



REPRODUCTIVE ROULETTE

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

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Introduction

Reproductive health in the United States is headed in the wrong direction on a host of indicators. Fertility problems, miscarriages, preterm births, and birth defects are all up. These trends are not simply the result of women postponing motherhood. In fact, women under 25 and women between 25 and 34 reported an increasing number of fertility problems over the last several decades. Nor are reproductive health problems limited to women. Average sperm count appears to be steadily declining, and there are rising rates of male genital birth defects such as hypospadias, a condition in which the urethra does not develop properly. Part I of this presentation gives an overview of the current state of reproductive health.

As reproductive health has declined, chemical production has increased dramatically. The number of chemicals registered for commercial use now stands at 80,000—a 30 percent increase since 1979. Americans are exposed to these chemicals in a variety of ways, including through industrial releases, contaminated food, household products and cosmetics, and workplaces where chemicals are used. Tests of blood and urine confirm rising and widespread exposure to a chemical soup of metals, pesticides, plasticizers, and other substances, many of which are dangerous to reproductive health. Young children are often exposed to significantly higher levels of these chemicals than adults. Part II of this presentation explains this problem and spotlights three chemical groups—phthalates, BPA, and PBDEs—that are linked to reproductive health problems and are present in the daily lives of all Americans.

Our chemical safety laws do not provide adequate protection from these chemical groups and other dangerous substances. Indeed, the Government Accountability Office recently added chemical safety to its “high risk list” of areas that should be addressed immediately. Chemical manufacturers are not required to conduct pre-market testing of industrial chemicals or chemicals used in cosmetics and household products. Rather, human beings in the real world end up as guinea pigs. Government agencies responsible for chemical safety also lack the authority and resources necessary to evaluate safety and set strong standards against dangerous chemicals.

The prospects for addressing this situation fortunately appear to be brightening. Congress took a first step last year following the discovery of contaminated Chinese-made toys, passing legislation that requires pre-market testing of children’s products sold in the United States and bans lead and phthalates from being contained in such products. Legislation has also been introduced to ban BPA in all food and beverage containers, and there will likely be a renewed push for the Kids Safe Chemical Act, which would reform the ineffectual Toxic Substances Control Act. Part III of this presentation offers recommendations for modernizing chemical safety. Implementing these recommendations would reduce human exposure to dangerous chemicals, which in turn promises to lift reproductive health.



PART I

Declining reproductive health

Reproductive health has declined over the last several decades in the United States, according to recent studies. As shown in the following slides:

- Reported infertility and impaired fertility are up among both men and women, regardless of age.
- There are more premature births and more infants with low birth weight.
- There are more birth defects and disabilities.

Even seemingly small upticks can have large consequences. There were a total of 4.3 million births in the United States in 2006. A rise in birth defects of just 1 or 2 percent increases the total number of afflicted children by tens of thousands. This is a tragedy for families that must deal with these problems. It also puts additional strain on the health care system.

Part II of this presentation focuses on one possible reason for the decline in reproductive health—the increase in human exposure to chemicals found in consumer products and used for industrial activities. Other factors, such as inadequate health care, poor nutrition, and delayed childbirth, may also share blame for at least some problems. But new research reveals a chemical share in the bodies of virtually all Americans that appears to be taking a toll.

I. Fertility problems on the rise

More men and women today experience difficulty having children, according to recent studies. The data in the following slides show:

- Sperm count appears to have steadily declined since the 1930s.
- Impaired fertility among women increased almost 2 percent from 1982–2002.
- Impaired fertility among women under 25 and women between 25 and 34 has increased significantly.
- An estimated 3 to 10 percent of women have endometriosis—a leading cause of infertility that has been linked to chemical exposures.
- The annual number of reported miscarriages and stillbirths are significantly higher than in the 1970s and '80s.

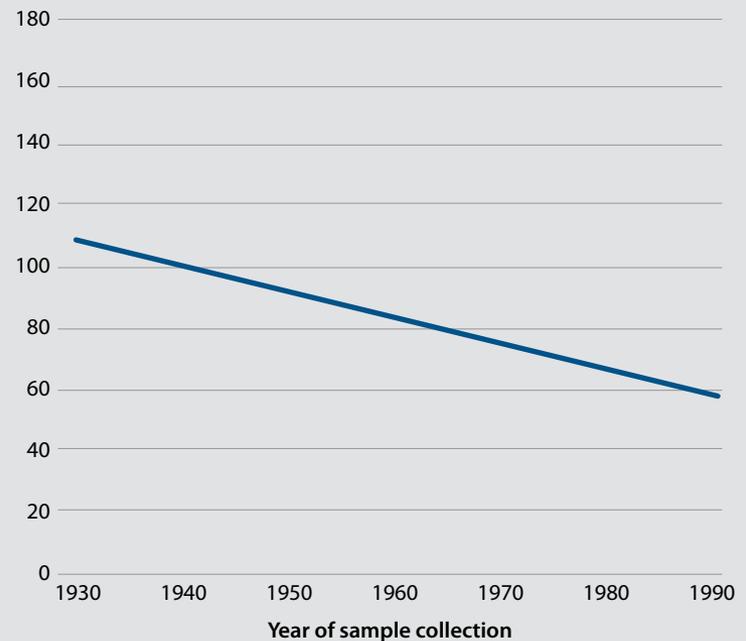
Average sperm count is falling

Average sperm count appears to have steadily declined since the 1930s. This graph shows a regression line of the mean sperm density in North America over a 50-year period based on the findings of multiple studies. Studies have also found falling average sperm count in Europe. A low sperm count can impair or inhibit a man's ability to reproduce.

Source: Shanna H. Swan, et al., "The Question of Declining Sperm Density Revisited: An Analysis of 101 Studies Published 1939–1996," *Environmental Health Perspectives* 108 (10) (Oct. 10, 2000); E. Carlsen et al., "Evidence for Decreasing Quality of Semen During Past 50 Years," *British Medical Journal* 305 (Sept. 12, 1992).

Average sperm count, 1930–1990

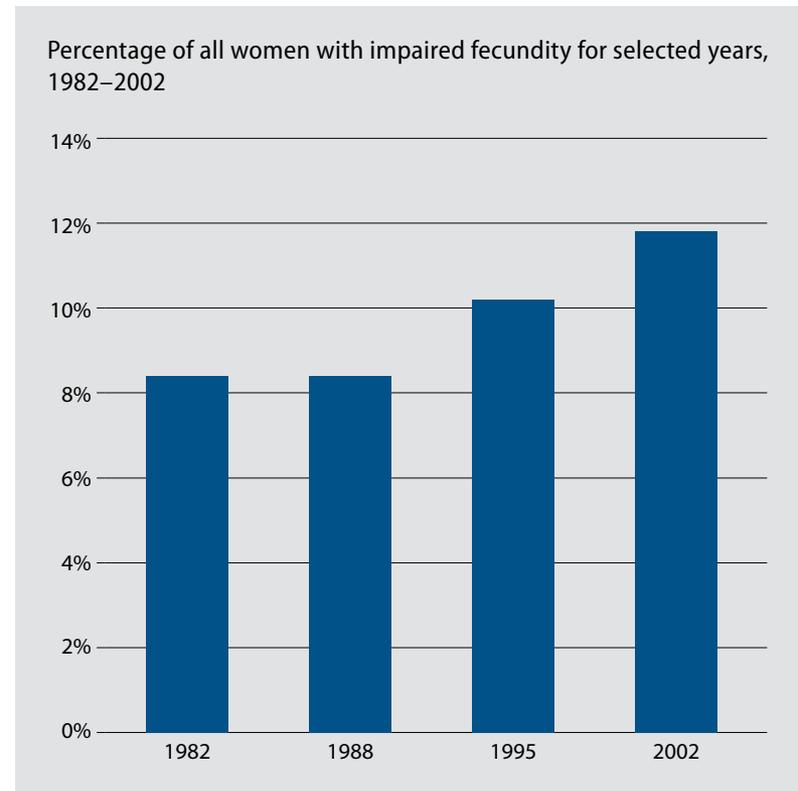
Sperm density ($10^6/\text{mL}$)



More women experience fertility problems

More women are experiencing impaired fecundity, defined as difficulty or inability to conceive. This graph demonstrates the trend over a 20-year period. A leading cause of female infertility is endometriosis, which has been linked to chemical exposures. An estimated 3 to 10 percent of women have endometriosis, a disease in which tissue that lines the uterus also grows outside the uterus. Of these women, 30 to 40 percent are infertile.

Source: Anjani Chandra and Elizabeth Hervey Stephen, "Impaired Fecundity in the United States: 1982–1995," *Family Planning Perspectives* 30 (1) (1998): 34–42; Chandra, et al., "Fertility, Family Planning, and Reproductive Health of U.S. Women: Data from the 2002 National Survey of Family Growth," *National Center for Health Statistics, Vital Health Stat* 23 (25) (2005).

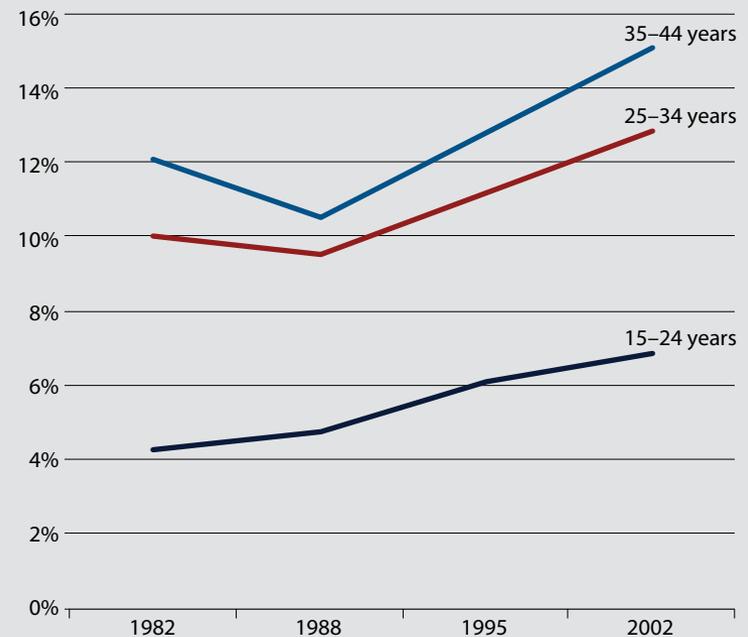


Fertility problems are rising across age groups

Women today are having children later in life; the mean age for childbirth increased from 25 in 1980 to 27 in 2006. This trend is often cited as the reason for declining female fertility. Yet more women report experiencing impaired fecundity regardless of age. From 1982–2002, women under 25 and women between 25 and 34 reported an increasing number of fertility problems.

Source: Anjani Chandra and Elizabeth Hervey Stephen, "Impaired Fecundity in the United States: 1982–1995," *Family Planning Perspectives*, 30 (1) (1998): 34–42; Chandra, et al., "Fertility, Family planning, and Reproductive Health of U.S. women: Data from the 2002 National Survey of Family Growth," National Center for Health Statistics, *Vital Health Stat* 23(25) (2005).

Trends in the percentage of women (15–44 years) with impaired fecundity by age group, 1982–2002



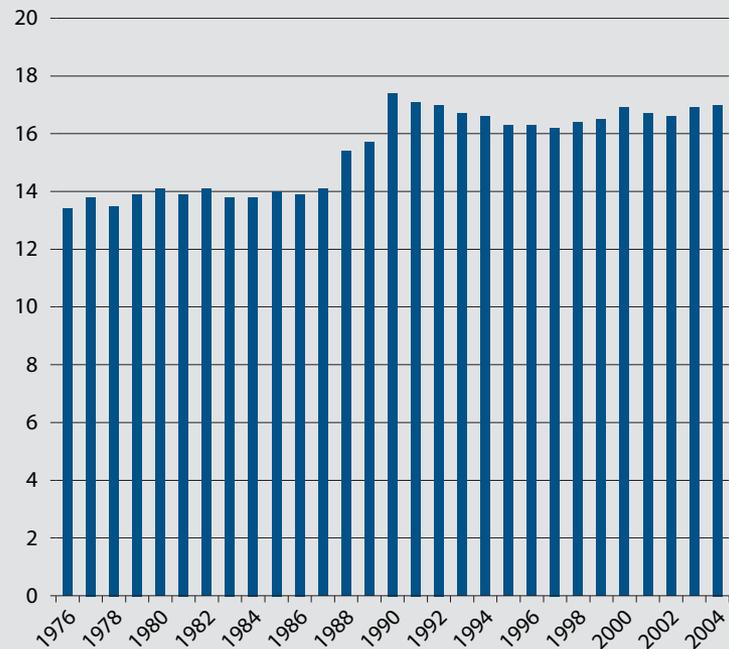
Miscarriages and stillbirths are up

The number of miscarriages and stillbirths have increased notably since the 1970s and 80s, according to [survey data collected by the National Center for Health Statistics](#). This chart shows the rate per 1,000 women aged 15–44 years who experienced spontaneous fetal losses from recognized pregnancies of all gestational periods. Miscarriages and stillbirths jumped above 16 per 1,000 pregnancies in the 1990s and 2000s, compared to 14 per 1,000 during the 1980s.

Source: Stephanie J. Ventura et al, "Estimated Pregnancy Rates by Outcome for the United States, 1990–2004" National Center for Health Statistics, *National Vital Statistics Reports* 56 (15) (April 14, 2008); Stephanie J. Ventura et al, "Trends in Pregnancies and Pregnancy Rates by Outcome: Estimates for the United States, 1976–96," National Center for Health Statistics, *Vital and Health Statistics* 21 (56) (January 2000).

