United States Government Accountability Office

Testimony

Before the Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
Expected at 10:15 a.m. EDT
Thursday, June 13, 2013

CHEMICAL REGULATION

Observations on the Toxic Substances Control Act and EPA Implementation

Statement of Alfredo Gomez, Director
Natural Resources and Environment

June 13, 2013

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GAO Highlights

Highlights of GAO-13-696T, a testimony before the Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In 1976, Congress passed TSCA to give EPA the authority to obtain more health and safety information on chemicals and to regulate chemicals it determines pose unreasonable risks of injury to human health or the environment. GAO has reported that EPA has found many of TSCA's provisions difficult to implement. In 2009, EPA announced TSCA reform principles to inform ongoing efforts in Congress to strengthen the act. At that time, EPA also initiated a new approach for managing toxic chemicals using its existing TSCA authorities.

This testimony summarizes GAO's past work describing: (1) challenges EPA has faced historically in regulating chemicals and (2) the extent to which EPA has made progress implementing its new approach, and challenges, if any, which persist. This statement is based on GAO reports issued between 1994 and 2013.

GAO is not making new recommendations in this testimony. In prior reports, GAO suggested that Congress consider statutory changes to TSCA to give EPA additional authorities to obtain information from the chemical industry and shift more of the burden to chemical companies for demonstrating the safety of their chemicals. In these reports, among other things, GAO recommended that EPA require companies to provide chemical data they submitted to foreign governments, require companies to reassert confidentiality claims, and develop strategies for addressing challenges that impeded EPA's ability to ensure chemical safety. EPA's responses to these recommendations have varied.

View GAO-13-696T. For more information, contact Alfredo Gomez at (202) 512-3841 or gomezj@gao.gov.

What GAO Found

GAO reported in June 2005 that EPA has historically faced the following challenges in implementing the provisions of the Toxic Substances Control Act (TSCA):

- *Obtaining adequate information on chemical toxicity and exposure*. EPA has found it difficult to obtain such information because TSCA does not require companies to provide it; instead, TSCA requires EPA to demonstrate that chemicals pose certain risks before it can ask for such information.
- *Banning or limiting chemicals*. EPA has had difficulty demonstrating that chemicals should be banned or have limits placed on their production or use under section 6—provisions for controlling chemicals. The agency issued regulations to ban or limit production or use of five existing chemicals, or chemical classes, out of tens of thousands of chemicals listed for commercial use. A court reversal of EPA's 1989 asbestos rule illustrates the difficulties EPA has had in issuing regulations to control existing chemicals.
- *Disclosing data and managing assertions of confidentiality.* EPA has not routinely challenged companies' assertions that data they provide are confidential business information and cannot be disclosed. As a result, the extent to which companies' confidentiality claims are warranted is unknown.

GAO reported in March 2013 that EPA has made progress implementing its new approach to managing toxic chemicals under its existing TSCA authority but, in most cases, results have yet to be realized. Examples are as follows:

- EPA has increased efforts to collect toxicity and exposure data through the rulemaking process, but because rules can take 3 to 5 years to finalize and 2 to 2 ½ years for companies to execute, these efforts may take several years to produce results. Specifically, since 2009, EPA has (1) required companies to test 34 chemicals and provide EPA with the resulting toxicity and other data, and (2) announced, but has not yet finalized, plans to require testing for 23 additional chemicals.
- EPA has increased efforts to assess chemical risks, but because EPA does not have the data necessary to conduct all risk assessments, it is too early to tell what, if any, risk management actions will be taken. In February 2012, EPA announced a plan that identified and prioritized 83 existing chemicals for risk assessment; the agency initiated assessments for 7 chemicals in 2012 and announced plans to start 18 additional assessments during 2013 and 2014. At its current pace, it would take EPA at least 10 years to complete risk assessments for the 83 chemicals.

In addition, it is unclear whether EPA's new approach to managing chemicals will position the agency to achieve its goal of ensuring the safety of chemicals. EPA's *Existing Chemicals Program Strategy*, which is intended to guide EPA's efforts to assess and control chemicals in the coming years, does not discuss how EPA will address identified challenges. Consequently, EPA could be investing valuable resources, time, and effort without being certain that its efforts will bring the agency closer to achieving its goal of ensuring the safety of chemicals.

