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CHEMICAL REGULATION

Observations on Improving the Toxic Substances Control Act

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Natural Resources and Environment



G A O

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Highlights of GAO-10-292T, a testimony before the Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

The Environmental Protection Agency (EPA) is authorized under the Toxic Substances Control Act (TSCA) to obtain information on the risks of chemicals and to control those that it determines to pose an unreasonable risk. EPA also conducts assessments of chemicals under its Integrated Risk Information System (IRIS) program. Nonetheless, EPA does not have sufficient information to determine whether it should establish controls to limit public exposure to many chemicals that may pose substantial health risks. GAO has recommended statutory changes to TSCA to, among other things, provide EPA with additional authorities to obtain health and safety information from the chemical industry and to shift more of the burden to chemical companies for demonstrating the safety of their chemicals. GAO has also recommended that EPA adopt a streamlined, more transparent IRIS assessment process to address significant productivity and credibility issues. Problems with TSCA and IRIS led GAO to add transforming EPA's processes for assessing and controlling toxic chemicals to its list of high-risk areas warranting attention by Congress and the executive branch.

This testimony, based on prior GAO work, addresses EPA's implementation of TSCA and IRIS and options for (1) obtaining more information on chemical risks, (2) controlling these risks, and (3) sharing more of the information collected under TSCA.

To view the full product, including the scope and methodology, click on GAO-10-292T. For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

CHEMICAL REGULATION

Observations on Improving the Toxic Substances Control Act

What GAO Found

EPA lacks adequate scientific information on the toxicity of many chemicals. One major reason is that TSCA generally places the burden of obtaining data about existing chemicals on EPA rather than on chemical companies. For example, the act requires EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA does not routinely assess the risks of the over 83,000 chemicals already in use. Moreover, TSCA does not require chemical companies to test the approximately 700 new chemicals introduced into commerce each year for toxicity, and companies generally do not voluntarily perform such testing. Furthermore, the procedures EPA must follow to obtain test data from companies can take years. Regarding IRIS, in 2008, GAO reported that this significant chemical assessment program—which provides EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals—is at serious risk of becoming obsolete because the agency has not been able to complete timely, credible assessments. In May 2009, EPA announced reforms to its IRIS assessment process, citing GAO's past recommendations and its high-risk designation. Overall, GAO believes that, if the reforms are effectively implemented, they will address GAO's recommendations and provide a sound framework for conducting IRIS assessments. However, given the number of obstacles that can impede the progress of IRIS assessments, the viability of this program will depend on effective and sustained management.

While TSCA authorizes EPA to ban, limit, or otherwise regulate existing toxic chemicals, EPA must meet a high legal threshold, which has proven difficult. For example, EPA must demonstrate "unreasonable risk" to ban or limit chemical production, which EPA believes requires it to conduct extensive cost-benefit analyses that can take many years to complete. Since 1976, EPA has issued regulations to control only five existing chemicals. Furthermore, its 1989 regulation phasing out most uses of asbestos was largely vacated by a federal appeals court in 1991 because it was not based on "substantial evidence." In contrast, the European Union and a number of other countries have largely banned asbestos, a known human carcinogen that can cause lung cancer and other diseases. GAO previously suggested that Congress amend TSCA to reduce the evidentiary burden EPA must meet to control toxic substances and continues to believe such change warrants consideration.

Because of TSCA's prohibitions on the disclosure of confidential business information, EPA has limited ability to share information on chemical production and risk. According to EPA officials, about 95 percent of the notices companies have provided to EPA on new chemicals contain some information claimed as confidential. Evaluating the appropriateness of confidentiality claims is time- and resource-intensive, and EPA does not challenge most claims. GAO previously suggested that Congress, among other things, consider amending TSCA to authorize EPA to share the confidential business information that chemical companies provide to EPA with states.

Madam Chairman, Ranking Member and Members of the Committee:

I am pleased to appear here today to discuss the need to transform EPA's processes for assessing and controlling toxic chemicals. The Environmental Protection Agency's (EPA) ability to effectively implement its mission of protecting public health and the environment is critically dependent on credible and timely assessments of the risks posed by toxic chemicals. Such assessments are the cornerstone of scientifically sound environmental decisions, and regulations, and policies. In previous reports, we have recommended both statutory and regulatory changes to, among other things, strengthen EPA's authority to obtain additional information from the chemical industry, shift more of the burden to chemical companies for demonstrating the safety of their chemicals, and enhance the public's understanding of the risks of chemicals to which they may be exposed. In 2009, we added transforming EPA's processes for assessing and controlling toxic chemicals to our list of areas at high risk for waste, fraud, abuse, and mismanagement because EPA has failed to develop sufficient chemical assessment information on the toxicity of many chemicals that may be found in the environment and tens of thousands of chemicals used commercially in the United States.¹ We reported that the lack of this information significantly limits the agency's ability to limit public exposure to many chemicals that may pose substantial health risks in fulfillment of its mission of protecting human health and the environment.