Trends in the fetal loss rate, 1976–2004

Rate per 1,000



II. More premature births and infants with low birth weight

More infants are born prematurely and with low birth weights than ever before. The data in the following slides show:

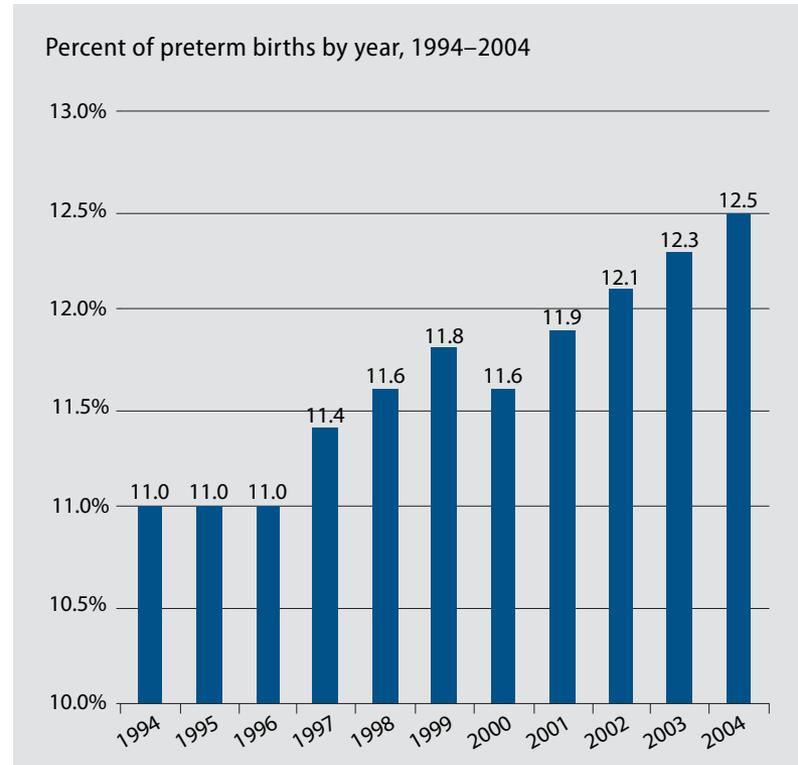
- Premature births have increased significantly since the mid-1990s.
- Premature births are rising among whites and Hispanics but remain highest among African Americans.
- The number of infants born with low birth weight increased almost 1 percent in just 10 years from 1994 to 2004.
- Low and very low birth weights are rising among all racial and ethnic groups, but are rising faster and remain significantly higher among African Americans.

It is still unclear whether chemical exposures are contributing to this rise in premature births and infants born with low birth weight, but recent research suggests this is a possibility.

Premature births are up significantly

This chart shows a significant increase in the percentage of births that are premature, from 11 percent in 1994 to 12.5 percent in 2004.

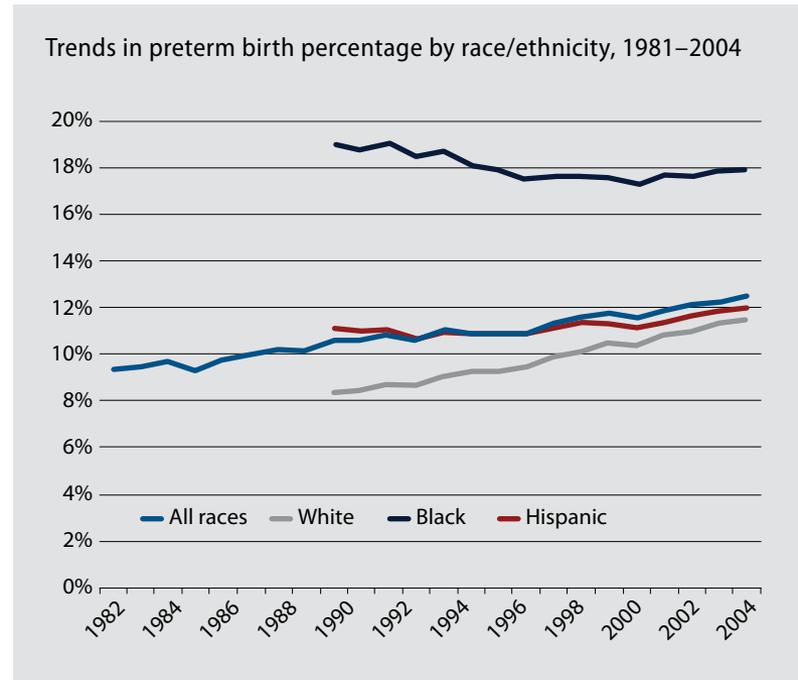
Source: National Center for Health Statistics, final natality data. National Center for Health Statistics, final mortality data, 1990–1994, and period-linked birth/infant death data, 1995–present; March of Dimes, Peristats, “Perinatal Data Snapshots: United States Maternal and Infant Health Overview” (April 2007).



Premature births are rising for whites and Hispanics, but are more common for African Americans

Black communities are more commonly urban and lower income, and thus generally have higher exposure rates to dangerous chemicals. It is unclear whether this contributes to the discrepancy shown here. Other factors, such as differences in nutrition and health care, may also be part of the story.

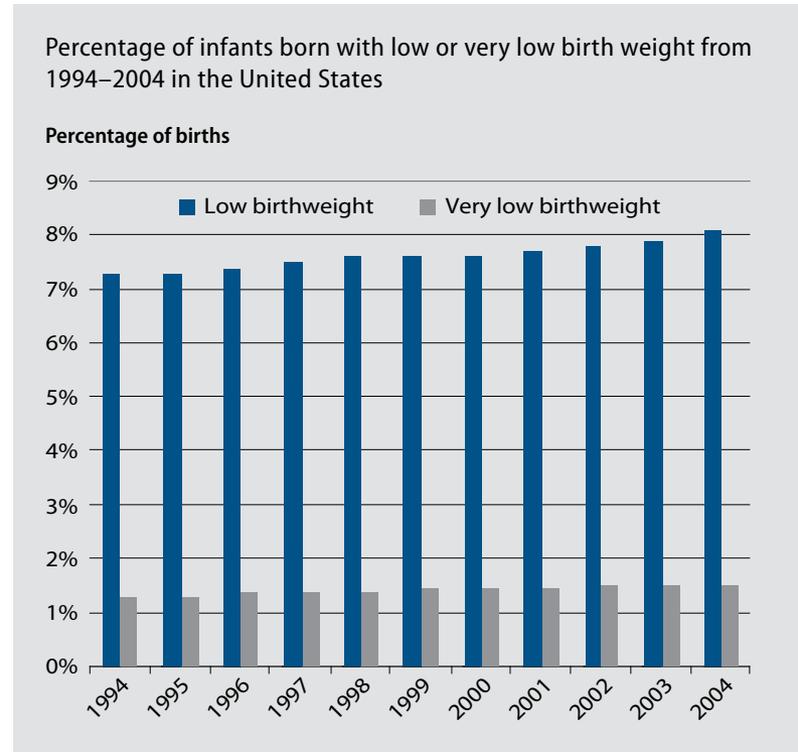
Source: T.J. Mathews and Marian F. MacDorman, "Infant Mortality Statistics from the 2003 Period Linked Birth/Infant Death Data Set," National Vital Statistics Reports 54 (16) (May 2006); Robert L. Goldenberg and Dwight J. Rouse, "Prevention of Premature Birth," *New England Journal of Medicine* 339 (5) (1998): 313–20; Bernard Weiss and David C. Bellinger, "Social Ecology of Children's Vulnerability to Environmental Pollutants," *Environmental Health Perspectives* 114 (10) (2006):1479–85.



More infants are born with low birth weight

The number of infants born with low birth weight (under 6.6 lbs) increased almost 1 percent in just 10 years from 1994 to 2004. Very low birth weights (under 3 lbs, 4 oz) also increased.

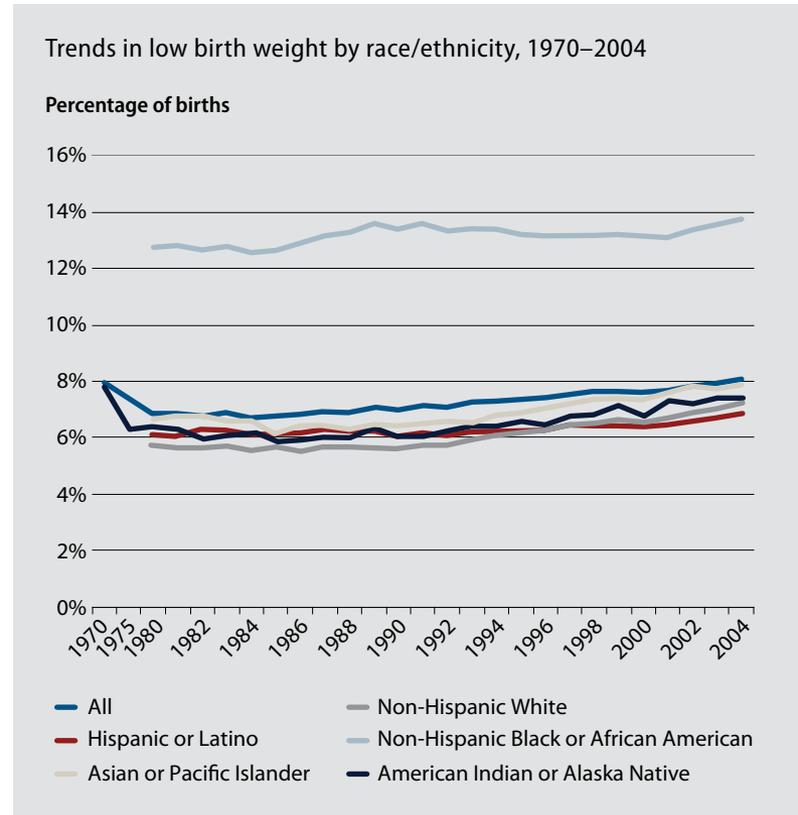
Source: National Center for Health Statistics, final natality data; National Center for Health Statistics, final mortality data, 1990–1994, and period-linked birth/infant death data, 1995–present; March of Dimes, Peristats, “Perinatal Data Snapshots: United States Maternal and Infant Health Overview” (April 2007).



Black infants are more commonly born with low birth weight

Low birth weight (under 6.6 lbs) is rising among all groups, but is still significantly higher for African Americans.

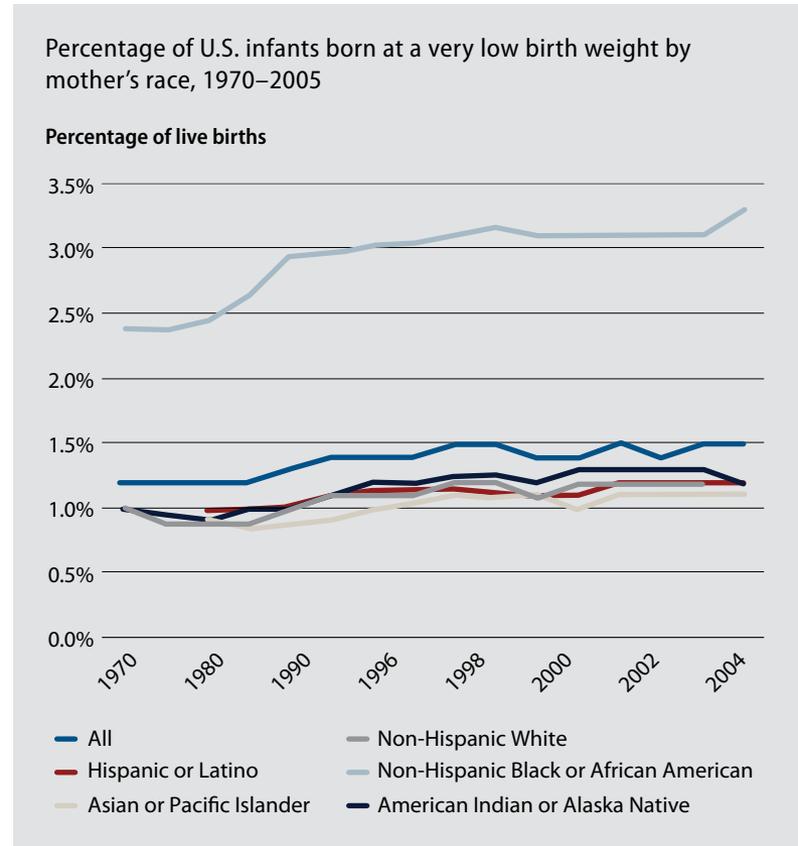
Source: National Center for Health Statistics, National Vital Statistics System, Birth File; Centers for Disease Control and Prevention, Pediatric and Pregnancy Nutrition Surveillance System.



More black infants are born with very low birth weight

African Americans have also seen a far steeper rise in very low birth weight (under 3 lbs, 4 oz) than other groups.

Source: National Center for Health Statistics, National Vital Statistics Reports, "Births: Preliminary data for 2005" Vol. 55, Table 4.



III. More birth defects and disabilities

Birth defects and disabilities are on the rise. The data in the following slides show:

- Cases of hypospadias, in which the male urethra does not develop properly, have doubled since the 1970s.
- Gastroschisis, a rare malformation in which the fetal intestines protrude through the stomach wall, has steadily increased over the last two decades.
- The percentage of U.S. students treated for a learning disability has increased from 8.3 percent in 1976 to 13.8 percent in 2005.
- Reported cases of autism have increased 10-fold since the early 1990s.

Chemical exposures have been linked to birth defects, including hypospadias and gastroschisis, as well as learning disabilities. A recent study also found a higher incidence of autism among children who live in homes with vinyl floors, which contain phthalates, one of the chemical groups profiled in Part II of this presentation. Research in this area is limited, however, and the connection between chemical exposures and autism remains unclear.

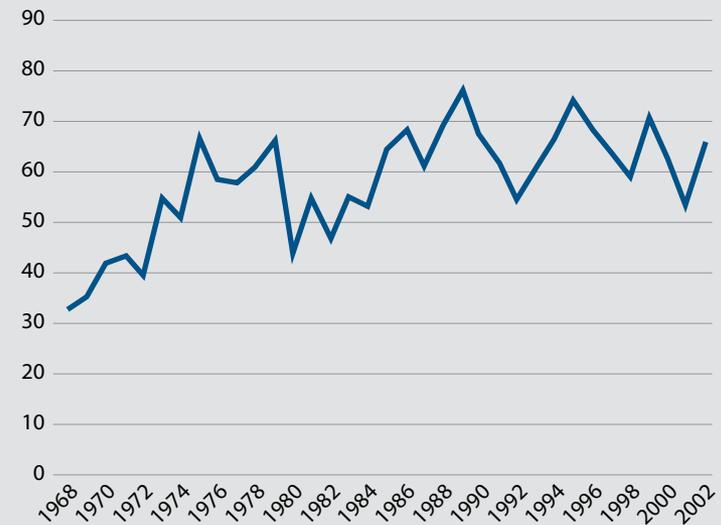
More cases of hypospadias

Birth defects are on the rise. One example is hypospadias, a condition in which the male urethra does not develop properly in the womb, resulting in the opening being located on the underside of the penis or occasionally in the perineum. Hypospadias is estimated to have doubled since the 1970s, and now occurs in 1 of every 125 live male births in the United States. This chart shows rising levels of hypospadias in Atlanta.

Source: Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities, "Temporal and Spatial Variations in Birth Defects in Atlanta" (March, 2004); Laurence S. Baskin, et al., "Hypospadias and Endocrine Disruption: Is There a Connection?" *Environmental Health Perspectives* 109 (11) (November 2001): A542-A543.

