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

CDC measured 212 substances in the 2003-04 NHANES cohort.
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 Meironytė (57).

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

<table>
<thead>
<tr>
<th>Function</th>
<th>Price</th>
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<td>Performance</td>
<td>Hazards</td>
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Data Gap: Governance Effects

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

Existing governance structure under TSCA provides none of these.
Regulatory Context: Europe


- 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.”


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

Coalition of >100 environmental public interest groups

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

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<tr>
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<th>1-3/yr</th>
<th>10’s/yr</th>
<th>100’s/yr</th>
<th>10,000’s/day</th>
<th>100,000’s/day</th>
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High Throughput & Molecular mechanisms

Early Warnings – Late lessons

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.