Toxic Substances: A Half Century of Progress

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EPA Alumni Association

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The EPA Alumni Association (EPA AA) has developed this and six other web-based subject matter essays in support of its Half Century of Progress project. An integrated summary based on these materials is contained in Protecting the Environment: A Half Century of Progress, which 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 latter half of the 20th century, as well as the actions taken and progress made in mitigating these problems.

A number of retired EPA program managers and subject matter experts worked together to produce each of the essays. This document was reviewed by the EPAAA Board of Directors and members of the association. We welcome comments on this document, which you may email to the EPA Alumni Association.

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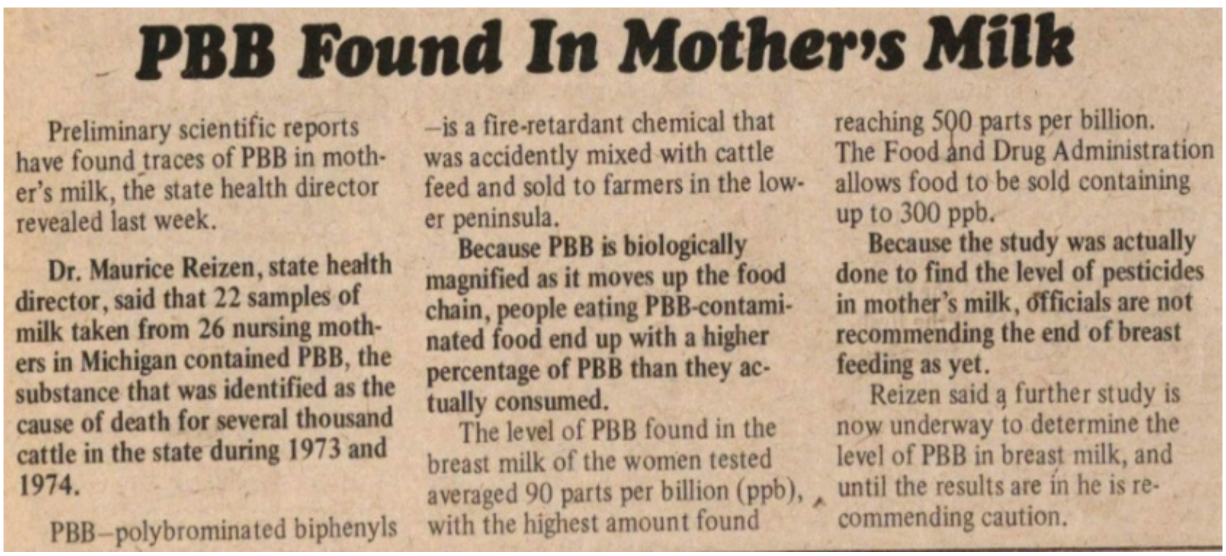
PUBLIC CONCERNS LEAD TO CHEMICAL LAW[1,2,3]

In the 1960s and early to mid-1970s, new reports of chemicals causing cancer 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.[4] 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.[5] Asbestos, a mineral fiber widely used in insulation, caused lung cancer, especially in workers.[6] Polybrominated biphenyls used as flame retardants were mistakenly mixed into



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[7]

animal feed and poisoned people and cattle in Michigan.[7] Eating fish contaminated with mercury caused a severe neurological syndrome in adults as well as birth defects in Minamata, Japan.[8] And the list went on.

Although society reaps enormous benefits from chemicals, there was little or no knowledge of the effects on health or the environment of 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 environmental chemicals 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.

TSCA Becomes Law

Congressional debate on the Toxic Substances Control Act (TSCA) began in 1971. The act encountered opposition from industry and environmental groups and a long stalemate ensued.[9] In 1976, when Congress was adjourning in an election year, it agreed to a number of compromises and TSCA passed into law.[10]

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 and industry to notify EPA before producing *new chemicals* not listed on the Inventory. While TSCA did not specifically require EPA to review *existing chemicals*, it gave EPA authority to regulate chemical production and use, specifically including PCBs. When TSCA passed into law, EPA Administrator Russell E. Train stated that TSCA is "one of the most important pieces of 'preventive medicine' legislation" ever passed by Congress.[11]

TSCA, like the pesticides law discussed in the pesticides essay, differs from other EPA laws in that it regulates commercial products, rather than air or water pollution. TSCA covers a large and 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, and building materials. Over the decades since its passage, TSCA—unlike most of EPA's other statutes—was never revised. However, Congress passed additional laws to deal with important newly recognized issues, including:

- The Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA)[12] addressed concerns raised by the accidental release of methyl isocyanate in Bhopal, India, in 1984, which killed thousands of nearby residents. EPCRA authorized gathering Toxics Release Inventory (TRI) data to inform the public about releases of toxic chemicals.
- The Pollution Prevention Act of 1990[13] created a national policy to prevent or reduce pollution at the source wherever possible.
- TSCA Title IV on Lead Exposure Reduction (1992)[14] recognized that children's exposure to lead in paint caused serious health risks. It authorized EPA, working with other agencies, to implement a comprehensive program for reducing lead exposures.

