

# Risk and Regulation Beyond Bis Phenol A



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# Our Current Approach Does not Protect Public Health



**EXAMINE RISK ASSESSMENT**

**EXAMINE REGULATION**

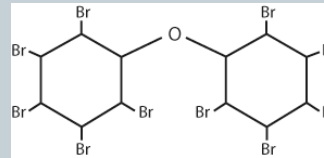
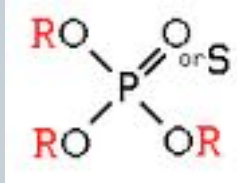
# BPA Case



- Illustrates the need for testing of subtle, low dose effects using timely methods;
- Demonstrates that our regulatory system doesn't allow for timely reversal of decisions;
- Shows the “power” of consumer response
- Provides an opportunity for restructuring approach for testing and risk assessments (inc. alternatives testing)

# Our Current Approach does NOT Protect Health or Environment

- We are now learning that perfectly legal chemicals are harmful to public health
  - organophosphate pesticides, brominated flame retardants



- Doesn't allow for change in course when environmental data or dose-response demonstrate accumulating evidence of harm

# Widespread Detection of Chemicals



BPA  
Pesticides  
Flame retardants  
Teflon precursors  
Plasticizers  
Solvents

AIR & DUST & SOIL

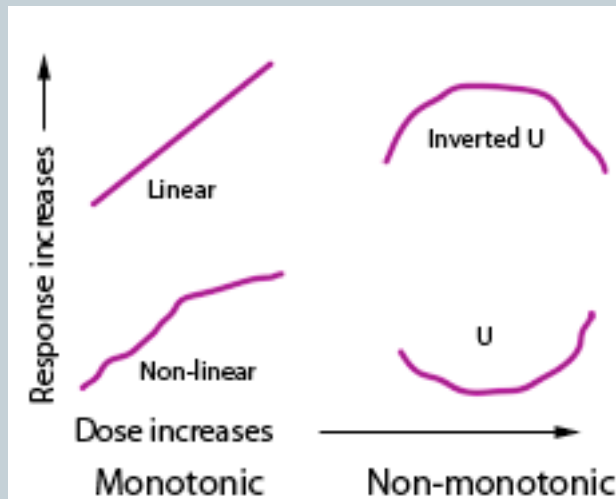


# Relevant Dose-Response Data



- From academic, not from regulatory/safety testing laboratories;
- Integration of data from multiple disciplines;

## Dose Response Curves

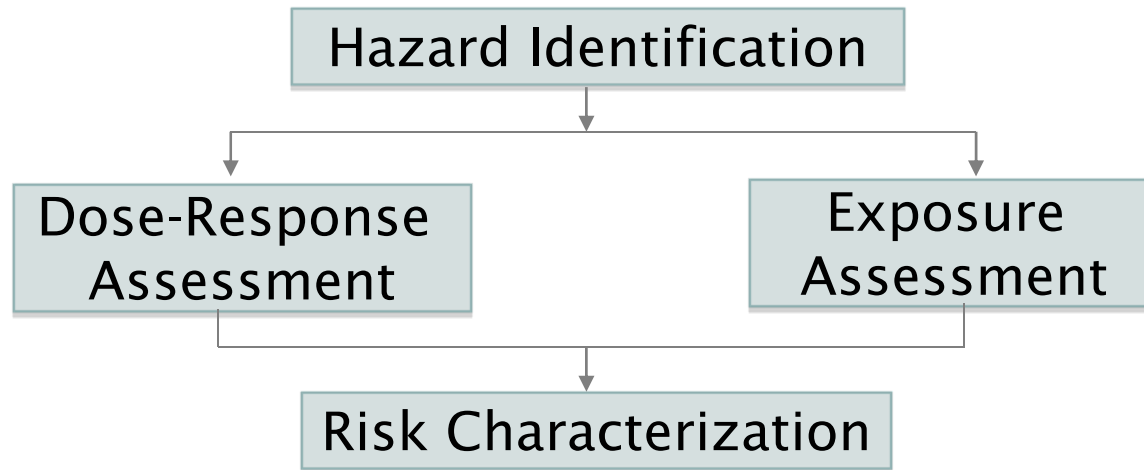


Low Doses

↓

Immunotoxicity  
Neurotoxicity  
Reproductive Effects  
Metabolic Disorders  
Cancers

# What is a “Risk Assessment”?



**Determine if risk is “acceptable” or if exposure is “safe”**

# Hazard Assessment



- Is there evidence of potential harm to humans (or ecological organisms)?
  - Acute toxicity and evidence of clinical disease?
  - Environmental behavior (chemical/physical properties)

**Often the end of the evaluation**

# Risk = Dose Response X Exposure

## Dose Response Assessment

- Single chemical evaluations
- Relies on traditional toxicity testing
- Outcomes are clinical measurements
  - Liver damage by BPA (1982)

## Exposure Assessment

- Evaluates upper %ile individuals
- Lacks adequate population-based assessments
- Magnitude of the exposure

**Determine if risk is “acceptable” or if exposure is “safe”**

# Dose Response Assessments – Science



- Lead – encephalopathy → neurocognitive effects
- Organophosphate pesticides – acute cholinesterase → subtle neurodevelopmental effects
- Brominated Flame Retardants – liver damage → thyroid effects → reproductive effects → neurodevelopmental effects
- 
- Diethylhexyl phthalate - liver damage → immune system suppression
- Teflon (PFOAs) → ???

