RISK MANAGEMENT – SHOULD THE PRECAUTIONARY PRINCIPLE BE REPLACED BY RISK-RELATED ANALYSIS FOR INDIVIDUAL NEW TECHNOLOGIES?

MEETING OF THE PARLIAMENTARY AND SCIENTIFIC COMMITTEE ON MONDAY 14TH NOVEMBER 2005

Disputes and uncertainties are an essential part of the concept of science and are not an indication of disagreements between individuals. Should we therefore improve our ideas and models by testing them to destruction, or are some so potentially dangerous and possibly irreversible in their consequences that we dare not take any action for fear of the unknown? Would it be possible to replace the Precautionary Principle with an analysis of the risks associated with individual new technologies?

Risk and Precaution: changing perspectives from the Royal Commission on Environmental Pollution

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Principle 15 of the Rio Declaration neatly encapsulates the key elements of the precautionary principle:

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

Application of this principle – increasingly influential in environmental policy since the 1970s – is typically associated with taking pre-emptive action rather than waiting for proof of harm, with less reliance on the capacity of the natural environment to assimilate and neutralise pollution, and with greater emphasis on reducing potential problems at source using the "best technology not entailing excessive costs".

Since 1970, when it was created by Harold Wilson in response to mounting environmental concern, the Royal Commission on Environmental Pollution (RCEP) has been influenced by and has itself influenced a broader trend towards precaution in environmental affairs. In its early days, the precautionary principle was regarded with suspicion in the UK as a "contintental" philosophy, alien to the British ("dilute and disperse") approach to pollution. Demands for tighter control typically met with a robust response: "you haven't proved that there's a problem, the science is uncertain, it's too expensive and would damage business".

In this climate, the Royal Commission's position – best characterised as one of "cautious precaution" – was quite radical. One of its best known earlier recommendations – that there should be no significant commitment to civil nuclear power until the possibility of dealing safely with nuclear waste had been demonstrated – was essentially precautionary (RCEP 1976). The argument in its ninth report (RCEP 1983) that lead additives should be phased out of petrol was classically so, grounded in the possibility of serious harm to children's health in the absence of scientific "proof". (The recommendation was accepted with alacrity by the government in the run up to the 1983 General Election). But one can also trace a more general shift towards precaution, exemplified by the Commission's treatment of water pollution and of chemicals in the environment.

In the case of water, the Commission became convinced over time that "[t]he question of how much waste can be disposed of to the environment without adverse impact should be preceded by asking how far the pollution from a process can be reduced" (RCEP 1992: para 9.44). From its earliest days it was concerned about limits to the assimilative capacity of the environment – even that of the seas which might seem vast – and was worried about irreversible impacts: "there could be points of no return in the deterioration of water" (RCEP 1972b: para 10). By the mid-1980s, when Britain was staunchly resisting European pressures for stringent control of dangerous water pollutants at source, the Royal Commission urged reconsideration:

"the United Kingdom should reappraise its stance on irretrievable discharges to the sea of toxic substances which are unarguably persistent and bioaccumulative" (RCEP 1984: para 3.26). The UK did indeed shift to technology-based controls, at least for a restricted "Red List" of substances, in 1987. Later the Royal Commission argued for a more general extension of the precautionary approach in the context of water pollution (RCEP 1992).

Another example of a general shift towards precaution can be found in the Royal Commission's treatment of chemicals in the environment. In its second report, it argued for a degree of circumspection in launching new products that contained substances with potentially hazardous properties: "While it would not be reasonable to regard substances with these properties as 'guilty until proved innocent' it is reasonable to regard them as 'under suspicion'" (RCEP 1972a: para 13). This should be reflected in toxicological testing in advance of marketing and monitoring for environmental impacts afterwards. During the 1970s and 1980s, the Commission was influential (behind the scenes as well as through its reports) in institutionalising arrangements for the control of agricultural pesticides. By 2003, it was expressing concern about the tens of thousands of chemicals about whose impacts very little is known, and arguing for a paradigm shift in the slow process of assessment. Since uncertainty has to be regarded, at least for now, as inherent, the Commission recommended "a precautionary approach based on substitution of hazardous chemicals with ones of lower hazard or a non-chemical alternative" (RCEP 2003: summary p. 5).

