Defining the Precautionary Principle: Uncertainties and Values in Science for Policy*

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The French aristocrat, philosopher, scientist and statesman Condorcet was perhaps one of the earliest and strongest protagonists of the belief in progress writ large. In his last book ***Sketch for a Historical Picture of the Progress of the Human Mind*** *(1795) he lays down his optimistic vision of the progress of man, both past and future. The book was written under great strain while already in hiding from the Revolution that Condorcet once supported and that now had turned against him. In the end he asks the question (that later Malthus is asking as well) whether increased welfare and improved health of man will lead to largely increased populations – and, if population increases, will not necessarily there be a time when the number of people has outgrown the natural resources that nature can supply? And is it not reasonable to assume that when resources become scarce, then there will be fight for the resources, war between people, just the opposite of his vision of progress? Condorcet has two answers in stock to this challenge.*

Firstly, nobody could claim that such a time is imminent (written in 1794), it is assumedly far into the future. And nobody can know what technological progress might have achieved at that time. Technology might have the answer in store. This is Condorcet's technology-fix argument. Secondly, he argues that once humankind has progressed that far by means of knowledge and technology, one must assume that also people's ethics and morality has progressed alongside reason. And then it must be clear that our moral duty is not to make sure that unborn life is born, but that those that are born are secured a life in reasonable welfare, dignity and happiness. For Condorcet, the progress of knowledge and technology is unthinkable without implying a parallel progress of human morality. This is Condorcet's ethics argument.

* Parts of this paper are based on previously published work and taken from Kaiser (2003, 2004, 2005). Other parts are taken from the preparations to the report UNESCO/COMEST 2005, in which the author was involved as chair of the expert group.

Yet, it is precisely this coupling of scientific/technological progress with a matured sense of morality and ethics that is questioned by many people at end of the 20^{th} and the brink of the 21^{st} century, two-hundred years after Condorcet. People ask whether technology is out of control, a run-away train without steering and aim. And people ask whether our science no longer feels a commitment to serve the public good but has become the servant of powerful interests, benefiting only a few and risking the harm of many? Have we developed the right moral attitudes and instruments to manage the risks that science and technology produces? Has innovation lost sight of solidarity and neglected the challenge of socially desirable ends?

For a long time scientific progress was seen as exclusively being indebted to so-called epistemic values, i.e. increasing our knowledge about the world. Science as such was deemed to be essentially value-free. But science and the technology following it has changed our life-world in many ways, more rapidly than ever before in history. This has given rise to new questions and challenges.

The belief in social progress reached its peak some time during the 19^{th} century, arguably most vividly expressed in the 1851 world exhibition in London and the building erected for this purpose: the Crystal Palace. But it did not last. The sinking of the Titanic in 1912 was a foreboding of the limits of technological control. Gas warfare during WWI sent a signal that science not only has the capacity to produce inhuman technology, it also showed that such technology will be used. The atom-bombs that were released over Hiroshima and Nagasaki at the end of WWII were the result of intense scientific research (the "Manhattan project") and they raised the same worry: will science and technology turn out to be more of a threat to humanity than a blessing? When the book by Rachel Carlson *Silent Spring* came out during the 1960's it apparently documented how what was originally perceived as scientific breakthroughs later turned out to be a big environmental problem. This was the Janus-face of scientific progress: every benefit that resulted from science and technology seemed to be coupled to the downside of producing new problems as unintended side-effects. The belief in progress was shattered or at least perceived with ambiguity. In the mind of the public, including some of the political decision makers, something needed to be done to correct these negative consequences of science and technology.

Two things resulted from this:

1. a call for more ethical responsibility in science and technology
2. a new generation of environmental regimes that aimed at controlling or managing the consequences of human interaction with the environment.

In the following I shall make the claim that the celebrated Precautionary Principle (hereafter abbreviated as PP) can be understood as combining these two trends. I shall try to elaborate what the PP is, what it implies and how it is justified.