Prevalence of hypospadias in Atlanta

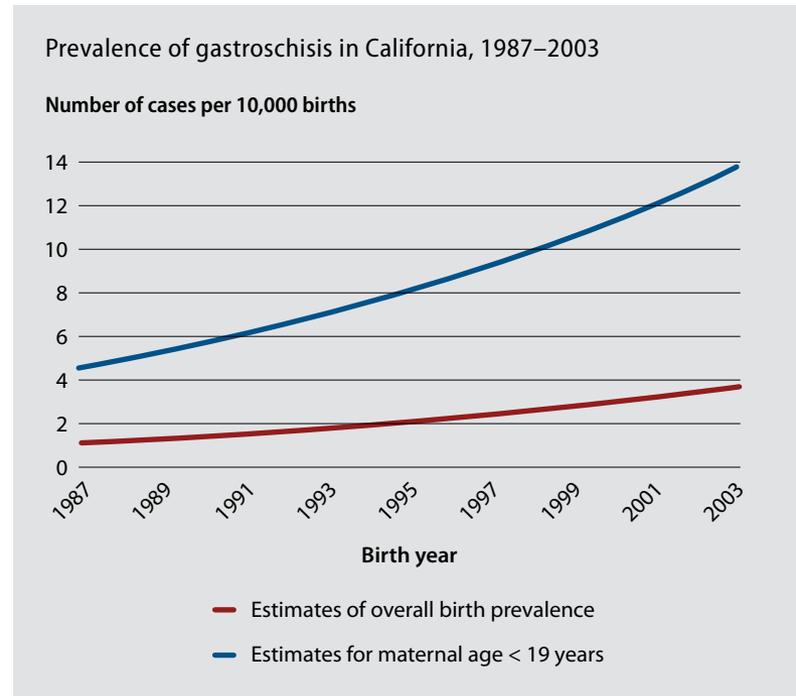
Prevalence per 10,000 births



More cases of gastroschisis

Another birth defect on the rise is gastroschisis, a rare malformation in which the fetal intestines protrude through the stomach wall and are externally visible. This graph shows a significant rise of gastroschisis in California over a 16-year period. The estimates are based on a regression model that controlled birth prevalence in California for maternal age and ethnicity, as well as paternal age. Mothers younger than 19 are at greater risk of having babies with gastroschisis.

Source: Lan T. Vu, Kerilyn K. Nobuhara, Cecile Laurent, and Gary M. Shaw, "Increasing Prevalence of Gastroschisis: Population-Based Study in California," *The Journal of Pediatrics* (February 2008).



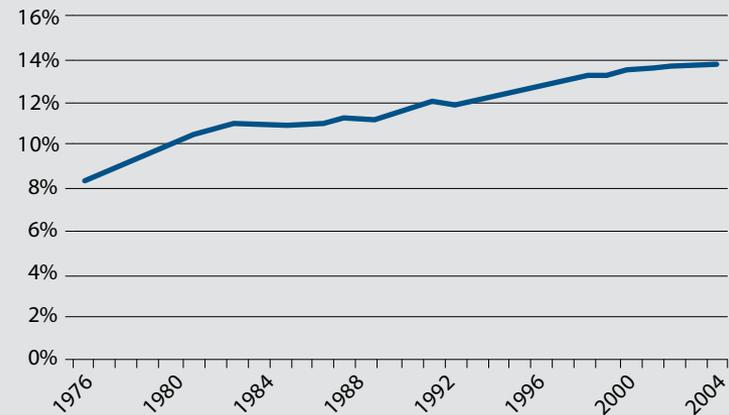
More children are treated for learning disabilities

The percent of U.S. students treated for a learning disability increased from 8.3 percent in 1976 to 13.8 percent in 2005. Improved and more uniform diagnostic criteria are thought to account for some, but not all, of the difference.

Source: Office of Special Education and Rehabilitative Services, Office of Special Education Programs, *Data Analysis System* (U.S. Department of Education, 1976–2005); Greater Boston Physicians for Social Responsibility, "In Harm's Way" (2001).

Total school enrollment treated under the Individuals with Disabilities Education Act, 1976–2004

Percent of students



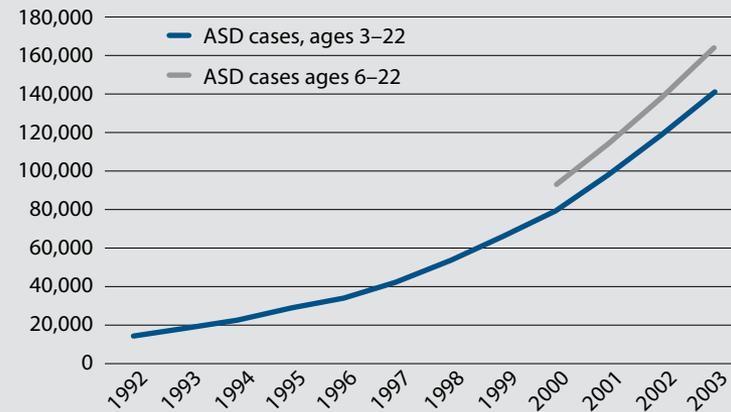
More cases of autism

Reported cases of autism spectrum disorders have increased 10-fold since the early 1990s.

Source: Michael Szpir, "Tracing the Origins of Autism", *Environmental Health Perspectives* 114 (7) (July 2006): A412–A419.

Reported cases of autism spectrum disorders in the United States and outlying areas, 1992–2003

Cases



INGREDIENTS / INGRÉDIENT
NITRIDE, TALC, DIMETHICONE,
POLYMETHYL METHACRYLATE, Z
RATE, POLYETHYLENE, POLYGLYCE
STEARATE, DIMETHICONOL, ME
AURYL PEG/PPG-18/18 METHICOM
TEARYL MALATE, LECITHIN, AC
OPOLYMER, SILICA SILYLATE, PH
HANOL, METHYLPARABEN, ETH
N, PROPYLPARABEN MAY COI
JT CONTENIR [+/-: MICA, BISMUT
LORIDE (CI 77163), CHROMIUM
EENS (CI 77288), IRON OX
7491, CI 77492, CI 77499), ULTI
S (CI 77007), BLUE 1 LAKE (CI 4
DW 5 LAKE (CI 19140), FERRIC FER
E (CI 77510), CARMINE (CI 75470),
SE VIOLET (CI 77742), TITANIUM [
77891)] 21727

PART II

Dangerous chemical exposures

U.S. chemical production has increased dramatically over the last half century, with 80,000 chemicals now approved for commercial use. Americans are exposed to these chemicals in a variety of ways, including through industrial releases, contaminated food, household products and cosmetics, and workplaces where chemicals are used. Tests of blood and urine confirm widespread exposure to chemicals that are dangerous to reproductive health.

The following slides provide an overview of this problem and spotlight three chemical groups—phthalates, Bisphenol A, and polybrominated diphenyl ethers—that are linked to reproductive health consequences, including miscarriages, endometriosis, male genital defects, low sperm count, and others. Phthalates and BPA are found in toys, food containers, cosmetics, and many other consumer products. PBDEs are used as flame retardants in household furniture and electronics. Other chemicals also threaten reproductive health, but these three are among the most prevalent in the daily lives of all Americans and are just starting to receive serious attention from the U.S. Congress and federal regulators.

I. Overview of chemical dangers

Americans are widely exposed to dangerous chemicals. The data in the following slides show:

- The number of chemicals registered for commercial use now stands at 80,000—a 30 percent increase since 1979.
- The bodies of most Americans contain a chemical soup according to testing by the Centers for Disease Control and Prevention.
- Exposure to chemicals occurs *in utero*—testing found 287 industrial chemicals present in newborn umbilical cords.
- Poor and minority children are exposed to lead and other dangerous chemicals at the highest levels.
- Polluters released a reported 4.1 billion pounds in toxic chemicals to the air, water, and soil in 2007 alone.
- Chemicals contaminate the environment—in 2006, there were a total of 3,852 state advisories against eating fish because of chemical contamination.
- Chemicals bioaccumulate in the food chain—more than 95 percent of human exposure to dioxin comes from food consumption.
- Consumer products are a major source of exposure. Adolescents are widely exposed to hormone-disrupting chemicals found in cosmetics as their reproductive systems mature.
- Workplaces can be dangerous—one study found that women plastics workers more frequently sought treatment for infertility than the general population.

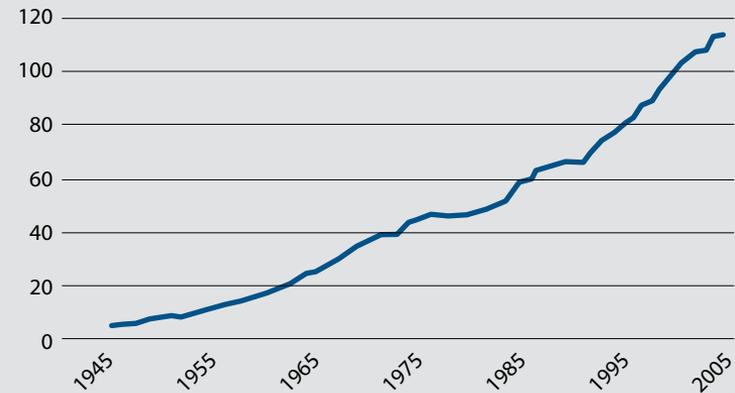
Chemical production is rising

U.S. chemical production has increased dramatically over the last 60 years. The number of chemicals registered for commercial use now stands at 80,000—a 30 percent increase since 1979.

Source: UCSF Program on Reproductive Health and the Environment, "[Shaping Our Legacy: Reproductive Health and the Environment](#)" (September 2008).

U.S. chemical production, 1947–2007

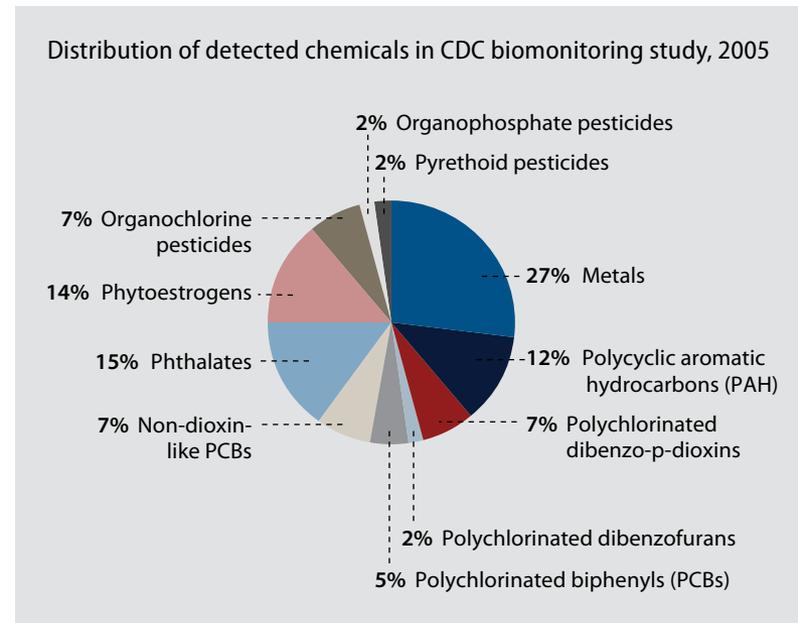
Production index (100 = year 2002)



Americans are exposed to a chemical soup

Americans are exposed to a multitude of chemicals, which accumulate in the body over time. The Centers for Disease Control and Prevention conducts “biomonitoring” to measure chemicals in people’s blood and urine. This chart shows the distribution of chemicals found in a random sample of the U.S. population. Chemicals are generally evaluated—to determine their safety and whether regulation is necessary—in isolation from each other, one at a time. The reality, however, is that people are exposed to many chemicals at the same time. Very little is known about how multiple chemicals interact to affect human health.

Source: Centers for Disease Control and Prevention, *Third National Report on Human Exposure to Environmental Chemicals* (July 2005).



Chemical exposures occur *in utero*

Pregnant women pump blood through the umbilical cord from the placenta to the fetus. This blood provides the essential nutrients for life. It may also expose the fetus to dangerous chemicals contained in the mother's body. A 2004 study tested blood samples from 10 newborn umbilical cords. These samples found 287 industrial chemicals present in the cords (out of 413 chemicals tested for), including pesticides, consumer product chemicals, and wastes from burning coal, gasoline, and garbage. The chart shows the percentage of newborns whose umbilical cords contained at least one chemical from the chemical families listed. Also shown is the number of chemicals in each chemical family tested for and the number detected.

Chemicals found in 10 newborn umbilical cords

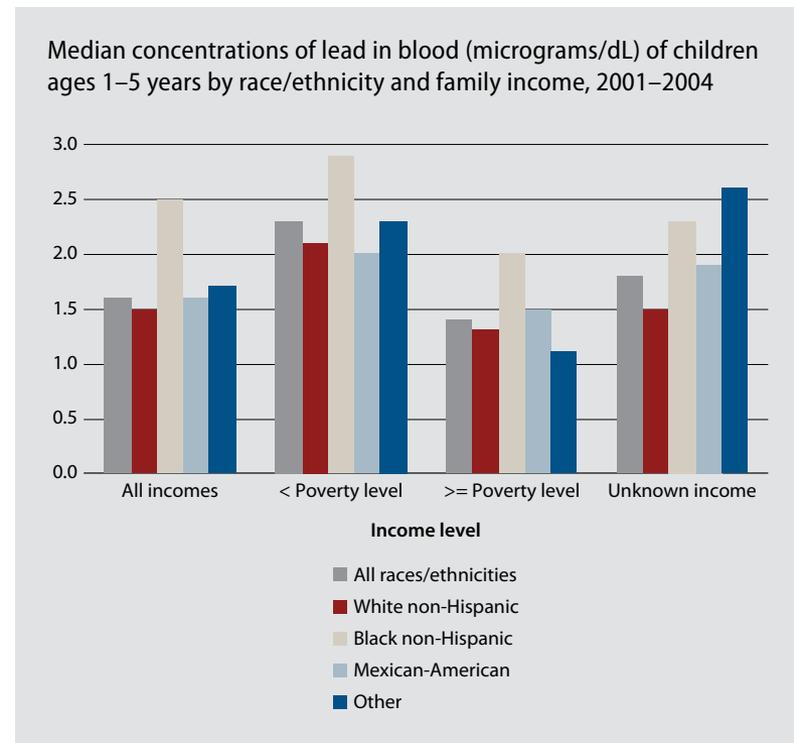
Chemical family	Source/use	Percent detected in newborns	Chemicals found/chemicals tested for
Mercury	Emitted from coal-fired power plants, other industrial facilities	100%	1/1
Polybrominated diphenyl ethers (PBDEs)	Fire retardants used for furniture, electronics	100%	32/46
Polyaromatic hydrocarbons (PAHs)	Waste from burning gasoline and garbage	100%	9/18
Polychlorinated dibenzodioxins and furans (PBCD/F)	Byproducts of PVC production, industrial bleaching and incineration	100%	11/17
Polybrominated dibenzodioxins and furans (PBDD/F)	Found in brominated flame retardants; byproducts from plastic production and incineration	70%	7/12
Perfluorinated chemicals (PFCs)	Used for fabric and carpet protectors, food wrap	100%	9/12
Organochlorine pesticides (OCs)	Includes DDT; largely banned, but persists in environment	100%	21/28
Polychlorinated Naphthalenes (PCNs)	Wood preservatives, machine lubricating oils	100%	50/70
Polychlorinated biphenyls (PCBs)	Industrial insulators, lubricants; banned since 1976, but persist in environment	100%	147/209

Source: Environmental Working Group, "Body Burden—The Pollution in Newborns. A benchmark investigation of industrial chemicals, pollutants and pesticides in umbilical cord blood" (July 14, 2005).

