Governing with uncertain science: from reaction to precaution

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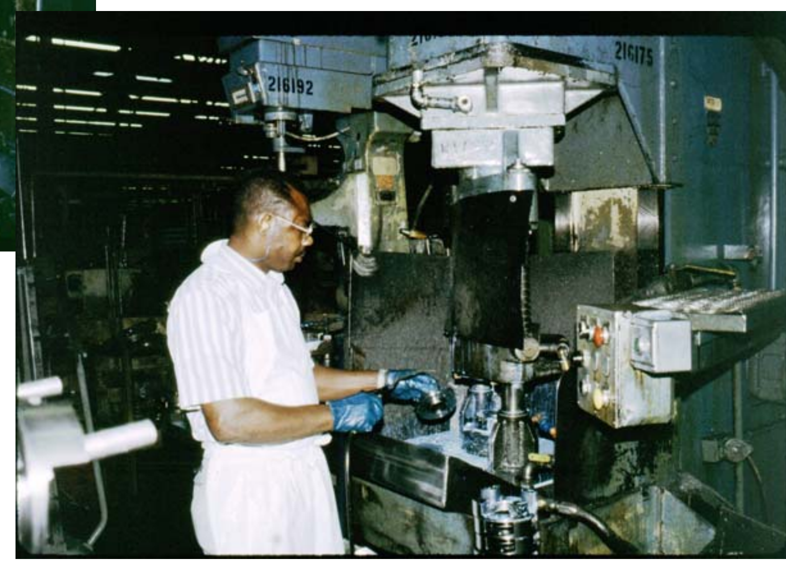
What I was taught

1. Epidemiologists do studies which identify risks
   - publish in the peer-reviewed literature
2. Gov't agencies & citizens use these findings to propose regulations
3. Standards are set to control the hazards
4. People are protected
5. This process is leading towards an ever-safer environment

Metalworking Fluids



1.2 million workers
in the U.S. exposed

Evidence of carcinogenicity has been accumulating since the 1970's

ORIGINAL ARTICLE

Prostate Cancer Incidence in Relation to Time Windows of Exposure to Metalworking Fluids in the Auto Industry

Ilir Agalliu, David Kriebel,* Margaret M. Quinn,* David H. Wegman,* and Ellen A. Eisen*†*

ORIGINAL ARTICLE

Risk of upper aerodigestive tract cancers in a case-cohort study of autoworkers exposed to metalworking fluids

A Zeka, E A Eisen, D Kriebel, R Gore, D H Wegman

Occup Environ Med 2004;61:426–431. doi: 10.1136/oem.2003.010157

Occupational Exposure to Metalworking Fluids and Risk of Breast Cancer Among Female Autoworkers

Deborah Thompson, ScD,[1*] David Kriebel, ScD,[2] Margaret M. Quinn, ScD,[2] David H. Wegman, MD,[2] and Ellen A. Eisen, ScD[2]

This research has had no impact on legal control of MWFs

- Metalworking fluids are regulated in U.S. workplaces by OSHA standards adopted in 1970
  - “oil mists” < 5 milligrams/m^3 in air
    - a “laundry” standard

Why what I was taught was wrong

- ✓ Thousands of chemicals have little or no safety information
- ✓ New hazards are introduced faster than epidemiologists can study them
- ✓ Gov't agencies and citizens are very weak, & new regulations are rare
- ✓ Corporations aggressively block regulation
  - Including through manipulation of the science

Synthetic organic chemistry – an historic analog to nanotechnology?

- Revolution in organic chemistry
  - Creation of synthetic organic molecules exploded after World War II
  - New compounds entered and transformed nearly all aspects of the economy
- Both are true:
  - Tremendous benefits throughout society
  - Many serious environmental & health effects, and certainly many more still to be discovered

Synthetic organic chemistry has been a prolific source of innovation

- 82,000 chemicals in commerce
  - ~ 3,000 high volume (> 1 million pounds/year)
  - very few have been adequately screened for toxicity
- 700 to 1,000 new chemicals every year
  - ~ half have basic human toxicity data

But we know very little about the toxicity of most of these chemicals

- Government and industry are developing screening-level toxicity data on about 2,200 high-production-volume chemicals
  - but we do not know how to use these "lower quality" data in regulatory policy
  - current risk assessment approach is slow and presumes strong evidence

Newly identified mechanisms of toxicity – even more complexity!

