Science for Effective Public Policy

Through the Lens of the Breast Cancer and Chemicals Policy Project





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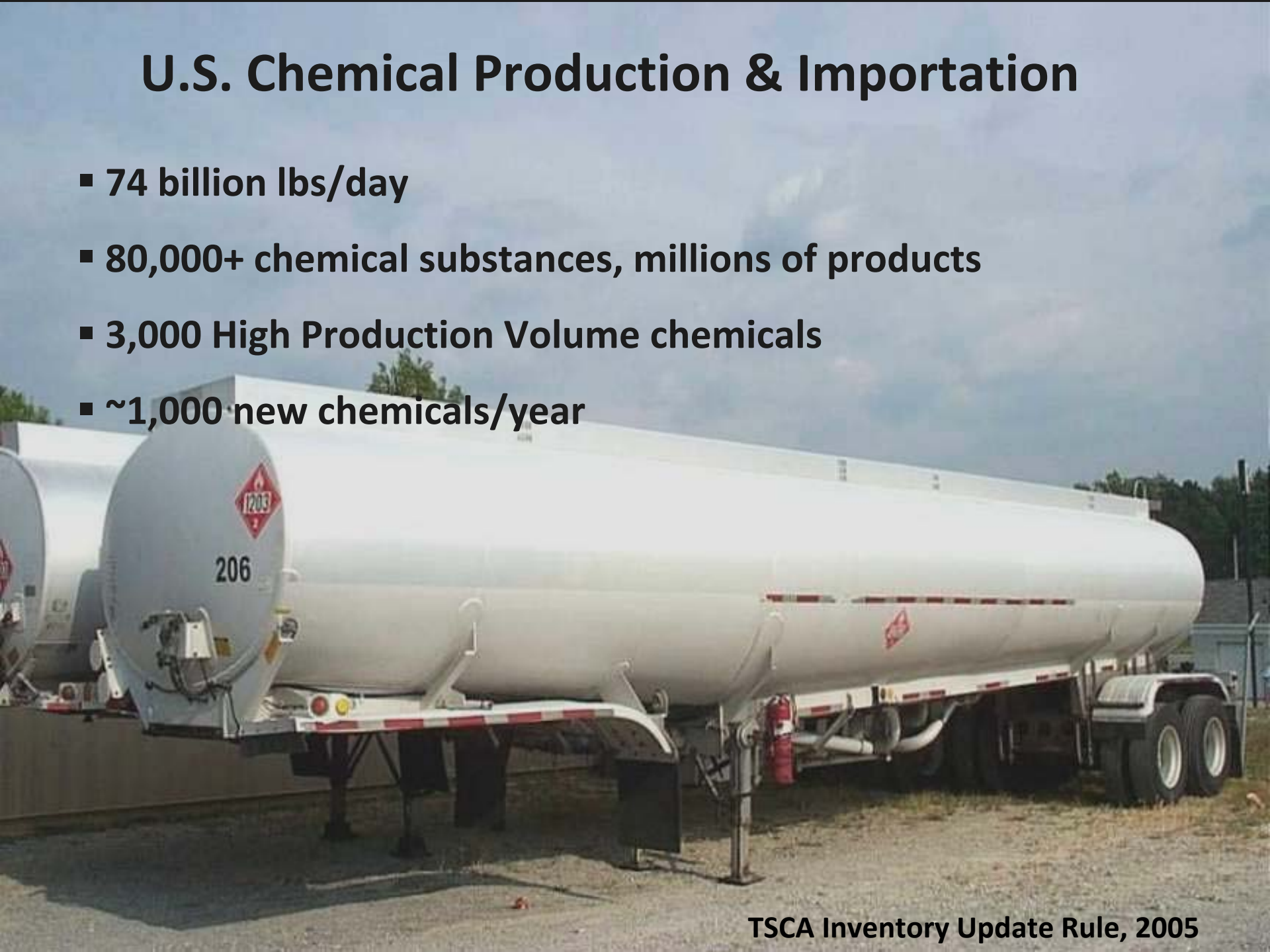
U.S. Chemical Production & Importation

