REPRODUCTIVE ROULETTE

Declining Reproductive Health, Dangerous Chemicals, and a New Way Forward

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Contents

PART III

A new way forward

Americans are exposed to chemicals everyday that threaten reproductive health. Indeed, reproductive health has declined as exposure to chemicals such as BPA, PBDEs, and phthalates has increased. We should act to protect Americans from these chemicals by taking the following steps:

- Adopt standards to significantly reduce exposure to chemicals that threaten reproductive health and move to safer chemical alternatives.
- Expand collection, assessment, and public dissemination of chemical safety data.
- Strengthen and modernize our laws governing chemical exposures and provide the resources necessary for regulatory agencies to deliver chemical safety.

I. Stronger standards, safer chemicals

Americans are now exposed to dangerous chemicals even when safer substitute chemicals and other alternatives are available. The following slides recommend measures to limit these exposures. Specifically:

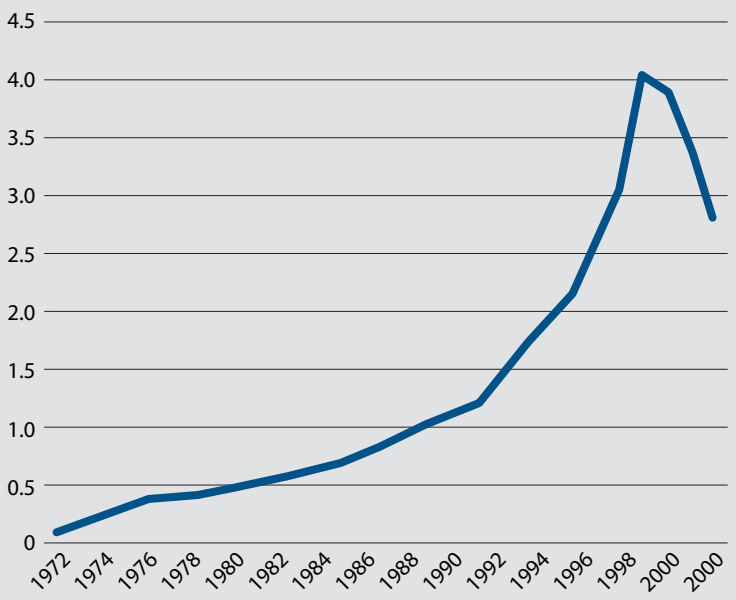
- Stronger standards should be adopted to reduce human exposure. Testing in Sweden found a 30 percent drop in PBDE levels in women's breast milk after stronger standards were adopted.
- High levels of occupational exposure should not be tolerated. Most workplace exposure standards are currently far weaker than standards for the general population.
- Safer alternatives to PBDEs, BPA, and other dangerous chemicals are available and should be required. Congress should pass recently introduced legislation that would ban BPA in all food and beverage containers.
- More research is needed to find safer alternatives. Green chemistry now constitutes a miniscule portion of the federal budget.

Protective standards are needed to reduce chemical exposures

In 1997, Sweden responded to research that showed a drastic rise in PBDEs in breast milk by imposing PBDE restrictions. PBDEs in the breast milk of Swedish women subsequently fell 30 percent, according to a follow-up study. The United States can achieve similar success by adopting new protective standards for PBDEs, BPA, and other dangerous chemicals.

Source: Natural Resources Defense Council, "Healthy Milk, Healthy Baby: Chemical Pollution and Mother's Milk" (2005); D. Meironyte, K. Noren, and A. Bergman, "Analysis of Polybrominated Diphenyl Ethers in Swedish Human Milk, A Time-related Trend study, 1972–1997," *Journal of Toxicology and Environmental Health* Part A, 58 (6) (1999): 329–341; K. Noren and D. Meironyte, "Certain Organochlorine and Organobromine Contaminants in Swedish Human Milk in Perspective of Past 20–30 Years," *Chemosphere* 40 (9–11) (2000): 1111–1123.

PBDEs in breast milk in Sweden



Source: NRDC.

