

# **The Reality of Precaution Project**

**Jonathan B. Wiener**

**Professor of Law, Environmental Policy & Public Policy**

**Faculty Director, Center for Environmental Solutions**

**Duke University**

**University Fellow, RFF**

**Fourth Transatlantic Dialogue on Precaution**

**Duke University**

**19 September 2004**

# Choices: Comparing US and European Precautionary Risk Regulation

- **Why compare?**
  - **Getting the facts straight – comparative historical record.**
  - **Descriptive claims often convey normative claims.**
  - **Policy evaluation, learning, and regulatory improvement.**
  - **Mutual understanding; easing transatlantic disputes. Concrete case studies as an alternative to sharp rhetoric.**
  - **Testing explanatory factors.**
  - **Testing outcomes.**
- **Dialogue co-organizers: CEC/GOPA, Duke CES, GMF-US, US Mission to EU, EPC**
- **Research team:**
  - Michael Rogers, European Commission
  - James Hammitt, Harvard
  - Peter Sand, Munich
  - Jonathan Wiener, Duke
  - Kathryn Saterson, Brendon Swedlow, Denise Kall, Zheng Zhou, more...
  - Chapter authors

# Divergence on Precaution?

EU



- 1970s: Sweden; German “Vorsorgeprinzip”
  - 1980s: Marine treaties
  - 1990s: Rio treaties.
- Maastricht Treaty 130r (now 174) adopts PP. Mmbr.
- States adopt & moderate PP.
- 2000: Commission issues “Communication on the PP”
  - 2001: ECJ on BSE. *Late Lessons*.
  - 2002: Action Plan - Improving Regulation, Impact Assmts. (BCA)
  - ECFI case on antibiotics in feed
  - 2003: Env’t & Health initiative

US



- Lead phaseout (*Ethyl Corp. v. EPA*, D.C. Cir. 1976)
- Species (*TVA v. Hill*, S.Ct. 1978)
- Default assumptions in RA
- ***Benzene*** (S.Ct. 1980) (OSHAct) (“show us your risk assessment” before you regulate). ... Alar controversy.
- Carter, Reagan, Clinton = Exec. orders requiring Cost-Benefit
- 27 Questions re Communication
- Revisions at Rio; Cartagena
- WTO case on Beef Hormones
- No to Kyoto. Jo’burg WSSD.
- Iraq War. WTO case on GM foods. San Francisco adopts PP.

# Comparing Precaution: More Precautionary Than Thou ?

“More and More, Europeans Find Fault with US: Wide Range of Events Viewed as Menacing” -- NY Times, 9 April 2000, p.A1

“Precaution is for Europeans” – NY Times, April 2003

“Europe is considered fairly risk-averse ... America, on the other hand, is often seen as having a strong risk-taking culture” – The Economist, 24 January 2004

## View espoused by:

- **EU officials**
- **NGOs**
- **News media**
- **Scholars**

“In the US they believe that if no risks have been proven about a product, it should be allowed. In the EU we believe something should not be authorized if there is a chance of risk.”  
-- Pascal Lamy, EU Trade Commissioner, 1999

E.g. Vogel et al. (2000, 2001): Reversal (“flip-flop”) in relative US/EU precaution over 1970-2000

# Defining Precaution: 3 Narrative Versions

PP version 1: “Lack of full scientific certainty about a risk shall **not justify postponing** action to prevent it.”

