

Prudent Precaution
in a Multi-Risk World

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The Precautionary Principle:
Coming to a law near you . . .

in Europe:

- **Swedish Env't Protection Act (1969)**
- **German Env't Report (1976) (“Vorsorgeprinzip”)**
- **Swiss Federal Env't Protection Act (1983)**
- **North Sea Conferences (1984, 1987)**
- **French “Loi Barnier” (1995)**

- **Maastricht Treaty on the EU, article 130r (1994)**
- **European Commission communication (Feb. 2, 2000)**

in international agreements:

- **Bergen Declaration (1990)**
- **Rio Declaration (1992)**
- **Biosafety Protocol (Jan. 29, 2000)**

in the U.S. too:

- **FFDCA** (pre-market safety review of new drugs, food additives)
- **Ethyl Corp. v. EPA (D.C. Cir. 1976)** (EPA can regulate lead under CAA 211 despite uncertain health effects).
But see *Benzene* (S.Ct. 1980) (before regulating under OSHA 3(8), OSHA must demonstrate risk at low doses).
- **TVA v. Hill (S.Ct. 1978)** (ESA enacts “institutionalized caution”)
- **Default assumptions in risk assessments**
- **U.S. PCSD (1996)**

... everywhere?

- **The Precautionary Principle “could become *the* fundamental principle of environmental protection policy and law”**
 - **Cameron & Abouchar (1991)**

Versions of the PP

1. Uncertainty about risk does *not* justify *inaction*.

“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing measures to prevent environmental degradation.”

– Bergen Declaration (1990), Article 7.

2. Uncertain risk justifies *action*.

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established.”

– Wingspread Statement (1998)

3. Shift the burden of proof.

“As described in the Wingspread Statement . . . the proponent of an activity or process or chemical needs to demonstrate . . . that the environment and public health will be safe.”

– deFur (1999)

To implement the PP, “One would first compile a list of substances that were known to be toxic. For premarket statutes, firms would not be permitted to introduce substances chemically similar to those on the list without proof beyond a reasonable doubt that they were not toxic. For post-market statutes, ... [one could] require them to be phased out over time [unless firms] could show beyond a reasonable doubt that any exposures posed no risk of harm”

– Cranor (1999) (illustrating, not advocating)

Evaluating the PP

Version 1: Uncertainty does not justify inaction.

On its own, correct.

- We never have full certainty. We always must decide in the face of uncertainty.**
- PP as an apt rejoinder to the statement “The science is uncertain, therefore we should not act.” On its own, this statement is incorrect. Neglects costs of delay. Decision to act (or not) depends on the expected consequences in light of the uncertainty.**
- PP responds to problem of false negatives.**
- PP responds to problem of latent harms.**
- Many cases do warrant precaution.**
 - e.g.:**
 - lead (Pb)**
 - tragedy of the commons**
 - civil liability (does not require proof beyond a reasonable doubt)**
 - military deterrence**

But beyond that, PP Version 1 is not very helpful.

- We cannot say that the PP “only applies to cases of uncertainty,” because all cases involve uncertainty. Hence PP Version 1 merely describes all decision making in the real world; it is common sense, and it is not new.**
- PP Version 1 provides no guidance on what action is warranted.**
- PP Version 1 neglects the value of gaining information to improve the policy action, where $VOI > COI$.**

Evaluating the PP...

Version 2: Uncertain risk justifies action.

Again, does not say what kind of action.

Problems:

- Hasty action; false positives
- Everything poses some risk at some dose or time. Paracelsus: “the dose makes the poison.” E.g. oxygen, salt, giving birth... This version of the PP seems to urge prevention of everything.
- The world is Multi-Risk. (CRAM 1997)
- Ecological systems are interconnected (Muir 1869)
- Preventing *Target risks* (TR) can create *Countervailing risks* (CR) = *Risk-Risk Tradeoffs*. (Graham & Wiener 1995)

– **Examples of Risk-Risk tradeoffs:**

Medical care: “iatrogenic” risk. (Wiener 1998)

Aspirin: head vs. stomach

Surgery: wound infection (Joseph Lister)

NAS/ IOM (1999): 40-100k deaths / year

– e.g. adverse drug reactions, info gaps,
diagnostics, surgery, anesthesia

– do we need a modern-day Lister?

