United States Government Accountability Office

GAO

Report to Congressional Requesters

March 2013

TOXIC SUBSTANCES

EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach

GAO-13-249

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GAO Highlights

Accountability * Integrity * Reliability

Highlights of GAO-13-249, a report to congressional requesters

Why GAO Did This Study

In 1976, Congress passed TSCA to provide EPA with the authority to obtain more information on chemicals and to regulate those chemicals that EPA determines pose unreasonable risks of injury to human health or the environment. GAO has reported that EPA has found much of TSCA difficult to implement—hampering the agency's ability to obtain certain chemical data or place limits on chemicals. Of the thousands of chemicals listed for commercial use in the United States, EPA has used its authority to limit or ban five chemicals since TSCA was enacted. 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 with the goal of ensuring the safety of chemicals using its existing authorities.

GAO was asked to evaluate EPA's efforts to strengthen its management of chemicals. This report determines the extent to which (1) EPA has made progress implementing its new approach and (2) EPA's new approach positions it to achieve its goal of ensuring the safety of chemicals. GAO examined agency documents and TSCA rulemaking and interviewed agency officials and stakeholders from industry and environmental organizations.

What GAO Recommends

GAO recommends, among other things, that EPA develop strategies that address challenges impeding its ability to ensure chemical safety and identify the resources needed to so. EPA neither agreed nor disagreed with GAO's recommendations.

View GAO-13-249. For more information, contact David Trimble at (202) 512-3841 or trimbled@gao.gov.

What GAO Found

Since 2009, the Environmental Protection Agency (EPA) has made progress implementing its new approach to managing toxic chemicals under its existing Toxic Substances Control Act (TSCA) authority; particularly by increasing efforts to obtain chemical toxicity and exposure data and initiating chemical risk assessments—which EPA uses, along with other information, to decide what regulatory or other actions, if any, are warranted. The results of EPA's data collection activities, in most cases, have yet to be realized, and it may take several years before EPA obtains much of the data it is seeking. Also, EPA has not pursued some opportunities to obtain chemical data that companies submit to foreign governments or to obtain data from chemical processors that prepare chemical substances after their manufacture for distribution in commerce—some of which could help support the agency's risk assessment activities. Of the 83 chemicals EPA has prioritized for risk assessment, it initiated 7 assessments in 2012 and plans to start 18 additional assessments in 2013 and 2014. However, it may take several years to complete these initial risk assessments and, at the agency's current pace, over a decade to complete all 83, especially as EPA does not have the toxicity and exposure data needed for 58 of the 83 chemicals prioritized for risk assessment. In addition to its risk assessment activity, EPA has initiated other actions—such as increasing review of certain new uses of chemicals—that may discourage the use of these chemicals, but it is too early to tell whether these actions will reduce chemical risks.

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 said that the agency's new approach, 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 include leading federal strategic planning practices that could help guide its effort. Specifically, EPA has not defined strategies that address challenges—many of which are rooted in TSCA's regulatory framework—that may impede EPA's ability to meet its long-term goal of ensuring chemical safety. Specifically, EPA has not clearly articulated how it will address challenges associated with obtaining toxicity and exposure data needed for risk assessments and placing limits on or banning chemicals under existing TSCA authorities. In addition, EPA's strategy does not describe the resources needed to execute its new approach. For example, EPA's strategy does not identify roles and responsibilities of key staff or offices or identify staffing levels or costs associated with conducting the activities under its new approach. Without a plan that incorporates leading strategic planning practices, EPA cannot be assured that its new approach to managing chemicals, as described in its *Existing Chemicals Program Strategy,* will provide a framework to effectively guide its effort. 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.

Contents

Abbreviations

ADP	Action Development Process
ATO	antimony trioxide
BPA	bisphenol A
CAS	Chemical Abstracts Service
DCM	dichloromethane
EPA	Environmental Protection Agency
HHCB	1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[g]-2-benzopyran
HPV	High Production Volume
IUPAC	International Union of Pure and Applied Chemistry
IRIS	Integrated Risk Information System
NCEA	National Center for Environmental Assessment
NMP	n-methylpyrrolidone
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
OCSPP	Office of Chemical Safety and Pollution Prevention
PBDE	polybrominated diphenyl ether
PCB	polychlorinated biphenyls
PVC	plastics/rubber compounding
TCE	trichloroethylene
TSCA	Toxic Substances Control Act

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

March 22, 2013

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate

The Honorable Tom Udall
Chairman
Subcommittee on Superfund,
Toxics and Environmental Health
Committee on Environment and Public Works
United States Senate

The Honorable Frank Lautenberg
United States Senate

Tens of thousands of chemicals are listed with the Environmental Protection Agency (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). The scope of TSCA includes those chemicals manufactured, imported, processed,[1] distributed in commerce, used, or disposed of in the United States but excludes certain substances regulated under other laws.[2] 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

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

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

data disclosing chemical processes, as confidential business information.[3]

We have reported in the past, among other things, that EPA has found many of the provisions of TSCA difficult to implement—which has hampered the agency's ability to obtain certain chemical data, place limits on chemicals, and manage company assertions of confidentiality. Specifically, EPA has found it difficult to obtain adequate information on chemical toxicity and exposure[4] 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. Without adequate information on chemical toxicity and exposure, EPA is unable to assess the risks posed by many chemicals.

Even when EPA has had adequate information on toxicity and exposure, the agency has had difficulty demonstrating, under the standards required by TSCA, that harmful chemicals pose an unreasonable risk and, therefore, should be banned or have limits placed on their production or use. Consequently, EPA has used its authority to limit or ban the use of five chemicals since TSCA was enacted in 1976. The agency last used this authority in 1990. In addition, while EPA has reported that 95 percent of information it receives on new chemicals contains assertions of confidentiality, EPA officials have stated that they have not had the resources that would be needed to investigate and, as appropriate, challenge such claims.

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. In addition, we have identified a number of options that could strengthen EPA's ability to

[3]Throughout this report, we use the phrase "chemical companies" to refer 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, we specify the type of company to which we are referring.

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

regulate harmful chemicals under TSCA.[5] For the past several years, congressional committees annually have considered legislation aimed at reforming TSCA, but Congress has not passed such legislation. We have also made recommendations to EPA. In June 2005, we reported that EPA had not used its TSCA authority to obtain information that U.S. companies submit to foreign governments, which may contain important information on chemical toxicity, and we recommended that EPA promulgate a rule requiring that companies submit copies to the agency 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.[6] We also recommended that the agency improve and validate its models for assessing and predicting the risks of chemicals and revise its regulations to require companies to reassert confidentiality claims within a certain period. EPA implemented our recommendation to improve its models. EPA did not disagree with our 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. For this and 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.[7]

Interest in reforming TSCA has heightened in recent years and, in 2009, EPA announced principles for reforming TSCA to help inform efforts under way in Congress. These principles include, among other things, 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 would be required to provide sufficient toxicity, exposure, and use data for a chemical to support a determination by EPA that the 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 flexibility to take into account a range of

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

[6]GAO-05-458.

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

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—which, according to agency documents, will transition the agency from an approach dominated by voluntary data submissions by industry to a more proactive approach in which EPA will use its data collection and other rulemaking authorities under TSCA to ensure chemical safety. In this context, you asked us to evaluate EPA's recent efforts to strengthen its management of chemicals. Our objectives were to determine the extent to which (1) EPA has made progress implementing its new approach to managing toxic chemicals under its existing TSCA authority and (2) EPA's new approach positions the agency to achieve its goal of ensuring the safety of chemicals.