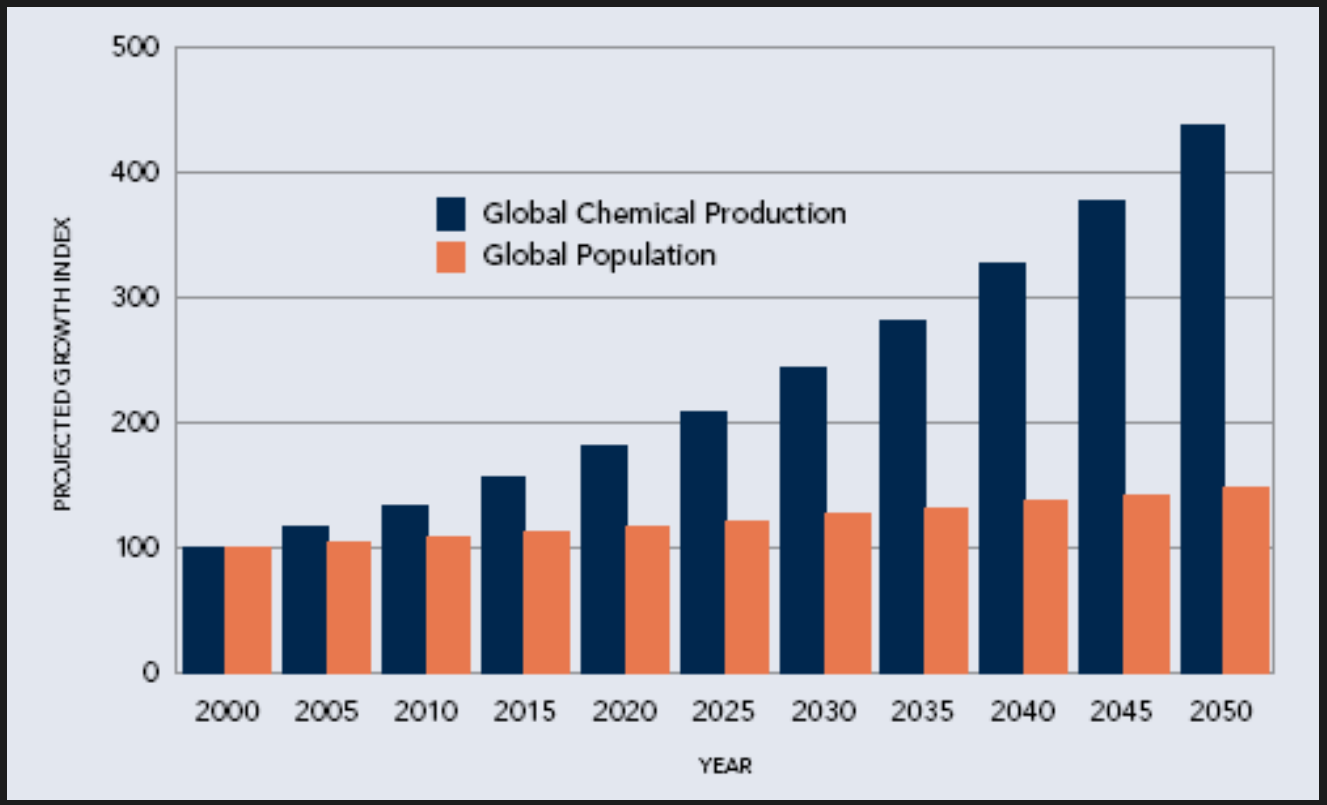
- 74 billion lbs/day
- 80,000+ chemical substances, millions of products
- 3,000 High Production Volume chemicals
- ~1,000 new chemicals/year



TSCA Inventory Update Rule, 2005

Global Chemical Production

- Growing 3% per year
- Doubling every 24 years
- Four-fold growth by 2050, indexed to 2000



Wilson and Schwarzman, *Environmental Health Perspectives*, 117:8, August, 2009.

Biomonitoring of Chemicals & Pollutants

CDC measured 212 substances
in the 2003-04 NHANES cohort

Acrylamide
- Acrylamide hemoglobin adducts *
- Glycidamide hemoglobin adducts *

Cotinine

N,N-Diethyl-*meta*-toluamide (DEET)

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

Perchlorate *

Pesticides

Fungicides
- Pentachlorophenol
- *ortho*-Phenylphenol

Herbicides
- Acetochlor mercapturate
- Alachlor mercapturate
- Atrazine mercapturate
- 2,4-Dichlorophenoxyacetic acid
- Metolachlor mercapturate
- 2,4,5-Trichlorophenoxyacetic acid

Carbamate Insecticides
- Carbofuranphenol
- 2-Isopropoxyphenol

Organochlorine Pesticides
- Aldrin
- Dieldrin
- Endrin
- *o,p'*-Dichlorodiphenyltrichloroethane
- *p,p'*-Dichlorodiphenyldichloroethene (DDE)
- *p,p'*-Dichlorodiphenyltrichloroethane (DDT)
- Heptachlor epoxide
- Hexachlorobenzene
- *beta*-Hexachlorocyclohexane
- *gamma*-Hexachlorocyclohexane (Lindane)
- Mirex
- *trans*-Nonachlor
- Oxychlordane
- 2,4,5-Trichlorophenol
- 2,4,6-Trichlorophenol

Organophosphorus Insecticides: Dialkyl Phosphate Metabolites
- Diethyldithiophosphate (DEDTP)
- Diethylphosphate (DEP)
- Diethylthiophosphate (DETP)
- Dimethyldithiophosphate (DMDTP)
- Dimethylphosphate (DMP)
- Dimethylthiophosphate (DMTP)