Poor, minority children are exposed to higher levels of chemicals

Poor and minority children are generally exposed to chemicals at higher levels. Poor black children have the highest concentrations of lead in their blood. Lead exposure is down sharply following the removal of lead from gasoline and paint, but it still poses reproductive and developmental risks. About 310,000 U.S. children between ages 1 and 5 have blood lead levels above CDC's "safe" level.

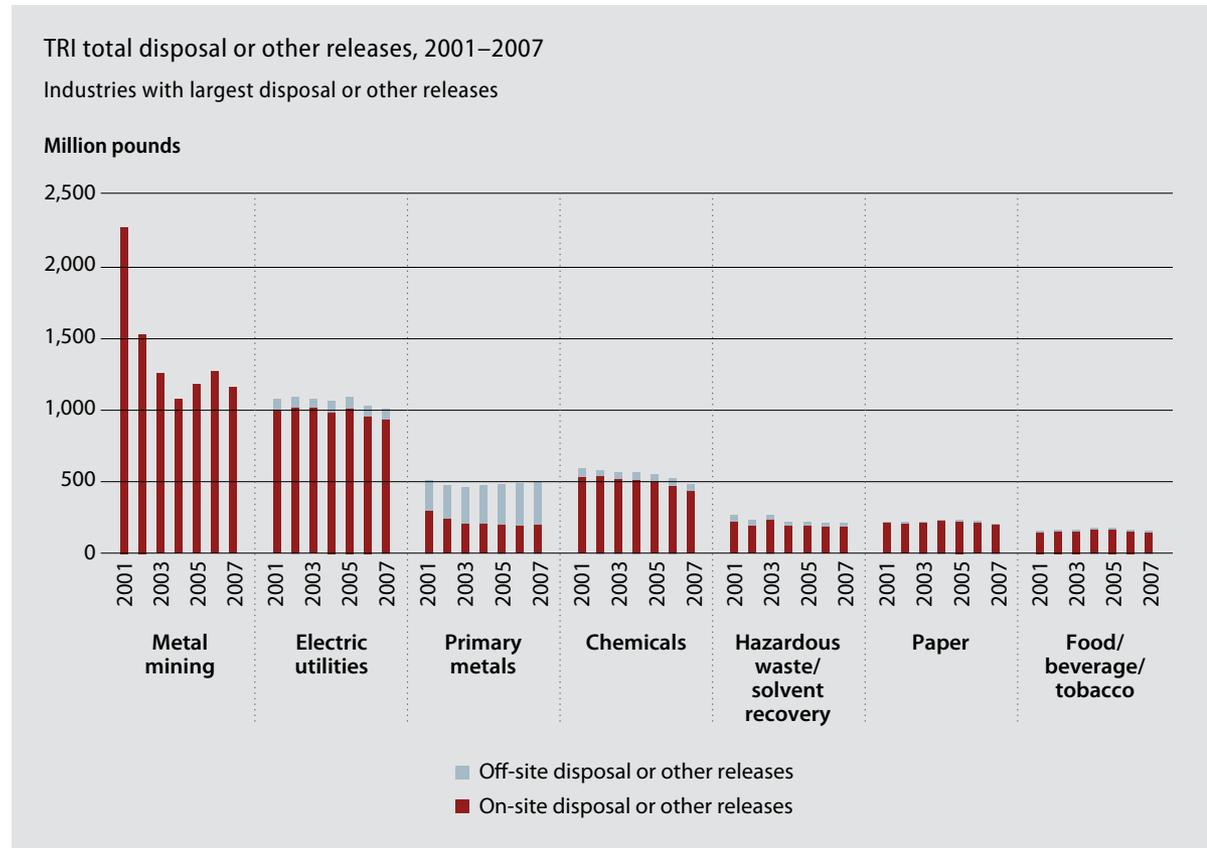
Source: Environmental Protection Agency, *America's Children and the Environment, Measure B-2*; Centers for Disease Control and Prevention, National Center for Health Statistics, *National Health and Nutrition Examination Survey*.



U.S. industries release billions of pounds of chemicals each year

In 2007, U.S. polluters reported a total of 4.1 billion pounds in toxic releases to the air, water, and soil, according to the EPA's Toxics Release Inventory, or TRI. Metal mining and electric utilities accounted for the greatest share, followed by chemical and primary metal facilities.

Source: Environmental Protection Agency, *2007 TRI Public Data Release, Section A* (March 19, 2009)

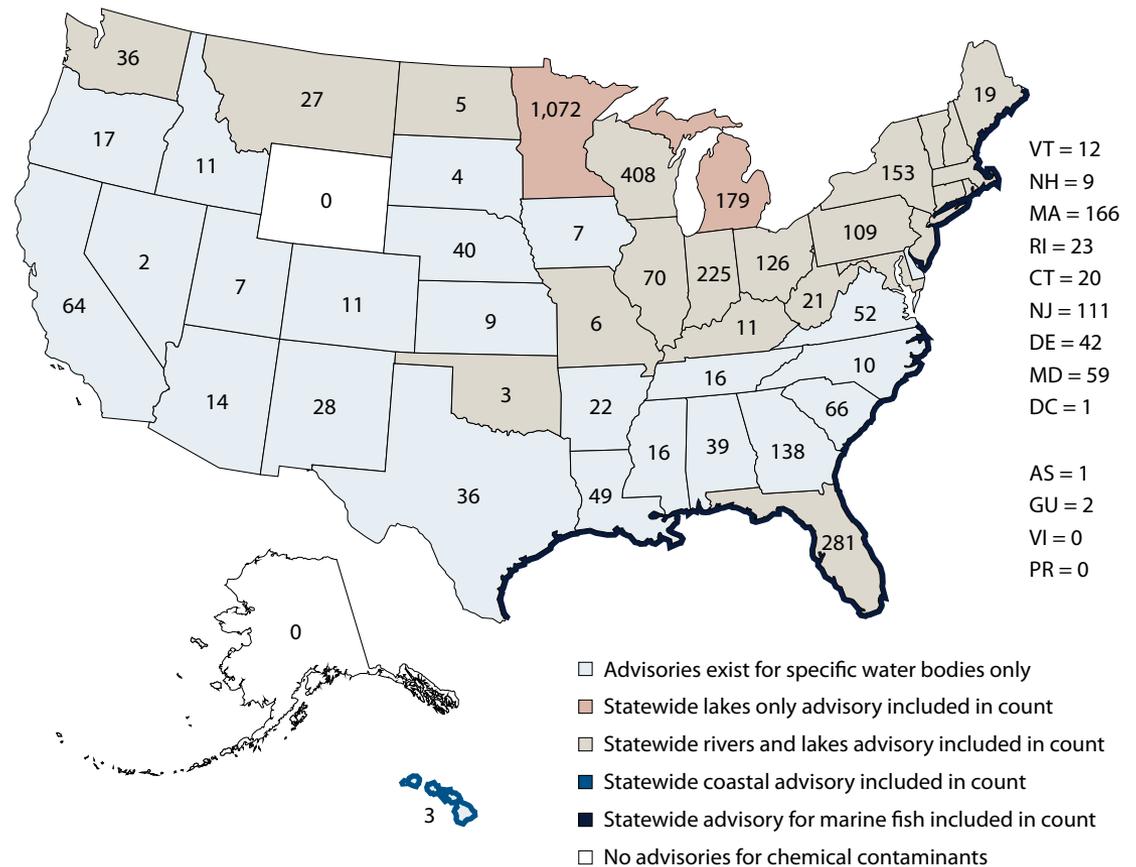


Chemicals contaminate the environment and food chain

States have issued an increasing number of advisories against consumption of fish because of chemical contamination. As this map shows, there were a total of 3,852 fish advisories in 2006, covering 38 percent of the nation's total lake acreage and 26 percent of the nation's total river miles. Of these advisories, 3,080 were the result of mercury. Mercury emissions from coal-fired power plants and other sources contaminate the water and bioaccumulate in the food chain, sometimes making fish dangerous to eat. Pregnant women who eat mercury-contaminated fish are at greater risk of having children with neurological disorders.

Source: EPA, National Listing of Fish Advisories, *Technical Fact Sheet: 2005/06 National Listing* (July 2007).

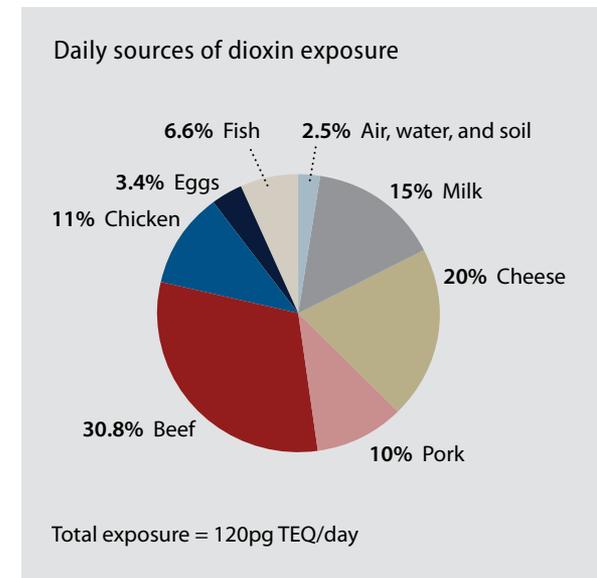
Fish advisories by state, 2006



Chemicals are part of the daily diet

Avoiding certain fish may reduce mercury exposure, but chemicals are found throughout the food supply. More than 95 percent of human exposure to dioxin, for example, comes from food intake. Dioxin refers to a group of toxic chemicals that include polychlorinated biphenyls, or PCBs, polychlorinated dibenzo dioxins, and polychlorinated dibenzo furans. These chemicals accumulate in animals' fat stores from contaminated air, water, and soil. Americans are exposed to dioxin as part of the daily diet, with beef as the leading source. Dioxin exposure, like lead exposure, has declined significantly over the last several decades as a result of stronger regulation. But even at lower levels, dioxin is linked to a number of reproductive health problems, including miscarriages and birth defects. An EPA reassessment of dioxin's health effects has been in the works since 1991. This reassessment is [available in draft](#), but the Bush administration held up its completion, seemingly because the findings point to stronger regulation. Environmental groups are urging the Obama administration to [release the reassessment without delay](#).

Source: Agency for Toxic Substances and Disease Registry, "Toxicological Profile for Chlorinated Dibenzo-p-dioxins" Chapter 5, p. 464 (December 1998).



Consumer products are a major source of chemical exposure

Americans are exposed to dangerous chemicals in consumer products. The following sections highlight chemicals found in furniture and plastics used for toys, food containers, and a host of other products. But cosmetics are another area of concern. A 2008 study tested 20 teenage girls for hormone-disrupting chemicals found in cosmetics. The chart shows the percentage of girls tested whose blood and urine contained at least one chemical from the chemical families listed. Also shown is the number of chemicals in each chemical family tested for and the number detected. Adolescents are at particular risk because their reproductive systems are in the process of maturing. Consumers can [view safety ratings](#) for 42,000 personal care products through the Environmental Working Group's website.

Chemicals found in 20 teenage girls

Chemical family	Use/source	Percent found in teen girls	Chemicals found/chemicals tested for
Phthalates	Ingredient in nail polish, other cosmetics	100%	7/7
Triclosan	Preservative in liquid hand soap, toothpaste	100%	1/1
Nitro- and polycyclic musks	Artificial fragrance in soap, shampoo, deodorant, and cosmetics	70%	2/11
Parabens	Preservative in cosmetics	100%	6/6

Exposure to these chemicals may also come from sources besides cosmetics. Phthalates, for example, are found in many plastics.

Source: Environmental Working Group, "[Teen Girls' Body Burden of Hormone-Altering Cosmetics](#)" (Sept. 24, 2008).

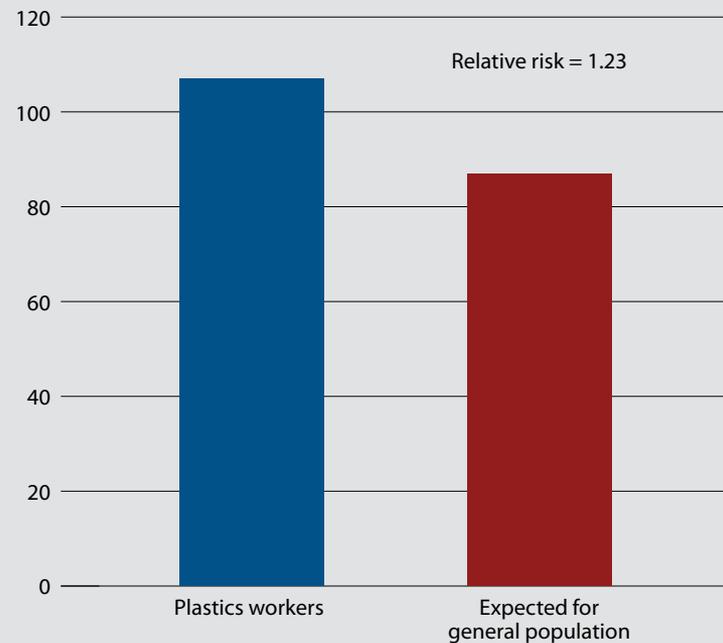
Workplaces can be dangerous

Chemical exposures are often highest in occupational settings, putting workers at risk of reproductive health problems. A recent study examined infertility among Danish workers in the plastics industry from 1995–2005. Women plastics workers between the ages of 20 and 39 more frequently sought treatment for infertility than women in the general population.