The Toxic Substances Control Act (TSCA) was enacted in 1976 to authorize EPA to obtain information on the risks of chemicals and to control those chemicals that EPA determines to pose unreasonable risks. TSCA authorizes EPA to review chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals). TSCA also provides that certain information, such as data disclosing chemical processes, can be claimed as confidential business information by chemical manufacturers and processors. EPA's ability to provide the public with information on chemical production and risk has been limited by TSCA's strict confidential business information provisions, which generally prohibit the disclosure of such information. In addition to its authorities under TSCA, EPA conducts assessments of toxic chemicals in the environment under its Integrated Risk Information System (IRIS) program. EPA's IRIS database provides the agency's scientific position on the

¹GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: Jan. 22, 2009).

potential health effects that may result from exposure to more than 540 chemicals in the environment. IRIS toxicity assessments constitute critical steps of the risk assessment process and provide the basic information EPA needs to determine whether it should establish controls to protect the public from exposure to toxic chemicals in the air and water and at hazardous waste sites, among other things.

My testimony today is based on our prior work on EPA's processes for assessing and controlling toxic chemicals, in which we identified challenges associated with implementing TSCA and some of the legislative options available to address these challenges. Specifically, my statement addresses EPA's implementation of TSCA and options for (1) obtaining more information on the risks posed by chemicals, (2) controlling these risks, and (3) sharing more of the information gathered under TSCA.

Background

TSCA provides EPA with the authority, upon making certain determinations, to collect information about the hazards posed by chemical substances and to take action to control unreasonable risks by either preventing dangerous chemicals from making their way into use or placing restrictions on those already in commerce. Of the over 83,000 chemicals currently in the TSCA inventory, about 62,000 were already in commerce when EPA began reviewing chemicals in 1979. Since then, over 21,000 new chemicals—about 700 each year, on average—have been added to the inventory and are now in use as existing chemicals. To assess a chemical's risks, EPA examines its toxicity or potential adverse effects and the amount of human and environmental exposures.

TSCA generally requires the industry to notify EPA at least 90 days before producing or importing a new chemical. These notices are to contain such information as the chemical's molecular structure and intended uses, which EPA uses to evaluate the chemical's potential risks. TSCA also authorizes EPA to promulgate rules to require manufacturers to perform tests on chemicals in certain circumstances or to provide other data, such as production volumes, on existing chemicals. In addition, TSCA requires chemical companies to report to EPA any

data that reasonably support a conclusion that a chemical presents a substantial risk. If EPA finds that a chemical's risks are unreasonable, it can prohibit or limit the chemical's production, processing, distribution, use, and disposal or take other action, such as requiring warning labels on the substance. While TSCA authorizes EPA to release some chemical information obtained by the agency under the act, it allows chemical companies to claim certain information, such as data disclosing chemical processes, as confidential business information. EPA generally must not disclose such information unless such disclosure is necessary to protect against an unreasonable risk of injury to health or the environment. Evaluating the appropriateness of confidentiality claims is time- and resource-intensive, and EPA does not challenge most claims. State environmental agencies and others have expressed interest in obtaining information claimed as confidential business information for use in various activities, such as developing contingency plans to alert emergency response personnel to the presence of highly toxic substances at manufacturing facilities. In previous reports, we have identified options for statutory changes to improve EPA's ability to make more chemical information publicly available.