Caring for the environment by different regimes

The early stages of national and international environmental policies can be characterised by a *curative* model of our natural environment: with increased environmental impacts of growing populations and industrialisation, the environment could no longer cure itself; it should thus be helped to repair the damage inflicted upon it by human activities. For reasons of equity and feasibility governments sought to apportion the economic costs of such intervention by requiring polluters to pay the cost of pollution. It soon became apparent, however, that this *Polluter Pays Principle* was practicable only if accompanied by a preventive policy, intended to limit reparation to what could be compensated. This 'prevention is better than cure' model marks the second stage of governmental action for environmental protection. This stage was characterised by the idea that risks are known and quantifiable, and the *Prevention Principle* guided policy making. This was the heyday of quantitative risk assessment and risk-cost-benefits analyses. The emergence of increasingly unpredictable, uncertain, and unquantifiable but possibly catastrophic risks such as those associated with GMOs, climatic change etc., has confronted societies with the need to develop an additional third, anticipatory regime to protect humans and the environment against unanticipated risks of (new) technologies: the *Precautionary Principle* or 'better safe than sorry' model. The emergence of the PP has marked a paradigmatic shift from *a posteriori* control (civil liability as a curative tool) to the level of *a priori* control (anticipatory measures) of risks (de Sadeleer, 2002).

Over the past decades, the PP has become an underlying rationale of a large and increasing number of international treaties and declarations in the fields of *inter alia* sustainable development, environmental

protection, health, trade, and food safety. The PP is on its way to become a widely accepted part of international law. In its basic form, the PP states that action to protect human health and the environment to avoid possible danger of severe and irreversible damage, need not wait for rigorous scientific proof (Weiss, 2003). In practice, different and somewhat diverging formulations, definitions and interpretations of the PP can be found. Further, a multitude of contradicting perspectives of what makes up a precautionary approach coexist amongst major players in the international arena.

The PP forms a meeting ground of tremendous tensions: between supra-national and national legal orders, between the global and the local, between law and science, between North and South, and between certainty based 'positivist' views of science and uncertainty based 'post-modern' and 'post normal' interpretations of science (Funtowicz & Ravetz 1992).

Thus, some see the PP as essentially anti-scientific, anti-rational, anti-innovation, anti-sustainable use, or Northern in outlook. Others defend it as an ethically founded principle for responsible co-existence in a globalised context, as a safeguard to care for future generations, as integral to sustainable development, as truly responsible science. Much of the debate has focused on the use or abuse of the PP in international trade where some fear it may be used as a new instrument for trade barriers, while others stress that the PP provides the assurance to Nation States that their chosen levels of safety will not be compromised by international trade.

In discussing the PP one needs to be aware of four different contexts which must be understood as relevant background for the complex discussions about PP. These contexts are: 1. the scientific context; 2. the legal context; 3. the political context, and 4. the ethical and cultural context. In the following sections we shall not have the space to discus all of these aspects in detail.

1. The *scientific* context: It emerged early that some scientists, while embracing the principal ideas of precaution, assumed it had no repercussions on science, and would leave science basically unaffected. The PP was seen as a principle for politicians and administrators. The "science as usual" position met opposition by those who claimed that it seems incoherent to say on the one hand that the PP is directly linked to the state of knowledge,

i.e. the uncertainty of information, that science provides, while on the other hand leaves the burden of interpreting the significance of the incomplete state of knowledge to others who may lack the expertise to understand the uncertainties or see them in their appropriate context. To further stress the relevance to science, it is pointed out that the image of science as a linear accumulation of facts and the gradual eradication of all uncertainty is misguided. Uncertainty is increasingly seen as inherent to the production of scientific knowledge and may increase as knowledge increases. This is particularly so when our knowledge depicts unbounded complex or chaotic systems in nature as opposed to the idealised and controlled conditions of science in the laboratory. These systems are a challenge to the assumed ability of science to control and predict outcomes. It is furthermore claimed that risk assessments as practiced in regulatory science is strongly influenced by value decisions and non-scientific considerations. Thus, there is an intimate linkage between science and politics that seems to bespeak that the PP affects both the production of relevant scientific knowledge and the decision-making based on it.

