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CHE Café Call
Chemical Policy: Recent Developments and Controversies

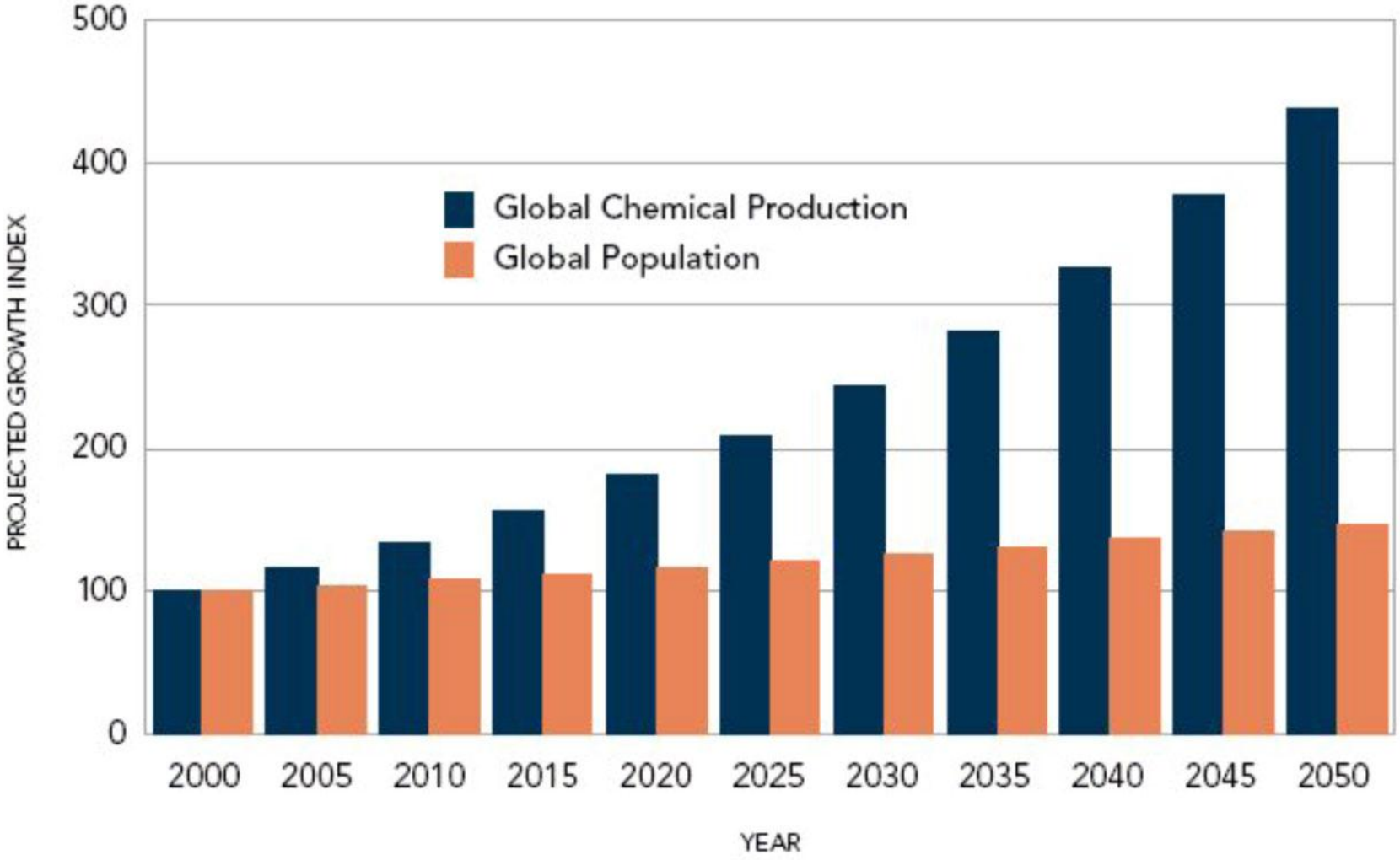
February 14, 2013

EDF
ENVIRONMENTAL DEFENSE FUND™
Finding the ways that work

Drivers for chemical policy reform

Chemicals are ubiquitous

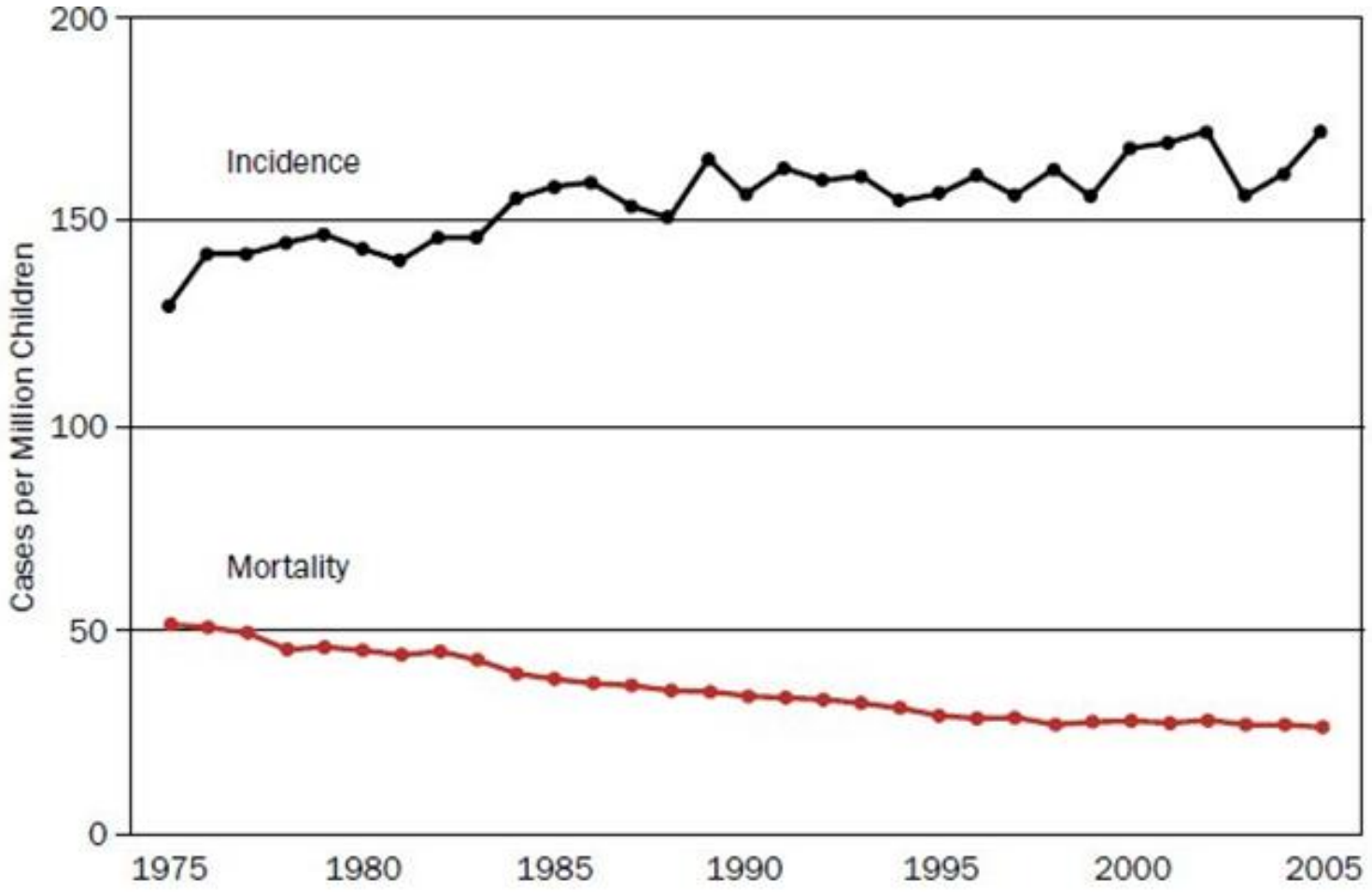
- >10 trillion pounds produced per year in the U.S.
  - 90 pounds per person per day
- Used to make 96% of all materials and products
- Number of chemicals in U.S. commerce unknown
  - 85,000 listed on Toxic Substances Control Act (TSCA) Inventory – not all in commerce today
  - 62,000 were on the market in 1979 (1st Inventory)
  - 23,000 new chemicals added since (ca. 1,500 per year)