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Chairman Shimkus, Ranking Member Tonko, and Members of the Subcommittee:

I am pleased to be here today to discuss the Environmental Protection Agency's (EPA) efforts to assess and control toxic chemicals. Tens of thousands of chemicals are listed with EPA for commercial use in the United States, with an average of 600 new chemicals listed each year. EPA's ability to effectively implement its mission of protecting public health and the environment depends on credible and timely assessments of the risks posed by toxic chemicals. In 1976, Congress passed the Toxic Substances Control Act (TSCA) to provide EPA with the authority to obtain more information on chemicals and to regulate those chemicals that EPA determines pose unreasonable risks to human health or the environment. TSCA authorizes EPA to review chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals).[1]

We have reported in the past that EPA has found many of the provisions of TSCA difficult to implement. In our past reports, we have suggested that Congress consider making statutory changes to strengthen EPA's authority to obtain toxicity information from the chemical industry and establish a framework for taking action that is less burdensome for EPA. We have also made several recommendations to better position EPA to collect chemical toxicity and exposure-related data and ensure chemical safety under existing TSCA authority. Among other recommendations, in June 2005,[2] we recommended that EPA strengthen its ability to regulate harmful chemicals under TSCA by, for example, promulgating a rule requiring that companies submit copies to EPA 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.[3] In

[1]Existing chemicals are composed of those that were in commerce in 1979 when EPA began reviewing chemicals, as well as those listed for commercial use after that time.

[2]GAO, *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).

[3]Throughout this testimony, the phrase "chemical companies" refers generally to companies that manufacture, import, process, distribute in commerce, use, or dispose of chemicals regulated under TSCA. When it is important to differentiate between, for example, manufacturers and processors, the type of company to which I am referring is specified.

that report, we also recommended that EPA improve and validate its models for assessing and predicting the risks of chemicals and revise its regulations to require chemical companies to reassert confidentiality claims within a certain period.[4] EPA implemented our 2005 recommendation to improve its models. EPA did not disagree with our 2005 recommendations regarding obtaining health and safety studies and other information that companies submit to foreign governments and requiring companies to reassert confidentiality claims, but it provided substantive comments and has not fully implemented these recommendations.

In 2009, EPA announced principles for reforming TSCA to help inform efforts under way in Congress. These principles include goals for reforming TSCA so that: (1) EPA would have clear authority to establish safety standards that are based on scientific risk assessments; (2) manufacturers' data on toxicity, exposure,[5] and use for chemicals would be required at sufficient levels so that EPA could support a determination that a chemical meets the safety standard; (3) EPA would have clear authority to take regulatory or other actions when chemicals do not meet the safety standard, with the flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns; (4) EPA would have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations; and (5) EPA would receive a sustained source of funding from manufacturers of chemicals to support the costs of agency implementation, including the review of information provided by manufacturers.

Along with the announcement of these principles in 2009, EPA initiated a new approach to managing chemicals within the limits of existing authorities that focuses largely on existing chemicals. According to agency documents, EPA will transition from an approach dominated by voluntary data submissions by industry to a more proactive approach in which the agency will use its data collection and other rulemaking

[4]As described later in this testimony, TSCA contains provisions for governing the disclosure of chemical data. Chemical companies can claim certain information, such as data disclosing chemical processes, as confidential business information.

[5]In this testimony, exposure represents the magnitude, frequency, and duration of contact with a chemical. Toxicity represents the degree to which a chemical is harmful. In this testimony, the terms toxicity and hazard are used synonymously.

authorities under TSCA to ensure chemical safety. In February 2012, EPA summarized many of the activities it had initiated under its new approach in the agency's *Existing Chemicals Program Strategy*. Collectively, these activities address the following four areas: (1) collecting toxicity and exposure data, (2) conducting risk assessments, (3) discouraging the use of some chemicals, and (4) expanding public access to some chemical data.

In our most recent report in March 2013, we reported on the extent to which EPA had made progress implementing its new approach.[6] We recommended, among other things, that EPA consider promulgating a rule requiring chemical companies to report exposure-related data from processors to EPA. EPA stated in its comments that downstream chemical processors have little exposure-relevant data—which suggests that it does not intend to implement that recommendation.[7] Because EPA has not developed sufficient chemical assessment information to limit exposure to many chemicals that may pose substantial health risks, among other reasons, in 2009, we added EPA's processes for assessing and controlling toxic chemicals to our list of programs at high risk of waste, fraud, abuse, and mismanagement.[8]

My testimony today is based on our prior work on EPA's processes for assessing and controlling toxic chemicals. Specifically, my statement today discusses: (1) challenges EPA has faced historically in regulating chemicals and (2) the extent to which EPA has made progress implementing its new approach, and challenges, if any, which persist. This statement is based on our extensive body of work on TSCA and EPA's programs to assess and control chemicals, including reports issued from September 1994 to March 2013. Detailed information on our scope and methodology is available in each issued product. We

[6]GAO, *Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach*, GAO-13-249 (Washington, D.C.: Mar. 22, 2013).