The work of the Royal Commission illustrates a number of important points about the precautionary principle. One is that it is tempered in application by other principles. Perhaps the most significant is the principle of proportionality, requiring that measures taken should be proportional to the potential threat, and should take account, as far as possible, of the costs and benefits to society of the action or inaction involved: acting "ahead of the evidence" does not mean acting "whatever the cost". Proportionality was part of the context for the original (West German) *Vorsorgeprinzip*, which influenced the Royal Commission's thinking in the 1980s (RCEP 1988). One might argue that the Commission's radical recommendation on lead in petrol was facilitated by its finding that the phasing out of lead additives could be achieved at modest cost: in effect, it sidestepped the intense scientific controversy about causal links with human health by asking two simple questions: "do we need lead in petrol? and how much would it cost to take it out?" Later, the Commission was to argue that "the strength of the economic or technical case for [a] substance's continued use" should be among the criteria for any shift in the burden of proof about possible harmful effects (RCEP 1984: para 2.31).

A second important point is that the precautionary principle is not something to be set apart from "sound science". Its proper application must involve some assessment of the plausibility and magnitude of the threat, and should be based on the best information that a rigorous scientific analysis can provide. But the principle is grounded in a recognition that, certainly in the case of many environmental controversies, we are dealing not only with uncertainties (which might be reduced over time) but with indeterminacies and ignorance, placing some of these issues into the realm that Weinberg (1972) described as "trans-scientific". In such circumstances, the principle of precaution can be seen not as an alternative to science but as "a rational response to uncertainties in the scientific evidence relevant to environmental issues and uncertainties about the consequences of action or inaction" (RCEP 1998: para 4.44).

Nor is the precautionary principle an alternative to risk assessment: its application *entails* an assessment of risk. But in making this connection, we must acknowledge that thinking about risk itself has changed. Most notably, the old dichotomy between "objective" and "perceived" environmental risk (which featured in some of the Royal Commission's earlier reports) has been substantially undermined, and the "information deficit" model of public risk perception discredited (Owens 2000). Particularly in the case of complex systems, we now appreciate that "risk estimates, often presented as the objective outcome of a scientific assessment, may involve important (but often obscure) assumptions and value judgements" (RCEP 2003: para 1.21). We have also come to understand that public responses to risk are not necessarily "irrational" but are crucially dependent both on context and on trust in institutions.

The final point follows from the others. Those who look to science alone to make difficult decisions in environmental policy must inevitably be disappointed. Application of the precautionary principle should of course be informed by science, but "must of necessity make heavy demands on judgement" (RCEP 1998: para 2.31). Like all important principles guiding human affairs, precaution is essentially an exercise in practical reason. This has two important implications. First, action taken in its name "should be transparent and subject to review in the light of development of understanding" (*ibid*. para 4.48). Second, acceptable risk and appropriate precaution are not matters to be determined by experts alone, but should properly be subjects for public and political debate in a mature democratic society.

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The Precautionary Principle – more sorry than safe

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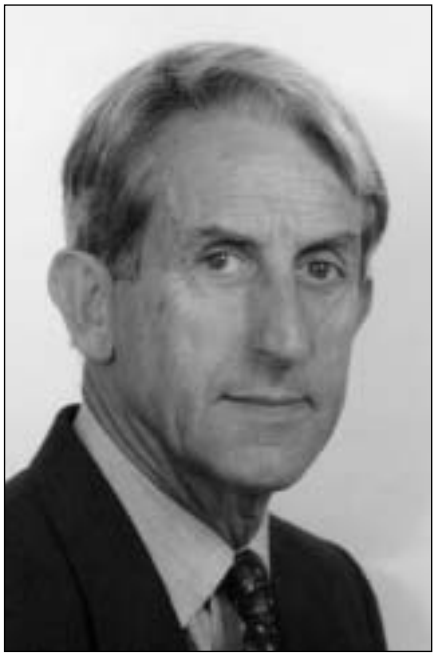