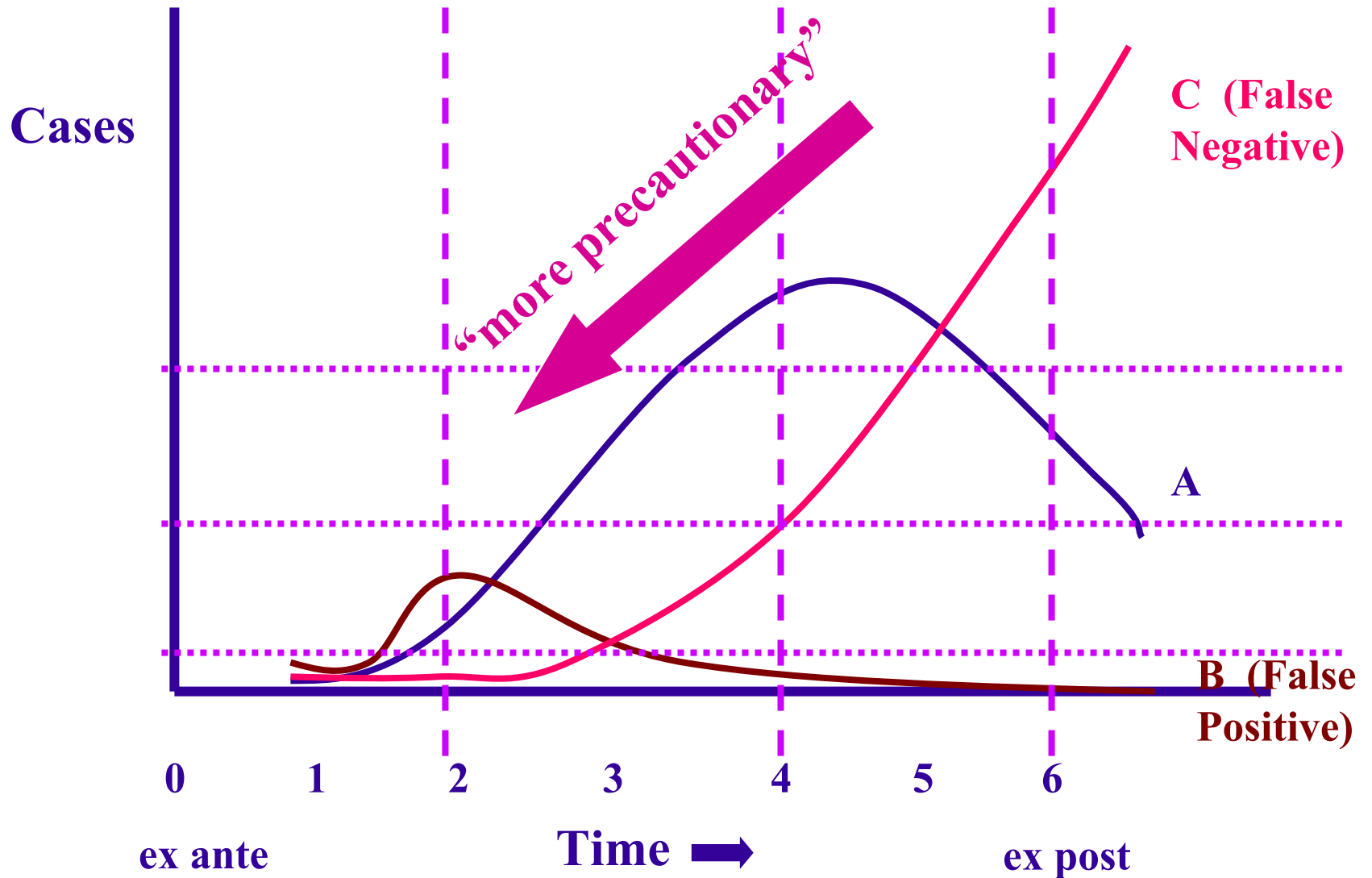
E.g.: Bergen 1990; Rio 1992 (plus “cost-effective”); European Commission Communication 2000 (with qualifications)

PP version 2: “Uncertainty about a risk **justifies action** to prevent it.” E.g.: “better safe than sorry”; “prevention > cure”

PP version 3: “The proponent of an activity posing uncertain risk bears the **burden of proving** that the activity poses **[no] / [acceptable]** risk before the activity can go forward.”

E.g.: pre-market screening (e.g. new drugs, toxics, pesticides); German nuclear licenses

# Defining Precaution: Degrees of Precaution

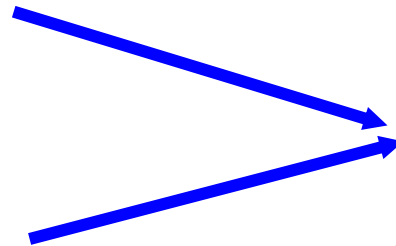


# Comparing US and European Risk Regulation: Prior Research

- **1980s research: divergent styles, but similar results**
  - **Kelman (1981) -- US vs. Sweden**
  - **Rehbinder & Stewart (1985) -- federalism**
  - **Brickman, Jasanoff & Ilgen (1985) -- chemicals regulation: divergent approaches, similar results**
  - **Jasanoff (1986) -- US exceptionalism re science, formality, conflict**
  - **Vogel (1986) -- US v. UK: divergent “styles,” similar results**
- **Recent research: more divergence?**
  - **Rose-Ackerman (1995) -- US v. Germany: greater transparency, accountability, oversight in US law**
  - **Kagan (2001), Kagan & Axelrad (2000) – greater “adversarialism” in US**
  - **Lynch & Vogel (2000), Lofstedt & Vogel (2000), Vogel (2001) -- “flip-flop”**

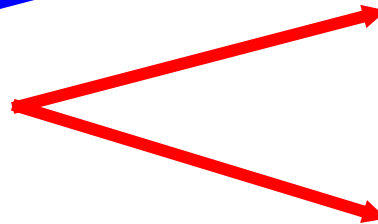
# Comparing Precaution: Hypotheses about the Evolution of US and European Policies

- **Convergence**



- Globalization yields Harmonization

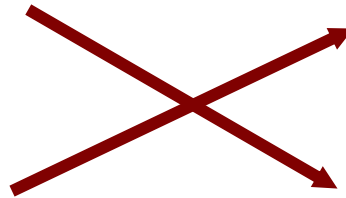
- **Divergence**



- EU risk-averse, US risk-taking ? Or,

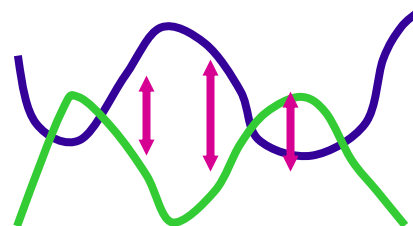
- US adversarial legalism, EU informal corporatist ?