KEY ACTIONS AND IMPROVEMENTS OVER TIME

Since the 1970s, EPA's implementation of its chemical authorities produced a basic infrastructure for assessing and managing risks from chemicals. EPA's efforts evolved to include three complementary roles: as a source of public information on and understanding of chemical hazards (toxicity), exposures, and risks; as a gatekeeper/guardian protecting against chemical risks; and as a facilitator of and advocate for pollution prevention and environmental stewardship actions.[15]

EPA as the Source for Information on Chemical Hazards, Exposures, and Risks
Both TSCA and EPCRA focus on developing information and providing public access. The laws gave EPA authority to collect information in unprecedented and novel ways, as discussed below. Over time, however, implementation of these acts created tensions between EPA's competing duties of providing public access to information while fulfilling TSCA requirements to prevent disclosure of information claimed by industry as proprietary or trade secret *confidential business information* (CBI).

Creation of the first National Inventory of chemicals in commerce. EPA completed the TSCA Inventory in the late 1970s.[16] This unprecedented and complex undertaking 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.[17] The policies and approaches developed by EPA served as the model for other National Inventories, including those of the European Union, Canada, and Japan. The Inventory also established the baseline for determining *new chemicals* that required EPA notification prior to their commercial manufacture.

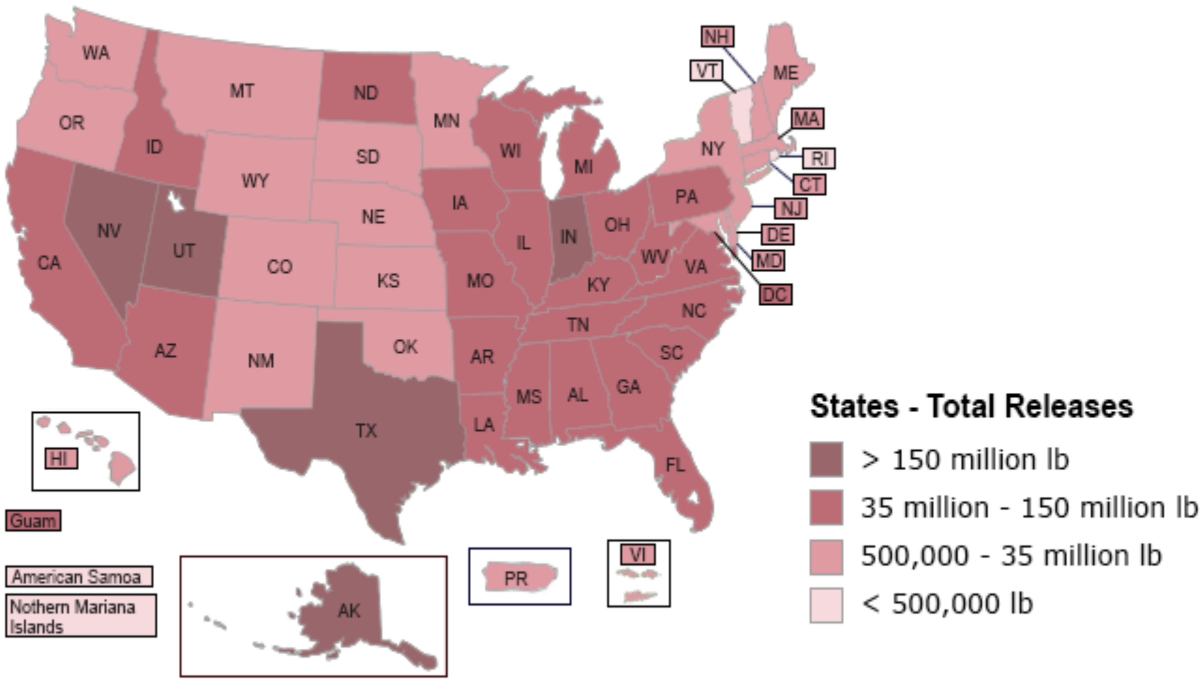
Development of and access to hazard, exposure, and risk information. TSCA and EPCRA included a number of reporting requirements and capabilities EPA could use to obtain the information needed to understand chemical risks and exposures. Important examples include:

- A requirement that companies *immediately* report to EPA any *new* information indicating a chemical presents a "substantial risk" to public health or the environment.[18] This provision addressed the concern that manufacturers had not promptly disclosed information on the dangers of chemicals. New information on the chemical vinyl chloride that showed it caused a rare form of liver cancer (angiosarcoma) in workers[19,20] is one example.

  Since 1977, EPA received over 20,000 of these substantial risk submissions, including information on toxicity test results, worker fatalities and injuries, and product contamination. EPA used that information to publicize new concerns and target chemicals for further assessment or testing. EPA's efforts contributed to a growing recognition by the chemical industry of its responsibilities to understand and appropriately manage chemical risks under such concepts as product stewardship.[21]

- TSCA's Chemical Data Reporting rule provides EPA with regularly updated industry reporting on the volumes, uses, and exposures of some 7,000 of the highest-volume chemicals in commerce.[22] Those data routinely assist EPA in setting priorities for additional review and potential action on these chemicals.