Organophosphorous Insecticides: Specific Metabolites
- 3-Chloro-7-hydroxy-4-methyl-2H-chromen-2-one/ol
- 2-(Diethylamino)-6-methylpyrimidin-4-ol/one
- 2-Isopropyl-4-methyl-6-hydroxypyrimidine
- Malathion dicarboxylic acid
- *para*-Nitrophenol
- 3,5,6-Trichloro-2-pyridinol

Pyrethroid Pesticides
- *cis*-3-(2,2-Dibromovinyl)-2,2-dimethylcyclopropane carboxylic acid
- *cis*-3-(2,2-Dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid
- *trans*-3-(2,2-Dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid
- 4-Fluoro-3-phenoxybenzoic acid
- 3-Phenoxybenzoic acid

Metals
- Antimony
- Arsenic, Total *
  - Arsenic (V) acid *
  - Arsenobetaine *
  - Arsenocholine *
  - Arsenous (III) acid *
  - Dimethylarsinic acid *
  - Monomethylarsonic acid *
  - Trimethylarsine oxide *
- Barium
- Beryllium
- Cadmium
- Cesium
- Cobalt
- Lead
- Mercury
- Molybdenum
- Platinum
- Thallium
- Tungsten
- Uranium

Perfluorochemicals
- 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-PFO
- 2-(N-Methyl-perfluorooctane sulfonamido) acetic acid (Me-P
- Perfluorooctanoic acid (PFOA) *
- Perfluoroundecanoic acid (PFUA) *

Phthalates
- Mono-benzyl phthalate (MBzP)
- Mono-*n*-butyl phthalate (MnBP)
- Mono-(3-carboxypropyl) phthalate (MCPP)
- Mono-cyclohexyl phthalate (MCHP)
- Mono-ethyl phthalate (MEP)
- Mono-(2-ethyl-5-carboxypentyl) phthalate (MECPP) *
- Mono-(2-ethyl-5-hydroxyhexyl) phthalate (MEHHP)
- Mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP)
- Mono-2-ethylhexyl phthalate (MEHP)
- Mono-isobutyl phthalate (MiBP)
- Mono-isononyl phthalate (MiNP)
- Mono-methyl phthalate (MMP)
- Mono-*n*-octyl phthalate (MOP)

Phytoestrogens
- Daidzein
- Enterodiol
- Enterolactone
- Equol
- Genistein
- O-Desmethylangolensin

Brominated Fire Retardants
- 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) *

Non-Dioxin-Like Polychlorinated Biphenyls
- 2,4,4'-Trichlorobiphenyl (PCB 28)
- 2,2',3,5'-Tetrachlorobiphenyl (PCB 44) *
- 2,2',4,5'-Tetrachlorobiphenyl (PCB 49) *
- 2,2',5,5'-Tetrachlorobiphenyl (PCB 52)
- 2,3',4,4'-Tetrachlorobiphenyl (PCB 66)
- 2,4,4',5-Tetrachlorobiphenyl (PCB 74)
- 2,2',3,4,5'-Pentachlorobiphenyl (PCB 87)
- 2,2',4,4',5-Pentachlorobiphenyl (PCB 99)
- 2,2',4,5,5'-Pentachlorobiphenyl (PCB 101)
- 2,3,3',4',6-Pentachlorobiphenyl (PCB 110)
- 2,2',3,3',4,4'-Hexachlorobiphenyl (PCB 128)
- 2,2',3,4,4',5' and 2,3,3',4,4',6-Hexachlorobiphenyl (PCB 138 & 158)
- 2,2',3,4',5,5'-Hexachlorobiphenyl (PCB 146)
- 2,2',3,4',5',6-Hexachlorobiphenyl (PCB 149)
- 2,2',3,5,5',6-Hexachlorobiphenyl (PCB 151)
- 2,2',4,4',5,5',-Hexachlorobiphenyl (PCB 153)
- 2,2',3,3',4,4',5-Heptachlorobiphenyl (PCB 170)
- 2,2',3,3',4,5,5'-Heptachlorobiphenyl (PCB 172)
- 2,2',3,3',4,5',6'-Heptachlorobiphenyl (PCB 177)
- 2,2',3,3',5,5',6-Heptachlorobiphenyl (PCB 178)
- 2,2',3,4,4',5,5'-Heptachlorobiphenyl (PCB 180)
- 2,2',3,4,4',5',6-Heptachlorobiphenyl (PCB 183)
- 2,2',3,4',5,5',6-Heptachlorobiphenyl (PCB 187)
- 2,2',3,3',4,4',5,5'-Octachlorobiphenyl (PCB 194)
- 2,2',3,3',4,4',5,6-Octachlorobiphenyl (PCB 195)
- 2,2',3,3',4,4',5,6' and 2,2',3,4,4',5,5',6-Octachlorobiphenyl (PCB 196 & 203)
- 2,2',3,3',4,5,5',6-Octachlorobiphenyl (PCB 199)
- 2,2',3,3',4,4',5,5',6-Nonachlorobiphenyl (PCB 206)
- 2,2',3,3',4,4',5,5',6,6'-Decachlorobiphenyl (PCB 209) *