- **“Flip-Flop”**



- US more PP in 1970s, EU more PP since 1990s

- **“Hybridization”**



- Borrowing, learning

- Heterogeneity across & within regulatory systems

# Cautions re Comparing Regulatory Systems

- **Broad claims may be overstated**
  - **Both US and EU are at high end of global spectrum of relative precaution**
  - **Fixed claims clash with dynamic hypotheses**
    - E.g., “Europeans are more risk-averse” conflicts with “Flip-flop”
  - **Heuristic exaggeration of intergroup contrasts -- Henri Tajfel, social psychology**
  - **End of Cold War, contest for leadership?**
  - **Sampling bias**
    - Availability heuristic: broad claims drawn from a few recent visible cases. E.g.: GM foods.
    - Sampling by convenience. Cases under the streetlamp.
- **Two methods to test:**
  - **Case Studies**
  - **Aggregate Data**

# Key Events since 1<sup>st</sup> Dialogue

- EU Governance / Better Regulation initiative
  - EU Impacts Assessment initiative
- US OIRA/CEQ initiative on Emerging Risks
- First case of BSE in US
- US lawsuit in WTO vs. EU re GM foods
- War in Afghanistan; War in Iraq
- EU Constitution

# Multiple Strata of Comparison & Hybridization

## Policy Stratum

## US and EU Approaches

- Framing (rhetoric) Divergent (PP)
- Risk assessment methods Convergent ??
- Risk management approach Convergent (BCA)
- Choice of which risks to regulate Divergent
- Choice of policy instruments Borrowing (MBI, info)
- Degree of integration (hazards, media) Divergent?
- Enforcement mechanisms Convergent?
- Hierarchical level of government Convergent?

