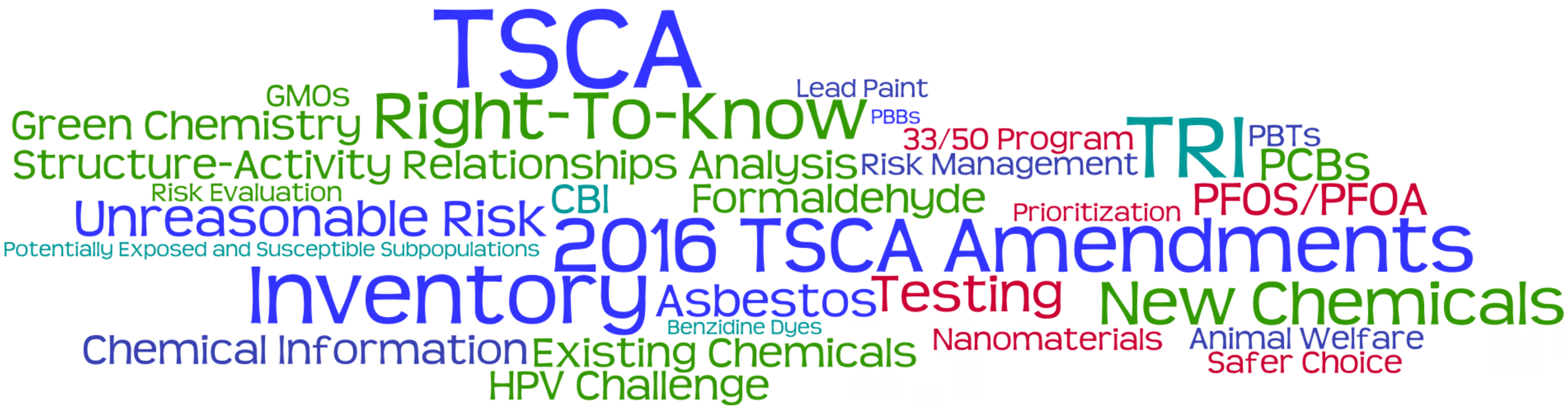
# Toxic Substances

## *A Half Century of Progress*




EPA Alumni Association

**April 2020**

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**Preface**

Former managers and staff of the U.S. Environmental Protection Agency (EPA) have formed an EPA Alumni Association (EPA AA). The Association has developed this and six other web-based environmental reports in support of our *Half Century of Progress* project. An integrated summary based on all of these reports, ***Protecting the Environment: A Half Century of Progress***, is available on the Association website. The Association has developed these materials to inform high school and college students and other members of the public about the major environmental problems and issues encountered in the United States in the 1960s and 70s and the actions taken and progress made in mitigating these problems over the last half-century. We also want to highlight continuing and emerging environmental challenges we face today. We hope that, besides summarizing the history of U.S. environmental programs, these reports might inspire some students and others to consider careers in the environmental field.

A number of retired EPA program managers and subject matter experts worked together to produce the first editions of these reports in 2016. Additional experts have updated these documents in 2020 in recognition of the 50th anniversary of Earth Day and the creation of the EPA. This updated report has been reviewed by relevant members the EPA AA Board of Directors and other alumni. We welcome comments on this document, which you may provide at this EPA Alumni Association link.

The Association has also produced a *Teacher's Guide* to facilitate the use of these materials by educators interested in including the *Half Century of Progress* in high school and college curricula. The *Guide* contains data interpretation and other questions related to the report topics, with answers. It also includes activities that challenge students to learn more about environmental issues in their communities, web-based resources for additional activities, and three lesson plans related to the HCP materials. These plans were designed and tested by three AP Environmental Science Teachers. Teachers may request a copy here.

# PUBLIC CONCERNS LEAD TO CHEMICAL LAWS[1]

In the 1960s and early-to-mid 1970s, new reports of cancer caused by chemicals appeared in the press or on TV almost every month. Polychlorinated biphenyls (PCBs), used in electrical transformers for over 40 years, were being found in fish and environmental samples from around the country.[2] Other chemicals, including those not thought to be harmful, caused serious health or environmental effects. Chlorofluorocarbons (CFCs) were depleting the earth's protective ozone layer.[3] Asbestos, a mineral fiber widely used in insulation, caused lung cancer, especially in workers.[4] Polybrominated biphenyls (PBBs) used as flame retardants were mistakenly mixed into animal feed and poisoned people and cattle in Michigan.[5] Eating fish contaminated with mercury caused a severe neurological syndrome in adults and birth defects in Minamata, Japan,[6] and the list went on.

**PBB Found In Mother's Milk**

Preliminary scientific reports have found traces of PBB in mother's milk, the state health director revealed last week.

Dr. Maurice Reizen, state health director, said that 22 samples of milk taken from 26 nursing mothers in Michigan contained PBB, the substance that was identified as the cause of death for several thousand cattle in the state during 1973 and 1974.

PBB–polybrominated biphenyls –is a fire-retardant chemical that was accidently mixed with cattle feed and sold to farmers in the lower peninsula.

Because PBB is biologically magnified as it moves up the food chain, people eating PBB-contaminated food end up with a higher percentage of PBB than they actually consumed.

The level of PBB found in the breast milk of the women tested averaged 90 parts per billion (ppb), with the highest amount found reaching 500 parts per billion. The Food and Drug Administration allows food to be sold containing up to 300 ppb.

Because the study was actually done to find the level of pesticides in mother's milk, officials are not recommending the end of breast feeding as yet.

Reizen said a further study is now underway to determine the level of PBB in breast milk, and until the results are in he is recommending caution.

**Ann Arbor Sun newspaper clipping from 1976.**

Although society reaps enormous benefits from chemicals, there was little or no knowledge of the effects on health or the environment regarding the thousands of chemicals used and released into the environment. There was not even a list of the chemicals made and used in America. The drumbeat of concerns contributed to a growing realization that chemicals in the environment might cause major problems. People were suddenly aware that a man-made chemical environment of unknown dimensions literally surrounded them. Other studies pointed to the large gap in existing laws for dealing with these problems. During the 1970s, the groundswell of public concern resulted in legislative action.

## Congress Responds with TSCA

In 1971, the Nixon Administration's Council of Environmental Quality (CEQ) issued a report to Congress about the threat of toxic substances and called for the enactment of a new law—the *Toxic Substances Control Act* (TSCA)—to address the problem.[7] CEQ's report concluded that then-existing programs of the relatively new U.S. Environmental Protection Agency (EPA) were inadequate to protect the public from the multiple pathways of exposure (air,

water, soil, food, industrial products, consumer products) to toxic substances. It further noted the need for a preventive approach, stating "We should no longer be limited to repairing damage after it has been done; nor should we continue to allow the entire population or the entire environment to be used as a laboratory."[8] However, the Administration's proposal encountered opposition from industry and environmental groups, and a long stalemate ensued. In 1976, when Congress was adjourning in an election year, it agreed to a number of compromises and TSCA passed into law.[9]

As originally enacted, TSCA gave EPA broad authority to gather information and require testing on chemicals. The new law required EPA to create a National Inventory listing the *existing chemicals* in commerce, along with a duty for chemical manufacturers to submit notifications of *new chemicals* (i.e., chemicals not on the Inventory) to EPA for review before they would enter commerce. While TSCA did not specifically require EPA review of *existing chemicals*, it gave EPA authority to regulate the manufacture, importation, processing, distribution, use, and disposal of "chemical substances," a broadly defined term. The law also specifically directed EPA to phase out production and use of one class of chemical substances—PCBs—which had become a significant public concern. When TSCA passed into law EPA Administrator Russell E. Train stated that TSCA was "one of the most important pieces of 'preventive medicine' legislation" ever passed by Congress.[10]

TSCA, like the pesticides law discussed in the pesticides report in this series, differs from other EPA laws in that it focuses on chemicals in ***products*** rather than air or water pollution released from facilities. At the same time, TSCA's jurisdiction is much wider, touching a vast, diverse array of industrial, commercial, and consumer chemicals. These include solvents, dyes and colorants, polymers (used, for example, in plastics), cleaning products, paints and coatings, and chemicals employed in many other uses, including in the manufacture of toys, furniture, building materials, airplanes, automobiles, and industrial equipment.

In the years that followed enactment of TSCA, there were various Congressional oversight hearings and reports conducted by the General Accounting Office (GAO), now known as the General Accountability Office. Congress modified the statute several times, adding special provisions to address concerns about specific chemicals. Some of these additions established relatively modest regulatory requirements (such as reporting on mercury supply, use, and trade every three years). Other additions, like the *Residential Lead-Based Paint Hazard Reduction Act of 1992*, added a major new program to TSCA requiring EPA to set standards and certification requirements to address lead hazards in residential and child-occupied buildings. While these changes to TSCA expanded the range of EPA's activities to protect the public from toxic substances, the core elements of the original law were not comprehensively evaluated and changed until 2016.

Beginning in 2005, Congress undertook a comprehensive reconsideration of TSCA, motivated by EPA's long experience with implementation of the core TSCA provisions. This effort was driven by concerns from multiple stakeholders that the TSCA program had not met its potential. They believed it needed to be upgraded to better address the challenges of chemical management in the 21st century. Many of the proposed changes to TSCA highlighted long-standing issues marked by deep disagreements among stakeholders. For this reason, working out the differences proved controversial and difficult. Nonetheless, after 11 years of deliberations, agreement was eventually reached on a comprehensive set of legal reforms to the TSCA program. These were signed into law on June 22, 2016. The amendments to TSCA were given the title *Frank R. Lautenberg Chemical Safety for the 21st Century Act* in recognition of the most active Senate proponent of TSCA modernization.[11]

Senator Frank Lautenberg

The policy changes to EPA's chemical program made by the 2016 TSCA amendments are discussed more specifically in the next section of this report. The most important changes to the law were:

- The existing chemical program was transformed from a broad statutory authority to a structured program. This included processes for setting the program agenda, establishing policies for conducting risk assessments, and enhancing EPA's authority to collect information. The 2016 TSCA amendments also created deadlines for regulatory action, revised the legal standard for such action, and established an expedited process for regulating substances qualifying as persistent, bioaccumulative, and toxic (PBT) chemicals.[12]

**PBT chemicals combine three critical properties. They persist in the environment, bioaccumulate in living organisms AND cause significant toxicity. Well-known examples of PBT chemicals include PCBs and the pesticide DDT.**

- The new chemical program was revised to establish a new standard for safety and to require that EPA make an affirmative finding on the safety of a new chemical under review before it is allowed into commerce.
- A series of measures were added to the program to increase the public transparency of chemical information held by EPA. These measures included a more rigorous process for asserting and maintaining claims that information submitted

to EPA as confidential business information (CBI) should be withheld from public disclosure.[13] They also required a comprehensive review of the chemicals listed on the TSCA Inventory to determine whether CBI claims for the names of such chemicals are still warranted.