2. Obviously, the PP has an important *legal* context. There is discussion whether precautionary action should be framed within a context of recognising an environmental law "principle", or whether one should rather talk about a precautionary approach when dealing with uncertain risks. The latter seems less demanding and open to alternative approaches as well. It seems a matter of fact that even states that strongly oppose the PP, have implemented policies in certain areas that are precautionary. Thus not having a generally binding legal principle still leaves room for precautionary action should a state decide so. The crucial question seems to be whether precaution has become part of customary international law. One element of the debate is the question of burden of proof. The invocation of the PP often requires either to shift some of the burden of proof showing the technology to be safe to those who develop and market the technology, or to relax somehow the standards of evidence for the suspicion of unacceptable risks (de Sadeleer 2002, Andorno 2004).

3. There is an important *political context* behind these issues as well. This can perhaps best be illustrated by pointing to the fact that acceptance or rejection of the PP is seldom coherent even within the domestic policies of a country, but seem to follow considerations of national interest. For instance, the USA has policies that are strongly precautionary in wildlife protection, but opposes the PP in a global trade context. Australia has domestic obligations to apply the PP in their national environmental policy decisions, but joins the USA in their resistance to accepting PP as an international legal principle. In other areas, e.g. within the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) or within the International Whaling Commission both countries are supportive of the PP. Within the EU one has noted that Southern European countries allow the sales of unpasteurised cheeses in spite of the risk that it may harbour *Listeria monocytogenes* and other dangerous bacteria. In this they seem to contradict the precautionary policies for food safety the EU propagates in other areas. They do so because of the long traditions of this kind of cheese making and their role in the food-culture of the countries. Such variation in the preferred approach to the PP within different areas of application easily gives rise to the suspicion that states support the PP when it can meet their environmental and other safety standards at little or no cost, but that they reject other states' use of it when this implies high costs for their own economy. In the context of globalisation of trade and technology it emerges that the interests of states to protect certain rights (IPRs) over a technology or the interest to export technologies to countries with less stringent safety regulations may further intensify the inequalities between the developing countries and the industrialised countries.
4. Finally, there is an *ethical and cultural* context. Our dealings with nature, our considerations of human health and our dealings with risks imposed on us by others are typically deeply embedded in a cultural framework of understanding and valuation. How risk-aversive or risk-taking people are in various areas is influenced by value-laden concepts and their role in the respective culture. Other values, e.g. values stressing individual autonomy versus values

> conducive to social coherence, vary culturally. The same holds for religious versus secular values. The European/World Values Surveys provide evidence based on empirical data from almost 80 societies worldwide that post-industrial change brings remarkable changes in people's world-views (Inglehart 1997; Inglehart and Baker 2000; Inglehart and Welzel forthcoming). As the knowledge economy replaces the prominence of the industrial sector, values that emphasise conformity to group discipline and institutional authority tend to give way to values that emphasise human self-expression and individual choice (Welzel 2003). These attitudes have a profound impact on our views on moral responsibility. This applies e.g. to conceptions of both inter-generational and intra-generational justice. These cultural factors also have a large impact on how we view the moral standing of nature and wildlife.

One may roughly distinguish between a precautionary approach and the PP. This is relevant when describing the history. Precautionary "thinking" has been with humanity probably for a very long time and one may trace examples of it in the history of technology. Precautionary approaches also go back in history for quite some time. An important study on *Late lessons from early warnings* (Harremoës *et al.* 2001) mentions the example of Dr John Snow, who in 1854 recommended removing the handle of a London water pump in order to stop a cholera epidemic. The evidence for the causal link between the spread of cholera and contact with the water pump was weak and not a "proof beyond reasonable doubt". The simple and relatively inexpensive measure was very effective. The PP, however, seems of a more recent historical date, and it implies a comprehensive and legally binding obligation to use precaution in special cases.