Dioxin-Like Chemicals

Polychlorinated Dibenzo-p-dioxins
- 1,2,3,4,6,7,8-Heptachlorodibenzo-*p*-dioxin (HpCDD)
- 1,2,3,4,7,8-Hexachlorodibenzo-*p*-dioxin (HxCDD)
- 1,2,3,6,7,8-Hexachlorodibenzo-*p*-dioxin (HxCDD)
- 1,2,3,7,8,9-Hexachlorodibenzo-*p*-dioxin (HxCDD)
- 1,2,3,4,6,7,8,9-Octachlorodibenzo-*p*-dioxin (OCDD)
- 1,2,3,7,8-Pentachlorodibenzo-*p*-dioxin (PeCDD)
- 2,3,7,8,-Tetrachlorodibenzo-*p*-dioxin (TCDD)

Polychlorinated Dibenzofurans
- 1,2,3,4,6,7,8-Heptachlorodibenzofuran (HpCDF)
- 1,2,3,4,7,8,9-Heptachlorodibenzofuran (HpCDF)
- 1,2,3,4,7,8-Hexachlorodibenzofuran (HxCDF)
- 1,2,3,6,7,8-Hexachlorodibenzofuran (HxCDF)
- 1,2,3,7,8,9-Hexachlorodibenzofuran (HxCDF)
- 2,3,4,6,7,8-Hexachlorodibenzofuran (HxCDF)
- 1,2,3,4,6,7,8,9-Octachlorodibenzofuran (OCDF)
- 1,2,3,7,8-Pentachlorodibenzofuran (PeCDF)
- 2,3,4,7,8-Pentachlorodibenzofuran (PeCDF)
- 2,3,7,8-Tetrachlorodibenzofuran (TCDF)

Coplanar Polychlorinated Biphenyls
- 3,4,4',5-Tetrachlorobiphenyl (PCB 81)
- 3,3',4,4',5-Pentachlorobiphenyl (PCB 126)
- 3,3',4,4',5,5'-Hexachlorobiphenyl (PCB 169)

Mono-ortho-substituted Polychlorinated Biphenyls
- 2,3,3',4,4'-Pentachlorobiphenyl (PCB 105)
- 2,3',4,4',5-Pentachlorobiphenyl (PCB 118)
- 2,3,3',4,4',5-Hexachlorobiphenyl (PCB 156)
- 2,3,3',4,4',5'-Hexachlorobiphenyl (PCB 157)
- 2,3',4,4',5,5'-Hexachlorobiphenyl (PCB 167)
- 2,3,3',4,4',5,5'-Heptachlorobiphenyl (PCB 189)

Polycyclic Aromatic Hydrocarbons (PAHs)
- 2-Hydroxyfluorene
- 3-Hydroxyfluorene
- 9-Hydroxyfluorene
- 1-Hydroxynaphthalene (1-Naphthol)
- 2-Hydroxynaphthalene (2-Naphthol)
- 1-Hydroxyphenanthrene
- 2-Hydroxyphenanthrene
- 3-Hydroxyphenanthrene
- 4-Hydroxyphenanthrene
- 1-Hydroxypyrene

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

Volatile Organic Compounds (VOCs)
- Benzene *
- Chlorobenzene (Monochlorobenzene) *
- 1,2-Dibromo-3-chloropropane (DBCP) *
- Dibromomethane *
- 1,2-Dichlorobenzene (*ortho*-Dichlorobenzene) *
- 1,3-Dichlorobenzene (*meta*-Dichlorobenzene) *
- 1,4-Dichlorobenzene (*para*-Dichlorobenzene) *
- 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 (DMF) *
- Ethylbenzene *
- Hexachloroethane *
- Methyl *tert*-butyl ether (MTBE) *
- Nitrobenze *
- Styrene *
- 1,1,2,2-Tetrachloroethane *
- Tetrachloroethene (Perchloroethylene) *
- Tetrachloromethane (Carbon tetrachloride) *
- Toluene *
- 1,1,1-Trichloroethane (Methyl chloroform) *
- 1,1,2-Trichloroethane *
- Trichloroethene (Trichloroethylene, TCE) *
- *meta*- and *para*-Xylene *
- *ortho*-Xylene *