1. Endocrine disruption

chemicals can interfere with hormonal regulation:

- (a) timing of exposure can be as important as dose
- (b) low doses sometimes more toxic than higher doses

2. Fetal programming

- chemical exposures in the womb can alter later health status

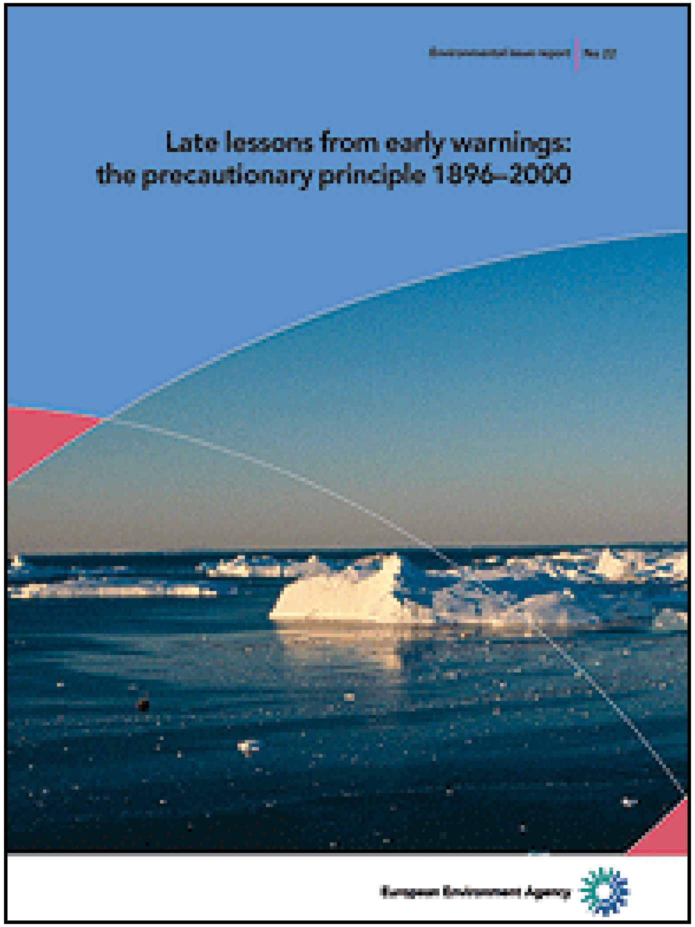
Newly identified mechanisms of toxicity – even more complexity!

3. Epigenetics
   - environmental exposures can switch on/off genes, producing heritable changes without modifying DNA

4. Low exposures to mixtures of chemicals can act in unexpected ways

- toxins acting through different biologic mechanisms can have combined effects which none alone would produce

There is a sad historical record of failure to act to prevent harm from chemicals



- *Late lessons from early warnings: the precautionary principle 1896-2000*

http://www.eea.europa.eu/

Late lessons from early warnings: the precautionary principle 1896–2000

- There were long delays in acting on evidence of risk for:
  - Fluorocarbons
  - Tributyl tin
  - Benzene
  - PCBs
  - DDT
  - Many others

While there are political pressures that make risk reduction difficult, this is not the main roadblock

- There are fundamental limits to how much we can accomplish with one chemical-at-a-time risk assessment and management

- How to decide how much evidence is enough to take action on a technological development?