Workers should be protected

Occupational limits on chemical exposures are often less protective than environmental standards meant to safeguard the general population. This chart shows the substantial difference in occupational and environmental standards for four dangerous chemicals. Environmental standards are set where they are because higher exposure levels are considered dangerous. Yet workers are exposed to these higher levels every day. This discrepancy in protection should be closed.

Source: Amanda Hawes, "Why We Must Put the Precautionary Principle to Work at Work: Occupational Disease in the U.S. Semiconductor Industry as Case-in-Point" (November 2006).

Occupational protections are weaker than environmental protections for the general population

Chemical	Occupational standard	Environmental standard*
Benzene	1 part per million	1 part per billion
Trichloroethylene (TCE)	25 parts per million	7 parts per billion
Perchlorate	25 parts per million	.3 parts per billion
Methylene chloride	25 parts per million	1 part per billion

*Environmental standards were converted from micrograms per day (µg/day) to the measurement used for occupational standards, which is based on time-weighted average, or TWA, exposure over an 8-hour period.

Safer alternatives are available

Chemicals that threaten reproductive health are frequently not necessary and can be phased out. This table shows that safer alternatives to PBDEs are already available. The Consumer Product Safety Commission should complete a pending national flammability standard that would reduce the use of PBDEs and other dangerous flame retardants.

Safer alternatives to PBDEs

PBDE exposure pathway	Design strategies to reduce PBDEs	Alternatives to PBDEs (selected examples)
Electronics	Reduce the need to use flame-retarded plastics through the use of non-halogenated compounds	• Bromine-free circuit boards for TVs, VCRs, and DVD players (Sony) • Phosphorous-based flame retardants for printed circuit boards (Hitachi) • Flame resistant plastic without Deca-PBDE (Toshiba) • Halogen-free low-voltage internal wires (Panasonic)
Furniture and soft foams	Use natural fibers such as wool	• Many furniture companies such as IKEA are transitioning to PBDE-free products • Fire-barrier technologies for mattresses (Serta)

Safer alternatives should be required

Safer alternatives to dangerous chemicals should be required where they are available. Congress enacted legislation in August 2008 that bans phthalates in children's products. Congress should also pass recently introduced legislation to ban BPA in all food and beverage containers. As the chart shows, BPA is not necessary.

Safer alternatives to BPA

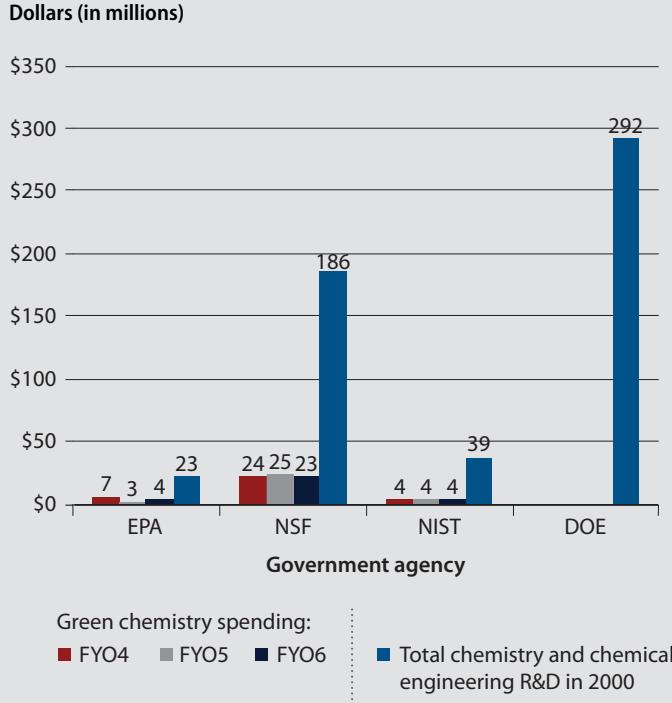
BPA exposure pathway	BPA alternatives
 Baby bottles and sippy cups	• Baby-safe glass • Polyethylene (plastic #'s 1, 2, & 4) • Polypropylene (plastic #5)
 Consumer products with polycarbonate and epoxy	• Reusable aluminum sports bottles • Fresh, frozen, and dried foods instead of canned • Copolyester water bottles • Unlined stainless steel for beverage containers (e.g., Klean Kanteen)

More research is needed to find safer chemical options

Safer chemical options may not be readily available for all products and industries that threaten reproductive health. Finding solutions should be a priority in these cases. Funding for green chemistry, however, constitutes a very small part of the federal budget—and indeed, a very small part of total chemistry and chemical engineering research and development, as this chart shows.