To address these objectives, we identified and reviewed EPA's efforts to obtain and analyze toxicity and exposure data, prioritize and perform risk assessments on chemicals, initiate regulatory and other actions to reduce risks; and make more chemical information—particularly data classified as confidential business information—available to the public. As part of this work, we reviewed EPA's TSCA rulemaking actions for the last 10 years and examined EPA's key policy, planning, and strategy documents. We interviewed officials from EPA's Office of Chemical Safety and Pollution Prevention, including its Office of Pollution Prevention and Toxics, regarding EPA's efforts to strengthen its management of chemicals. We interviewed officials from EPA's Office of Research and Development and Office of Policy relating to EPA's use of new analytical methods and tools and EPA's rulemaking process, respectively. We also interviewed representatives from stakeholder groups, such as industry associations and environmental organizations. A more detailed description of our scope and methodology can be found in appendix I.

We conducted this performance audit from December 2011 to March 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe

that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

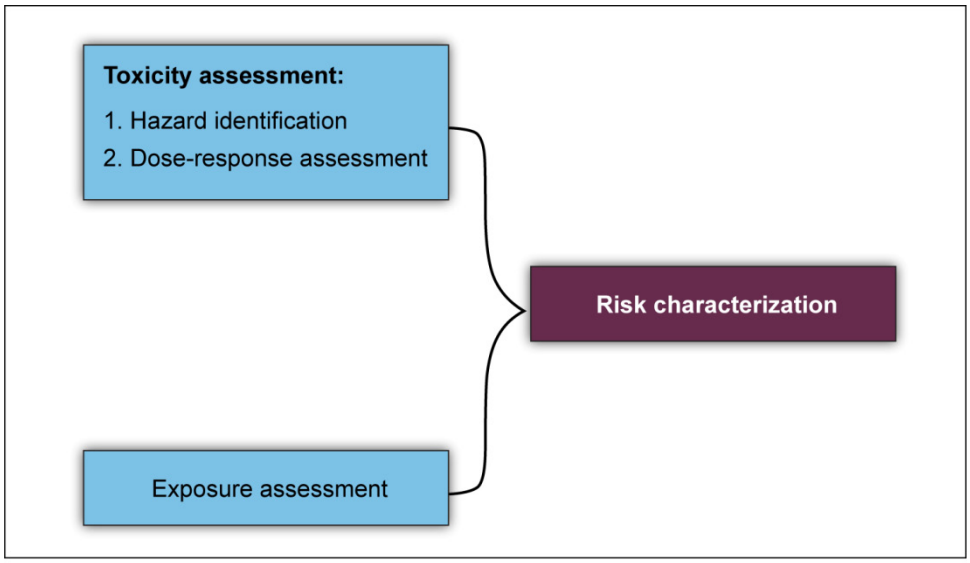
This section discusses (1) chemical risk assessments, (2) the structure of TSCA and prior findings that have impeded EPA's ability to assess and control toxic chemicals, and (3) EPA's new approach to managing chemicals within the limits of existing authorities.

Chemical Risk Assessments

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 chemicals. EPA assesses the risks chemicals pose to human health (human health risk assessments) as well as to the environment (ecological risk assessments).

The human health risk assessment model EPA uses (see fig. 1) includes steps to (1) identify a chemical's toxicity, or hazardous properties, which are the potential noncancer and cancer human health effects of exposure to a chemical; (2) assess the dose-response relationship between exposure to a chemical and the resultant health effects, which describes the magnitude of hazard for potential noncancer effects and increased cancer risk; (3) assess the extent of human exposure to the chemical; and (4) characterize risk by determining the probability that populations or individuals so exposed to the chemical will be harmed and to what degree. Such assessments are the cornerstone of scientifically sound environmental decisions, policies, and regulations under a variety of statutes, including TSCA.

Figure 1: Human Health Chemical Risk Assessment Model Used by EPA



Sources: GAO presentation of the risk assessment component of the National Academies' risk assessment model used by EPA.

For some, but not all, chemicals, EPA conducts the first two steps of its chemical risk assessment model—that is, the hazard identification and dose-response assessment—under its Integrated Risk Information System (IRIS) program.[8] Taken together, these two steps are commonly referred to as toxicity assessments. EPA created the IRIS program in 1985 to help develop consensus opinions within the agency about the human health effects from chronic exposure to chemicals, and it is the only federal program that provides qualitative and quantitative assessments of both cancer risks and noncancer effects of chemicals. EPA's IRIS program—managed by EPA's National Center for Environmental Assessment (NCEA) within the Office of Research and Development (ORD)—develops new IRIS toxicity assessments and updates existing IRIS assessments if revisions are warranted on the basis of newly published peer-reviewed studies. For many chemicals, however, IRIS toxicity assessments are not available, current, or applicable to EPA's program offices—including the Office of Pollution Prevention and

[8]We have reported on EPA's difficulty producing timely, credible IRIS assessments, which contributed to our decision in 2009 to add EPA's processes for assessing and controlling chemicals to our list of areas at high risk for waste, fraud, abuse, and mismanagement or in need of broad-based transformation.

Toxics, which is responsible for implementing TSCA. Therefore, these offices, in some cases, prepare their own toxicity assessments.

EPA program offices, including the Office of Pollution Prevention and Toxics, combine information from IRIS toxicity assessments or other toxicity assessments with the results from chemical exposure assessments to develop human health risk assessments, which characterize the risks posed by chemicals, and make risk management decisions. Risk management, as opposed to risk assessment, involves integrating the risk assessment information with other information—such as economic information on the costs and benefits of mitigating a risk, technological information on the feasibility of managing the risk, and the concerns of various stakeholders—to determine whether the health risks identified in a chemical risk assessment warrant EPA taking regulatory or other risk management actions.

In the case of EPA's ecological risk assessment model, EPA's guidelines suggest a three-step process consisting of (1) problem formulation, (2) analysis, and (3) risk characterization, rather than the four-step process used for human health risk assessments. While for a human health risk assessment EPA is primarily concerned with a chemical's toxicity to humans, for an ecological risk assessment, the agency might consider a range of adverse effects on natural resources (e.g., crops, livestock, commercial fisheries, and forests), wildlife (including plants), aesthetic values (e.g., clear air in a national park), and recreational opportunities. According to EPA's ecological risk assessment guidelines, an ecological risk assessment is a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more environmental stressors, such as chemicals, disease, invasive species, and climate change, and one stressor or many stressors may be considered. EPA's guidance on ecological risk assessments focuses on stressors and adverse ecological effects generated or influenced by human activity that could be addressed by the agency's risk management decisions.

TSCA's Structure and Prior Findings on Challenges Posed by TSCA

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.

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	Chemical regulation	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 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. As we have previously reported, EPA has found this authority to be difficult, time-consuming, and costly to use.[9] The structure of section 4 of the act 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.

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

[9]GAO-05-458.

(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. For both new chemicals and significant new use reviews, the required notification to EPA must include certain information on chemical identity, use, production volume, and worker exposure, among other information. EPA has 90 days to review the information in the notice and identify potential risks. If EPA takes no action, manufacturing may commence.[10] 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. In promulgating a rule, EPA must consider and publish a statement in the *Federal Register* regarding the following: (1) the effects of the chemical on health and the environment and the magnitude of human and environmental exposure; (2) the benefits of the chemical for various uses and the availability of substitutes for those uses; and (3) the reasonably ascertainable consequences of the rule, after consideration of the effect on the national economy, small businesses, technological innovation, the environment, and public health.

[10]Companies are not required to submit new notices if any information provided in the original notice changes.

As we have reported in the past, EPA has had difficulty demonstrating that chemicals should be banned or have limits placed on their production or use under section 6.[11] Since Congress enacted TSCA in 1976, EPA has issued regulations under section 6 of the act 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—polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavalent chromium.[12] 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,[13] 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 necessary evidence and failed to show that the control action it chose was the least burdensome reasonable regulation. The court further criticized EPA for banning a product for which no substitutes were currently available. EPA has not proposed a new section 6 rule since the court's ruling in 1991.