In managing the risks that beset us, of infectious and degenerative disease, accidents in the home, the problems related to various means of transport or the actions of other living beings, it is proper that we use **Caution**, the taking of heed and **Precaution**, the use of prudent foresight. No system of regulation or pattern of avoidance of risk can give an **Indemnity** enabling the prevention of contingent harm. The desire for certainty about hazards and new technologies has led to the development of scientifically flawed ideas, including the Precautionary Principle. Despite the obvious impracticability of an indemnity, changes in society that lead to a risk-averse view of life have become prevalent; as **Frank Furendi** has it, "the defining feature is the belief that humanity is confronted by powerful and destructive forces that threaten our everyday existence". Part of this thinking comes from a profound underestimation of the real risks that confront us and it follows from this that the presentation of a hazard that might produce a low level and remote risk assumes an unreasonable significance.

This is abetted by a lack of understanding of the scientific method in the untrained, often illustrated by a tendency to over-value single steps in a chain of causation. The dependence of an hypothesis on a complete chain of confirmed steps is counter-intuitive to many and has been commented on by non-science writers such as PJ O'Rorke. It is not easy to provide instant certainty with science and Bertrand Russell's dictum that "what man desires is not knowledge but certainty" is relevant. In 2001, the apparent discovery of trans-gene migration in Mexican maize by Quist and Chapela (2001) reported in Nature caused considerable alarm to some. I do not mean to discuss whether the technique they used was faulty (or better, inappropriate) nor to consider whether trans-genes would be expected to persist but the later study of Ortiz Garcia et al (2005), who found no transgenes in 150,000 samples over a four years' study period illustrates the danger of acting on unverified information. In the same way, initial reports on the dangers of a GM crop to the Monarch butterfly were discredited

Similar concerns apply to the controversy about the MMR (measles, mumps and rubella) vaccine where a set of indifferent data was made much of by the uninformed. Even had the hypothesis been true, the suggested hazard (there were no data to describe a risk) should have been balanced against the facts – to consider measles alone; it is highly contagious and will occur in outbreaks in communities with immunisation rates much below 75-80%. The illness will be accompanied by ear infection in 1 in 20 cases; by pneumonia or bronchitis in 1 in 25 cases (with some permanent sequelae in terms of lung disease); by convulsions in 1 in 200 cases; meningitis or encephalitis in 1 in 1000 cases; death in 1 in 2500-4000 cases; and the terrible problem of sub-acute sclerosing panencephalitis in perhaps 1 in 8000 children.

But there is a better documented example of the precautionary advice being damaging. In the years between 1986 and 1988 there were around 1500 deaths described as belonging to the Sudden Infant Death Syndrome (SIDS) in England and Wales per year. In 2004 there were 313. What had happened?

Perhaps as a result of the view that the immature brain stem function of infants made them vulnerable to certain stimuli affecting the airways it was assumed that it would be sensible to sleep infants on their front or side, in the way it was accepted that it was better to nurse unconscious or vulnerable adult patients. At that time there was also an increasing use of intensive care methodology in premature

infants. This practice was precautionary – there were no data. After a great deal of investigation, some absurd hypotheses and irritation with funding bodies (such as the Medical Research Council) that they were not doing enough to investigate the problem, a series of observations, mainly Australasian, demonstrated that this position was dangerous. The "Back to Sleep" campaign resulted in a drop in SIDS that has continued (0.65 deaths/1000 live births in 1996, 0.55/1000 in 2000 and 0.43/1000 in 2004). Blair (2003) estimated that the change in policy had saved 10,000 infant lives in the last decade; my own estimate is higher. It is important to notice that the main epidemiological characteristics of these cases has not changed (marital status, maternal age etc – see Leach et al, 1999) although a change in practice by some Coroners in the description of SIDS vs an "unascertained" course of death in death certification may have altered the figures in a very small fraction of the cases.

