

# **The Reality of Precaution**

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**Paris  
22 September 2008**

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# The Ambition of Precaution

- Rebut the claim that uncertainty warrants inaction
- Empower government to take anticipatory action (despite uncertainty)
- Oppose and replace the standard decision analysis tools of modern regulation (risk assessment & benefit-cost analysis)
- Protect health and environment against emerging risks

## The Rise of the “Precautionary Principle”

- 1970: German *Vorsorgeprinzip*
- 1976: US Court of Appeals decision in *Ethyl Corp v. US* (Clean Air Act = “precautionary”)
- 1992: Rio Declaration, paragraph 15
- 1992: Maastricht Treaty, art. 130r (now Nice Treaty, art. 174)
- 2000: European Commission, “Communication on the PP”
- 2005: Charte de l’Environnement de la France

## The Ambition of Precaution: achieved?

- “the Precautionary Principle ... could become *the* fundamental principle of environmental protection policy and law.” Cameron & Abouchar (1991)
- “If international environmental law were to develop Ten Commandments, the precautionary principle would be near the top of the list.” Bodansky (2004)
- “The precautionary principle may well be the most innovative, pervasive, and significant new concept in environmental policy over the past quarter century. It may also be the most reckless, arbitrary, and ill-advised.” Marchant & Mossman (2004)

# The Reality of Precaution

- Increasing adoption since 1970
  - Especially in Europe?
- Expansion beyond environment, to health, safety, security

But ...

1. Elusive definition
2. Selective application – in both Europe and the USA
3. Conflict, and then reconciliation, with decision analysis (risk assessment & benefit-cost analysis)
  - Qualification & moderation
  - From Precaution to Better Regulation / Impact Assessment

## Defining Precaution: 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”.

Wingspread 1998.

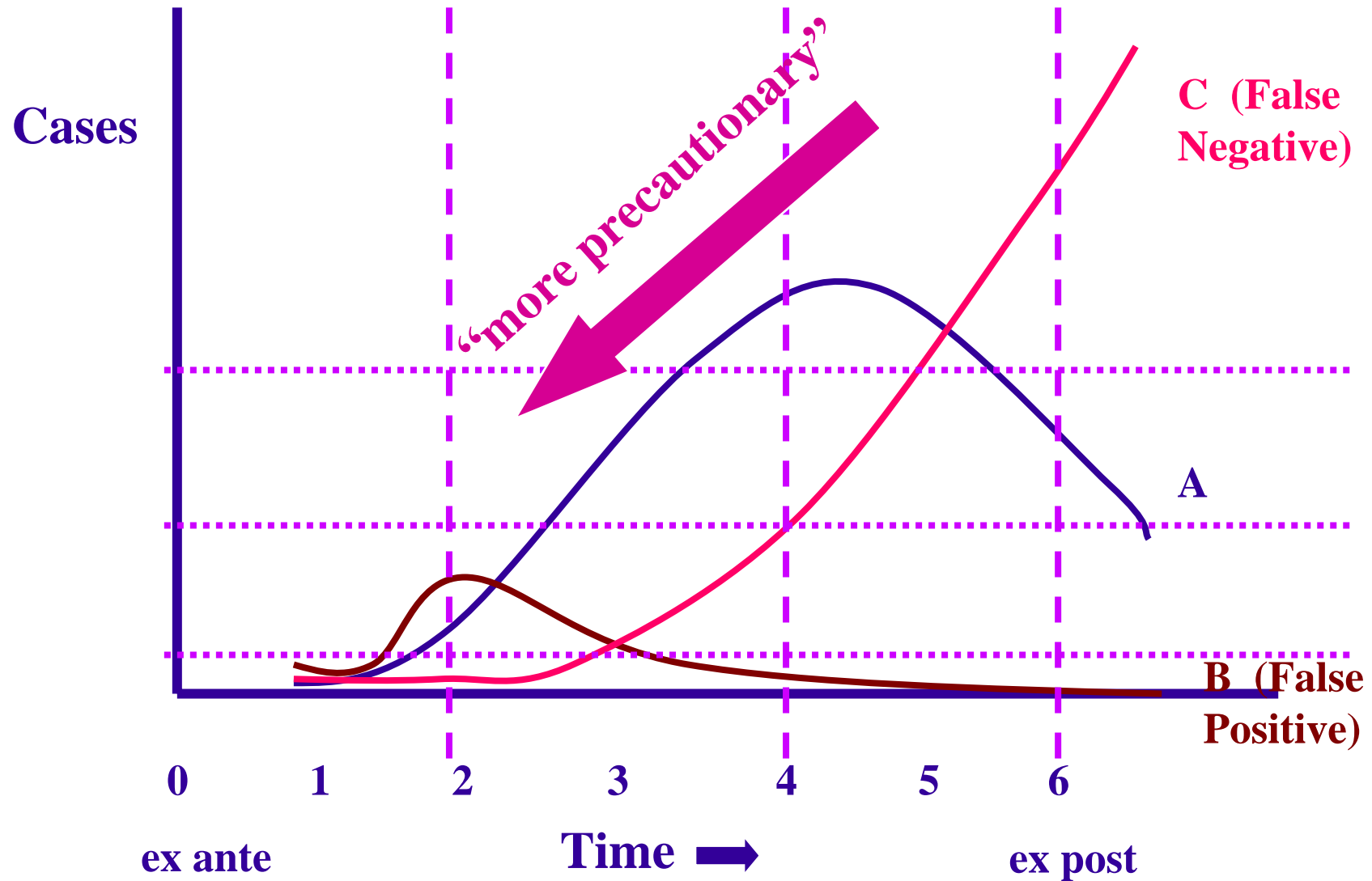
PP version 3: “The proponent of an activity posing uncertain risk bears the **burden of proving** that the activity poses **[no] / [acceptable]** risk before the activity can go forward.”

E.g.: pre-market screening (e.g. for new drugs, toxics, pesticides); German nuclear licenses. Wingspread 1998. If must prove “no risk,” this is tantamount to a ban; O.Godard calls this the “Abstention Rule.”

## Definition of “The PP” is elusive

- Sandin (1999): 19 different versions
- Stone (2001): no coherent statement, ‘disarray’
- Bodansky (2004): differences on key dimensions, including legal instruction (reason not to postpone action, license to act, duty to act), trigger of application, and what action should be taken; concludes the PP has ‘not moved ... towards consensus’ and ‘the only point of overlap is a truism’
- Jordan & O’Riordan, in Raffensberger & Tickner (1999):  
“Paradoxically, we conclude that the application of precaution will remain politically potent so long as it continues to be tantalizingly ill-defined and imperfectly translatable into codes of conduct, while capturing the emotions of misgiving and guilt ... [I]t is neither a well-defined nor a stable concept. Rather, it has become the repository for a jumble of adventurous beliefs that challenge the status quo of political power, ideology, and environmental rights.”

