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The Precautionary Principle

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COMEST

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Foreword

In today's environment of rapid scientific research and technological development, different ways to apply new knowledge and innovations are constantly being engendered that present us with ever more possibilities and challenges. We stand to benefit from the greater range of options this progress brings. However, with more choice also comes more responsibility. Conscious of our roles as stewards of the world in which we live, notably on behalf of future generations, we must therefore take care in exercising these options.

This need to proceed in an ethical manner is expressed in debates concerning the precautionary principle. Although the concept of precaution is not a new one, understanding of the precautionary principle has, with time, come to mean different things to different people and application of the precautionary principle has proven controversial on occasion.

Born of environmental considerations, the precautionary principle has since matured into an ethical principle with a far broader scope and the potential value of the precautionary principle as a policy guide should be envisaged.

Given its mandate in ethics of science and technology, UNESCO has a role to play here in fashioning the precautionary principle into a form that Member States can properly use in making ethical assessments of the choices science and technology present.

In conformity with the mandate received from the Member States (31 C/5), UNESCO, together with its advisory body, the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), has brought together a group of experts to propose a clear definition of the precautionary principle and provide clarification of the possible uses of this principle, aiming at offering an ethical platform to ensure proper risk management and correct information to the public and to policy makers, in view of the impact of new technologies.

We are pleased to present this report of COMEST's expert group on the precautionary principle, which provides Member States with a solid base for discussion and clarifies the principle in a pragmatic way. This is part of a wider effort UNESCO is making to promote capacity and raise awareness in the field of ethics of science and technology.

We wish to thank the group of experts for bringing to this task their intellect, enthusiasm and effort, which has resulted in this work of quality.

Jens Erik Fenstad
Chairperson of COMEST

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Director-General of UNESCO

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1. Introduction

1.1 General introduction to the Precautionary Principle

Human life is, has always been, and will always be full of risks. The urge to deal with the risks we face is a basic condition of our existence. Sailors sail on boats with lifeboats not because they expect wreckage, but because they know that it would be irrational not to be prepared for the potential dangers that they might encounter on their voyage. Science and technology not only ease some hardships of life, but can contribute to avoiding or diminishing some of the most threatening risks of nature. Recent history provides ample examples of beneficial effects of technological and scientific developments. Life expectancy has gone up significantly in most countries during the last century and many hardships of human life now belong to history. But awareness has grown that science and technology have also contributed to the creation of new threats to human existence or quality of life. Human development has come to a point where it must control its effect on the biosphere that provides the basis for all human existence.

The early stages of national and international environmental policies can be characterized by a curative model towards our natural environment. With increased environmental impacts of growing populations and industrialization, the environment was no longer able to cure itself; it had to be helped in repairing 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 damage to what could be repaired or compensated for. This 'prevention is better than cure' model marks the second stage of governmental action for environmental protection. This stage was characterized by the idea that science can reliably assess and quantify risks, and the *Prevention Principle* could be used to eliminate or diminish further damage.

The emergence of increasingly unpredictable, uncertain, and unquantifiable but possibly catastrophic risks such as those associated with Genetically Modified Organisms, climate change etc., has confronted societies with the need to develop a third, anticipatory model to protect humans and the environment against uncertain risks of human action: the *Precautionary Principle* (PP). The emergence of the PP has marked a shift from *post-damage* control (civil liability as a curative tool) to the level of a *pre-damage* control (anticipatory measures) of risks.

Over the past decades, the PP has become an underlying rationale for a large and increasing number of international treaties and declarations in the fields of sustainable development, environmental protection, health, trade and food safety. In its most basic form, the PP is a strategy to cope with scientific uncertainties in the assessment and management of risks. It is about the wisdom of action under uncertainty: 'Look before you leap', 'better safe than sorry', and many other folkloristic idioms capture some aspect of this wisdom. Precaution means taking action to protect human health and the environment against possible danger of severe damage. However, in the international arena, different views exist of what precaution is and the PP has different interpretations.