The dollar figures shown here were compiled for a report by the Committee on Science and Technology of the U.S. House of Representatives. Funding for green chemistry is not broken out in federal agency budgets, so updated information is not available. But there has not been any significant bump in funding for green chemistry since this information was compiled.

Source: Committee on Science and Technology, U.S. House of Representatives, "Green Chemistry Research and Development Act of 2005," House Report 109–82 (2005).



II. Knowledge for action

The federal government needs good information to set appropriate standards and target green chemistry research. But decision-making suffers from enormous gaps in knowledge about commercial chemicals and their health consequences. The following slides recommend measures to close these gaps. Specifically:

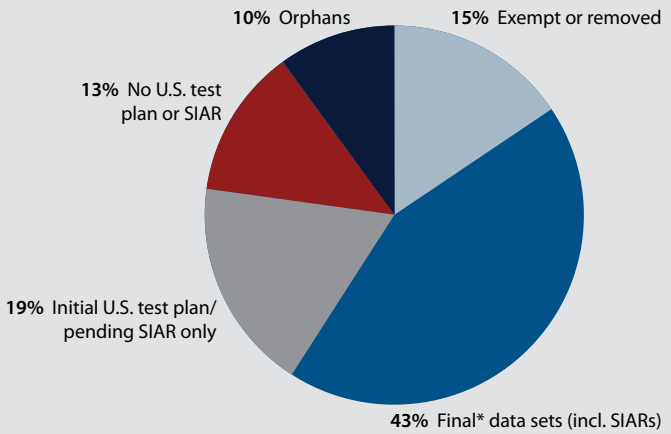
- Chemical companies should be required to provide the necessary data to ensure their products are safe. More than 85 percent of chemicals have not been tested for their effects on human health, including more than 50 percent of high-volume chemicals.
- The EPA's chemical assessment process, conducted through the Integrated Risk Information System, must be improved. The EPA is now completing fewer than five assessments per year and more than half of current assessments may be outdated.
- Public disclosure of chemical safety information should be expanded. Disclosure under the Toxics Release Inventory contributed to a 60 percent reduction in releases of "core" toxic chemicals.
- Pre-market safety testing should be required. No such testing is currently required for chemicals found in consumer products and cosmetics or industrial chemicals used in occupational settings and released into the environment.
- Research is needed to examine possible environmental triggers of reproductive health problems. The landmark National Children's Study, in particular, deserves full support.

More data is needed on chemical safety

The EPA, chemical industry, and Environmental Defense Fund partnered in 1998 to establish the U.S. High Production Volume, or HPV, Chemical Challenge to address significant gaps in chemical hazard data. This program sought to enlist chemical manufacturers to voluntarily test HPV chemicals—chemicals produced or imported in the United States in quantities of 1 million pounds or more per year. Testing was supposed to be completed by 2004, but only 43 percent of these HPV chemicals have final data sets, and 10 percent are "orphans" that lack an industry sponsor for testing. Even less is known about chemicals that are not high volume. Fewer than 15 percent of the 80,000 chemicals registered in the United States have been tested for their effects on human health. Chemical companies should be required to provide the necessary data to ensure their products are safe.

Source: Environmental Defense Fund, "HPV Chemical Tracker" (July 30, 2008).

Overall status of the 2,782 HPV challenge core list of chemicals



The purpose of the HPV Challenge program is to generate for each chemical a Screening Information Data Set, or SIDS, which includes data on reproductive toxicity. SIAR stands for SIDS Initial Assessment Report.