History: The "Vorsorgenprinzip" in German environmental policy

The PP is one among altogether five central principles in German environmental policy (see Boehmer-Christiansen's contribution in O'Riordan & Cameron 1994.) The other principles are "the polluter pays", "cooperation" (*Kooperation*), "proportionality between costs and profit (*Wirtschaftliche Vertretbarkeit*) and "joint responsibility" (*Gemeinlastprinzip*). While the principle of proportionality indicates that no enterprise or trade should be subjected to higher costs than it is able to bear without going bankrupt,

common responsibility means that any enterprise or trade can be subsidised in order to introduce measures to stimulate the environment. The PP may be traced back to the first draft of a Bill in 1970 aiming at securing clean air. This document expressed that the Bill aimed at preventing damaging environmental effects: the greater the danger, the greater the need for measures taken by the authorities to protect the people. This also set the legal framework for active measures that were not aiming at repairing damage that had already taken place. The law was passed in 1974 (as *Bundes-Immissionsschutzgesetz, BimSchG*) and covered all potential sources of "air pollution, noise, vibrations and similar processes".

The most unambiguous explanation and definition of the PP in German environmental policy came in a report from the Ministry of the Interior of the Federal Parliament (*Bundestag*) in 1984. Here it was stated that: "Responsibility towards future generations commands that the natural foundations of life are preserved and that irreversible types of damage, such as the decline of forests, must be avoided". Thus:
"The principle of precaution commands that the damages done to the natural world (which surrounds us all) should be avoided *in advance* and in accordance with opportunity and possibility. *Vorsorge* further means the early detection of dangers to health and environment by comprehensive, synchronised (harmonised) research, in particular about cause and effect relationships . . . , it also means acting when conclusively ascertained understanding by science is not yet available. Precaution means to develop, in all sectors of the economy, technological processes that significantly reduce environmental burdens, especially those brought about by the introduction of harmful substances" (Bundesministerium des Innern, Dritter Immissionsschutzbericht, 1984, Drucksache Bonn 10/1345, p. 53; here quoted after the translation by Sonja Boehmer-Christiansen in O'Riordan, T. & J. Cameron 1994).

The combination of the PP with the development of cleaner technologies is typical of the German ideas of environmental protection. By way of structural measures one has given support to the development of technical solutions to environmental problems. In Germany the environment is first of all protected via the use of technology (BAT, "best available technology", *bester Stand der Technik* respectively). This has created jobs and environmental technology has become a growth area.

Defining the Precautionary Principle

The German interpretation of the PP is one of many definitions. There seems to have been little convergence yet towards a common definition of the PP in the various international treaties. The North Sea Treaties (Bremen 1984, London 1987, Den Haag 1990, Esbjerg 1995; all reprinted in Esbjerg 1995) are early examples of international treaties where the PP has had a very strong position. What is interesting is the shift of reference to the PP in the various North Sea Treaties:

From: "... timely preventive measures ..." given "insufficient state of knowledge" (1984) to: "... a precautionary approach is necessary which may require action ... even before a causal link has been established by absolutely clear scientific evidence ..." (1987) and: "... apply the precautionary principle ... even when there is no scientific evidence to prove a causal link ..." (1990) to finally: "... the guiding principle ... is the precautionary principle ... — ... the goal of reducing discharges and emissions ... with the aim of their elimination" (1995).