# Defining Degrees of Precaution



# Precaution as Applied: 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. David Vogel et al. (2000, 2001): Reversal (“flip-flop”) in relative US/EU precaution over 1970-2000

# Stéréotypes transatlantiques ?

## USA

- Favorise les risques (“risk-taking”)
- Optimisme sur la science et la technologie
- Individualisme
- Scepticisme du gouvernement
- Système du droit stricte et formel (“adversarial legalism”)

## Europe

- Évite les risques (“risk-averse”)
- Scepticisme sur la science et la technologie
- Collectivisme
- Favorise le gouvernement
- Corporatisme, système du droit informel

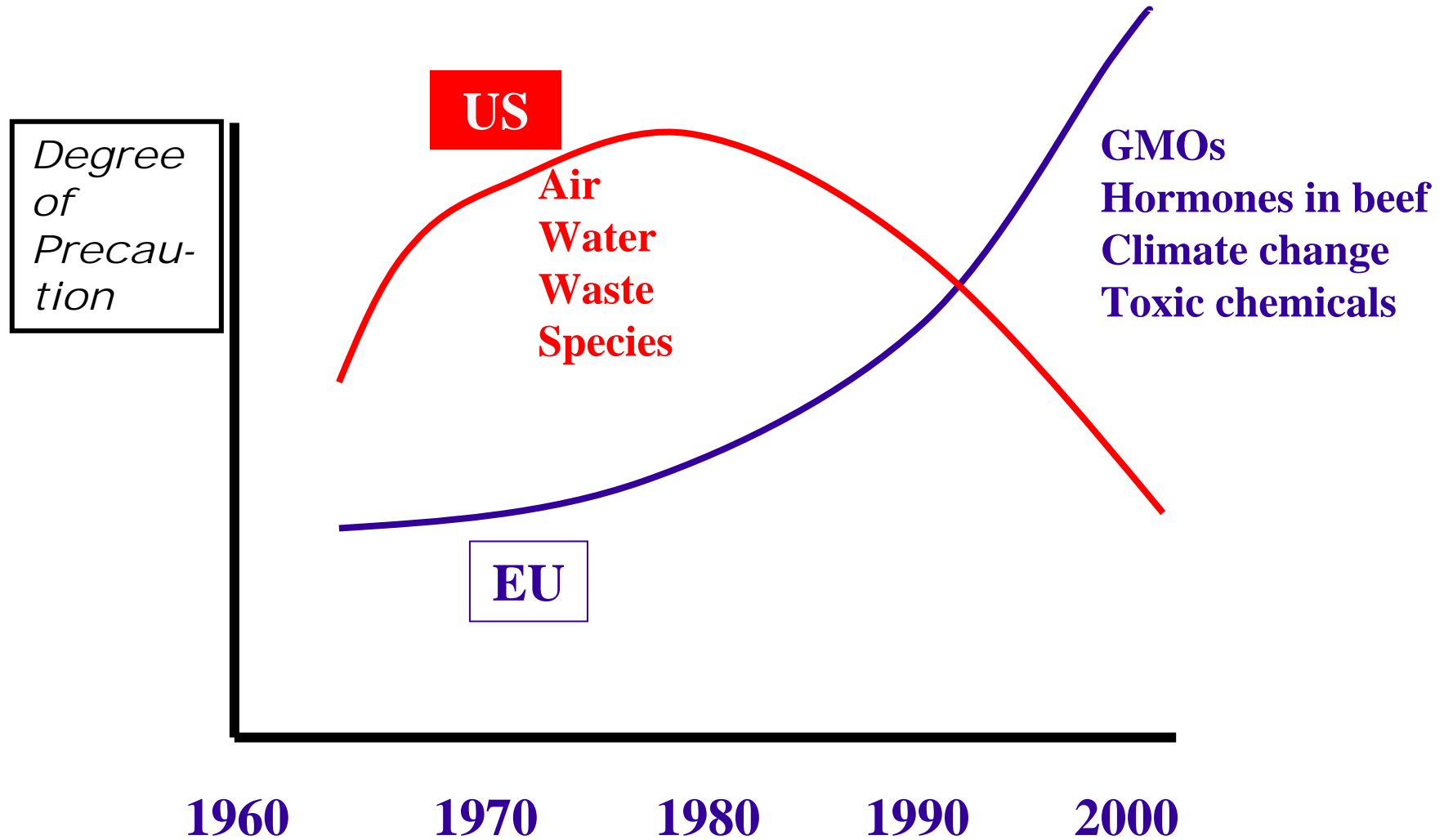
*Mais ces stéréotypes ne décrivent pas la vérité:*

- Reconnus depuis longtemps comme exagérations
  - Oscar Wilde, *The Canterville Ghost* (1887)
- Incompatibles avec changements du temps
- N’expliquent pas des exemples clés
  - Tabagisme, énergie nucléaire

# Risques étonnants à chaque côté de “l'étang” ?

- Aux français qui font un séjour aux États-Unis:
  - Quatre-quats (SUVs)
  - Fusils, armes
  - Émissions de gaz à effet de serre
  - OGM
  - Agriculture et nourriture industrielle
  - Obésité
  - Etc.
- Aux américains en France:
  - Énergie nucléaire
  - Motos sur le trottoir
  - Portes du Métro s'ouvrent avant l'arrêt
  - Pas de barrières sur les quais de la Seine
  - Fèves dans les Galettes de Roi
  - Canicules et peu de climatisation
  - Amiante et désamiantage
  - Fromage pas pasteurisé
  - Tant de tabagisme
  - Etc.

# “Flip-Flop” hypothesis (volte-face) ?



# Flip-Flop: Evidence

EU



- 1970s: Sweden; German “Vorsorgeprinzip”
- 1980s: Marine treaties
- 1990s: Rio treaties. Maastricht Treaty 130r (now 174) adopts PP. Member States adopt PP. ‘No’ to GMOs, beef.
- 2000: Commission issues “Communication on the PP”
- 2001: ECJ on BSE. *Late Lessons*.
- 2002: Action Plan - Better Regulation, Impact Assmts. (BCA)
- ECFI case on antibiotics in feed
- 2006: REACH

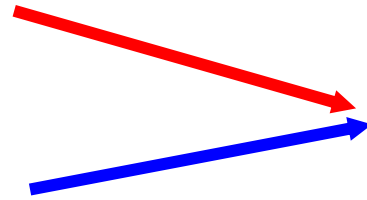
US



- 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.

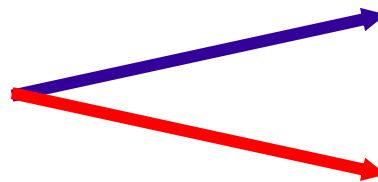
# Several hypotheses for the evolution of US and European policies

- **Convergence**



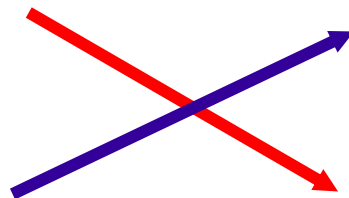
- Globalization yields Harmonization

- **Divergence**



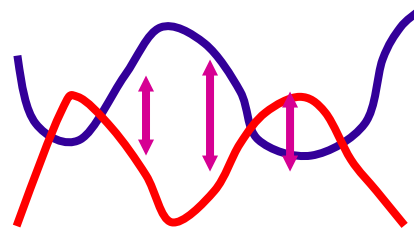
- EU risk-averse, US risk-taking ? Or,
- US adversarial legalism, EU informal corporatist ?