CDC, *Fourth National Report on Human Exposure to Environmental Chemicals, 2009*

Biomonitoring of Chemicals & Pollutants:
Umbilical Cord Blood and Breast Milk

PBDE Levels in Breast Milk, Sweden

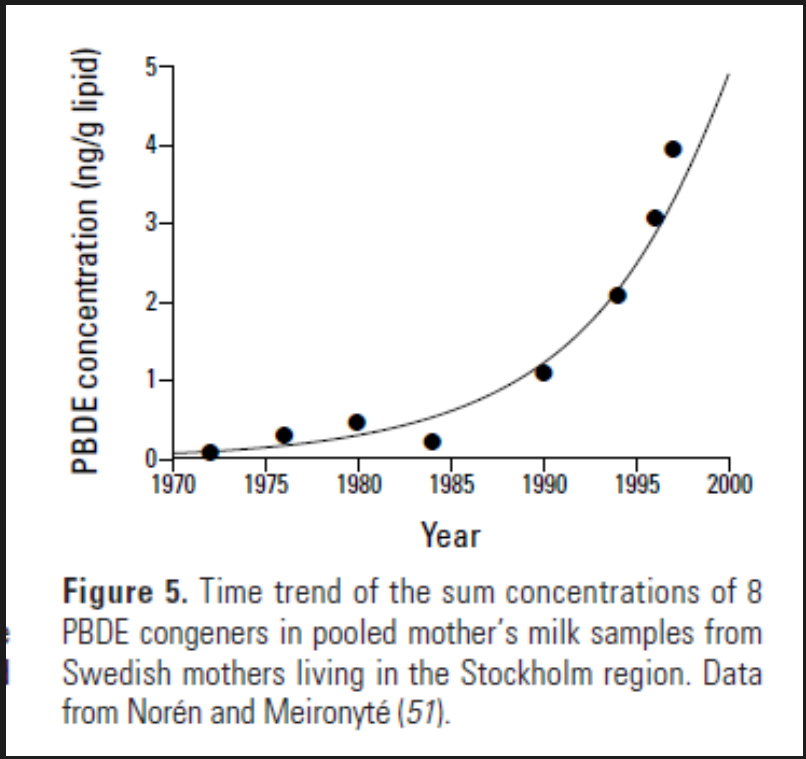


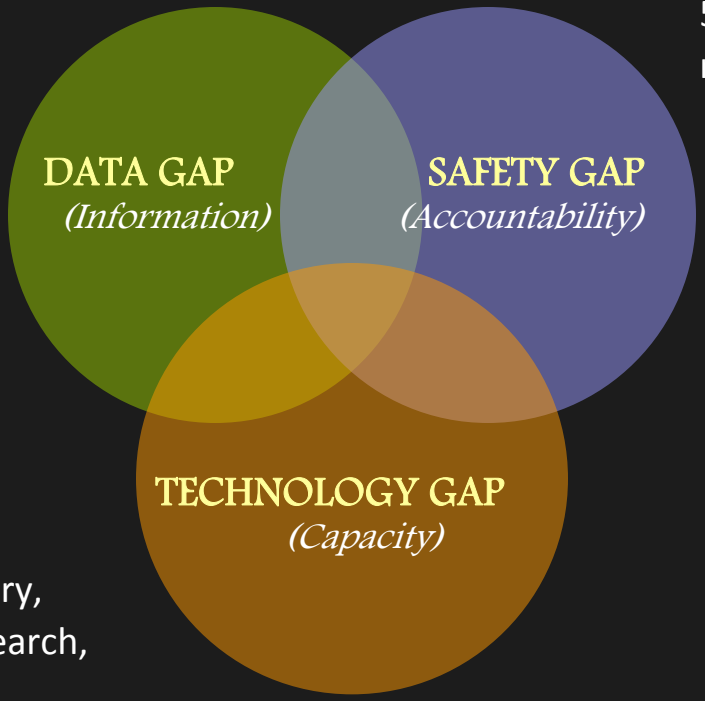
Figure 5. Time trend of the sum concentrations of 8 PBDE congeners in pooled mother's milk samples from Swedish mothers living in the Stockholm region. Data from Norén and Meironyté (*51*).

Darnerud et al. *Environ Health Persp,* 107 (supp1), March, 2001.

The Toxic Substances Control Act (TSCA)

A Legacy of Three Policy Gaps

62,000 chemicals grandfathered;
90 day review for new chemicals;
Health data absent in 85% of new chemical notices



5 chemicals/classes formally regulated under TSCA since 1976

Minimal investment by industry, government, academia in research, development, and education.

Wilson and Schwarzman, *Environmental Health Perspectives*, 117:8, August, 2009.

Data Gap: Market Effects

To make informed decisions, businesses need four pieces of chemical information:

The existing market under TSCA supplies three

Function	**Price**
Performance	**Hazards**

Data Gap: Governance Effects

To assess & prioritize risks, states need four pieces of information:

Existing governance structure under TSCA provides none of these.