500
400
300
200
100
0
PROJECTED GROWTH INDEX
Global Chemical Production
Global Population
2000
2005
2010
2015
2020
2025
2030
2035
2040
2045
2050
YEAR

Science drivers: Connecting the dots

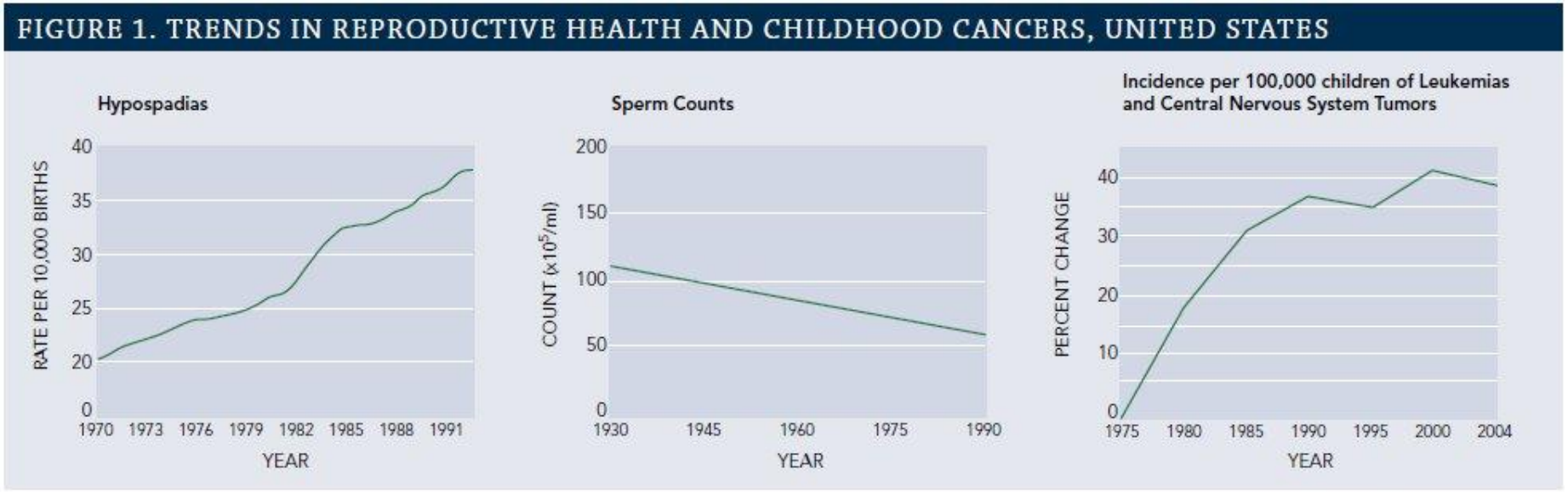
- Certain chronic diseases are on the rise
- Certain chemicals are linked to those same chronic diseases
- Many of those same chemicals are in us

Cancer incidence and mortality for children under 20



Source: U.S. EPA. America's Children and the Environment. *www.epa.gov/envirohealth/children*
Data: National Cancer Institute, Surveilance, Epidemiology and End Results Program

Rising incidence of diseases/ disorders linked to chemical exposures



The incidence of certain pediatric and reproductive health disorders is on the rise, including hypospadias, reduced sperm count (variable by region), and the childhood cancers that are most commonly linked to chemical exposures. Source: Sharpe and Irvine, 2004, Surveillance Epidemiology and End Results (SEER) Program 2004.[17]

Source: Wilson and Schwarzman (2008) *Green Chemistry: Cornerstone to a Sustainable California*, University of California