[7]This position, however, conflicts with EPA's principles for TSCA reform, which state that, "EPA's authority to require submission of use and exposure information should extend to downstream processors…" In addition, EPA officials have said that data from downstream processors would provide the agency with a better understanding of potential exposure to chemicals, for example, chemical exposure from consumer products such as those designed for children.

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

conducted this work in accordance with generally accepted government auditing standards.

Background

Federal laws have been enacted over the years to determine the health and environmental hazards associated with toxic chemicals and to address these problems. Even with the existence of media-specific environmental laws enacted in the early 1970s, such as the Clean Air Act and the Clean Water Act, problems with toxic chemicals continued to occur. In addition, Congress became increasingly concerned about the long-term effects of substantial amounts of chemicals entering the environment.

TSCA was enacted to authorize EPA 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. Under the act, EPA can control the entire life cycle of chemicals from their production, distribution in commerce, and use to their disposal. Other environmental and occupational health laws generally control only disposal or release to the environment, or exposures in the workplace. The scope of TSCA includes those chemicals manufactured, imported, processed,[9] distributed in commerce, used, or disposed of in the United States but excludes certain substances regulated under other laws.[10] TSCA also specifies when EPA may publicly disclose chemical information it obtains from chemical companies and provides that chemical companies can claim certain information, such as data disclosing chemical processes, as confidential business information.

EPA's authority to ensure that chemicals in commerce do not present an unreasonable risk of injury to health or the environment is established in five major sections of TSCA. The purpose and application of these sections are shown in table 1 and described in further detail below.

[9]Processing refers to the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce.

[10]Excluded substances include certain nuclear materials, pesticides, food, food additives, tobacco, drugs, and cosmetics.

Table 1: Purpose and Application of TSCA's Major Sections

Section	Purpose	Provides EPA with a mechanism to:
4	Chemical testing	Require companies to develop toxicity data under certain circumstances
5	New chemical review and significant new use rules	Review existing information, including exposure and toxicity data for new chemicals and certain new uses of existing chemicals
6	Control of chemicals	Limit or ban a chemical, among other controls
8	Industry reporting of chemical data	Obtain existing data, including exposure and toxicity data
14	Disclosure of chemical data	Disclose certain data provided to or obtained by EPA while also protecting confidential business information

Source: GAO analysis of TSCA.

Under the provisions for chemical testing in section 4 of TSCA, EPA can promulgate rules to require chemical companies to test potentially harmful chemicals for their health and environmental effects. However, EPA must first determine that testing is warranted based on some toxicity or exposure information. Specifically, to require such testing, EPA must find that a chemical (1) may present an unreasonable risk of injury to human health or the environment or (2) 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 or may reasonably be anticipated to enter the environment in substantial quantities. EPA must also determine that there are insufficient data to reasonably determine or predict the effects of the chemical on health or the environment and that testing is necessary to develop such data.

Under the provisions for new chemical review and significant new use rules in section 5 of TSCA, chemical companies are to notify EPA at least 90 days before beginning to manufacture a new chemical (premanufacture notice review). Section 5 also allows EPA to promulgate significant new use rules, which require companies to notify EPA at least 90 days before beginning to manufacture a chemical for certain new uses or in certain new ways (significant new use notice review). Such rules require existing chemicals to undergo the same type of review that new chemicals undergo. For example, EPA may issue a significant new use rule if it learns that a chemical that has previously been processed as a liquid is now being processed as a powder, which may change how workers are exposed to the chemical. Section 5 of the act also authorizes EPA to maintain a list of chemicals—called the chemicals of concern

list—that present or may present an unreasonable risk of injury to health or the environment.

Under the provisions for chemical regulation in section 6 of TSCA, EPA is to apply regulatory requirements to chemicals for which EPA finds a reasonable basis exists to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment. To adequately protect against a chemical's risk, EPA can promulgate a rule that bans or restricts the chemical's production, processing, distribution in commerce, disposal, or use or requires warning labels be placed on the chemical. Under TSCA, EPA must choose the least burdensome requirement that will adequately protect against the risk.

Under the provisions for industry reporting of chemical data in section 8(a), EPA is to promulgate rules under which chemical companies must maintain records and submit such information as the EPA Administrator reasonably requires. This information can include, among other things, chemical identity, categories of use, production levels, by-products, existing data on adverse human health and environmental effects, and the number of workers exposed to the chemical, to the extent such information is known or reasonably ascertainable. Under section 8(a), EPA issues rules to update the TSCA inventory. For example, in August 2011, EPA finalized its TSCA Chemical Data Reporting rule (previously referred to as the Inventory Update Reporting Modifications Rule); the rule requires companies to report, among other things, exposure-related information, such as production volume and use data, on chemicals manufactured or imported over a certain volume per year. In addition, section 8(d) provides EPA with the authority to promulgate rules under which chemical companies are required to submit lists or copies of existing health and safety studies to EPA. Section 8(e) generally requires chemical companies to report any information to EPA that reasonably supports a conclusion that a chemical presents a substantial risk of injury to health or the environment.