The PP is often seen as an integral principle of sustainable development, that is development that meets the needs of the present without compromising the abilities of future generations to meet their needs. By safeguarding against serious and, particularly, irreversible harm to the natural resource base that might jeopardize the capacity of future generations to provide for their own needs, it builds on ethical notions of intra- and inter-generational equity.

The increasing presence of the PP in a variety of international instruments and the potential implications the PP may have for scientific and technological development make it necessary to develop a common understanding of what the PP is. UNESCO, as an intergovernmental organization among whose priorities is the promotion of ethics of science and technology, seeks to provide its Member States with a clear understanding of the PP in order to facilitate standard-setting in this area, to raise awareness of the ethical notions upon which the PP is based, and to help Member States to build relevant human and institutional capacities.

Within the United Nations system, the PP is included in the 1992 Rio Declaration on Environment and Development, and in the United Nations Framework Convention on Climate Change. Later, the PP was incorporated into the article on precaution (Article 5.7) of the World Trade Organization's (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) of 1994, as well as into the Biosafety Protocol that was approved in Montreal in January 2000. In fact, the explicit introduction of this principle today in operational articles of the Biosafety Protocol is part of a wider-reaching movement towards giving this principle shape in the legal framework.

For these reasons, as a follow-up to the World Conference on Science of 1999 and in conformity with the Programme and Budget for the biennium 2002/2003 (31 C/5), UNESCO has decided to consolidate the role of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) as a multicultural and transdisciplinary advisory body and to focus on the ethics of the environment, taking into account both its natural and human aspects. The main objective is to offer an ethical platform from which to manage risks and keep the public and policy makers informed, in view of the impact of emerging new technologies. In this context, the PP will be an overarching consideration, with special emphasis on concepts such as environmental responsibility and sustainable development. As a consequence UNESCO and COMEST will focus on a number of issues that have been identified for the future, such as the impact of complexity on the development of scenarios for decision-making. These issues are crucial in a very practical and immediate sense because dealing with complex systems that cannot be fully predicted (for example climate change) requires a

shift of attitude from computability of consequences, to the awareness and readiness to face and manage basically unpredictable developments.

The present report is part of this initiative. It aims to reduce the gaps in the understanding of the principle and to clarify the PP for decision-makers and scientists in order to achieve a more informed debate of the principle and to serve as reference for possible further implementations of the PP. This may have positive implications for national and international environmental and health policies as well as for world trade. COMEST is working to address remaining issues of the PP, to critically discuss objections to the PP, and to clarify recurring misunderstandings in its application.

The remainder of this report is structured as follows: Section 1.2 sketches the history of the PP. Section 1.3 reviews concepts and definitions of the PP and identifies common elements in the various definitions. On that basis a working definition of the PP is given. Section 2.1 explains the ethical basis of the PP and the questions of responsibility, inter- and intra-generational equity and deliberative democracy. Section 2.2 deals with legal issues. Section 3.1 explores the characteristics of complex systems and elaborates on the concepts of robustness and resilience. Section 3.2 discusses the multiple dimensions of uncertainty in scientific assessment. These uncertainties are at the heart of the PP. Section 3.3 discusses the concept of risk and associated decision-making problems for which the PP can be helpful. Section 3.4 deals with the possibilities and limitations of cost benefit analysis, a tool widely used in decision-making.

In section 4 a range of application issues of the PP is discussed. Section 4.1 reviews the main implications of the PP for science. Section 4.2 deals with the implications for policy and governance. Section 4.3 discusses implications for industry and trade. Finally, section 4.4 discusses the social and cultural implications of the PP. In two text boxes, examples are given of decision-making problems where invoking the PP is helpful. Appendix 1 summarizes, in the form of Frequently Asked Questions (FAQ), some of the key points from this report and offers practical guidance.