Two models of getting to “causal”

1. Knowledge accumulates until a threshold is reached: risk is “real”

OR:

2. Knowledge accumulates, never reaching a threshold.
   - different amounts of evidence justify different responses, e.g.:
     - “more study needed”
     - eliminating unnecessary uses
     - banning

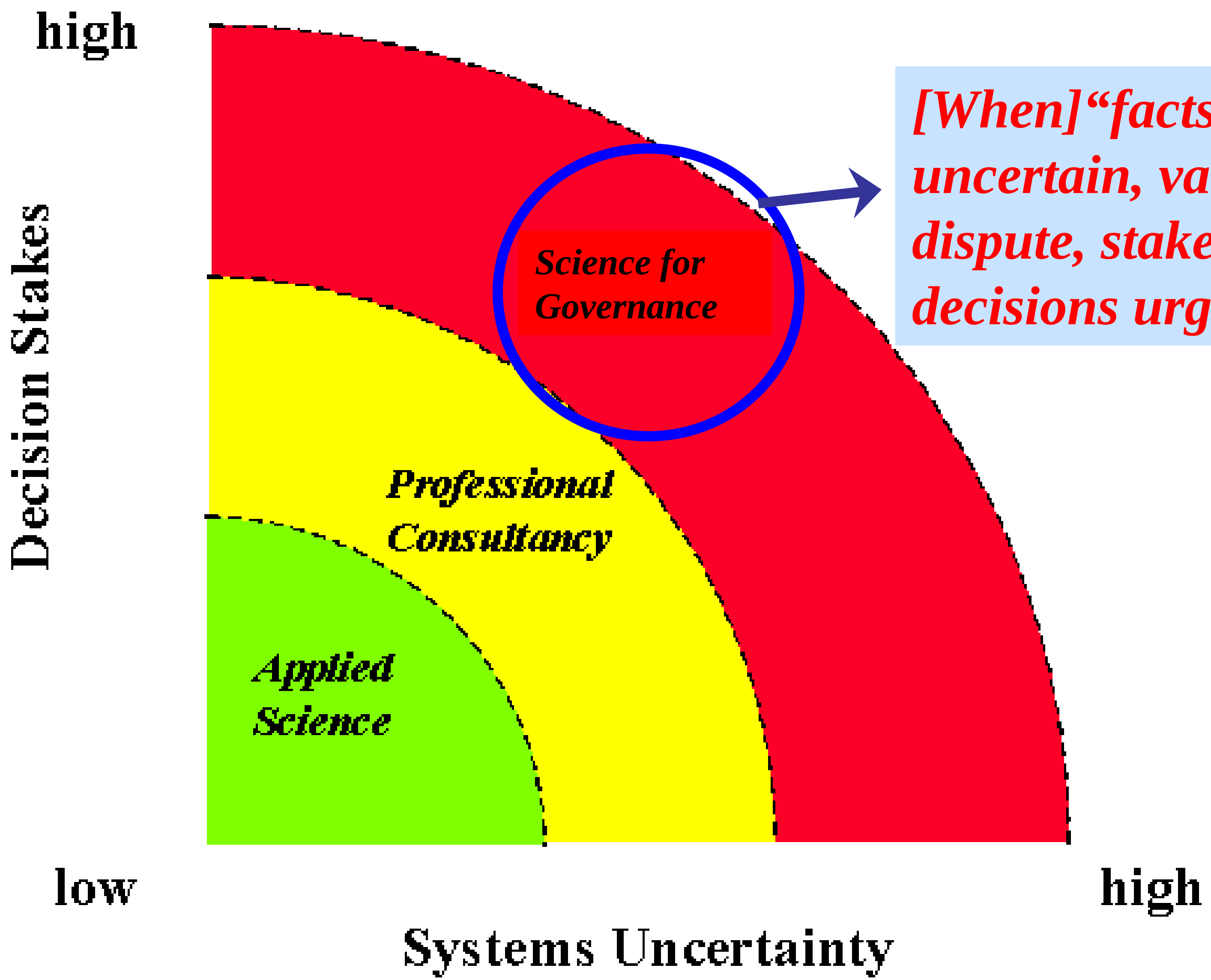
Two models of getting to “causal”

- Under 2nd model, process cannot be entirely conducted within scientific community

- Regulators, courts, public necessarily have relevant roles
  - scientists need to speak to a broader audience: assumptions, choice of methods, etc. have implications for weight of evidence

When do we know enough to act?