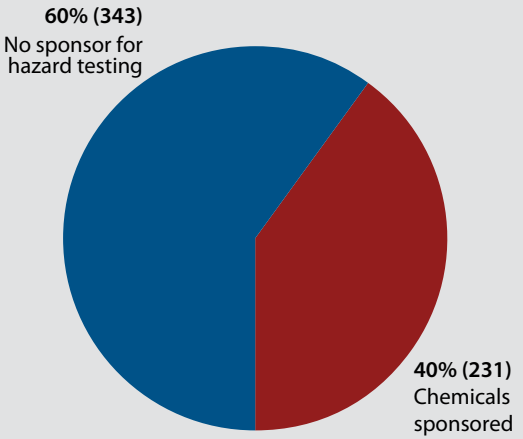
* Most final U.S. datasets not yet reviewed for quality or completeness.

Data on new high-volume chemicals is lacking

The number of High Production Volume chemicals is growing. Yet the HPV Challenge program does not include chemicals that have more recently cracked the threshold of 1 million pounds annually. In 2005, the chemical industry, on its own, initiated the Extended HPV Program to once again enlist chemical manufacturers, on a voluntary basis, to test 574 "new" HPV chemicals. Unfortunately, sponsors were found for only 40 percent of these chemicals, and most sponsors have still not produced hazard data.

Source: American Chemistry Council, "Extended HPV Program" (May 2006). In response to the author's inquiry, an ACC spokesperson confirmed that these numbers are still accurate and current. In other words, no new sponsors have been added since 2006.

Status of 574 'new' HPV chemicals



The 574 "new" HPV chemicals are drawn from the EPA's 2002 Toxic Substances Control Act Inventory Update. Even more chemicals have reached HPV levels since this update. These chemicals are generally not being tested.

Chemical assessments are becoming obsolete

Another problem is the EPA's Integrated Risk Information System, or IRIS, a publicly searchable database that contains assessments of more than 540 toxic chemicals. IRIS "is at serious risk of becoming obsolete because EPA has not been able to keep its existing assessments current or to complete assessments of the most important chemicals of concern," according to the Government Accountability Office, the independent investigative arm of Congress. The EPA is now completing fewer than five assessments per year and more than half of its current assessments may be outdated. The Bush administration changed the assessment process in ways that produced even greater delays, GAO found. The Obama administration, in response, recently announced much-needed reforms to streamline the system.

Source: Government Accountability Office, "New Assessment Process Further Limits the Credibility and Timeliness of EPA's Assessments of Toxic Chemicals," GAO-08-1168T (Sept. 18, 2008).