- A key element of EPCRA was the creation of TRI. This was the first EPA statutory program that called for the collection and dissemination of chemical information for the sole purpose of informing the public. This "right to know" program grew significantly over its history. Under TRI, EPA collects data annually from over 20,000 facilities on environmental releases and waste generation for hundreds of toxic chemicals. Through this program, EPA also pioneered new ways to communicate chemical information to the public and developed a range of accessible online databases, interactive maps, and analytical tools for use by the public. These tools allowed users to conduct geographic analyses based on a zip code, as well as at state and national levels, as illustrated in the figure below.[23]



EPA also used TRI data to encourage voluntary reductions in emissions and to track progress over time. One example of the former is the "33/50 Program," which in 1991 challenged industry to reduce TRI emissions of 17 priority chemicals by 33% in one year and by 50% by 1995. 33/50 was successful in achieving the emission reductions ahead of both commitment deadlines and in demonstrating EPA's flexibility in approaching the issue.[24] Regarding TRI's progress over time, data show that total releases of TRI chemicals decreased by 7% during the period 2003–2013.[25] More recently, in a major step forward, TRI provides tools that allow communities at the neighborhood level to learn about toxic chemicals that industrial facilities are using and releasing.[26]

- Based on the success of the TRI program, EPA began an effort in the early 1990s to increase public access to the data collected through the TSCA program. The growth of the Internet helped make information about chemicals even more readily accessible to the public. EPA recently undertook an effort to present information in a more integrated format through its *ChemView* database.[27] *ChemView* 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.

EPA also used both regulatory and voluntary efforts to obtain existing human and environmental toxicity test data needed to assess thousands of chemicals over the years. An example is EPA's High Production Volume Challenge Program, which involved a voluntary challenge by EPA to 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. Where needed, EPA followed up with test rules on high-volume chemicals[28] to obtain needed test data on chemicals not voluntarily sponsored in the program.[29] At the same time, EPA struggled to use TSCA effectively to require industry to conduct new testing. This issue and the problems that EPA encountered have been the subject of repeated critical reports by the Government Accountability Office.[30]

EPA must balance these efforts to provide information to the public with its obligations under a variety of federal laws to ensure the protection of company trade secrets and other proprietary information recognized legally as CBI.[31] Effective implementation of TSCA's requirements, particularly its new chemical review, necessitates EPA access to CBI while preventing unauthorized public disclosure At the same time, certain kinds of chemical data, such as "health and safety studies," do not have the same level of protection against disclosure.[32]

To maintain a balance between public access to data and protection of intellectual property, EPA developed a series of legal and policy measures that 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.[33]

The issue of how much or how little information to keep confidential remains controversial. For example, TSCA does not allow state officials to access CBI data collected by EPA, and many stakeholders believe that industry's CBI claims have been unreasonably broad.

EPA as the Gatekeeper/Guardian for Protecting Against Chemical Risks

New chemicals: making a good play from a bad hand. Following establishment of the Inventory, TSCA required that industry notify EPA before introducing a "new" chemical—i.e., one not on the Inventory. In addition, TSCA allowed EPA to require testing and impose risk management controls to address potential risks of new chemicals.[34] 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 companies to include test data in the notification provided to EPA. For this reason, initial hopes were not very high for EPA's ability to implement an effective program.

EPA rose to the challenge by breaking new scientific ground in developing analytical tools to predict how the structure of a chemical relates to its properties and biological activities. The term given to these tools 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 publicly released its structure-activity tools and strongly encouraged their use by industry in developing new chemicals that can meet performance requirements while avoiding toxicity or other concerns.[35]

Since 1979, EPA received over 50,000 notices on new chemicals and regulated or required testing to protect health or the environment on over 30% of those chemicals.[36] In meeting these responsibilities, EPA functioned both as a gatekeeper to ensure that risky chemicals do not enter commerce and as a facilitator to encourage the development of innovative "safer" or "greener" new chemicals.[37] EPA's 1999 statement of policy on persistent, bioaccumulative, and toxic (PBT) chemicals illustrates EPA's efforts to encourage safer and greener new chemicals. Like PCBs and the pesticide DDT, PBTs persist in the environment, bioaccumulate in living organisms, and cause toxicity. The national policy represented the first formal statement regarding new chemical PBTs and served to discourage their introduction into commerce.[38]

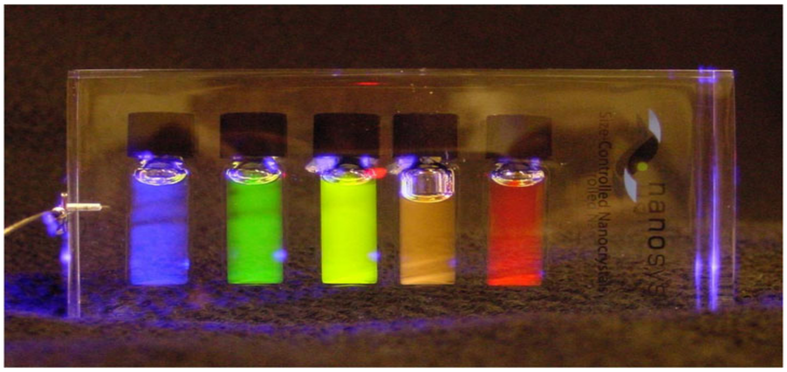
Through its efforts, EPA defied initial expectations and contributed significantly to managing new chemical risks and to innovation in safer and greener new chemicals.[39]

The challenge of emerging technologies. EPA also had to develop approaches within the TSCA framework 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 essay. 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 while appropriately encouraging 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.[1,40] EPA reviewed approximately 75 new microorganisms over the past 20 years,[41] most of which were used in the manufacture of commercial chemicals in production facilities that minimized exposures and releases to the environment.

[1] Intergeneric microorganism contain genetic material from more than one genus of organisms; "genus" is the biological classification of organisms that comes above species and below family.