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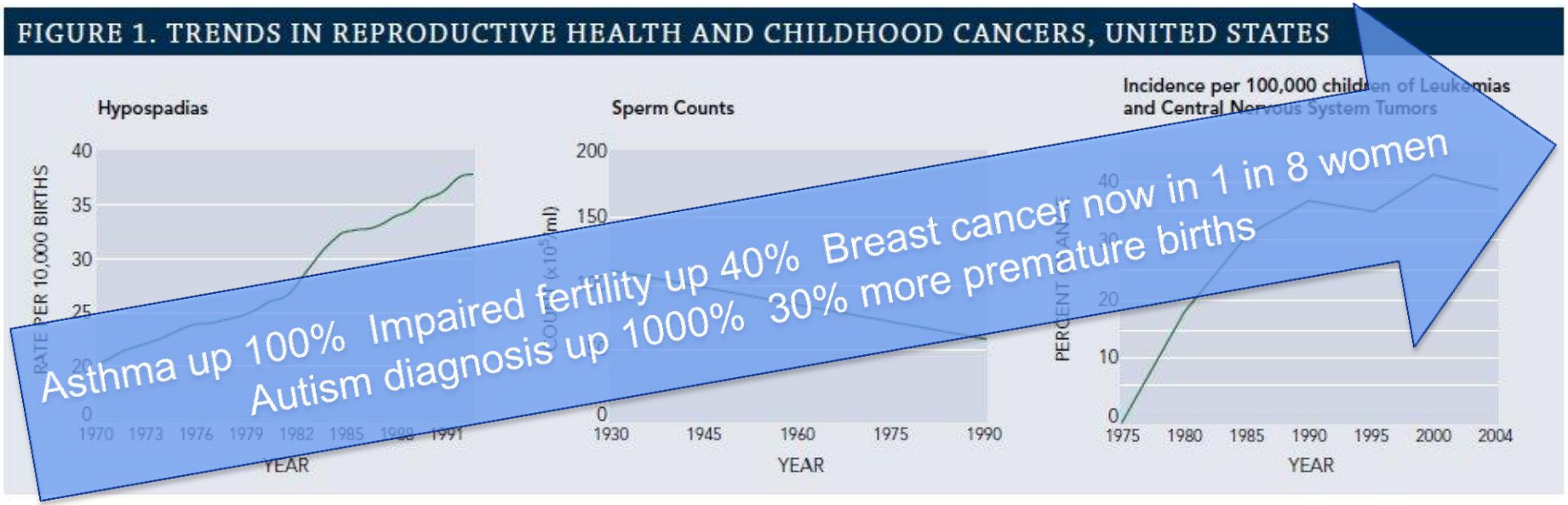

