# The Reality of Precaution: Comparing Risk Regulation in the US and Europe ~ and ~ The Global Diffusion of Regulatory Oversight

#### Jonathan B. Wiener

Perkins Professor of Law, Environmental Policy, and Public Policy,
Duke University
USA

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# **Comparing risk regulation**

- Is European risk regulation "more precautionary" than American risk regulation?
  - Always? different cultures of risk?
  - Recently? Vogel (2012) asserts a shift since about 1990, from greater US precaution toward greater EU precaution
  - Or are the US and EU selective precautionary as to different risks?
- Are there distinctive national styles of regulation?
  - Or is the reality more fluid and complex diffusion, borrowing?
- What is the real pattern of precaution? Why?
  - (Wiener, Hammitt, Rogers, Sand, Swedlow, et al., 2011, 2013)
- Implications for:
  - Better methodology for comparing regulation
  - Better regulatory policy

# Claims of divergent risk cultures

#### Europe seen as:

- Risk-averse
- Skeptical of technology
- Collectivist
- Favorable toward government
- Informal, corporatist

#### USA seen as:

- Risk-taking
- Optimistic about technology
- Individualist
- Skeptical of government
- Adversarial, legalistic

"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 But:

- Long understood as caricatures, stereotypes, parodies
  - de Beaumarchais, *The Barber of Seville* (1773); James Fenimore Cooper, *Precaution* (1820); Oscar Wilde, *The Canterville Ghost* (1887)
- Inconsistent with claims of significant change over time
  - e.g. claim of reversal from greater US precaution in 1970-90
- Inconsistent with variation within EU, within US
- Inconsistent with variation across risks, e.g. tobacco, nuclear, air, food
- Culture evolves with risk selection (Jasanoff 1986, 2005)

# Claims of national regulatory styles/origins

- Comparative law: legal systems/families (e.g. Zweigert & Kotz 1998)
- Vogel 1986: "national styles of regulation"
  - But: Vogel (2012) concedes that risk regulation has not adhered to stable national styles he now claims a US-EU "reversal"
  - Jasanoff (1986, 2005): regulatory culture evolves
- La Porta, Lopez-de-Silanes, Shleifer, Vishny (LLSV) (e.g. *J. Econ. Lit.* 2008; World Bank "Doing Business" country rankings): "legal origins" explain modern regulation
  - Focused on business start-up, finance, employment
  - But: LLSV (2008) observe that legal origins do not explain "new spheres of social control," nor regulation spurred by crisis events
- From discrete systems to variation, diffusion, hybridization: Watson 1993; Slaughter 2004, 2009; Wiener et al. 2003, 2011

# Claims of reversal: From greater US to greater EU precaution

# EU \*\*\*

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

"Americans seem to be pragmatic about new ideas and inventions. Europeans tend to worry. ... a pervasive technophobia ... -- T.R. Reid, Wash. Post, 2001

"Precaution is for Europeans" – NY Times, April 2003

"Europe is considered fairly riskaverse ... America, on the other hand, is often seen as having a strong risk-taking culture" – *The Economist*, 24 January 2004 <u>View espoused</u>

y:

**EU officials** 

**NGOs** 

News media

"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

**Scholars** 

E.g. David Vogel (2001, 2003, 2012), Anu Bradford (2012): Shift/Reversal ("flip-flop") in relative US/EU precaution from 1970-90 to 1990-2012

# Vogel's claim of reversal in US/EU precaution

#### David Vogel, 2012. The Politics of Precaution (Princeton Univ. Press):

"Around 1990, the locus of transatlantic regulatory policy innovation and global regulatory leadership began to shift. While American policy makers previously had been 'quicker to respond to new risks, more aggressive in pursuing old ones,' more recently it is European policy makers who have been more likely to identify new risks and been more active in attempting to ameliorate existing ones. Europe has not simply 'caught up' to the United States; rather, many of the risk regulations adopted by the EU since 1990 are now more stringent and comprehensive than those of the American federal government. In 'many policy areas [the EU] has taken over the role of world leader,' a role formerly played by the United States. ... To borrow Lennart Lundqvist's influential formulation, ... since around 1990 the American federal regulatory policy 'hare' has been moving like a 'tortoise,' while the pace of the European 'tortoise' resembles a 'hare.' - p.4.

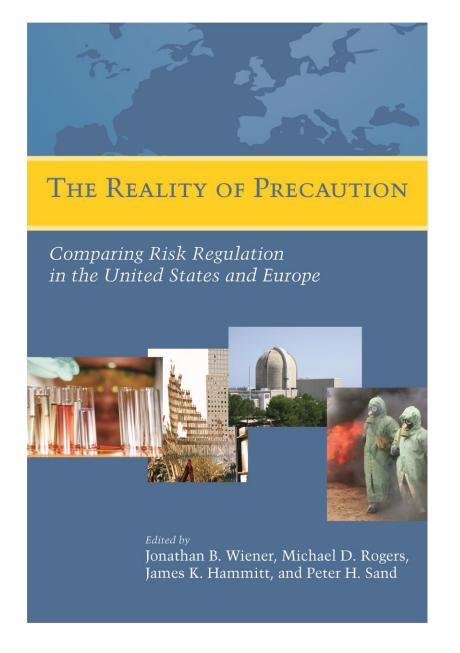
"Recent European regulations are likely to be more stringent and often more precautionary than those of the United States for those health, safety, and environmental risks that have emerged or become more salient since around 1990, such as global climate change, genetically modified food and agriculture, antibiotics in animal feed, hazardous materials in e-waste, and chemicals in cosmetics." -- p.6.

Asserted causes of this claimed shift:

public opinion; leadership priorities; criteria for policymaking.

# The Rise of the "Precautionary Principle"

- 1970: German Vorsorgeprinzip
- 1976: US DC Circuit Court of Appeals decision in *Ethyl Corp* v. US (Clean Air Act = "precautionary")
- [1980: US Supreme Court decision in *Benzene*]
- 1992: Rio Declaration, paragraph 15
- 1992: Maastricht Treaty, art. 130r (now TFEU, art. 191)
- 2000: European Commission, "Communication on the PP"
- 2005: Charte de l'Environnement de la France
- Diffusion of the PP: widely adopted, e.g. Australia, Canada, ...



