# Toxic Substances Control Act:
## *Data Needs and Prospects for Reform*

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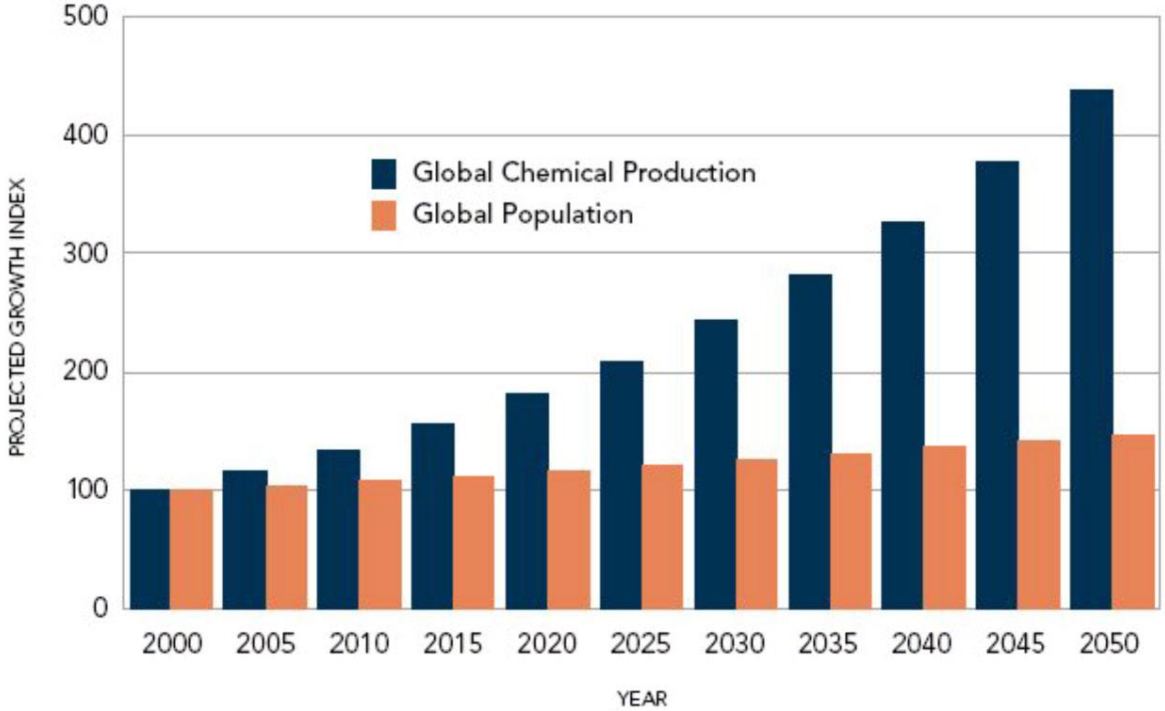
Finding the ways that work

# *What's changed since 1976?*

- Chemical production: 25x ↑ globally, $171 billion in 1970 to $4.1 trillion in 2010
  - Growth in #, types of chemicals has been less dramatic




Source: Wilson and Schwarzman (2008) *Green Chemistry: Cornerstone to a Sustainable California*, University of California, based on data from American Chemistry Council 2003; OECD 2001; United Nations 2004

- ↑ diversity of use: especially in consumer products and building materials
  - Used to make 96% of all materials and products

# *What's changed since 1976?*

- Understanding of extent and pathways of chemical exposures
  - Advent of biomonitoring
  - Long-range transport, importance of airborne as well as waterborne pathways for both movement and uptake
  - Migration of chemicals from products into environment, people
    - Coal tar-based sealants used on parking lots
    - BFRs in furniture foam
  - Disproportional exposures: Environmental justice issues

# *What's changed since 1976?*

- Science drivers: Connecting the dots
  - Certain chronic diseases are on the rise
  - Certain chemicals linked to those same chronic diseases
  - Many of those same chemicals are in us
- Growing recognition of importance of:
  - Early-life exposures
  - Low-dose effects (endocrine disruption)
  - Epigenetics – is it a basis for explaining/elucidating:
    - early-life exposures → later-life disease outcomes?
    - variability in susceptibility?
    - transgenerational effects?

# *What's changed since 1976?*

- Risk assessment evolution and controversy
  - Red Book (1983) → Silver Book (2009)
    - Human variability
    - Uncertainty
    - D-R: Cancer vs. non-cancer effects
    - Should no-effect thresholds be presumed to exist across a diverse human population?
    - Cumulative effects and exposures
      - Multiple chemicals
      - Chemicals and other stressors

# *What's changed since 1976?*

- Emerging high-throughput testing: Tox21
  - Potential to:
    - address huge backlog of untested chemicals
    - increase human relevance
    - identify biomarkers of exposure to specific chemicals
    - consider multiple cell types and life stages
    - test at many different doses
    - assess mixtures
    - inform green chemistry

# *What's changed since 1976?*

- Emerging high-throughput testing: Tox21
  - Challenges
    - *In vitro* vs. *in vivo*
    - Can all potential effects pathways ever be captured?
    - How to account for real world: multiple exposures at different times, chronic exposures
    - Determining whether a perturbation is adverse
    - False positives vs. negatives

# *TSCA: Problems with current paradigm*

Existing chemicals

- 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

# *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 37 years
- **5** of these chemicals have been regulated in limited ways
- **22 years** since EPA last tried (and failed) to regulate a chemical: *asbestos*

# *TSCA: Problems with current paradigm*

New chemicals

- ***No data, no problem***: No up-front testing requirement or minimum data set
  - Unlike virtually every other developed country in world
- ***Guessing game***: EPA is forced to heavily rely on limited prediction models
  - No reliable models for most mammalian tox endpoints
- ***Catch-22***: To require testing, EPA must first show potential risk or high exposure