IRIS was created in 1985 to help EPA develop consensus opinions within the agency about the health effects from chronic exposure to chemicals. Its importance has increased over time. EPA, state and local environmental programs, international regulatory bodies, academia, industry, and others now rely heavily on the IRIS database to support risk-based decision making to protect public health and the environment. A typical IRIS assessment contains a qualitative description of the hazard posed by a chemical and a quantitative assessment of the relationship between exposure and the likelihood and severity of adverse health effects. The focus of IRIS toxicity assessments is on the potential health effects of long-term (chronic) exposure to chemicals. According to the Office of Management and Budget (OMB), EPA is the only federal agency that develops qualitative and quantitative assessments of both cancer and noncancer risks of exposure to chemicals, and EPA does so largely under the IRIS program. The quantitative estimates of potency that EPA provides are particularly important, as they are required to conduct quantitative risk assessments. EPA uses risk assessments developed with IRIS toxicity data to determine whether the identified health risks warrant regulatory or other actions. Examples of subsequent decisions that could stem from a determination that action is necessary to protect public health include how much of a chemical a company may discharge

into a river, which substances may be stored at a hazardous waste facility, the extent to which a hazardous waste site must be cleaned up, levels for air emissions, and allowable levels of contamination in drinking water.

EPA Lacks Adequate Information on Potential Health and Environmental Risks of Chemicals

EPA lacks adequate scientific information on the toxicity of many chemicals that are or may be found in the environment. For existing chemicals, TSCA generally places the burden of obtaining data on EPA, rather than on the companies that produce the chemicals. This approach requires that EPA demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA has only limited information on the health and environmental risks posed by these chemicals. Furthermore, while TSCA authorizes EPA to review existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so. Significantly, chemical companies are not required to develop and submit toxicity information to EPA on existing chemicals unless the agency finds that a chemical may present an unreasonable risk of injury to human health or the environment or is or will be produced in substantial quantities and that either (a) there is or may be significant or substantial human exposure to the chemical or (b) the chemical enters the environment in substantial quantities. EPA must also determine there are insufficient data on a chemical to reasonably determine its effects on health or the environment and that testing is necessary to develop such data before the agency can require a company to test its chemicals for harmful effects. This structure places the burden on EPA to demonstrate a need for data on a chemical's toxicity rather than on a company to demonstrate that a chemical is safe. As a result, EPA does not routinely assess the risks of the more than 83,000 commercial chemicals in use.

As we have previously reported,² TSCA's chemical review provisions could be strengthened by requiring EPA's systematic review of existing chemicals. TSCA could be amended to establish a time frame for the review of existing chemicals, putting existing chemicals on a more equal

²GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005).

footing with new chemicals. However, because of the large number of existing chemicals, EPA would need the flexibility to identify which chemicals should be given priority. TSCA could be amended to require individual chemical companies or the industry as a whole to compile and submit chemical data as a condition of manufacture or import above some specified volume or other criteria.

Regarding new chemicals, TSCA generally requires chemical companies to submit a premanufacture notice to EPA before they manufacture or import new chemicals and to provide any available test data. Yet EPA estimates that most premanufacture notices do not include any test data, and only about 15 percent include health or safety test data. These tests may take over a year to complete and cost hundreds of thousands of dollars, and chemical companies usually do not perform them voluntarily. Because EPA generally does not have sufficient data on a chemical's properties and effects when reviewing a new chemical, EPA uses models to compare new chemicals with chemicals that have similar molecular structures and for which test data on health and environmental effects are available, which can take years. Furthermore, EPA bases its exposure estimates for new chemicals on information contained in premanufacture notices—information that chemical companies generally are not bound by and that may change without notice. For example, companies may increase production levels or expand the uses of a chemical, potentially increasing the risk of injury to human health or the environment.

An option that we have previously reported could make TSCA more effective and provide EPA with adequate information on chemicals—that is, revising the act to require companies to test their chemicals and submit the results to EPA with their premanufacture notices.³ Currently, such a step is required only if EPA makes the necessary findings and promulgates a testing rule. A major drawback to testing is its cost to chemical companies, which may reduce their willingness to perform chemical research and invest in innovation. To reduce such costs or to delay them until production is sufficient to offset them, requirements for testing could be based on production volume. For example, in Canada and the European Union, testing requirements for low-volume chemicals are less extensive and complex than for high-volume chemicals. We previously reported that Congress could give EPA, in addition to its current

³GAO-05-458.

authorities under section 4 of TSCA, the authority to require chemical substance manufacturers and processors to develop test data based on, for example, substantial production volume and the necessity for testing.⁴

Another option we reported was to provide EPA with greater authority to require additional testing in areas where EPA's analysis models do not adequately predict toxicity.⁵ Under such an option, EPA could establish a minimal set of tests for new chemicals to be submitted with premanufacture notices. Additional and more complex and costly testing could be required as a new chemical's potential risks increase, based on, for example, production or environmental release levels. According to some chemical companies, the cost of initial testing could be reduced by amending TSCA to require EPA to review new chemicals before they are marketed, rather than before they are manufactured. This could substantially reduce the expense of testing because, according to EPA, about half of the premanufacture notices the agency receives from chemical companies are for new chemicals that, for various reasons, never enter the marketplace.