- **“Flip-Flop”**



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

- **“Hybridization”**



- Borrowing, learning (e.g. EIA, ET, BCA, TRI, PP)
- Heterogeneity across & within regulatory systems

# Cautions in Comparing Regulatory Systems

- **Broad claims may be overstated**
  - **Stereotypes clash with dynamic hypotheses**
    - e.g., “Europeans are more risk-averse” while “Americans are technological optimists” (see Oscar Wilde, *The Canterville Ghost* (1887))
    - conflicts with “Flip-flop” (greater US precaution in 1970s)
  - **Comparisons may vary by component:** risk assmt., risk mgmt., review, enforcement
  - **Heuristic exaggeration of inter-group contrasts (Henri Tajfel, social psychology)**
    - Both US and EU are at high end of global spectrum of relative precaution
    - E.g., end of Cold War = rhetorical 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 – cherry-picking.
- **Two methods to test:**
  - **Case Studies**
  - **Aggregate Data**

# **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 --  
Wiener, Rogers, Hammitt, Sand**

## **II. Ten Case Studies of Specific Risks**

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

**Beef: Hormones and BSE – Gray et al.**

**Smoking – Blanke**

**Nuclear power – Ahearne & Birkhofer**

**Automobile emissions – Walsh**

**Climate and Strat. Ozone – Hammitt**

**Biodiversity – Saterson**

**Chemicals – Renn & Elliott**

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

**Terrorism and WMD – Stern & Wiener**

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

**Political Systems – Majone**

**Legal Systems – Bergkamp & Smith**

**Risk Perceptions – Sunstein; Weber**

**Information Disclosure Systems – Sand**

**Risk Analysis Methods – Rogers &  
Charnley**

## **IV. Quantitative Empirical Analysis of Comparative US and EU**

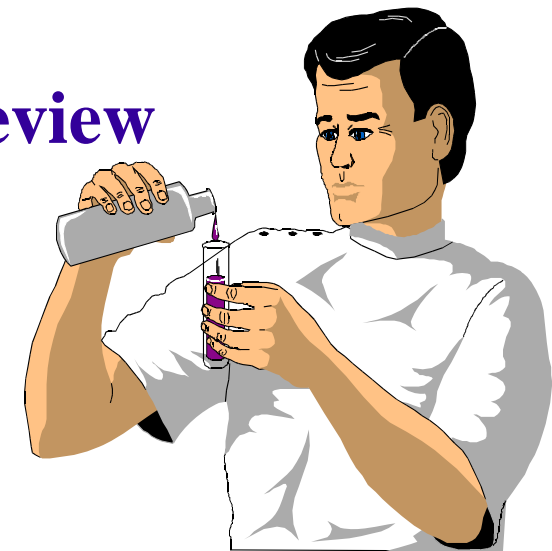
**Precaution – Hammitt, Wiener,  
Swedlow, Kall & Zhou**

# Comparing Choices: Method 1: Case Studies

- **“Narrow and deep” inquiry**
- **Not just GMOs, Climate ... more cases**
- **Fosters pragmatic dialogue, reduces acrimony over abstract rhetoric of “principle”**
- **Sheds light on real policies, consequences, choices**
- **Greater detail on institutional context and process history, and other principles & objectives** (Blomquist), 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”**

# 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: greater US precaution**
  - Molina & Rowland paper 1974
  - Bans on CFCs in aerosols: Oregon 1975, all of US in 1978
  - US halts SST. Europe goes ahead with Concorde.
  - Europe adopts production cap that exceeds current production
  - “Ozone Hole” 1985
  - Montreal Protocol 1987, followed by London, Copenhagen: phaseout
- **Climate Change: greater EU precaution**
  - 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.

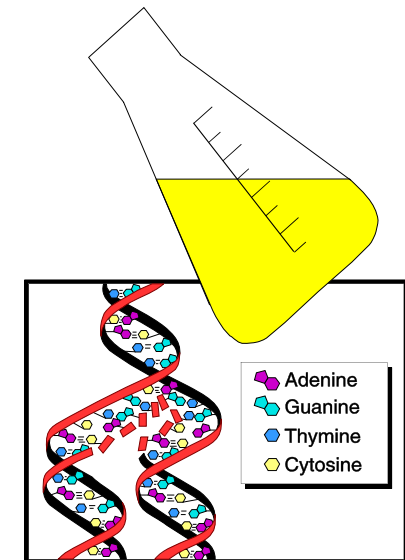
# Hormones in Beef and GM Foods

## 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
- WTO rules against EU; sanctions ... ?



# Chemicals

- USA

- FIFRA (1972)  
“unreasonable risks”
- TSCA (1974)  
“unreasonable risks”
- High Priority  
chemicals

- Europe

- New chemicals
- White Paper
- REACH  
potential
- Swedish

Flip-flop in chemicals regulation:

“Whereas U.S. chemical policy in the 1970s and the early 1980s often acted as an inspiration for European policymaking, the EU has taken over the role as leader in chemical policy development. The EU is increasingly replacing the United States as the de facto setter of global product standards and the center of much global regulatory standard setting is shifting from Washington, DC, to Brussels.”

- Henrik Selin & Stacy VanDeveer, *Environment* magazine 48(10) (Dec. 2006), p.14 (footnotes omitted).

- Compare standards: US still more stringent than WHO for 89 of 111 chemicals (George Gray 2003)

# Nuclear energy

- US
  - 109 civilian nuclear reactors, 20% of electricity
  - De facto moratorium since 1979
- Europe
  - 140 civilian nuclear reactors, 31% of electricity
  - Some countries halting (Sweden, Germany?), some adding (Finland, Belgium?)
  - France
    - 59 reactors, 78% of electricity
    - Public opinion: ~75% of both French and Americans perceive serious risks, but French see greater benefits and put greater trust in expert managers (Slovic et al., 1996)



## “Mad Cow” BSE/vCJD



	<u>UK</u>	<u>EU</u>	<u>USA</u>
<b>Cases of BSE</b>	~ 200,000 (1986-)	~ 2,000 (1990-)	~ 3 (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 (leukodepletion)</b>	No	No	Yes (1999-)

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

## **BSE/vCJD 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**
- **Rules in Europe adopted later and less stringent (despite AIDS blood scandal in France); leukodepletion in UK.**

### **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**
  - **via fuel taxes**
  - **to reduce CO2**
  - **> 20% of passenger vehicle fleet**
- **US: restricts Diesel**
  - **via regs incl. Clinton (on-road) & Bush (off-road)**
  - **to reduce fine Particulate Matter (PM)**
  - **< 3% of passenger vehicle fleet**
- **Simultaneous precaution, but vs. conflicting risks**