Although this tragic loss of precious lives is the price of precaution without information, there is a more important issue for Science as a methodology. The "background noise" of these deaths had obscured a significant number of deaths caused by overlying in those sleeping with their infants. Further advice last year (2004) from the Department of Health has further reduced unexplained deaths in infancy from a cause that any pig farmer would have anticipated from his data.

There are plenty of other exploded certainties relating to both therapies and diet, some documented in Ruth Gilbert and her colleagues' review of the SIDS issue (Gilbert et al, 2004), readily illustrated by the β-carotene and anti-oxidant story and by increasing difficulties with the "5 a day" mantra. Here again inadequate science may obscure the real value of a concept; there are good data on the benefits of some types of diet for populations but they often fail to confirm their promise in trials (as for carcinomas of the breast and colon). I have recently examined a PhD thesis from New Zealand by Dr Barbara Thompson, a food scientist from New Zealand, which may explain why; it is possible that the advice given with relationship to fruit and vegetable intake may need modification.

It is possible to provide endless examples; perhaps the most recent a conjunction of interest about the effects of PCB's and the concern about flame retardants – the 309 survivors of an Air France A340 Airbus crash in Toronto might have a view on this.

Apart from problems with the PP and its essentially non-scientific nature, its erratic application is a major difficulty. Why is the PP applied to GM crops but not organic food? I know of no regular monitoring scheme for mycotoxins in these foods yet food-related mycotoxin toxicity is a well established phenomenon and fungicide treatment has been demonstrated to prevent it. A number of papers have demonstrated the consequences of failure to treat (notably well documented in root crops). Why are some "natural" products not subjected to precautionary regulation when we have the REACH initiative? I suspect that we have a "mind-set" problem; it is obvious to some that particular things are dangerous. Professor Ernst in his survey of 95 British Complementary and Alternative Medicine (CAM) organisations found that few understood the concept of adverse reactions and some said that "adverse events were only connected with mainstream medicine, but were inconceivable in their own practice". This despite L-tryptophan and the eosinophilia/myalgia story (with many deaths), germanium and selenium and renal toxicity, the loss of a transplanted heart to St Johns Wort and deaths from Asinasin (a new vegetable juice) and from a Chinese herbal dieting regime.

I have concentrated on the problems of bad science, is there an alternative? The definition of the PP that I have used dwells on possible causative links that have occurred as a possibility to someone but have not been established. This is irresponsible; when so many examples of getting it wrong exist. It is possible to estimate risks for most interventions as well as for new technologies and thus to design monitoring studies that would enable a response to be modified if adverse outcomes are the result of an initiative. In the first report on Risk from the Royal Society (the second is not nearly so good) there was a category of "Risks not Foreseen". There is no system to protect us from these – attempts to do so will be stultifying.

In discussing those who should rule the Republic, Plato was emphatic that they must be an elite. There were three classes of citizens, the Guardians who ruled the polis, the Auxiliaries who were guardians who remained warriors, and the Craftsmen (the rest). In order to ensure that the leadership of the Guardians was accepted by the citizens a "noble lie" was told about their origins – that they were all born of the same mother but that some had gold in their souls, some silver and some bronze, determining the role they would play in society. This myth was told "for the sake of those being ruled". That is how we are beginning to regulate. The study of Trewby and his colleagues (2002) shows that we are in danger of destroying a trust by assuming we can decide what is good for people. We may be able to give good advice; but only if we have data.

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The present and future European use of the precautionary principle

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Introduction

The precautionary principle is one of the main regulatory tools of European Union environmental and health policy with important ramifications for member states. Over the past twenty years the precautionary principle has also increased in popularity beyond Europe, underpinning international agreements such as the Convention of Biodiversity. The precautionary principle has not been welcomed by all regulators in all governments as the use of the principle for regulatory purposes is highly controversial. This paper analyses the use of the precautionary principle and provides insights regarding its future use in Europe.