# Convergence on Regulatory Review ?

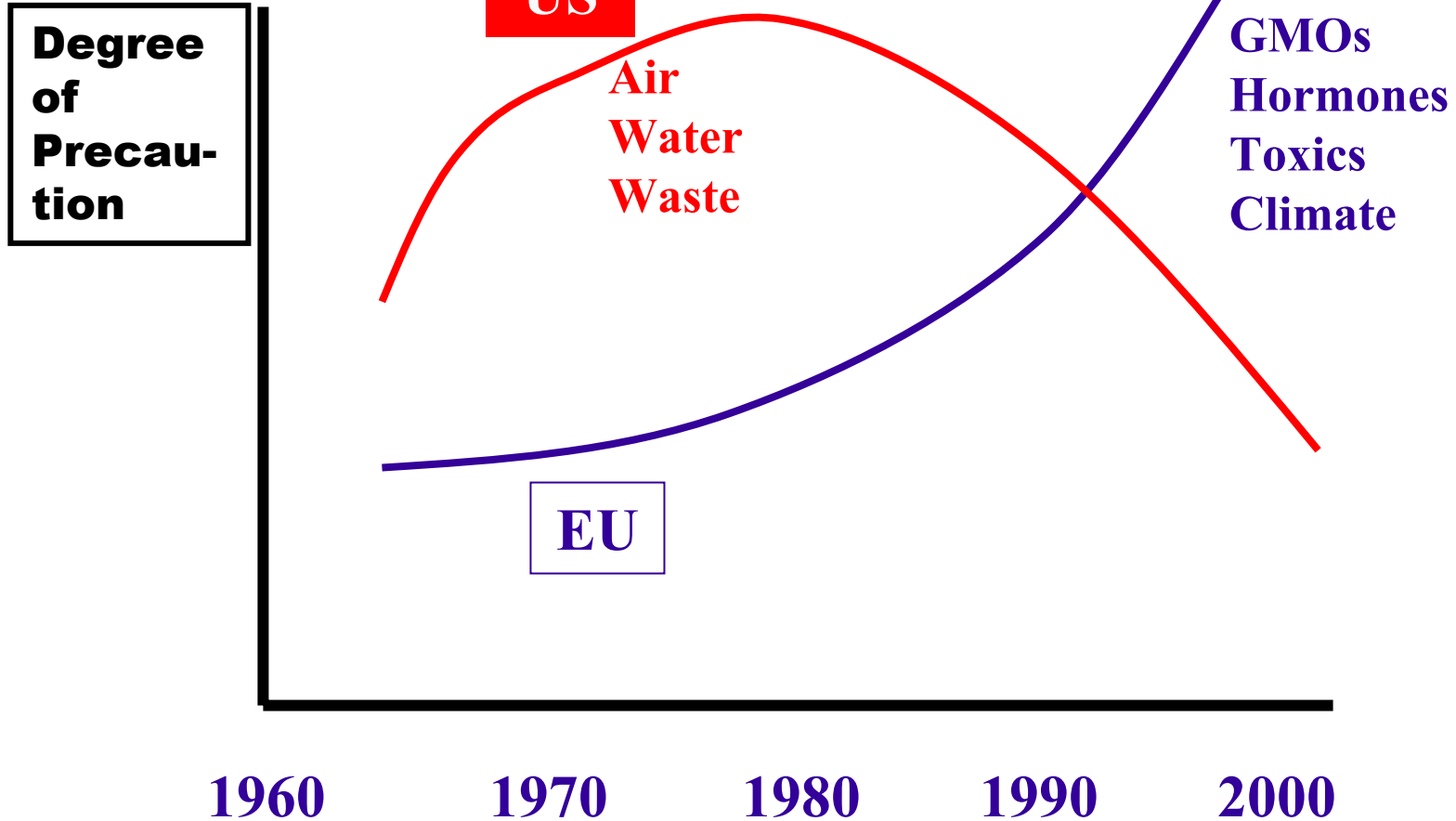
## USA

- Every President since Jimmy Carter has required BCA of new regulations
- Carter EO 12044 (1978): economic impact
- Reagan EO 12291 (1981): Bs must “outweigh” Cs, else OMB “return letter”
- Clinton EO 12866 (1993): “justify”; plus qualitative, distributional effects
- Congress: PaperworkReductAct (1980), UMRA (1995), SDWA amdts. (1996)
- 2001- : using Clinton EO; yet returning more regs. Plus new “Prompt letters”: using BCA to say Yes (e.g. trans-fat labels, defibrillators).
- Proposed guidelines (2003): lower discount rates; BCA of homeland security regs

## Europe

- Proportionality principle = BCA
- “Communication on PP” (Feb. 2000): requires BCA
- Member States’ implementation of PP: cost, proportionality criteria added
- Action Plan on Improving Regulation, Impact Assessments (June 2002): BCA
- Communication on Use of Experts (Dec. 2002)
- But: no OMB/OIRA to supervise BCA

# “Flip-Flop” Hypothesis



# Hybridization Hypothesis

- **Legal Borrowing / Transplants** (Watson, Kahn-Freund)
  - Mimesis (Toynbee); Disease (Goethe)
  - Diffusion of ideas (Hagerstrand); Interfusion (Sand)
  - Borrowing (Watson); Bricolage (Tushnet)
  - Transnational networks across disaggregated states (Nye & Keohane; Slaughter)
  - Policy learning
  - Gains from trade -- in legal concepts
- **Insights from Biology** (Arnold, Grant & Grant, Schluter)
  - Interspecies breeding found to be more prevalent than once thought
  - Hybrid offspring typically unsuccessful, till environment changes...
  - Now seen as a major source of evolution
  - Parallel inattention to hybridization in “evolution of law” literature
- **May overcome path dependence of insular evolution**

# Method 1: Case Studies

- **“Narrow and deep” inquiry**
- **Not just GMOs, Climate ...**
- **Fosters pragmatic dialogue, reduces acrimony over abstract rhetoric of “principle”**
- **Sheds light on real policies, consequences, choices**
- **Greater detail on institutional context surrounding the PP, e.g. Implementation/Enforcement, Proportionality Principle, Impact Assessment, Tort law as a backup to ex ante regulation.**
- **But: sampling bias remains -- my cases vs. your cases**

# **“The Reality of Precaution” Project**

**Project Objective: Move beyond abstract rhetoric to compare actual policies over a wide array of cases**

## **1st Dialogue, Bruges, January 2002:**

- Genetically Modified Foods
- Mad Cow Disease (BSE)
- New Drug Approval
- Chemicals
- Phthalates

## **2nd Dialogue, Airlie House, June 2002:**

- Pest-Protected Crops
- Nuclear Power
- Climate (GHGs) and Stratospheric Ozone (CFCs)
- Automobile Fuels (Diesel)
- Smoking
- Information Policies
- Risk Perceptions

## **3rd Dialogue, Berlin, June 2003:**

- Antibiotics
- Children’s Health
- Cell phones
- Youth violence
- Food Safety / Acrylamides
- Cognition
- Dynamics
- Political / Legal Context

# **“The Reality of Precaution”**

## **4<sup>th</sup> Dialogue, Duke: Case Studies**

- **Marine Environment**
- **Biodiversity**
- **Terrorism & WMD**
- **Ozone Depletion & Climate Change**
- **Medical Errors, ADRs, Patient Safety**
- **Health Supplements**
- **Genetically Modified Foods**
- **Nuclear Energy**
- **Risk Analysis Methods**