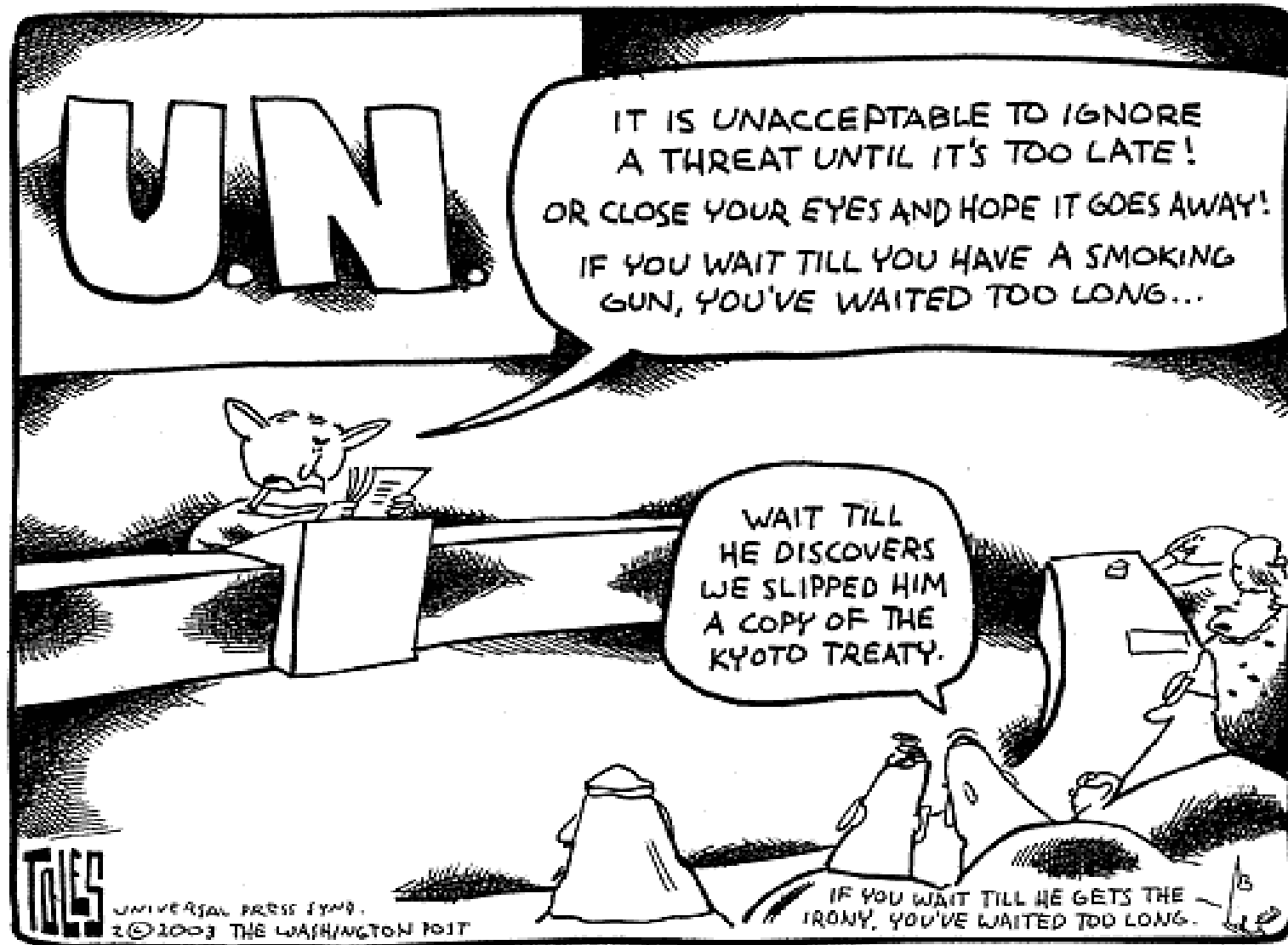
# Terrorism -- Parallel Justifications

- **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, June 2002: “If we wait for threats to fully materialize, we will have waited too long.”**
- **US National Security Strategy, September 2002: “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."**

# Risk Selection – Precautionary Particularity



# More Precautionary Than Thou ?

## Selective application of precaution

**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 ?

## **Method 2: Aggregate Quantitative Data**

(Hammit, Wiener, Swedlow, Kall & Zhou, *Risk Analysis* (2005))

- **Larger database: all risks mentioned in risk literature (254 references) in US and EU, 1970-2004.**
  - **Broad, but shallow.**
  - **Unbiased sampling: random samples**

### **But:**

- **True universe of risks?**
- **Random vs. Representative sampling**
- **Less information regarding foreign law, member state law ?**
- **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 over 1970-2004**
- **Scoring ambiguities: e.g., ambient vs. emissions standards**
- **Scoring of standards, not of implementation & enforcement**
- **Scoring of earliness & stringency, not of degree of uncertainty, and not weighted by severity of risk**

## 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

2,878  
“unique”  
risks  
(recom-  
bining  
essentially  
identical  
“verbatim”  
risks)

In 18  
categories  
and 92  
sub-  
categories

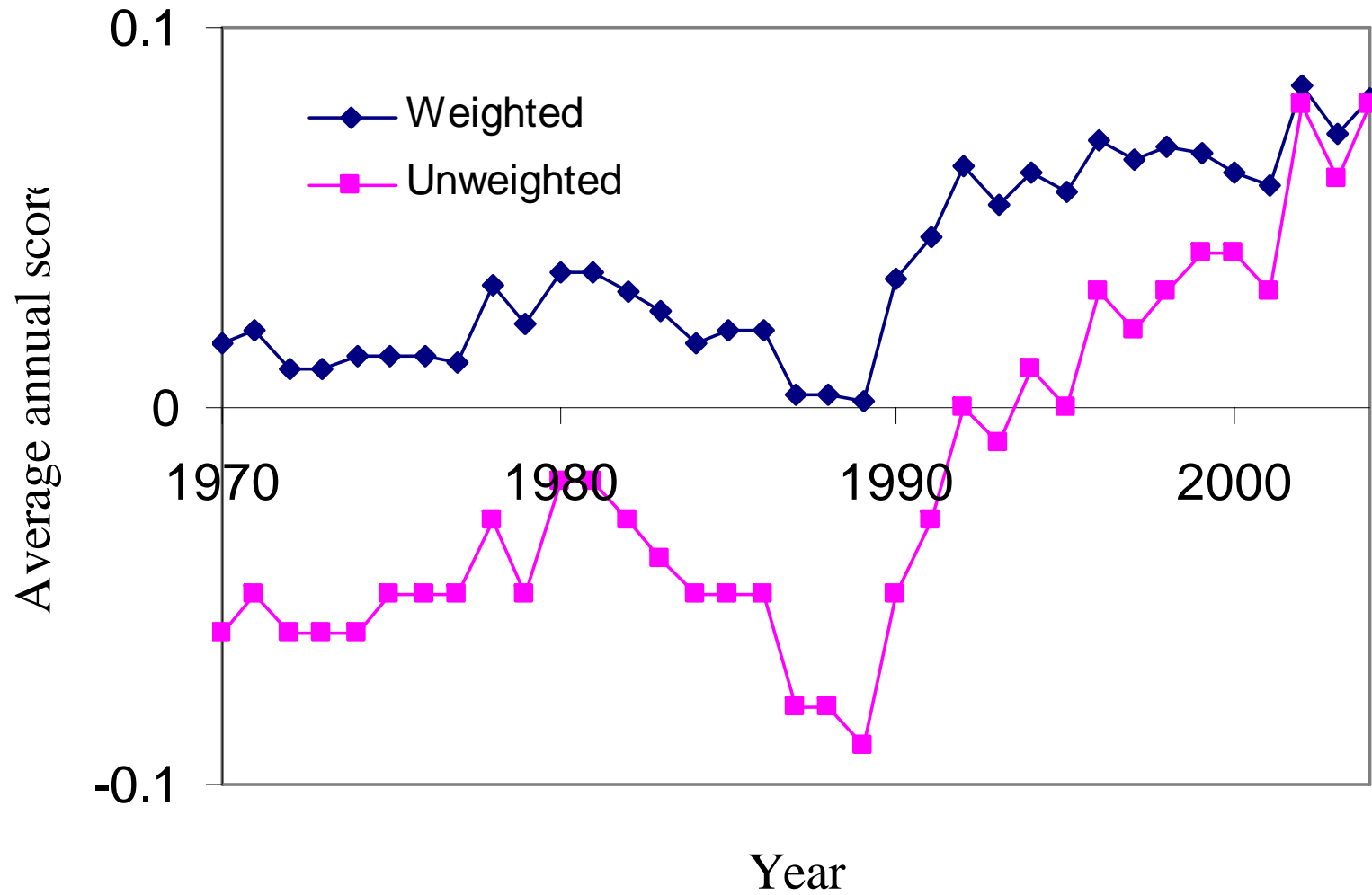
**100 in random  
sample;  
92 in stratified  
random sample**

**Scored each risk in  
each year, 1970-2004:  
+1 if greater EU  
stringency  
0 if tie  
-1 if greater US  
stringency**