- EPA was given enhanced authority to collect fees from the chemical industry to support its review of new chemicals and implementation activities related to existing chemicals.

## Congress Establishes a Public Right to Know with EPCRA

In December 1984, the world's attention was drawn to the problem of chemical mismanagement when an accidental release of methyl isocyanate from a chemical plant in Bhopal, India, killed thousands of nearby residents. Less than a year later, another release of methyl isocyanate from a chemical plant in Institute, West Virginia, sent over 100 local residents to the hospital. Ironically, the West Virginia facility had recently upgraded its safety measures in the wake of the Bhopal disaster. In response to these events, Congress passed the *Emergency Planning and Community Right-to-Know Act* (EPCRA) in November 1986.[14] The law established a network of state and local emergency planning entities to facilitate more effective responses to chemical accidents. These planning efforts were supported by new requirements that industrial facilities report potential risks to local response authorities such as fire departments.[15]

In addition, EPCRA established a broader set of annual reporting obligations concerning chemical releases at commercial and industrial facilities, aimed at informing the public about potential risks in their communities. EPA was obligated to publish a Toxic Release Inventory (TRI) from this reported data, and to actively distribute this information to the general public.[16] This program was unique in EPA history. Previous information collection efforts had focused on supporting the Agency's own regulatory programs. In contrast, the TRI program was EPA's first initiative to collect information about chemicals for the primary purpose of sharing such information with the public. With this program, EPA helped establish a "public right to know" certain environmental information, a legal and policy approach which has grown over time. Visit https://www.epa.gov/trinationalanalysis for more information.

The core elements of the TRI program have remained in place since it began. Identified categories of facilities report release information on a specified set of TRI chemicals that they manufacture, process or use above certain thresholds in a calendar year. EPA is then obligated to share that information with the public "by computer telecommunications and other means."[17] In 1990, Congress enacted the *Pollution Prevention Act* (PPA), which required more detailed reporting by TRI facilities, including information about chemicals entering waste streams and recycling or treatment operations, as well as source reduction practices.[18]

Note: When you see this symbol ▶, click it to see additional information.

# KEY ACTIONS AND IMPROVEMENTS OVER TIME

Since the 1970s, EPA's implementation of the laws described above produced a basic framework for assessing and managing risks from chemicals. EPA's efforts evolved to include three complementary roles: (1) as a source of public information to facilitate understanding of chemical hazards (toxicity), exposures, and risks; (2) as the public's guardian/gatekeeper, protecting against chemical risks; and (3) as a facilitator of—and advocate for—pollution prevention and environmental stewardship actions. This section of the report summarizes the major steps EPA has taken over the last several decades to perform these three roles.

## EPA as the Source for Information on Chemical Hazards, Exposures, and Risks

Both TSCA and EPCRA gave EPA broad powers to collect information about chemicals in commerce. In the early years of the two laws, however, chemical information was collected for distinct purposes. EPA collected information under the TRI program to educate and empower the public, while it collected information under the TSCA program to guide and support regulatory action as needed to protect public health and the environment.

Beginning in the early 1990s, however, the TSCA program embraced the "public right to know" objective of the TRI program and began to assemble the chemical information it had collected into public databases intended for broader audiences. This trend, which was reinforced by several aspects of the 2016 TSCA amendments, is now a core component of the Agency's chemical program. With this expanded role for TSCA as a source of public information, EPA and the Congress have needed to revisit policies that have guided the protection of confidential business information (CBI).

### 1. Enhancements of the TRI Program

EPA collected its first round of TRI data in 1988, for "reporting year" 1987, and provided its public report on the data in June 1989.[19] From the beginning, the TRI program placed new obligations on EPA to annually collect, manage and assure the accuracy of a very large body of data (e.g., 74,000 reporting forms from approximately 19,000 facilities were received in 1988.) As a result, the TRI program became, out of necessity, one of the leading centers in the federal government for experimentation and development of new data submission tools that could be more easily used by a wide range of businesses. These included early efforts to use approaches like optical character recognition (OCR) technology for converting paper reports to digital computer data and, eventually, online electronic submissions.

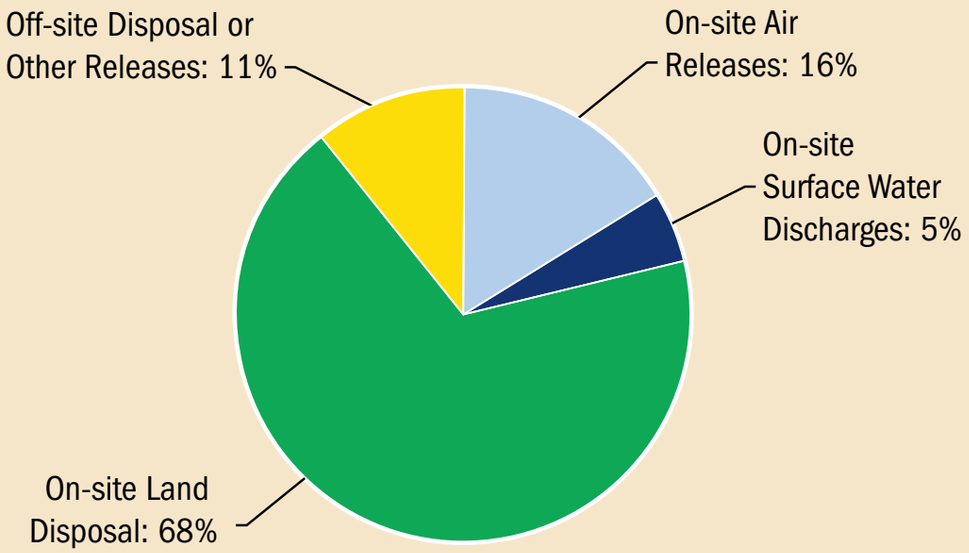
EPA also undertook several initiatives to expand the scope of TRI reporting. Some of these expansions of the program—such as

inclusion of more information on source reduction, recycling and treatment—were dictated by statutes like the *Pollution Prevention Act* as noted earlier. Other additions to the program's data universe, such as expansions of the chemicals to be reported, were initiated by EPA based on available scientific data. The most recent national report, issued in February 2020 for reporting year 2018, reflects data submitted by 21,557 facilities on 755 chemicals and 33 chemical categories.[20]

The TRI program has also continued to develop new approaches for delivery of its data to public audiences, along with tools that link to other data sources and allow users to conduct their own analyses. In 1998, for example, EPA issued the TRI Explorer software, which remains one of the most frequently used tools for extracting information of interest from the database. The Agency has also offered several versions of mapping software that allow users to align the TRI data with information from other EPA programs, demographic statistics, and community information down to the zip code level.

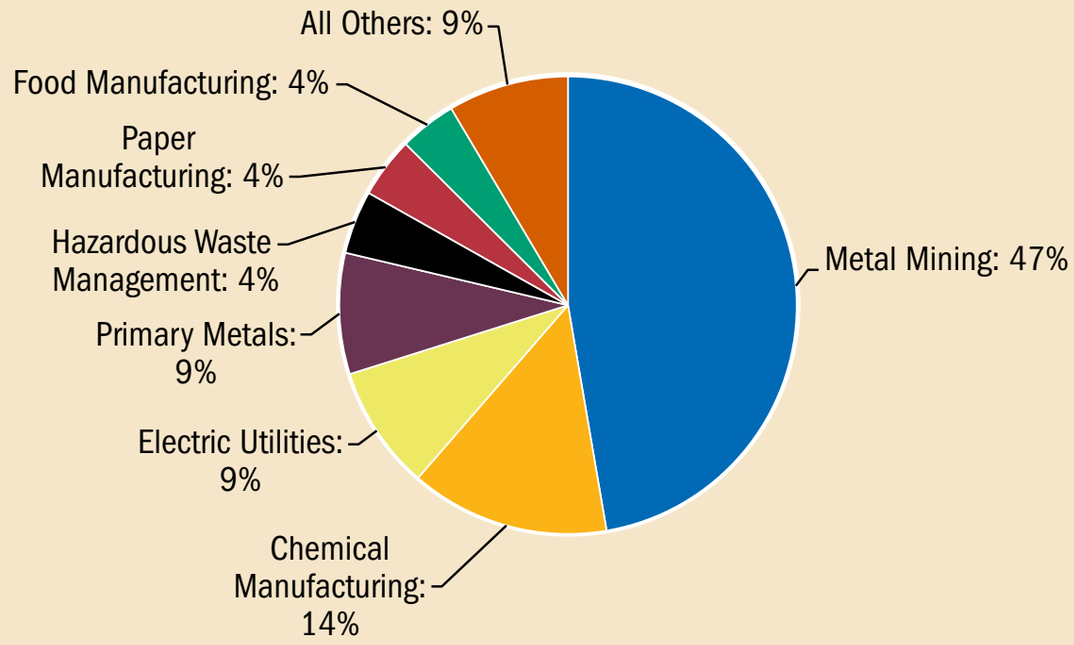
The information that EPA has brought forth to the public through the TRI program has provided important insights on how chemicals are being managed nationally, as portrayed in these two figures.