Sweden

The first use of the concept in law was the 1969 Swedish Environmental Protection Act. This introduced the reversed burden of proof with regard to environmentally hazardous activities. Industry was required to demonstrate the safety of its products to regulators, rather than requiring regulators to prove harm, as was the case in existing regulatory regimes. In effect the whole act is based on the burden of proof concept. As Westerlund 1981 writes:

"The idea is that the authorities do not have to demonstrate that a certain impact will occur. Instead, the mere risk (if not too remote) is to be deemed enough to warrant protective measures or a ban on the activity. Coupled with this is a rule in the Act stating that anyone applying for a licence must demonstrate the effects of the activity."

The purpose of the Act was to protect public interests, both environmental and public health. The concept was not called "precautionary principle" at this stage, but the core element, namely reversal of proof, was put to legal use.

West Germany

At about the same time, the German government began to develop a less radical version, *Vorsorgungsprinzip*, or "cautionary principle". This variant emerged from the Social Democrat-Liberal Democrat election victory in 1969, won partially on an environmental platform, as well as a promise to promote a fairer society. The use of the term precautionary principle was a way to address both issues, as its implementation led to a move away from economic criteria and all the legal implications associated with this approach. With regard to environmental legislation, the first draft of the new clean air act in 1970 contained the statement that translates into English as "to prevent the development of harmful effects". Interest in the environment was driven not by public pressure but by the Liberal Democrat Hans Dietrich Genscher to establish the party's environmental credentials. Environmental affairs were treated as a federal responsibility and moved from the Department of Health to the more powerful Ministry of Interior (BMI), headed by Mr Genscher.

German industry, as well as the Christian Socialist Union (CSU) and Christian Democratic Union (CDU), became more receptive to the precautionary principle, possibly as they had power bases in Bavaria and Baden-Wurttemberg which have most of the country's forest cover, car manufacturing and nuclear power plants. The link between Waldsterben (Forest death) and auto emissions created conflict between the environment and economic growth. Promoting nuclear power, as an alternative to fossil fuel power plants, provided a way to reduce pressure on the auto industry.

Ironically, this invocation of the precautionary principle endorsed a technology surrounded by greater uncertainty than the one it was intended to replace. Nonetheless, it reflected a conceptual change, advancing a more holistic perspective to investment and R&D strategies. The new incentives were intended to encourage "ecological modernisation" in which environmental protection and economic development became mutually reinforcing. They were also designed to stimulate applied industrial research and open export markets for German environmental technology

Europe

The precautionary principle was discussed internationally as early as 1982, at the World Charter for Nature. However, the first significant use of the concept was in relation to the North Sea. As a result, most discussion regarding the precautionary principle has focused on the marine environment. At the same time Germany was also lobbying the European Union to have the principle adopted as its standard for environmental policy as well. This was part of a drive to "Germanise" European environmental policy by means of political initiatives at the EU level aimed at minimising

administrative adjustment costs which were expected to follow from the Single European Act. The German version of the precautionary principle was increasingly used in European environmental legislation, culminating in its inclusion in the 1992 Fifth Environmental Action Program and the 1992 Maastricht Treaty.

Present use of the precautionary principle

The precautionary principle has been used at member state and EU levels with mixed results. Sweden has been one of its most active proponents where industry has been operating under a strict reversed burden of proof, "substitution principle" and needs-based regulatory environment since 1969, ensuring that the country's regulations are more stringent than those of other European nations. Examples of such legislation include the banning of antifouling paints for pleasure boat owners, the banning of the domestic use of glysphophosphates (a common weed killer sold under the trade name "Round Up") and the proposed banning of all brominated flame retardants. The country is proposing to put into place a toxic free environment by the year 2020, by which time all concentrations of "artificial" chemicals should be at natural background levels.