Hormesis: low-dose benefits

e.g. vitamins, alcohol, toothpaste

Regulatory policy:

Airbags

Energy sources (coal, oil, gas, nuclear...)

Oil spill cleanup

EPA-OSHA (outdoor vs. indoor)

Pesticides

Blood-borne TSE

Asbestos in automobile brakes

Ozone and UV

Police chases

War on Drugs

- Thus, regulation must *weigh the competing risks*.
Minimize the sum of ${}^a\text{TR} + {}^a\text{CR}$.
- Even certain risks might not justify action,
if ${}^a\text{CR} > {}^a\text{TR}$.
- “Ignore side effects” (ignore ${}^a\text{CR}$)
(Lindblom 1959) is too lax; will yield more
net envt’l harm (more CR) than minimizing
 ${}^a\text{CR} + {}^a\text{TR}$.
- “Do No Harm” (ensure zero ${}^a\text{CR}$)
(Hippocratic Oath) is too stringent; will
yield more net envt’l harm (more TR) than
minimizing ${}^a\text{CR} + {}^a\text{TR}$.
- Which is the “activity” of target concern?

Drinking water: Chlorination ? Microbes ?	Vaccination: The disease ? The vaccine ?
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- Problem of “risk roulette”:
action vs. Risk A invites Risk B
action vs. Risk B invites Risk C ...

- **Regulation is itself an “activity” that can cause harm.**

Every intervention (medical, legal) is a *risk vector*: multiple divergent consequences.

**The problem is not “pollution” *per se*.
The problem is *flawed human institutions*.**

- *Market externalities (inaction by gov’t)*

- *Regulatory externalities (action by gov’t)*

Need to minimize the sum of *both*.

- **Optimize along the Risk Protection Frontier**

Toward *risk-superior options*.

- **move the Risk Protection Frontier outward
(*not* “maintain the status quo”)**

- **a modern Lister for the Regulatory State?**

Evaluating the PP

Version 3: Shift the burden of proof

“Better safe than sorry.”

“Guilty till proven innocent.”

Make industry, not taxpayers, pay for risk research.

But:

- **Need to distinguish *burden* of proof from *standard* of proof. Could shift burden to industry, but make standard “no harm,” or “acceptable risk.”**
 - PP proponents urge standard of “no harm”; = problem of false positives, over-regulation.**
 - In practice, PP law adopts standard of “acceptable risk” (e.g. TSCA, FIFRA, FFDCA for new drugs)**

- **Preventive regulation is itself “an activity” that can “raise threats of harm to human health or the environment.”**

The state is a human institution. It is not exogenous; it is endogenous.

So: PP swallows itself !

Under the PP, “the proponent of [precautionary regulation] . . . needs to demonstrate . . . that the environment and public health will be safe.”

Result: no regulation ??

Better result:

“Prudent Precaution.”

- **Weigh the conflicting risks.
Ben Franklin’s “prudential algebra.”**
- **Seek risk-superior moves.
Joseph Lister’s antiseptis
Schumpeterian innovation**

Not anti-environment, anti-government;

Pro-environment.

Countervailing risks are real risks.

One era's countervailing risks are the next era's target risks.

Ex.: Drinking water

Ex.: NEPA (manifests environmentalism's *healthy skepticism* about environmental harm caused by *government*)

Pro-*smart* government.

How much to worry about CRs?

Paralysis by analysis ? No. Not infinite analysis.

**Weigh improved policy (reduced CR)
vs. delayed policy (increased TR)**

Minimize (error cost + deliberation cost)

What role for the PP ?