**Total Disposal or Other Releases, 2018**
**3.80 billion pounds**




**The majority of TRI chemicals disposed or released to the environment in 2018 went to on-site land disposal[21]**

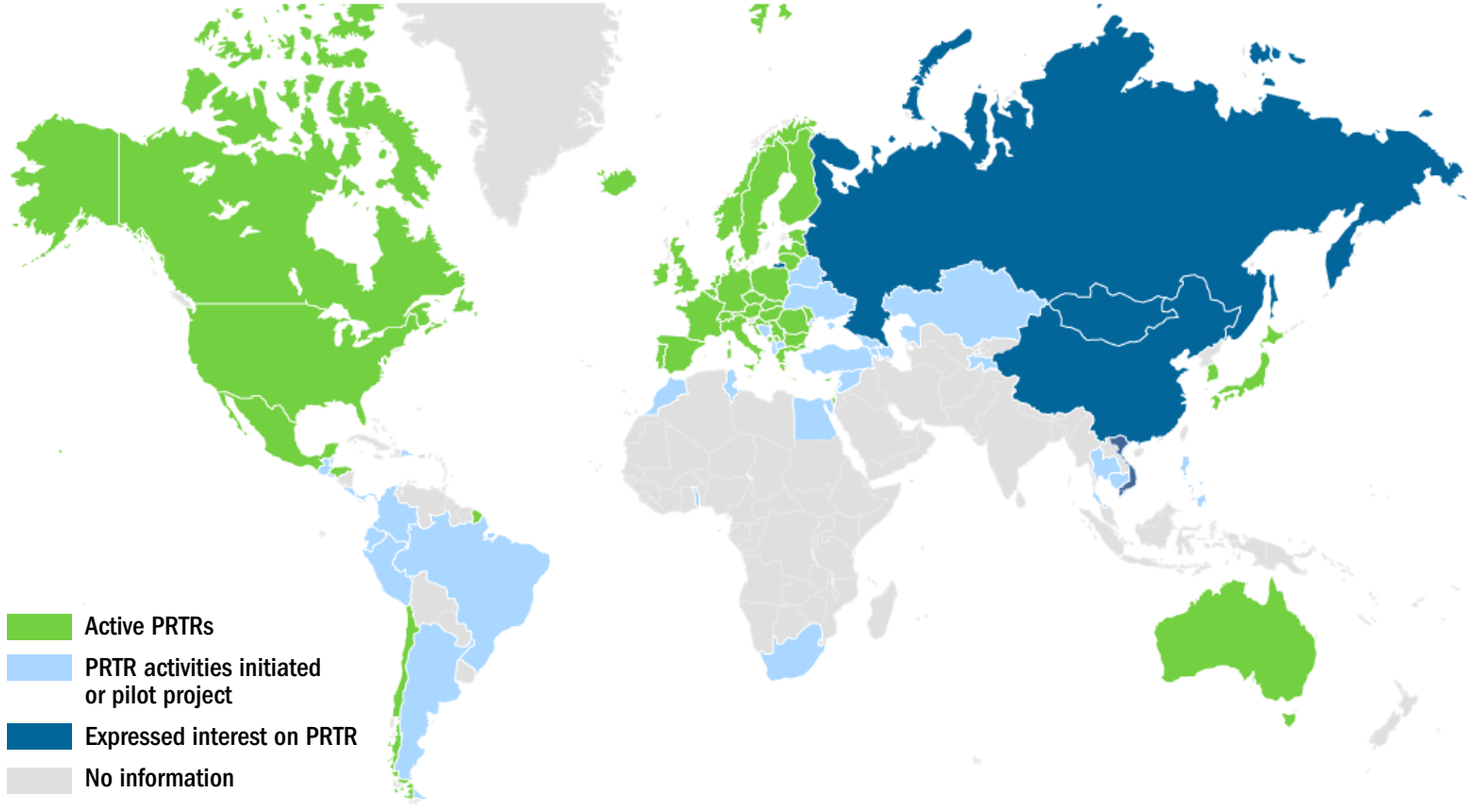
**Total Disposal or Other Releases by Industry, 2018**
**3.80 billion pounds**




**Four of the 29 TRI industry categories accounted for 79% of disposal and releases to the environment in 2018[22]**

The data have been used as metrics to guide multiple projects aimed at reducing chemical releases in communities. One example of such projects is the "33/50 Program" launched by EPA in 1991. Under this initiative EPA invited TRI-reporting companies who had reported releases of 17 priority chemicals (and chemical categories) to make company commitments for reductions in those releases that would collectively lead to national reductions of 33% by 1992 and 50% by 1995. Nearly 1,300 companies made commitments to the program. The strong response to this program lead to the 50% goal being achieved early, in the 1994 Reporting Year.[23]

The most important lesson about the TRI program, however, has been that the "public right to know" model has proven to be one of EPA's most successful pathways for engaging and supporting collective efforts to improve public health and the environment. The TRI data have been used in a variety of ways by different organizations and individuals. These included residents living in communities, government agencies at the federal, state and local levels, the academic and research community, industry and investors (to assess sustainability performance), and journalists.[24] The TRI program has also served as a model for Pollutant Release and Transfer Registries (PRTRs) that have been adopted by countries all over the world.




**At least 50 countries have established or are pursuing Pollutant Release and Transfer Registries programs[25]**

## 2. TSCA Information: Expanding Chemical Data and Improving Transparency

In enacting TSCA in 1976, Congress anticipated that EPA would need to substantially expand its information base on chemicals. Thus, the statute included multiple mandates and tools to accomplish this objective. For the first 15 years of the TSCA program, EPA saw its chemical information collection and analysis activities primarily as support for risk management actions under its new and existing chemical programs. In the early 1990s, however, the TSCA program made an important policy shift, based on its experience with the TRI program. The program adopted an additional purpose for the chemical information stored in its files—serving as a resource for a wide range of stakeholders (e.g., government, business, researchers, consumers) to help them make informed decisions on the use of chemicals in society. These purposes can be seen at work in a range of EPA information programs and projects.

### *A. The TSCA Inventory*

One of key building blocks of EPA's chemical program is the TSCA Inventory of Existing Chemicals, which serves as the regulatory gateway for any commercial chemical. A chemical substance may not be manufactured, imported, processed, or used in the country unless it is on the TSCA Inventory. If a chemical is not on the Inventory, a notification regarding the chemical must be submitted for review by EPA before it can be added to the Inventory and thereby become commercially available in the U.S.

EPA completed the initial version of the TSCA Inventory in the late 1970s. This was an unprecedented and complex undertaking. It required EPA to develop and implement procedures for naming and identifying the dizzying array of over 60,000 existing chemicals then in U.S. commerce. The policies and approaches developed by EPA served as the model for other national inventories, including those of the European Union, Canada, and Japan. Besides clarifying what is considered a "new chemical" under TSCA, the Inventory has also served as a list of potential candidates for information collection and risk management activities. Over the last forty years, the Inventory has continued to grow and now includes the names of over 86,000 distinct chemical substances, a list that has long ceased to be a practical agenda for chemical-by-chemical risk evaluation.

One of the reforms of the 2016 TSCA amendments, which was supported by multiple stakeholders, was an evaluation of the Inventory to determine how many of the listed chemicals were, in fact, in U.S. commerce. As originally conceived, the TSCA Inventory was supposed to be an initial list of chemicals that were ***allowed*** in U.S. commerce, not necessarily a list of chemicals that were ***active*** in U.S. commerce. While it has been well-understood that many older chemicals have been replaced and some newer chemicals do not actually succeed in the marketplace, neither EPA nor industry had definitive information about which chemicals were actually in active commerce. As required by the 2016 TSCA amendments, EPA has now completed a reporting process that received more than 90,000 responses from chemical

manufacturers, importers, and processors to identify chemicals that have been active in commerce over the last ten years.[26] The Agency determined that there are 40,655 chemicals that have been ***active*** in U.S. commerce over that period, a number that is certainly substantial but approximately 47% of the chemicals otherwise ***allowed*** in U.S. commerce.[27]

### *B. Hazard, Exposure and Risk Information*

TSCA includes a number of reporting obligations and information collection authorities that EPA has used to generate a large body of data on chemical hazard, exposure and risk. Important examples include:

- TSCA includes a requirement that companies *immediately* report to EPA any *new* information indicating a chemical presents a substantial risk to health or the environment.[28] This provision addressed the concern that manufacturers had not promptly disclosed information on the dangers of chemicals.[29] Since 1977, EPA has received over 21,000 of these substantial risk submissions including information on toxicity test results, worker fatalities and injuries, product contamination, etc.[30] EPA has used this information to publicize new concerns and target chemicals for further assessment or testing.

- TSCA also includes authorities allowing EPA to require submission of existing hazard and exposure studies,[31] and to require chemical manufacturers or processors to initiate new testing of chemicals.[32] EPA has obtained a large volume of data under these authorities, particularly unpublished studies on existing chemicals.[33] The volume of new testing has not been as robust, in part because of the statutory findings that must be met to support a rule requiring new testing.[34] The 2016 TSCA amendments modified the law to address these concerns. TSCA now allows EPA to impose testing requirements by enforceable consent decrees or administrative orders, rather than rules, which is expected to facilitate more expeditious action by the Agency, and clarifies EPA's authority to require testing to prioritize chemicals for risk evaluation, to meet exposure information needs, and to meet the regulatory testing needs of other federal agencies.

- In 1977, EPA issued a rule requiring reporting about certain chemicals on the TSCA Inventory. This rule has been modified several times, expanding information EPA collects. The current version of this rule, called the Chemical Data Reporting (CDR) rule, requires chemical manufacturers and importers to provide a broad range of information about chemicals manufactured or imported above certain thresholds at a single site. The reported information includes production volume, manufacturing information, worker exposure, industrial processing and use data, commercial and consumer use data, and potential use in products intended for children. The most recent version of these data, received in 2016 for the four preceding years, included data on 8,707 chemicals manufactured by 2,247

companies at 4,917 sites.[35] These data routinely assist EPA in setting priorities for additional review and potential action on these chemicals.