Under the provisions for disclosure of chemical data in section 14, EPA may disclose chemical information it obtains under TSCA under certain conditions. Chemical companies can claim certain information, such as data disclosing chemical processes, as confidential business information. EPA generally must protect confidential business information against public disclosure unless necessary to protect against an unreasonable risk of injury to health or the environment. Other federal agencies and federal contractors can obtain access to this confidential business

information to carry out their responsibilities. EPA may also disclose certain data from health and safety studies.

Historical Challenges EPA Has Faced Regulating Chemicals under TSCA

We have previously reported that EPA has historically faced challenges implementing many of the provisions of TSCA, in particular (1) obtaining adequate information on chemical toxicity and exposure through testing provisions; (2) banning or limiting chemicals; and (3) disclosing chemical data and managing company assertions of confidentiality.

Obtaining Adequate Information on Chemical Toxicity and Exposure

EPA has found it difficult to obtain adequate information on chemical toxicity and exposure because TSCA does not require companies to provide this information and, instead, requires EPA to demonstrate that chemicals pose certain risks before it can ask for such information.

Specifically, we reported in 2005 that under section 4—provisions for chemical testing—EPA has found its authority to be difficult, time-consuming, and costly to use.[11] The structure of this section places the burden on EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. While TSCA authorizes EPA to review existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so. Instead, EPA conducts initial reviews after it receives information from the public or chemical companies that a chemical may pose a risk. As a result, EPA has only limited information on the health and environmental risks posed by these chemicals. In our June 2005 report, we suggested that Congress consider amending TSCA to provide explicit authority for EPA to enter into enforceable consent agreements under which chemical companies are required to conduct testing, and give EPA, in addition to its current authorities under section 4 of TSCA, the authority to require chemical substance manufacturers and processors to develop test data based on substantial production volume and the necessity for testing.

In addition, we reported in June 2005 that under section 5—provisions for new chemical review—TSCA generally requires chemical companies to submit a notice to EPA (known as a “premanufacture notice”) before they manufacture or import new chemicals and to provide any available test

[11] GAO-05-458.

data. EPA estimated that most notices do not include any test data and that about 15 percent of them included 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. However, chemical companies are not generally required under TSCA to limit the production of a chemical or its uses to those specified in the premanufacture notice or to submit another premanufacture notice if changes occur. 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.

Banning or Limiting Chemicals

EPA has had difficulty demonstrating that chemicals should be banned or have limits placed on their production or use under section 6—provisions for controlling chemicals. Specifically, we reported, in June 2005, that since Congress enacted TSCA in 1976,[12] EPA has issued regulations under section 6 to ban or limit the production or restrict the use of five existing chemicals or chemical classes out of tens of thousands of chemicals listed for commercial use on the agency's TSCA inventory.[13]

EPA's 1989 asbestos rule illustrates the difficulties EPA has had in issuing regulations to control existing chemicals. In 1979, EPA started considering rulemaking on asbestos. After concluding that asbestos was a potential carcinogen at all levels of exposure,[14] EPA promulgated a rule in 1989 prohibiting the future manufacture, importation, processing, and distribution of asbestos in almost all products. 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 1991, the Fifth Circuit Court of Appeals ruled for the manufacturers and returned parts of the rule to EPA for reconsideration. In reaching this conclusion, the court found that EPA did not consider all

[12]GAO-05-458.

[13]TSCA requires EPA to compile, keep current, and publish a list of each chemical substance that is manufactured or processed in the United States, which is called the TSCA inventory. Of the over 84,000 chemicals currently on the TSCA inventory, approximately 8,000 chemicals are produced at annual volumes of 25,000 pounds or greater.

[14]EPA came to this conclusion after reviewing over 100 studies of the health risks of asbestos, as well as public comments on the proposed rule.

necessary evidence and failed to show that the control action it chose was the least burdensome reasonable regulation required to adequately protect human health or the environment. Since the court's 1989 decision, EPA has only exercised its authority to ban or limit the production or use of an existing chemical once—for hexavalent chromium, a known human carcinogen widely used in industrial cooling towers—in 1990.[15]

Disclosure of Chemical Data

EPA has limited ability to publicly share the information it receives from chemical companies under TSCA. Specifically, as we reported in 2005, EPA has not routinely challenged companies' assertions that the chemical data they disclose to EPA under section 14—disclosure of chemical data—are confidential business information, citing resource constraints. TSCA requires EPA to protect trade secrets and privileged or confidential commercial or financial information against unauthorized disclosures. When information is claimed as confidential business information, it limits EPA's ability to expand public access to this information—such as sharing it with state environmental agencies and foreign governments, which potentially limits the effectiveness of these organizations' environmental risk programs.