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

[11]GAO-05-458.

[12]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. TSCA requires EPA to compile, keep current, and publish a list of each chemical substance that is manufactured or processed in the United States.

[13]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.

information is known or reasonably ascertainable. Under section 8(a), EPA issues rules to collect additional or updated information on certain TSCA inventory chemicals. 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. EPA uses production volume and use data reported by companies as a proxy to estimate the extent of human exposure to the chemicals. 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) 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, unless the company has actual knowledge that EPA already has the information.

The provisions for disclosure of chemical data in section 14 of the act specify when EPA may disclose chemical information it obtains under TSCA. 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 in order to carry out their responsibilities. EPA may also disclose certain data from health and safety studies. Over the years, companies have classified much of the information they submitted to EPA as confidential business information, and, prior to 2009, EPA did not routinely challenge their assertions, citing resource constraints. As a result, the extent to which companies' confidentiality claims were warranted was unknown.

EPA's New Approach to Managing Chemicals

In September 2009, EPA initiated a new approach to managing chemicals that focuses largely on existing chemicals—that is, the approximately 84,000 chemicals already on the TSCA inventory.[14] EPA's new approach has evolved over time and includes a variety of different activities and initiatives. 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 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.

EPA Has Made Progress Implementing Its New Approach to Managing Chemicals, but, in Most Cases, Results Have Yet to Be Realized

EPA has made progress implementing its new approach to managing toxic chemicals under its existing TSCA authority—particularly by increasing efforts to (1) obtain toxicity and exposure data, (2) assess risks posed by chemicals, (3) discourage the use of some chemicals, and (4) expand public access to some chemical information. However, the results of EPA's activities, in most cases, have yet to be realized.

[14]Existing chemicals listed on the TSCA inventory are composed of approximately 62,000 that were in commerce in 1979 when EPA began reviewing chemicals and 22,000 chemicals that were listed for commercial use after 1979. Under EPA's periodic chemical data reporting rules, approximately 8,000 chemicals are reported as being produced or imported at annual volumes of 25,000 pounds or greater but, for the remaining 76,000 chemicals on the inventory, EPA does not know how many are currently in commerce.

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

Since 2009, EPA has increased its efforts to collect toxicity and exposure data. Specifically, since 2009, EPA has required companies to test 34 chemicals and provide EPA with the resulting toxicity and other data. In addition, in 2011, EPA announced, but has yet to finalize, plans to require testing for 23 additional chemicals.[15] By comparison, EPA promulgated test rules for 197 chemicals from the time TSCA was enacted in 1976 until 2009 when the agency undertook its new approach to managing chemicals.[16] The 57 chemicals that are part of EPA's current and proposed testing requirements were identified but not sponsored as part of the agency's1998 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).[17]

Due to requirements under TSCA that place the burden of developing toxicity data on EPA, rather than on industry, and because EPA's past efforts to obtain these data voluntarily were not successful, EPA proposed or promulgated rules to require chemical companies to test these 57 chemicals. However, because rules can take years to finalize and additional time for companies to execute, 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 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, toxicity data eventually obtained on the 57 chemicals may not, in all cases, 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). EPA officials told us that much of the chemical toxicity information obtained previously through its 1998 voluntary effort to obtain testing data

[15]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).

[16]In addition to promulgating test rules, EPA told us that it has required testing for an additional 68 chemicals in enforceable consent agreements.

[17]Under the 1998 High Production Volume (HPV) challenge program, EPA asked chemical companies to sponsor chemicals that were manufactured in or imported into the United States in quantities greater than 1 million pounds per year—at the time, 2,800 chemicals—and voluntarily provide existing toxicity data and, if data did not exist, conduct testing and provide EPA with the resulting data. Companies sponsored more than 2,200 HPV chemicals.

from companies is considered "screening level" information. That is, the information was 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. EPA's efforts since 2009 to require companies to test chemicals is based on testing parameters similar to those used under its voluntary effort and thus may produce similar basic screening level data.[18]

With regard to exposure data, 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,[19] 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. 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. EPA received the first batch of exposure-related data under the new reporting requirements for approximately 8,000 chemicals in August 2012, and EPA officials told us they expect to begin analyzing these data in the coming months. After receiving and analyzing these

[18]The data set sought by EPA is known as the Screening Information Data Set, and was developed by the Organization for Economic Cooperation and Development. The data set provides an internationally agreed upon set of test data for screening high-production volume chemicals for human and environmental hazards, and it is intended to allow the EPA and others to make an informed, preliminary judgment about the hazards of HPV chemicals. The data set is not intended to describe a chemical thoroughly, but rather it is intended to provide enough information to support an initial (or screening level) assessment and to assign a priority for further work, if necessary.

[19]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.

exposure-related data, according to agency documents, EPA plans to determine how to use the information to identify additional data collection needs or identify chemicals that may warrant further review or risk assessment.

Even with the steps it has taken since 2009 to increase the toxicity and exposure data it collects, EPA has not pursued all opportunities to obtain chemical data. In particular, EPA has not broadly sought toxicity and exposure data that companies submit to the European Chemicals Agency on chemicals that the companies manufacture or process in, or import to, the United States.[20] 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. According to EPA, it has an informal agreement, or Statement of Intent, for cooperation and sharing of information with European Chemicals Agency, and had hoped that such an agreement would allow for the sharing of detailed studies, beyond the summaries made publically available by European Chemicals Agency. 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.

EPA has also not used its authority to obtain exposure-related data from chemical processors that prepare chemical substances or mixtures, after

[20]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.

their manufacture, for distribution in commerce.[21] Specifically, EPA has not issued a rule under section 8 of TSCA to extend its periodic chemical data reporting requirements to chemical processors. EPA's chemical data reporting requirements apply only to chemical manufacturers and importers. However, chemical processors are often the downstream users of chemical substances produced by chemical manufacturers and, therefore, may be in a better position to understand end users' exposure scenarios. EPA's principles for TSCA reform stress the importance of these data, stating that, "EPA's authority to require submission of use and exposure information should extend to downstream processors…" In addition, EPA officials told us that data from processors would provide the agency with a better understanding of potential exposure to chemicals, for example, from consumer products such as those designed for children, and that these data are necessary to conduct chemical risk assessments and make risk management decisions on potentially harmful chemicals. Nonetheless, the same EPA officials told us that the agency has not sought to collect such data from all processors because the agency does not currently have the resources to receive, store, and analyze the additional data. Instead, according to EPA officials, the agency has worked on a case-by-case basis with processors and processor associations to ask them to voluntarily submit data.

With regard to obtaining toxicity and exposure data submitted to the European Chemicals Agency and exposure-related data from chemical processors, EPA officials told us that they have considered using EPA's subpoena authority under TSCA section 11(c) to obtain the information if they are unable to obtain it voluntarily—which is an approach EPA has not frequently used before.[22] EPA officials said that they recognized that rules under section 8 of TSCA could be fashioned in such a way as to establish general access to information while also providing EPA with the flexibility to request the information as needed. However, according to EPA officials, TSCA section 11(c) authority may be appropriate in

[21]EPA identifies a broad range of activities that may cause a person or entity to be considered a chemical processor. Examples of chemical processors include, but are not limited to, producers of paint, automotive products, specialty cleaners, rubber, and plastics; or tire manufacturers, tanneries, textile mills, and metal coating facilities.