- In addition to use of its regulatory authorities, EPA has had success working with stakeholder groups to develop chemical testing information through collaborative mechanisms. A notable example of this approach, EPA's High Production Volume (HPV) Challenge Program, began in 1998 when the Agency requested chemical manufacturers and importers to provide a basic set of test data on the thousands of chemicals produced at or above one million pounds per year. The HPV initiative, which was supported by industry and environmental groups, was conducted in coordination with international efforts to assemble chemical hazard screening data for a long list of HPV chemicals. The effort has certainly led to an expanded understanding of the risks associated with chemicals in commerce, but it also made clear some of the limitations inherent in EPA's TSCA information collection authorities. As noted above, Congress has acted to address some of those limitations in the 2016 TSCA amendments.

The combined results of these multiple TSCA information collection efforts is a substantial body of chemical information at EPA. Over the last several decades, EPA has been systematically making these data available to the public, subject to protection of CBI as described below. Initially, EPA made this information available to the public through stand-alone databases for each information collection program. More recently, however, the Agency has been developing more integrated chemical databases, with sophisticated search tools. These tools allow the public to assemble, review, and analyze data from multiple databases on specific chemicals.

One of the most useful of these tools is a website called ChemView, which EPA launched in 2013.[36] The site provides easy, searchable access to test data, EPA hazard and risk assessments, and regulatory information on thousands of TSCA chemicals, including virtually all of the information sources discussed in this paper. The Agency has been continuously updating the site with additional historical and new data. Besides data generated from the TSCA program, ChemView also includes relevant information from other EPA programs, as well as data from the National Institutes of Health, the Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health.

While EPA's efforts to collect and disseminate chemical testing information have had important benefits for protecting public health, there have also been long-standing animal welfare concerns associated with the conduct of chemical testing on rats, mice, and fish, among other vertebrate animal species. In enacting the 2016 TSCA amendments, Congress recognized the importance of these ethical concerns and addressed them specifically. The law directs EPA to reduce and replace such testing to the extent practicable and scientifically justified. It

also requires that EPA develop and implement a strategic plan to promote the development and use of alternative test methods and strategies. This is the only EPA statute that requires a sustained effort to reduce animal testing. EPA has made considerable progress in the early implementation of this ground-breaking provision.[37]

### 3. Protection of Confidential Business Information and Transparency Reforms

Like any regulatory program focused on products in commerce, the TSCA program has had to grapple with the challenge of conducting its business in a publicly transparent manner, while also protecting proprietary private sector information from public disclosure based on a set of public laws, including TSCA itself. CBI protection is extended to trade secrets and other proprietary information (e.g., chemical formulas, manufacturing methods, production volumes, marketing data) where the holders of such information can show that the information is not generally known to their competitors and that disclosure of such data would harm the claimant's competitive position in the marketplace. Achieving the right balance between CBI protection and EPA's policy goals of sharing information with the public or conducting transparent risk management regulatory action has been one of the most difficult tasks in EPA's implementation of TSCA.

To maintain a balance between public access to data and protection of intellectual property, EPA developed a series of legal and policy measures. These included requirements for substantiation of CBI claims and targeted challenges to claims that may not be justified. EPA also applied strategies, such as using generic chemical names and reporting data in ranges, which allow for public data sharing without disclosure of CBI.

The CBI topic was a major subject of debate and negotiation among stakeholders in the development of the 2016 TSCA amendments. The result was a new framework and a set of policies for CBI protection that are leading to greater transparency in the TSCA program. Specifically, the following changes have been particularly significant:[38]

- **Substantiation** – Historically, submitters of TSCA information to EPA could claim their information as CBI. EPA would not review the merits of those claims until a *Freedom of Information Act* (FOIA) request was made for the information or EPA had an independent reason to make the information public. In addition, once a claim was made, the information could be held as confidential forever, unless EPA had a reason to evaluate the claim. The law now requires that CBI claims must be substantiated at the time the information is submitted, with some exceptions (e.g., detailed process technology, identification of suppliers and customers). EPA is required to make determinations on the adequacy of the substantiations within 90 days. In addition, certain CBI claims expire in 10 years, unless the submitter can again substantiate the continuing need for confidentiality of the information.

- **CBI claims for active substances** – In conjunction with review of the TSCA Inventory to determine what chemicals are active in commerce, EPA must require a company identifying a chemical as "active" ***and*** as "CBI" to provide substantiation of its claim. These claims must then be reviewed by the Agency to determine if such a claim is still valid.[39]

- **Sharing CBI Data with other Governmental Agencies** – Historically, EPA has been authorized to share CBI data it collects in specific situations (e.g., for federal law enforcement purposes, for health professionals in an emergency). The 2016 TSCA amendments expanded the situations where this form of data-sharing is allowed. Perhaps the most important of these changes authorized EPA to share TSCA CBI information with state, local and tribal governments. To receive the information, the recipient agencies must have in place information protection authorities, procedures and capabilities that are comparable to those used by EPA.

- **Unique Identifiers for Chemicals with a CBI Name** – Historically, EPA has assembled information, including toxicity data, on Inventory chemicals for which the chemical's name is CBI. It has been difficult for the public to understand what information relates to each such chemical. In an effort to provide greater data transparency about chemicals, Congress required EPA to establish a unique identifier for each confidential chemical name on the Inventory. For this purpose, EPA is assigning a unique number to such chemicals. Thereafter, EPA and data submitters are required to link additional information for these CBI chemicals to their unique identifier number. This step will allow the public to understand the potential hazards, exposures, and risks of CBI chemicals in the Inventory by referring to the unique identifier number, without revealing the formal name of the chemical. As of 2020, EPA is implementing this provision, and will be integrating it into future publications of the TSCA Inventory.

## EPA as the Guardian/Gatekeeper for Protecting Against Chemical Risks

### 1. Existing Chemicals: Mixed Results in Early Years Lead to a Revitalized Statutory Program

When TSCA was enacted in 1976, EPA faced high expectations that it would promptly begin regulating existing chemicals, using its broad powers under Section 6 of the statute.[40] EPA was able to move swiftly to ban commercial manufacture and use of CFCs in aerosol propellants under TSCA in 1978, an action later superseded by broader regulation to address stratospheric ozone depletion under the *Clean Air Act*.[41] The Agency found, however, that Section 6 contained several problematic provisions that tended to slow its ability to move forward. These provisions related to the findings necessary to support regulatory action

and to unique, complicated procedural requirements. In addition, EPA found that its statutory freedom to act on any existing chemical was actually an obstacle to quick action, due to multiple internal debates and interactions with stakeholders about what commercial chemicals warranted attention.

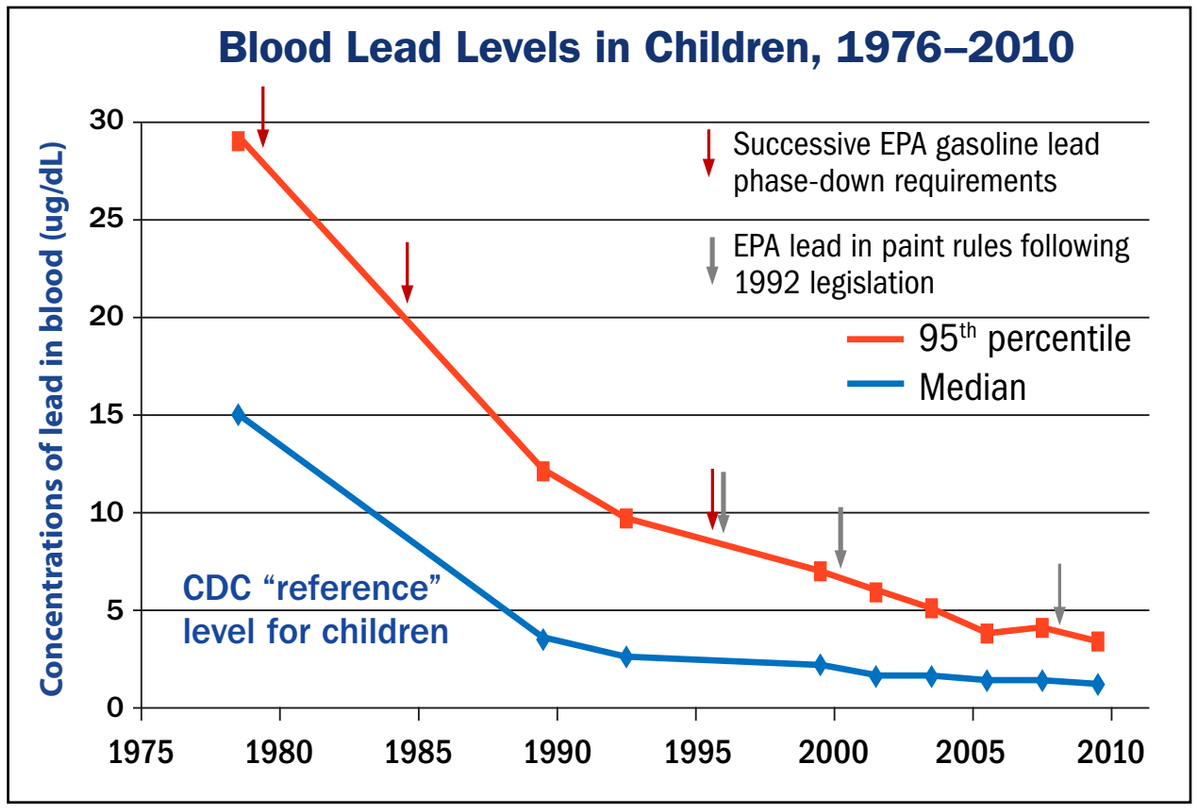
### *A. Chemicals Subject to Statutory Mandates*

Congress has, however, required EPA to act on specific chemicals presenting public health concerns, and EPA has responded diligently to these chemicals. Major examples of these situations include the following:

- **PCBs** – As noted earlier, the original TSCA statute required EPA to phase out PCBs.[42] In 1979, EPA banned the new manufacture of PCBs although, for economic reasons, the Agency allowed continued use of existing PCBs in electrical equipment, such as transformers. Over the years, EPA has taken dozens of regulatory actions to regulate any ongoing uses of PCBs strictly and to ensure the safe disposal of PCBs at the end of their commercial life.[43] The TSCA system established in the late 1970s for PCB disposal served as a model for EPA's hazardous waste disposal program under the *Resource Conservation and Recovery Act* (RCRA) which EPA established in the early 1980s. In recent years the PCB disposal program has been increasingly aligned with key elements (e.g., manifests for hazardous waste shipments) of the RCRA hazardous waste system.