Number of completed IRIS assessments

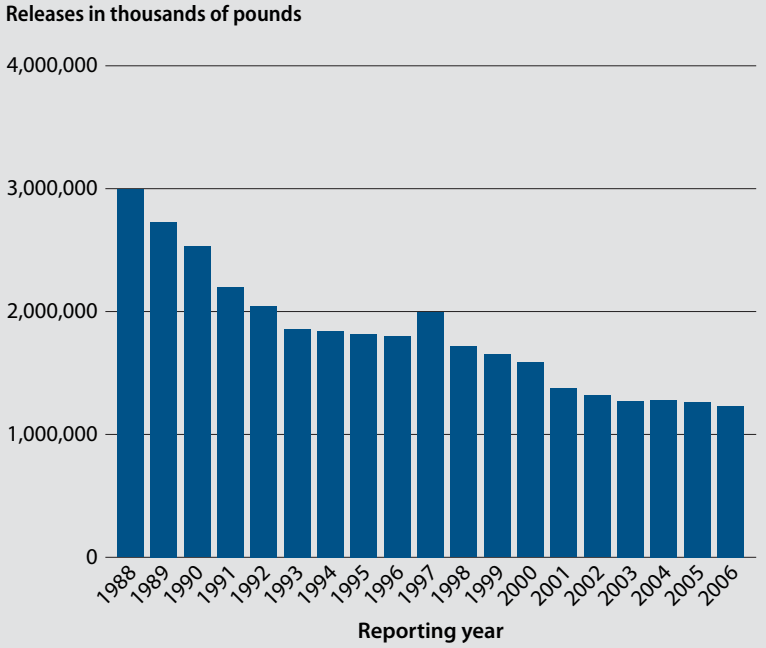
Fiscal years 2000–2007

Toxic exposure declines as public awareness rises

Addressing data gaps on chemical safety and reproductive health promises to engage the public. The Toxics Release Inventory, a public EPA database on chemical releases, demonstrates the effectiveness of information collection and disclosure. As this chart shows, releases of "core" chemicals have fallen 60 percent since the TRI was implemented in 1988. Information empowers the public to hold companies accountable and demand safer alternatives. Industries often respond with voluntary reductions to meet customer demands and protect their reputations. Indeed, this response can already be seen with the introduction of phthalate- and BPA-free baby products and toys. Accordingly, public disclosure of chemical safety information should be expanded.

Source: EPA, TRI Explorer.

Declining toxic releases of 'core' TRI chemicals, 1988–2006



"Core" chemicals refer to chemicals tracked since the inception of the Toxics Release Inventory.

Pre-market safety testing is needed

The Consumer Product Safety Improvement Act, signed into law August 15, 2008, requires that toys and other children's products be tested for chemical safety before they are brought to market. But pre-market testing is still not required for other consumer products, such as household appliances and cosmetics. In 2007, the Environmental Working Group investigated 23,000 cosmetic products sold in the United States. Hundreds of these products contained unsafe chemicals, many of which are banned in other countries, as the chart shows. Ninety-eight percent contained ingredients that have never been assessed for safety. Similarly, pre-market safety testing is not required for industrial chemicals that are released into the environment and used in occupational settings. The safety of a chemical should be evaluated before Americans are exposed.

U.S. cosmetics unsafe and untested

Products with ingredients banned in EU, Canada, or Japan	383
Products found unsafe by industry safety panels	447
Products with ingredients found by industry panel to lack sufficient data to determine safety	1,331
Products with ingredients for which no safety testing has been conducted	22,697

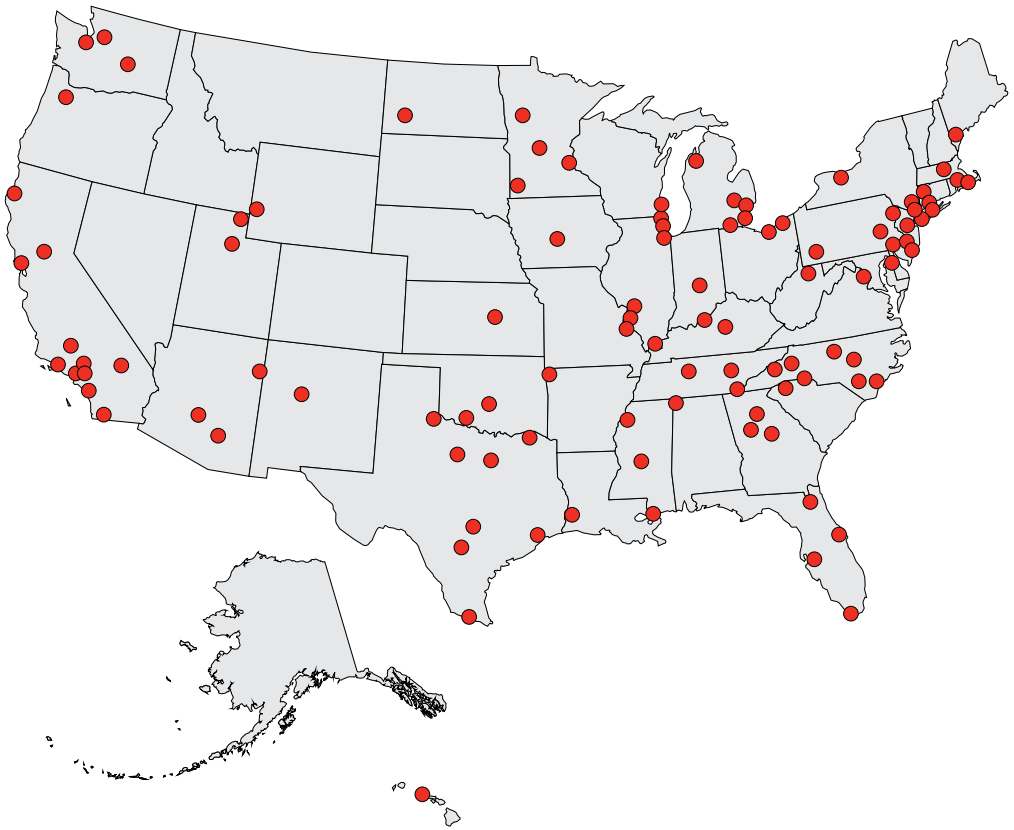
Source: Environmental Working Group, Letter from Richard Wiles to FDA Commissioner Andrew C. von Eschenbach, Sept. 26, 2007.