- Determination of “sufficient evidence” for preventive action depends on context:
  - availability of alternative ways of achieving the same social good
  - consequences of inaction or acting in error



[When]"facts are uncertain, values in dispute, stakes high, decisions urgent"

S. Funtowicz, J. Ravetz, NUSAP.net

The Precautionary Principle

- Providing guidance in the gray area between safe and hazardous

Central components of precautionary principle

1. Taking preventive action in the face of uncertainty
2. Shifting burden of proof to proponents of an activity
3. Exploring wide range of alternatives to possibly harmful actions
4. Increasing public participation in decision making

(from Wingspread Conference, 1998)

Current regulatory approach is guided by the ***Reactionary Principle***

1. Requiring incontrovertible evidence of harm before taking preventive action
2. Placing the burden on the public to show that each chemical is harmful
3. Not considering potential health and environmental impacts when designing new technologies
4. Discouraging public participation in decision-making about control of hazards and introduction of new technologies

Late lessons from early warnings for nanotechnology

"A new technology will only be successful if those promoting it can show that it is safe, but history is littered with examples of promising technologies that never fulfilled their true potential and/or caused untold damage because early warnings about safety problems were ignored. The nanotechnology community stands to benefit by learning lessons from this history."

Hansen SF, Maynard A, Baun A, Tickner JA. Nature Nanotechnology, 2008.

Assessing nanotechnology risks

- High throughput screening assays – an important step forward but
  - It is not clear how these ‘low quality’ data will be used in making policy
  - If the old risk assessment based approach is used, the process will still be too slow and easily blocked

Toxics use reduction: an example of precautionary governance

- **Mass. Toxics Use Reduction Act**
  - Requires toxics users to plan for eliminating uses
  - Toxics Use Reduction Institute, UMass Lowell
    - Trains "Toxics Use Reduction Planners"
  - More than 40% reduction in toxics use statewide

REACH: an example of precaution

- Registration, Evaluation & Authorization of Chemicals (REACH)
  - approved by EU in 2007
  - establishes a control system broader than EPA's TSCA regulations
  - requires chemical makers to provide toxicity data
  - establishes a list of 'substances of very high concern' – burden is on users to show they can be used safely and that no safer alternatives exist

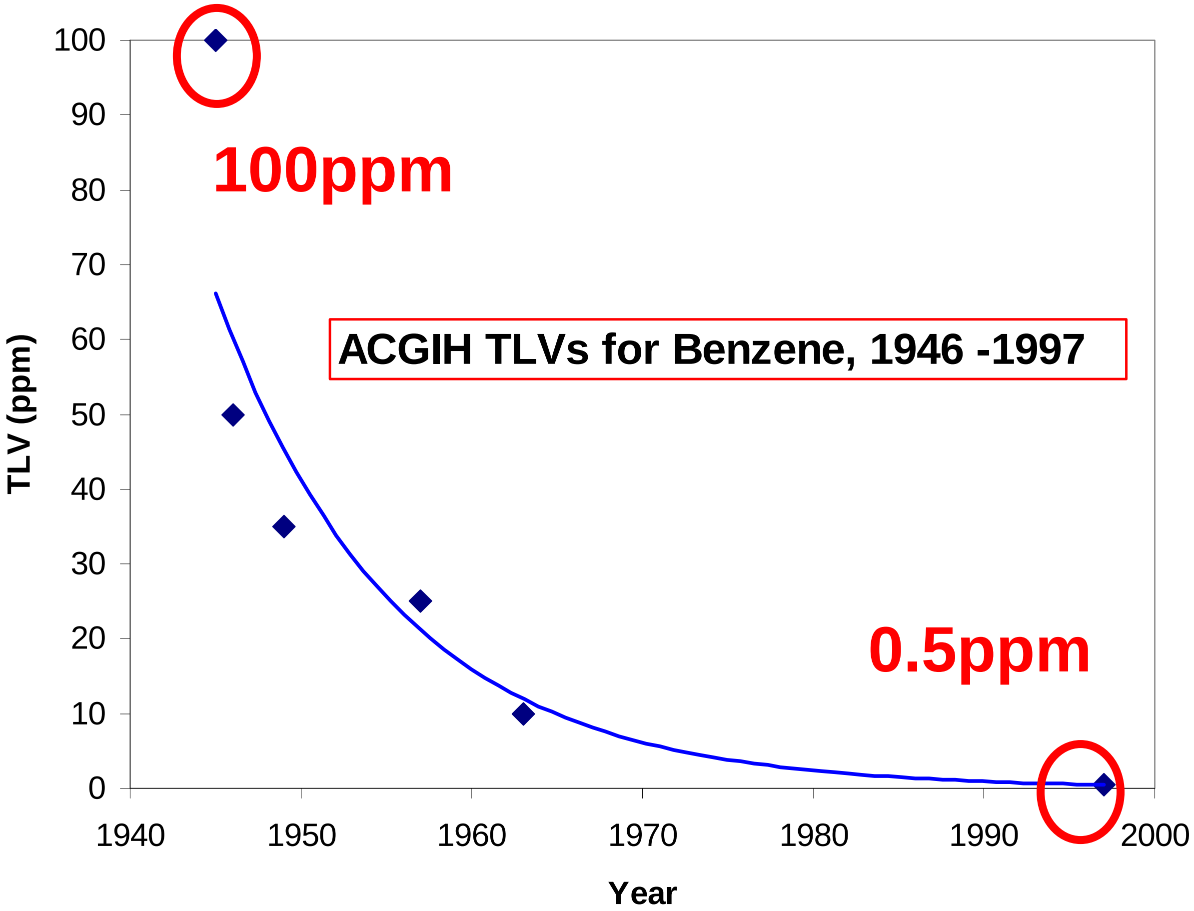
Conclusions – a positive vision of governing technologies