Because EPA has not routinely challenged these assertions, the extent to which companies' confidentiality claims are warranted is unknown. We recommended, in June 2005, that EPA revise its regulations to require that companies periodically reassert claims of confidentiality.[16] EPA did not disagree with our recommendation but has not revised its regulations. EPA has explored ways to reduce the number of inappropriate and over-broad claims of confidentiality by companies that submit data to EPA.

[15]However, EPA officials said that they had started the process for promulgating the rule for hexavalent chromium years prior to the asbestos decision.

[16]GAO-05-458.

EPA Has Made Progress to Implement Its New Approach to Managing Chemicals, but Some Challenges Persist

In March 2013, we reported on progress EPA has made implementing its new approach to manage toxic chemicals under its existing TSCA authority—particularly by increasing efforts to (1) obtain toxicity and exposure data, (2) assess risks posed by chemicals, and (3) discourage the use of some chemicals.[17] However, the results of EPA's activities, in most cases, have yet to be realized. We also reported that it is unclear whether EPA's new approach will position the agency to achieve its goal of ensuring the safety of chemicals.

EPA Has Increased Efforts to Collect Data on Toxicity and Exposure, but It May Take Several Years to Produce Results

EPA has increased its efforts to collect toxicity and exposure data, but because rules can take years to finalize and additional time for companies to execute, these efforts may take several years to produce results. Even with these efforts, EPA has not pursued all opportunities to obtain chemical data.

We reported, in March 2013, that EPA has made progress by taking the following actions but continues to face challenges in collecting such data, specifically:

- Since 2009, EPA has proposed or promulgated rules to require chemical companies to test 57 chemicals. Specifically, EPA has required companies to test 34 chemicals and provide EPA with the resulting toxicity and other data. In addition, EPA announced, but has yet to finalize,[18] plans to require testing for 23 additional chemicals.[19] However, requirements under TSCA place the burden of developing toxicity data on EPA. Because rulemaking can take years, EPA has yet to obtain much of the information it has been seeking. According to EPA officials, it can take, on average, 3 to 5 years for the agency to

[17]GAO-13-249.

[18]Final rules are located at 40 C.F.R. §§ 799.5087 and 799.5089 (2012). The proposed rule is located at 76 Fed. Reg. 65580 (Oct. 21, 2011).

[19]By comparison, EPA required testing for fewer than 200 chemicals from the time TSCA was enacted in 1976 until 2009 when the agency undertook its new approach to managing chemicals. The 57 chemicals that are part of EPA's current and proposed testing requirements were identified but not sponsored as part of the agency's 1998 voluntary effort to obtain testing data from companies on chemicals produced or imported at high volumes (i.e., amounts of 1 million pounds or more a year).

promulgate a test rule and an additional 2 to 2 ½ years for the companies to provide the data once EPA has requested them. In addition, the toxicity data eventually obtained on the 57 chemicals may not be sufficient for EPA to conduct a risk assessment (i.e., characterize risk by determining the probability that populations or individuals so exposed to a chemical will be harmed and to what degree). Specifically, EPA may obtain data that are considered to be "screening level" information. Screening level information is collected to identify a chemical's potential hazards to human health and the environment, but it was not intended to be the basis for assessing whether a chemical poses an unreasonable risk of injury to human health or the environment, according to agency documents describing the program.

- In August 2011, EPA revised its periodic chemical data reporting requirements to obtain exposure-related information for a greater number of chemicals. Under the revised requirements, EPA (1) lowered the reporting thresholds, in some cases,[20] which will allow it to look at exposure scenarios for a larger number of chemicals than in the past and (2) shortened the reporting cycle from every 5 years to every 4 years. In addition, starting in 2016, the revised requirements for reporting will be triggered when companies exceed applicable production thresholds in any year during the 4-year reporting cycle.[21]

Even with the increased efforts EPA has taken to collect toxicity and exposure data, in March 2013, we reported that EPA has not pursued all opportunities to obtain such data. For example, EPA has not sought toxicity and exposure data that companies submit to the European Chemicals Agency on chemicals that the companies manufacture or

[20]For example, the production threshold for providing processing and use information went from 300,000 pounds or more to 100,000 pounds or more in 2012 and will be reduced to 25,000 pounds thereafter.