More research is needed

Funding is also needed to conduct further research on the causes of reproductive health problems and possible links to chemical exposures. In particular, the landmark National Children's Study is just getting off the ground and deserves full support. This study, which launches in 2010, will track 100,000 children from the womb until age 21 to examine possible environmental triggers of autism, learning disabilities, preterm births, birth defects, and other health problems. The map shows study locations where participating children reside.

Source: Ruth Brenner, "Pre-Proposal Conference," National Children's Study (April 2, 2008).

Locations of children participating in the National Children's Study



III. A new foundation

Europe is now implementing an ambitious new program that demands chemical safety testing and restricts chemicals found to be dangerous. Canada also recently adopted similar reforms. Laws in the United States, however, have been largely unchanged for decades. These laws offer insufficient protection and should be modernized. The following slides recommend:

- Congress should pass the Kids Safe Chemical Act to reform the Toxic Substances Control Act, which does not require pre-market testing and places the burden of proof on the EPA to demonstrate a chemical is unsafe before undertaking regulation.
- Congress should give the Food and Drug Administration and the Consumer Product Safety Commission greater authority to protect Americans from dangerous chemicals used in cosmetics and consumer products—deference is now given to voluntary industry actions.
- Congress should provide government agencies responsible for chemical safety with the resources necessary to assess chemicals and act quickly where dangers are found. Budgets and staffing levels have been mostly down or flat over the last three decades despite the dramatic rise in commercial chemicals.

Europe is implementing a tough new program for chemical safety

The European Union is in the process of implementing an aggressive new chemical safety program, known as REACH—Registration, Evaluation, Authorization and Restriction of Chemicals. A key component of this process is identifying "substances of very high concern." The EU announced the first 15 such substances in late 2008, and many more are expected to follow. Of these 15, five are harmful to reproduction, including three phthalates. Companies will ultimately have to receive specific authorization to use these substances. This has significant implications for U.S. firms that do business in Europe and may spur adoption of safer alternatives in the United States.

EU 'substances of very high concern' linked to reproductive health problems

Substance name	Reason identified as substance of very high concern
Dibutyl phthalate (DBP)	Toxic to reproduction
Bis (2-ethylhexyl) phthalate (DEHP)	Toxic to reproduction
Benzyl butyl phthalate (BBP)	Toxic to reproduction
Sodium dichromate	Carcinogenic, mutagenic and toxic to reproduction
Lead hydrogen arsenate	Carcinogenic and toxic to reproduction

Source: European Chemicals Agency, "Candidate List of Substances of Very High Concern."

U.S. chemical safety law is inadequate

In January 2009, the Government Accountability Office added chemical safety to its "high risk list" of areas that should be addressed immediately. "EPA's inadequate progress in assessing toxic chemicals significantly limits the agency's ability to fulfill its mission of protecting human health and the environment," the GAO explained. This chart compares the information-gathering requirements of the primary U.S. law governing chemical safety, the Toxic Substances Control Act of 1976, with those of the European Union's new and much stronger REACH program.