Nanotechnology is the understanding and control of matter at the nanoscale[2] () where unique physical or chemical phenomena enable novel applications.[42] Nano-sized materials can, and often do, have fundamentally different physical and chemical properties than their larger-sized counterparts.



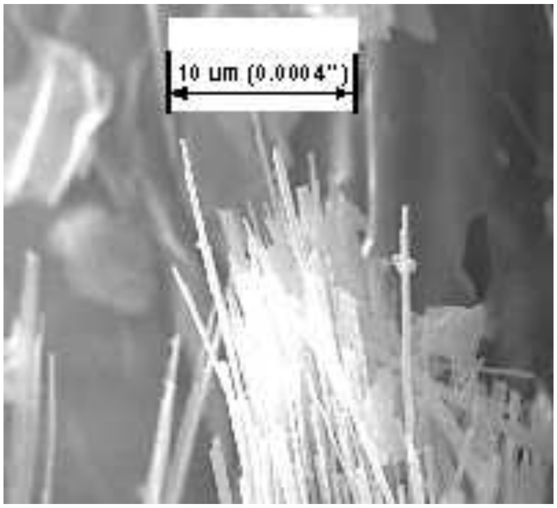
Quantum dots are nano-sized semiconductors with unique optical and electrical properties used in energy-efficient LED lights and solar cells. Each vial contains different sized particles that produce different colors of fluorescence.[43]

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. Since 2005, EPA has reviewed over 100 new chemical[44] nanoscale materials, including carbon nanotubes, fullerenes, and quantum dots. EPA is in the process of developing regulations to provide a better understanding of the commercial scope, hazards, and exposures of *existing chemical* nanoscale materials.[45]

Existing chemicals: early high hopes, followed by asbestos, and the need for creative adaptation.

Early hopes and successes. Given the breadth of TSCA's existing chemical risk management authorities,[46] hopes were high at the outset. EPA's efforts started with a bang in the late 1970s when it promptly completed control actions on "old problems," such as fully halogenated CFCs and PCBs. EPA banned 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.[47] In 1979, EPA banned the new manufacture of PCBs—although, for economic reasons, it allowed continued use of existing PCBs in electrical equipment, such as transformers. Over the years, EPA took more than a dozen actions to strictly regulate this use and ensure the safe disposal of PCBs at the end of their commercial life.[48] Following these early successes, however, EPA struggled to regulate existing chemicals, as discussed below.[49]

2 The nanoscale is about 1 to 100 nanometers; a nanometer is 10^{-9} meter, or one billionth of a meter.



Microscopic asbestos fibers[50]

Asbestos.[50] Perhaps the most important effort by EPA to regulate existing chemicals concerned asbestos. In 1989, after an extensive rulemaking process, EPA issued a rule that would have banned and phased out virtually all uses of asbestos.[51] Following a legal challenge by several parties, a judicial decision overturned the rule.[52] This decision profoundly affected EPA's regulatory approach to existing chemicals. EPA's leaders and legal advisors concluded that the regulatory burdens imposed by the court's decision—most notably, the extent of analysis needed to determine that a regulation used "the least burdensome requirements"—threatened to stifle, if not preclude, EPA's future ability to regulate existing chemicals.

Creative adaptation. In response, 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" regulatory authority.[53] EPA used this rule to regulate a number of "bad actors," including polybrominated biphenyls, carcinogenic benzidine dyes, and the toxic flame retardant "tris" (used in children's pajamas).[54] In these instances, EPA acted, often after encouraging voluntary industry phase-outs, to regulate reintroduction of these chemicals into commerce.

Lead in paint. EPA's work on reducing exposure to lead in paint began in earnest following the 1992 congressional requirement that EPA implement programs to reduce blood lead levels in children. EPA promulgated several regulations[55] requiring the use of lead-safe work practices by firms engaged in renovation and remodeling projects that disturb lead-based paint in certain structures built before 1978 (the year in which a regulation banned the use of lead-based paint in residential properties and commercial buildings[56]). Data developed by the Centers for Disease Control and Prevention (CDC) National Biomonitoring Program[57] show significant progress in the ongoing effort to eliminate childhood lead poisoning as a public health concern.[58]