Testing the claims:

- •4 conferences the "Transatlantic Dialogues on Precaution"
- •27 authors
- •a dozen case studies on specific risks
- •a large-N quantitative study
- •cross-cutting chapters on institutions and perceptions
- •concluding synthesis chapter

(RFF Press/Earthscan/Routledge, 2011)

# The Reality of Precaution

Edited by J.B.Wiener, M.D.Rogers, J.K.Hammitt, P.H.Sand (RFF Press/Earthscan/Routledge, 2011)

- I. Introduction
- The Rhetoric of Precaution Wiener
- **II.** Case Studies of Specific Risks
- **Genetically Modified Foods Lex & Cantley**
- **Beef Hormones and BSE Gray et al.**
- **Smoking Tobacco Blanke**
- Nuclear Power Ahearne & Birkhofer
- **Automobile Emissions Walsh**
- Climate and Strat. Ozone Hammitt
- **Biodiversity Saterson**
- **Marine Environment Freestone**
- **Chemicals Renn & Elliott**
- Medical Errors, new drug approval and patient safety Miller
- **Terrorism and WMD Stern & Wiener**

- III. Information Systems
- **Information Disclosure Sand**
- Risk Analysis Methods Rogers & Charnley
- IV. Quantitative Empirical Analysis of Comparative US and EU Precaution – Swedlow, Hammitt, Wiener, Kall & Zhou
- V. Explanations?
- Political Systems Majone
- Legal Systems Bergkamp & Smith
- Perceptions and Culture Weber & Ancker
- **Perceptions and Selection Sunstein**
- VI. Conclusions
  - The Real Pattern of Precaution Wiener

# 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 is has become the repository for a jumble of adventurous beliefs that challenge the status quo of political power, ideology, and environmental rights."

# **Defining Precaution: Narrative Versions**

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

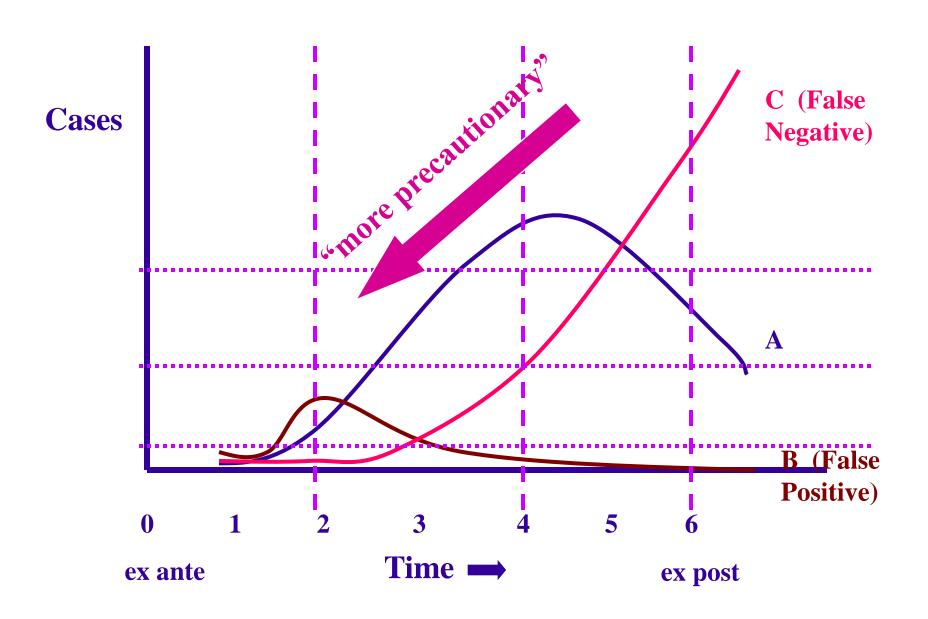
E.g.: Bergen 1990; Rio 1992 (plus "cost-effective"); European Commission Communication 2000 (with qualifications).

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."

# **Defining Degrees of Precaution**

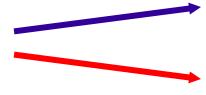


# Hypotheses for comparative precaution in the US and Europe over time

Convergence

• Globalization yields Harmonization?

Divergence



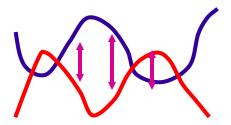
EU risk-averse,US risk-taking?

• Reversal/"Flip-Flop"



• US more PP in 1970s, EU more PP since 1990s?

"Hybridization"



• Diffusion, borrowing, learning?

# **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" conflicts with "reversal" (greater US precaution in 1970s)
  - Comparisons may vary by component: risk assessment, risk management, review, enforcement; and across different laws, agencies, topics
  - Heuristic exaggeration of inter-group contrasts (Henri Tajfel, social psychology)
    - Both US and EU are at high end of global spectrum of relative precaution
    - End of Cold War = rhetorical contest for leadership?
  - **Sampling bias:** broad claims based on just a few recent visible cases (e.g.: GM foods). Sampling by convenience cases under the streetlamp cherry-picking. The "availability heuristic" in politics replicated in research.
- Methodologies:
  - Case Studies
  - Aggregate Data

# **Comparing Precaution: Method 1: Case Studies**

- "Narrow, but deep"
- 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

#### But:

- Sampling bias undermines attempts to generalize from unrepresentative sample
- Vogel's "scope": HSE risks caused by business (unclear why; and our cases also fit this scope)
- Contrary cases help rebut claimed generalization, but sampling problem remains "my cases vs. your cases"

# **New Drug Approval**

(Miller, chapter 11)

- 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**

(Hammitt, chapter 7)

#### 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 CO2 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**

(Lex & Cantley, chapter 2)

#### 6 hormones in beef, rBST in dairy:

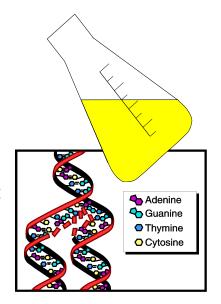
- EU banned in 1989; US, Canada sued
- WTO ruled against EU in 1997, 1998

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**

(Renn & Elliott, chapter 10)

#### • USA

- FIFRA (1975): new pesticides require approval.
- TSCA (1976): new chemicals require approval.
- High Production Volume (HPV) testing program for existing chemicals (1990s ).
- TSCA reform?

#### Europe

- New chemicals require approval (1981).
- White Paper (2001).
- REACH (2006): requires testing of existing chemicals, sorting by potential risk. Removes new/old distinction.
- Swedish goal: Toxics-Free Society by 2020.

### **Reversal in Chemicals Policies**

- "Years ago ... the United States was the acknowledged global pioneer of tough new laws that aimed to safeguard the public from chemicals considered risky. Today, the United States is no longer the vanguard. Instead, the planet's most stringent chemical policies ... are often born in Stockholm and codified in Brussels." Cone, *LA Times* (2005)
- "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).
- Is REACH really precautionary?