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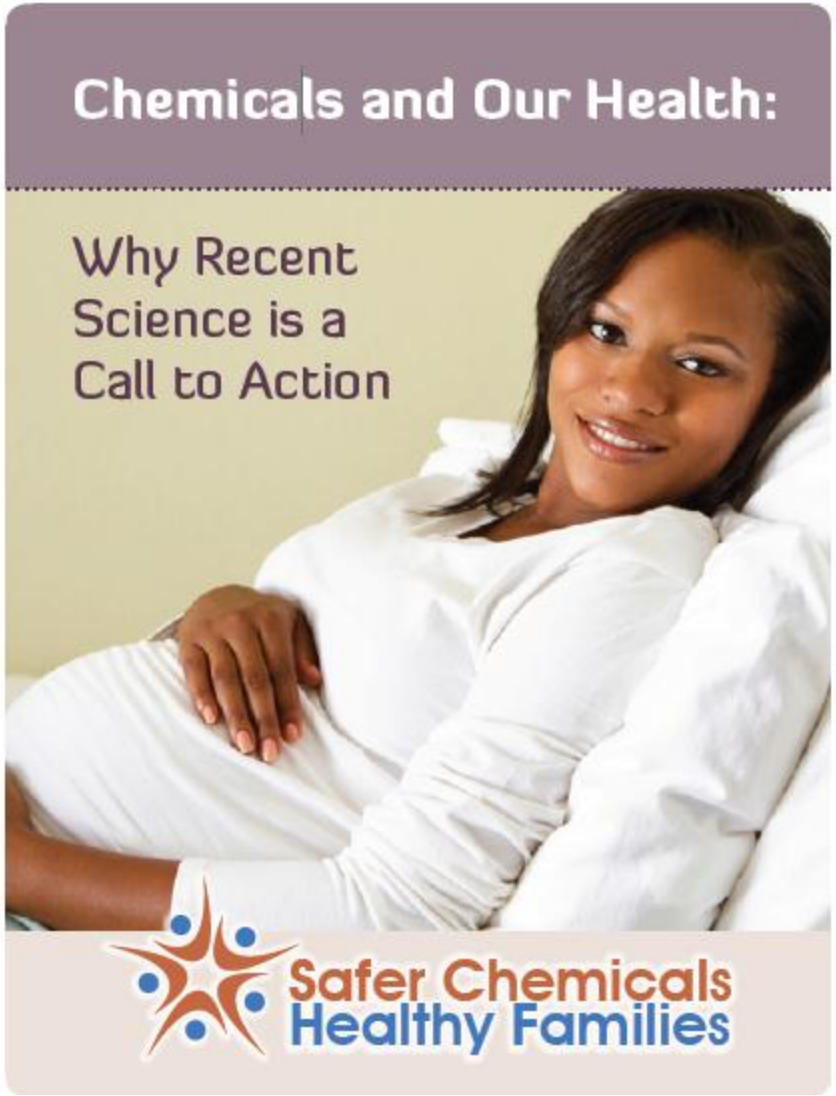
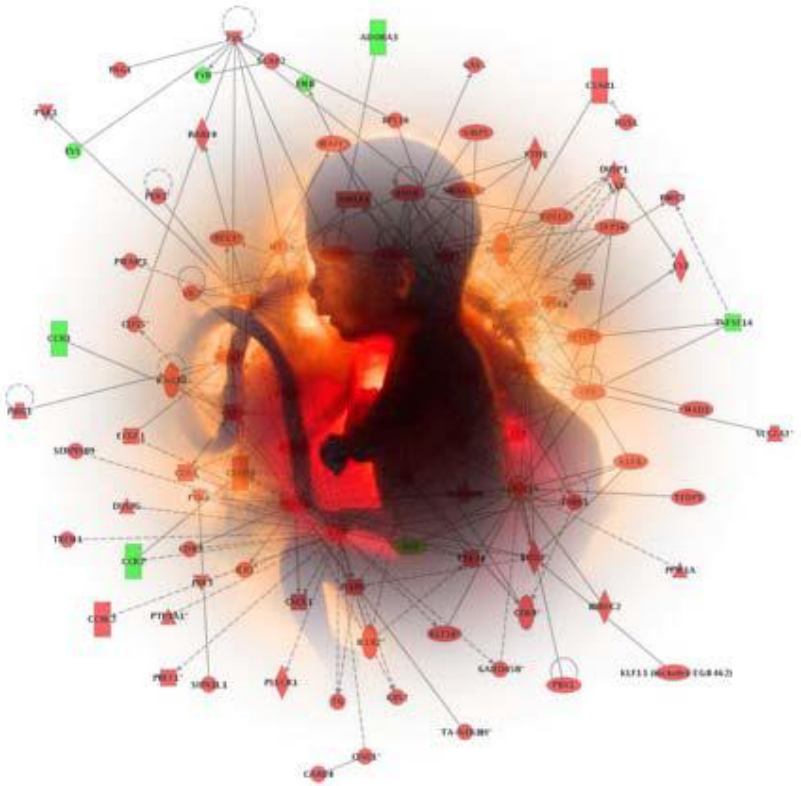
Diseases linked to chemical exposures



- Cancer
- Learning and Developmental Disabilities
- Parkinson's and Alzheimer's Disease
- Reproductive Health and Fertility Problems
- Asthma
- Diabetes
- Obesity
- Immune disorders
- Cardiovascular disease

Early life exposures can lead to adverse outcomes later in life



Complex, carefully orchestrated human development starts at the point of fertilization