Source: Karin S. Hougaard, et al., "Increased Incidence of Infertility Treatment Among Women Working in the Plastics Industry," *Reproductive Toxicology* 27 (Jan. 21, 2009): 186–189.

More infertility treatment among women in plastics industry

Cases of infertility treatment out of 27,445 person years*



*"Person years" is the sum of the number of years that each person in the study was under observation

Chemical protections are inadequate

Industrial chemicals. The Toxic Substances Control Act, enacted in 1976, places the burden of proof on the Environmental Protection Agency to demonstrate that a chemical is unsafe. Companies have no responsibility to test for safety before bringing a chemical into commerce. Thus, the guinea pigs turn out to be people in the real world. Regulation occurs only after terrible health consequences have occurred and all reasonable doubt has been removed. Indeed, since the TSCA's adoption, the EPA has mandated restrictions on just five substances—halogenated chlorofluoralkanes, PCBs, dioxin in certain wastes, asbestos, and hexavalent chromium.

Personal care products. The introduction of new cosmetics does not follow the same process as drugs, which must receive approval from the Food and Drug Administration after a safety review. Rather, according to the FDA, the Food, Drug and Cosmetic Act “contains no provision that requires demonstration to FDA of the safety of ingredients of cosmetic products...prior to marketing the product.” Again, people end up as the guinea pigs.

Consumer product safety. In 2007, millions of popular Chinese-made toys, including Big Bird and Elmo toys, were found to contain lead paint, which led to massive recalls. A year later, President Bush signed the Consumer Product Safety Improvement Act, which phases out lead and phthalates in toys and other children's products and requires pre-market chemical safety testing of such products. This law represents significant progress, but the Consumer Product Safety Commission, which is responsible for implementation, still operates under cumbersome regulatory procedures and lacks resources to adequately protect consumers. The CPSC had not adopted a new toy standard for a decade prior to the act, and the former acting CPSC chairman, Nancy Nord, expressed resistance even after the recalls of Chinese-made toys. “Noticeably absent from the majority of your public remarks is an emphasis on protecting consumer safety, which happens to be the mission of the agency you lead,” wrote Sen. Richard Durbin (D-IL) in a recent letter rebuking Nord. The Senate recently confirmed President Obama's choice as new chair of the CPSC, Inez Moore Tenenbaum.

Occupational safety and health. Federal laws and standards permit higher chemical exposures for workers than for the general population. The difference in protection is frequently substantial. For some dangerous chemicals, such as BPA, there are no workplace exposure limits at all.

II. Phthalates

Phthalates are a group of chemicals used to soften plastics for a variety of products, including toys, blood bags, IV tubes, cosmetics, and food containers. About a billion pounds of phthalates are produced worldwide every year.

Phthalates are linked to the following reproductive health problems:

- Premature births
- Endometriosis
- Genital abnormalities in boys
- Sperm damage and reduced sperm count

Testing shows that virtually everyone has some phthalates in their bodies. Particularly high levels are found in children.

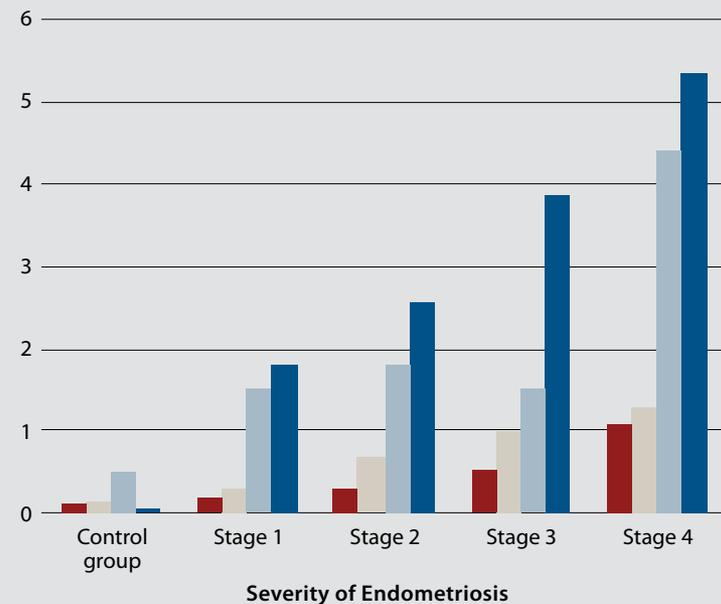
Phthalates are linked to endometriosis

Phthalates are linked to a host of reproductive health problems in both men and women. A study of Indian women, for example, found that as the severity of endometriosis increases (stage 4 being the most severe), there tends to be an increase in the presence of various phthalates in the blood. Control subjects without endometriosis had the lowest levels of phthalates in the blood.

Source: B. Satyanarayana Reddy, et al, "High Plasma Concentrations of Polychlorinated Biphenyls and Phthalate Esters in Women with Endometriosis: a Prospective Case Control Study," *Fertility and Sterility* 85 (3) (March 2006): 775–779.

Correlation between severity of endometriosis and phthalate levels in blood

Phthalate metabolites/xenoestrogens in blood, µg/ml



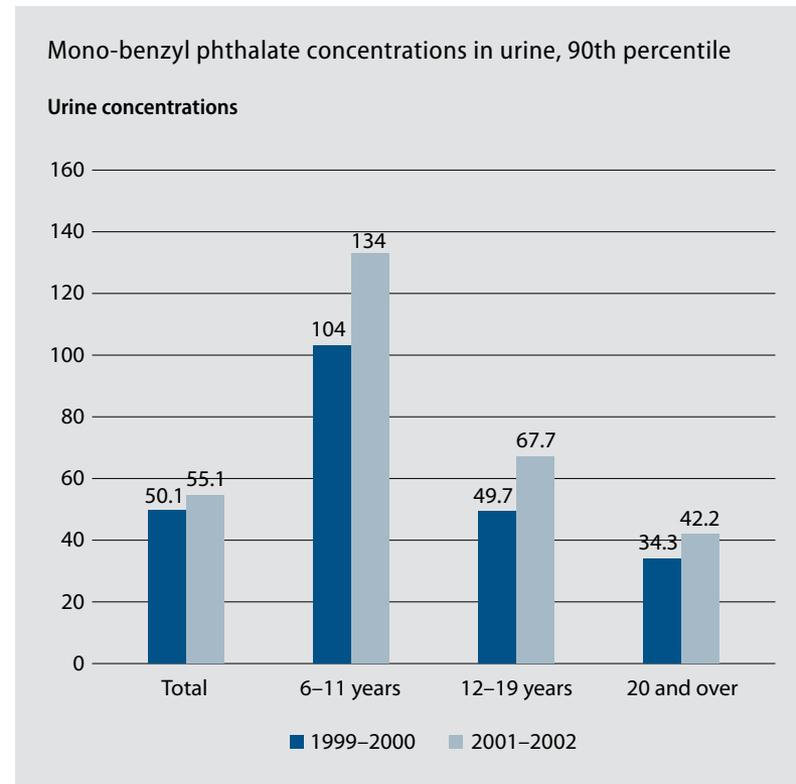
Phthalate metabolites/Xenoestrogens:

■ Di-n-butyl ■ Butyl benzyl ■ DEHP ■ Di-n-octyl

Americans are widely exposed to phthalates

The CDC tested the urine of hundreds of Americans for phthalates from 1999–2002. Virtually everyone had phthalates in their urine. The chart shows concentrations of mono-benzyl phthalate found in the survey's 90th percentile. Mono-benzyl phthalate is a metabolite for the industrial solvent benzylbutyl phthalate, which is used in adhesives, vinyl flooring, and car care products. Younger age groups had the highest levels in their urine. The CDC's testing also found concentrations increasing over time—and not just for mono-benzyl phthalate, but for all phthalates. More biomonitoring is needed, however, to determine whether this is a long-term trend.

Source: Centers for Disease Control and Prevention, *Third National Report on Human Exposure to Environmental Chemicals* (2005).



Exposure to phthalates comes from a variety of sources

Phthalates are most commonly used to soften polyvinyl chloride (PVC or vinyl). Exposure can occur orally (children chewing on toys, for example, or from leaching food containers), through dermal application of personal care products, or through inhalation of dust and air—that “new car smell” partly comes from phthalates. The following are just some of the products that contain phthalates.



Toys



Food containers



Flooring and wall coverings



Medical devices such as blood bags and IV tubes



Air fresheners



Cosmetics and personal care products, including baby products

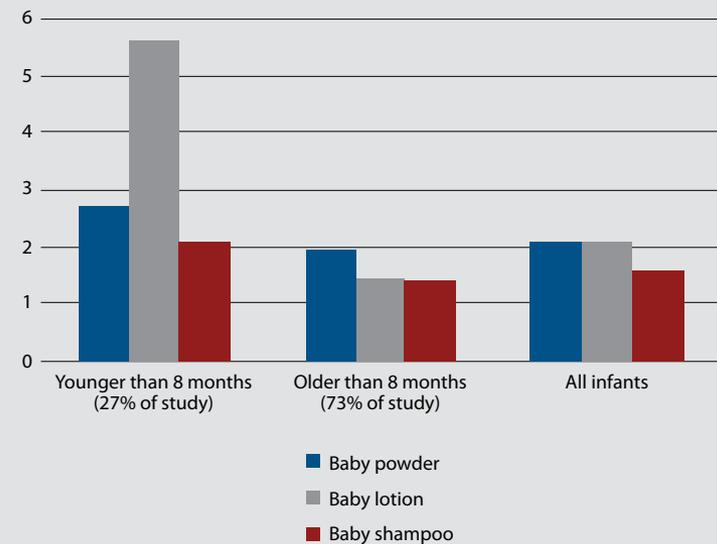
Infants are exposed to phthalates from baby products

Public and political attention has recently focused on baby products that contain phthalates. This chart shows the results of a study that examined the levels of phthalates in infants exposed to baby powder, baby lotion, and baby shampoo. This study found that in all children, in particular those younger than 8 months old, there is a correlation between their exposure to these products and an increased number of phthalates present in their urine samples.

Source: Sheela Sathyanarayana, et al, "Baby Care Products: Possible Sources of Infant Phthalate Exposure," *Pediatrics* 121 (Feb. 2008): e260-e268.

Significant correlation between presence of phthalates in infants and products used

Correlation (z score—all significant within 95% confidence interval)



New limits on phthalates

Limitations on phthalates are starting to be put in place. On August 14, 2008, President Bush signed into law the Consumer Product Safety Improvement Act, which bans three types of phthalates in children's products and temporarily outlaws three others while their effects are studied. Congress overwhelmingly supported the act, which also sets new limits for lead.

Independent of the legislation, Wal-Mart, Toys R Us, Lego, Evenflo, and Gerber also agreed to phase out children's products containing phthalates by Jan. 1, 2009.



Sen. Mark Pryor (D-AR) and House Speaker Nancy Pelosi (D-CA) congratulate each other after passage of the Consumer Product Safety Improvement Act. (Photo courtesy Public Citizen)

III. BPA

Bisphenol A, or BPA, is a plastic monomer and plasticizer that ranks among the highest-volume chemicals worldwide, with over 6 billion pounds produced each year. Many products contain BPA, including toys, food and drinking containers, medical equipment, and electronics.

BPA has been linked to the following reproductive health problems:

- Reduced sperm count
- Development of later-life health problems, including prostate and breast cancer, due to prenatal exposure
- Altered reproductive tract development
- Abnormal brain development in offspring
- Miscarriage

BPA is harmful even at low doses

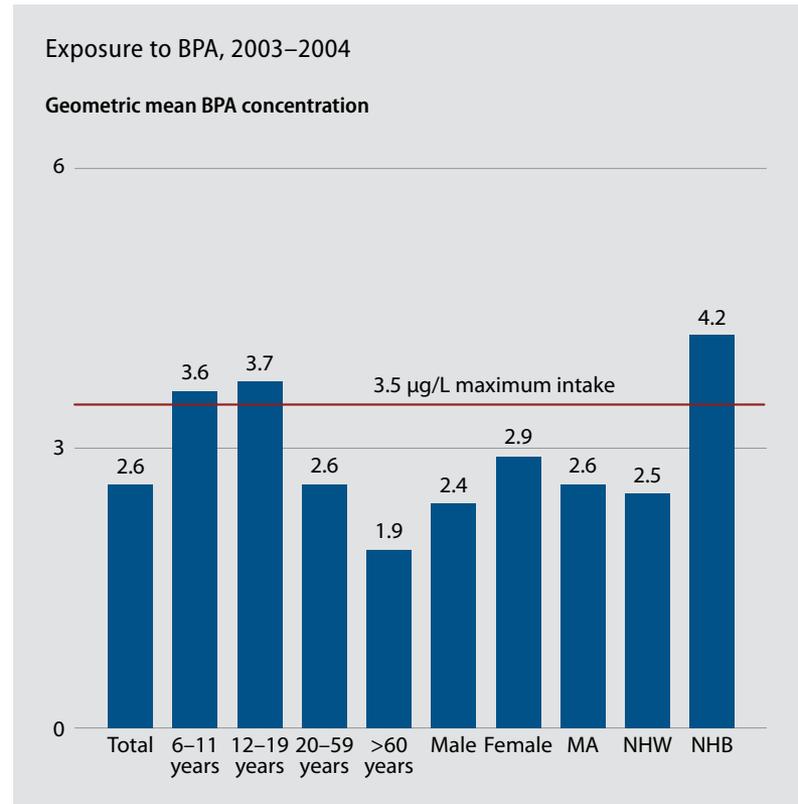
This table, adapted from the [Environmental Working Group](#), shows that BPA may have serious reproductive health consequences even at low exposures. These studies were all rated as “very useful” or “useful” by an expert panel of the [Center for Evaluation of Risks to Human Reproduction](#) within the National Institutes of Health.