**Table I.** Risks by Type

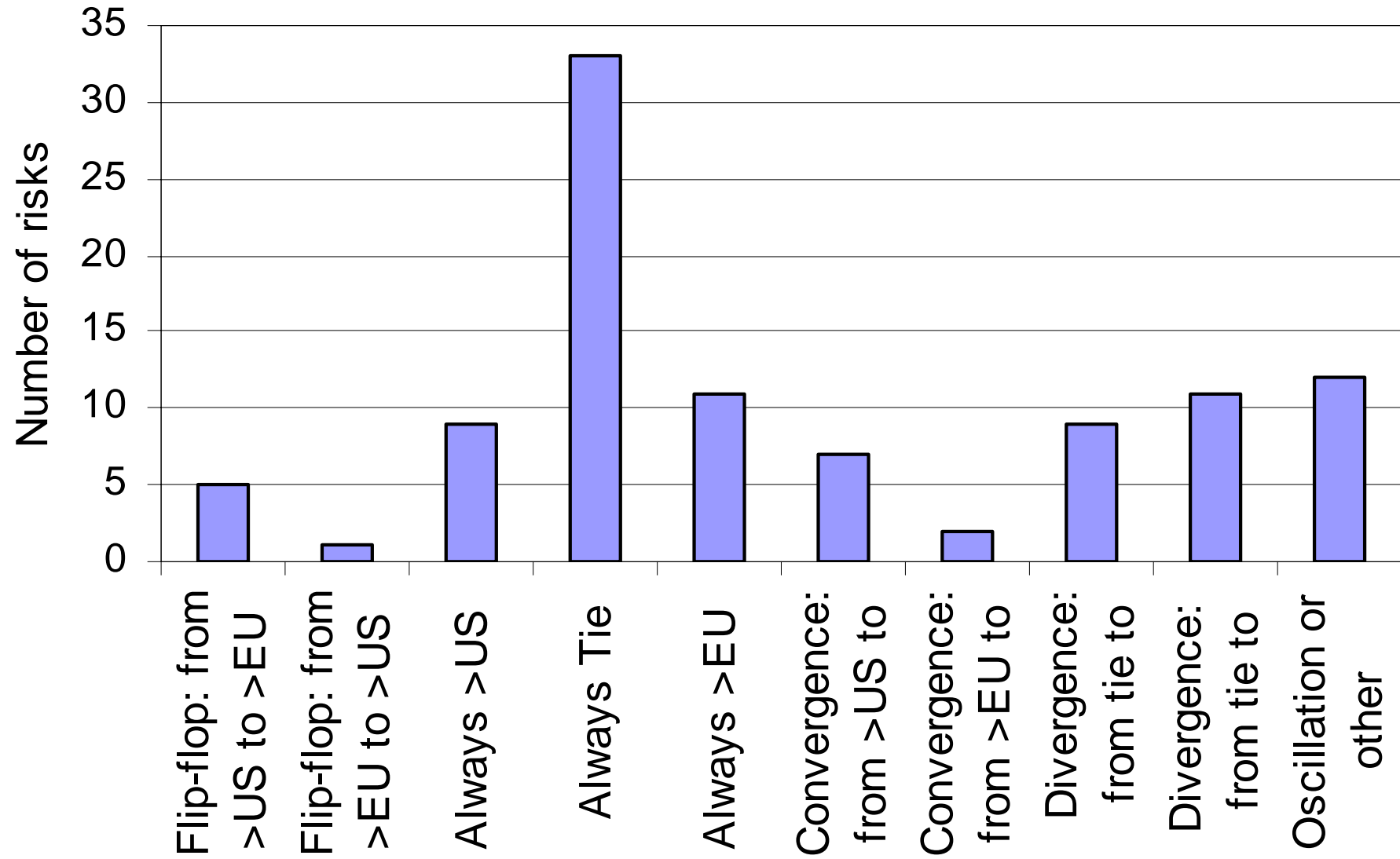
Code	Category	Percentage in:		
			Matrix	Sample
1	Crime and violence	1.8	3	
2	Alcohol, tobacco, and other drugs	3.0	3	
3	Medication and medical treatment	6.8	8	
4	Transportation	8.2	13	
5	Accidents not elsewhere classified	2.4	2	
6	Recreation	5.5	8	
7	War, security, and terrorism		1.5	3
8	Toxic substances		9.8	8
9	Food and agriculture	9.5	9	
10	Pollution		7.5	8
11	Energy production		5.0	3
12	Political, social, and financial	3.4	1	
13	Ecogeological	4.0	2	
14	Global	2.2	1	
15	Human disease/health	9.7	9	
16	Occupational	15.0	17	
17	Consumer products	3.4	2	
18	Construction	1.4	0	
Total percentage		100	100	
Total number		2,878	100	

Figure 1. Trends in relative precaution  
(all risks)



From: Hammitt, Wiener, Swedlow, Kall & Zhou, *Risk Analysis* (October 2005).

Figure 4. Patterns of Relative Precaution

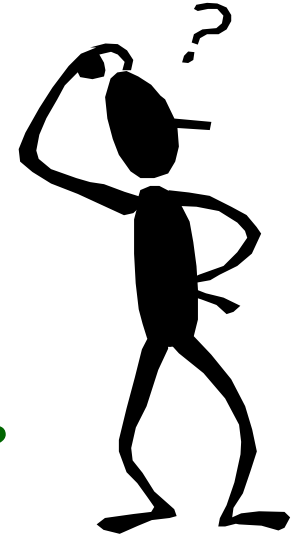


## Summary of Quantitative Sample

- No significant trend over 1970 – 2004
- Slight shift toward relatively more precaution in EU over 1990 – 2004
  - But very slight: <10%, or equivalent to a switch toward greater EU precaution in only 3-6% of sample
- Diversity across risks
  - Shift toward greater EU precaution: 21 risks
  - Shift toward greater US precaution: 14 risks
  - Always equal: 33 risks
  - EU always more precautionary: 11 risks
  - US always more precautionary: 9 risks

# Can we Explain the Complex Pattern?

- **Merits (policies well tailored to each risk, BCA) ?**
- **Protecting domestic interests (industry, culture) ?**
- **Risk perceptions ?**
  - **dread of the unfamiliar, unnatural**
  - **“availability” heuristic (recent crises)**
  - **(dis)trust in institutions**
  - **cultures of risk-taking, risk-aversion**
- **Politics (3rd parties e.g. Greens; parliamentary vs SOP) ?**
- **Legal systems ?**
  - **asymmetric domestic enforcement (US > EU ?) = US reluctance re PP**
  - **ex post remedies (tort law, US > EU) = PP less urgent in US**
  - **proportionality principle as a limit on PP in EU**
  - **centralized regulatory review in US**
- **Other ?**
- **If complex pattern, explanations cannot simply contrast US vs. EU.**
- **Heuristics explain selective application: “availability,” “mass numbing”**