# **Nuclear energy**

(Ahearne & Birkhofer, chapter 5)

- 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

(Gray et al., chapter 3)

UK	$\mathbf{EU}$	USA
~ 200,000	~ 2,000	~ 3
(1986-)	(1990-)	(2003 - )
No	<b>Temporary</b> (1996-99)	Yes (1989-)
Yes	Yes	Yes
Yes	Yes	(1997) No
Yes	No	No
No	Yes (2000)	No
No (leukodepletion)	No	Yes (1999-)
	~ 200,000 (1986-) No  Yes (1988) Yes (1989) Yes (1996) No	~ 200,000

## **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?

## **Automobiles and Fine Particle Emissions**

(Walsh, chapter 6)

- 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) emissions
    - PM deaths/year in US: ~50,000; in EU: ~350,000.
  - < 3% of passenger vehicle fleet
- Simultaneous precaution, but vs. conflicting risks

# Terrorism – Borrowing Justifications (reversal in the opposite direction)

(Stern & Wiener, chapter 12)

- 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." (SEHN)
- European Environment Agency, January 2002: "Forestalling disasters usually requires acting before there is strong proof of harm."
- EU Env't Commissioner Margot Wallstrom, April 2002: "If you smell smoke, you don't wait until your house is burning down before you tackle the cause."

- 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 ..."
- (In 2010, the Obama administration revised the NSS to "carefully weigh the costs and risks of action against the costs and risks of inaction.")
- Foreign and domestic measures

# **Terrorism – Reversal of 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."

# Parity and Particularity: Selective Precaution

EU



#### 1970s - 80s:

- Marine environment
- Guns

#### **1990s - present:**

- Hormones in Beef, rBST
- GM foods / crops
- Climate change
- Toxic Chemicals

# US



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

#### **1990s - present:**

- Mad Cow (BSE/vCJD) in Beef, Blood
- Tobacco smoking
- Particulate Matter (PM) air pollution
- Terrorism/Security

# **Method 2: Aggregate Quantitative Data**

(Swedlow et al., chapter 15)

- 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
(recombining
essentially
identical
"verbatim"
risks)

In 18 categories and 92 sub-categories

100 in random sample;

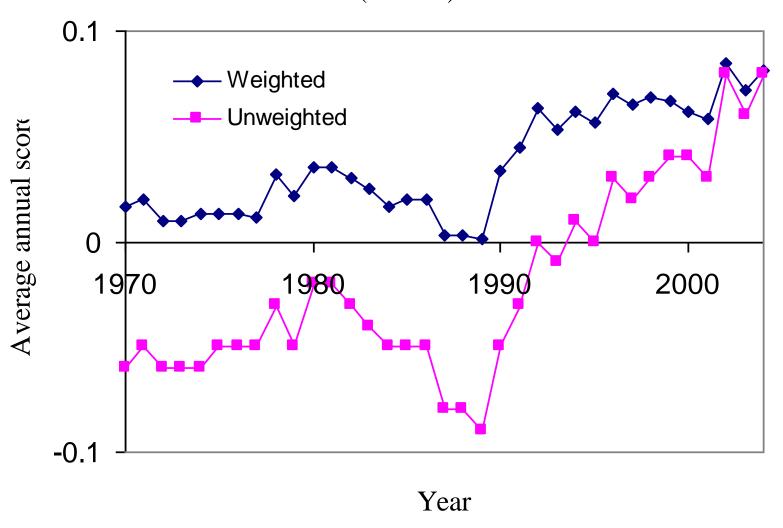
92 in stratified random sample

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

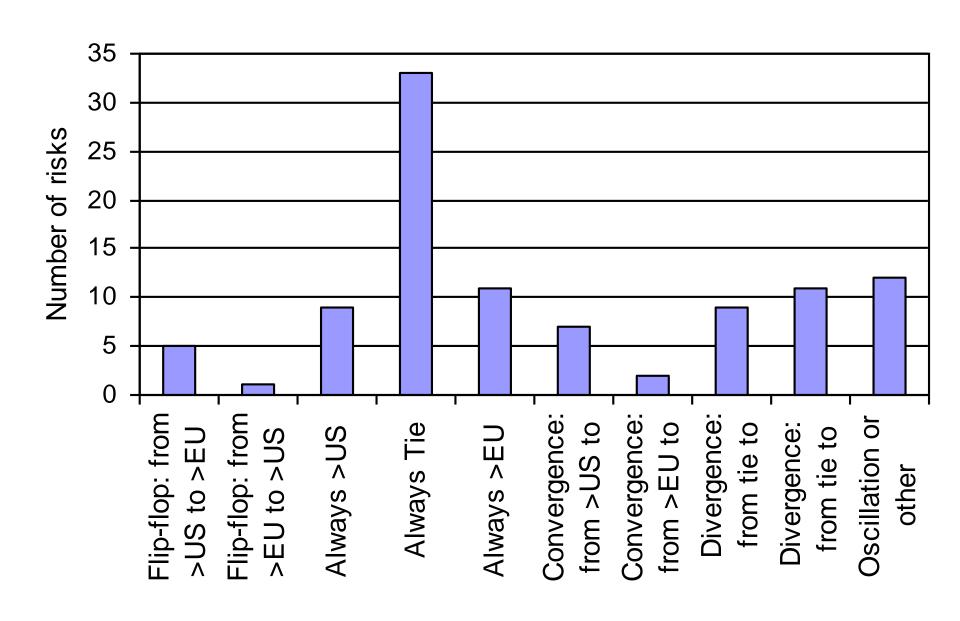
	<u> </u>	Percentage in:	
Code	Category	Matrix	Sample
1	Crime and violence	1.8	3
2	Alcohol, tobacco, and other drugs	3.0	3
3	Medication and medical treatment	6.8	8
4	Transportation	8.2	13
5	Accidents not elsewhere classified	2.4	2
6	Recreation	5.5	8
7	War, security, and terrorism	1.5	3
8	Toxic substances	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: Swedlow et al., chapter 15.

Figure 4. Patterns of Relative Precaution



# **Summary of Quantitative Sample**

- *Parity:* Overall, no significant US-EU difference.
  - Very slight shift toward relatively more precaution in EU since 1990.
  - But very slight: equivalent to a switch toward greater EU precaution in only 3-6% of sample.
- Particularity: Diversity across specific risks; selective precaution.
  - 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

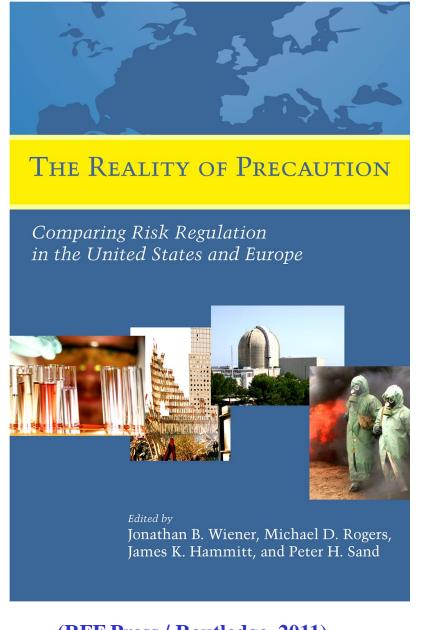
# Can we Explain the Pattern of Particularity?