Daily BPA exposure (µg/kg body weight-day)	Toxic effect	Reference
0.025	persistent changes to breast tissue, predisposes cells to hormones and carcinogens	Muñoz-de-Toro 2005
0.025	permanent changes to genital tract	Markey 2005
2	increased prostate weight 30 percent	Nagel 1997
2.4	earlier puberty, differences in genital development	Howdeshell 1999 , Honma 2002
2.5	breast cells predisposed to cancer	Murray 2007
10	prostate cells more sensitive to hormones and cancer, malformation of urethra	Ho 2006 (infant), Timms 2005 (fetal)
10	decreased maternal behaviors	Palanza 2002
50	EPA's safe exposure level, based on outdated high dose studies	EPA 1998

BPA is present in most Americans, but highest among younger age groups

A biomonitoring study in 2003–2004 found BPA in 92.6 percent of its research subjects. Concentrations were measured in $\mu\text{g/L}$, which denotes BPA weight per liter of urine. Younger age groups had mean concentrations above even the Food and Drug Administration’s outdated safety threshold, which does not incorporate recent studies showing harmful effects at lower doses. Non-Hispanic blacks, or NHB, had significantly higher levels of BPA than Mexican-Americans, or MA, and non-Hispanic whites, or NHW.

Source: National Center for Environmental Health, “Exposure of U.S. Population to BPA: 2003–2004” (January 2008).



BPA exposure comes from a variety of sources

Exposure to BPA typically comes from ingesting food or fluids stored in containers or packages made with BPA. BPA also contaminates the environment and is found in drinking water supplies as well as indoor and outdoor air. Workers with manufacturing jobs involving BPA have been found to have higher exposure levels than the general adult population. The following are just some of the products that contain BPA.



Foods stored in cans with epoxy resin linings



Dental products containing resin-based monomers



Polycarbonate bottles and food containers



Plastic dinnerware



Papers and cardboards used for food packaging

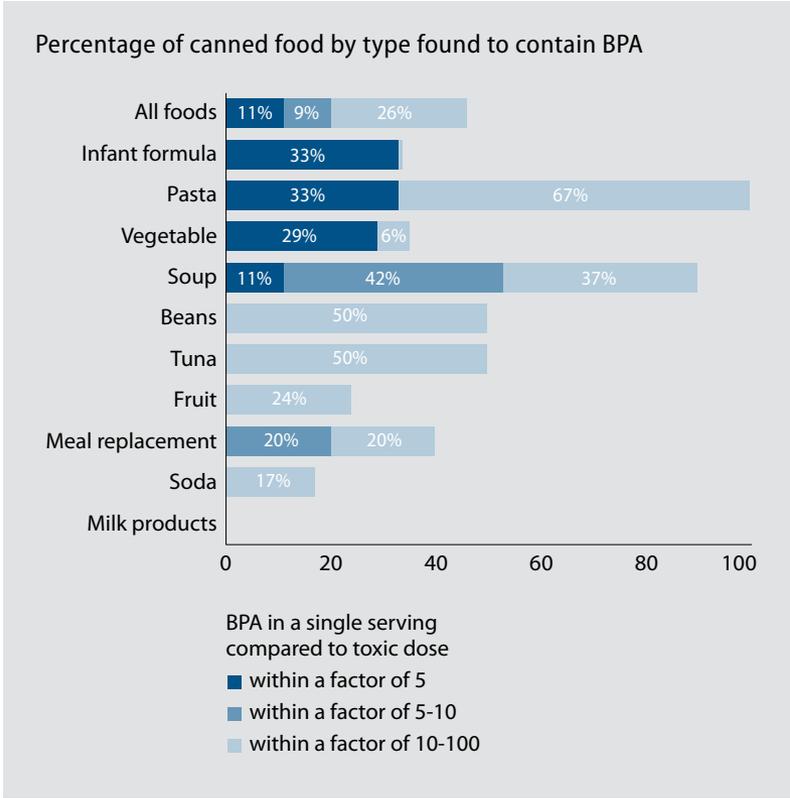


Compact discs

BPA is found in canned food

An estimated 17 percent of the U.S. diet comes from canned food, which is a primary source of BPA exposure. The Environmental Working Group detected BPA in 55 of 97 cans of name-brand food purchased in March 2006. The chart shows the percentage of cans by food type that contained potentially dangerous levels of BPA. In some cases, a single serving contained BPA levels less than five times lower than doses that caused reproductive problems in lab animals. The government usually mandates a much larger margin of safety. The chart shows the proximity of BPA levels in cans to the “toxic dose” of 2 µg/kg/day. Instant baby formula and canned pasta and vegetables contain some of the highest levels of BPA per dose.

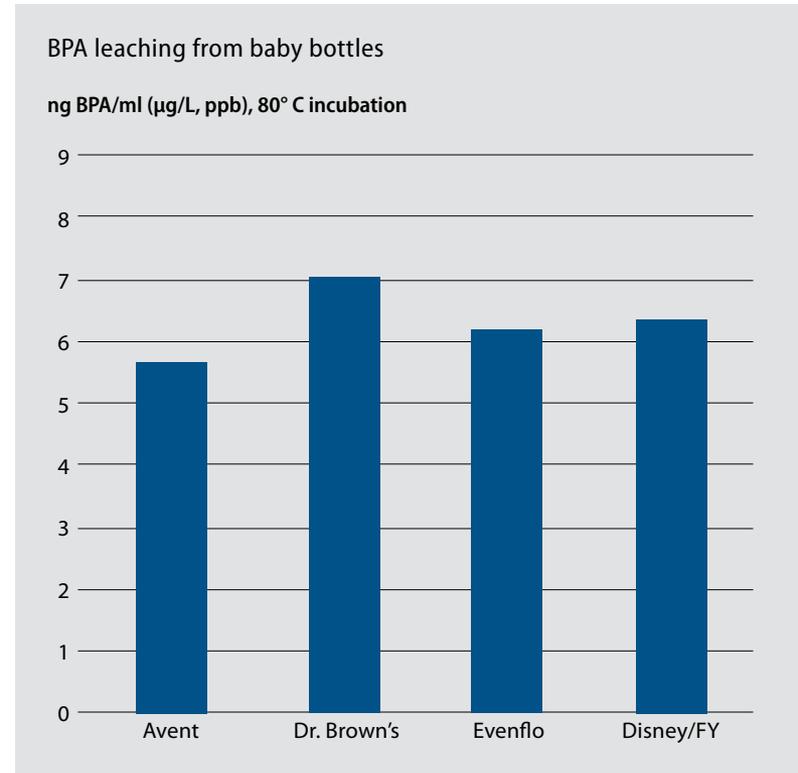
Source: Environmental Working Group, "Bisphenol A: Toxic Plastics Chemical in Canned Food" (May 2007).



Drinking containers may contain BPA

Many baby bottles contained BPA until recently. This chart shows the leaching results from baby bottles, purchased in December 2007, of the most popular U.S. brands. When repeated washing was simulated, each brand showed a high level of BPA leaching into the liquids they held. Manufacturers stopped using BPA in baby bottles in response to growing public concern. But BPA is still used in other drinking containers. [A recent study](#) measured BPA levels in 77 Harvard students who spent one week drinking from polycarbonate bottles, which contain BPA. BPA levels in the urine of these students increased 69 percent by the end of the week.

Source: The Work Group for Safe Markets, "[Baby's Toxic Bottle: Bisphenol A Leaching from Popular Baby Bottles](#)" (Feb. 2008).



Action on BPA

- April 2008** Canada banned BPA in all baby bottles.
- May 2008** John Dingell, then chairman of the U.S. House Committee on Energy and Commerce, and Bart Stupak, chairman of that committee's Oversight and Investigations Subcommittee, wrote to four major companies requesting voluntary removal of BPA from their products.
- Sept. 2008** The National Toxicology Program at the U.S. Department of Health and Human Services released a monogram expressing "some concern" that BPA has adverse effects on the prostate gland, brain, and behavioral development in fetuses. The monogram contradicted the Food and Drug Administration's determination that BPA was not harmful. A scientific advisory panel later criticized the FDA for failing to consider a wide variety of studies that link BPA to reproductive problems.
- March 2009** The chemical manufacturer Sunoco announced that it would no longer sell BPA for use in products meant for children aged 3 and younger. This decision marked the first time a member of the American Chemistry Council (a major industry trade association) acknowledged BPA hazards.
- Rep. Ed Markey (D-MA) and Sens. Dianne Feinstein (D-CA) and Chuck Schumer (D-NY) introduced legislation to ban BPA in all food and beverage containers.
- Suffolk County, NY, became the first jurisdiction to ban BPA in baby bottles and cups.
- May 2009** Minnesota and Chicago banned BPA in baby bottles and cups—the first state and city to do so.
- June 2009** Connecticut banned BPA in infant formula and baby food cans and jars, as well as reusable food and drink containers.

IV. PBDEs

Polybrominated diphenyl ethers, or PBDEs, are used as flame retardants in many household products, including couches, fabrics, and electronics. They are bioaccumulative and are present in breast milk and food. PBDEs are linked to the following reproductive health problems:

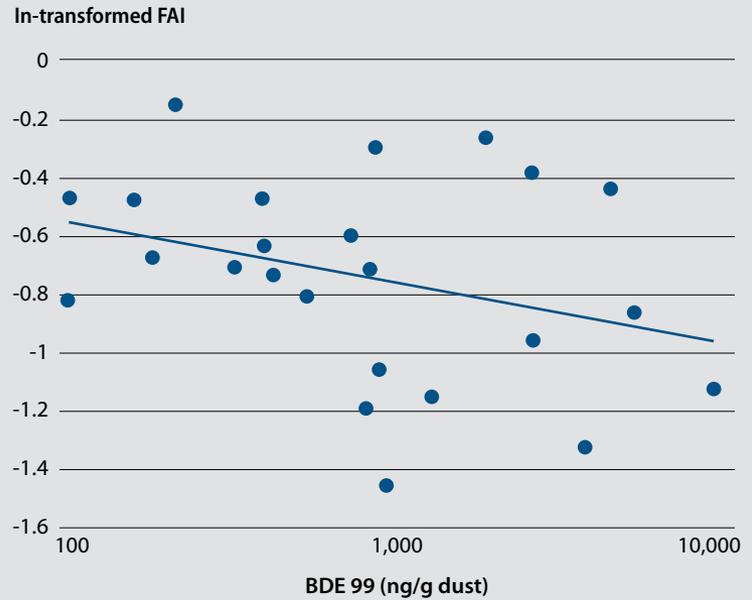
- Disruption in maternal and fetal thyroid hormones, which are important to brain development
- Lower sperm count
- Behavioral disorders in offspring
- Inhibition of endogenous androgen activity, a potential cause of reproductive failure

PBDEs alter hormone levels

PBDEs have been found to affect hormone levels in both men and women. One recent study compared the testosterone levels of 24 men to PBDE levels found in dust in their homes. Testosterone levels were significantly lower in men exposed to higher levels of BDE 99, a type of PBDE.

Source: John D. Meeker, et al, "Polybrominated diphenyl ether (PBDE) Concentrations in House Dust Are Related to Hormone Levels in Men," *Science of the Total Environment* 407 (10) (May 1, 2009): 3425–3429.

Correlation between testosterone levels in men and PBDE levels in household dust



FAI refers to "free androgen index," which is based on a calculation involving levels of testosterone and sex hormone binding globulin, or SHBG.

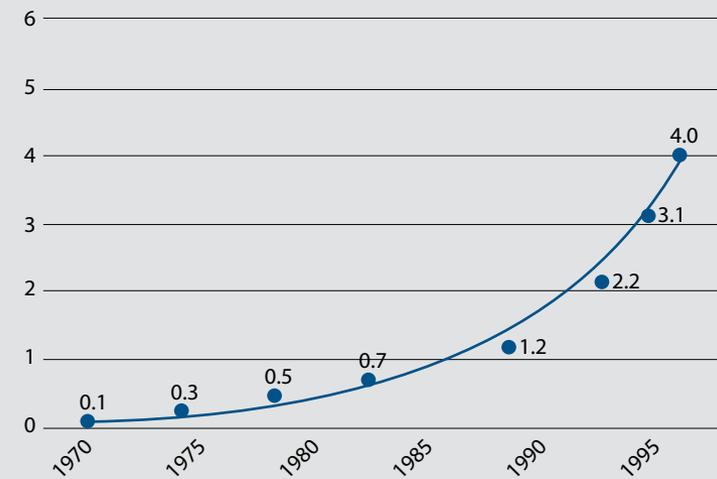
PBDEs are present in breast milk

This graph illustrates the exponential increase in the presence of PBDEs in the breast milk of Swedish women from 1972 to 1997. These findings led to the realization that women worldwide, including in the United States, were being exposed to dangerous levels of PBDEs. Breast milk is an indicator of the level of maternal exposure and thus a measure of possible exposure of the fetus.

Source: Sonya Lunder and Renee Sharp, "Mother's Milk: Toxic Fire Retardants (PBDEs) in Human Breast Milk," Environmental Working Group (2003).