Scientists often criticise the notion of precaution as being too imprecise; that there is no definition available that allows an immediate operationalisation of the principle (cf. Sandin 1999; Graham 2001; Goklany 2001; Morris 2000). This is, of course, true for all the diverse definitions and formulations that this principle has undergone over the years. None of these formulations allow for a mechanical application of the principle. All need interpretation. The scepticism seems to persist in many quarters of science, in spite of the many academic efforts to clarify precaution further (cf. e.g. O'Riordan & Cameron 1994; FoS 1997, JoRR 2001, JAGE 2002; Cottam *et al.* 2000; Freestone & Hey 1996; Fjelland 2002; Raffensperger & Tickner 1999; Tickner 2003; see also Lemons & Brown 1995; Lemons 1996).

Here is the formulation that is the most cited in the literature on the PP:

Rio Declaration 1992, §15:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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."

There are several weaknesses in this attempt to define the PP. The Rio Declaration for instance can be criticised for trying to characterise the PP by using a ***triple*** negation ("... ***lack*** *of full scientific certainty shall* ***not*** *be used as a reason. ... for postponing cost-effective measures* [=***not*** *acting*]" my emphasis). Many people have claimed that such a "definition" does not amount to operationalising the PP and that it remains inherently vague.

A recent UNESCO report under the auspices of its *World Commission on the Ethics of Scientific Knowledge and Technology* (COMEST) compares some of the better known versions of the principle (UNESCO/ COMEST 2005). In the following table we add some additional ones:

Source	Definition	Optional/Mandatory action
United Nations World Charter for Nature (1982)	*"[When] potential adverse effects [of activities] are not fully understood, the activities should not proceed."*	Strong: requires a moratorium in the case of uncertainty.
London Declaration (Second International Conference on the Protection of the North Sea 1987)	*"Accepting that, in order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence."*	Weak: includes qualifying language such as "may require action" and "before ... absolutely clear ... evidence."
Rio Declaration (United Nations 1992b)	*"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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."*	Weak: includes qualifying language such as "according to their capabilities" and "... postponing cost-effective measures." Contains triple negation.

contd.

International Joint Commission (1994)	*"All persistent toxic substances are dangerous to the environment, deleterious to the human condition, and can no longer be tolerated in the ecosystem, whether or not unassailable scientific proof of acute or chronic damage is universally accepted."*	Strong: bans use despite uncertainty of effects.
EU communication on the PP, 2000	*"The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU"*	Strong: requires intervention to maintain the high level of protection chosen by the EU.
Wingspread Statement on the Precautionary Principle	*"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if cause and effect relationships are not fully established scientifically ... [The] proponent of the activity, rather than the public, should bear the burden of proof."*	Strong: clearly places the burden of proof on the proponent of an action to show that it does not pose a danger of environmental harm.

Already in 1994 it was pointed out (O'Riordan & Cameron 1994) that the vagueness of the principle is by no means surprising, nor is it a drawback. In 1999 Jordan and O'Riordan stated that "the application of precaution will remain politically potent so long as it continues to be tantalisingly ill-defined and imperfectly translatable into codes of conduct, while capturing the emotions of misgivings and guilt" (Jordan & O'Riordan 1999). The PP has a similar semantic status to moral norms or ethical principles (like human dignity, equity, and justice) or the principles of human rights. It needs to be interpreted and specified on a case-by-case basis, and it will sometimes change its specific content according to

the available information and current practices. With ethical principles it is well recognised that for instance the protection of human dignity sometimes calls for a certain measure of paternalism (e.g. when institutionalising certain patients) while paternalism in other cases might be the direct opposite of respect for human dignity. This is quite similar to precaution. In order to protect for instance the biodiversity of a given region it may be a wise measure simply to leave a disturbed or polluted river leading into this region to its further natural course, and stop all kinds of human interaction with the river. But in some cases it may rather be indicated to take active steps to bring this river back into a quasi-natural state again, e.g. by restocking fish species, reducing its salinity etc. We need to look at the case at hand in order to find out what precaution means in that specific case. Partly this is due to the complexity of the scientific facts that we need to relate to. But partly this is also due to the varying interests and values that enter such a case. Typically there will be competing interests (aside from e.g. biodiversity) at stake, and sometimes these interests indeed deserve special attention (e.g. to preserve some cultural diversity by providing the economic basis for some human settlements). While the PP can remind us of our moral duty to prevent harm in general, it cannot prescribe what kind of sacrifice we should be prepared to make in each and every case. Thus the PP has the semantic status of a general norm rather than that of a detailed step-by-step rule of operation. It follows from this that it may make its occurrence in the guise of a multitude of different formulations and goal expressions.