- Politics (European Greens; US Republicans; parliamentary vs SOP) ?
- Risk perceptions?
  - Cultures of risk-taking, risk-aversion, (dis)trust in gov't?
  - "Availability" heuristic (salient crisis events spur regulation)?
- Protecting domestic interests (trade, industry, culture) ?
- Legal systems ?
  - "National styles" (Vogel), "Legal origins" (LLSV)? But much variation in "new spheres of social control" (risk regulation)
  - Asymmetric domestic enforcement (US > EU) = US reluctance re PP?
  - Ex post tort law (US > EU) = PP less urgent in US?
  - Proportionality principle as a limit on PP in EU
  - Regulatory oversight (RIA) using BCA? But no change around 1990; US adopted RIA earlier, and EU later (so, contra Vogel's shift).
- US-EU "system" contrasts don't fit the selective pattern of precaution.
  - Why do societies choose to worry about and regulate different risks?
  - "Legal origins" or "families" don't match selective precautionary regulation
  - Better explained by selective stimuli, such as trade protectionism and the availability heuristic response to crisis events.

# Are some societies "more precautionary" than others?

# ... about which risks?

- Studied US and Europe, 1970-present:
  - a dozen case studies.
  - a large-N quantitative study.
  - explanatory factors.
  - impacts.



(RFF Press / Routledge, 2011)

#### **Findings:**

- *Selective* application of precaution, in both Europe and the USA.
- Often spurred by trade protectionism, 'available' crisis events.
- No stark US-EU divide or reversal.
- Hybridization: legal borrowing: e.g. PP, Better Reg., Impact Assessment (IA).
- Precaution can yield risk-risk tradeoffs.
   Need IA too. Toward optimal foresight

# Implications of The Reality of Precaution

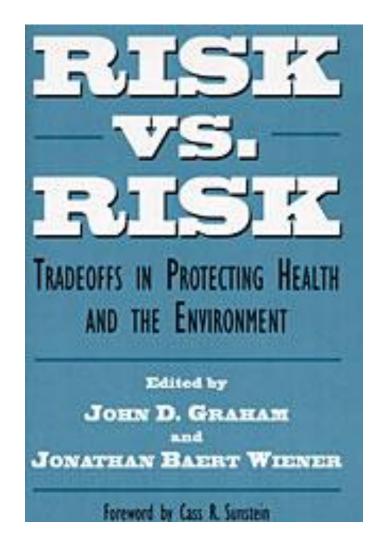
- Reality: complex pattern of Parity and Particularity.
  - Neither EU nor USA is *generally* more precautionary than the other.
  - Must study wide array of cases (not just rhetoric, or recent visible examples).
  - Selective application: Precautionary particularity, not principle.
  - Comparing legal "systems/origins/families" overlooks complex variation by issues, laws, institutions, context. Need a more modular comparative law.
- Multiple explanations for the observed complex pattern
  - Including: trade protectionism, public perceptions, crisis events
- Actual precautionary regulation is often moderated.
  - False negatives, but also False positives, Costs, Risk-Risk tradeoffs
  - Toward optimal (not maximal) precaution
- Move to "Better/Smarter Regulation" in both the USA and EU
  - Transatlantic consensus: Regulatory Impact Assessment and Oversight
  - Precaution and RIA are both forms of "regulatory foresight"
- Diffusion, borrowing: increasingly interwoven "hybridization" of regulatory systems (more than convergence, divergence, reversal).
  - Opportunity for learning through comparison and exchange.
  - Toward a Global Policy Laboratory

### Areas for future research

- More risks, case studies, e.g.:
  - Pesticides
  - Occupational health & safety
  - EMFs, mobile phones and masts
  - Sweeteners
  - Oil spills
  - Financial shocks
  - Nanotechnology
  - Synthetic Biology
  - Geoengineering / SRM
- More time future, past
- More jurisdictions
  - Member states of US, EU; and scale/competence/federalism/subsidiarity
  - Other OECD members
  - Global countries around the world
- Institutions legislatures, agencies, courts, etc.

## The Precautionary Principle and Risk-Risk Tradeoffs

- The PP can block itself.
  - If the PP requires the proponent of an activity to prove safety before the activity may go forward
  - Regulation is an activity
  - Efforts to reduce one risk can increase other risks
  - The PP could block itself
- Solution: Confront the reality of the multi-risk world. Incorporate multi-risk approach into precaution.
  - Reduce not just Target Risk (TR), but overall risk: TR-CR.
  - In practice, precaution is often moderated to avoid Countervailing Risks (CRs).
  - Both TRs and CRs can be uncertain, irreversible, catastrophic
  - If precaution is warranted for TRs, then CRs also warrant precaution. Symmetric multi-risk PP.



(Harvard University Press, 1995)

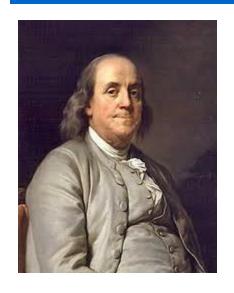


(Showado Press, 1999)

## The Diffusion of Regulatory Oversight

- Diffusion of regulatory tools around the world, e.g.:
  - Environmental Impact Assesment (EIA)
  - Market-based incentive instruments (cap & trade, taxes, information disclosure)
  - Precautionary Principle (PP)
  - Regulatory Impact Assessment (RIA)
  - Regulatory Oversight Bodies (ROBs)
- RIA and ROBs vary across countries in functions & powers, capacity & expertise, structure & location, ...
- Explaining diffusion? What can we learn for better regulation?
- References
  - J.B. Wiener et al., eds., *The Reality of Precaution* (RFF Press/Routledge 2011)
  - J.B. Wiener & A. Alemanno, "Comparing US OIRA and EU IAB," in Rose-Ackerman & Lindseth, eds., *Comparative Administrative Law* (2011)
  - J.B. Wiener, "The Diffusion of Regulatory Oversight," in Livermore & Revesz, eds., *The Globalization of Cost-Benefit Analysis in Environmental Policy* (Oxford Univ. Press, 2013)

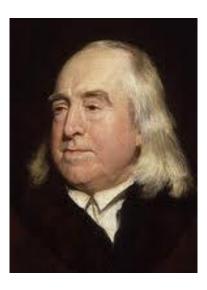
# Early international exchange of ideas on regulation and benefit-cost analysis



Benjamin Franklin



Joseph Priestley



Jeremy Bentham



Jules Dupuit

continuing today...

