The rhetorics and realities of 'precaution' and 'innovation' 'principles': a cautionary tale

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Adopting the word 'precaution' and/or the adoption of a text endorsing 'precaution', or even a 'Precautionary Principle' are neither necessary nor sufficient for acting in a precautionary way.



We have seen precautionary action avant le mot, eg Red flagged motor cars. The UK's Locomotive Act 1865 stated: "...at least three persons shall be employed to drive or conduct such locomotive...one..., while any locomotive is in motion, shall precede such locomotive on foot by not less than sixty yards [~55 metres], and shall carry a red flag constantly displayed..."



More recently, the 1958 Delaney Amendment to the US Food Drugs & Cosmetics Act of 1938 stipulated that the FDA:

"...shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals."



In April 1977, referring to the Delany Amendment, and citing a well-conducted chronic feeding study showing that saccharin had caused dose-related increase in bladder cancer in male rats, especially over two generations, the FDA proposed to ban Saccharin from all processed food, in soft drinks, and as a table-top sweetener.



But Congress introduced a 'temporary' Moratorium that prevented the banning of Saccharin, and this has subsequently been repeatedly renewed. Congress only requires that all food products containing Saccharin must carry a warning label saying that:

"...the use of this product may be hazardous to your health. This product contains Saccharin which has been determined to cause cancer in laboratory animals."



### Precaution in practice in the USA:

From the 1960s to the mid-70s, US regulatory policies were often more precautionary than those in Europe, but a de-regulatory agenda began under the Reagan administration, and has subsequently intensified.

But, the US-UK invasion of Iraq in 2003 was justified by the Bush administration on essentially precautionary grounds. 'We don't need to wait until we have proof, proof will be found once the invasion has succeeded.



Precaution is often portrayed as a response to uncertainty. But uncertainties complicate policy-making, so policy institutions have often chosen to conceal or ignored inconvenient uncertainties, and to proclaim convenient ones.

One of the most important and least frequently acknowledged facts in food chemical toxicology emerged in 1978 when a US NAS panel estimated the upper and lower bounds of the risk that Saccharin might pose to the US population.



It estimated that if, on average, the population of the USA were to ingest some 120 mgs of saccharin daily for a period of 70 years (which then corresponded to the average US intake) it was unlikely that fewer than 0.22 extra deaths from bladder cancer might occur, while on the other hand it was unlikely to cause more than 1,144,000 extra deaths.



Sometimes something seemingly certain is shown to be false. In March 2018 we learnt that chlorinated water does not disinfect, it just disables the standard test.





RESEARCH ARTICL

#### Viable-but-Nonculturable *Listeria monocytogenes* and *Salmonella enterica* Serovar Thompson Induced by Chlorine Stress Remain Infectious

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- Some US scholars have tried to offer a technocratic interpretation of precaution.
- In True Warnings and False Alarms: Evaluating
- Fears about the Health Risks of Technology, 1948-1971, Mazur proposed calculating the costs of precautionary actions and of not acting; but he assumed that adequate knowledge was readily available. The example of BSE reveals the key flaw
- in his methodology.



If the UK government had acted promptly in 1985 and eradicated BSE pathogens from animals and feed, it would have cost of ~£20 millions. But we would never have known whether or not BSE could be transmitted to people. nvCJD would not have emerged so the UK government could not have known that it had avoided future costs of ~£20 billions, ie a thousand-fold rate of return! Precaution is inherently political, and it cannot be purely science-based.



## The evolution of Precaution in the EU

The precautionary principle did not emerge in EU law until the 1992 Maastricht Agreement establishing the European Union. It said that EU environmental policy shall be based, inter alia, on the precautionary principle.



'Precaution' was never invoked by the UK or EC over BSE until > 3/96, instead the uncertainties were deliberately concealed and denied by officials in the UK's MAFF and in DG-Ag & DG-Internal Market.

For ~10 years the UK and EC repeatedly claimed that BSE was known for certain not to be a risk, even in the face of evidence from 'Mad Max' (in 1990) and 8 species of Zoo animals ('90-2). Their assurances were intended to try to save the cattle, meat and dairy industries, but precaution was invoked >3/96 for similar reasons.



It was the BSE crises starting in the UK March 1996 and erupting in Germany in 2000 -2001 that forced precaution up the EU's policy agenda, and framed the reception of GM foods.

Initially the precautionary principle was only held to apply to the EU's environmental policies, but after the BSE saga its scope was extended into other areas of EU policy including the protection of public health.