1.2 History of the Precautionary Principle

The PP is a narrower concept than merely looking for safety. Precautionary 'thinking' has a much longer history. The *Late Lessons from Early Warnings* report (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, however, was very effective in halting the spread. The report then mentions a series of other examples, such as asbestos, where a precautionary approach could have saved many lives if early warnings of potential – at the time unproven but still reducible – harm had been taken more seriously. The asbestos case is summarized in Box 1.

The PP, however, dates from the 1970s. Some scholars mention a Swedish and some a German origin of the PP. In Germany the PP ('Vorsorgeprinzip') may be traced back to the first draft of a bill (1970) aimed at securing clean air. The law was passed in 1974 and covered all potential sources of air pollution, noise, vibrations and similar processes. The most unambiguous

elaboration of the PP in German environmental policy is from a later date and reads: '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, synchronized (harmonized) 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, 1984).

Box 1. The example of asbestos

Nowadays it is known that asbestos is the main cause of mesothelioma, a disease with a very long incubation time, which once it manifests is normally fatal within one year. Health experts estimate that in the European Union (EU) alone, some 250,000 – 400,000 deaths from mesothelioma, lung cancer, and asbestosis will occur over the next 35 years, as a consequence of exposure to asbestos in the past.

Mining for asbestos began in 1879. At that time science was not aware of the dangers of asbestos. The annual production of asbestos worldwide grew to 2 million tonnes in 1998. Imports to the EU peaked in the mid 1970s and remained above 800,000 tonnes a year until 1980, falling to 100,000 tonnes in 1993. There is a delay of 50 to 60 years between the peak in import of asbestos and the peak in occurrence of mesothelioma in a country.

Early warnings and actions are summarized in the following timeline:

1898	UK Factory Inspector Lucy Deane warns of harmful and 'evil' effects of asbestos dust
1906	French factory report of 50 deaths in female asbestos textile workers and recommendation for controls
1911	'Reasonable grounds' for suspicion, from experiments on rats, that asbestos dust is harmful
1911 and 1917	UK Factory Department finds insufficient evidence to justify further actions

1930 UK 'Merewether Report' finds 66 % of long-term workers in Rochdale factory with asbestosis

1931 UK Asbestos Regulations specify dust control in manufacturing only and compensation for asbestosis, but this is poorly implemented

1935–1949 Lung cancer cases reported in asbestos manufacturing workers

1955 Research by Richard Doll (UK) establishes high lung cancer risk in Rochdale asbestos workers

1959–1964 Mesothelioma cancer identified in workers, neighborhood 'bystanders' and the public in South Africa, the United Kingdom, and the United States, amongst others

1998–1999 EU and France ban all forms of asbestos

2000–2001 WTO upholds EU/French bans against Canadian appeal

In the case of asbestos, a lack of full scientific proof of harm contributed to the long delay before action was taken and risk reduction regulation was put in place. The early warnings of 1898–1906 were not followed up by any kind of precautionary action to reduce exposure to asbestos, nor by long-term medical and dust exposure surveys of workers that would have been possible at the time, and which would have helped strengthen the case for tighter controls on dust levels. A Dutch study has estimated that a ban in 1965, when the mesothelioma hypothesis was plausible but unproven, instead of in 1993 when the hazard of asbestos was widely acknowledged, would have saved the country some 34,000 victims and Euro 19 billion in building costs (clean up) and compensation costs. This is in a context of 52,600 victims and Euro 30 billion in costs projected by the Dutch Ministry of Health over the period 1969–2030.

Today, a substantial legacy of health and contamination costs has been left for both mining and user countries, while asbestos use continues, now largely in developing countries.

(Source: EEA 2001)

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, The Hague 1990, 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)

1.3 Concepts and definitions

In the literature and in international treaties and declarations, a variety of definitions can be found. A sample of the range of definitions is given in Table 1. The triple negative notion in the definition in the Rio Declaration that the *absence* of rigorous proof of danger does *not* justify *in*action is rather weak: it forces the consideration of precautionary intervention but does not require such intervention. The definition in the EU communication on the other hand does require intervention to maintain the high level of protection chosen by the EU.