#### 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

## The rise of BCA, RIA and ROB – in the USA

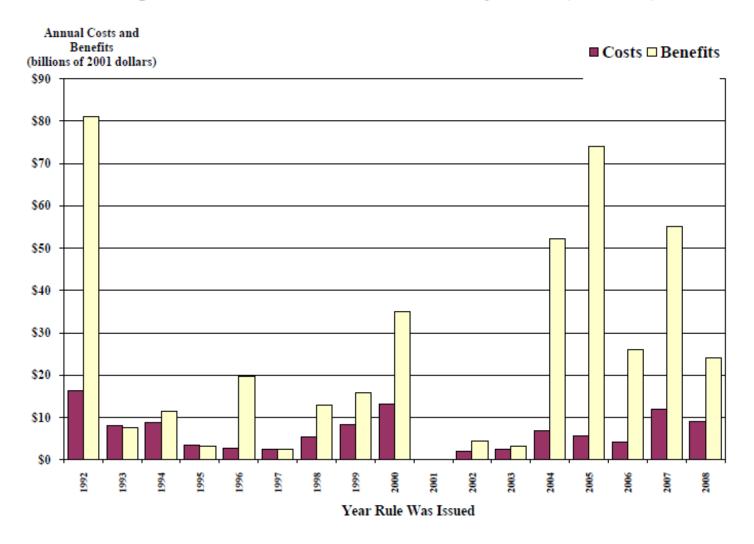
- BCA at least since 1936 (flood control), 1947 (tort law), 1978 (RIA)
- ROBs: Bipartisan executive consensus. Every President since Jimmy Carter has required economic impact assessment of major new regulations, by Executive Order (EO).
- Carter EO 12044 (1978): economic impact analysis; RARG. Paperwork Reduction Act.
- Reagan EO 12291 (1981): Regulatory Impact Analysis (RIA); Bs must "outweigh" Cs, max(B-C); OMB/OIRA authority to review & "return."
- Clinton EO 12866 (1993): maintained BCA; changed "outweigh" to "justify"; added qualitative & distributional effects; added Risk-Risk impacts; enhanced transparency.
- Bush admin.: retained Clinton EO 12866. Issued more "return" letters ("No"). Plus new "prompt letters": using BCA to say "Yes" (e.g. trans-fat labels on food; defibrillators in the workplace). Issued Circular A-4 (2003): guidelines for analysis; lower discount rates (3% as well as 7%); probabilistic scenarios if impacts >\$1B. BCA of homeland security regs. Ex post reviews. EO 13422 (Jan. 2007): covered "guidance documents," required agency decision by Presidential appointee.
- Obama: rescinded EO 13422, retained Clinton EO 12866. Issued memo (30 Jan. 2009) inviting ideas on a new EO. Then, issued EO 13563 requiring ex post reviews (18 Jan. 2011); EO 13579 extending to independent agencies (11 July 2011); EO 13609 on International Regulatory Cooperation (1 May 2012); EO 13610 on reducing burden (10 May 2012).

## Obama administration actions on regulatory review

- Jan. 30, 2009: President Obama issued a memorandum to the Office of Management & Budget (OMB), seeking OMB's recommendations within 100 days on a new Executive Order on Regulatory Review, see 74 Fed. Reg. 5977 (Feb. 3, 2009).
- OMB issued a request for public comments, requesting public input by March 16, 2009, see 74 Fed. Reg. 8819 (Feb. 26, 2009). See <a href="http://www.reginfo.gov/public/jsp/EO/fedRegReview/fedRegReview.jsp">http://www.reginfo.gov/public/jsp/EO/fedRegReview/fedRegReview.jsp</a>. Public comments posted at <a href="http://www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp">http://www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp</a>.
- June 2010: Guidelines on Information Disclosure as a Regulatory Tool
- January 2011: EO 13563 (supplementing and leaving in force EO 12866)
  - Sec. 3. "Each agency shall also seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation."
  - **Sec. 4.** "Flexible Approaches. Where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include warnings, appropriate default rules, and disclosure requirements as well as provision of information to the public in a form that is clear and intelligible.
  - Sec. 5. "Science. Consistent with the President's Memorandum for the Heads of Executive Departments and Agencies, "Scientific Integrity" (March 9, 2009), and its implementing guidance, each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions.
  - Sec. 6. "Retrospective Analyses of Existing Rules" calling on each agency to "promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned" and requiring "plans" to be periodically submitted to OMB/OIRA and regulations "modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives." (Similar to EO 12866, sec. 5.)
- Followed by memos from Cass Sunstein nudging agencies to conduct ex post reviews.
  - July 2011: EO 13579, extending regulatory oversight to include independent agencies.
  - May 2012: EO 13609 on International Regulatory Cooperation
  - May 2012: EO 13610 on Reducing Regulatory Burden

## Trend in ex ante BCAs in USA (aggregate):

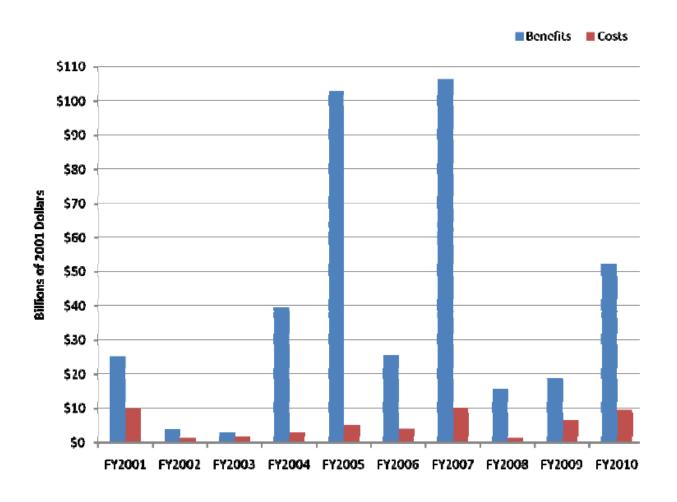
Figure 2-2: Annual Benefits and Costs of Major Rules (1992-2008)



Source: U.S. OMB, 2009 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities (Jan. 2010), p.34, at

http://www.whitehouse.gov/omb/assets/legislative\_reports/2009\_final\_BC\_Report\_01272010.pdf .

Figure 1-1: Total Annual Benefits and Costs of Major Rules by Fiscal Year



From U.S. OMB, 2011 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities (June 2011), p.21.