Identity	**Sales volume**
Uses	**Hazards**

Regulatory Context: Europe

REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals (2006)

- No data, no market: manufacturers provide basic information on ~30,000 substances
- Designation of Substances of Very High Concern (SVHC) based on hazard properties
- Authorization for use of highest-risk chemicals requires demonstration of safety or necessity
- Expected to improve transparency
- May create a *de facto* global standard

Schwarzman and Wilson, New Science for Chemicals Policy, *Science,* November 20, 2009

Chemicals Policy Reform: United States

U.S. Environmental Protection Agency

9/2009: U.S. Administration Priorities for Chemical regulatory reform

Chemical producers should be required to submit sufficient hazard, exposure, and use data for EPA to determine that chemicals meet a health-based safety standard.

12/2009: Congressional Hearing on TSCA

"The public is turning to government for assurance that chemicals … have been assessed using the best available science, and that unacceptable risks have been eliminated. But, under existing law, we cannot give that assurance."

U.S. Government Accountability Office

"Without greater attention to EPA's efforts to assess toxic chemicals, the nation lacks assurance that human health and the environment are adequately protected."

U.S. GAO. High Risk Series. Report to Congress (2009)

Coalition of 13 states 12/2009 Call for chemicals policy reform

Safer Chemicals Healthy Families

Coalition of >100 environmental public interest groups

American Chemistry Council

American Chemistry Council

Chemicals Policy Reform: California

California EPA Green Chemistry Initiative

- Expand Pollution Prevention
- Develop Green Chemistry Capacity
- Create an Online Product Ingredient Network
- Create an Online Toxics Clearinghouse (SB 509)
- Accelerate the Quest for Safer Products (AB 1879)
- Move Toward a Cradle-to-Cradle Economy

AB 1879 (Feuer):

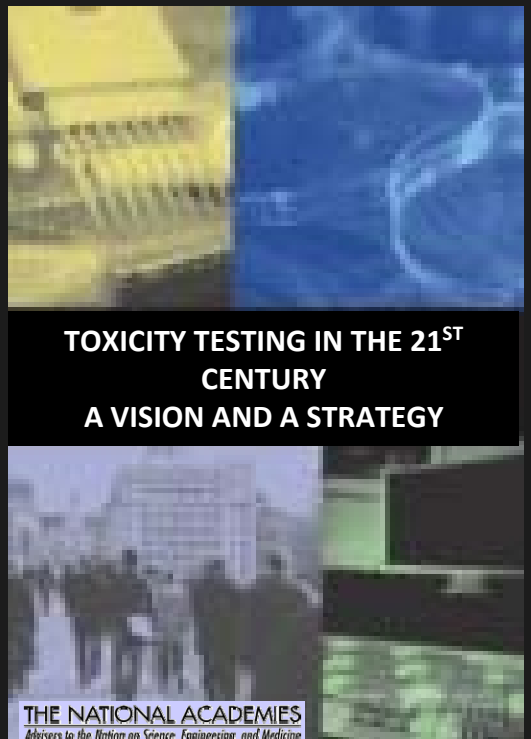
Identify & Prioritize Chemicals of Concern → **Alternatives Analysis** → **Regulatory Response**

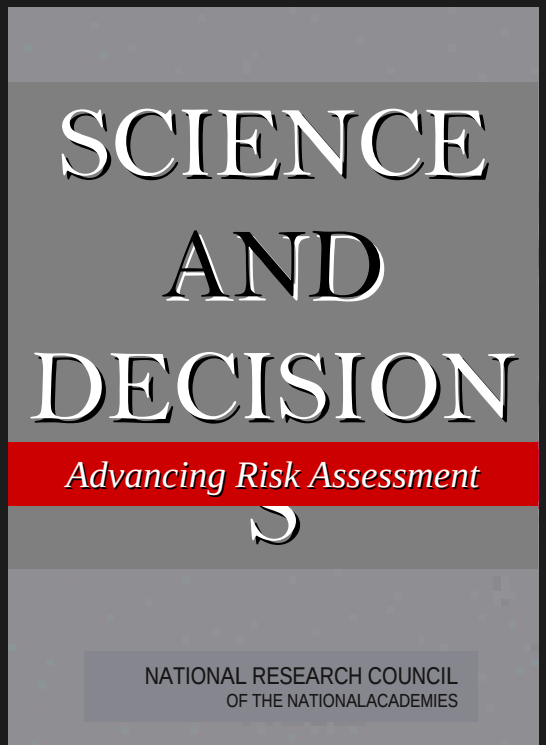
Information Needs

Methods for using existing data and current test methods in chemical decision-making.