- **Asbestos in Schools** – In 1986, Congress enacted the *Asbestos Hazard Emergency Response Act* (AHERA) to address increasing public concerns about student exposure to asbestos in the many older school buildings where asbestos was routinely used in a variety of building materials. EPA moved quickly to implement this program, issuing its AHERA regulations in 1987.[44] The regulations required public and non-profit schools to (a) inspect their facilities, conducting specified sampling and analysis as needed; (b) develop and implement management plans for asbestos-contaminated areas in the school, to remediate conditions where needed, and provide for maintenance and warning labels for asbestos left in place; (c) provide for training of custodial and maintenance staff to avoid release of asbestos fibers; (d) assure transparency of the management plan to parents and others; and (e) conduct periodic re-inspections. To assure that school evaluations and management plans were developed by knowledgeable experts, EPA and the states set up a national training and accreditation program to create a cadre of trained professionals who would be capable of creating effective, practical management plans for individual schools. Thousands of schools are managing asbestos-containing materials in place, presenting an ongoing challenge for EPA to protect students and teachers from asbestos exposure.

- **Lead in Paint and Residential Buildings** – Lead has been another pervasively used, highly toxic chemical that has been a particular focus of multiple EPA programs.[45] The TSCA program's primary role in this widespread public health threat has involved addressing the legacy of lead-based paint in residential housing. The Consumer Product Safety Commission (CPSC) began restricting lead in paint in 1978.[46] EPA's work on reducing exposure to lead in paint began in earnest following enactment of the *Residential Lead-Based Paint Hazard Reduction Act* of 1992. That law directed the Agency to develop a comprehensive program to reduce childhood exposure to lead from deteriorating paint in residences (see graph). In 1996 EPA adopted regulations establishing best practices for the conduct of renovation, repair and painting in houses, apartments, and child-occupied facilities (such as schools and day-care centers) built before 1978. These requirements apply to rental owners and property managers, general contractors and specialty trades firms (e.g., painters, plumbers, carpenters, electricians). They further mandate certification (with appropriate training) for the firms conducting these activities. EPA also worked with the Department of Housing and Urban Development to issue disclosure regulations in 1996. These require sellers and lessors of housing units built before 1978 to provide buyers and renters warnings, including information from EPA and CPSC, about potential lead hazards that may be present in the building. The regulations also allow an opportunity for a lead inspection before completing the real estate transaction.

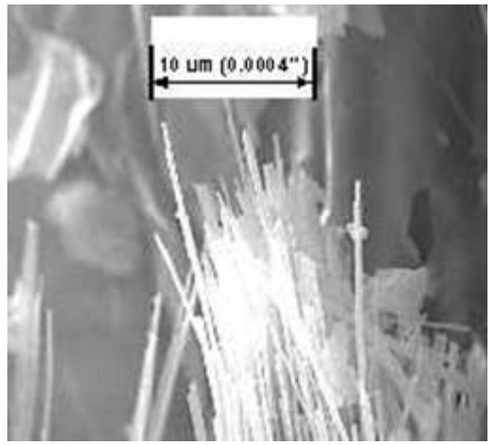




**U.S. EPA, America's Children and the Environment, Third Edition (2013); see http://www.epa.gov/ace/biomonitoring-lead. As shown in the figure, median blood lead levels decreased from 15 micrograms/deciliter (µg/dL) in 1976–1980 to 1.2 µg/dL in 2009–2010 (a µg is equal to a millionth (1×10−6) of a gram while a dL is equal to one tenth of a liter). The arrows indicate the timing of EPA actions to regulate lead in gasoline and to require use of lead-safe practices in renovation and remodeling projects that disturb lead-based paint. Also see the 2019 update on lead (https://www.epa.gov/sites/production/files/2019-07/documents/ace3-lead-updates.pdf).**

- **Formaldehyde Emission Standards for Composite Wood Products** – Formaldehyde is used, among other things, as an adhesive in a wide range of wood products, such as furniture, flooring, cabinets, bookcases, plywood, and wood panels. Exposure to formaldehyde can cause adverse health effects, including eye, nose, and throat irritation, other respiratory symptoms, and cancer. The *Formaldehyde Emission Standards for Composite Wood Products Act* of 2010 (TSCA Title VI) established emission standards for formaldehyde from composite wood products and directed EPA to finalize implementing regulations. EPA's regulations required certain composite wood products sold, supplied, offered for sale, manufactured, or imported in the U.S. to be labeled as TSCA Title VI compliant. These products include hardwood plywood, medium-density fiberboard, and particleboard, as well as household and other finished goods containing these products. The regulations also set testing requirements to ensure that products comply with those standards, established eligibility requirements for third-party certifiers (i.e., organizations that assess and certify a product's conformance with standards), and established eligibility requirements for accreditation bodies that will accredit the third-party certifiers.[47]

### *B. EPA's Attempt to Phase Out Asbestos and Its Precedential Impact*

While EPA responded effectively to the statutory mandates noted above, it was criticized during the 1980s for its slow start in using the broad authority of Section 6 to regulate other chemicals. The most important effort it initiated during this period concerned a regulation to phase out the major uses of asbestos, one of the most notorious chemical ever addressed by EPA. This action became the test case for the capability of the existing chemical program under Section 6.



Microscopic asbestos fibers.

The asbestos rulemaking, which began in 1979, was one of the most complicated administrative proceedings in EPA history and thus took ten years to complete.[48] The final rule, issued in July 1989, was immediately challenged in the U.S. Court of Appeals for the Fifth Circuit. In a stunning defeat, the court vacated the major portions of the rule in 1991.[49] The key precedential ruling by the court focused on the requirement in Section 6 that EPA must choose the least burdensome alternative to remedy the unreasonable risk that it had identified. Specifically, the court concluded that Section 6 required EPA to evaluate ***every*** alternative remedy available in order to identify the ***least*** burdensome alternative.

The court's ruling in this case had a profound effect on the TSCA program for the next 25 years. For many EPA managers and lawyers, the major lesson learned from the asbestos rulemaking was that the courts would be imposing unrealistic analytical burdens and burdensome TSCA procedural obligations on any

Agency effort to use Section 6 to protect public health and the environment. The former included the need to assess all potential regulatory alternatives while the latter involved cross-examination and briefing steps not required for rulemaking in other EPA programs. Thus, the regulatory tool that many stakeholders had seen as the centerpiece of the original 1976 statute was seen as ineffective by EPA and a wide range of stakeholders.

Over the years that followed, EPA began to develop and apply regulatory strategies under other TSCA authorities to address existing chemicals of concern. One example is EPA's use of TSCA's *Significant New Use Rule* (SNUR) authority.[50] EPA used this to regulate a number of "bad actors," including Polybrominated Biphenyls (PBBs), carcinogenic benzidine dyes, the toxic flame retardant "tris" (used in children's pajamas),[51] and many others. In these situations, EPA acted, often after encouraging voluntary industry phase-outs, to regulate reintroduction of these chemicals into commerce.

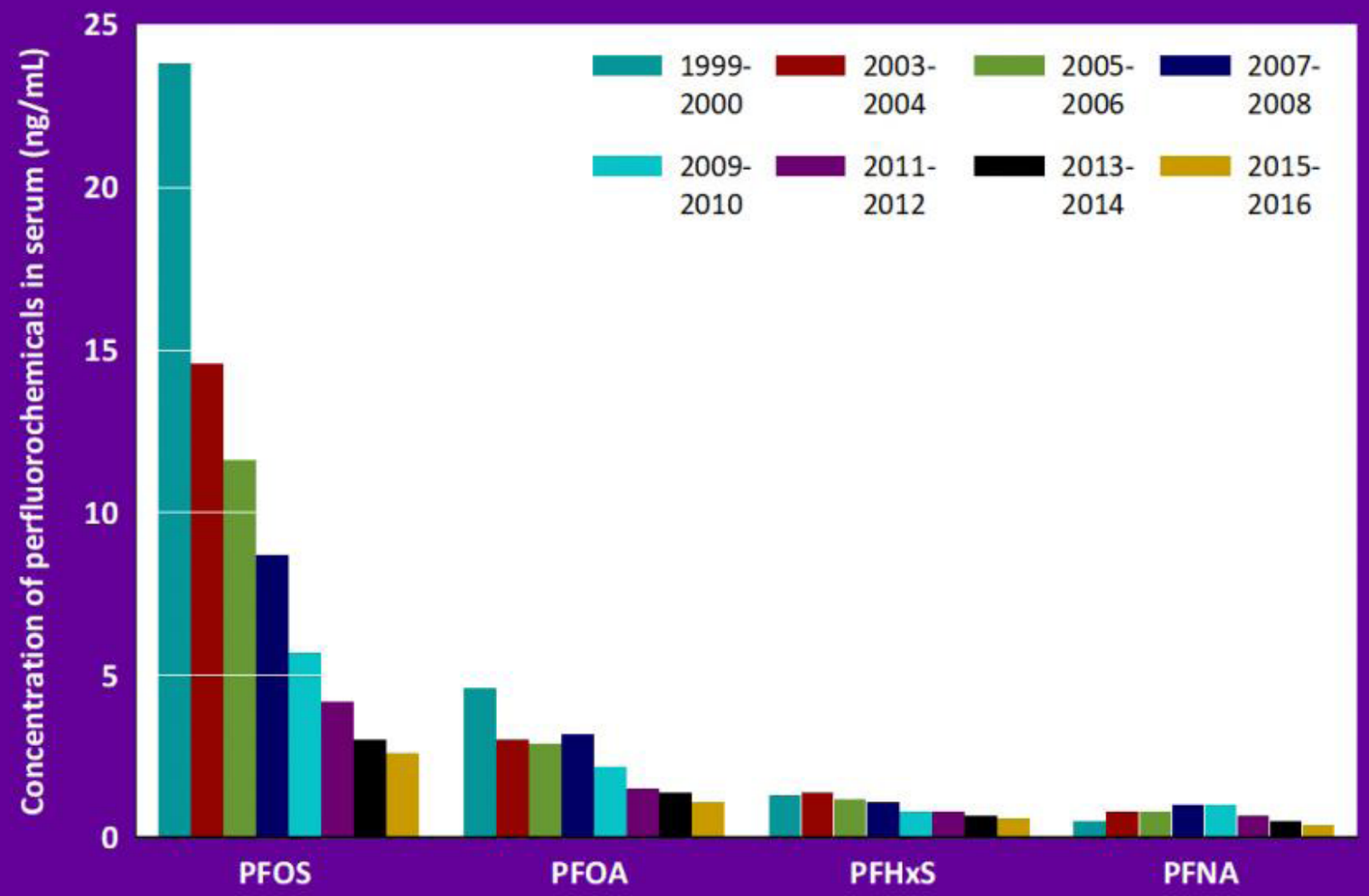
EPA also pursued collaborations with industry and other stakeholders to replace problematic chemicals with safer alternatives. One example of such an effort concerned what are now known as PFAS (per- and polyfluoroalkyl substances). EPA was the first regulatory agency worldwide to recognize the unique issues presented by this large and varied class of chemicals. The work began with EPA's effort to replace two broadly used, environmentally persistent fluorinated substances—perfluorooctyl sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA)—which have been found in the bloodstream of people around the world. In 2000, one of the manufacturers PFOS brought to EPA's attention information indicating that the chemical was toxic in animal studies. After engaging with EPA, the U.S. manufacturer of PFOS voluntarily phased out production. EPA then used its SNUR authority to regulate the use of some 270 PFOS-related chemicals.[52]