[21]Previously, the reporting requirement was triggered only if production levels were exceeded during the reporting year. According to EPA officials, this change was important because, under the previous requirement, production volumes of chemical substances fluctuated above and below reporting thresholds in different reporting periods, resulting in a change of approximately 30 percent in the composition of the chemical substances reported as being produced from one reporting period to the next.

process in, or import to, the United States.[22] Under the European Union's chemicals legislation, the European Chemicals Agency may share information it receives from chemical companies with foreign governments in accordance with a formal agreement concluded between the European Community and the foreign government, but EPA has not pursued such an agreement. In addition, EPA has not issued a rule under section 8 of TSCA requiring companies to provide EPA with the information provided to the European Chemicals Agency. EPA officials told us that the agency has not sought to obtain chemical data—from either the European Chemicals Agency or companies directly—because it does not believe that this would be the best use of EPA or industry resources. They also said that it is unclear whether these data would be useful to EPA. EPA officials believe it is a more effective use of resources to gain access to data, as needed, on a case-by-case basis from chemical companies. As a result, we recommended that EPA consider promulgating a rule under TSCA section 8, or take action under another section, as appropriate, to require chemical companies to report chemical toxicity and exposure-related data they have submitted to the European Chemicals Agency. In its written comments on a draft of our March 2013 report, EPA stated that it intends to pursue data submitted to the European Chemicals Agency from U.S. companies using voluntary or regulatory means as necessary but did not provide information on its planned approach to pursue such data. Consequently, the extent to which EPA plans to continue to rely on voluntary efforts to obtain the needed data is unclear.

EPA Has Begun Assessing Chemical Risks, but It Is Too Early to Tell What, If Any, Risk Management Actions Will Be Taken

EPA has increased its efforts to assess chemical risks, but because EPA does not have the data necessary to conduct all risk assessments, it is too early to tell what, if any, risk management actions will be taken. Even with these efforts, it is unclear how EPA is going to obtain the data necessary to continue to conduct all risk assessments.

We reported, in March 2013, that EPA has made progress to assess chemical risks by taking the following actions but continues to face

[22]The European Chemicals Agency implements the European Union's chemicals legislation. The European Union's chemicals legislation requires companies to develop information on chemicals' effects on human health and the environment before entering commerce, while TSCA does not require companies to develop such information absent EPA rulemaking requiring them to do so.

challenges. Specifically, in February 2012, EPA announced a plan that identified and prioritized 83 existing chemicals for risk assessment—known as the TSCA Work Plan.[23] From this list of 83 chemicals, EPA's Office of Pollution Prevention and Toxics—the office responsible for implementing TSCA—initiated risk assessments for 7 chemicals in 2012—5 of which were released for public comment—and announced plans to start risk assessments during 2013 and 2014 for 18 additional chemicals.[24] EPA officials told us that they expect that all 7 risk assessments will be finalized early in 2014. However, it may be years before EPA initiates regulatory or other risk management actions to reduce any chemical risks identified in these assessments. Before EPA can determine such actions are warranted, the agency would need to consider other factors—such as costs and benefits of mitigating the risk, technological information, and the concerns of stakeholders—which could require additional time and resources. Moreover, assuming EPA meets its 2014 target for completing these 7 assessments and initiating new assessments, at its current pace, it would take EPA at least 10 years to complete risk assessments for the 83 chemicals in the TSCA Work Plan.

As we reported, in March 2013, even with these increased efforts, it is unclear whether EPA can maintain its current pace given that it currently does not have the toxicity and exposure data it will need to conduct risk assessments for all of the 83 chemicals in its TSCA Work Plan. According to EPA officials and agency documents, the agency has started or plans to start risk assessments on the 25 chemicals for which it has well-characterized toxicity and exposure data. However, before EPA can initiate risk assessments for the remaining 58 chemicals, the agency will need to identify and obtain toxicity and exposure data. According to agency officials, to obtain the toxicity data needed, EPA may need to promulgate rules to require companies to perform additional testing on some of these chemicals. However, EPA has not clearly articulated how or when it plans to obtain these needed data. Moreover, without exposure-related data, such as those potentially available from chemical processors, EPA may still be missing the data necessary to conduct risk

[23]In 2011, EPA convened a stakeholder meeting to discuss proposed screening criteria and data sources and took public comment over a 35-day period. Based on the input received, EPA devised and executed a protocol that used a combination of risk factors and other criteria. Using this protocol, EPA winnowed an initial group of 1,235 chemicals down to 83.

[24]78 Fed. Reg. 1856 (Jan. 9, 2013).

assessments. To better position EPA to ensure chemical safety under existing TSCA authority, in our March 2013 report we recommended that EPA develop strategies for addressing challenges associated with obtaining toxicity and exposure data needed for risk assessments. However, based on EPA's written response to a draft of our 2013 report, it is unclear what action, if any, EPA intends to pursue.