# RIA with BCA can say 'yes' as well as 'no'

- Is ex ante BCA biased against regulation?
  - Costs overstated (because industry exaggerates)?
  - Benefits understated (because difficult to quantify)?
- BCA can promote regulation:
  - Lead (Pb) phasedown in gasoline (petrol), 1980s
  - CFC phaseout, 1987-95
  - Diesel emissions PM limits, 2000-05
- Question is *institutional* as well as (or more than) analytic: traditional posture was to use BCA to respond to agency proposals
- "Prompt letters": an institutional innovation
  - About 12 so far, e.g.:
    - Trans-fat content on food labels
    - Defibrillators in the workplace
    - PM air pollution research
  - How best to make routine?
    - Advisory panel of experts, or NAS panel (SRA recommendation)
    - Appeals to OIRA of denials of petitions for rulemaking (Revesz & Livermore)

# Ex post evaluation of ex ante BCA

- Need ex post evaluation (1) to improve the stock of existing policies, and (2) to improve methods of ex ante evaluation of the flow of new policies.
- Ex's: US EO 13563 (Jan. 2011). EU Smart Regulation (Oct. 2010). Australia Productivity Commission Report (Dec. 2011). US EO 13610 (May 2012).
- Do ex ante BCAs overstate costs and understate benefits (anti-reg bias)?
  - Harrington, Morgenstern & Nelson 2000: ex ante, costs were overstated, but benefits were also overstated; no bias.
  - OMB 2005: benefits overstated more often than costs; pro-reg bias.
  - Winston Harrington, 2006: no bias.

Table 7. Benefit-Cost Ratios: Summary of Revised OMB Results with New Cases Added

	Accurate	Over	Under				
OMB							
In validation chapter	11	22	14				
Excluding all Gianessi (1999) pesticide cases	2	4	6				
Excluding remaining contested cases	0	1	0				
Net OMB	9	17	8				
Added cases							
OSHA health studies (asbestos and vinyl chloride)	1	0	1				
DOE appliance standards (Dale et al. 2002)	0	1	4				
Mobile source fuel regulations (AS)	2	0	1				
Mobile source vehicle emissions regulations	0	0	1				
Unadjusted pesticide cases (Gianessi (1999))	4	3	9				
Net added cases	7	4	16				
Final tally	16	21	24				
Excluding pesticide cases	12	18	15				

## The rise of BCA, RIA and ROB – in the EU

- Maastricht Treaty (1992), now the Lisbon TFEU (2009)
  - article 191(2): "precautionary principle"
  - article 191(3): assess "the potential benefits and costs of action or lack of action"
- "Proportionality Principle" = BCA
- "Precautionary Principle": European Commission, "Communication" of Feb. 2000: PP requires BCA.
- Member states: sometimes require BCA (including in adoption of PP).
- "Better Regulation" initiative (2001-): Impact Assessment (IA).
  - IA Guidelines in 2005, 2006, 2009
  - Impact Assessment Board (IAB) since 2006
  - Strengthened in 2010

# Reconciling the PP with BCA 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.
- France, Charte de l'Environnement (2005): précaution provisoire, proportionnée

## The PP and RIA/BCA in France

Charte de l'Environnement de la France (2005):

« 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 » (article 5)

Loi organique n° 2009-403 du 15 avril 2009, relative à l'application des articles 34-1, 39 et 44 de la Constitution: l'Article 8:

avec chaque projet de loi proposé par le gouvernement, il faut soumettre une étude d'impact au Conseil d'Etat, notamment sur "l'évaluation des conséquences économiques, financières, sociales et environnementales, ainsi que des coûts et bénéfices financiers".

# **Borrowing for "Better Regulation"**

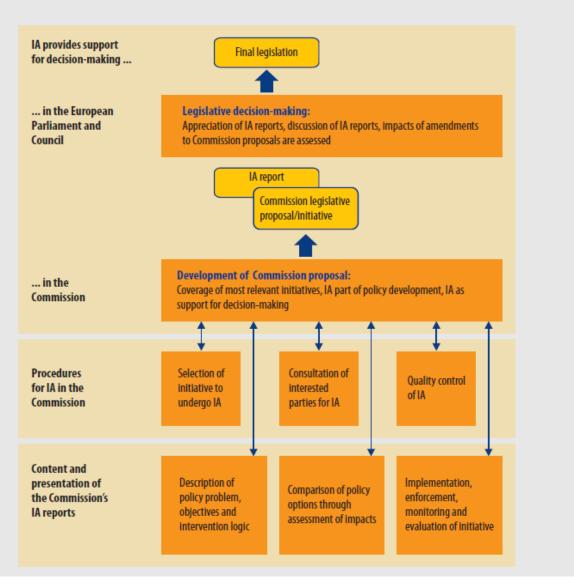
"Better Regulation is a core theme of our EU Presidency . . . There is a long tradition in American Public Administration of focusing on the quality and impact of regulation. Many of the policies, institutions, and tools that support Better Regulation have their origins in the U.S.A. ... There is much that we have learned from the United States in relation to regulatory management and, through occasions like this, much that we can continue to learn. . . . We hope too that there will be shared learning. While we in the European Union are newer to the game, I hope that we have moved beyond our rookie season! The Union is making up ground quickly in respect of Better Regulation. This is as it should be. There is a deeper understanding within the European Institutions and Member States of the need for regulatory reform."

— Bertie Ahern, 2004. Speech by the Taoiseach (head of government of Ireland), Bertie Ahern, at the IBEC Conference on EU-U.S. Perspectives on Regulation. April 19, Dublin. www.betterregulation.ie/index.asp?docID\_57\_ (accessed May 24, 2010).

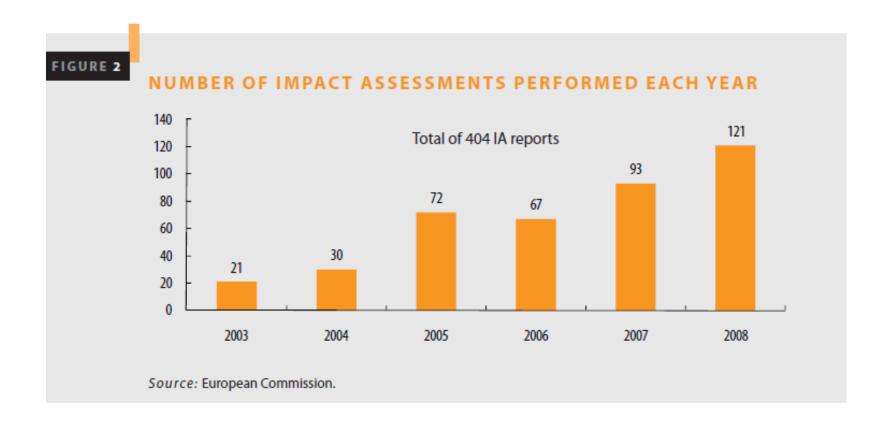
## EU "Better Regulation" Initiative: initial phase