[22]Section 11(c) of TSCA gives EPA the authority, in carrying out the provisions of TSCA, to use a subpoena to require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the EPA Administrator deems necessary.

situations where EPA is seeking specific data and information from a specific entity, rather than a more general unknown population where rulemaking might be more appropriate. EPA has yet to take such action under its new approach to managing chemicals, however, and it is unclear whether such an approach would provide the agency with timely access to needed information. Without access to the data that companies have submitted to the European Chemicals Agency and by not pursuing exposure-related data from processors, regardless of the mechanism used, EPA is missing an opportunity to collect data that it has identified as an essential part of assessing chemical risk and future chemical regulation.

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

In February 2012, EPA announced a plan that identified 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[24] and announced plans to start risk assessments during 2013 and 2014 for 18 additional chemicals. While EPA's effort to initiate TSCA-related risk assessments represents a significant increase in risk assessment activity,[25] it may be years before EPA initiates risk management actions to reduce any chemical risks identified in these assessments. In January 2013, EPA released 5 draft risk assessments for public comment; from the 7 chemicals for which it initiated risk assessments in 2012.[26] The two remaining assessments are to be released for public comment at a later date, according to EPA's website. EPA officials told us that, upon completion of the public comment periods and its external peer-review process, all 7 risk assessments will

[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]These chemicals are: antimony and antimony compounds, HHCB (1,3,4,6,7,8-hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[g]-2-benzopyran), long-chain chlorinated paraffins, medium-chain chlorinated paraffins, methylene chloride, n-methylpyrrolidone, and trichloroethylene.

[25]Prior to its effort under its TSCA Work Plan, EPA conducted two TSCA-related risk assessments since 2001.

[26]78 Fed. Reg. 1856 (Jan. 9, 2013).

be finalized early in 2014. After EPA completes each risk assessment, according to EPA documents, the agency plans to determine what risk management actions, if any, are warranted to address identified risks. As discussed previously, before EPA can determine whether regulatory or other risk management action is warranted, the agency would need to consider other factors—such as economic information on the costs and benefits of mitigating the risk, technological information on the feasibility of managing the risk, and the concerns of various stakeholders such as industry and environmental organizations—which could require additional time and resources beyond completing risk assessments. Moreover, assuming EPA meets its target for completing these 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.

In addition, it is not clear that 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, and it is unclear how or when EPA will obtain these data. According to EPA officials and agency documents, of the 83 chemicals identified in its TSCA Work Plan, the agency has started or plans to start risk assessments on the 25 chemicals for which it has well-characterized toxicity and exposure data. Before EPA can initiate risk assessments for the remaining 58 chemicals, the agency will need to identify the toxicity and exposure data it needs and then obtain them. 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 assessments.

The type and scope of each of EPA's planned risk assessments are also unclear. For the 76 risk assessments in the TSCA Work Plan that EPA has yet to initiate, it is not clear what type of risk assessment EPA will perform. That is, whether a risk assessment will focus on human health, ecological hazards, or both—or how broadly or narrowly focused a risk assessment will be in terms of assessing exposure scenarios. The type and scope of a risk assessment will, in part, affect the risk management options available to EPA—which can include a number of alternatives such as requiring special labeling and banning or limiting the use of a chemical. More is known about the type and scope of the 7 risk

assessments EPA has initiated—particularly the 5 draft assessments released in January 2013. Examples are as follows:

- For two chemicals, EPA produced draft risk assessments that were focused on potential ecological hazards from specific chemical uses.[27] The draft risk assessments indicate a "low concern for ecological health."

- For two chemicals, EPA produced draft risk assessments that were focused on the human health hazards to consumers, including bystanders and workers, when exposed to these chemicals during paint stripping.[28] The draft risk assessments identified "potential concern for human health under specific exposure scenarios for particular uses."

- For one chemical, EPA produced a draft risk assessment focused on human health hazards to consumers, including bystanders and workers, from inhalation exposures when the chemical is used as a degreaser or a "clear protective coating spray" in the arts and crafts field.[29] The draft risk assessment identified "potential concern for human health under specific exposure scenarios for particular uses."

- For the two chemicals for which EPA has yet to release draft risk assessments, EPA plans to focus primarily on releases to the environment from the processing and use from metalworking fluids and plastics/rubber (PVC) compounding.[30]

It is also not clear where EPA will obtain and who will develop the toxicity assessments needed to support its planned risk assessments—for example, whether IRIS toxicity assessments will be used, in whole or in part, or if some other type of assessment will be developed or used. According to EPA officials with the Office of Pollution Prevention and

[27]Antimony trioxide (ATO) as a synergist in halogenated flame retardants; and 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta-[γ]-2-benzopyran (HHCB) as a fragrance ingredient in commercial and consumer products.

[28]Methylene chloride or dichloromethane (DCM) and n-methylpyrrolidone (NMP) in paint stripper products.

[29]Trichloroethylene (TCE) as a degreaser and a spray-on protective coating.

[30]Medium and long chain chlorinated paraffins.

Toxics, they plan to incorporate information from IRIS toxicity assessments to the extent such information is available, recent, and relevant. For example, two of the three draft risk assessments discussed above that focused on human health hazards incorporated information from IRIS toxicity assessments, according to agency officials.[31] However, as we have reported previously,[32] IRIS toxicity assessments are not available or current for many chemicals, including many of the remaining chemicals in the TSCA Work Plan. Officials with the Office of Pollution Prevention and Toxics have not requested IRIS assessments through the formal IRIS nomination process for any of the 83 chemicals prioritized for risk assessment in the TSCA Work Plan but, according to IRIS program officials, they are working to find other options for assessing toxicity when IRIS assessments are not available, recent, or applicable. According to officials with the Office of Pollution Prevention and Toxics, they have not requested IRIS assessments for these 83 chemicals because IRIS toxicity assessments often take years to complete, among other reasons. In addition, these officials noted that IRIS assessments are generally used to estimate risks associated with continuous exposures to a pollutant in the air or water rather than the intermittent exposures that workers and consumers are subject to from chemicals contained in products.[33] While IRIS toxicity assessments are not essential for conducting a risk assessment, EPA officials have described IRIS assessments as the premier national and international source for qualitative and quantitative chemical risk information. In addition, no other federal toxicity assessment

[31]According to EPA officials, the IRIS program is charged with evaluating chronic hazard potential including hazard identification and dose response information for cancer and noncancer outcomes. Many of the chemical uses and particularly the consumer uses are acute and short term in nature. In most cases, the information used to develop the dose-response assessments is based on intermittent exposures to workers or animals in a controlled environment. IRIS assessments include an adjustment to continuous exposure in the derivation of toxicity values. Often data are available in IRIS for shorter term exposures scenarios that have long-lasting/ persistent effects (e.g., development toxicity). In these cases, evaluation of hazard and dose response information described in an IRIS assessment is useful.

[32]GAO-08-440.

[33]This focus is consistent with the fact that media-specific environmental laws such as the Clean Air Act and Clean Water Act are available to limit the concentration of contaminants in water or the ambient air, and TSCA generally requires EPA to defer action to such other laws. However, information on such continuous exposures is still critical for regulation under TSCA. For example, to promulgate a rule under section 6 of TSCA, EPA must establish the effects of a chemical on health and the environment and the magnitude of the exposure of human beings and the environment to such a chemical.

program has internal and external peer-review processes that are as rigorous according to EPA's recent *Human Health Risk Assessment Strategic Research Action Plan*.[34] The rigor associated with an IRIS assessment may be an important consideration in defending regulations that ban or limit the use of a chemical.

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

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, EPA officials told us that the agency generally considers section 6 authority only after exhausting all other available options. As such, since 2009, EPA has taken other actions that may discourage the use of certain chemicals by (1) making greater use of significant new use rules under section 5 and (2) proposing actions that use its TSCA authority in new ways. However, it is too early to tell whether some of these actions will reduce chemical risks.