In addition to TSCA, EPA assesses chemicals under its IRIS program. We reported in March 2008 that this key program was at serious risk of becoming obsolete because the agency has not been able to keep its existing assessments current; decrease its backlog of 70 assessments; or complete assessments of key chemicals of concern, such as dioxin, formaldehyde, and trichloroethylene (TCE).⁶ Among other things, we found that EPA's efforts to finalize IRIS assessments were impeded by a combination of factors, including OMB's requiring two additional reviews of IRIS assessments by OMB and other federal agencies with an interest in the assessments, such as the Department of Defense. Moreover, the two interagency reviews involved other federal agencies in EPA's IRIS assessment process in a manner that hindered EPA's ability to manage its assessments and limited their credibility and transparency. For example, the input these agencies provided to EPA was treated as "deliberative" and was not released to the public. As a result, we recommended that EPA adopt a streamlined, more transparent assessment process. A revised process that EPA subsequently adopted in 2008 did

⁴GAO-05-458.

⁵GAO-05-458

⁶GAO, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, GAO-08-440 (Washington D.C.: Mar.7, 2008).

not incorporate our recommendations and actually exacerbated the concerns we identified about productivity and credibility. As a result, we included the IRIS program along with TSCA in our high-risk designation on assessing and controlling toxic chemicals.

However, in May 2009, EPA again announced comprehensive reforms to its IRIS assessment process, citing our designation of this program as high risk as well as key recommendations from our reports. We reviewed EPA's reforms and testified that overall, if implemented effectively, these reforms will address our recommendations and provide a sound framework for conducting IRIS assessments and significantly improve the IRIS process.⁷ For example, under the new process EPA is to manage the entire assessment process, including the interagency reviews. Under EPA's prior process, these reviews were required and managed by OMB—and at various stages, EPA was not allowed to proceed with assessments until OMB notified EPA that it had sufficiently responded to comments from OMB and other agencies. The independence restored to EPA under the new process will be critical to ensuring that EPA has the ability to develop transparent, credible IRIS chemical assessments. While the broad reforms provide a sound general framework for conducting IRIS assessments, the manner in which EPA implements the new process will determine whether the agency will be able to overcome its long-standing productivity problems and complete credible and transparent assessments. Specifically, certain aspects of the new process are incomplete or lack clarity and thus warrant management attention. For example, EPA has likely understated the time required to complete an assessment because its estimated time frames do not include the time required to complete two key steps. Overall, the viability of the IRIS program will depend on effective and sustained management, given the number of factors that can impede the progress of IRIS assessments—even one delay can have a domino effect, requiring the process to essentially be repeated to incorporate changing science. We note that, unlike some other EPA programs with statutory deadlines for completing various activities, the IRIS program is discretionary. As we have previously stated, we believe the absence of statutory deadlines in completing assessments may contribute to EPA's failure to complete timely IRIS assessments.⁸

⁷GAO, *Scientific Integrity: EPA's Efforts to Enhance the Credibility and Transparency of Its Scientific Processes*, GAO-09-773T (Washington, D.C.: June 9, 2009).

⁸GAO, *EPA Chemical Assessment: Process Reforms Offer the Potential to Address Key Problems*, GAO-09-774T (Washington, D.C.: June 11, 2009).

TSCA's Regulatory Framework Impedes EPA's Efforts to Control Risks Posed by Chemicals

While TSCA authorizes EPA to issue regulations that may ban, limit, or otherwise regulate the production or use of existing toxic chemicals, EPA must meet a high legal threshold, which has proven to be difficult. Specifically, in order to regulate an existing chemical under section 6 of TSCA, EPA must find that there is a reasonable basis to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment. EPA officials have said that this requires an extensive cost-benefit analysis. In addition, before regulating a chemical under section 6, the EPA Administrator must consider and publish a statement regarding the following:

- the effects of the chemical on human health and the magnitude of human exposure to the chemical;
- the effects of the chemical on the environment and the magnitude of the environment's exposure to the chemical;
- the benefits of the chemical for various uses and the availability of substitutes for those uses; and
- 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.