PBDE concentration in women's breast milk in Sweden, 1972–1997

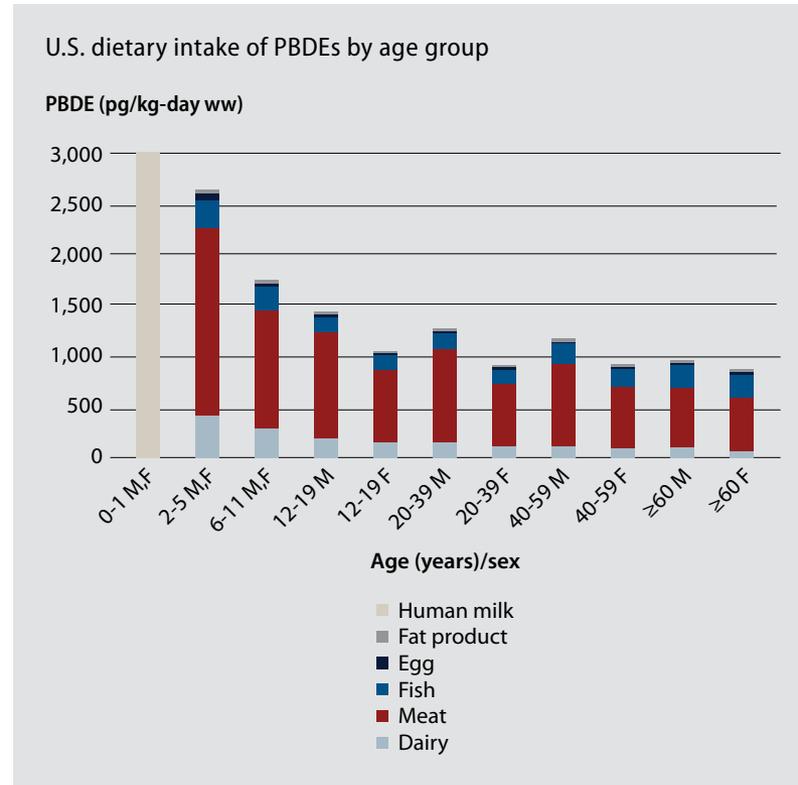
Total PBDE levels in pooled breast milk samples (ppb lipid)



Americans are exposed to PBDEs in food

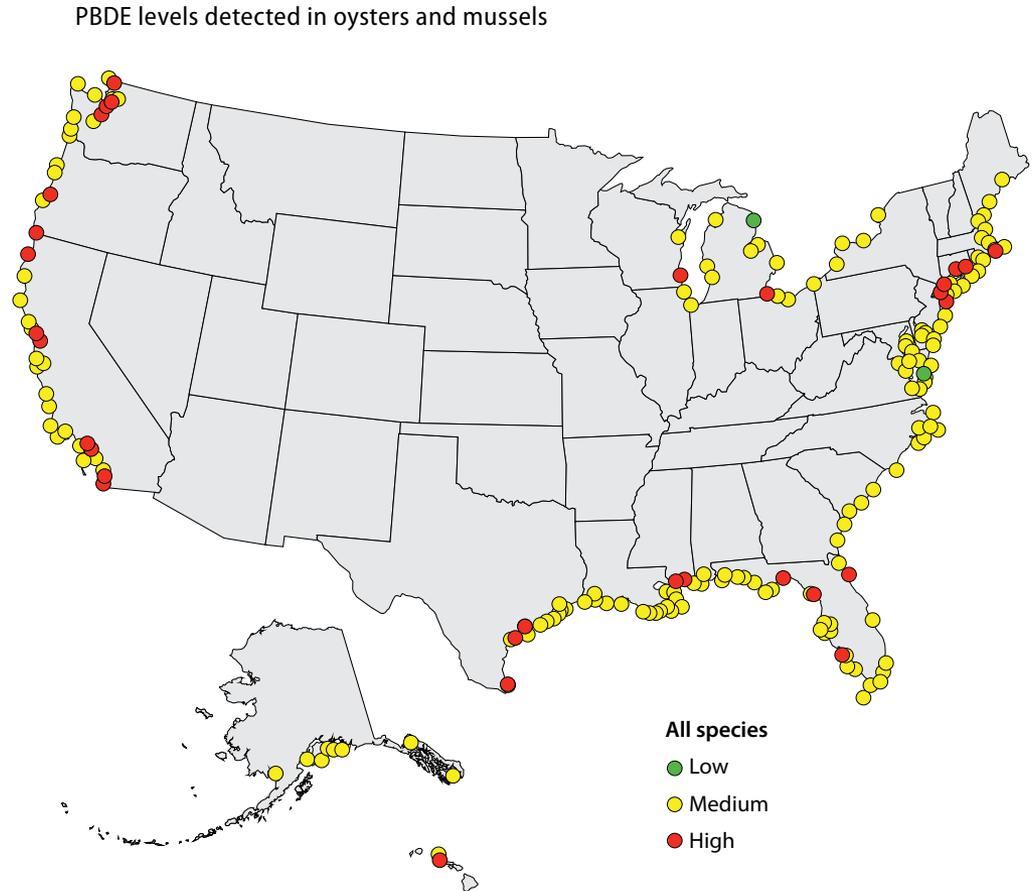
Household dust is not the only way Americans are exposed to PBDEs. PBDEs contaminate the environment and bioaccumulate in the food chain. This chart shows the sources of U.S. dietary intake of PBDEs by age group. Nursing infants and young children are exposed to the highest levels.

Source: Arnold Schecter, et al, "Polybrominated Diphenyl Ether (PBDE) Levels in an Expanded Market Basket Survey of U.S. Food and Estimated PBDE Dietary Intake by Age and Sex," *Environmental Health Perspectives* 114 (10) (October 2006): 1515–1520.



PBDEs are found in coastal waters and the Great Lakes

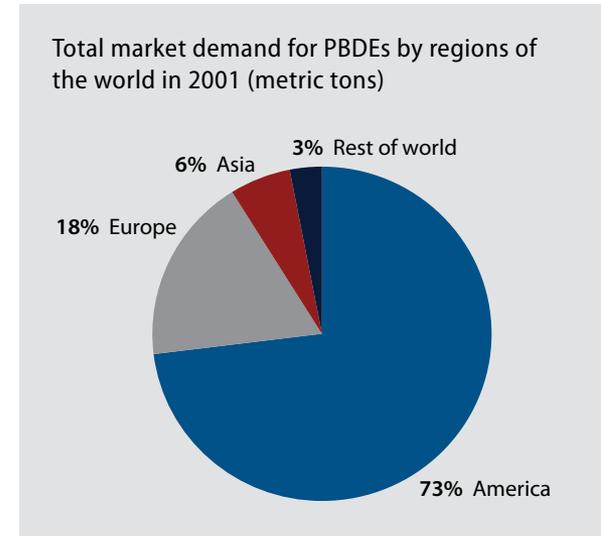
A 2008 report from the National Oceanic and Atmospheric Administration found PBDE contamination in all U.S. coastal waters and the Great Lakes. This map depicts PBDE levels found in oysters and mussels. Humans can be exposed to PBDEs by eating contaminated fish and marine life. “Scientific evidence strongly documents that these contaminants impact the food web and action is needed to reduce the threats posed to aquatic resources and human health,” said [John H. Dunnigan](#), NOAA assistant administrator of the National Ocean Service.



The United States leads the world in use of PBDEs

The United States has the largest market demand for PBDEs, nearly tripling European demands. The levels of PBDEs in people's bodies have doubled every two to five years, and are 40 times higher in North America than other continents.

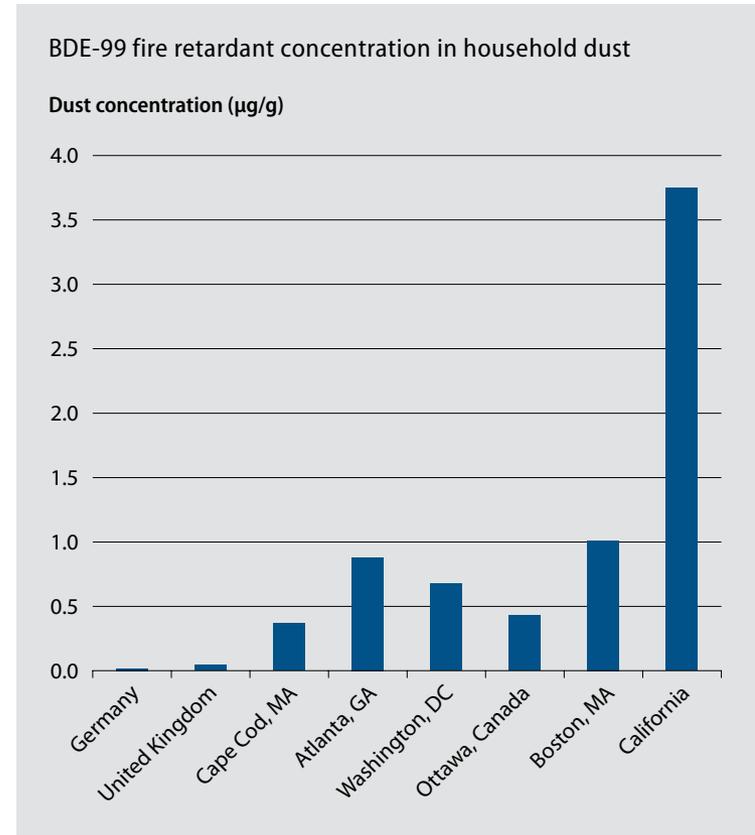
Source: Agency for Toxic Substances and Disease Registry, "[Toxicological Profile for Polybrominated Biphenyls and Polybrominated Diphenyl Ethers \(PBBs and PBDEs\)](#)" (September 2004); Centers for Disease Control and Prevention, "[Spotlight on PBDEs and PBBs](#)," Kellyn S. Betts, "Rapidly rising PBDE levels in North America," *Environmental Science and Technology* 36 (3) (Feb. 2002): 50A–52A.



California flammability standard leads to higher PBDE exposure

The U.S. market demand for PBDEs is driven by California, the only state with a flammability standard for home furniture. Manufacturers must use flame retardants such as PBDEs to meet this strict standard. As a result, Californians are exposed to elevated levels of PBDEs. The chart shows concentrations of household dust in various locations. California recently banned two types of PBDEs, but other dangerous chemicals are being used as replacements. Replacements include the chemical mix Firemaster 550—which is likely toxic to reproduction, according to EPA Design for the Environment—and chlorinated tris, which shows testicular toxicity, among other health consequences, and was banned from use in children’s garments in 1977. The California Senate narrowly defeated legislation in 2007 to revise the state’s flammability standard after a multi-million dollar campaign by chemical manufacturers to preserve it.

Source: Arlene Blum, “Toxic Tragedy: The Fire Retardant Dilemma” (Green Science Policy Institute, May 1, 2009).

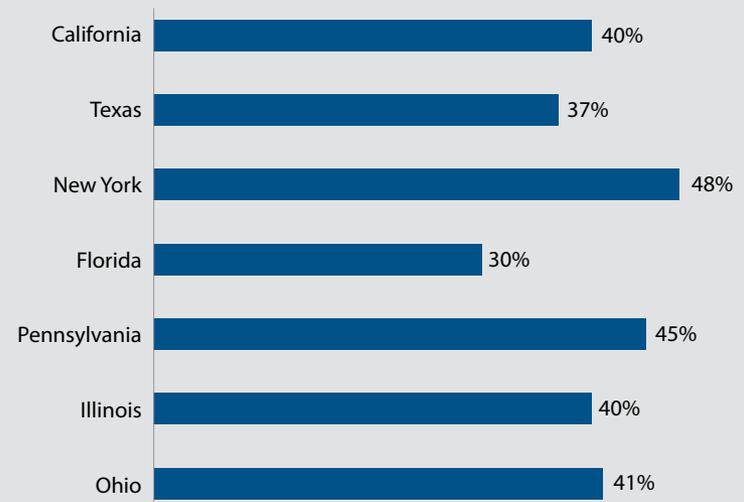


Flame retardants do more harm than good

Fire deaths have declined significantly across the country, largely because indoor cigarette smoking has decreased. California's flammability standard does not appear to have delivered significant safety benefits based on a comparison to other states that have no standard. The graph shows the percent reduction in fire deaths in the most populous states over a 20-year period. The Consumer Product Safety Commission [proposed a regulation](#) in March 2008 that would supplant California's standard with a national flammability standard that could be met without using dangerous flame retardants. It will be up to CPSC's new leadership, appointed by President Obama, to issue a final standard.

State reductions in fire deaths, 1980–1984 compared to 2000–2004

Fire death reductions



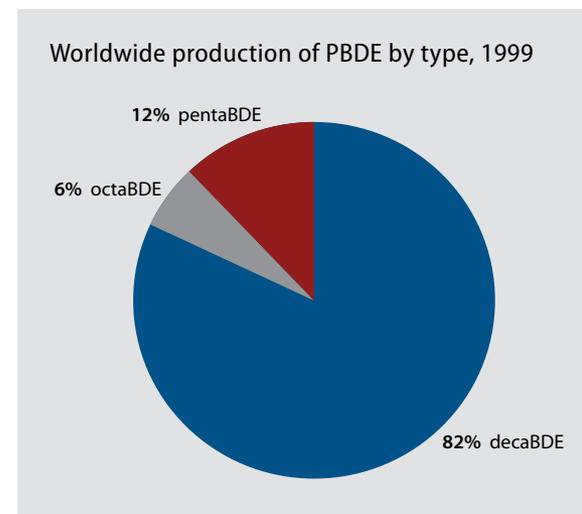
Types of PBDEs

DecaBDE. Found in high-impact plastic used for computers, TVs, and electrical appliances; upholstery and drapes; and wires, cables, and pipes.

PentaBDE. Found in the upholstery foams used in furniture, mattresses, car seats, and office chairs, as well as the solid foams used in appliances.

OctaBDE. Found in the ABS hard plastic used in computer monitors, TV housing, and circuit boards.

DecaBDE accounted for an estimated 82 percent of PDBEs produced worldwide in 1999. DecaBDE breaks down into the PentaBDE and OctaBDE forms, which are highly toxic. New restrictions have curtailed production of Penta- and OctaBDEs in recent years, but many products containing these substances remain in use. PBDEs from disposed products also contaminate the environment, persist for many years, and bioaccumulate in the food chain.



Source: Jon B. Manchester-Neesvig, et al., "Comparison of Polybrominated Diphenyl Ethers (PBDEs) and Polychlorinated Biphenyls (PCBs) in Lake Michigan Salmonids" *Environmental Science and Technology* 35 (6) (Feb. 14, 2001); Bromine Science Environmental Forum, "Major Brominated Flame Retardants Volume Estimates" (Brussels, Belgium, 2000).

Action on PBDEs

- 2003** The European Union banned use of Octa- and PentaBDE in all products.
- California banned the manufacture, processing, and distribution of Octa- and PentaBDEs. Ten other states have since banned Octa- and PentaBDEs.
- EPA established the Furniture Flame Retardancy Partnership to identify and move toward environmentally safer alternatives to PBDEs in furniture.
- 2004** The sole U.S. manufacturer of PentaBDE voluntarily phased out production.
- 2006** The EU banned electronic products containing DecaBDE.
- EPA began its Flame Retardants in Printed Circuit Boards Partnership. Printed circuit boards use the highest volume of brominated flame retardants, and the partnership seeks to find alternatives.
- 2007** Washington state became the first state to ban DecaBDE use in household goods. Maine also banned Deca in 2007, and several other states are currently considering similar legislation.