Despite the differences in the wording, there are several key elements that most definitions or mentions of the PP in treaties have in common. These are, according to (UNESCO/COMEST 2005):

- "The PP applies when there exist considerable scientific uncertainties about causality, magnitude, probability, and nature of harm;
- Some form of *scientific analysis* is mandatory; a mere fantasy or crude speculation is not enough to trigger the PP. Grounds for concern that can trigger the PP are limited to those concerns that are *plausible* or scientifically tenable (that is, not easily refuted);
- Because the PP deals with risks with poorly known outcomes and poorly known probability, the unquantified *possibility* is sufficient to trigger the consideration of the PP. This distinguishes the PP from the prevention principle: if one does have a credible ground

for quantifying probabilities, then the prevention principle applies instead. In that case, risks can be managed by, for instance, agreeing on an acceptable risk level for the activity and putting enough measures in place to keep the risk below that level;

- Application of the PP is limited to those hazards that are *unacceptable*; although several definitions are more specific: Possible effects that threaten the lives of future generations or other groups of people (for example inhabitants of other countries) should be explicitly considered. Some formulations refer to 'damage or harmful effects', some to 'serious' harm, others to 'serious and irreversible damage', and still others to 'global, irreversible and trans-generational damage'. What these different clauses have in common is that they contain value-laden language and thus express a moral judgment about acceptability of the harm;
- Interventions are required before possible harm occurs, or before certainty about such harm can be achieved (that is, a wait-and-see-strategy is excluded);
- Interventions should be proportional to the chosen level of protection and the magnitude of possible harm. Some definitions call for 'cost-effective measures' or make some other reference to costs, while others speak only of prevention of environmental damage. Costs are only one consideration in assessing proportionality. Risk can rarely be reduced to zero. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk;
- There is a *repertoire of interventions* available:
  (1) measures that *constrain the possibility of the harm*;
  (2) measures that *contain the harm,* that is limit the scope of the harm and increase the controllability of the harm, should it occur;
- There is a need for ongoing systematic empirical search for more evidence and better understanding (long-term monitoring and learning) in order to realize any potential for moving a situation beyond the PP towards more traditional risk management" (UNESCO/COMEST 2005).

It was on the basis of these common elements that the working group that wrote the above mentioned report suggested a new working definition of the PP. The suggested definition is this:

Precautionary Principle, a working definition

When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.

Morally unacceptable harm refers to harm to humans or the environment that is

- threatening to human life or health, or
- serious and effectively irreversible, or
- inequitable to present or future generations, or
- imposed without adequate consideration of the human rights of those affected.

The judgment of *plausibility* should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review.

Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm.

Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.

When to apply the PP?

The basic condition for the application is the presence of major scientific uncertainty. Note that risk alone, if not accompanied by uncertainty, does not qualify one to apply the PP. It may for instance be the case that a reliable risk assessment of a certain product shows that there exists a very low probability for negative health effects for certain groups of the population, e.g. small children. In that case one does not need to employ the PP. A policy of prevention may be sufficient, and one may e.g. decide that even such a low risk may be too high for the group in question. This

is certainly dependent on one's values and the level of protection that a society tries to uphold. Yet, all this can be achieved without any recourse to the PP. Prevention is not the same as precaution.