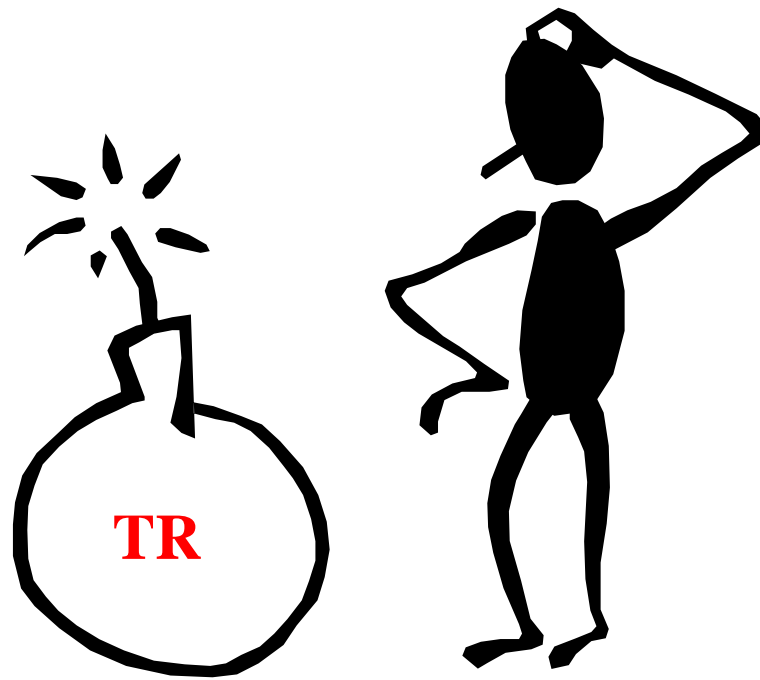


# Reconciling the PP with Decision Analysis

- Early and recent work:
  - Arrow & Fisher, *QJE* (1974)
  - Henry, *AER* (1974)
  - Cross, *Wash. & Lee L. Rev.* (1996)
  - Wiener, *Risk: Health Safety & Environment* (1998)
  - Keeney & von Winterfeldt, *J. Risk Research* (2001)
  - Graham, *J. Risk Research* (2001)
  - Godard, Henry, Lagadec & Michel-Kerjan, *Traité des Nouveaux Risques* (2002)
  - Dekay, Small, Fischbeck, Farrow, Cullen, Kadane, Lave, Morgan, & Takemura, *J. Risk Research* (2002)
  - Stewart, *Research in Law and Economics* (2002)
  - Wiener, in *Human and Ecological Risk Assessment* (2002)
  - Farrow, *Risk Analysis* (2004)
  - Gollier & Treich, *J. Risk & Uncertainty* (2003)
  - Barrieu & Sinclair-Desgagné, *Management Science* (2006)
  - Sunstein, *Worst-Case Scenarios* (2007)
  - Weitzman (2007)
- Key themes: irreversibility, learning (value-of-information, option value), fat tail distributions, risk-risk tradeoffs

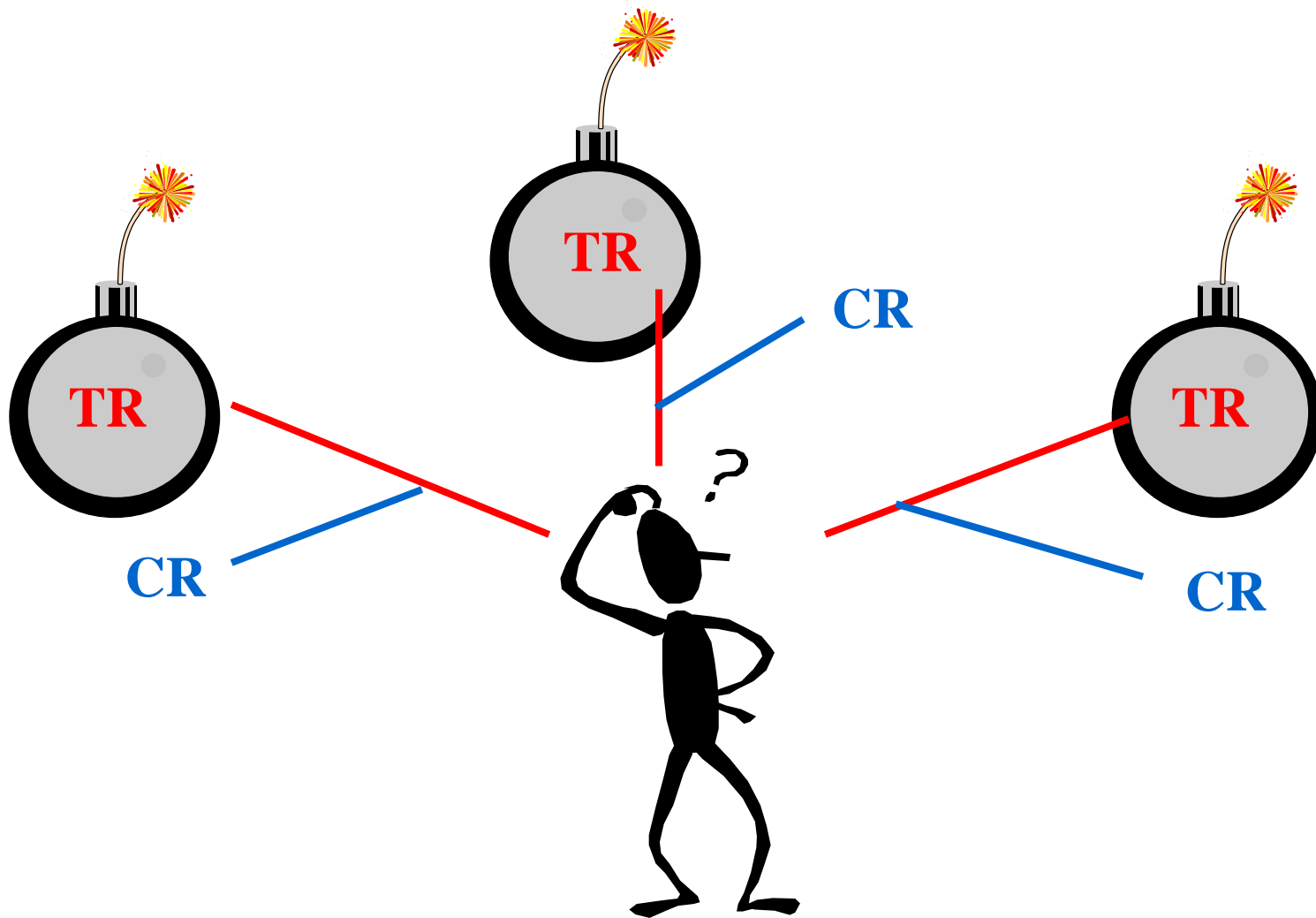
## Conventional Paradigm: One Target Risk (TR).

PP: “better safe than sorry.”