- Speaks to “liability” (“listing”), not “remedy” (“action”).**
- Science alone never dictates action or inaction.**

Both sides try to couch their views as dictated by science.

Optimal action depends on consequences and values.

- Action under uncertainty should be dynamic, adaptive: adjusting as information accumulates.**

The Reality of the PP: its Roots

Rising risks ?

Rising concern

Rising wealth

Rising detection ability

Resurrection of “moral outrage” paradigm

Risk perceptions:

Dread; unfamiliarity; natural / unnatural

Xenophobia of the Left ?

Changing information costs

Value in motivating industry to generate risk information. Examples:

TRI

Prop 65

CAA 112(r)

Europe: no FOIA, less public input

The Reality of the PP: its Application

Inverse relationship: strength of PP vs. strength of law

PP is much stronger in *less* legally binding texts

- International declarations**
 - Bergen (1990) (ministers)**
 - Rio (1992) (heads of state)**

More qualified in more legally binding texts

- International treaties**
 - Climate Change Convention (1992)**
 - Biosafety Protocol (Jan. 2000)**
 - EU Commission proposal (Feb. 2000)**
- National law**
 - France**
 - Germany**
 - U.S.**

U.S. law examples:

- FFDCA: pre-market safety review**
 - Drugs: standard is benefit-risk**
 - Food additives: standard was Delaney...**

- ESA**
 - sec. 7 “jeopardy”**
 - TVA v. Hill: “institutionalized caution”**
 - But ...**
 - sec. 7 “God Squad” exemptions**
 - sec. 4 “critical habitat” delineation**
 - sec. 10 “incidental take” permits**
 - sec. 3(6) insect pest exemption**
 - sec. 3(16) definition of “species”**

- FIFRA**
 - Premarket review**
 - but standard is “unreasonable risk”**

- TSCA**
 - Premarket review**
 - but standard is “unreasonable risk”**

- CFC phaseout; sec. 612 re alternatives**
 - (multi-risk analysis)**

The Reality of the PP: a Comparative Perspective

It's not just that "Europe is more precautionary than the U.S." It's more complex. Consider:

EU more precautionary

Foods

hormone-fed beef

BSE in beef

Biotech foods

Toxic substances

Climate change

Guns

US more precautionary

Drugs

New medicine approval

Illegal drugs

Lead in gasoline

Cigarette smoking

CFCs in spray cans

Automobile speed limits

Nuclear energy

- electricity

- irradiated food

What explains this complex pattern?

– Culture

Frontier ethic in US (risk-taking, dominion)

Technological optimism, mass market foods in US

Risk perceptions – involuntariness, dread, unfamiliarity, unnaturalness

– Politics – more potent Green parties in Europe

– News media – more concentrated in Europe

– Legal system

US = more litigious, more information (e.g. FOIA, TRI), more citizen oversight of gov't regulation (e.g. notice & comment, judicial review)

– reduces necessity for action-forcing legal mandate such as PP

– more binding in US = makes USG more reluctant to agree to PP in international law

US lacks “proportionality” principle

– Trade rivalry

Restrictions sought to benefit domestic industries, one industry group vs. another

- **European fear of US as a whole? NYT 4/9/00, p.A1**
- **Other?**

Upshot:

Version 1 of PP makes sense, but is incomplete; does not answer the serious question (namely: what action to take in the face of inevitable uncertainty?).

Versions 2 & 3 are flawed insofar as they neglect the Countervailing Risks of actions to combat Target Risks. If precautionary action poses risk, the PP swallows itself.

The PP needs to be qualified or supplemented to shape smart remedies.

- **avoid overreacting to false positives**
- **deal with multiple risks**
- **minimize sum of market risk and regulatory risk (TR and CR)**
- **seek “risk-superior” moves**
- **be dynamic, adaptive**

The PP has indeed been qualified when actually

implemented in binding law.

Toward “Prudent Precaution”