## The evolution of Precaution in the EU

Signing the 1998 Aarhus Convention statutorily committed the EU to exercising precaution – it gave legal traction to that commitment - it became 'judiciable'.

Precaution was enshrined in Article 191(2) of the 2007 Lisbon Treaty on the Functioning of the EU.



The Euro Commission's 2001 *Communication on the Precautionary Principle* said that:

"Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty."



In response to the BSE crises the EU initiated an *Anticipatory Research* activity in 2002 in FP6.

The Commission described anticipatory research as: "Research to assess rapidly new discoveries, or newlyobserved phenomena, which may indicate emerging risks or problems of high importance to European society, and identify appropriate responses to them."

It was part an initiative called NEST, or New and Emerging S&T, which in turn evolved into the ERC.



The idea for Anticipatory Research was to try to locate, understand and avoid 'elephants traps' before falling into them. But more recently that has not been something that the European Commission or the ERC now mention or encourage.

DG-Environment has even actively (but quietly) tried to avoid uncovering new evidence that might provoke calls for tighter regulations on industrial technologies.



The precautionary principle allows for the adoption of protective measures without having to wait until the reality and seriousness of those risks has been proved – but it does not require such measures.

The ECJ has ruled that protective measures "cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture that has not been scientifically verified", and EU institutions cannot base their policies on the pursuit of a 'zero-risk' level of protection.



Precaution has been invoked by the European Commission selectively and opportunistically, while the ECJ helped widen its application.

Examples of precautionary actions have included: neonicotinoids, paraquat, nanotechnology, GM crops, 'persistent, bioaccumulative and toxic' substances under REACH, protected habitats and in respect of hazards (rather than just risks) from active pesticide ingredients; **but not for eg Glyphosate, Aspartame or SF<sub>6</sub>**.



EFSA ANS panel's December 2013 interpretation of the reliability of studies for those that had, and had not, indicated possible harm, from aspartame by number of studies

	Number of studies reviewed	Number deemed reliable	Number deemed unreliable	Number of studies on which the panel was self- contradictory
Studies not indicating harm	81			
Studies indicating possible harm	73			

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Studies not indicating harm	81	62	19	2
Studies indicating possible harm	73	0	73	8

The European Commission is a technocratic institution, which claims to be neutral and objective. Technocratic institutions try to conceal, ignore or discount policy-relevant uncertainties, especially those that are intractable with a bit more research of the same sort.

Intractable uncertainties undermine the legitimacy of its decisions. Technocrats are therefore uncomfortable with precaution as it is overtly normative. They typically try to narrow debates to quantifiable and manageable sub-sets of risks.



The orthodox technocratic narrative on policymaking is: policy is based on, and only on (scientific) facts.

That does not mean that values are absent, but that they are concealed or entirely unconscious.

Eg DEFRA Secretary to ACRE: "We only use natural scientific evidence and criteria, we don't use socio-economic criteria – we leave it to the market."



A technocratic interpretation of precaution is that it is only a risk management consideration, not one that arises in scientific risk assessments. It can only be relevant if risk assessors highlight important policy-relevant uncertainties.

But that is wrong. Firstly official risk assessors typically only highlight readily tractable uncertainties, but fail to engage with more profound uncertainties.

Secondly, risk assessments can be more or less precautionary, depending on their scope and the interpretation of data and sensitivity to possible false -ves and +ves.



To understand how risk assessments can be more or less precautionary, it helps to understand in general terms the roles that scientific and policy considerations play in the science-based policy making.







## Model 2 - a co-dynamic model: reciprocal links between science and policy





Codex refers to **Risk Assessment Policy** in the following terms:

"Determination of **risk assessment policy** should be included as **a specific component of risk management**.

Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties...

The mandate given by risk managers to risk assessors should be as clear as possible."



There are at least 3 main types of RAPs

Substantive

Procedural, and

• Interpretative.



A risk assessment that addresses a comprehensive range of possible risks will be more precautionary than one that focusses only on a sub-set of risks.

A risk assessment that reviews publicly accessible data with open and accountable procedures will be more precautionary than one that relies on unpublished studies and data, and only meets behind closed doors.

A risk assessment that deliberately tries to detect false negatives as much as false positives will be more precautionary than one that does not.



In 2013 an 'innovation principle' (IP), was proposed by the European Risk Forum (ERF), a lobby organisation jointly established by chemical, tobacco and fossil fuel companies, as a complement to the PP, or to over-ride it.