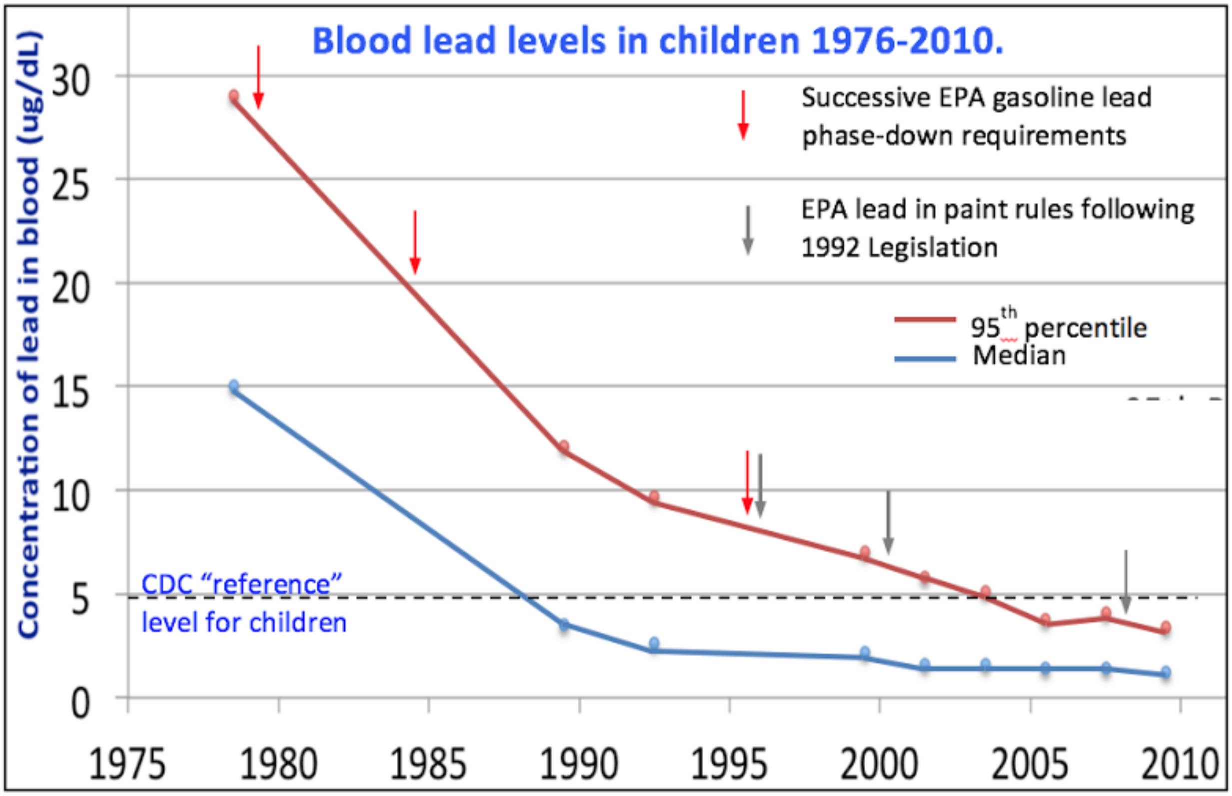
EPA's assessment of CDC data indicates the median concentration of blood lead levels of children between the ages of 1 and 5 years dropped by 92% over the past three to four decades,[59] as shown in the figure below. This decrease resulted from a series of efforts, starting with removal of lead from gasoline, as discussed in the essay on air pollution, and the continuing efforts to manage or eliminate exposure to lead paint. However, there are no known safe blood lead levels for children. While the decreasing levels are favorable, there are still approximately 535,000 children with blood lead levels above CDC's "reference" level for children of 5 micrograms per deciliter[60] and 37 million homes with lead-based paint.[61] Many of these homes are in low-income and minority communities. Therefore, EPA's efforts must continue to focus on preventing or eliminating children's exposure to lead.

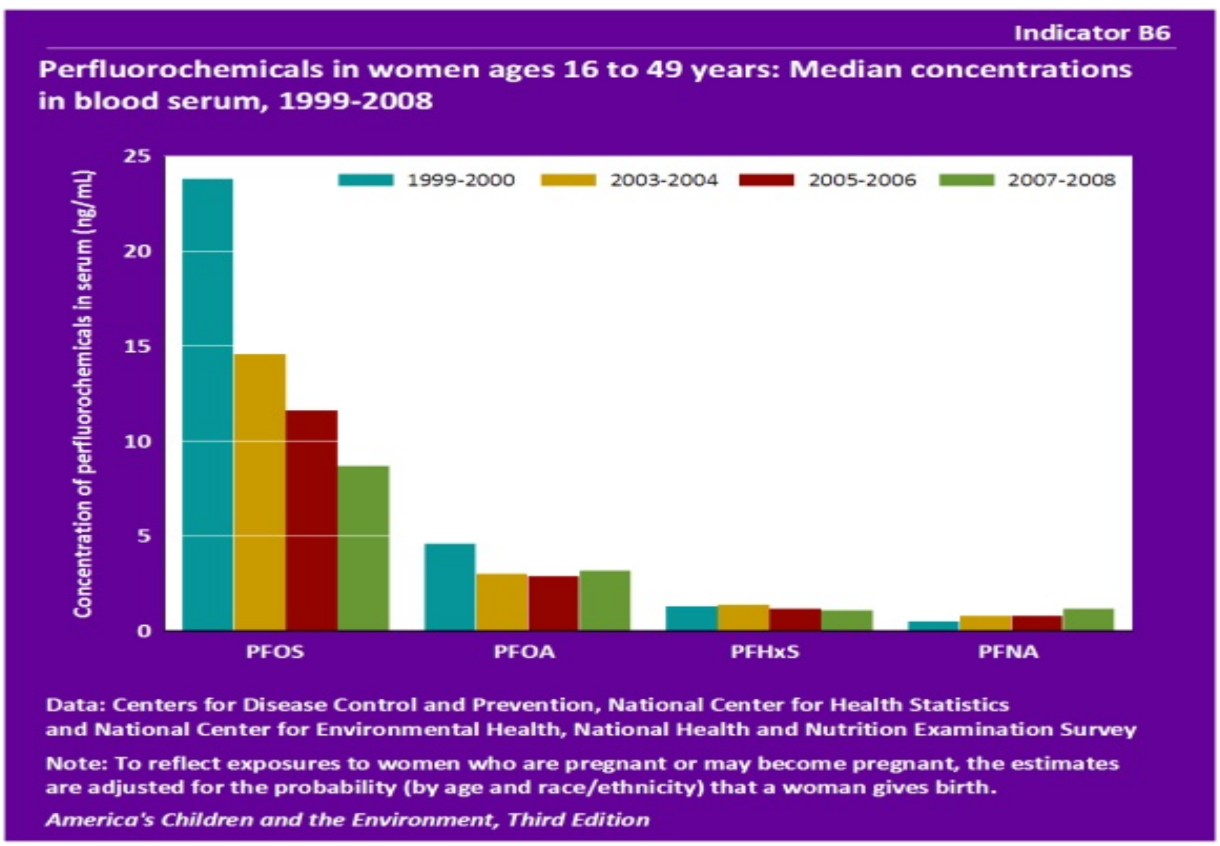
Perfluorinated chemicals came to EPA's attention in the late 1990s through substantial risk notices reporting on PFOS (perfluorooctyl sulfonic acid). The chemical was widely used in both consumer and industrial applications, including spray-on soil and stain repellants used by consumers. New studies showed that PFOS caused unusual and serious effects in animal toxicity tests, was present worldwide in humans and wildlife, and was highly persistent in the environment. After engaging with EPA, the U.S. manufacturer of PFOS voluntarily phased out production. EPA then used its significant new use authority and strictly limited the use of some 270 PFOS-related chemicals.[62]