# *TSCA: Problems with current paradigm*

New chemicals

- ***One bite at the apple***: EPA typically gets only a single review opportunity
- ***Crystal-ball gazing***: EPA must anticipate future production and use
- ***Black box***: New chemical reviews lack transparency
- ***Anti-precaution***: Lack of evidence of harm taken as evidence of no harm

# *TSCA: Lack of production/use/exposure data*

- Collected only from manufacturers under CDR
  - Subset of estimated 30-50,000 chems in commerce
    - reporting threshold is ≥25,000 lbs/yr/site
    - many reporting exemptions
  - 2012: ca. 7,700 chemicals reported made/imported
- Use information still very limited
  - Use reporting threshold is ≥100,000 lbs/yr/site
  - 2012: ca. 3,600 chemicals reported comm/cons use
    - For 74% of these, at least one of the 6 reportable consumer/commercial use data items was reported as “not known or reasonably ascertainable”

# *Broader lack of use/exposure data*

- EPA's Aggregated Computational Toxicology Resource (ACToR) database:
  - 550,000 chemicals
    - only 4% have *any* exposure-related data
      - 90% of these have only one type of such data (usually production volume)
    - only 1.4% have *any* use information
  - Of 700 ACToR chemicals of concern for children, only 185 have any exposure-related information

Source: Egeghy et al. (2012) "The exposure data landscape for manufactured chemicals" *Science of the Total Environment*

# *Limited availability of hazard data*

- ca. 9,900 ACToR chemicals examined
  - HPV and MPV chemicals
  - pesticide and antimicrobial active and inert ingredients
  - air and drinking water pollutants
  - IRIS chemicals
  - TRI chemicals
  - EDSP chemicals
- < ⅔ have even limited hazard information
- ≈ ¼ have detailed toxicology information

Source: Judson et al. (2009) “The toxicity data landscape for environmental chemicals,” *Environmental Health Perspectives*

## *Limited availability of hazard data*

*For the 9,900 chemicals:*

| | |
|---|---|
| Hazard data | 58.6% |
| – Carcinogenicity | 26.0 |
| – Genotoxicity | 27.5 |
| – Developmental toxicity | 28.9 |
| – Reproductive toxicity | 10.9 |

Source: Judson et al. (2009) “The toxicity data landscape for environmental chemicals,” *Environmental Health Perspectives*

# *Time for a paradigm shift*

- Current: Unless there is evidence of harm, assume safety and don’t look any further

- Needed: Require affirmative evidence of safety to enter or remain on the market

# *TSCA reform legislation in 2013*

- April 10:  Safe Chemicals Act (S. 696)
  - Lead sponsor Lautenberg, 28 co-sponsors (all Ds)
- May 22:  Chemical Safety Improvement Act (S. 1009)
  - Lead sponsors Lautenberg and Vitter, 25 co-sponsors (12 Ds, 13 Rs)

# *TSCA reform legislation in 2013*

- April 10: Safe Chemicals Act (S. 696)
  - Lead sponsor Lautenberg, 28 co-sponsors (all Ds)
- *ca. May 1: "The Vitter Bill"*
  - *Lead sponsor Vitter, ?? co-sponsors (likely 2-3 Ds)*
- May 22: Chemical Safety Improvement Act (S. 1009)
  - Lead sponsors Lautenberg and Vitter, 25 co-sponsors (12 Ds, 13 Rs)
- June 3: Lautenberg dies

# *Positive aspects of CSIA*

- For first time, safety reviews mandated for all chemicals
- New chemicals must be found likely to meet the safety standard before being made and sold
- States, medical personnel gain access to CBI
- Addresses two main reasons TSCA's safety standard failed:
  - Replaces cost-benefit requirement with a health-only standard
    - But not for bans/phaseouts
  - Strikes "least burdensome" requirement (led to paralysis-by-analysis)
    - But requires potentially endless analysis of alternatives
- Eases EPA's ability to get new data:
  - Provides for test orders
  - Strikes TSCA's "Catch-22" that EPA show risk to require testing

# *Major concerns with CSIA*

- Standard doesn't ensure protection of vulnerable populations
- Doesn't ensure all claimed CBI merits trade secret protections
- Bars testing of a new chemical or for prioritization
- Lacks deadlines, imposes excessive procedural requirements
  - Conservative estimates – Date of enactment to:
    - 1st prioritized chemicals = 39 months or 3.25 years
    - 1st safety determination = 86 months or 7.17 years
    - 1st final risk mgmt rule = 104 months or 8.67 years

# *Major concerns with CSIA, cont'd.*

- Sweeping pre-emption of state authority
  - States can't enact same requirements as EPA to allow for co-enforcement
  - "Restriction" can be read broadly to apply to warning labels (e.g., CA Prop 65), monitoring, release limits, other purposes (e.g., GHG limits)
  - Pre-emption of new requirements triggered long before EPA acts to identify/control risks
    - Low-priority: No judicial review, yet final agency action
    - High-priority: Start of safety determination years before action
  - Pre-emption of existing requirements triggered by safety determination
    - should be final risk management rule for such chemicals

# *Key improvements needed*

- more deadlines, fewer procedural requirements
- defining and explicitly protecting vulnerable populations
- narrowing the bill’s preemption of state authority to ensure that states can act when EPA does not
- ensuring low-priority designations of chemicals are based on sufficient hazard and exposure information and do not preempt state authority
- providing EPA with adequate resources, with a fair share coming from industry

# *For more information*

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

*EDFHealth Blog*
http://blogs.edf.org/health/