# **The Reality of Precaution: Book Project**

*Edited by J.B.Wiener, M.D.Rogers, J.K.Hammitt, P.H.Sand*

## **I. Overview**

**Comparative Precaution: An Introduction and Overview (eds.)**

**Quantitative Empirical Analysis of Comparative Precaution in the US and EU**

## **II. Case Studies on Precaution Regarding Specific Risks**

**Genetically modified foods and crops – Lex & Cantley**

**Beef: Hormones and BSE – Gray**

**Smoking – Blanke**

**Nuclear power – Ahearne & Birkhofer**

**Automobile emissions – Walsh**

**Climate and Ozone Protection – Hammitt**

**Marine Environment – Freestone**

**Biodiversity – Saterson**

**Chemicals and Toxic Substances – Renn & Elliott**

**Medical Errors, New Drug Approval and Patient Safety – Miller**

**Violence & Guns - tba**

**Terrorism and WMD – Stern & Wiener**

## **III. Cross-Cutting Explanatory Variables**

**Political Systems – Majone**

**Legal Systems – Bergkamp & Smith**

**Risk Perceptions – Sunstein; Rohrman**

**Information Disclosure Systems – Sand**

**Risk Analysis Methods – Rogers & Charnley**

## **IV. Conclusions**

**Lofstedt**

**Vogel**

**Wiener, Rogers, Hammitt, Sand**

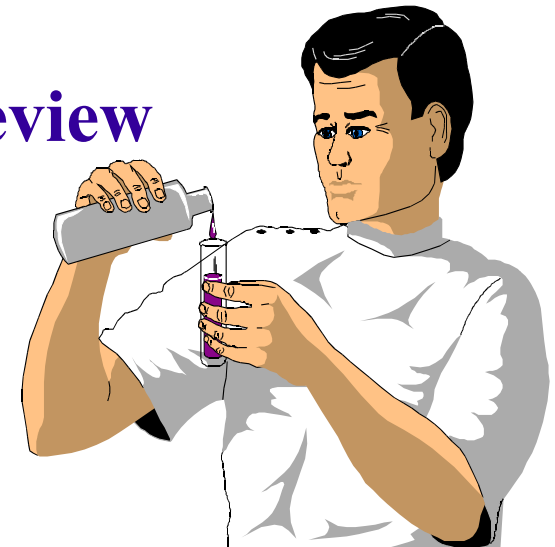
# The Reality of Precaution – Book Project

Asked of each Case Study chapter:

- 1. What has been the actual pattern of precaution in the United States and Europe over the last three decades (1970-2004)?**
- 2. What explains the observed pattern of precaution in the US and Europe?**
- 3. What have been the impacts of precautionary approaches in practice ?** – reducing target risks, inducing countervailing risks, reducing ancillary risks, cost, innovation, public confidence, other outcomes
- 4. Based on the observed experience, when and to what degree is precaution desirable?** What lessons can be drawn for future regulatory policy? What lessons can be drawn for transatlantic relations?

# New Drug Approval

- **1950s - 1980s: US FDA more cautious about approval than European regulators**
  - Safety and Efficacy tests
  - Thalidomide case
  - US FDA too cautious? Concern about “Drug Lag”
- **1980s-2000: US FDA speeds up review**
  - AIDS drugs
  - User fees for approval process



# CFCs and GHGs

- Stratospheric Ozone Depletion
  - Molina & Rowland paper 1974
  - Bans on CFCs in aerosols: Oregon 1975, US 1978
  - US halts SST
  - Europe adopts production cap that exceeds current production
  - “Ozone Hole” 1985
  - Montreal Protocol 1987, followed by London, Copenhagen: phaseout
- Climate Change
  - Arrhenius 1896; rising CO<sub>2</sub> concentration; hotter years 1988- .
  - Europe presses for treaty; US joins FCCC (Rio 1992) provided no targets & timetables.
  - US signs Kyoto Protocol (1997) but Clinton Admin. never submits to Senate for ratification. Bush Admin. withdraws (2001).
  - EU moves ahead with Kyoto targets, emissions trading.

# Chemicals

- USA
  - FIFRA 1975: new pesticides require approval. Denied if “unreasonable risk.”
  - TSCA 1976: new chemicals require approval. Denied if “unreasonable risk.”
  - High Production Volume (HPV) testing program for existing chemicals, 1990s - .
- Europe
  - New chemicals requirements 1981.
  - White Paper 2001.
  - Draft legislation 2003. REACH: requires testing of existing chemicals, sorting by potential risk. Eliminates new/old distinction.
  - Swedish goal: Toxics-Free Society by 2020.
- Compare standards: US still more stringent than WHO for 89 of 111 chemicals (George Gray 2003)

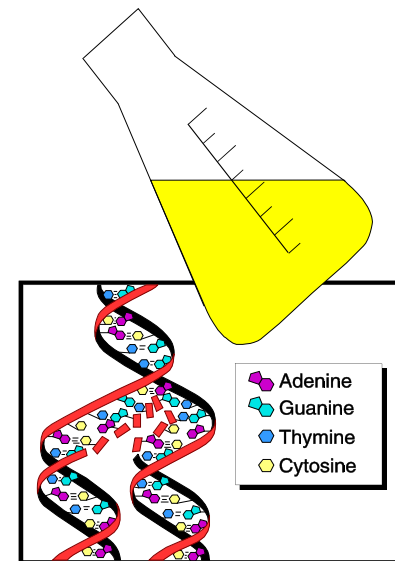
# Hormones in Beef and GM Foods

## 6 hormones in beef, rBST in dairy:

- EU banned in 1989; US, Canada sued
- WTO ruled against EU in 1997, 1998  
Held: health risk can be a valid basis,  
but not shown here
- Retaliation, negotiation ...