- Precaution can be a useful component of anticipatory governance
  - ‘Foresight’ or ‘forecaring’ might be a better word

- Choosing evidence-based actions in the face of uncertainty
  - different amounts of evidence justify different actions
  - continually and democratically re-evaluated

end

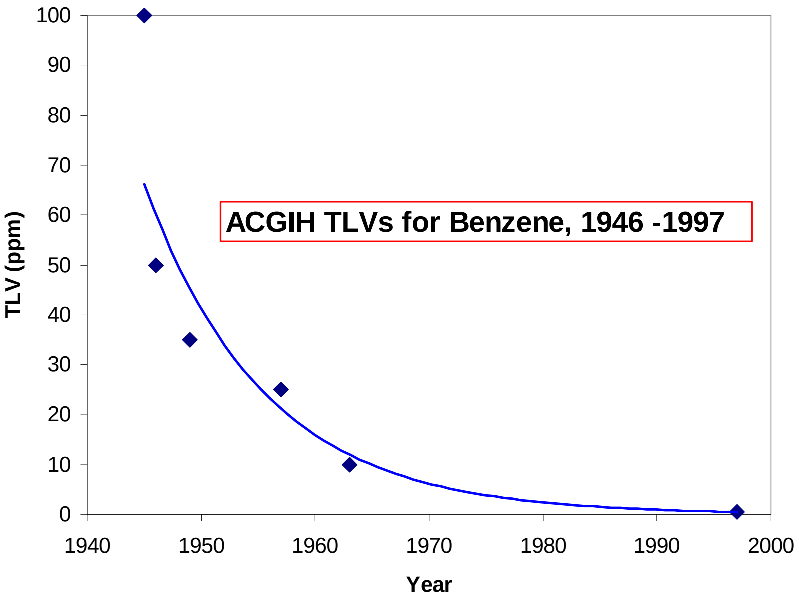
“Safe” air concentration of benzene (TLV) has declined 200-fold in 50 years



American Conference of Government Industrial Hygienists Threshold Limit Values

“Safe” air concentration of benzene

It might have been better to focus on eliminating uses of benzene instead of trying to control it with costly and often ineffective technology



Decisions will need to be made about whether an alternative is 'plausibly safer'

- An alternative might be considered an improvement over current practice if:
  - current chemical is persistent or bioaccumulative, and alternative is biocompatible, biodegradable, or renewable; and
  - current chemical shows strong evidence of harm, and alternative shows evidence of less harm, or little evidence of harm

Decisions will need to be made about whether an alternative is ‘plausibly safer’

- But because knowledge is always provisional:
  - alternatives should always subject to future surveillance
  - alternatives should be amenable to flexible production or future substitution
    - through continuous improvement