Prenatal Exposures to Toxic Chemicals and Suspected Human Health Consequences

BPA

- Behavioral abnormalities like hyperactivity and aggressiveness

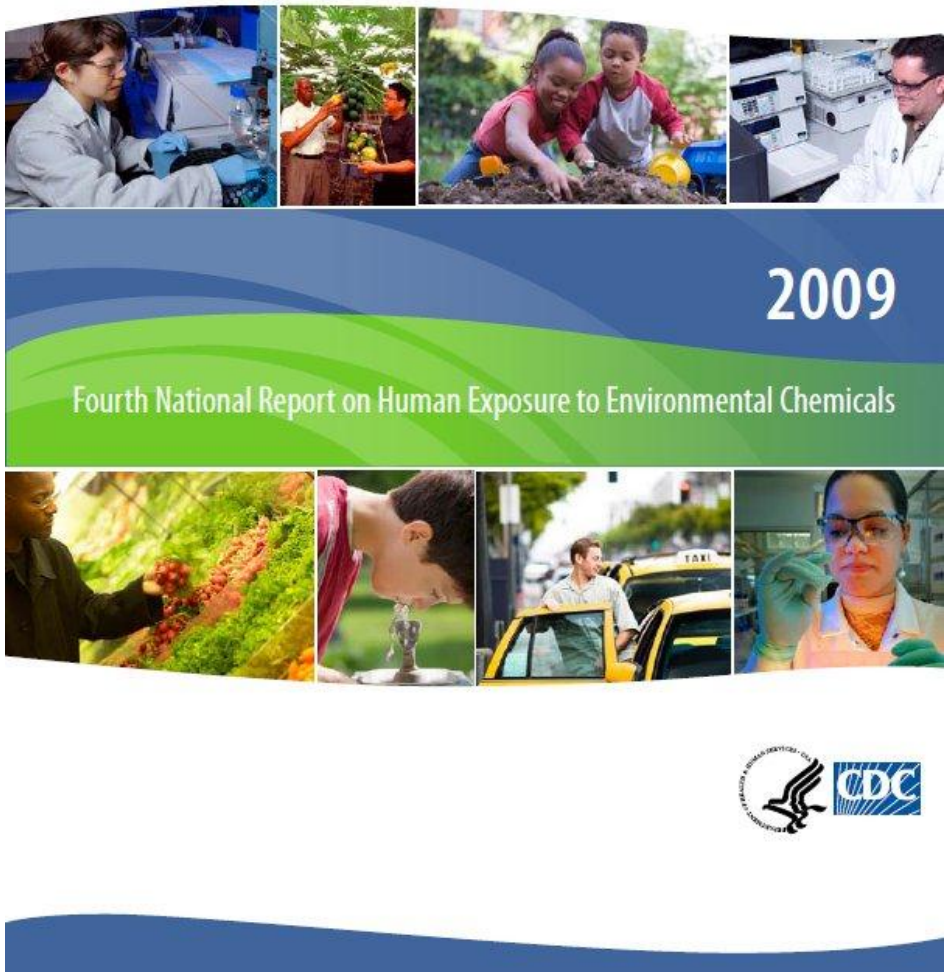
Flame Retardants

- Learning disabilities
- Impaired motor skills

Phthalates

- Attention deficit hyperactivity disorder (ADHD)
- Abnormal reproductive development

They're in us – Federal Biomonitoring Program



What's New in this *Report*

In this *Fourth Report*, 75 new chemicals are added for the 2003-2004 survey period and are listed in Table 1. The process for selection is described at http://www.cdc.gov/exposurereport/chemical_selection.html.

Table 1. Chemicals reported for the first time in the *Fourth National Report on Human Exposure to Environmental Chemicals, 2009*

Acrylamide Adducts
Acrylamide
Glycidamide

Total and Speciated Arsenic
Arsenic, Total
Arsenic (V) acid
Arsenobetaine
Arsenocholine
Arsenous (III) acid
Dimethylarsinic acid
Monomethylarsonic acid
Trimethylarsine oxide

Disinfection By-Products (Trihalomethanes)
Bromodichloromethane
Dibromochloromethane (Chlorodibromomethane)
Bromoform (Tribromomethane)
Chloroform (Trichloromethane)

Environmental Phenols
Benzophenone-3 (2-Hydroxy-4-methoxybenzophenone)
Bisphenol A (2,2-*bis*[4-Hydroxyphenyl] propane)
4-*tert*-Octyl phenol (4-[1,1,3,3-Tetramethylbutyl] phenol)
Triclosan (2,4,4'-Trichloro-2'-hydroxyphenyl ether)

