability to potential pre- and post-natal exposures by applying an additional ten-fold safety factor to the level established for adults.

- Require biomonitoring studies within five years after enactment of the bill and every three years thereafter for:

  - any chemical manufactured in quantities greater than 1,000,000 pounds during one calendar year, and

  - any chemical substance distributed in commerce to which humans are exposed, and for which there is cause for concern regarding the exposure, such as a potential for persistence or bioaccumulation.

Given the current political makeup of Congress, it is unlikely the bill will go anywhere this year. Senator Lautenberg has already stated that he does not expect hearings on the bill during this Congressional session.

Chemical Concerns: Implications for Industry

The lack of expected activity on the Kid Safe Chemicals Act does not mean that the issues raised by the bill are unimportant or without consequence. The right-to-know movement has made clear that the public cares a great deal about the risks potentially posed by chemicals.

Vigorous and high-profile campaigns have taken the debate about the "harm" caused by chemical exposure to a new and deeply personal level by demonstrating, through biomonitoring

data, that we are all carrying a chemical "body burden." Since little effort is made in such campaigns to characterize the biological relevance, if any, of this presence, inferences drawn from these data tend to be adverse to the chemical industry.

The most recent infusion of high-profile biomonitoring information came on July 21, 2005, when the Centers for Disease Control and Prevention (CDC) released its *Third National Report on Human Exposure to Environmental Chemicals*.[10] The Kid Safe Chemicals Act's heavy reliance on biomonitoring information is further evidence of the power of these data.

Another factor that needs to be considered in assessing these issues is the diminished trust the public has in the government's ability to control potential risks from chemical exposures. Recent high-profile incidents involving perceived breakdowns within federal agencies have contributed greatly to this public trust crisis.

For example, the Food and Drug Administration's credibility has been eroded as a result of the fallout from its approval of Vioxx. The Federal Emergency Management Agency's response to the aftermath of Hurricane Katrina also comes to mind.

According to a recent report prepared by the Project on Emerging Nanotechnologies, at the Woodrow Wilson International Center for Scholars, there is "low trust in government" in relation to its management of nanotechnology. This finding mirrors a similar finding in a 2004 study, where participants cited asbestos, dioxin, lead paint, Prozac accumulating in bodies of water, PCBs, and Agent Orange as reasons for the government's low confidence rating.[11]

A final factor to consider is the EU's REACH. Efforts to make REACH more palatable to the chemical business community have slowed its passage, but the measure is unlikely to go away. Once implemented, the influence of REACH will extend far beyond the EU. The relentless drive to put in place a comparable U.S. law or program addressing potential risks from existing chemicals will be all the greater.

The GAO report and the proposed Kid Safe Chemicals Act are unlikely to have any immediate effect. Nonetheless, the report will almost certainly be rolled out as evidence of TSCA's failure should there be another major chemical incident.

Such an incident could take many forms. It could be an accidental chemical release of catastrophic proportion. Or perhaps it might involve the emergence of new information showing that a particular chemical is persistent in the environment or found in human blood (consider the questions that recently have been raised about perfluorooctanoic acid and polybrominated diphenyl ether). Or an issue may arise involving how best to address potential risks from a release into the environment of nanoscale materials consisting of chemical substances.

Any of these developments is possible. Given the right combination of circumstances, a high-profile event that is believed to cause adverse impacts on human health and the environment, coupled with the public's lack of trust in government to manage risks, could form a perfect storm that might jump start legislative efforts to revise TSCA sooner rather than later.

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Notes

1 GAO-05-458 (2005, June), available online at http://www.gao.gov/new.items/d05458.pdf. The report was requested by Senators James Jeffords (I-VT), Frank Lautenberg (D-NJ), and Patrick Leahy (D-VT).

2 TSCA § 2(b), 15 U.S.C. § 2601(b) (policy to regulate "chemical substances").

3 TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A). *See also* 40 C.F.R. § 720.3(e).

4 Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act; Final Rule, 62 Fed. Reg. 17909, 17911 (April 11, 1997) (to be codified at 40 C.F.R. Parts 700, 720, 721, 723, and 725) (promulgating final rule under TSCA Section 5 to establish notification procedures for review of certain new microorganisms).

5 According to GAO, in 1993 EPA and the European Union (EU) jointly conducted a study to assess the validity of EPA's predictions about certain physical and chemical properties or health and environmental effects compared to those identified by the EU based on test data submitted with EU notifications. The evaluation showed that the accuracy of EPA's predictions varied depending upon the effect of the property being compared. The study concluded, "EPA methods are likely to identify those substances that are not readily biodegradable -- in other words, slowly degrading chemicals. However, . . . EPA methods do not appear to work as well in identifying chemicals that readily degrade as determined by the EU's 'ready biodegration' base set test."

6 The REACH system would require the registration of approximately 30,000 chemicals that are manufactured or imported into the EU in quantities exceeding one ton, evaluation of approximately 5,000 chemicals that are manufactured or imported into the EU in quantities exceeding 100 tons, and authorization for use of approximately 1,350 chemicals that are classified as being of "very high concern."

7 On October 2, 1991, EPA proposed to ban grouts made with acrylamide and N-methylacrylamide (NMA). 56 Fed. Reg. 49863 (October 2, 1991). The proposed rule would have prohibited the manufacture, importation, distribution in commerce, and use of acrylamide grout, as well as all uses of NMA grout except for sewer line repair. After a decade of debate, EPA eventually withdrew the proposal, and instead urged the adoption of management practices to abate potential risks from these chemicals.

[8] According to some, including the authors of the GAO report, EPA's burden of proof under TSCA Section 6 is largely to blame for the relative lack of action under this section. Section 6(c) requires EPA to consider four factors in making a determination under TSCA Section 6(a) to limit or ban chemical substances: (1) the effects of a substance or mixture on human health and the magnitude of the human exposure to it; (2) the effects of a substance or mixture on the environment and the magnitude of the environmental exposure; (3) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses; and (4) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health. The seminal decision interpreting TSCA Section 6 is *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

[9] ACC (2005, July 13). Chemical Makers' Comments on GAO Report on TSCA (Toxic Substances Control Act).

[10] The Third Report is available online at http://www.cdc.gov/exposurereport. The Third Report covers the years 1999-2000 and 2001-2002, and provides blood and urine levels for 148 environmental chemicals measured in people who participated in CDC's National Health and Nutrition Examination Survey (NHANES). The Third Report includes first-time data on 38 chemicals added since compilation of the Second Report. The measurements presented in the latest report were conducted at CDC's Environmental Health Laboratory.

[11] Informed Public Perceptions of Nanotechnology and Trust in Government, Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts, (September 2005), available at http://www.wilsoncenter.org/index.cfm.