Moreover, while TSCA offers EPA a range of control options when regulating existing chemicals, the agency must choose the least burdensome regulation that will be adequately protective. For example, if EPA finds that it can adequately manage the risk of a chemical by requiring chemical companies to place warning labels on the chemical, EPA may not ban or otherwise restrict its use. EPA must also develop substantial evidence in support of the action it proposes to take in order to withstand judicial review. Under TSCA, a court reviewing a TSCA rule must set it aside if such evidence is lacking.⁹ As several courts have noted, this standard is more rigorous than the "arbitrary and capricious" standard normally applied to rulemaking. Furthermore, according to EPA officials, the economic costs of regulating a chemical are usually more easily documented than the risks of the chemical or the benefits

⁹Specifically, a court reviewing a rule "shall hold [it] unlawful and set [it] aside...if the court finds that the rule is not supported by substantial evidence in the rulemaking record." 15 U.S.C.A. § 2618(c)(1)(B)(i).

associated with controlling those risks, and it is difficult to show substantial evidence that EPA is promulgating the least burdensome requirement.

EPA has had difficulty demonstrating that harmful chemicals pose an unreasonable risk and consequently should be regulated. In fact, since Congress passed TSCA in 1976—over 33 years ago—EPA has issued TSCA regulations on only five existing chemicals or chemical classes. In 1991, one of these regulations—the 1989 regulation banning most uses of asbestos—was largely vacated by a federal appeals court decision that cited EPA’s failure to meet statutory requirements. In contrast to the United States, the European Union and a number of other countries have banned all, or almost all, asbestos and asbestos-containing products. Asbestos is a known human carcinogen that can cause lung cancer and other diseases if inhaled. Asbestos has been used widely in products such as fireproofing; thermal insulation; and friction products, including brake linings.

EPA spent 10 years exploring the need for the asbestos ban and developing the regulation. On the basis of its review of over 100 studies of the health risks of asbestos as well as public comments on the proposed rule, EPA determined that asbestos is a potential carcinogen at all levels of exposure—that is, that it has no known safe exposure level. EPA’s 1989 rule under TSCA section 6 prohibited the future manufacture, importation, processing, and distribution of asbestos in almost all products. In response, some manufacturers of asbestos products filed suit against EPA arguing, in part, that the rule was not promulgated on the basis of substantial evidence regarding unreasonable risk. In October 1991, the U.S. Court of Appeals for the Fifth Circuit agreed with the manufacturers, concluding that EPA had failed to muster substantial evidence to justify its asbestos ban. Specifically, the court concluded that EPA did not consider all necessary evidence and failed to show that the control action it chose was the least burdensome regulation that would adequately protect human health or the environment. EPA had not calculated the risk levels for intermediate levels of regulation because it believed there was no asbestos exposure level for which the risk of injury or death was zero. As articulated by the court, the proper course of action for EPA would have been to consider each regulatory option listed in TSCA, beginning with the least burdensome, and the costs and benefits of each option. Since completing the 1989 asbestos rule, EPA has completed only one regulation to ban or limit the production or use of an existing chemical (for hexavalent chromium in 1990).

With EPA's limited actions to control toxic chemicals under TSCA, state and federal actions have filled the void by establishing controls for some toxic chemicals. For example, a California statute enacted in 2007 prohibits the manufacture, sale, or distribution of certain toys and child care articles after January 1, 2009, if the products contain concentrations of phthalates exceeding 0.1 percent. In 2008, Congress took similar action. California has also enacted limits on formaldehyde in pressed wood. In response to a petition asking EPA to use section 6 of TSCA to adopt the California formaldehyde regulation, EPA recently issued an advance notice of proposed rulemaking suggesting several regulatory options the agency could pursue under its TSCA section 6 authority to limit exposure to formaldehyde. However, because of the legal hurdles the agency would face in regulating formaldehyde under TSCA, some stakeholders have recommended that EPA pursue legislation instead.

In our previous reports, we identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA.¹⁰ Potential changes to TSCA include reducing the evidentiary burden that EPA must meet to take regulatory action under the act by amending (1) the unreasonable risk standard; (2) the standard for judicial review, which requires substantial evidence in the rulemaking record; and (3) the requirement that EPA choose the least burdensome regulatory requirement.

TSCA Limits EPA's Ability to Share Information

TSCA's confidential business information provisions limit EPA's ability to make the information that it collects under the act available to outside entities if chemical companies designate such information as confidential business information. EPA is required under the act to protect trade secrets and privileged or confidential commercial or financial information against unauthorized disclosures, and this information generally cannot be shared with others, including state health and environmental officials and foreign governments that may have legitimate needs for the information. For example, some state officials said this information would be useful for informing and managing their environmental risk programs.