## GM Foods:

- EU 1990 and 2001 directives: de facto ban?
- US “Coordinated Framework” and agency regulations: product-based approvals
- Biosafety Protocol: US non-party
- 2003: US brings case in WTO



# BSE (“Mad Cow Disease”)

## Transmissible spongiform encephalopathy (TSE)

- Sheep: “scrapie”
- Cows: “BSE”
- Deer: “chronic wasting disease”
- Cannibals: “kuru” (Nobel Prize 1976)
- “Creutzfeld-Jakob Disease” (CJD)
  - Young victims: “variant CJD” (vCJD)
  - more than 100 in UK since 1996
- Agent of transmission: the “prion” (Nobel Prize 1997)
  - A protein that is mal-folded (unclear why)
  - Propagates in host; low dose; long latency
  - Difficult to “kill”



# Comparing BSE/vCJD Policies

	<u>UK</u>	<u>EU</u>	<u>USA</u>
<b>Cases of BSE</b>	~ 200,000 (1986-)	~ 2,000 (1990-)	~ 1 (deer/elk 2001-? Canada 2003)
<b>Ban on UK Beef</b>	No	Temporary (1996-99)	Yes (1989-)
<b>Ban on MBM in feed</b>	Yes (1988)	Yes (1994)	Yes (1997)
<b>Ban on eating SRM</b>	Yes (1989)	Yes (1997)	No
<b>Ban on beef &gt; 30 months old</b>	Yes (1996)	No	No
<b>Testing at slaughter</b>	No	Yes (2000)	No
<b>Ban on UK, EU Blood Donors</b>	No (leukodepletion)	No	Yes (1999-)

(Source: Wiener & Rogers, 2002; George Gray, Harvard School of Public Health, 2002)

## **BSE in Blood ?**

- vCJD from blood donations from donors who ate BSE-tainted beef ? (human evidence? animal ev.?)
- Aug. 1999: as a “Precautionary Measure,” US FDA requires blood banks to exclude all donors who have spent > 6 months in UK during 1980-1996
- July 2001: US FDA proposes banning blood from donors who have spent > 5 years anywhere in Europe
- No such rules in Europe; leukodepletion

### **Countervailing Risk: blood shortages, risky new donors**

- ‘No-UK’ rule excludes 2% of US donors
- ‘No-Europe’ rule excludes 6% of US donors, 25% in NYC
- Needed: risk-superior option ... e.g., artificial blood?

# Diesel Emissions

- **EU: promotes Diesel**
  - to reduce CO<sub>2</sub>
  - > 20% of passenger vehicle fleet
- **US: restricts Diesel**
  - to reduce fine Particulate Matter (PM)
  - < 3% of passenger vehicle fleet
- **Simultaneous precaution, but vs. conflicting risks**

# Violence

- **Guns: EU more precautionary**
  - tighter gun controls; fewer guns per person
  - lower homicide rate (causal link ?)
- **Youth violence: US more precautionary**
  - 1980s: Forecast of youth violence (“superpredators”) -- an uncertain future risk -- later seemed overstated
  - States lowered age for treatment as adults in courts, prisons
  - Stiffer sentences; even the death penalty (once murderer turns 18)
  - **Countervailing Risks (recidivism; prisons breed hardened criminals)**
- **Other examples**
  - **Sex offenders: US more precautionary (CR: privacy)**
  - **Mental illness: US more precautionary (CR: freedom)**
  - **“War on drugs”: US more precautionary (CR: violence)**

# Terrorism -- Parallel Justifications

- **European Environment Agency, 1/02: “Forestalling disasters usually requires acting before there is strong proof of harm.”**
- **EU Env’t Commissioner Margot Wallstrom, 4/02: “If you smell smoke, you don’t wait until your house is burning down before you tackle the cause.”**
- **NGO advocate of the PP: “Sometimes if we wait for proof it is too late. ... If we always wait for scientific certainty, people may suffer and die, and damage to the natural world may be irreversible.”**
- **Pres. Bush at West Point, 6/02: “If we wait for threats to fully materialize, we will have waited too long.”**
- **US National Security Strategy, 9/02: “America will act against such emerging threats before they are fully formed. ... The greater the threat, the greater is the risk of inaction — and the more compelling the case for taking anticipatory action to defend ourselves, even if uncertainty remains ...”**

# Terrorism -- Parallel Objections

- **US response to EU demands for environmental precaution (e.g. re GMOs): uncertainty warrants no action until more evidence of risk is found.**
- **Joschka Fischer, German Foreign Minister and Green Party leader, 9/02: "To what consequences would military intervention lead? ... Are there new and definite findings and facts? Does the threat assessment justify taking a very high risk? ... we are full of deep skepticism regarding military action ..."**
- **UN weapons inspector Hans Blix, 2003: "It is clear that the critical thinking we applied led us less astray than did the assertive thinking of the US administration ... We never said there were weapons of mass destruction. What we said was that the Iraqis could not answer all our questions regarding their arsenal. But, for the Bush administration, 'unaccounted for' equaled 'existing.'"**
- **NY Times editorial, 2003: "If intelligence and risk assessment are sketchy -- and when are they not? -- using them as the basis for pre-emptive war poses enormous dangers."**

# More Precautionary Than Thou ??

**EU**



**1970s – 80s:**

- **Marine environment**
- **Guns**

**1990s - present:**

- **Hormones in Beef, rBST**
- **GM foods / crops**
- **Climate**
- **Toxic Chemicals**
- **Diesel - more (CO<sub>2</sub>)**

**US**



**1970s – 80s:**

- **New drug approval**
- **CFCs**
- **Nuclear power**
- **Endangered species**
- **Lead (Pb) in gas/petrol**