Comparison of U.S. and EU chemical safety laws

Questions about chemical information requirements	TSCA (U.S.)	REACH (EU)
Are chemical companies obligated to provide immediate notification of changes in chemical use or production?	No	Yes
Are chemical companies required to conduct risk assessments for new and existing chemicals?	No	Yes
Are downstream users required to report chemical safety information?	No	Yes
Are companies required to analyze possible safer alternatives for dangerous chemicals?	No	Yes
Are there restrictions on what companies can claim as confidential business information and thereby block from public disclosure?	No	Yes

Source: Government Accountability Office, "Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect Against the Risks of Toxic Chemicals," GAO-07-825 (August 2007); Richard A. Denison, "Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals" (Environmental Defense Fund, April 2007).

Congress should modernize chemical safety law

The Toxic Substances Control Act places the burden of proof on the EPA to demonstrate "unreasonable risk" before the agency can regulate. But EPA cannot require industry testing unless it already has information indicating potential risk. This catch-22 assures little safety information will be generated and almost no action will be taken. In more than 30 years under TSCA, the EPA has required testing of only 200 chemicals (out of 80,000) and mandated restrictions on just five chemicals, as the chart shows.

Congress should move forward with the Kids Safe Chemical Act to modernize TSCA. This legislation—introduced in 2008 by Sen. Frank Lautenberg (D-NJ) as S. 3040, and Reps. Hilda Solis (D-CA) and Henry Waxman (D-CA) as H.R. 6100—would require manufacturers to demonstrate the safety of chemicals they wish to bring to market and those that are already in use. The Obama administration should also provide its full support.

Substances banned under TSCA since 1976	Year banned
Hexavalent chromium used in water treatment in comfort cooling towers	1990
Asbestos	1989
Dioxin in certain wastes	1980
Polychlorinated biphenyls (PCBs) in response to congressional mandate	1979
Halogenated chlorofluoroalkanes used as aerosol propellants	1978

Source: Richard A. Denison, "Ten Essential Elements in TSCA Reform," *Environmental Law Reporter* (January 2009); Government Accountability Office, "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage its Chemical Review Program," GAO-05–458 (2005).

A new framework is needed for chemicals in consumer products

Chemicals in cosmetics and most consumer products—like industrial chemicals, but in contrast to drugs—are presumed safe until proven otherwise. No safety testing is required before they are introduced to market. This puts the Food and Drug Administration and the Consumer Product Safety Commission, which regulate cosmetics and consumer products, respectively, in a weak position to address chemical dangers. But authority is lacking in other ways as well.

The FDA has stated it cannot require warning labels on products whose safety has not been substantiated. Nor can it require recalls of dangerous products—recalls are voluntary company actions. CPSC similarly must give deference to voluntary industry actions when it considers new regulation. Not surprisingly, chemical safety standards are extremely rare. Only eight chemicals have ever been banned for cosmetic use, as the chart shows. And the CPSC did not adopt a new toy standard for a decade prior to the recent discovery of lead in Chinese-made toys.

Substances banned by the FDA for cosmetic use	Year banned
Prohibited cattle materials (to prevent "mad cow disease")	2005
Methylene chloride	1989
Chlorofluorocarbon propellants	1978
Zirconium-containing complexes	1977
Chloroform	1976
Halogenated salicylanilides	1975
Vinyl chloride	1974
Bithionol	1968

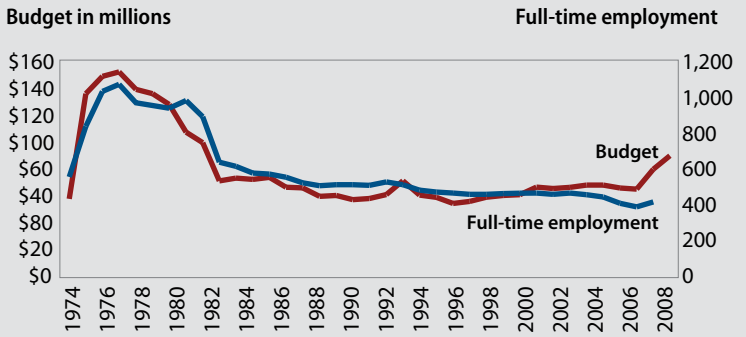
Source: Katherine Harmon, "Saving Face: How Safe are Cosmetics and Body Care Products?" Scientific American (May 5 2009); Food and Drug Administration, "Ingredients Prohibited and Restricted by FDA Regulations" (June 2006).