Within a few years, similar concerns were shown for other perfluorinated chemicals, including PFOA (perfluorooctanoic acid), 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.[63]

The results from the voluntary program show that the companies are on track to reach the program's goal of phasing out these chemicals in the United States and in meeting their global commitments by the end of 2015. EPA is applying additional significant new use regulations to lock in the results of the voluntary phase-outs. EPA complemented and supported its efforts on existing chemical perfluorinated chemicals by using its new chemicals regulatory authority to oversee industry efforts to commercialize over 150 safer alternatives to the perfluorinated chemicals.[64]

Results. The results of the CDC's National Biomonitoring Program demonstrate the success of EPA's efforts to regulate PCBs,[65] lead paint exposures,[57] perfluorinated chemicals,[66] and other toxic and bioaccumulative chemicals.[67] The CDC program shows sustained decreases in the presence of these chemicals in human tissue over time. The figures below show plots of the progress achieved in this regard for lead[59] and for a series of perfluorinated chemicals.[68]


Blood lead levels in children 1976-2010.
Concentration of lead in blood (ug/dL)
Successive EPA gasoline lead phase-down requirements
EPA lead in paint rules following 1992 Legislation
95th percentile
Median
CDC "reference" level for children
0
5
10
15
20
25
30
1975
1980
1985
1990
1995
2000
2005
2010


Indicator B6
Perfluorochemicals in women ages 16 to 49 years: Median concentrations in blood serum, 1999-2008
Concentration of perfluorochemicals in serum (ng/mL)
1999-2000
2003-2004
2005-2006
2007-2008
0
5
10
15
20
25
PFOS
PFOA
PFHxS
PFNA
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

EPA as a Facilitator/Advocate for Pollution Prevention and Environmental Stewardship

While during its early years EPA was primarily concerned with "end-of-pipe" and "command-and-control" approaches, this focus 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 TRI, *ChemView*, and other information sources.

Pollution prevention was the subject of several Executive Orders on "Greening the Government,"[69] 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 industrial chemicals ranging from cleaning products to electronics to chemical production.[70]

Safer Choice[71] (formerly known as Design for the Environment) is a voluntary partnership helping consumers, businesses, and purchasers to find products that perform well and are safer for human health and the environment. This program, which provides information about chemical safety to consumers and commercial buyers to help them make decisions about products in their daily lives, has identified more than 650 safer chemicals through 2015. Moreover, its certification and labeling program has labeled over 2,000 safer products for consumer, institutional, and industrial markets.

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.[72] Through the Presidential Green Chemistry Challenge alone, EPA received more than 1,500 nominations and recognized almost 100 winning technologies. Over time, these technologies significantly reduced the hazards associated with designing, manufacturing, and using chemicals. The presidential 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, and eliminating 7.8 billion pounds of carbon dioxide-equivalent releases to the air.[73]

Over the years, EPA continued to refine these programs to support networks of institutions outside EPA that conduct research and provide education on ways to incorporate pollution prevention and environmental protection into technological innovation. EPA also worked to complement its traditional command-and-control efforts though a variety of pollution prevention and environmental stewardship initiatives that over time contributed to a reduced environmental footprint by both industry and the public. These efforts represent work very much in progress.[74]

GOING FORWARD: DEALING WITH THE MIXED LEGACY OF THE PAST AND MEETING FUTURE CHALLENGES

The public's concerns with toxic chemicals led initially to enactment of TSCA—legislation considered groundbreaking at the time. Since then, EPA struggled in some areas. This may have been because TSCA did not include legislative deadlines for the review of existing chemicals, and its statutory authorities for testing and controlling such chemicals were often difficult to apply. Examples of the latter include TSCA's requirements for legal findings to require testing and for undue risk-benefit balancing in taking control actions. In contrast, other TSCA efforts (new chemicals, information collection and dissemination) were more successful, perhaps because of greater legal flexibility and authority.