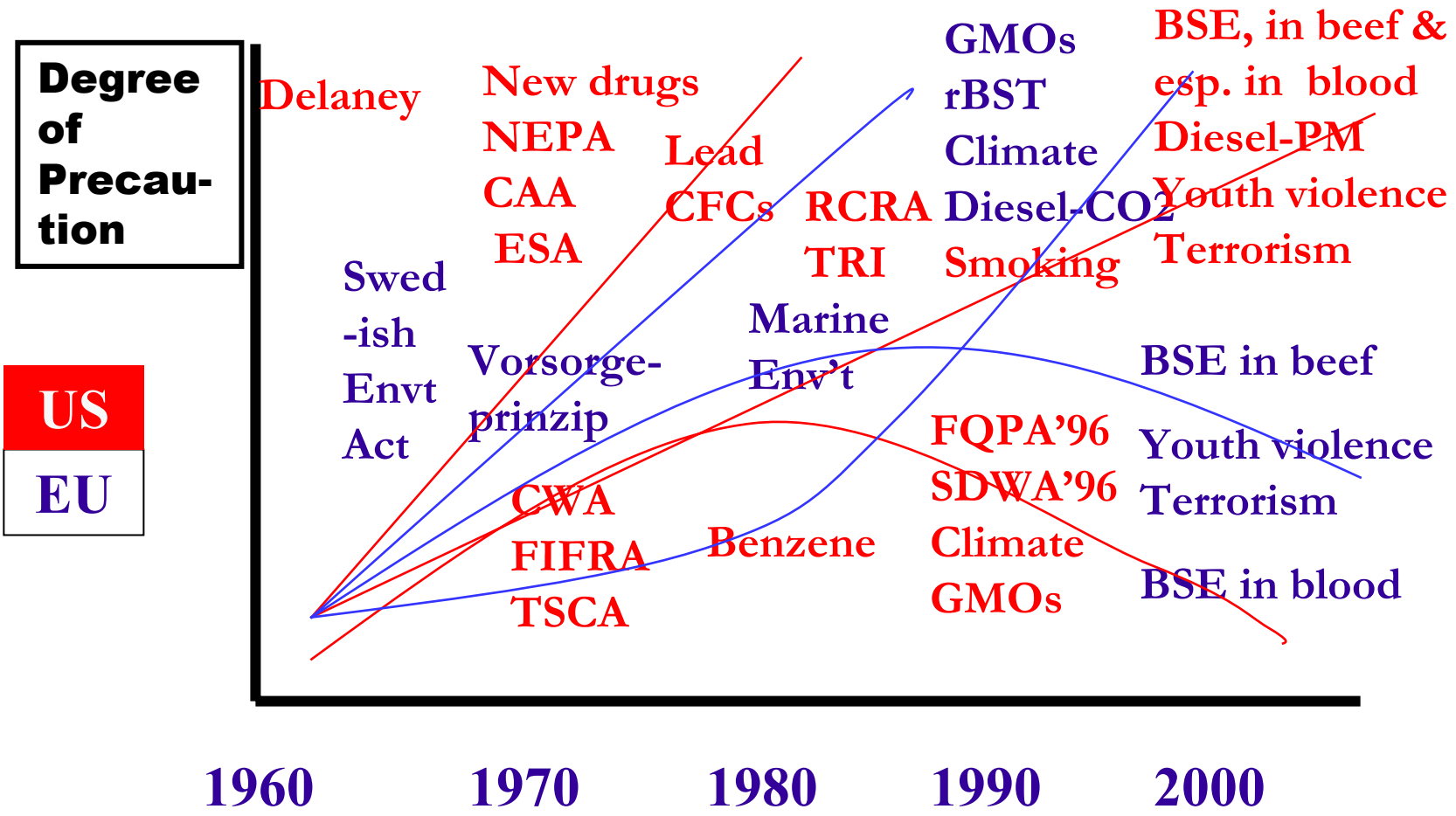
**1990s - present:**

- **BSE in Beef (?), Blood**
- **Smoking**
- **Diesel - less (PM)**
- **Youth violence**
- **Terrorism & WMD**
- **Children's Health ?**

# Risk Selection – Precautionary Particularity



# Flip-Flop vs. a More Complex Reality ?



## Method 2: Aggregate Data

- **Larger database: all risks mentioned in risk literature (254 references) in US and EU, 1970-2003.**
  - Broad and shallow.
- **Unbiased sampling: random & stratified random**

### **But:**

- **True universe?**
- **Random vs. Representative sampling**
- **Less information regarding foreign law, member state law ?**
- **Differential implementation & enforcement**
- **Variation within each system & over time**
  - **Policies by member states within US, EU**
  - **Rise of EU & its competence over E/H/S issues, since late 1980s**
  - **Change in EU membership**
- **Units of comparison: e.g., ambient vs. emissions standards**

# Testing a Larger Sample

Universe  
of all  
risks

11,086  
“verbatim”  
risks from  
254 sources  
in literature  
on risk  
perceptions,  
ranking, and  
classification,  
1960-2003,  
in US and  
Europe

3,000  
“unique”  
risks  
(recom-  
bining  
essentially  
identical  
“verbatim”  
risks)