- EU White Paper on Governance, Mandelkern Group Report (2001)
- Impact Assessment (IA)
  - of proposed legislation
  - IA Guidelines (2002) (Prodi Comm'n).
  - Revised IA Guidelines (2005, 2006, 2009) (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% quantified and monetized 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.
  - What influence on key decisions? e.g. REACH

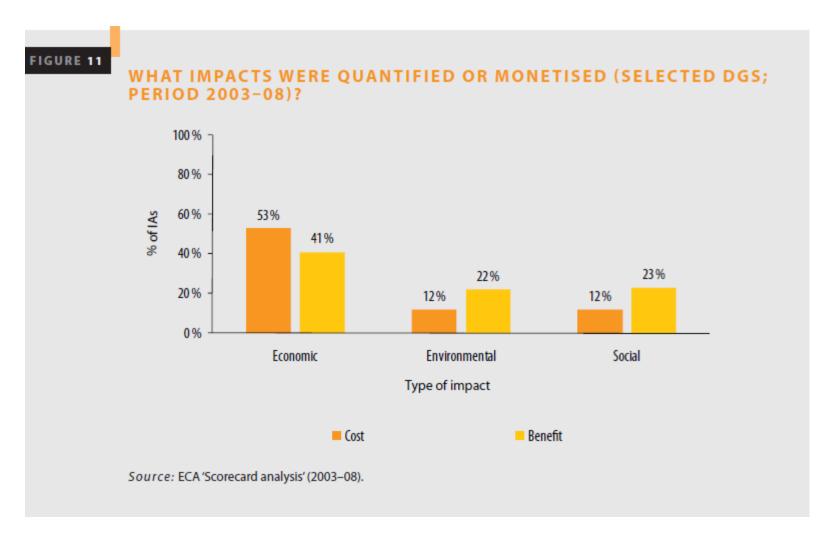
#### THE ROLE OF IMPACT ASSESSMENT IN DEVELOPING AND DECIDING ON THE COMMISSION'S INITIATIVES AND LEGISLATIVE PROPOSALS



European Court of Auditors, Special Report 3/2010, "Impact Assessments in the EU Institutions: Do They Support Decision-making?" (2010), p.12.



European Court of Auditors, Special Report 3/2010, "Impact Assessments in the EU Institutions: Do They Support Decision-making?" (2010), p.15.



European Court of Auditors, Special Report 3/2010, "Impact Assessments in the EU Institutions: Do They Support Decision-making?" (2010), p.38.

## The EU's 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."
- Questions:
  - Adequate staff, with expertise? Funding?
    - Can seek "internal" and "external" expertise. In the Mmbr States? the US?
  - IAB members too loyal to their DGs?
  - Will a 5-member board have trouble making decisions?
  - Timeline too tight (1 month to review draft IA, 1 meeting to decide)?
  - Power to influence decisions? 2010: Pres. Barroso orders that legislative proposals may not proceed if they earn an unfavorable opinion from the IAB.
  - Transparency, access?
  - IA of amendments to proposed legislation (in the EU Parliament, Council)?

# Strengthening the IAB and "Smart Regulation"

- Power to influence decisions:
  - "In principle, the positive assessment of the Impact Assessment Board is required before an interservice consultation can be launched."
    - -- President Barroso, "Communication from the President: The Working Methods of the Commission 2010-2014" C(2010) 1100 (Feb. 10, 2010).
- Communication from the Commission [on] "Smart Regulation in the European Union," COM(2010) 543 final (Oct. 8, 2010).
- "tighter quality standards were adopted in the IA guidelines in 2009 and have been increasingly enforced since 2010" European Commission, Impact Assessment Board Report for 2012 (January 2013), p.13, at <a href="http://ec.europa.eu/governance/impact/key\_docs/docs/iab\_report\_2012\_en\_final.pdf">http://ec.europa.eu/governance/impact/key\_docs/docs/iab\_report\_2012\_en\_final.pdf</a>.

#### European Commission, Impact Assessment Board Report for 2012 (January 2013)

Figure 5 - Board key activity statistics, 2007-2012

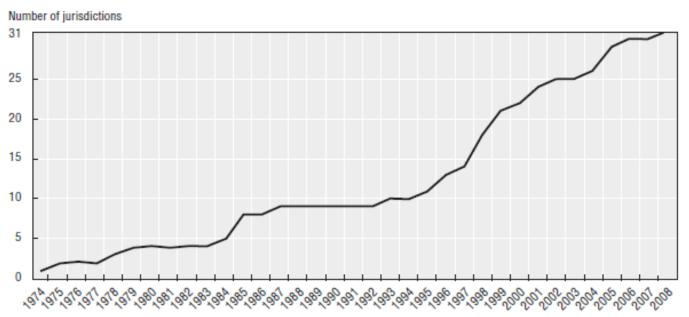
	2007	2008	2009	2010	2011	2012
Impact assessments						
Total impact assessments examined	102	135	79	66	104	97
Legislative proposals	57	86	53	49	80	76
Non-legislative proposals	45	49	26	17	24	21
Share of legislative proposals	56 %	64 %	68 %	74 %	78 %	78 %
Opinions						
Number of opinions issued	112	182	106	83	138	144
_						
On the first submissions	102	135	76	64	103	97
On the second submissions	10	43	30	18	34	44
On the third submissions	0	4	0	0	1	3
On special case submission	0	0	0	1	0	0
•						
Number of opinions	9	44	28	27	37	46
requesting resubmission, after first submission						
	0.8/	22.0/	27.0/	42.9/	26.9/	47.0/
Resubmission rate	9 %	33 %	37 %	42 %	36 %	47 %
Procedures applied						
Number of meetings	22	26	21	23	25	20
Cases in oral procedure	57	101	67	57	78	81
Cases in written procedure	45	34	12	7	26	16
Share of oral procedures	56%	75 %	85 %	89 %	75 %	83 %
Share of oral procedures	0070	70 70	00 70	02.70	70 70	03 70

http://ec.europa.eu/governance/impact/key\_docs/docs/iab\_report\_2012\_en\_final.pdf

## Global diffusion of RIA and ROBs

- US
  - RIA since 1978
  - ROB: OIRA, since 1980 ('Return' power since 1981 ('prompts'' since 2001))
- Australia
  - RIA since 1985
  - ROB: OBPR; Productivity Commission
- New Zealand
  - RIA / RIS: since 1990s
  - ROB: Ministry of Commerce, then Treasury; Productivity Commission (2010)?
- EU
  - RIA since 2002
  - ROB: IAB, since 2006 ('Return' power since 2010 ('prompts' since 2006))
- OECD member states
  - RIAs: from 50% in 1998, to 100% in 2010 (incl. Korea, Mexico, Chile)
  - ROBs: from ~33-50% in 1998, to ~50-90% in 2010
- Other countries: increasing
  - E.g. South Africa, Uganda, Kenya, Brazil, Philippines, Vietnam, ...