Much work remains to complete TSCA's "unfinished business," particularly as it relates to testing, assessing, and appropriately managing the risks of existing chemicals. EPA must also address emerging technologies. This requires that EPA develop the understanding and regulatory approach needed to assess and manage risks from increasingly complex and more widely used nanomaterials and the commercial use of "synthetic biology" products. Synthetic biology is expected to lead to an influx of new genetically modified microorganisms used in the environment (e.g., in biomining, bioremediation, or production of algal biofuels in ponds). While future challenges remain in many areas, a central question is the prospect for congressional revision of the 40-year-old act.

EPA's efforts on chemicals benefitted over the years from new legislative concepts. Examples include the public's "right to know" under EPCRA, the goal of pollution prevention, and the need to reduce children's exposure to lead in paint. The original concept of pollution prevention as first articulated in the 1990s now includes such topics as product design, reducing the environmental footprint of technology, and environmental sustainability. These concepts (and others currently unknown) will undoubtedly undergo further development and expansion in the years ahead.

Whither TSCA? TSCA's primary statutory provisions remain unchanged after almost four decades. This distinguishes TSCA from the evolving nature of EPA's other major statutes over time. It also raises important questions about whether EPA's chemical program is keeping pace with chemical management trends in the current global economy. These trends include increasing support for such concepts as sustainability and environmental stewardship.

In addition, while the United States relies on an unchanged law, major U.S. trading partner nations are now implementing improved and strengthened second- and third-generation laws.

Examples include the Canadian Environmental Protection Act and the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals. Further, perceived limitations in EPA's chemical management program have led states to act on their own to regulate chemicals.

Legislatively, TSCA was a curious orphan from the point of view of congressional interest. Until the mid-2000s, Congress showed less interest in TSCA and its implementation than in almost any other major environmental law, as evidenced by the very few oversight hearings that occurred in the 30-plus years of TSCA's history. One example, the title of which says a lot, was the 1988 hearing "Whatever Happened to the Toxic Substances Control Act?"[75]

Recently, however, there have been multiple hearings in both the House and the Senate, and there is renewed interest and progress in reauthorizing and reforming TSCA. Among the changes under consideration are amendments to prioritize, test, and assess chemicals and allow EPA to control or prohibit significant chemical risks without the burdensome review requirements mandated by current law. Other changes allow for more expansive release of CBI, including to states, and sort through issues concerning federal preemption of state actions on TSCA chemicals.

Since 2009, the chemical industry, environmental groups, and the Executive Branch issued "principles" of TSCA reform that broadly agree with each other, but specific legislative progress built on those principles has been slow. Sen. Frank Lautenberg (D-NJ), who made various proposals, spearheaded the legislative effort until his death in June 2013. There were also several legislative proposals considered by a House subcommittee. Most recently, in 2015, Sen. Tom Udall (D-NM) and Sen. David Vitter (R-LA) offered significantly changed legislative proposals, some of which have the potential to be the basis of an agreement on a set of amendments to TSCA,[76] and progress continued in the House.[77] The most troublesome issue in the current debate, among many, is federal preemption. This issue concerns the authority that a state government should have to control a TSCA chemical once EPA has taken some legal steps under a revised and strengthened TSCA. The issues surrounding preemption are difficult, but until they are resolved, they will likely remain as roadblocks to successful legislation.

The pace picked up considerably in 2015, starting with the House's passage of the TSCA Modernization Act (H.R. 2576) in June by a 398–1 vote.[78] Then in December 2015, in a unanimous voice vote, the Senate passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697).[79] Hopes are higher than they have ever been for TSCA reform. The remaining steps are for the two chambers to reconcile the differences in their competing bills and pass the new version that, after its signature by the President, will lead to enactment of the new legislative approach. Such a momentous event opens a very real possibility for a profoundly different future for the assessment and management of chemicals in the United States.

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James V. Aidala. EPA experience: 1975-76; 1979-81; 1993-2001; held various positions including summer intern in the pesticide program as well as Associate Assistant Administrator for the Office of Pollution Prevention and Toxic Substances (1993-2000), and left EPA as Assistant Administrator for OPPTS in 2001. Education: undergraduate studies at Massachusetts Institute of Technology and Brown University (B.A. and M.A. in Sociology); graduate studies at Harvard University 1979-81.

Mark Greenwood. EPA experience: 1978-1994; held various legal and management positions including Associate General Counsel for Pesticides and Toxic Substances, Assistant General Counsel for Superfund, Assistant General Counsel for RCRA, and from 1990-1994, Director of EPA Office of Pollution Prevention and Toxics. Education: University of Michigan (B.A., M.P.P., and J.D.

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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[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] Testimony of John R. Quarles, EPA Deputy Administrator (1975) http://www2.epa.gov/aboutepa/quarles-testifies-need-toxic-substances-act

[3] Schweitzer, Glenn E., Borrowed Earth, Borrowed Time: Healing America's Chemical Wounds (1991)

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

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

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

[7] 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.

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

[9] Schweitzer, pp. 12-16.

[10] Public Law 94-469

[11] http://www2.epa.gov/aboutepa/train-sees-new-toxic-substances-law-preventive-medicine

[12] Public Law 99-499

[13] Public Law 101-508

[14] Public Law 102-550

[15] General information and statistics can be found in the EPA report "Overview: Office of Pollution Prevention and Toxics Laws and Programs" (2008) http://archive.epa.gov/oppt/pubs/oppt101_tscalaw_programs_2008.pdf

[16] TSCA Section 8(b) (15 U.S.C. 2607(b))

[17] http://www.epa.gov/tsca-inventory

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

[19] Library of Congress, Legislative history of the Toxic Substances Control Act, together with a section-by-section index (1976; https://archive.org/details/leehisto00unit), p. 164.