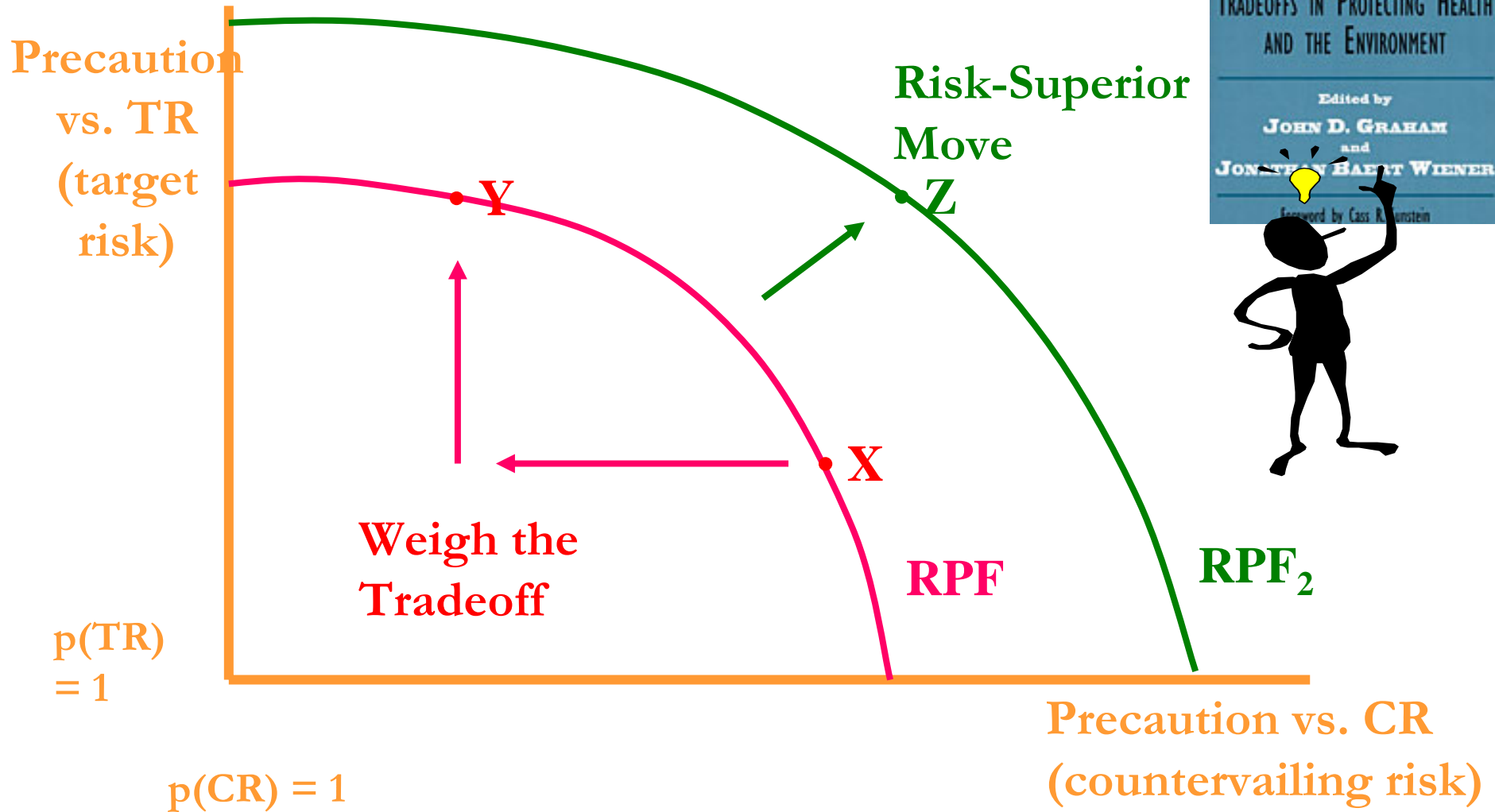
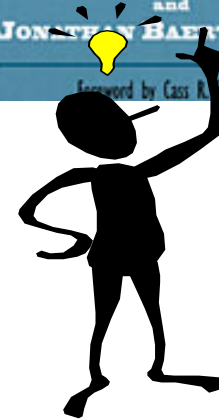
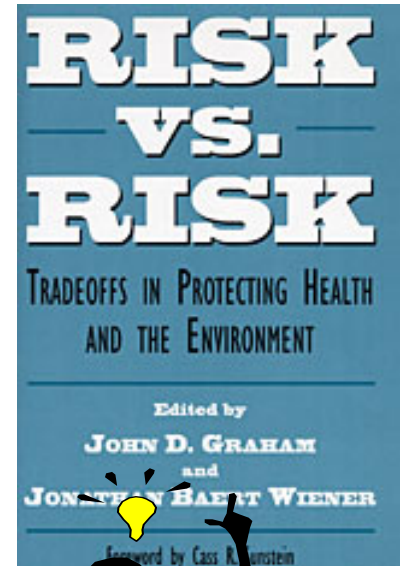


# Reality: Multiple, Interconnected Risks

(TR = target risk, CR = countervailing risk)



# RTA: Risk-Risk Tradeoffs and Risk-Superior Moves



## Risk-Risk Tradeoffs are Pervasive

<u>Intervention</u>	<u>TR</u>	<u>CR</u>	<u>(Risk-superior option?)</u>
• Aspirin	Head	Stomach	(Acetaminophen)
• Toothpaste	Teeth	Fluoride poisoning	
• Vaccines	Most people	Some people	
• Ban foreign blood	vCJD / BSE	Blood shortage	(Synthetic blood ?)
• Chlorinating H <sub>2</sub> O	Microbial	Carcinogen	(Ozonation?)
• Ban DDT	Wildlife	Malaria; farmworkers	
• Airbags in cars	Adults	Kids	(Kids in back; smart airbags)
• Reduce trop. O <sub>3</sub>	Lungs	Skin/UV	
• Ban asbestos	Lungs	Highway braking	
• Pollution Control	Public	Workers	
	(Superfund & other cleanups; Pesticides; EPA-OSHA)		
• Suppress forest fires	Some fires	Worse fires	
• Police chases	Catch suspects	Bystanders	
• War on drugs	Drug use	Violence	

# Uncertainty, Irreversibility, and Multiplicity

- The PP and many analyses focus on a single risk, for which uncertainty & irreversibility warrant precaution
- But:
  - All risks are uncertain; the real question is what actions to take, against which risks
  - Focusing on more uncertain risks skews policy away from more certain risks
  - Uncertainty & irreversibility likewise apply to the *countervailing risks* induced by precautionary interventions
- Thus the more important issue is *multiplicity of risks*: assessing the full portfolio of risk-risk consequences for each policy option

## Reality: Qualification of the PP to account for other social goals

- Early versions of the PP spoke in absolutes:
  - US Clean Air Act (sec. 109) and Endangered Species Act (sec. 7): courts in 1970s interpret to authorize precaution, but to bar consideration of cost
  - UN World Charter for Nature (1982): “where potential adverse effects are not fully understood, the activities should not proceed.”
- Qualification over time: PP spurs its own moderation
  - New Deal (1930s) → Administrative Procedure Act (1946)
  - Great Society (1960s) → Presidents’ orders on Impact Assessment (1978, 1981, 1985, 1993, 2007)
  - Framework Convention on Climate Change (1992), art. 3.3, adds “cost-effective”
  - French Loi Barnier (1995) adds “economically acceptable cost”
  - European Commission, Communication on the PP (2000)
  - French Environment Charter (2004-05)
  - European “Better Regulation” / Impact Assessment (2001- )

# Qualification of PP in European Union (EU) Law

- Nice Treaty article 174(2) requires the “precautionary principle” (undefined), and article 174(3) requires assessing “the potential benefits and costs of action or lack of action” in environmental policy (OJ C 325, 24 Dec. 2002).
- “Proportionality Principle” = BCA
- “Precautionary Principle”: European Commission, “Communication” of Feb. 2000: PP requires BCA.
- Member states’ laws: sometimes require BCA (including in adoption of PP).
- “Better Regulation” initiative (2002 - ).

## BCA: not a new idea

**Benjamin Franklin, letter to Joseph Priestley, Sept. 19, 1772:**

“In the Affair of so much Importance to you, wherein you ask my Advice, I cannot for want of sufficient Premises, advise you *what* to determine, but if you please I will tell you *how*. When those difficult Cases occur, they are difficult, chiefly because while we have them under Consideration, **all the Reasons *pro* and *con* are not present to the Mind at the same time**; but sometimes one Set present themselves, and at other times another, the first being out of Sight. . . .

“To get over this, my Way is, to divide half a Sheet of Paper by a Line into **two Columns**; writing over the one **Pro**, and over the other **Con**. Then during three or four Days Consideration, I put down under the different heads short Hints of the different Motives, that at different Times occur to me, *for* or *against* the Measure. When I have thus **got them all together in one View**, I endeavour to **estimate their respective Weights** . . . and thus proceeding I find at length where the Ballance lies . . .

“And, tho’ **the Weight of Reasons cannot be taken with the Precision of Algebraic Quantities**, yet, when each is thus considered, separately and comparatively, and **the whole lies before me, I think I can judge better, and am less liable to make a rash Step**; and in fact I have found great Advantage from this kind of Equation, in what may be called ***Moral or Prudential***

# Reconciling the PP with Decision Analysis – at the European Commission

- European Commission, “Communication on the Precautionary Principle” (February 2000): measures based on the PP should be:
  - *proportional* to the chosen level of protection,
  - *non-discriminatory* in their application,
  - *consistent* with similar measures already taken,
  - *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an *economic cost/benefit analysis*),
  - *subject to review*, in the light of new scientific data, and
  - *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.