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. According to EPA officials, for chemicals subject to significant new use rules, EPA typically recommends that companies submit testing information when they notify EPA of their intent to manufacture or process chemicals subject to such rules, 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. One industry stakeholder told us that while EPA has not directly regulated chemicals through significant new use rules, EPA's use of these rules has deterred companies from pursuing new uses of these chemicals.

[34]EPA Office of Research and Development, *Human Health Risk Assessment Strategic Research Action Plan 2012-2016* (June 2012), 15.

EPA has also proposed actions that use its TSCA authority in new ways and that, according to agency officials, are intended to discourage the use of certain chemicals that may pose health or environmental risks. 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, the Office of Management and Budget (OMB) has not met the established 90-day time for reviewing EPA's proposed actions—which has increased the time frames for finalizing them.[35] These proposed actions include 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 OMB in May 2010.[36] Although the period for OMB review is generally limited by executive order to 90 days,[37] as of December 2012, EPA's proposed "chemicals of concern" list has been under review at OMB for over 900 days. Stakeholders we interviewed had differing perspectives on EPA's proposed use of this list. One said that EPA did not assert clear criteria for a chemical's inclusion on the list and that being on the list has the effect of blacklisting a chemical and negatively impacting the market. Alternatively, another stakeholder we spoke with said that the list is analogous to the European Union's candidate list, which acts to provide companies sufficient time to respond to possible future regulation. The list thus gets the market moving to either defend the safety of the chemical or to get the chemical out of production.

[35]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.

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

[37]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.

- *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 Polybrominated Diphenyl Ethers (PBDE)—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. As of January 2013, this rule has yet to be finalized.

- *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 exempted from compliance with a significant new use rule. EPA's proposals would eliminate this exemption for certain chemicals.[38] Some stakeholders stated that the move to eliminate the article exemption for certain chemicals represents an attempt by EPA to regulate consumer products, not just the chemical substances they contain. Other stakeholders noted that EPA's ability to regulate potentially harmful chemicals is diminishing given their increased production outside of the United States, and that an increasing focus on articles allows EPA

[38]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.

to minimize exposure to potentially harmful chemicals by targeting chemicals in imports as part of consumer products.[39]

EPA Has Expanded Public Access to Some Chemical Information

EPA has made progress in expanding public access to some chemical information—which according to EPA documents is an important underpinning of a credible chemical management program. When information is claimed as confidential business information, it limits EPA's ability to share it with state environmental agencies and foreign governments, which potentially limits the effectiveness of these organizations' environmental risk programs. Since 2009, EPA has made 617 formerly confidential chemical identities public.[40] By reviewing past claims of confidentiality and comparing them with more current reporting—such as reporting of periodic production and use data—EPA was able to identify chemicals for which companies were no longer making confidentiality claims. Since 2009, EPA has also made 783 previously unavailable health and safety filings available to the public after reviewing approximately 15,500 such filings.[41] In addition, EPA issued new policies regarding how it handles confidentiality claims and, according to EPA officials, has begun reviewing and challenging new confidentiality claims—including claims associated with chemical identity information listed on the TSCA inventory and in health and safety

[39]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.

[40]Chemical identity is a name that uniquely identifies a chemical. This can be a name in accordance with the nomenclature systems of, for example, the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS).

[41]EPA determined that many of the identified health and safety filings (1) were misidentified as having confidentiality claims for the chemical name or as being or containing health and safety studies, (2) had valid confidentiality claims for the chemical name, or (3) contained claims that were considered invalid under the law.

studies.[42] Further, as part of the 2011 Chemical Data Reporting rule, EPA included new upfront substantiation requirements for CBI claims related to processing and use information. According to EPA, the change has resulted in significantly decreased CBI claims for those data.

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

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 that might impede its goal of ensuring chemical safety. Specifically, and as detailed in the list that follows, EPA's strategy does not discuss challenges associated with (1) obtaining toxicity and exposure data; (2) identifying the resources needed to execute EPA's new approach; and (3) banning or limiting the use of chemicals, given the agency's past difficulties with taking such actions.

- *Obtaining toxicity and exposure data*. EPA's strategy does not discuss how the agency will meet the challenge of obtaining the toxicity and exposure data it will need for conducting risk assessments for all 83 chemicals in its TSCA Work Plan. As discussed previously, EPA has not broadly sought toxicity and exposure data that companies submit to the European Chemicals Agency or exposure-related data from chemical processors and instead plans to obtain these data, as needed, on a 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 its ongoing or future risk assessment activities, if at all.

[42]The first policy, published in January 2010, involves confidentiality claims related to chemical identities included in health and safety studies submitted under section 8(e) of TSCA. Under this policy, when the agency receives a health and safety study for a chemical already listed on the public portion of the TSCA inventory, it will not accept a claim that the identity of the chemical is confidential. The second policy, published in May 2010, involves confidentiality claims related to chemical identities and data included in health and safety studies more generally. Under this policy, EPA does not extend confidential treatment to health and safety studies or data contained in health and safety studies unless the studies or data reveal (1) processes used in making the chemical or (2) the portion of the chemical in a mixture.

- *Identifying the resources needed.* EPA's strategy does not include a description of the resources needed to meet its goal of ensuring chemical safety. For example, EPA's strategy does not include a description of 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. In response to our questions regarding resources, EPA officials provided us with an estimate of the staffing levels and contract support costs needed to conduct its first 7 risk assessments; however, EPA does not include this or any other information regarding staffing levels or cost in its strategy.[43] As discussed previously, at its current pace—which it may not be able to sustain—it will take more than a decade for EPA to complete the 83 risk assessments it has identified in its TSCA Work Plan. However, EPA officials were unable to tell us—and EPA strategy does not discuss—whether the agency has the capacity to accelerate the pace of its risk assessment activities. Further, the plan does not discuss how EPA will keep pace with the introduction of approximately 600 new chemicals each year, some of which may require risk assessments to determine whether they pose risks to health or the environment. 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.

- *Banning or limiting the use of chemicals.* EPA's strategy also does not discuss how it will address specific regulatory challenges that might impede the agency's ability to meet its goal of ensuring chemical safety. According to EPA officials, to demonstrate that a chemical presents or will present an unreasonable risk of injury to health or the environment—which would be required before EPA could ban or limit

[43]In August 2012, EPA provided us with an estimate that stated that it needed 17.5 full-time EPA staff and about $800,000 in contractor support to prepare the 7 risk assessments; it needed an additional $160,000 per chemical to support contractor peer reviews. According to EPA officials, they will be in a better position to provide an accounting of expenditures toward the end of fiscal year 2013.

the chemical under section 6 of TSCA—EPA must develop or obtain toxicity and exposure data and then conduct a risk assessment. However, EPA officials told us that, even if EPA has substantial toxicity and exposure data and wants to protect the public against known risks, the agency is challenged in meeting the statutory requirement under TSCA to limit or ban chemicals. While agency planning documents related to EPA's new approach state that it would consider using its authority under section 6 of TSCA to limit or ban the use of some chemicals, EPA has yet to publicly take steps toward that end and has not articulated, in its strategy or elsewhere, how it would overcome the regulatory challenges it experienced in the past. As discussed previously, EPA officials told us that they would consider using the agency's authority under section 6 only after exhausting all other available options, but EPA's strategy does not discuss what other options the agency plans to pursue—for example, whether it plans to continue to rely on significant new use rules under section 5 of TSCA to discourage the use of certain chemicals. As a result, EPA cannot be assured that its new approach best positions the agency to ensure the safety of chemicals.