Figure 1.1. Trend in RIA adoption across OECD juridictions

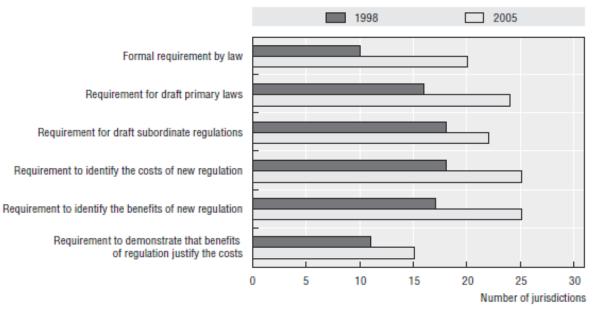


Note: This represents the trend in the number of OECD juridictions with a formal requirement for regulatory impact analysis (beyond a simple budget or fiscal impact).

Source: OECD, RIA as a Tool for Policy Coherence 15 (2009).

Figure 1.2. Regulatory Impact Analysis: Requirement for RIA

Recent trends 1998-2005



Notes: See Q11 on Regulatory Impact Analysis, 2005 OECD Regulatory Indicators Questionnaire.

The sample includes 27 countries. The responses of the EU, Luxembourg, Poland and the Slovak Republic could not be taken into account since no data was available for 1998. These data do not include any update as part of the 2008 data collection survey and peer review.

Source: OECD, RIA as a Tool for Policy Coherence 16 (2009).

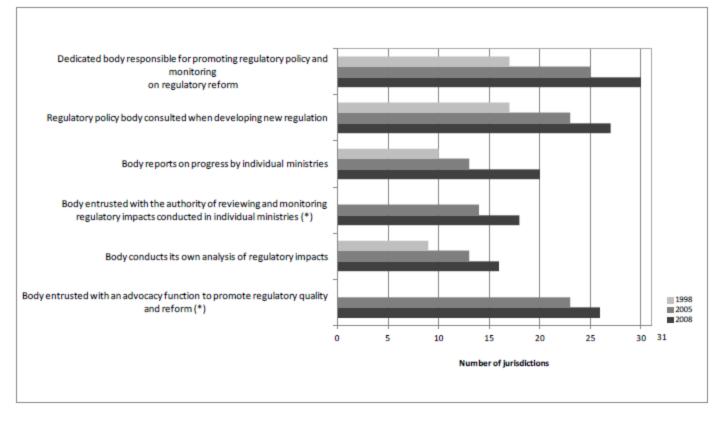


Figure 3. Institutional arrangements to promote regulatory policy (Part 1)

Notes: Data for 1998 are not available for the European Union, Luxembourg, Poland and the Slovak Republic. This means that this figure is based on data for 27 countries in 1998 and for 30 countries and the EU in 2005/2008. (\*) No data are available prior to 2005.

Source: OECD Regulatory Management Systems' Indicators Survey 1998, 2005 and 2008, www.oecd.org/regreform/indicators

Source: C. Cordova-Novion and S. Jacobzone (2011). "Strengthening the Institutional Setting for Regulatory Reform: The Experience from OECD Countries," OECD Working Papers on Public Governance, No. 19.

# Factors explaining this diffusion

## • Independent evolution

- Economic pressure. E.g. US, Korea, EU
- Growth of regulatory state
  - US: APA 1946, after New Deal; EOs 1978-on, after 1969-77 laws
  - EU: "Better Regulation" 2001-on, after 1992-2000 treaties and PP
- Presidential interest in managing the regulatory state. Kagan 2001.

## Borrowing, learning

- Exchange of ideas across legal systems (Watson 1993; Deakin 2002)
- Networks, interconnectedness (Slaughter 2004, 2009; Dobbin, Simmons & Garrett 2007, 2008)
- Bilateral information sharing e.g. US-EU (Ahern 2004; HLRCF/TEC)
- OECD role in information sharing (De Francesco 2012 more influential than trade, legal system origin, etc.)
  - But are countries continuing to evaluate their RIA systems and learn about improvements? De Francesco 2013: a few, not a lot

## Learning from the USA and Europe: Toward "Even Better Regulation"

- Match the IA system to the structure of governance
- Not just Administrative Cost. Broader: Integrated Impact Assessment of full portfolio effects.
- Use RIA more broadly and evenhandedly:
  - Cover legislation (as in EU) as well as rulemaking (as in USA). An office in Congress?
  - Use "Warm analysis": proportionate analysis, qualitative too, not narrow quantification
  - "Prompt" good policies ("Yes") as well as discourage/revise bad policies ("No")
  - Use IA more widely: not only for health & environmental regulation but also for financial (including SEC), homeland security, trade, and other regulations; decisions not to regulate, deregulation, and regulatory moratoria; as well as for subsidies, public projects, forest management, military procurement, foreign policy, etc.
  - 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 both ancillary harms and ancillary benefits
  - Ex post evaluations of ex ante IAs: to revise policies, and to improve ex ante RIA methods
- Learning: over time, across agencies, across countries.
  - Intrenational regulatory cooperation: to reduce trade conflicts, and also to learn about opportunities for better regulation.
  - Comparative observation, and purposive experiments. Toward a global policy laboratory.

## **Implications**

### Comparative law

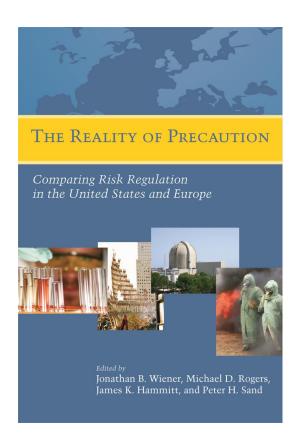
- End/erosion of discrete "national styles of regulation" (Vogel 1986) and "legal origins" of modern regulation (LLSV 2008 conceding inapplicable to "new spheres of social control")
- Hybridization: sharing genes/memes; mixture of systems; modular and selective
- As across US and EU in *The Reality of Precaution* (Wiener et al. 2011): highly selective application of precaution, not discrete system approaches
- Need to study ROB elements: timing, functions, powers, capacity, structure, location, etc. to test explanations, and impacts
- Opportunities to learn and borrow (e.g. ex ante/ex post; legislation; scope of agencies; prompt/return; proportionate analysis; warm/cold; full impacts)

## "Regulatory foresight"

- Precaution and RIA/ROBs, often seen as opposed, are both tools for foresight
- Demand for foresight may increase with prosperity, science, safety
- Need better attention to extreme catastrophic risks often neglected due to unavailability, mass numbing

## Toward a global policy laboratory

# Thank you.



www.law.duke.edu/fac/wiener