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

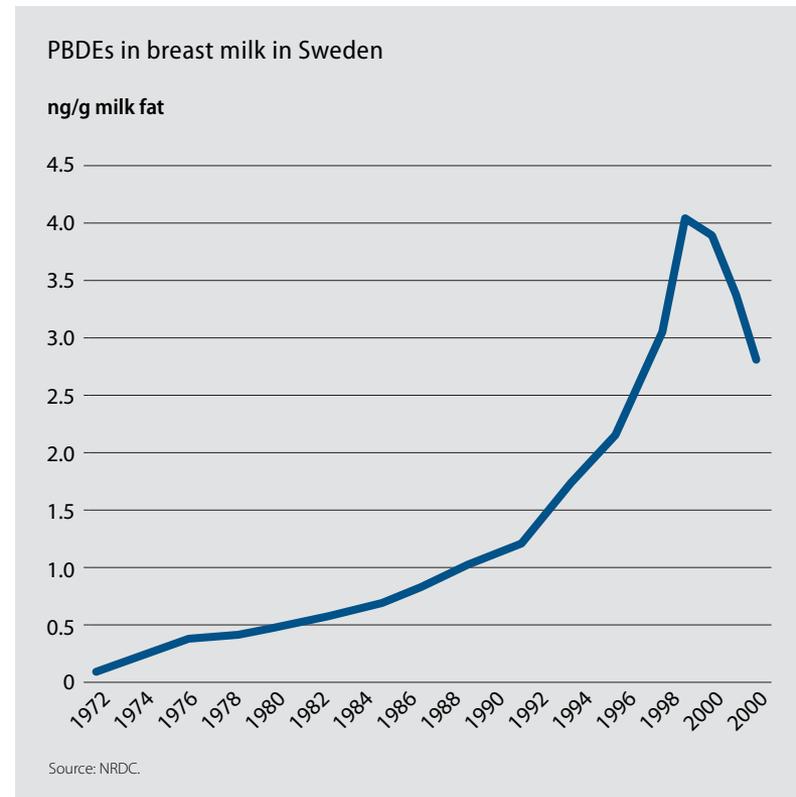
Americans are now exposed to dangerous chemicals even when safer substitute chemicals and other alternatives are available. The following slides recommend measures to limit these exposures. Specifically:

- 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.



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 ($\mu\text{g}/\text{day}$) 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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

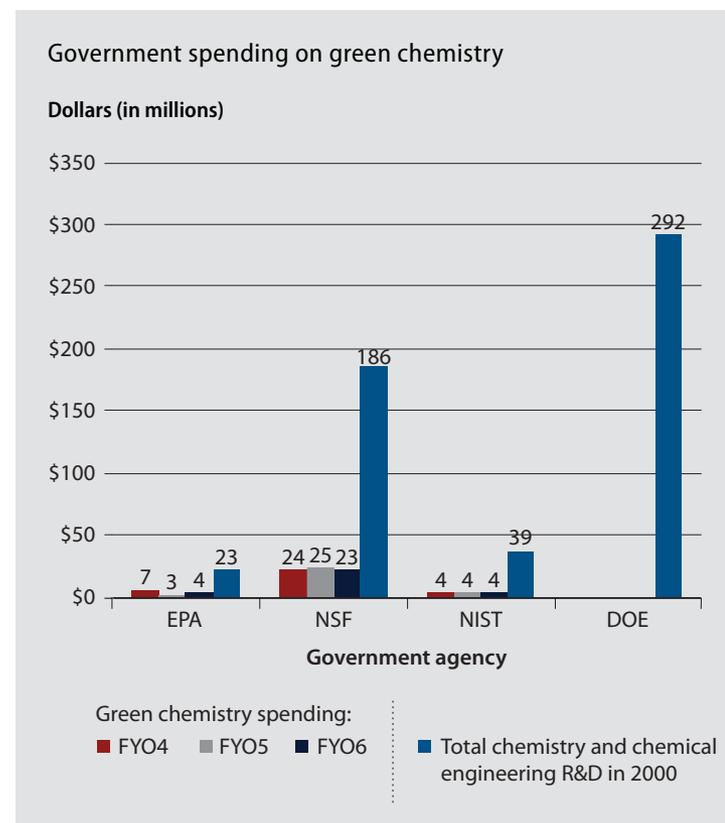
BPA exposure pathway	BPA alternatives
 <p>Baby bottles and sippy cups</p>	<ul style="list-style-type: none"> • Baby-safe glass • Polyethylene (plastic #'s 1, 2, & 4) • Polypropylene (plastic #5)
 <p>Consumer products with polycarbonate and epoxy</p>	<ul style="list-style-type: none"> • Reusable aluminum 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:

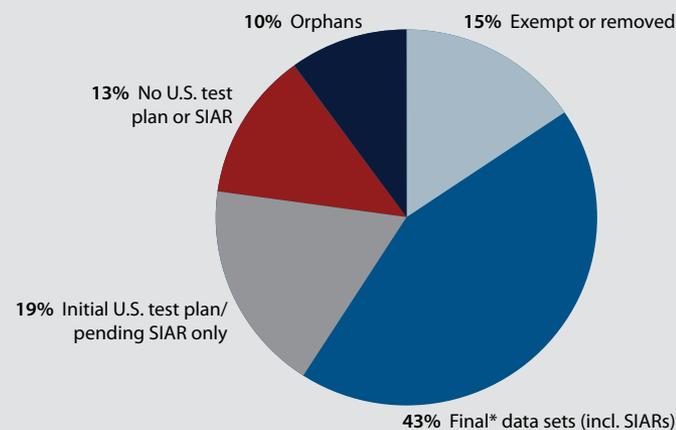
- Chemical companies should be required to provide the necessary data to ensure their products are safe. More than 85 percent of chemicals have not been tested for their effects on human health, including more than 50 percent of high-volume chemicals.
- The EPA's chemical assessment process, conducted 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.

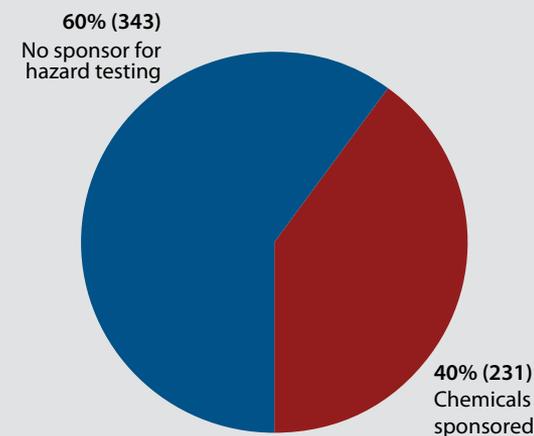
* Most final U.S. datasets not yet reviewed for quality or completeness.

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

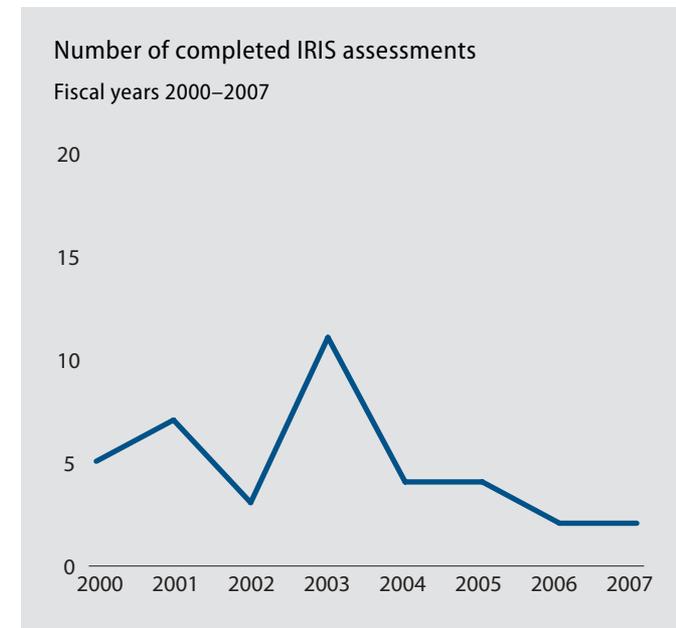


The 574 “new” HPV chemicals are drawn from the EPA’s 2002 Toxic Substances Control Act Inventory Update. Even more chemicals have reached HPV levels since this update. These chemicals are generally not being tested.

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.

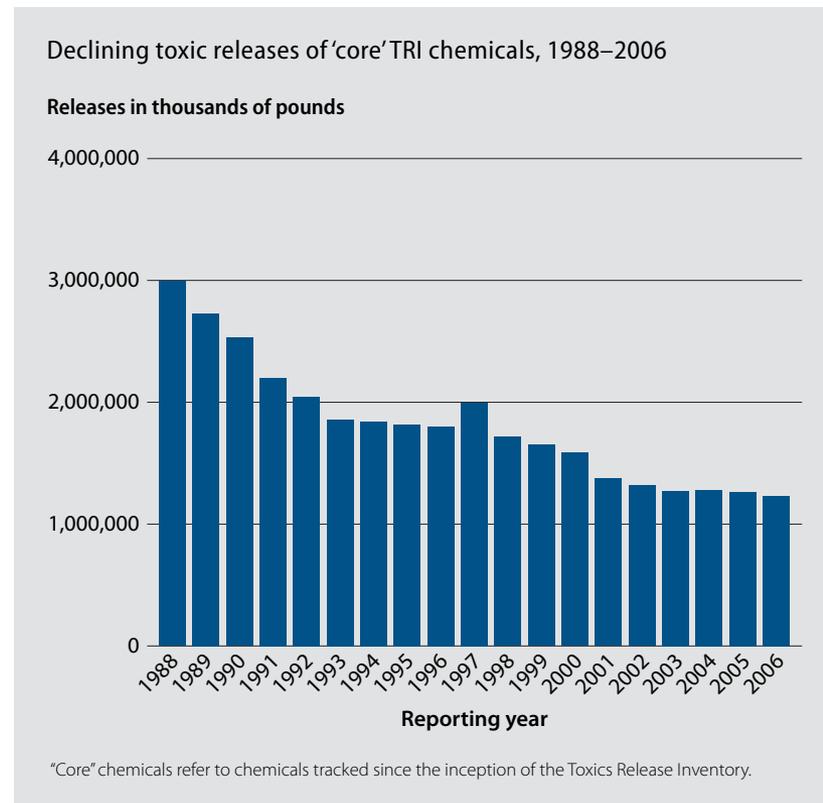
Source: Government Accountability Office, "New Assessment Process Further Limits the Credibility and Timeliness of EPA's Assessments of Toxic Chemicals" GAO-08-1168T (Sept. 18, 2008).



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.



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.

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

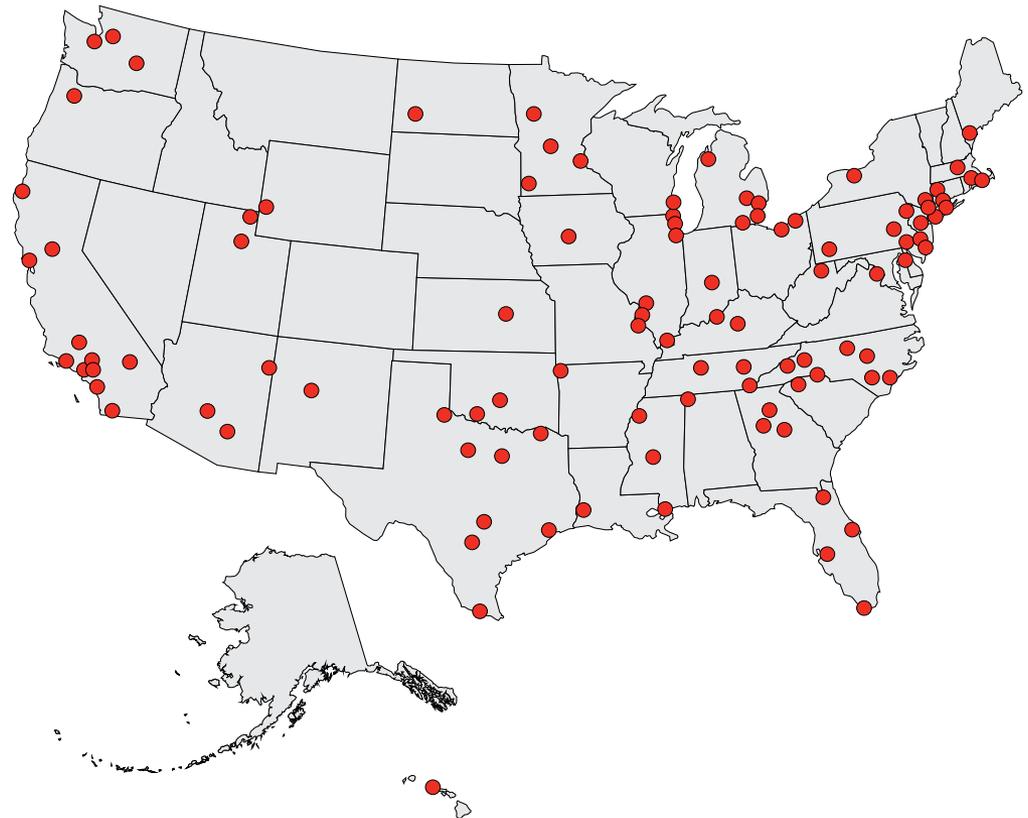
U.S. cosmetics unsafe and untested

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

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.

Locations of children participating in the National Children's Study



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

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.

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

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

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

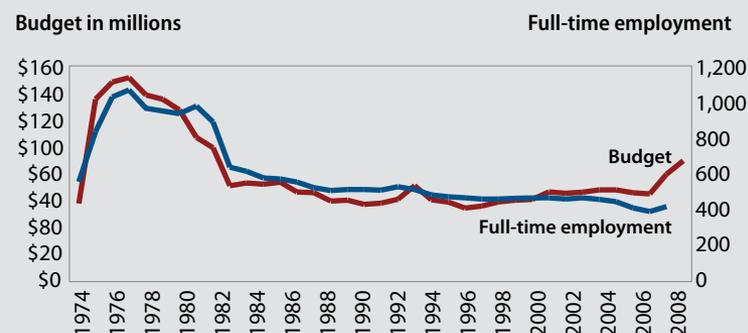
Source: Katherine Harmon, “Saving Face: How Safe are Cosmetics and Body Care Products?” *Scientific American* (May 5 2009); Food and Drug Administration, “Ingredients Prohibited and Restricted by FDA Regulations” (June 2006).

Regulatory agencies need more resources

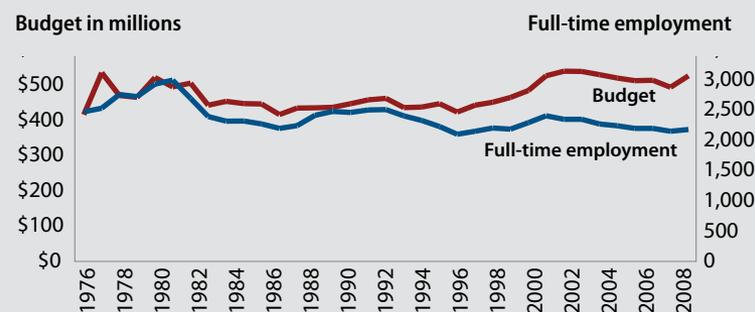
Federal regulatory agencies are challenged not only by limitations in their legal authority but also by resource constraints. The number of chemicals in use has climbed 30 percent since 1979, but budget and staffing levels have been mostly down or flat over this time. The Consumer Product Safety Commission 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.

About the author

Reece Rushing is the director of regulatory and information policy at the Center for American Progress.

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