## French version of the PP

Charte de l'Environnement de la France (février 2005), article 5:

« Lorsque la réalisation d'un dommage, bien qu'**incertaine** en l'état des connaissances scientifiques, pourrait affecter de manière **grave et irréversible** l'environnement, les autorités publiques veilleront, par application du **principe de précaution**, et dans leurs domaines d'attribution, à la mise en œuvre de procédures d'évaluation des risques et à l'adoption de **mesures provisoires et proportionnées** afin de parer à la réalisation du dommage »

# EU “Better Regulation” Initiative

- EU White Paper on Governance, Mandelkern Group Report (2001)
- Impact Assessment (IA) of proposed legislation
  - IA Guidelines (2002) (Prodi Comm’n). After Santer: ‘Good governance.’
  - Revised IA Guidelines (2005, 2006) (Barroso Commission) require BCA (“positive and negative impacts” of each option, incl. no action; direct & indirect impacts). Lisbon Agenda: ‘competitiveness.’
  - Analysis “proportionate” to significance of impacts.
  - Of the 70 Extended IAs in 2003-05, fewer than 40% quantify and monetize either Bs and Cs; only 17% compared net benefits (Renda 2006, p.63).
- Administrative Cost reduction. Simplification (repealing, revising old laws).
- Subsidiarity. Consultation.
- Issues:
  - Too much focus on Administrative Costs and Simplification ?
  - Any central oversight mechanism such as OMB/OIRA ?
  - Quality of IAs uneven
  - Attention to risk-risk tradeoffs? Ad hoc ex’s: BSE in blood; counterterrorism.
  - Member State programs vary
  - What influence on key decisions? e.g. REACH

Variation in Better Regulation measures across the EU member states.

(Source: European Commission, “Communication on Better Regulation for Growth and Jobs in the EU,” COM(2005)97, 16/03/2005, p.17.)

	Better regulation programme	Specific RIA policy	Obligatory RIA	Alternative instruments considered	Guidelines on RIA	Coordinating body for RIA	Consultation part of RIA	Formal consultation procedures	Direct stakeholder consultation	Tests of impact on small enterprises	Exemptions for SMEs	Total Y+(Y)
Belgium	(Y)	N.A.	(Y)	N.A.	(Y)	(Y)	N	(Y)	(Y)	(Y)	N	7
Czech Republic	Y	N.A.	N	Y	N.A.	N.A.	N.A.	N.A.	N.A.	(Y)	N	3
Denmark	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	10
Germany	Y	N.A.	N.A.	N.A.	Y	Y	Y	Y	N.A.	N.A.	N.A.	5
Estonia	N	N	Y	Y	Y	N.A.	N.A.	N	N	N.A.	Y	4
Greece	(Y)	(Y)	N	N	N	N	Y	N	N	N	N.A.	3
Spain	Y	(Y)	Y	Y	(Y)	(Y)	N	N	N	N	N.A.	6
France	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	0
Ireland	Y	N	N	(Y)	(Y)	N	(Y)	(Y)	N	N	N	5
Italy	(Y)	Y	N	(Y)	Y	(Y)	(Y)	N	Y	(Y)	N	8
Cyprus	N	N	N	N	N	N	N	N	N	N	N.A.	0
Latvia	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	N	9
Lithuania	N.A.	Y	Y	Y	Y	N.A.	N.A.	N.A.	N	N.A.	N.A.	4
Luxembourg	Y	N.A.	Y	Y	N.A.	Y	Y	Y	N	N	Y	7
Hungary	Y	(Y)	Y	N	N	Y	(Y)	(Y)	N	N	N	6
Malta	Y	N.A.	N.A.	N	N.A.	(Y)	N	N	Y	N	Y	4
Netherlands	Y	Y	N.A.	Y	Y	Y	N	N	Y	(Y)	Y	8
Austria	Y	Y	Y	Y	Y	N	Y	Y	Y	N.A.	N	8
Poland	Y	Y	Y	Y	Y	Y	Y	Y	(Y)	N	Y	10
Portugal	N	N	N	N	N	N	N	N	N	N	N	0
Slovenia	Y	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	1
Slovakia	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	(Y)	N.A.	N	1
Finland	Y	Y	Y	Y	Y	(Y)	Y	Y	Y	N.A.	N.A.	9
Sweden	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	9
United Kingdom	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	10
Total Y+(Y)	19	13	12	15	15	14	12	12	11	7	5	

Legend

Y	Measures exist	(Y)	Measures planned/ Available partially	N	No measures exist	N.A.	Information not available
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# The EU's new Impact Assessment Board (IAB)

- IAB, launched November 2006:
  - “group of high-level officials selected on the basis of their expert knowledge and experience” [Deputy Secretary General & 4 Directors of DGs Enterprise, Environment, Employment, Economics & Finance]. 2-year terms.
  - “under the direct authority of the President of the European Commission and independently of departmental influence” – but nominated by the DGs
  - Initial focus on “quality control of draft final IAs”; will gradually address earlier stages in the IA process
  - Can issue prompt letters on “additional initiatives that could be subject to IA.”
  - Review is to be “qualitative” and “proportionate”
- Questions:
  - Adequate staff, with expertise? Funding?
    - Can seek “internal” and “external” expertise. In the Mmbr States? the US?
  - Timeline too tight (1 month to review draft IA, 1 meeting to decide) ?
  - Power to influence decisions? Can issue “opinions on IAs,” “prompt letters” [to do an IA], and “notes,” but effect on decisions is unclear.
  - IAB members too loyal to their DGs?
  - Will a 5-member board have trouble making decisions?
  - Transparency, access?

# Implications: The Reality of Precaution

- **Reality: complex pattern of Parity and Particularity.**
  - Neither EU nor US is *generally* more precautionary than the other.
  - Must study wide array of cases (not just rhetoric or recent visible examples)
  - Highly contextual, risk-specific
  - Selective application: “Precautionary particularity,” not principle
  - Illustrates conflicting social objectives, law, politics
  - Illustrates heuristic influences on risk selection
  - Weakens claim that PP = customary international law. No clear state practice.
- **Reality: actual Precautionary regulation is often moderated, qualified. The PP needs decision analysis.**
  - False negatives (and fat tails), but also False Positives, Costs
  - Learning, Value-of-information, Option value
  - Risk-Risk tradeoffs from precaution
  - Increasing use of Impact Assessment, Benefit-Cost Analysis
  - Goal should be: Prudent, or Optimal, Precaution

# Opportunity in Europe: “Even Better Regulation”

- Not just Administrative Cost. Broader: Integrated Impact Assessment of full portfolio effects.
- Use BCA more broadly and evenhandedly:
  - Good to cover Legislation as well as rulemaking
  - Use “Warm analysis”: full portfolio effects framework, not narrow quantification
  - Use BCA to “Prompt” good policies (“Yes”) as well as to reject bad policies (“No”)
  - Use BCA more widely: not just for regulation but also for trade measures, subsidies, projects, forest management, counterterrorism measures.
  - Use Risk-Risk Analysis as well as (or as part of) BCA – to evaluate the full portfolio effects of policies in a multi-risk world
- Create an expert central oversight body, akin to OMB/OIRA. New IAB. Member States’ expert groups.
- Conduct ex post evaluations of ex ante assessments: to revise policies, and to improve ex ante RIA methods
- Cultivate a culture of reasoned analysis
- Learning: over time, across agencies, across countries.
  - The EU should not just imitate the US: learn, do better than the US, and adapt to EU setting.
  - The US can borrow back. A transatlantic policy laboratory.

## Future Directions ?

- Will Better Regulation / Impact Assessment moderate the PP ?
  - Is REACH consistent with “Better Regulation”?
  - Whither GMOs ?
  - Climate change, post-Kyoto Protocol ?
  - After the Iraq War, will the USA moderate its security strategy?
- Will the US and EU converge on “Better Regulation”?
  - “Warm analysis”
  - Effective oversight of regulation (OIRA, IAB)
- Will crisis events drive new waves of regulation?
- What of the PP and risk policy in the rest of the world ?