The conditions for applying the PP can be spelled out in some detail. The conditions the Norwegian National Committee for Research Ethics in Science and Technology NENT (1997) adopted are essentially the following:

1. there exist considerable scientific uncertainties;
2. there exist scenarios (or models) of possible harm that are scientifically plausible (i.e. based on some scientifically acceptable reasoning);
3. uncertainties cannot be reduced without at the same time increasing ignorance of other relevant factors; (i.e. attempts to reduce uncertainties by e.g. model-building or laboratory studies typically imply abstractions that lead away from the real system under study and there is no "adding back" to real conditions; cf. Fjelland 2002)
4. the potential harm is sufficiently serious or even irreversible for present or future generations;
5. if one delays action now, effective counter-action later will be made more difficult.

While the NENT conditions for the application of the PP do not in any sense lay claim to expressing a widespread agreement, it is noteworthy that e.g. the EU communication on the PP (EU 2000) seems in part to express a similar spirit, for instance when it states 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".

It should be noted that all of these conditions need to be met. Without for instance the last condition being fulfilled one does not need to apply the PP. In such cases one may rather adopt a wait-and-see strategy.

Choice of precautionary strategies

Once one has established that the PP has to be applied, one faces the question of what to do about it. How precisely shall we act (including

refraining from acting at all)? What measures should be counted as precautionary in some sense? This is the important question one has to address once the above conditions for the application of the PP are met. It is normally at this point that differences of opinion loom large.

Any action that can be assumed to effectively reduce the risk of the potential harm occurring, or that may contain the scope of the harm should it occur and that prepares us for handling the potential harm could be counted as a precautionary strategy. Given such a characterisation of a precautionary strategy, it seems clear that in most cases we have to select among a whole range of precautionary options. Choosing a strategy invariably involves taking a stand on basic value issues.

The EU Communication on the PP (2000) specifies a number of constraints on possible PP measures:

- ➢ non-discrimination (between identical problems in different areas)
- ➢ consistency (of policies)
- ➢ cost-benefit analysis (needs to be considered for action and non-action)
- ➢ proportionality (of measures in relation to possible harm)
- ➢ examination of scientific development (even after implementation)
- ➢ burden of proof (on those who propose a practice).

In a previous paper (Kaiser 1997) I argued that once it has been established that the PP should be applied, one is still facing a multitude of possible precautionary strategies. There is no one best strategy in any objective sense. One has to make trade-offs, for example between effects on nature and effects on society. This is certainly legitimate, but it is not a question of straightforward science. It is a value decision.

The example of xenotransplantation

It is, I think, useful to look at a specific example in order to see how the PP works or would work in practice.

Xenotransplantation is the transplantation of organs or body-cells from animals to human beings, for instance the heart of a pig. Xenotransplantation marks a qualitatively new challenge in medical technology assessment. The reasons for this claim are twofold: (i) in contrast to more traditional medical interventions, xenotransplantation involve risks not only to the patient, but also to larger segments of society, thus to public

health in general; (ii) while most medical technologies demand assessment and risk-management at the time when the technology is sufficiently developed to be put into practice, xenotransplantation demands pro-active action at a very early stage of development.

The main risks of xenotransplantation stem from the possible harm that infectious diseases are transferred from animals to humans. Scientists identified the so called 'porcine endogene retrovirus' (PERV) as a possible infection of particular concern. To date no studies have demonstrated any direct transfer of PERV outside the laboratory from pig cells to human cells. But the scientists tend to agree that seven steps are necessary for PERV-infections to be a health risk to human populations:

1) PERV must be present in pig cells from the donor animal,
2) infectious PERV must be able to infect human cells,
3) PERV must be released from the transplanted organ or cells,
4) released PERV must be able to infect human tissue of the recipient,
5) PERV must be able to reproduce in the recipient,
6) PERV must be excreted and transferred to other humans, and
7) the PERV infection must lead to disease in humans.

Condition 1) and 2) were shown to hold in laboratory studies; conditions 3) and 4) were demonstrated in immune-deficient mice; the three last conditions could not yet be demonstrated. The fact that the possibility of each step is uncertain but scientifically plausible (no step can be ruled out), and that four of the seven steps necessary for the harm to occur were already shown to occur in laboratory studies, provides ground for concern. PERV is only one type of virus. There could be other viruses of concern that are not yet identified.