Shortly thereafter, similar concerns were shown for PFOA, a chemical used in the manufacture of nonstick cookware, among other products. Once again, industry engaged with EPA and in 2006 EPA launched a voluntary 2010/2015 Stewardship Program. Under this program, major companies committed to a voluntary reduction of their global emissions of PFOA and other perfluorinated chemicals by 95% by 2010. They also committed to work toward eliminating such emissions by 2015. The companies reported that they have phased out the chemicals identified in the stewardship program, and in 2020 EPA is completing another SNUR to limit the further use of these substances as well.

Data collections by the U.S. Center for Disease Control, through its National Biomonitoring Program (portrayed on the next page), have shown that the phaseouts of PFOS and PFOA have helped reduce blood levels of these chemicals in people significantly as shown in the nearby figure.[53] EPA is now looking at the broader class of PFAS substances and has developed a comprehensive action plan for these chemicals that will combine a series of regulatory, scientific and collaborative stakeholder activities.[54]

Indicator B6

## Perfluorochemicals in women ages 16 to 49 years: Median concentrations in blood serum, 1999-2016




Data: Centers for Disease Control and Prevention, National Center for Health Statistics and National Center for Environmental Health, National Health and Nutrition Examination Survey

Note: To reflect exposures to women who are pregnant or may become pregnant, the estimates are adjusted for the probability (by age and race/ethnicity) that a woman gives birth.

*America's Children and the Environment, Third Edition, Updated August 2019*

### *C. 2016 TSCA Amendments: Major Reforms of the Existing Chemical Program*

One of the primary drivers of TSCA legislative reform was the widely held view that the law's capabilities to address risks from existing chemicals needed to be strengthened, particularly in light of the court decision rejecting the asbestos rulemaking. As a result, the 2016 TSCA amendments made many fundamental changes to this program. They convert Section 6 from a broad authority *allowing* EPA to take regulatory action into a specific set of directions to EPA about the structure, procedures, and timelines for an existing chemical program that it *must* implement. The result is a program design that will create responsibilities and accountability for both EPA and the regulated community, which is expected to be sustainable over time.

The primary changes to the existing chemical program made by the 2016 TSCA amendments and the status of EPA's implementation of these changes by the end of 2019 include the following:

- **An agenda of chemicals to address** – One of the challenges EPA faced in the early years of TSCA is that Congress had given the Agency broad authority to set its own agenda for the existing chemical program. This flexibility proved problematic as EPA's agenda was constantly changing, particularly when new administrations brought in new political leadership. The 2016 TSCA amendments required EPA to (a) define an initial list of 10 chemicals that it would address in the systematic risk evaluation specified by the statute; (b) specify a list of list of PBT chemicals that would be subject to an expedited regulatory review process through which EPA is required to reduce exposure "to the extent practicable;" and (c) designate an additional set of at least 20 high-priority chemicals to enter into the existing chemical risk evaluation process. EPA has implemented these provisions and now has a list of 35 chemicals, including five PBT chemicals, that will be evaluated for potential regulation under TSCA.[55]
- **Systematic review process with deadlines** – The new framework for Section 6 anticipates that EPA will continue to identify additional high-priority chemicals, which will then be moved into a risk evaluation stage and then a risk management stage.[56] The law sets the expectation that EPA will be conducting at least 20 risk evaluations on a rolling basis. Individual risk evaluations are to be completed within three years, and any follow-on risk management action rules are expected to be completed within two years.[57] EPA has been diligent in meeting these statutory deadlines. It is now working through risk evaluations on several designated high-priority chemicals, and recently proposed regulatory action for the PBT chemicals that are on an expedited schedule under Section 6.[58]

- **Removing obstacles** – Based on EPA's experience with the asbestos rule noted earlier in this report, Congress removed provisions of the 1976 law that it perceived to be unnecessary obstacles to action for EPA. In particular, Section 6 no longer requires EPA to select the least burdensome alternative when adopting a regulatory strategy for an unreasonable risk or to include the complex cross-examination and briefing administrative procedures, which had delayed the asbestos rulemaking, when undertaking Section 6 risk management action.

- **New standard of safety** – Under the 1976 version of Section 6, EPA could require actions necessary to remedy an unreasonable risk posed by an existing chemical. The statute did not specifically define the term "unreasonable risk." The term, however, had generally been recognized to allow an agency to balance the risk reduction benefits of an action against the costs and socio-economic impact of the action when determining what level of risk needed to be eliminated. After a torturous debate that took several years to resolve, the 2016 TSCA Amendments modified Section 6 to require that a risk evaluation determine whether a chemical "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including unreasonable risk to a potentially exposed or susceptible population", and that a Section 6 risk management rule would apply requirements necessary to eliminate that unreasonable risk.[59] Some stakeholders see this language as completely prohibiting EPA from considering costs in formulating risk management requirements. Other stakeholders point to another part of Section 6, which directs EPA to "factor in, to the extent practicable" a set of considerations that include the benefits of the chemical and the economic consequences of a Section 6 rule, when making a risk management decision, as evidence that EPA can consider additional factors in its regulatory decision.[60] The apparent tensions within these statutory provisions are likely to generate legal and policy debates in the future.

## 2. New Chemicals: EPA Responds to a Challenging Mandate with Innovative Approaches

Following establishment of the Inventory in the late 1970s, TSCA required that industry notify EPA before introducing a new chemical, i.e., one not on the Inventory. As part of this review, EPA was authorized to require testing and impose risk management controls to address potential risks of new chemicals.[61] Thus, the goal of the program was to oversee the introduction of new chemicals by industry and thereby prevent or control the manufacture and use of potentially risky new chemicals. However, the law did not require manufacturers to include specific test data in the notification provided to EPA. As a result, there were serious questions about whether EPA would have enough information to assess new chemicals adequately.

EPA rose to the challenge by breaking new scientific ground. The Agency developed a set of tools to predict how the structure of a chemical relates to its properties and biological activity. The term given to this form of scientific inquiry is "structure-activity relationship" analysis. Through use of these tools, EPA was able to predict a chemical's potential toxicity and environmental properties in the absence of test data. EPA's efforts became a major contribution to the science of risk assessment. EPA, industry, and other countries now routinely use structure-activity analysis to predict a wide array of chemical properties (e.g., water solubility, vapor pressure, environmental persistence and breakdown, bioaccumulation, and human and environmental toxicity).

EPA also developed an extremely efficient internal review process, maximizing effective collaboration among subject matter experts. It also established a set of guiding risk assessment and risk management policies, drawn from its experience with reviews of thousands of individual new chemicals, that permitted it to perform effective risk assessments on broad classes of chemicals.[62] One of the new chemical policies that has had a broader impact was the 1999 TSCA policy on PBT chemicals. This policy represented EPA's first formal statement of national policy on PBTs, identifying them as a class of chemicals to be discouraged.[63]

Between 1979 and the enactment of the 2016 TSCA amendments, EPA reviewed over 54,000 new chemical submissions, most of which were Pre-Manufacture Notices (PMNs) that received full reviews by EPA staff.[64] Approximately 13% of those PMN submissions were withdrawn in the face of planned EPA regulation or were regulated through administrative orders or SNURs. In performing these responsibilities, EPA functioned as both a gatekeeper to ensure that risky chemicals would not enter commerce and as an educator guiding the chemical industry toward new generations of "safer" or "greener" chemicals.