[20] Infante, Peter F., "Oncogenic and Mutagenic Risks in Communities with Polyvinyl Chloride Product Facilities," 271 New York Academy of Science Annals, pp 49-57 (1976).

[21] One example is the American Chemistry Council's "Responsible Care" program (http://responsiblecare.americanchemistry.com/) which has grown and evolved since its inception in 1988.

[22] 40 C.F.R. Part 711; http://www.epa.gov/chemical-data-reporting

[23] http://www.epa.gov/toxics-release-inventory-tri-program

[24] http://yosemite.epa.gov/ee/epa/eed.nsf/dcee735e22c76aef85257662005f4116/5eb52300315c914f8525777d000cbd0e!opendocument

[25] http://www.epa.gov/toxics-release-inventory-tri-program/2013-tri-national-analysis-releases-chemicals

[26] http://www.epa.gov/toxics-release-inventory-tri-program/tri-for-communities

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

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

[29] http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/data-development-and-information-collection-assess-risks#hpv

[30] See for example, Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective. GAO/RCED-94-103 (1994; http://www.gao.gov/products/RCED-94-103) which prompted Congressional hearings in 1994. GAO has also issued many other reports critical of TSCA and its implementation, a summary of which is available in Chemical Regulation: Observations on the Toxic Substances Control Act and EPA Implementation. GAO-13-696T (2013; http://www.gao.gov/products/GAO-13-696T).

[31] TSCA Section 14 (15 U.S.C. 2614)

[32] TSCA Section 14(b)(1) (15 U.S.C. 2614(b)(1))

[33] http://www.epa.gov/tsca-cbi; http://www.epa.gov/tsca-cbi/basic-information-effort-review-claims-confidential-business-information-cbi.

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

[35] EPA released and encouraged the use of structure activity tools through its Sustainable Future program (http://www.epa.gov/oppt/sf/index.htm; http://www.epa.gov/oppt/sf/tools/methods.htm).

[36] http://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epa-actions-reduce-risk-new#section 5; http://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-premanufacture-notice-epa#NOC; http://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-premanufacture-notice-epa#exempt; EPA, Overview: Office of Pollution Prevention and Toxics Laws and Programs, op. cit., p. 10-12.

[37] EPA, Overview: Office of Pollution Prevention and Toxics Laws and Programs, op. cit., p. 12-13.

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

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

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

[41] http://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-biotechnology-under-tsca

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

[43] http://www.epa.gov/expobox/exposure-assessment-tools-chemical-classes-nanomaterials; image courtesy of

National Nanotechnology Initiative.

[44] http://www.epa.gov/tsca-inventory/nanoscale-substances-tsca-inventory

[45]

http://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under

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

[47] 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

[48] http://www.epa.gov/epawaste/hazard/tsd/pcbs/index.htm

[49] http://www.epa.gov/assessing-and-managing-chemicals-under-tsca

[50] Image courtesy of and for more information on asbestos, see http://www2.epa.gov/region8/abcs-asbestos.

[51] 54 F.R. 29460 (July 12, 1989).

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

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

[54] 40 C.F.R. 721.1790; 40 C.F.R. 721.1660; and 40 C.F.R. 721.6000, respectively.

[55] http://www.epa.gov/lead/lead-laws-and-regulations.

[56] Consumer Product Safety Commission (CPSC) (16 C.F.R. Part 13); http://www.cpsc.gov/business--manufacturing/business-education/lead/lead-in-paint/.

[57] http://www.cdc.gov/biomonitoring/

[58] http://www.cdc.gov/biomonitoring/Lead_BiomonitoringSummary.html

[59] 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.

[60] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6213a3.htm

[61] http://portal.hud.gov/hudportal/documents/huddoc?id=AHHS_REPORT.pdf

[62] 40 C.F.R. 721.9582

[63] http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/20102015-pfoa-stewardship-program

[64]

http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/new-chemicals-program-review-alternatives-pfo a-and

[65] "PCBs have decreased by more than 80% since the 1980s" (http://www.cdc.gov/biomonitoring/DioxinLikeChemicals_BiomonitoringSummary.html)

[66] http://www.cdc.gov/biomonitoring/PFCs_BiomonitoringSummary.html

[67] http://www.cdc.gov/biomonitoring/biomonitoring_summaries.html

[68] U.S. EPA, America's Children and the Environment, Third Edition (2013); see http://www.epa.gov/ace/biomonitoring-perfluorochemicals-pfcs.

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

[70] More information on pollution prevention can be found at http://www.epa.gov/p2/

[71] http://www.epa.gov/saferchoice

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

[73] http://www.epa.gov/green-chemistry/information-about-presidential-green-chemistry-challenge

[74] http://www.epa.gov/p2/

[75] http://catalog.hathitrust.org/Record/011339960

[76] http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=3eae7787-b182-be85-c483-bdd391e4302b.

[77] https://energycommerce.house.gov/hearing/hr-tsca-modernization-act-2015

[78] https://www.congress.gov/bill/114th-congress/house-bill/2576

[79] https://www.congress.gov/bill/114th-congress/senate-bill/697