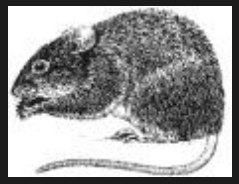
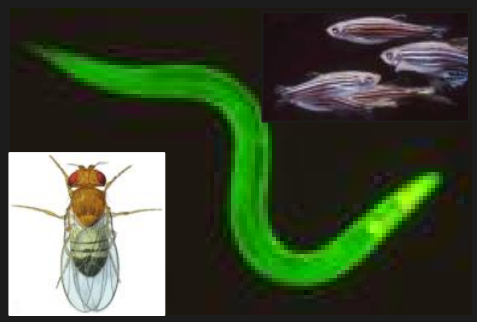
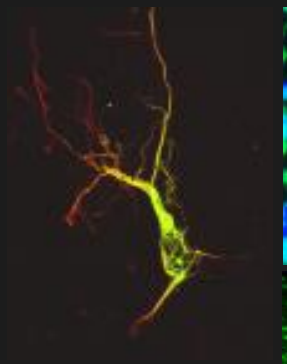
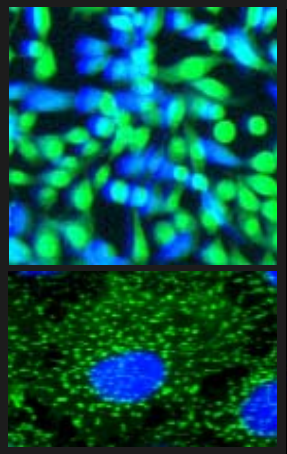
Better information and new tools

- Toxicity testing methods
- Understanding biological pathways
- Application of science in decisions