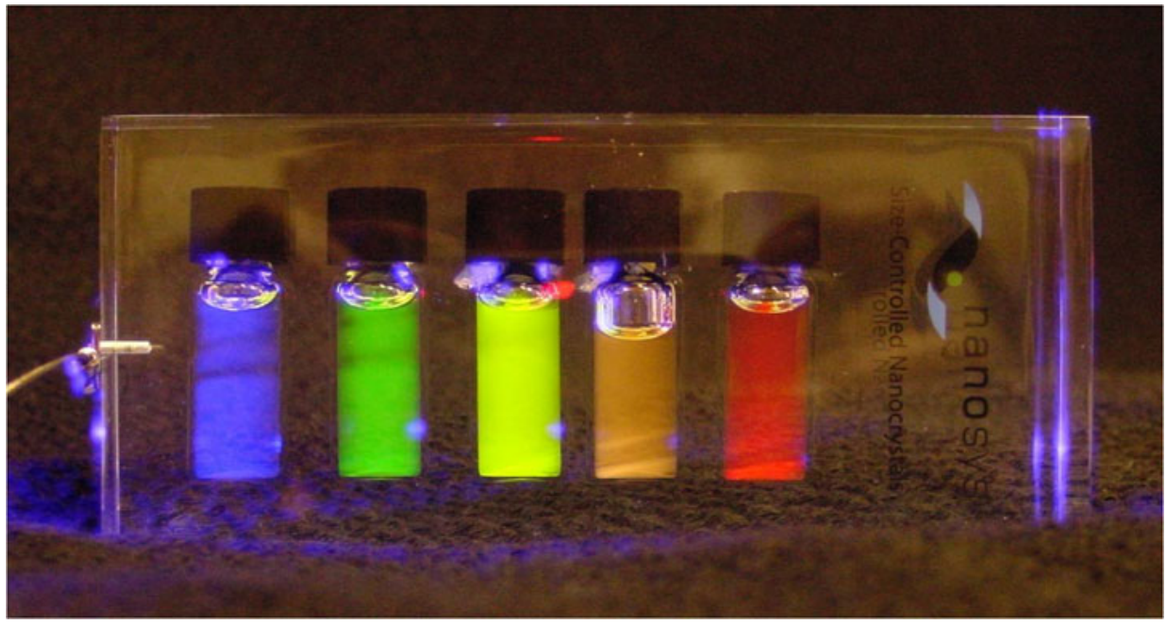
### *A. Facing the Challenges of Emerging Technologies*

In conjunction with its review of new chemicals under TSCA, EPA had to develop approaches that allowed it to keep up with technological revolutions unforeseeable in the 1970s. These include the products of biotechnology and nanotechnology, topics also discussed in the pesticides report. These products offer the potential for unprecedented innovation and commercial development, as well as environmental benefits (e.g., energy efficiency, use as renewable feedstocks and fuels). It is essential that EPA understand and control potential risks from these materials while recognizing the commercial and environmental benefits that can result from the products of these technologies.

***Biotechnology*** involves genetic manipulation of microorganisms to produce desired properties (e.g., degradation or recycling of wastes) or to manufacture chemicals. EPA regulates and requires new chemical notifications on intergeneric microorganisms

(those containing genetic material from more than one genus of organisms; genus is the biological classification of organisms that comes above species and below family[65]). EPA reviewed approximately 111 new microorganisms over the past 20 years,[66] most of which were used in the manufacture of commercial chemicals at production facilities that minimized exposures and releases to the environment.

***Nanotechnology*** is the understanding and control of matter at the nanoscale (about 1 to 100 nanometers; a nanometer is $10^{-9}$ meter, or one billionth of a meter) where unique physical or chemical phenomena enable novel applications.[67] Nano-sized materials can, and often do, have fundamentally different physical and chemical properties than their larger-sized counterparts.




**Quantum Dots are nano-sized semiconductors with unique optical and electrical properties used in energy efficient LED lights and solar cells. Each vial contains different sized particles that produce different colors of fluorescence.**

These novel properties can also result in very different toxicity characteristics and potential risks. Nanoscale materials when made and used for TSCA purposes are considered chemical substances under TSCA and, since 2005, EPA reviewed over 160 new chemical[68] nanoscale materials, including carbon nanotubes, fullerenes, quantum dots, etc. In 2017 EPA issued an information collection rule to obtain a better understanding of the commercial scope, hazards, and exposures of *existing chemical* nanoscale materials.[69]

### *B. 2016 TSCA Amendments Tighten New Chemical Provisions*

As indicated earlier in this report, the Congressional concerns that lead to the 2016 TSCA amendments centered on the flaws in the existing chemical program as conducted under the original TSCA. While Congress saw the new chemical program as reasonably successful, there were some key areas where it sought to strengthen the program. Two reforms were seen as particularly important in serving this objective:

- **New safety standard** – EPA was required to review new chemicals against a safety standard that was aligned with the amended Section 6 standard for existing chemicals. In particular, EPA was expected to assess whether the new chemical may present an "unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors." The amended law also allowed EPA to determine whether the information available to EPA was "insufficient to permit a reasoned evaluation of

the health and environmental effects." If EPA made these determinations, among others, it was required to regulate to the extent necessary to protect against an unreasonable risk. The amended law also specified that EPA cannot allow a new chemical into commerce, without further restrictions or testing obligations, unless EPA determines that the chemical is not likely to present such a risk.

- **Affirmative determination for chemicals meeting the safety standard** – Under the 1976 version of TSCA, EPA only made publicly stated determinations about new chemicals when the Agency had concerns about the chemical and had taken some form of regulatory action (e.g., administrative order, SNUR) against the chemical. Chemicals that appeared acceptable to EPA during its review were allowed to proceed to commerce without any formal public notice. The 2016 TSCA Amendments required EPA to make a public statement of its finding in the Federal Register that a new chemical was not likely to present an unreasonable risk, a step that some stakeholders believed would encourage EPA to apply greater rigor in its analysis of each new chemical.

It is not clear how significant these reforms will be in changing regulatory outcomes from the new chemical program. While it has only been a few years since the 2016 TSCA amendments were enacted, there are some indications that these statutory changes are leading to stricter controls and information collection obligations for new chemicals. Specifically, EPA data as of November 2019 indicate that of the 933 PMNs, biotechnology submissions and SNUR filings[70] that have completed review since the 2016 TSCA amendments were put in place, approximately 55% of these substances have faced some form of regulation. This contrasts with the situation prior to the 2016 amendments, when approximately 13% of chemicals in such filings were regulated by EPA or withdrawn by the submitters in the face of potential regulation.[71]

## EPA as a Facilitator/Advocate for Pollution Prevention (P2) and Environmental Stewardship

During its early years EPA was primarily concerned with end-of-pipe approaches to reduce pollution. This strategy began to change in the 1980s to include a stronger emphasis on preventing pollution at its source. With the passage of the *Pollution Prevention Act* in 1990, EPA began a more formal effort to build prevention practices into its mainstream activities. Some of those efforts include regulations, permitting, technical assistance, and enforcement actions. EPA also focused on encouraging businesses to reduce pollution at its source. EPA linked many of its efforts to promote pollution prevention to its parallel effort to disseminate information about chemicals to the public, including through the Toxics Release Inventory, ChemView, and other information sources.

Pollution prevention was the subject of several executive orders on "Greening the Government,"[72] and EPA promoted its use by businesses through competitive grants to states and tribes. EPA also implemented a number of pollution prevention initiatives focused on chemicals used in industries ranging from cleaning products to electronics to chemical production.


***Safer Choice***[73] Formerly known as the Design for Environment (DfE) program, Safer Choice is a voluntary partnership helping consumers, businesses, and purchasers find products that perform well and are safer for human health and the environment. This program provides information about chemical safety to consumers and commercial buyers to help them make decisions about products in their daily lives and businesses. An element of the program is a certification and labeling program, under which over 2,000 safer products for consumer, institutional and industrial markets have qualified to carry EPA's Safer Choice label.[74]


The ***Green Chemistry Program*** is a groundbreaking effort encouraging scientific solutions to real-world environmental problems through the design of products and processes consistent with green chemistry principles.[75] Through the Green Chemistry Challenge Awards program, created in 1996, EPA has received over 1,600 nominations and presented awards for 118 winning technologies. Over time, these technologies significantly reduced the hazards associated with designing, manufacturing, and using chemicals. The challenge program award winners contributed billions of pounds of progress, including reducing the use or generation of more than 826 million pounds of hazardous chemicals, saving 21 billion gallons of water per year, and eliminating 7.8 billion pounds of carbon dioxide equivalents released to air per year.[76]

The ***Sustainable Futures Program***, which began in 2002, is an EPA effort to encourage the chemical industry to adopt more environmentally sustainable design principles in their development of new chemicals. It is built upon the expertise EPA has developed through screening of tens of thousands of new chemicals under the TSCA new chemical program. The risk assessment principles and protocols of that program have been translated into a suite of software tools, which EPA now provides to the public. The Sustainable Futures Program provides training on the use of these tools to the staff of interested companies. Where companies can demonstrate to EPA a track record for appropriate application of these tools to actual new chemical submissions, the Agency will consider expedited consideration of the new chemical submissions by these companies.[77]

# CONCLUSIONS

Evaluating the success of the EPA chemicals program is a challenging task because the wide range of activities that are part of that program cannot be easily measured against a single, easily understood goal. What is clear, however, is that EPA pursued a range of strategies and actions over its history that resulted in tangible improvements in public health and environmental quality. Examples of these results include:

- In the face of EPA risk concerns and expressed intent to regulate specific new chemicals, the manufacturers of over 2,000 chemicals declined to pursue these chemicals in the U.S. market. Additionally, EPA imposed protective measures or testing obligations on more than 3,000 additional chemicals that were allowed into commerce.
- EPA set protective standards and built essential infrastructure to prevent children from receiving toxic exposures to lead and formaldehyde in their homes or to asbestos fibers in their schools.
- EPA's efforts lead to early phase outs for a number of major PFAS chemicals and its ongoing work to address this large class of chemicals continues across the Agency.
- EPA substantially expanded the body of scientific data and tools available to researchers and the public on the toxicity of, and potential public and occupational exposures to, chemicals in the country. This was achieved through regulatory actions mandating new testing and requiring reports of existing information that companies had not otherwise disclosed, and through the development of public data bases and software tools for analyzing scientific data.
- EPA directly served the American people by providing, on an ongoing basis, detailed and ***accessible*** information about the releases of hundreds of chemicals from industrial or commercial facilities in communities, which has galvanized a range of citizen engagement actions and localized improvements in how these facilities are managed.