Non-dioxin-like Polychlorinated Biphenyls
2,2'3,5'-Tetrachlorobiphenyl (PCB 44)
2,2'4,5'-Tetrachlorobiphenyl (PCB 49)
2,2',3,3',4,4',5,5',6,6'-Decachlorobiphenyl (PCB 209)

Perchlorate

Perfluorinated Compounds
Perfluorobutane sulfonic acid (PFBuS)
Perfluorodecanoic acid (PFDeA)
Perfluorododecanoic acid (PFDoA)
Perfluoroheptanoic acid (PFHpA)
Perfluorohexane sulfonic acid (PFHxS)
Perfluorononanoic acid (PFNA)
Perfluorooctane sulfonamide (PFOSA)
Perfluorooctane sulfonic acid (PFOS)
2-(N-Ethyl-Perfluorooctane sulfonamido) acetic acid (Et-PFOSA-AcOH)
2-(N-Methyl-perfluorooctane sulfonamido) acetic acid (Me-PFOSA-AcOH)
Perfluorooctanoic acid (PFOA)
Perfluoroundecanoic acid (PFUA)

Phthalate Metabolite
Mono-(2-ethyl-5-carboxypentyl) phthalate (MECPP)

Polybrominated Diphenyl Ethers (PBDE) and Polybrominated Biphenyl
2,2',4-Tribromodiphenyl ether (BDE 17)
2,4,4'-Tribromodiphenyl ether (BDE 28)
2,2',4,4'-Tetrabromodiphenyl ether (BDE 47)
2,3',4,4'-Tetrabromodiphenyl ether (BDE 66)
2,2',3,4,4'-Pentabromodiphenyl ether (BDE 85)
2,2',4,4',5-Pentabromodiphenyl ether (BDE 99)
2,2',4,4',6-Pentabromodiphenyl ether (BDE 100)
2,2',4,4',5,5'-Hexabromodiphenyl ether (BDE 153)
2,2',4,4',5,6'-Hexabromodiphenyl ether (BDE 154)
2,2',3,4,4',5',6-Heptabromodiphenyl ether (BDE 183)
2,2',4,4',5,5'-Hexabromobiphenyl (BB 153)

Volatile Organic Compounds (VOCs)
Benzene
Chlorobenzene (Monochlorobenzene)
1,2-Dibromo-3-chloropropane (DBCP)
Dibromomethane
1,2-Dichlorobenzene (*o*-Dichlorobenzene)
1,3-Dichlorobenzene (*m*-Dichlorobenzene)
1,4-Dichlorobenzene (*p*-Dichlorobenzene, Paradichlorobenzene)
1,1-Dichloroethane
1,2-Dichloroethane (Ethylene dichloride)
1,1-Dichloroethene (Vinylidene chloride)
cis-1,2-Dichloroethene
trans-1,2-Dichloroethene
Dichloromethane (Methylene chloride)
1,2-Dichloropropane
2,5-Dimethylfuran
Ethylbenzene
Hexachloroethane
Methyl-*tert*-butyl ether (MTBE)
Nitrobenzene
Styrene
1,1,2,2-Tetrachloroethane
Tetrachloroethene
Tetrachloromethane (Carbon tetrachloride)
Toluene
1,1,1-Trichloroethane (Methyl chloroform)
1,1,2-Trichloroethane
Trichloroethene (Trichloroethylene)
m- and *p*-Xylene
o-Xylene

Some of the chemicals widely detected in US population through biomonitoring

Chemical	Percent of US population with measurable levels*	Sources
Phthalates (7 kinds)	50 – 97%	Flooring, wall covering, medical devices, food wrap, personal care products, lacquers
Bisphenol A	92%	Polycarbonate plastic, food can lining dental sealant
Perfluorinated compounds (4 types)	91-99%	Nonstick cookware, stain resistant fabrics, food packaging, dental products
PBDEs (many)	100% (with at least one congener)	Chemical flame retardants, upholstery, carpet, electronics
Triclosan	80%	Antimicrobial agent , soaps
PCBs (many)	100% (with at least one congener)	Banned in 1977 – persistent through food

Source: Woodruff, TJ, Program on Reproductive Health and the Environment, UCSF

*Representative US sample from NHANES/CDC generally from 2003/2004, PCBs for women ages 16-39

Why legislative reform?