EPA Has Taken Actions That May Discourage the Use of Certain Chemicals, but It Is Too Early to Tell Whether These Actions Will Reduce Chemical Risk

EPA has taken actions that may discourage the use of certain chemicals, but because many of these actions have yet to be finalized, it is too early to tell whether they will reduce chemical risk. We reported in March 2013 that, given the difficulty that EPA has faced in the past using section 6 of TSCA to ban existing toxic chemicals or place limits on their production or use, the agency generally considers using this authority only after exhausting all other available options. Since 2009, EPA has made progress by increasing its use of certain options, including (1) making greater use of significant new use rules under section 5 and (2) proposing actions that use its TSCA authority in new ways as follows:

- EPA is making greater use of significant new use rules under section 5 to control new uses of existing chemicals. Our analysis of TSCA rulemaking from 2009 to 2012 shows that EPA has quadrupled its issuance of significant new use rules since 2009. From 2009 to 2012, EPA issued significant new use rules affecting about 540 chemicals, about 25 percent of all 2,180 chemicals subject to significant new use rules issued by EPA since 1976. EPA officials told us that EPA typically recommends that companies submit testing information when they notify EPA of their intent to manufacture or process chemicals, which enables EPA to better evaluate the potential risks associated with the new use. According to EPA officials, this approach allows the agency to "chip away" at chemicals that may pose risks to human health and the environment. Such recommendations may discourage companies from pursuing new uses of existing chemicals that may pose health or environmental risks either because testing itself can be expensive, or because the testing recommendation suggests that the agency may consider banning or limiting the manufacture or production of the chemical on the basis of that testing.

- EPA has also proposed actions that use its TSCA authority in new ways including the following:

  - *Creating "chemicals of concern" list*. In May 2010, EPA announced that it intended to create a list of chemicals that present or may present ‘‘an unreasonable risk of injury to health or

the environment.'' EPA has had the authority to create such a list under section 5 of TSCA since its enactment in 1976 but has never attempted to use this authority. EPA submitted the list, which consists of three groups of chemicals, for review by the Office of Management and Budget (OMB) in May 2010, and as of May 2013, EPA's proposed "chemicals of concern" list has been under review at OMB for over 1,000 days and remains listed as pending review by OMB.[25]

- *Pairing of test and significant new use rules*. In December 2010, EPA submitted to OMB for review a proposal to pair testing rules with significant new use rules for the first time. Specifically, EPA has proposed single rules that combine provisions requiring companies to develop toxicity and other data with provisions requiring companies to provide data for new uses of chemicals. EPA has proposed using this approach in two cases. In one case, for example, EPA proposed this approach for certain flame retardants that are being voluntarily phased out, effective December 2013. Under the proposed rule, any new use of the chemical after it has been phased out would qualify as a significant new use, triggering a testing requirement. According to EPA officials, the pairing of these types of rules is intended to discourage new uses of certain chemicals that may pose a risk to human health or the environment and create a disincentive for companies to continue current use of the chemical—something EPA has not done before. OMB's review of this proposal took 422 days and was completed on February 15, 2012.

- *Extending significant new use rules to articles*. Since 2009, EPA has made increasing use of its ability to subject chemicals contained in certain products, or "articles," such as furniture, textiles, and electronics, to significant new use rules. Generally, those who import or process a substance as part of a product are

[25]These three groups are: (1) a category of eight phthalates, (2) a category of polybrominated diphenylethers (PBDE), and (3) bisphenol A (BPA).

exempted from compliance with a significant new use rule. EPA's proposals would eliminate this exemption for certain chemicals.[26]

However, it is too early to assess the impact of EPA's proposed actions because they have yet to be finalized. In addition, in some cases, OMB has not met the established 90-day time for reviewing EPA's proposed actions—which has increased the time frames for formally proposing and finalizing them.[27] In particular, the period for OMB review is generally limited by executive order to 90 days, although it can be extended. [28]

It Is Unclear Whether EPA's New Approach Will Position the Agency to Achieve Its Goal of Ensuring the Safety of Chemicals

As we reported in March 2013, it is unclear whether EPA's new approach to managing chemicals within its existing TSCA authorities will position the agency to achieve its goal of ensuring the safety of chemicals. EPA officials have said that the agency's new approach, initiated in 2009 and summarized in its 2012 *Existing Chemicals Program Strategy*, is intended to guide EPA's efforts to assess and control chemicals in the coming years. However, EPA's strategy, which largely focuses on describing activities EPA has already begun, does not discuss how it will address challenges discussed earlier associated with obtaining toxicity and exposure data and banning or limiting the use of chemicals as follows:

- *Obtaining toxicity and exposure data*. EPA's strategy does not discuss how the agency will meet the challenge we described related to obtaining the toxicity and exposure data it will need to conduct all risk assessments. In particular, as discussed previously, EPA has not broadly sought toxicity and exposure data that companies submit to foreign governments; instead EPA plans to obtain these data on a

[26]In spring 2012, EPA proposed three significant new use rules that would require companies to report new uses of five groups of chemicals, including in domestic and imported articles. EPA has used this approach before but infrequently. EPA first eliminated the article exemption for a chemical substance in 1991, when it promulgated a significant new use rule for erionite fiber, and it used the same approach for a significant new use rule pertaining to the use of elemental mercury in certain switches in 2007.