We have previously reported[44] that, when developing new initiatives, agencies can benefit from following leading practices for federal strategic planning.[45] 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.[46] Without a plan that

[44]GAO, *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct. 6, 2011); GAO, *Environmental Protection: EPA Should Develop a Strategic Plan for Its New Compliance Initiative*, GAO-13-115 (Washington, D.C.: Dec. 10, 2012).

[45]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.

[46]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. For example, see GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, GAO/GGD-96-118 (Washington, D.C.: June 1, 1996); GAO, *Tax Administration: IRS Needs to Further Refine Its Tax Filing Season Performance Measures*, GAO-03-143 (Washington, D.C.: Nov. 22, 2002); and GAO, *Managing for Results: Strengthening Regulatory Agencies' Performance Management Practices*, GAO/GGD-00-10 (Washington, D.C.: Oct. 28, 1999).

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.

Conclusions

Since 2009, EPA has made progress implementing its new approach to managing toxic chemicals under its existing TSCA authority—particularly by increasing efforts to obtain toxicity and exposure data. However, due to requirements under TSCA that place the burden of developing toxicity data on EPA, rather than industry, and because promulgating the rules needed to obtain toxicity data from companies can take years to finalize, and additional time for companies to execute, EPA has yet to obtain much of the toxicity data it has been seeking. Also, EPA is in the process of analyzing exposure-related data it received in August 2012 and, therefore, is not yet in a position to use them to identify additional data collection needs or identify chemicals that may warrant further review or risk assessment. Moreover, while EPA's toxicity and exposure data collection efforts may be useful for identifying chemicals that are potentially harmful, it is unclear whether these data will be sufficient for conducting a risk assessment. According to EPA officials, EPA needs both toxicity and exposure data to conduct a risk assessment in order to demonstrate that a chemical presents or will present an unreasonable risk of injury to health or the environment—which would be required before EPA could ban or limit the use of a chemical under TSCA.

Even with the steps it has taken since 2009 to increase the toxicity and exposure data it collects, EPA has not pursued all opportunities to obtain chemical data. In particular, EPA has not sought (1) toxicity and exposure data that companies submit to the European Chemicals Agency or (2) generally pursued exposure-related data from chemical processors. That is, EPA has not pursued a formal agreement with the European Community or used its authority to promulgate rules under TSCA section 8 to require chemical companies to report chemical toxicity and exposure-related data they have submitted to the European Chemicals Agency. EPA has also not promulgated rules under TSCA section 8 to require chemical companies to report exposure-related data from processors to EPA. EPA officials said that they recognized that rules under section 8 of TSCA could be fashioned in such a way as to establish general access to

information while also providing EPA with the flexibility to request the information as needed—but were considering a different approach. Agency officials told us that they have considered using EPA's subpoena authority under TSCA section 11(c) to obtain the information—which is an approach EPA has not frequently used before. Regardless of the mechanism used, without access to the data that companies have submitted to the European Chemicals Agency and by not pursuing exposure-related data from processors, EPA is missing an opportunity to collect data that it has identified as an essential part of assessing chemical risk and future chemical regulation.

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 because EPA has not clearly articulated how its strategy will address challenges that threaten an agency's ability to meet its goal—particularly, challenges associated with obtaining toxicity and exposure data needed for risk assessments and with EPA's ability to ban or limit the use of chemicals, given the agency's past difficulties with taking such actions. EPA officials have said that the agency's approach, 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 does not include leading federal strategic planning practices, such as defining strategies for addressing management challenges that might help the agency achieve its goal of ensuring the safety of chemicals. For example, EPA's strategy does not address challenges associated with (1) obtaining toxicity and exposure data for the 58 TSCA Work Plan chemicals for which it currently needs such data, (2) gaining access to toxicity and exposure data provided to the European Chemicals Agency, (3) working with processors and processor associations to obtain exposure-related data, (4) addressing specific regulatory challenges with banning or limiting the use of chemicals under section 6 of TSCA, and (5) identifying the resources needed to achieve its goal.

It is worth noting that many of the challenges that EPA faces are rooted in TSCA's regulatory framework. 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; in addition, we have identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA. Until Congress passes any such legislation, however, EPA can do more to improve its

current effort to help bring the agency closer to achieving its goal of ensuring the safety of chemicals.

Recommendations for Executive Action

To better position EPA to collect chemical toxicity and exposure-related data and ensure chemical safety under existing TSCA authority, while balancing its workload, we are recommending that the Administrator of EPA take the following three actions:

- 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.
- Consider promulgating a rule under TSCA section 8, or take action under another section, as appropriate, to require chemical companies to report exposure-related data from processors to EPA.
- To better position EPA to ensure chemical safety under existing TSCA authority, direct the appropriate offices to develop strategies for addressing challenges that impede the agency's ability to meet its goal of ensuring chemical safety. At a minimum, the strategies should address challenges associated with:
    - obtaining toxicity and exposure data needed to conduct ongoing and future TSCA Work Plan risk assessments,
    - gaining access to toxicity and exposure data provided to the European Chemicals Agency,
    - working with processors and processor associations to obtain exposure-related data,
    - banning or limiting the use of chemicals under section 6 of TSCA and planned actions for overcoming these challenges—including a description of other actions the agency plans to pursue in lieu of banning or limiting the use of chemicals, and
    - identifying the resources needed to conduct risk assessments and implement risk management decisions in order to meet its goal of ensuring chemical safety.

Agency Comments and Our Evaluation

We provided a draft of this report to the Environmental Protection Agency for their review and comment. We received written comments from the Acting Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention. These comments and our detailed response to them are presented in appendix II. EPA also provided technical comments, which we incorporated into the report as appropriate.

In its written comments, EPA neither agreed nor disagreed with our findings and recommendations and instead stated that it appreciated the intent of our recommendations and will consider them as it further develops and implements the TSCA program. However, based on the comments the agency provided, it is unclear whether EPA intends to take any action toward implementing our recommendations. Specifically, it is unclear whether EPA plans to address our recommendations that the agency consider promulgating rules under TSCA section 8, or take action under another section, as appropriate, to require chemical companies (1) to report chemical toxicity and exposure-related data they have submitted to the European Chemicals Agency and (2) to report exposure-related data from processors to EPA. In its written comments, EPA states that it intends to pursue data submitted to the European Chemicals Agency from U.S. companies using voluntary or regulatory means as necessary but does 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. For example, it is not clear whether EPA intends to first ask companies to voluntarily comply with their data request and then, if that does not yield data, pursue regulatory action. In addition, it is unclear whether continuing to rely on voluntary efforts will provide the agency with timely access to needed data. As we noted in our report, EPA officials have recognized that rules under section 8 of TSCA could be fashioned in such a way as to establish general access to information while providing EPA with the flexibility to request the information as needed.

In addition, with regard to obtaining data from chemical processors, in its written comments, EPA states that downstream chemical processors have little exposure-relevant data—which suggests that it does not intend to implement that recommendation. This position, however, conflicts with previous statements by EPA officials and 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 told us 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. EPA officials also told us that these data are necessary to conduct chemical risk assessments and make risk management decisions on potentially harmful chemicals. In its written comments, EPA also states that the use of section 8 requires a lengthy and resource intensive rulemaking process. However, as previously noted, EPA officials have recognized that a rule under section 8 of TSCA could be promulgated to require chemical companies to report exposure-related data while also providing EPA with the flexibility to request the data as needed. In this way, should EPA identify a need for information from downstream processors, EPA would not have to go through the lengthy rulemaking process multiple times.