Main U.S. Chemical Safety Legislation

- Toxic Substances Control Act of 1976 (TSCA)
  - Covers most chemicals used in industry and in commercial/consumer products
  - Excludes:
    - uses in drugs, cosmetics, food and food packaging regulated by FDA
    - uses in pesticides covered by EPA under FIFRA
  - Basic provisions have never been amended

Problems with the current paradigm

- Presumption of innocence: TSCA grandfathered 62,000 chemicals
- Default: No or uncertain info = No action
- High hurdle to require testing
- Proof of harm needed to regulate
- Government shoulders burden of proof
- Contrast to pesticides, drugs
- Excessive trade secret allowances deny information to the public and the market

TSCA, the Dog that Didn't Even Bark

By the numbers:

- **62,000** chemicals grandfathered in when TSCA was passed in 1976
- Required testing on **<300** in 36 years
- **5** chemicals have been regulated in limited ways
- **22 years** since EPA last tried (and failed) to regulate a chemical: *asbestos*

Why now?

Drivers for TSCA Reform

- Major reform of others' policies:
  - European Union's REACH Regulation
  - Canadian Environmental Protection Act
- State legislation and policy changes
  - Shift from bans to policies: CA, ME, WA
- Top priority of EPA Administrator Lisa Jackson
- EPA: Principles for TSCA reform in Sep. '09
- Market demand, esp. from downstream users

REACH: Why all the commotion?

- "No data, no market"
  - Addresses legacy of grandfathered chemicals
- Shifting the burden of proof
  - Industry required to show safety
- Information flow in supply chains
  - 2-way flow between suppliers <--> customers
- Authorization required to use substances of very high concern (SVHCs)

Industry position shifts

"The public's confidence in the federal chemical management system has been challenged."

Cal Dooley, President, American Chemistry Council
Congressional testimony, February 26, 2009

"In the absence of reforms to TSCA we are seeing a plethora of State actions that are serving to create tremendous uncertainty in our markets."

Linda Fisher, Chief Sustainability Officer, DuPont
Congressional testimony, March 9, 2010

Proposed TSCA Reform Legislation

- *Safe Chemicals Act of 2011* (S. 847) introduced by Senator Lautenberg
- Gained 29 Cosponsors (all Ds)
- Passed by Senate EPW Committee in July 2012 on a partisan vote
  - Major changes were made to address industry concerns
- New Congress – we start over

Incorporating the latest science into chemical policy

- Safety data requirements
  - Multiple approaches to filling gaps
  - Emerging methods via Tox21
- Use of risk assessment
  - Science behind RA has evolved and will continue to do so: NRC reports *Science and Decisions*, *Cumulative Assessment of Phthalates*
  - Key needs: Addressing uncertainty, variability, co-exposures, low-dose effects

Safety standard

Under the Safe Chemicals Act:

- based "*solely on considerations of human health and the environment*, including the health of *vulnerable human populations*."
- provide a "*reasonable certainty that no harm* will result to human health or the environment from *aggregate exposure* to the chemical substance"
- "*to the extent practicable*, review and incorporate any available scientific information relating to the effect of *cumulative exposure* to that chemical substance on human health and the environment"

What’s next?

113th Congress

Two bills expected

- Safe Chemicals Act will be reintroduced soon
- An industry bill is also expected soon
  - Sen. Vitter (R-LA) working on legislation
  - Only chemical industry (a subset) is “in the room”
- What will happen in the Senate?
  - EPW Committee
  - Senate Floor (60 votes needed to pass)
- Then there’s the House of Representatives …

Key unresolved issues

- Scope:
  - All or only a subset of chemicals?
  - Comprehensive legislation or more piecemeal?
- Information requirements: who, what, when
- Information access and protection of CBI
- Safety standard
- New chemicals
- State authority

For more information

EDF's Chemicals Policy Webpage
www.edf.org/health/policy/chemicals-policy-reform

Safer Chemicals, Healthy Families
www.saferchemicals.org

Not a Guinea Pig
www.notaguineapig.org

EDF Chemicals & Nanomaterials Blog
www.edf.org/chemandnano