EPA has not, however, attempted to conduct risk assessments, followed by risk management regulations, on every chemical in U.S. commerce, as some stakeholders have suggested. Based on recent analyses mandated under the TSCA 2016 amendments, we now know that there are over 40,000 active chemicals in U.S. commerce. While it would not be feasible for EPA to conduct case-by-case reviews for that many chemicals, EPA has been expanding

its databases on chemical hazards, refining its tools for analyzing chemical toxicity where data are not available, and finding new ways to work with stakeholders to put best practices in place. These improvements, in conjunction with the new authorities and mandates of the 2016 TSCA amendments, offer an opportunity for EPA to create a next generation of improvements in how chemicals are managed in the country that will further enhance public health and environmental quality for the American people.

**Petrochemical processing plant, Texas City, Texas.** *©istockphoto*

## Authors

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Note: In the references that follow, the term "U.S.C." refers to the *United States Code* containing the laws of the United States, "C.F.R." refers to the *Code of Federal Regulations* containing Federal rules and regulations, while "F.R." refers to the *Federal Register,* the official journal of the Federal Government that publishes government agency rules, proposed rules, and public notices.

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## Endnotes

[1] Hearings on H.R. 7229, H.R. 7548, and H.R. 7664 before the Subcommittee on Consumer Protection and Finance of the House Committee on Interstate Commerce and Foreign Commerce, 94th Cong., 1st Sess., p.132–138 (1975).

[2] https://en.wikipedia.org/wiki/Polychlorinated_biphenyl

[3] National Research Council, "Halocarbons, Effects on Stratospheric Ozone" (1976).

[4] Selikoff, I.J., "Asbestos Criteria Document Highlights," American Society of Safety Engineers Journal, p.26 (March 1974).

[5] Dykstra, Susan, "PBB Contamination of Cattle Feed in Michigan, 1973," Department of Earth Resources and Science, University of Michigan-Flint (2010); image PBB Found In Mother's Milk | Old News courtesy of The Ann Arbor District Library. www.aadl.org (oldnews.aadl.org). The 1981 film "Bitter Harvest" portrayed the events associated with this incident.

[6] https://en.wikipedia.org/wiki/Minamata_disease

[7] Council of Environmental Quality, "Toxic Substances", (April 1971)

[8] Ibid., p. v

[9] Public Law 94–469

[10] David Markell, "An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation", 32 Washington University Journal of Law & Policy 333 (2010), at 337

[11] For purposes of discussing these amendments in this report, we refer to them as the "2016 TSCA Amendments".

[12] PBT chemicals combine three critical properties. They persist in the environment, bioaccumulate in living organisms AND cause significant toxicity. Well-known examples of PBT chemicals include PCBs and the pesticide DDT.

[13] CBI includes trade secrets and other proprietary information that companies may protect from public disclosure under a set of federal laws. Such information is generally known as *intellectual property*.

[14] Public Law 99–499.

[15] Within EPA, these aspects of EPCRA were integrated into the program structure of the Superfund program.

[16] EPCRA, Section 313

[17] Ibid., Section 313(j)

[18] The PPA also called upon EPA to establish strategies aimed at incorporating pollution prevention principles (i.e., adoption of source reduction measures, where possible, in favor of recycling, treatment or remediation measures). These principles influenced EPA programs after 1990, leading to several innovative chemical management projects and programs.

[19] EPA, "The Toxic Release Inventory: a National Perspective, 1987", EPA 560-4-89005 (June, 1989). Under EPCRA, regulated TRI facilities have until July 1 of the year following a calendar Reporting Year to submit their reporting forms.

[20] EPA, "TRI National Analysis 2018", https://www.epa.gov/sites/production/files/2020-02/documents/tri_national_analysis_complete_report.pdf (February 2020). Hereafter "2018 TRI National Report". The list of chemicals reportable for 2018 is identified at https://ww.epa.gov/toxics-release-inventory-tri-program/tri-listed-chemicals.

[21] 2017 TRI National Report, p. 35

[22] 2018 TRI National Report, p. 37

[23] EPA, "33/50 Program: the Final Record", EPA-745-R-99-004 (March 1999)

[24] See EPA, "The Toxic Release Inventory in Action: Media, Government, Business, Community and Academic Uses of TRI Data," (July 2013)

[25] 2018 TRI National Report, p. 189

[26] The rules that established these reporting obligations also require that, going forward, importers, manufacturers or processors shifting "inactive" chemicals to an "active" status in the future will need to notify EPA so that the Agency can flag those chemicals as "active" on the Inventory.

[27] EPA News Release, "EPA Releases First Major Update to Chemicals List in 40 Years," (February 19, 2019)

[28] TSCA Section 8(e) (15 U.S.C. 2607(e))

[29] Library of Congress, "Legislative History of the Toxic Substances Control Act," (December 1976), p. 164

[30] EPA's database for 8(e) notifications also includes notifications, known as "FYI" submissions, that are submitted voluntarily. This estimate for the number of substantial risk notifications submitted between 1977 and 2007 is cited in a letter from EPA Assistant Administrator James B. Gulliford to John Stephenson, General Accounting Office (July 2, 2007) ("Gulliford Letter 2007"). The estimate for the number of substantial risk notifications submitted between 2008 and 2019 is based on data provided from EPA staff in November 2019.

[31] TSCA Section 8(d) (15 U.S.C. 2607(d))

[32] TSCA Section 4 (15 U.S.C. 2603)

[33] Gulliford Letter 2007. The letter indicates that EPA had collected more than 50,000 health and environmental studies on existing chemicals.

[34] See Testimony of Alfredo Gomez, Director, Natural Resources and Environment, General Accounting Office, "Chemical Regulation: Observations on the Toxic Substances Control Act and EPA Implementation", GAO-13-696T, before the Subcommittee on Environment and the Economy, U.S. House of Representatives, (June 13, 2013), p. 9.

[35] EPA, "Fact Sheet: 2016 Chemical Data Reporting" (May 2017)

[36] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/introduction-chemview

[37] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce

[38] See Section 14 (U.S.C. 2613) generally for the new provisions related to CBI protection.

[39] Historically, EPA has found that several CBI claims for data that were valid when the chemical was first introduced in commerce cease to be valid once a chemical has been in the marketplace for a long time and competitors become familiar with the chemical's makeup and how it is manufactured.

[40] TSCA Section 6 (15 U.S.C. 2605)

[41] 40 C.F.R. Part 82, Subpart A (sec. 82.1–82.13); EPA Ozone Layer Protection – Regulatory Programs. http://www3.epa.gov/ozone/title6/index.html

[42] TSCA Section 6(e) (U.S.C. 2605(e))

[43] See EPA's Website, at https://www.epa.gov/pcbs/learn-about-polychlorinated-biphenyls-pcbs#lawsandregs, for a listing of the many regulatory actions that EPA has taken on PCBs.

[44] 40 CFR Part 763, Subpart E, promulgated at 52 Fed.Reg. 41846 (October 30, 1987)

[45] For example, the Air program has been particularly active in addressing lead pollution. Its effort to phase out the use of lead in gasoline has made an important contribution to public health.

[46] See 16 CFR Part 1303 for the CPSC's current regulations on lead in paint.

[47] https://www.epa.gov/formaldehyde/formaldehyde-emission-standards-composite-wood-products-0

[48] The proceeding included an Advance Notice of Proposed Rulemaking, two petitions for rulemaking from stakeholders (which required EPA responses before the rulemaking could proceed), an information collection rule on asbestos uses, a Proposed Rule, two rounds of cross-examination of EPA experts and stakeholder briefs (under a unique TSCA process), two re-proposals of the rule to consider new data, and a final rule.

[49] *Corrosion Proof Fittings, et al. v. Environmental Protection Agency,* 947 F.2d 1201 (5th Cir. 1991).

[50] TSCA Section 5(a)(2) (15 U.S.C. 2604(a)(2))

[51] 40 C.F.R. 721.1790; 40 C.F.R. 721.1660; and 40 C.F.R. 721.6000, respectively.

[52] 40 C.F.R. 721.9582

[53] https://www.epa.gov/americaschildrenenvironment/ace-biomonitoring-perfluorochemicals-pfcs

[54] https://www.epa.gov/pfas/epas-pfas-action-plan

[55] See 84 Fed. Reg. 71924 (December 30, 2019), for the list of 20 additional chemicals added to this list.

[56] The statute also creates a process by which a chemical manufacturer can request a risk evaluation for one of its chemicals, provided that the manufacturer pays certain fees to cover a portion of EPA's costs to conduct the evaluation.

[57] The statute allows for extensions of deadlines at the risk evaluation and risk management stages, but such extensions cannot add any more than 2 years in aggregate to the overall proceeding for a specific chemical.

[58] 84 Fed.Reg. 36728 (July 29, 2019). Additional information on prioritization, risk evaluation, and risk management is available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca.

[59] Section 6(b)(4) (U.S.C. 2605(b)(4))

[60] Section 6(c)(2)(B) (U.S.C. 2605(c)(2)(B))

[61] TSCA Section 5 (15 U.S.C. 2604)

[62] See EPA, "TSCA New Chemicals Program Chemical Categories", (August 2010). Documents like these, as well as various software tools, have incorporated EPA's lessons learned from the TSCA new chemical program, and have been shared with the public.

[63] http://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/policy-statement-new-chemicals

[64] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review

[65] https://en.wikipedia.org/wiki/Genus

[66] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review

[67] http://www.nano.gov/nanotech-101

[68] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under

[69] 82 Fed.Reg. 3641 (January 12, 2017), as modified at 82 Fed. Reg. 22088 (May 12, 2017)

[70] Under a SNUR, a chemical manufacturer (including importer) or processor may file a Significant New Use Notice with EPA to seek approval of an intended new use of the substance. These Notices are reviewed under the same process and standards as PMN new chemicals.

[71] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review (downloaded on December 1, 2019). It should be noted that the vast majority of these case involved PMN chemicals.

[72] http://www.epa.gov/p2/pollution-prevention-law-and-policies

[73] https://www.epa.gov/saferchoice

[74] https://www.epa.gov/saferchoice/learn-about-safer-choice-label

[75] http://www.epa.gov/green-chemistry

[76] https://www.epa.gov/greenchemistry/information-about-green-chemistry-challenge

[77] https://www.epa.gov/sustainable-futures/graduating-sustainable-futures#steps