Regarding our recommendation to develop strategies for addressing challenges associated with obtaining toxicity and exposure data needed for risk assessments, and with EPA's ability to meet its goal of ensuring chemical safety, it is also unclear what action, if any, EPA intends to pursue. In its written comments, the agency states that it will not be able to meet the goal of ensuring chemical safety now and into the future without legislative reform and, until then, EPA plans to utilize its *Existing Chemicals Program Strategy*. However, as discussed in this report, EPA's *Existing Chemicals Program Strategy*, which largely focuses on describing activities the agency is already undertaking and is therefore backward-looking, does not provide the framework needed to guide EPA's efforts into the future. We recognize that many of the challenges that EPA faces are rooted in TSCA but continue to believe that, without a plan that 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 will provide a framework to effectively guide its efforts. Consequently, EPA could be investing valuable resources, time, and effort without being certain that its investments will bring the agency closer to achieving its goal of ensuring the safety of chemicals.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Administrator of EPA, the appropriate congressional committees, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have questions regarding this report, please contact me at (202) 512-3841 or trimbled@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.

David C. Trimble
Director, Natural Resources and Environment

Appendix I: Scope and Methodology

This report focuses on the Environmental Protection Agency's (EPA) management of chemicals within the limits of its existing authorities under the Toxic Substances Control Act (TSCA). Our objectives were to determine the extent to which (1) EPA has made progress implementing its new approach to managing toxic chemicals under its existing TSCA authority, and (2) EPA's new approach positions the agency to achieve its goal of ensuring the safety of chemicals.

To determine the extent to which EPA has made progress implementing its new approach to managing toxic chemicals under its existing TSCA authority, we focused on EPA's new initiatives to manage chemicals beginning in September 2009.This was the date that EPA's Administrator announced that the agency was pursuing a comprehensive approach to enhance EPA's current chemicals management program within the limits of existing authorities. We identified and reviewed documents associated with activities that EPA identified as being part of its new approach, including the agency's Chemical Action Plans for 10 chemicals or chemical categories, its February 2012 *Existing Chemicals Program Strategy,* and March 2012 TSCA Work Plan and associated TSCA Work Plan Methods document. We also reviewed documents, including *Federal Register* Notices, and interviewed agency officials, with respect to EPA's efforts to obtain test data for High Production Volume Challenge chemicals. We reviewed applicable legislation, including the relevant sections of TSCA; relevant federal regulations; and EPA's policies and procedures on EPA's existing and new chemical programs. We analyzed TSCA rulemaking trends from January 2001 through October 2012. We selected this time frame to include a time period prior to and after the announcement of EPA's new approach to managing chemicals to see how rulemaking changed over this time period. In our report, we only present findings from 2009 to 2012 when the majority of the rulemaking activity took place. To identify TSCA rules that were issued, we searched online sources, including *Federal Register* Notices and the information available from the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA). We then analyzed proposed, final, and direct final rules exclusive of rule revocations, technical modifications, and withdrawals for rulemakings deriving from the implementation of Title I of TSCA. We excluded rules deriving from the implementation of other titles of TSCA from this rulemaking analysis as they derive from separate provisions or later amendments to TSCA; they are chemical-specific provisions that have specific rulemaking requirements and deadlines. From the list of identified TSCA rules, we determined frequencies of TSCA rulemaking by TSCA section; for example, we determined the number of proposed and final significant new

use rules under TSCA section 5, as well as the number of chemicals subject to these rules. We also analyzed such frequencies before and after 2009, which was when EPA announced its new approach to managing chemicals. As part of our rulemaking analysis, we also examined EPA's Action Development Process (ADP) and interviewed officials from EPA's Office of Policy, Office of Chemical Safety and Pollution Prevention (OCSPP), and Office of Pollution Prevention and Toxics (OPPT) on how individual TSCA rules are developed. We obtained and reviewed EPA's regulatory plans and agendas from 2011, to determine if TSCA rules were expected to be issued in proposed or final form during this period. We also reviewed Executive Order 12866 to characterize EPA's and OMB's processes for submitting and reviewing TSCA rules, respectively. In addition, we reviewed EPA's efforts, through discussions with EPA officials, and by reviewing recently issued policies, on confidential business information claims.

To determine the extent to which EPA's new approach positions the agency to achieve its goal of ensuring the safety of chemicals, we reviewed EPA's *Existing Chemical Program Strategy* , which EPA identified as the document that it intends to use to guide its current and future efforts, and compared it against leading practices in federal strategic planning, which include practices such as developing strategies to address challenges that may threaten the agency ability to achieve its goal including identifying the resources needed to achieve agency goals.[1] To further characterize how EPA is positioning itself to assess and control chemicals, we asked EPA officials to describe expected outcomes from EPA's recent rulemakings, for example, the extent to which TSCA rules would position EPA to obtain chemical data and reduce chemical risks. We also obtained documents and interviewed EPA officials on the agency's processes for screening existing chemicals to identify those requiring further review or a risk assessment. We also requested and obtained information on EPA's resource levels to carry out this work—particularly related to the resources required to conduct risk assessments indentified in its TSCA Work Plan. We reviewed EPA estimates on the costs and staff levels for performing such risk assessments.

For both objectives, we interviewed officials with EPA's Office of Chemical Safety and Pollution Prevention, including its Office of Pollution

[1]GAO-12-77 and GAO-13-115.

Prevention and Toxics (OPPT), the office with primary responsibility for implementing TSCA, regarding EPA's efforts to manage chemicals. Specifically, we interviewed officials across OPPT's divisions about how EPA obtains chemical data, analyzes existing chemicals, and conducts risk assessments, as well as agency reviews of new chemicals and new uses of existing chemicals, reviews of claims of confidential business information, and the process of promulgating rules under TSCA. We also interviewed officials from EPA's Office of Research and Development relating to EPA's development and use of new analytical methods and tools. In addition, we interviewed representatives from industry, including the American Chemistry Council (a national chemical manufacturers association); the Society of Chemical Manufacturers and Affiliates (a national, specialty chemical manufacturers association); American Fuel & Petrochemical Manufacturers (a trade association representing high-tech American fuel manufacturers); Consumer Specialty Products Association (a trade association representing companies manufacturing various cleaning products); Bergeson & Campbell, P.C. (a law firm that represents chemical manufacturers); and Greenwood Environmental Counsel (a law firm). We also interviewed other stakeholder groups, including the Environmental Defense Fund (a national, nonprofit environmental advocacy organization); Safer Chemicals, Healthy Families (a coalition of individuals, health professionals, advocates for people with learning and developmental disabilities, reproductive health advocates, environmentalists and businesses); and the Environmental Law Institute (a nonpartisan research and education center working to strengthen environmental protection by improving law and governance worldwide. We selected these stakeholder groups based on discussions with other stakeholders and our prior work on TSCA.[2] We sought to achieve a balance of perspectives between groups representing industry and those representing the environment.

To assess the reliability of EPA's data related to the types and numbers of TSCA rules promulgated, data from EPA on rules under OMB review over 90 days, and data on the number of chemicals regulated under TSCA and the number of chemicals under assessment, we reviewed relevant documents and interviewed knowledgeable agency officials. We worked with the EPA to ensure that we had the most updated data and, in

[2]GAO-05-458 and GAO, *EPA Should Focus Its Chemical Use Inventory on Suspected Harmful Substances*, GAO/RCED-95-165 (Washington, D.C.: July 7, 1995).

consultation with the EPA officials, revised the numbers of chemicals listed for commercial use under TSCA and the numbers of filings to reflect the most updated numbers. Based on this review and our discussions with the EPA officials, we concluded that the data were sufficiently reliable for the purposes of reporting on rulemaking trends and the numbers of chemicals listed with EPA for commercial use as authorized under TSCA.