#### The ERF claimed in Nov. 2017 that:

"In 2013, the European Risk Forum, with the support of CEOs from twenty-two of the world's largest corporate investors in innovation, launched the Innovation Principle (IP). Actively supported by BusinessEurope and the European Roundtable of Industrialists, endorsed by the European Council and supported by successive EU presidencies, it has achieved significant prominence within the EU institutions"



The IP is intended by the ERF and its corporate sponsors to be used to undermine EU legislation and regulation of eg chemicals, novel foods, pesticides, nano-products and pharmaceuticals.

The proposal to introduce an IP is in effect a recognition that the PP has occasionally been invoked and applied by the Commission and endorsed by the ECJ. That could be interpreted as an indicator of our partial success.



An IP was first officially mentioned in a European Commission document in 2015, and it was incorporated into the agenda of the Ministerial Competitiveness Council in 2016.

ERF mistakenly argued that the PP had inhibited innovation, when it had in fact redirected it, in safer directions.



In June 2016 the European Political Strategy Centre, ie the Commission President's Policy Unity, published on Juncker's instructions:

**EPSC Strategic Notes** 

European Commission

lssue 14 30 June 2016

## Towards an Innovation Principle Endorsed by Better Regulation

European **Political Strategy** Centre

It asserted that innovation: "...leads to high productivity and competitiveness while yielding social and environmental benefits." but without acknowledging the possibility of adverse social or environmental consequences.



The PP is optional, but the Commission wants the IP to be mandatory. Innovation Principle for a **Balanced Regulatory Approach** An innovation principle means ensuring that whenever policy is developed, the impact on innovation is fully assessed. The principle should provide guidance to ensure that the choice, design and regulatory tools foster innovation, rather than hamper it.

The document cited Article 173 of the TFEU as: "fostering better exploitation of the industrial potential of policies of innovation, research and technological development." to portray the IP as: "...an implicit Treaty-based innovation principle [that] sets guidelines for optimising the legal framework for innovation."

But I understand the IP and the arguments articulated in support as corporate special pleading, which could provide short-term private commercial benefits and long-term external costs to the public, and to public authorities.



In February 2017 DG Research established an 'Innovation Principle Task Force', which aspired to implement the 'innovation principle'. It was expected to focus on reducing industry's compliance cost, advocate greater regulatory flexibility. It proposed including 'sunset clauses' in regulatory legislation, and advocates more consultation of regulatory policy-makers with 'stakeholders', ie BINGOs not PINGOs. But that too was a product of corporate influence, if not capture.



These can be understood as energetic attempts to achieve *corporate capture* of regulatory policy-making institutions.

They don't just want an IP introduced, they want responsibility for it to be institutionally co-located with the PP; a tactic that neglects the historical lessons of eg BSE and Fukushima.

However, the ECJ stipulated in the 2002 Pfizer virginiamycin case that "...public health must take precedence over economic considerations"; a precedent that undermines some of the advocates for an 'Innovation Principle'.



Corporate Capture is an important sociological concept for natural scientists to understand. Its relevance for scientists is brilliantly explained in

# The Regulation Game

#### Strategic Use of the Administrative Process

Bruce M. Owen Ronald Braeutigam Copyright © 1978 by Ballinger Publishing Company.



#### Owen & Braetigam tell industrial executives that:

"Regulatory policy is increasingly made with the participation of experts, especially academics. A regulated firm or industry should be prepared whenever possible to coopt these experts. This is most effectively done by identifying the leading experts in each relevant field and hiring them as consultants and advisors, or giving them research grants and the like. This activity requires a modicum of finesse; it must not be too blatant, for the experts and freedom of action. At a minimum, a program of this kind reduces the threat that the leading experts will be available to testify or write against the interests of the regulated firms."



The challenge of identifying, revealing and diminishing corporate capture of science-based regulatory policy-making is a seemingly endless task.

While the precautionary principle, in combination with open access to all relevant studies, data and proceedings, helps to combat corporate capture, it has not been sufficient.



### ENSSER's commitment to:

Transparent, high quality scientific information that focuses on the ecological, health, and socioeconomic aspects of technology use. and

The assessment of alternative options within technology policy, strengthening innovation and long term sustainability, meanwhile prioritising public and environmental safety.



...is a text we can all endorse, but achieving those aspirations relies on our sustained attention, effort and collaboration.

If a precautionary approach is to be comprehensively implemented by the EU, and all EU Member States, then members of ENSSER and all our collaborators will have to remain vigilant and engaged amongst ourselves and with PINGOs, other civil society organisations, responsible professionals, the media, and even with politicians and public officials. SPRU CELEBRATIN 50 YEARS