# Individual Chemical Evaluations

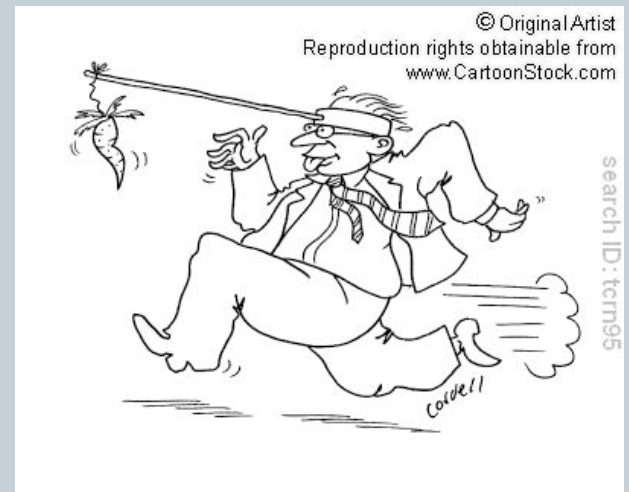


- Not product based -> Incomplete Examination
- Proprietary Chemicals

Undisclosed Chemicals

Scientists – several steps behind

e.g. Brominated (phthalate) flame retardants

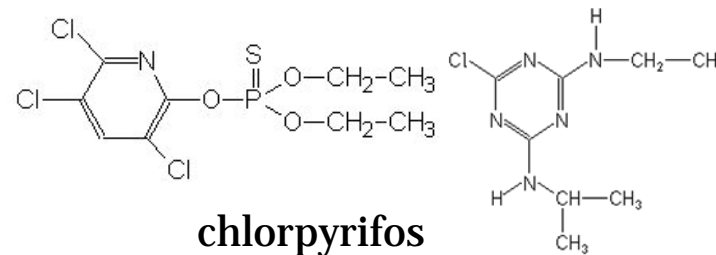


**Population-based exposures to endocrine disrupting chemicals**

# Beyond Bisphenol A

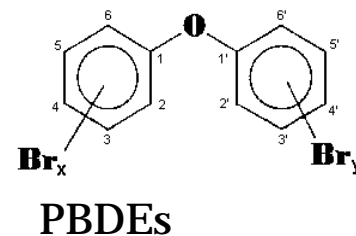
Chemicals with the ability to disrupt physiology or metabolic function in critical stages of life