EPA officials told us that some claims of confidential business information may be unwarranted, but challenging the claims is resource-intensive. EPA has not performed any

¹⁰GAO/RCED-94-103 and GAO-05-458.

recent studies of the appropriateness of confidentiality claims, but a 1992 EPA study indicated that problems with inappropriate claims were extensive. This study examined the extent to which companies made confidential business information claims, the validity of the claims, and the impact of inappropriate claims on the usefulness of TSCA data to the public. While EPA may suspect that some chemical companies' confidentiality claims are unwarranted, the agency does not have data on the number of inappropriate claims. According to EPA officials, about 95 percent of premanufacture notices contain some information that chemical companies claim as confidential. EPA officials also told us that the agency does not have the resources that would be needed to investigate and challenge claims to determine the number that are inappropriate. Consequently, EPA focuses on investigating primarily those claims that it believes may be both inappropriate and among the most potentially important—that is, claims relating to health and safety studies performed by the chemical companies involving chemicals currently used in commerce. The EPA official responsible for initiating challenges to confidentiality claims told us that EPA challenges about 14 such claims each year and that the chemical companies withdraw nearly all of the claims challenged.

As we have previously reported, state officials who have various responsibilities for protecting public health and the environment from the dangers posed by chemicals have said that having access to confidential TSCA information would allow them to examine information on chemical properties and processes that they currently do not possess, which could enable them to better control the risks of potentially harmful chemicals.¹¹ The general public may also find information provided under TSCA useful. Individual citizens or community groups may have a specific interest in information on the risks of chemicals that are produced or used in nearby facilities. For example, neighborhood organizations could use such information to engage in dialogue with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures.

In our June 2005 report, we suggested that Congress consider amending TSCA to authorize EPA to share the confidential business information that chemical companies provide to EPA with states and foreign governments.¹² This amendment would be subject to regulations to be established by EPA in consultation with the chemical industry and other interested parties,

¹¹GAO-05-458.

¹²GAO-05-458.

which would protect the information from unauthorized disclosures. In our September 1994 report, we recommended that Congress consider limiting the length of time for which information may be claimed as confidential without resubstantiation of the need for confidentiality.¹³

Concluding Observations

Although we have identified significant shortcomings with TSCA in numerous reports and made recommendations to remedy them, EPA still does not have the authority to develop sufficient information to support critical decisions regarding how to protect human health and the environment from toxic chemicals. In our previous reports on TSCA, we have recommended both statutory and regulatory changes to (1) strengthen EPA's authority to obtain additional information from the chemical industry, (2) shift more of the burden to chemical companies for demonstrating the safety of their chemicals, and (3) enhance the public's understanding of the risks of chemicals to which they may be exposed, among other things. With regard to IRIS, it is too soon to know if EPA's new IRIS assessment process will enable the agency to develop timely and credible assessments of chemicals of concern. Without greater attention to EPA's efforts to assess toxic chemicals, the nation lacks assurance that human health and the environment are adequately protected.

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Madam Chairman, Ranking Member, this concludes my prepared statement. I would be happy to respond to any questions that you or other Members of the Committee may have at this time.

GAO Contact and Staff Acknowledgments

For further information about this testimony, please contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Contributors to this testimony include David Bennett, Ben Shouse, Antoinette Capaccio, Christine Fishkin, and Ed Kratzer.

¹³GAO, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, GAO/RCED-94-103 (Washington, D.C.: Sept. 26, 1994).

Related GAO Products

EPA Chemical Assessment: Process Reforms Offer the Potential to Address Key Problems. GAO-09-774T. Washington, D.C.: June 11, 2009.

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High-Risk Series: An Update. GAO-09-271. Washington, D.C.: January 22, 2009.

EPA Science: New Assessment Process Further Limits the Credibility and Timeliness of EPA's Assessments of Toxic Chemicals. GAO-08-1168T. Washington, D.C.: September 18, 2008.

Chemical Assessments: EPA's New Assessment Process Will Further Limit the Productivity and Credibility of Its Integrated Risk Information System. GAO-08-810T. Washington, D.C.: May 21, 2008.

Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals. GAO-08-743T. Washington, D.C.: April 29, 2008.

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Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals. GAO-07-825. Washington, D.C.: August 17, 2007.

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