Further ground for concern arises from the scientific theory of zoonosis, which is widely known as one of the theories used to explain the origin of the HIV virus. According to this theory, HIV-infections have developed by zoonosis: viruses from apes became able to reproduce themselves in the human body after some initial contact with the animal, and were then spread to other humans through human contact.

Given these considerations one might conclude that:

a) there exist significant scientific uncertainties about the possible infectious consequences of xenotransplantation,
b) there exist scientifically-based models that indicate a possible scenario of harm (zoonosis),

c) this harm could be potentially great and difficult to contain and might be irreversible,
d) the harm affects an important value: human health,
e) once infectious diseases are transferred it may be too late to do something about it, and
f) there is no scientific proof that xenotransplantation can cause new viruses for humans, but
g) it is not feasible to reduce the uncertainties significantly without at the same time increasing the risk that the harm might occur, that is, perform xenotransplantations.

Conditions a)–g) can be seen as general conditions for applying the PP. Thus, precautionary measures might be indicated in this case.

Using the new definition of the PP provided by COMEST, one may also note the following: Xenotransplantation might lead to morally unacceptable harm, since human (population) health/life is potentially at stake. The evidence cited to show significant uncertainties is based on plausible scientific considerations, and not on mere speculation alone. There is significant uncertainty both in respect to what exactly might cause the potential harm, and in respect to the scope of that possible harm. A number of actions seem possible to either prevent the envisaged harm or to restrict it should it occur. This is discussed in the following paragraph.

What then are the precautionary strategies that one might want to implement as a consequence? A precautionary strategy can be defined as any measure that can be believed to effectively reduce either the risk of the harm itself, or the magnitude and spreading of the harm, should it occur. A Norwegian Governmental Commission Report (NOU 2001) discusses a number of possible strategies: a moratorium, a step-by-step and a case-by-case strategy, restrictions of uses to small and strictly monitored groups, and the international cooperation in monitoring the patients (and their families). The first is the strictest and the last is the most liberal, i.e. least effective strategy. As tempting as a moratorium may look from a societal point of view, it should be kept in mind that it only delays the problem. It might actually backfire, given that not all countries might implement a moratorium and that diseases know no borders. What one eventually wants to achieve is enough knowledge and a strong institutional apparatus to contain the possible harm should it materialise, but still allowing the

technology to develop for the benefits of patients. However, it is clear that any decision between these different precautionary strategies will be strongly influenced by value-assumptions and rest in the final instance on political decisions.

Conclusion

The Precautionary Principle has triggered extensive debate both among scientists and in political circles. The focus on scientific uncertainty and the need to manage uncertainties represents a major regime change in the way science serves as the provider of premisses/information for environmental and health policy. The PP demands that the scientist spells out all the relevant uncertainties that pertain to a situation. Furthermore, the scientist needs to assess whether there exists some scientifically plausible evidence or some science-based model that would indicate a scenario of possible future harm. This exercise asks the scientist to leave the dominating strong standards of proof within science behind, and use qualitative judgement in screening scientific knowledge for indications of what a certain technology, intervention or practice may lead to. The scientist must be prepared to engage in extra-scientific platforms with decision makers, stakeholders and the general public. Here the scientist should be ready to focus on values that are at stake and how science can contribute to protect human health, safety and the environment. Science is challenged to come up with a variety of possible precautionary strategies if the PP is to be employed, and to discuss them critically in their relevant context. The close relation to value aspects and ethics, bringing value aspects to the surface, is a challenge that scientists may not be quite prepared for yet. On the other hand, it may be precisely because of these aspects that the PP enjoys a large support in wide circles of the European population. It represents a novel idea of how scientific knowledge may indeed contribute to progress. Progress is, after all, a value concept.

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