- Pesticides



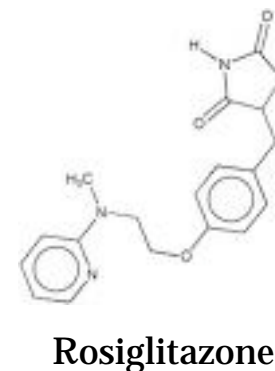
- Alkyl Tins

- Flame Retardants

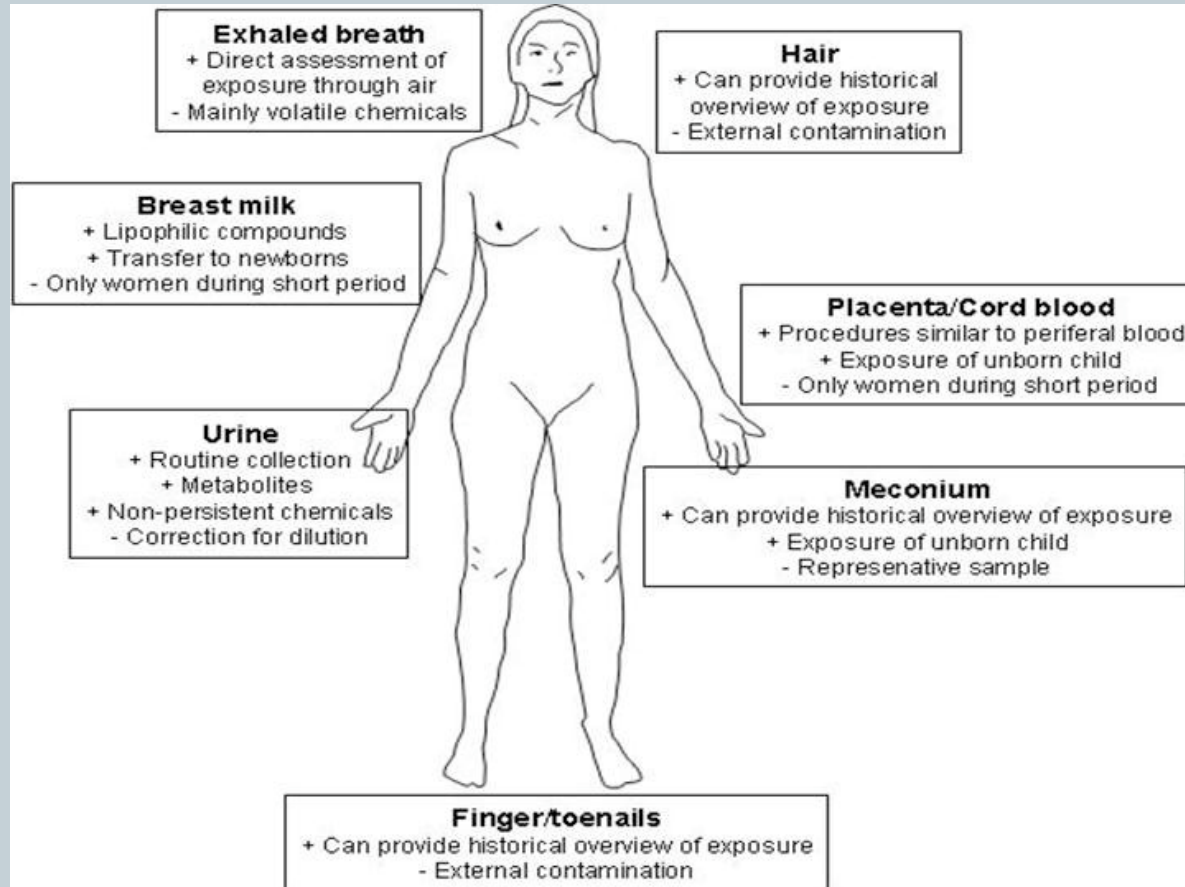


- Perfluorinated Compounds (teflon)

- Pharmaceutical Agents



# Establishing Population Exposure



BPA  
Pesticides  
Flame retardants  
Teflon precursors  
Plasticizers  
Solvents

# Health Risks of Chemicals?

## Dose-Response

- Repro, metabolic, immune, neurological effects demonstrated
- In vivo, in vitro, SAR
- Mechanistic data & biological plausibility

## Human Exposure

- Biomonitoring data – NHANES;
  - PBDEs
  - BPA
  - PFOA/PFOS
- Studies beginning to show associations

**WE ARE DOING THE IN VIVO EXPERIMENT**

# Protection of Public Health SHOULD be the Basis for Regulation



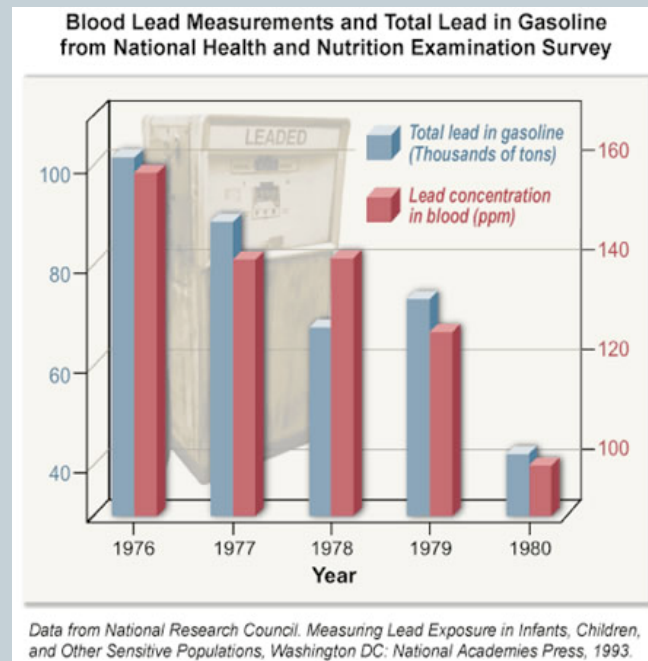
- Respond to data that demonstrate subtle, pre-clinical effects
- Respond to environmental data or biomarker data that demonstrate population-based exposures

**Robust Pre-market Testing AND Anticipatory Post-market Response**

# Unaccounted “Risks”



- **Societal costs**
  - Budgets focused on single chemicals
  - Costs of medical interventions and special education for effects on developing brain (population impacts vs individual impacts)
  - Cost of not using?



# How Should Testing Be Done?



Screening methods (hazard/exposure-based)

Examine **low dose** exposure to multiple chemicals/products that may act to **dysregulate biology** at **critical time periods** – using current methods!

**Pre-Clinical Effects MUST Trigger Regulatory Response!**

# Need a Revised Regulatory System

- Indication of harm – systematic examination should allow being careful. Signals? – pay attention!
  - Structural similarities (PCBs & PBDEs?)
  - Toxicological activity in relevant assay? (BPA & estrogenic activity?)
  - Epidemiological observations (cancers, neurological effects?)
- Timely response – to reverse or modify decisions – based on consensus NOT unanimity of interpretation

# In Summary



- **Sufficient evidence for revising chemicals policy;**
  - **Current approach is costly, not comprehensive & not protective**
- **Alternative approaches are being developed**
  - EU/Denmark
  - Design for Environment & Green Chemistry
- **Growing movement to be more cautious of chemical exposure**
  - BPA Banned in Denmark, voluntary restrictions or use in many – now Germany (as of June 10); Some brominated flame retardants - Persistent Organic Pollutants