The precautionary principle was increasingly used at the EU level as a "philosophy" for regulation. For example, in the period from 1994 to 1999 the term precautionary principle was referred to in 27 European Parliament resolutions. The most public European use of the precautionary principle has been associated with high level EU-US trade disputes ranging from European bans on hormones in beef to genetically modified organisms. These disputes led US business interests to take the view that elements within the EU were using the precautionary principle for protectionist purposes. Indeed, the contentiousness of this issue led the DG Environment Commissioner, Margot Wallström, to state in a recent Washington speech that: "We do not spend our days in Brussels, as some might think, in Machiavellian plotting to apply precaution to the detriment of US businesses." The European Commission therefore saw the need for an official clarification on the role of the precautionary principle in present regulatory policy. This is highly regarded within European Commission and places the precautionary principle within the existing framework of risk analysis to the displeasure of many environmental non-governmental organisations (NGOs) including Greenpeace.

Speculations on the future of European regulation

European regulatory politics changed after the formation of the Barroso Commission in late 2004, which is seen to be very much centre-right, with more attention devoted to reduction of regulatory burdens on industry to ensure European competitiveness. There is little consensus on further use of the precautionary principle in its strictest form, that is reversed burden of proof and regulation based on harm rather than on risk. Tools to promote better regulation such as Regulatory Impact Assessments (RIAs) are also very much in favour at present with the precautionary principle almost never mentioned at the European level.

The French Food Authority's decision to continue with the British beef ban following the EU decision to lift it indicated that the agency had the public's best interest at heart especially after the tainted blood scandal. The EU's precautionary actions also have a great deal to do with credibility and range from banning hormones in beef, to not introducing genetically modified crops on a commercial scale in Europe, to imposing hazard rather than risk criteria with regard to the forthcoming chemical legislation. The regulators want to be seen as acting in the best interest of the general public and not industry. In so doing they may be perceived as fair, one of the three components of trust, and thereby ultimately these agencies will, if all goes to plan, regain the public's trust that they have lost over the past 10 years.

Arguably the US underwent the same crisis of legitimacy with the same form of strategies in the early 1970s which the European Union is undergoing, albeit 30 years later. European regulators have therefore put forward the precautionary principle (specifically reversed burden of proof) as one of the main regulatory philosophies. Once trust is restored, and once regulators see that the costs of precautionary legislation outweigh the benefits of it (as occurred in the United States) then the popularity of the precautionary principle in European circles will decline and a more US based model will appear. The question is, of course, when will this occur? How much precautionary principle legislation needs to be enacted before regulators, as in the United States, see that the costs of regulation outweigh the benefits of it? There are already signs that the EU is considering going in this direction with the development of the better regulation agenda within the Barroso Commission.

In discussion the following points were made:

The application of the precautionary principle has peaked in Germany where it arose prior to the environmental movement and was adopted and monopolised by them. It is based on ideology rather than on sound science and should now be sidelined. The application of the precautionary principle to ban the importation of cattle treated with hormones could be justified by economic reasons such as the existence of beef mountains in the EU. The banning of groundnuts from Africa on the basis of aflatoxin contamination with a one in a hundred million chance of contracting cancer from this exposure may be related to trade protection. A discussion on the relative benefits and impacts of the banning of flame retardants on infant deaths followed.

The precautionary principle is difficult to characterise and risk is difficult to quantify. All one can do is to obtain the best possible data in every case since perfect knowledge can lead to perfect quantification. Most developed countries tend to be more precautionary. Although absurd examples of inappropriate application exist and there are no perfect answers.

The current handling by the media on bird flu was quoted as an example of the hysterical mishandling of scientific data that undermines the scientific assessment of risk and its management.

The precautionary principle is concerned with harmful outcomes, but positive outcomes are the primary objective of technological development such as the laser for example, on which so much technology now depends, but which could have been banned as a potential weapon of destruction.