Regulatory agencies need more resources

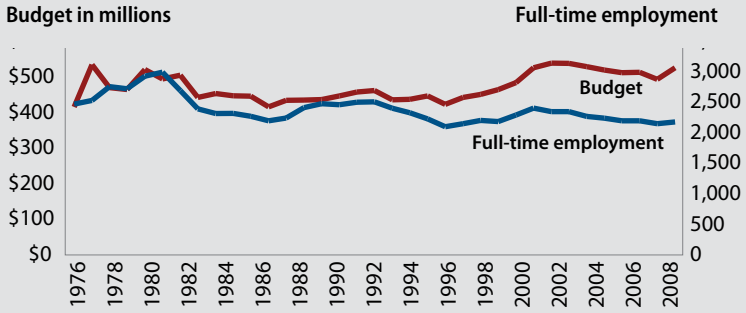
Federal regulatory agencies are challenged not only by limitations in their legal authority but also by resource constraints. The number of chemicals in use has climbed 30 percent since 1979, but budget and staffing levels have been mostly down or flat over this time. The Consumer Product Safety Commission recently received a bump after the discovery of lead in Chinese-made toys, as shown in the chart on the top. But President Obama's 2010 budget request is 10 percent less than the amount authorized by Congress. The Occupational Safety and Health Administration's budget and staffing levels began to climb at the end of the Clinton administration before falling through most of the Bush administration; the number of OSHA personnel is near an all-time low, as the chart on the bottom shows. Congress should ensure that regulatory agencies have the resources necessary to assess chemicals and act quickly where dangers are found.

Source: OMB Watch, "Product Safety Regulator Hobbled by Decades of Negligence" (Feb. 5, 2008); AFL-CIO, "Death on the Job: The Toll of Neglect" (April 2009).

CPSC staffing and budget, 1973–2009



OSHA staffing and budget, 1975–2009



Budget figures are adjusted for inflation in 2008 dollars.

IV. Conclusion: The Obama administration and Congress must strengthen chemical safety

Americans are not adequately protected from dangerous chemicals, which may explain the decline in reproductive health. The Obama administration and Congress should act quickly to address this problem. Specifically:

Executive branch agencies and Congress should limit exposures to chemicals harmful to reproductive health. At the top of the list are phthalates, BPA, and PBDEs. Executive branch regulatory agencies should use their existing authorities to protect the public and workers from these and other dangerous chemicals. The Consumer Product Safety Commission, in particular, should complete a proposed national flammability standard that would reduce use of PBDEs. Congress should pass recently introduced legislation to ban BPA in food and beverage containers.

Congress should strengthen laws governing chemical safety. In particular, reforms to the Toxic Substances Control Act and the Food, Drug, and Cosmetic Act are urgently needed to ensure that the EPA and FDA, respectively, have adequate information to evaluate chemical risks and necessary authority to safeguard the public. The Obama administration should actively support these efforts as Congress moves forward.

The Obama administration should provide the public with robust access to chemical safety data. The administration should expand and improve existing public resources for chemical safety data, including the IRIS database and the EPA's Toxics Release Inventory. It should also build new resources, including for data collected under the recently enacted Consumer Product Safety Improvement Act, and link data resources to each other.

The Obama administration should complete chemical assessments under the Integrated Risk Information System in a timely manner and free of political influence. President Obama's new team at the EPA took the first step by repealing Bush administration changes that impaired the IRIS process. The true test, however, will be the number and quality of assessments the agency produces.

Congress should boost funding for chemical safety action and research. Congress should provide the resources necessary to deliver chemical safety. This means supporting responsible executive branch agencies—including the CPSC, EPA, FDA, and OSHA—and funding research to identify both green chemistry solutions and chemical triggers of reproductive health problems. The National Children's Study, in particular, deserves full support.