In 19  
categories  
and 95  
sub-  
categories

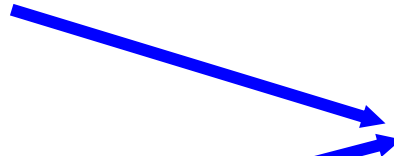
2,878  
“unique”  
risks  
In 18  
categories  
and 92  
sub-  
categories

(dropping  
122 unique  
risks, 1  
category,  
and 3  
subcategor-  
ies)

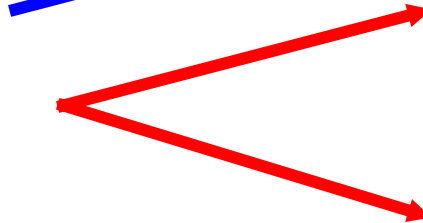
**100 in random  
sample;**  
**92 in stratified  
random sample**

# Testing Hypotheses: Evidence from the Random Sample

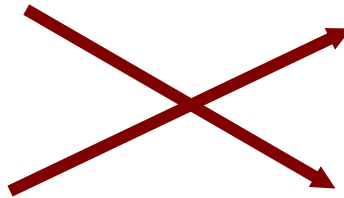
- **Convergence**



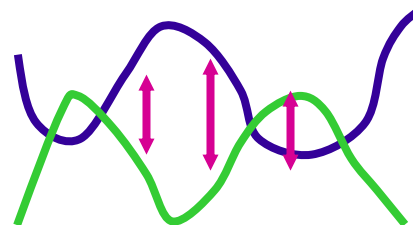
- **Divergence**



- **“Flip-Flop”**



- **“Hybridization”**

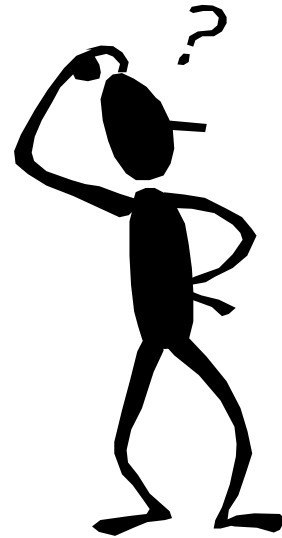


**Scoring method:**

- **Drew 100 risks at random**
- **Scored each risk in each year, 1970-2003:**
  - +1 if greater EU precaution**
  - 0 if tie**
  - 1 if greater US precaution**

# Can we Explain the Complex Pattern?

- **Merits (policies well tailored to each risk, BCA) ?**
- **Politics (3rd parties, interbranch relations) ?**
- **Protecting domestic interests (industry, culture) ?**
- **Risk perceptions / culture ?**
  - **dread of the unfamiliar, unnatural**
  - **“availability” heuristic (recent crises)**
  - **(dis)trust in institutions**
  - **cultures of risk-taking, risk-aversion**
- **Legal systems ?**
  - **legalism; likely domestic enforcement**
  - **proportionality principle, and other limits on PP**
  - **federalism/centralization**
  - **reliance on ex post remedies (tort law)**
- **Other ?**
- **If complex pattern, explanations cannot simply vary by US vs. EU.**



# Implications

- **Neither EU nor US is *always* more precautionary than the other. Reality: complex pattern of relative precaution.**
  - Must study wide array of concrete examples (not just rhetoric or recent visible examples)
  - Highly contextual, risk-specific
  - Claim that PP = “customary international law” is weak – no clear state practice
  - Why do societies choose to worry about different risks?
  - “Precautionary particularity,” not principle
- **Actual Precaution is often Heuristic**
  - Availability – recent visible crises
  - Dread
- **Actual Precaution is often Pragmatic**
  - concern re Cost, False Positives as well as False Negatives
  - concern re Countervailing Risks of excessive precaution
  - goal should be: Prudent or Optimal Precaution

## Uncertainty vs. Multiplicity

- Most studies of precaution are single-risk models, in which uncertainty & irreversibility warrant precaution
- But:
  - Inevitable: all risks are uncertain; the real question is what actions to take against which risks
  - Uncertainty and irreversibility can be handled with standard tools of decision analysis
  - Focusing on more uncertain risks would skew policies away from more certain risks
- Uncertainty and irreversibility likewise apply to the countervailing risks of precautionary interventions

## **Causes: Multiple simultaneous risks**

- **Risk assessment typically addresses 1 risk at a time**
- **Real world is multi-risk. Multiple simultaneous exposures may pose a stronger case for precaution**
  - **If synergistic effects**
  - **Joint effects – distinct from sum of partial effects**
  - **Example: Exposures plus poverty**
- **Efforts to address include:**
  - **FQPA aggregate risk, cumulative risk**
  - **HCPs for multi-species conservation**

# Future Directions

- **More Dialogues?**
  - US-EU
  - Rest of World
- **Multiplicity, not uncertainty, is pivotal**
  - Choices -- among multiple risks
  - Causes -- we face multiple risks in concert
  - Consequences -- policies affect multiple risks
- **Toward Prudent Precaution**
  - Assess multiple risks in concert
  - Minimize the sum of multiple interconnected risks
  - Seek “risk-superior” moves to reduce multiple risks
  - Dynamic, adaptive over time (“provisionality”) -- with incentives to produce and use new research
  - Outcomes studies – retrospective, “evidence-based regulation”