Chemical Testing Capacity

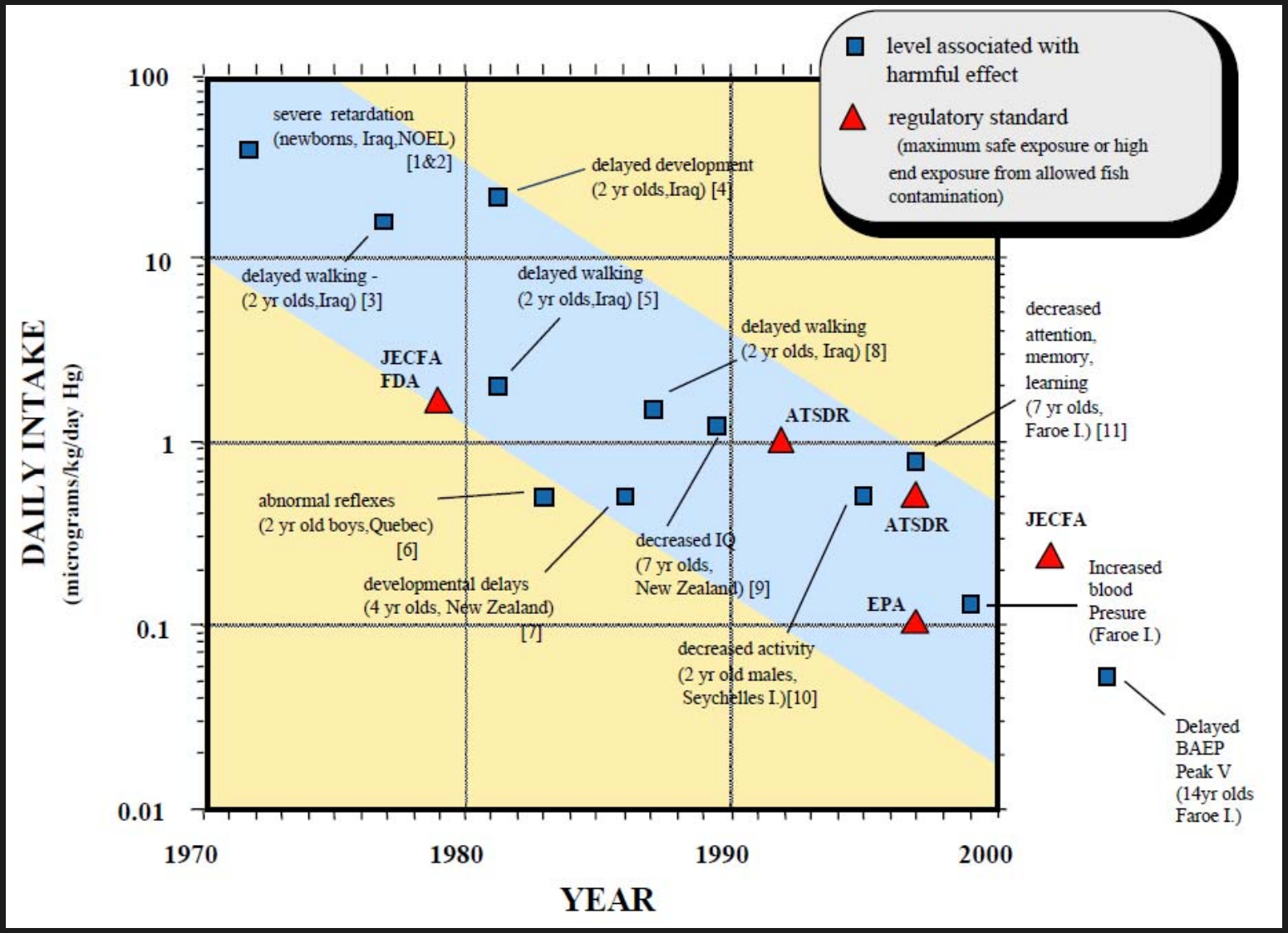







1-3/yr | 10's/yr | 100's/yr | 10,000's/day | 100,000's/day

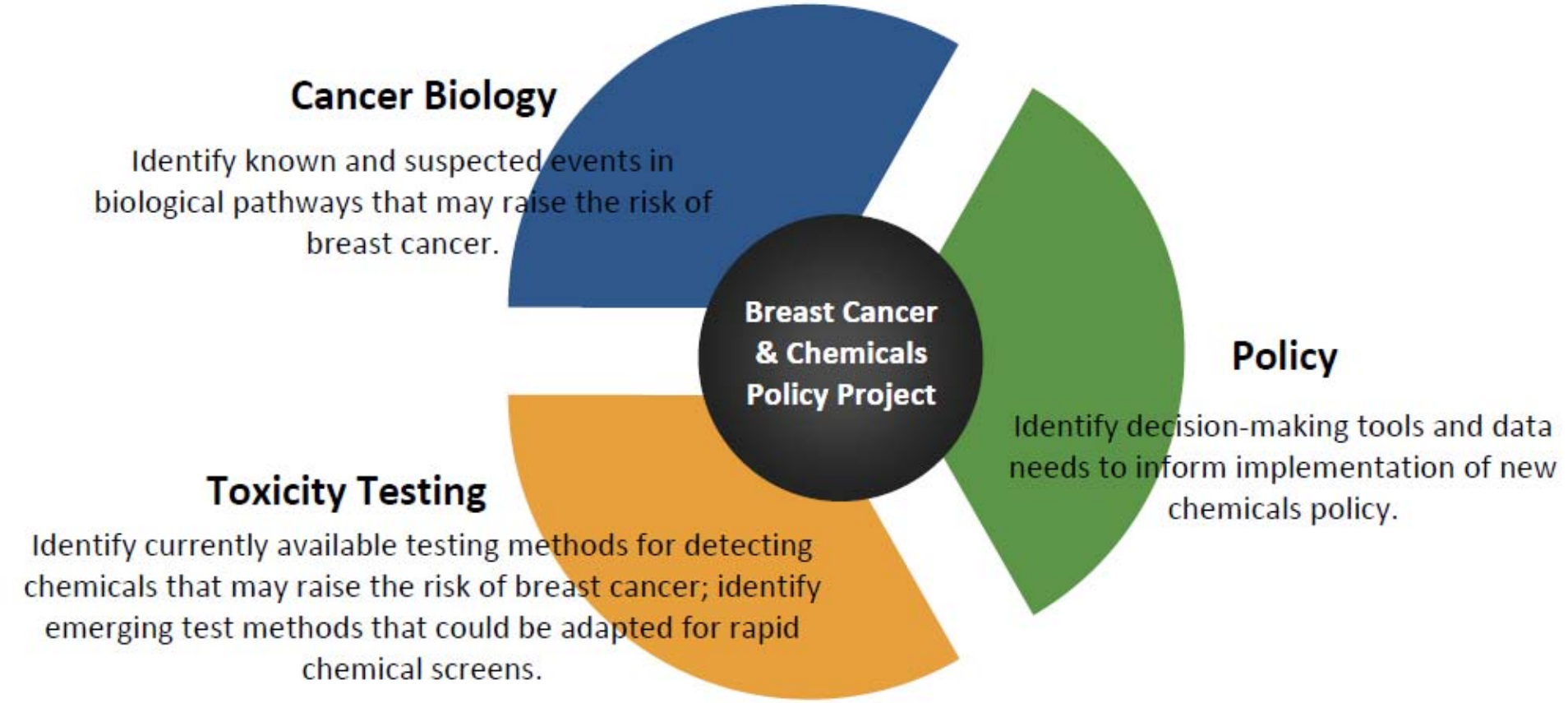
High Throughput &
Molecular mechanisms

Source: National Research Council, *Toxicity Testing in the 21st Century,* 2007

Early Warnings – Late lessons



Schettler T, et al. Physicians for Social Responsibility, 2002



GOALS

1. Develop an approach to chemical hazard identification based on currently available methods for detecting chemicals that may raise the risk of breast cancer; the approach should generate toxicity information relevant to a variety of users of chemical information.
2. Identify data gaps and research needs to improve chemical decision-making, including informing a shift toward rapid screening methods performed without laboratory animals.
3. Pilot a project model that could be applied to other disease endpoints, with the ultimate goal of producing a comprehensive approach to chemical hazard identification.