We conducted this performance audit from December 2011 to March 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Comments from the Environmental Protection Agency

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 13 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. David C. Trimble
Director, Natural Resources and Environment
Government Accountability Office
Washington, DC 20548

Dear Mr. Trimble:

Thank you for the opportunity to comment on the draft report entitled "EPA Has Increased Efforts to Address and Control Chemicals but Could Strengthen Its Approach (GAO-13-249)." Our comments include input from other relevant parts of the Environmental Protection Agency (EPA). Below are our general comments on the report and its recommendations. Our technical comments will be sent via email to your staff.

We appreciate the significant amount of time GAO staff spent on this audit, and their efforts to learn the intricacies of the Toxic Substances Control Act (TSCA) and the associated EPA program that implements the statute. The report, in general, does a good job of reflecting the challenges EPA faces in implementing TSCA. We also appreciate that the report recognizes the Agency's efforts over the past few years to strengthen our existing chemicals program and make information on chemicals more readily available. As the report indicates, it may take some time before the results of our efforts come into fruition and can truly be evaluated.

EPA appreciates the intent of GAO's recommendations with respect to improving the chemicals program under the current TSCA legislative framework, and we will consider them as we further develop and implement the program. We must emphasize, however, that EPA cannot be fully successful in ensuring the safety of chemicals absent statutory reform, for reasons discussed by GAO in previous reports and as addressed by the Administration's principles for TSCA reform.

Recommendations

(EPA should) 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.

See comment 1.

The EPA agrees that duplicative testing of chemicals should be avoided and existing, valid data be reviewed and used whenever possible. As our technical comments reflect, we do not believe the report adequately addresses the efforts EPA has made to work with the European Chemicals Agency to receive chemical data, or the challenges that we have faced in doing so. I assure you that as the EPA identifies needs for REACH-generated data (e.g., for use in risk assessments, for use in screening and prioritization), the Agency intends to pursue obtaining these data from U.S. companies using voluntary or regulatory means as necessary.

(EPA should) Consider promulgating a rule under TSCA section 8, or take action under another section, as appropriate, to require chemical companies to report exposure-related data from processors to EPA.

See comment 2.

The EPA agrees that obtaining current, valid information on the use of, and exposure to, chemicals "downstream" from chemical manufacturers and processors is a significant challenge. While TSCA does provide EPA with the authority to require data from processors, these entities are not always the end users of chemicals or those which incorporate them into commercial or consumer products. Those companies that are end users of chemicals or incorporate them into products often have little exposure-relevant data. Also, as with other data gathering authorities under TSCA, use of section 8 requires a lengthy and resource intensive rule-making process. The EPA is, nonetheless, committed to working toward improving the quality and quantity of use and exposure information available to it for chemical assessment and, as specific needs are identified, will consider both voluntary and regulatory means as necessary. Earlier this year, EPA made public the 2012 Chemical Data Reporting (CDR) information that contains comprehensive use and exposure information on more than 7500 of the most widely used chemicals in the U.S. Companies are now required to provide information on chemicals used in children's and other consumer products, along with reports on commercial applications and industrial uses of chemicals. This information will help EPA and others better assess chemicals, evaluate potential exposures and use, and expand efforts to encourage the use of safer chemicals.

To better position EPA to ensure chemical safety under existing TSCA authority, direct the appropriate offices to develop strategies for addressing challenges that impede the agency's ability to meet its goal of ensuring chemical safety.

See comment 3.

As the report notes, "many of the challenges that EPA faces are rooted in TSCA's regulatory framework" and, in past reports, GAO has suggested that Congress consider making statutory changes to strengthen EPA's authority to obtain information from the chemical industry and establish a framework for taking action that is less burdensome for EPA. It is EPA's position that, absent such statutory changes, the Agency will not be able to successfully meet the goal of ensuring chemical safety now and into the future. The Administration's principles for TSCA reform reflect the basic changes that we believe are necessary to a fully successful program. Change is needed in every significant aspect of the program which GAO has addressed in this and previous reports. Strategic planning is a useful exercise, but cannot substitute for the basic authorities needed for a modern, effective chemicals program. However, until legislative reform takes place, EPA developed and is utilizing an Existing Chemicals Strategy that outlines the Agency's comprehensive approach for prioritizing chemicals for risk assessment and risk reduction, increasing the public's access to chemical data and information, and advancing innovation for safer products and green chemistry. This effort includes the development of a TSCA Work Plan of chemicals for risk assessment development over the coming years, further targeting the agency's efforts on existing chemicals. Following stakeholder engagement, EPA released the Work Plan in March 2012, and identified seven chemicals for risk assessment in 2012. In June, 2012, the agency identified 18 chemicals slated for risk assessment in 2013 and 2014.

The Agency remains committed to continuing improvement of the TSCA program implemented under the current statutory framework and will continue to develop and implement the most effective approaches possible given our current statutory and resource limitations. If you have any questions or concerns regarding our comments, we would be pleased to meet with you prior to GAO finalizing this report. Please feel free to contact me or Janet Weiner of my staff at 202-564-2309 if there is any additional follow up required.

Sincerely,

James J. Jones
Acting Assistant Administrator

The following are GAO's comments on the letter from the Environmental Protection Agency dated March 13, 2013.

GAO comments

1. According to EPA officials, EPA has an agreement for cooperation and sharing of information (referred to as a Statement of Intent) with the European Chemicals Agency. EPA had hoped that this agreement would allow for the sharing of detailed studies beyond the summaries that the European Chemicals Agency makes publically available. However, the European Union's chemicals legislation requires a formal agreement be concluded between the European Community and the foreign government before the European Chemicals Agency may share information it receives from chemical companies, and EPA has not pursued such an agreement. While EPA has stated that the agency intends to pursue these data from U.S. companies using voluntary or regulatory means, as necessary, and notes that it has solicited and received some such data, EPA has yet to pursue comprehensive action. As we noted in our report, EPA officials have recognized that rules under section 8 of TSCA could be fashioned in such a way as to establish general access to information while also providing EPA with the flexibility to request the information as needed.

2. We recognize that rulemaking is a long and resource-intensive process but as previously noted, EPA officials have recognized that EPA could promulgate rules under section 8 of TSCA to require chemical companies to report exposure-related data while also providing EPA with the flexibility to request the information as needed. In this way, EPA would not have to go through the lengthy rulemaking process each time it identifies a need for information from downstream processors. In addition, it is unclear why EPA has stated that downstream chemical processors have little exposure-relevant data. This position conflicts with previous statements by EPA officials and 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 told us that data from downstream processors would provide the agency with a better understanding of potential exposure to chemicals, for example, from consumer products such as those designed for children. EPA officials also told us that these data are necessary to conduct chemical risk assessments and make risk management decisions on potentially harmful chemicals.

3. We do not believe that EPA's *Existing Chemicals Program Strategy*, which largely focuses on describing activities EPA has already begun and is therefore backward-looking, provides the framework needed to guide EPA's efforts into the future. We recognize that many of the challenges that EPA faces are rooted in TSCA but continue to believe that, without a plan that 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 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.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

David C. Trimble, (202) 512-3841 or trimbled@gao.gov

Staff Acknowledgments

In addition to the individual named above, Diane LoFaro, Assistant Director; Antoinette Capaccio; Irina Carnevale; Pamela Davidson; Les Mahagan; Alison O'Neill; Aaron Shiffrin; and Kiki Theodoropoulos made key contributions to this report. Richard Johnson also made important contributions.

Related GAO Products

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

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

Chemical Regulation: Actions Are Needed to Improve the Effectiveness of EPA's Chemical Review Program. GAO-06-1032T. Washington, D.C.: August 2, 2006.

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*Toxic Substances: EPA Should Focus Its Chemical Use Inventory on Suspected Harmful Substance*s. GAO/RCED-95-165. Washington, D.C.: July 7, 1995.

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