[27]Any rules that EPA plans to issue under TSCA that are considered significant regulatory actions, as defined by Executive Order 12866, are subject to review by the Office of Information and Regulatory Affairs, an office within OMB, prior to being proposed in the *Federal Register*. Among other things, a significant regulatory action may have an annual effect on the economy of $100 million or more or raise novel legal or policy issues.

[28]Under Executive Order 12866, the review period may be extended by the head of the rulemaking agency, and the OMB Director may extend the review period once for no more than 30 days.

case-by-case basis from chemical companies. However, the agency's strategy does not discuss how EPA would execute these plans or how the data obtained would be used to inform the agency's ongoing or future risk assessment activities, if at all.

- *Banning or limiting the use of chemicals*. EPA's strategy does not articulate how the agency would overcome the regulatory challenges it experienced in the past. In particular, EPA officials told us that, even if EPA has substantial toxicity and exposure data, the agency is challenged in meeting the statutory requirement under section 6 of TSCA to limit or ban chemicals.

Further, EPA's strategy does not identify the resources needed to meet its goal of ensuring chemical safety. For example, EPA's strategy does not identify the resources needed to carry out risk assessment activities, even though risk assessment is a central part of EPA's effort to manage chemicals under its new approach. Specifically, EPA does not identify roles and responsibilities of key staff or offices—for example which office within EPA will develop the toxicity assessments needed to support its planned risk assessments—or identify staffing levels or cost associated with conducting its risk assessment activities. Without a clear understanding of the resources needed to complete risk assessments and other activities identified in its strategy, EPA cannot be certain that its current funding and staffing levels are sufficient to execute its new approach to managing chemicals under existing TSCA authorities.

When developing new initiatives, agencies can benefit from following leading practices for federal strategic planning.[29] Of these leading practices, it is particularly important for agencies to define strategies that address management challenges that threaten their ability to meet long-term goals. In our March 2013 report,[30] we stated that without a plan that

[29]The strategic planning elements established under the Government Performance and Results Act (GPRA) of 1993 and associated OMB guidance and practices we identified, taken together, can serve as leading practices for strategic planning at lower levels within federal agencies, such as planning for individual divisions, programs, or initiatives. Leading practices in federal strategic planning include defining mission and goals, involving leadership and stakeholders, developing performance measures, and developing strategies to address management challenges and resources needed, among others. See GAO, *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct. 6, 2011); see GAO, *Environmental Protection: EPA Should Develop a Strategic Plan for Its New Compliance Initiative*, GAO-13-115 (Washington, D.C.: Dec. 10, 2012).

[30]GAO-13-249.

incorporates leading strategic planning practices—particularly a plan that clearly articulates how EPA will address management challenges—EPA cannot be assured that it its new approach to managing chemicals, as described in its *Existing Chemicals Program Strategy*, will provide a framework to effectively guide its efforts. Consequently, EPA could be investing valuable resources, time, and effort without being certain that its efforts will bring the agency closer to achieving its goal of ensuring the safety of chemicals. As a result, we recommended that the EPA Administrator direct the appropriate offices to develop strategies for addressing challenges that impede the agency's ability to meet its goal of ensuring chemical safety to better position EPA to ensure chemical safety under its existing TSCA authority. In its written response to our March 2013 report,[31] EPA's Acting Assistant Administrator stated that change is needed in every significant aspect of the program, and, while strategic planning is a useful exercise it cannot substitute for the basic authorities needed for a modern, effective chemicals program. Moreover, the Acting Assistant Administrator stated that it is EPA's position that, absent statutory changes to TSCA, the agency will not be able to successfully meet the goal of ensuring chemical safety now and into the future.

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

GAO Contact and Staff Acknowledgments

If you or your staff members have any questions about this testimony, please contact me at (202) 512-3841 or gomezj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Other individuals who made key contributions include Diane LoFaro, Assistant Director; Diane Raynes, Assistant Director; Elizabeth Beardsley; Richard Johnson; Alison O'Neill; and Aaron Shiffrin.

[31]GAO-13-249.

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