Table 1. A sample of definitions of the PP

Source	Definition	Optional/mandatory action
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.'*	Includes qualifying language such as 'may require action' and 'before … absolutely clear … evidence'.
Rio Declaration (United Nations 1992)	*'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.'*	Includes qualifying language such as 'according to their capabilities' and '…postponing cost-effective measures'.

EU communication on the PP (EU, 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'.*	Requires intervention to maintain the high level of protection chosen by the EU.

Common elements

Despite the divergence in the wording of the various formulations of the PP, there are several key elements that most definitions have in common. There are also emerging broadly shared insights on the PP in the scientific and policy-maker communities. These are:

- 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 judgement 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.

One possible articulation that captures the elements that are key to the PP and takes into account criticisms of earlier attempts to define the PP is given in Box 2. This working definition is the basis of this report.

To reiterate, the grounds for concern that can trigger the PP need to be plausible or tenable.

Box 2. 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 judgement 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.**

The hypothesis that an activity can cause harm should be consistent with background knowledge and theories. If a hypothesis requires one to reject widely accepted scientific theories and facts, then it is not plausible. The hypothesis should posit causal mechanisms or processes, or if no causal mechanism is known, there should be some evidence of a possible statistical correlation. However, if a hypothesis posits radically new and unfamiliar mechanisms and processes, it is not plausible. Further, obscure and complex hypotheses are not as plausible as simple and straightforward ones. Plausibility does not need to be correlated with probability and the two concepts should not be confused. For the PP it is important to understand the difference between plausibility and probability; see Box 3 for an example.

PP and innovation

Some people fear that a more precautionary approach to forestalling potential hazards of a morally unacceptable nature may stifle innovation or hamper scientific progress. They point to the fact that new technologies typically introduce new risks. However, there are immense challenges to, and opportunities in, understanding complex and emergent systems while meeting human needs with lower health costs and lower ecological damages. Wider use of the PP can help stimulate both innovation and science,

Box 3. Plausibility versus probability

When we judge that one hypothesis is plausible but another is not, we are not saying that the plausible hypothesis is more probable than the implausible, although we are saying the plausible hypothesis is more of a serious possibility than the other. We can only judge the relative probability when we have sufficient evidence to make this determination. When we lack sufficient evidence about both hypotheses, we should suspend our judgement about which hypothesis is true because we are ignorant about that. But we should not suspend our practical judgement, because we still must decide how to act with respect to these possible hypotheses. Thus, if I spot a new growth on my skin and my two hypotheses are 'it's cancerous' and 'it's benign', I do not have to determine that the growth is probably cancerous in order to go to the doctor and have it tested. I can regard the cancer hypothesis as a serious possibility even though I do not regard it as true or even minimally probable.

(Example taken from Resnik, 2003)

replacing nineteenth century technologies and the simple science of the first industrial revolution with the clean technologies and systems science of a new industrial revolution. This can help to achieve a better balance between the benefits of innovations and their hazards.

Where many historic examples (asbestos) were about false negatives (absence of precautionary intervention that in hindsight was necessary), there is also a concern that an overly wide adoption of the PP may lead to too many false positives (precautionary intervention that later on proves unnecessary). The delicate balance between the two extremes needs to be determined on a case by case basis, and needs to be taken into consideration when the proportionality of measures to be taken are decided.

While the PP indeed may impose a 'no-go' or a 'go-slow' on certain directions of innovation and scientific progress, the PP at the same time acts as a stimulant for other innovations and clean technological progress. The PP promotes the development of innovative alternatives for potentially risky technologies. This was for instance the case with CFCs that were banned because the hypothesis was deemed plausible that CFCs destroy the ozone layer. This ban triggered many innovations and led to cleaner alternatives for virtually all CFC applications. The PP inspires a diversification of technologies. The size and societal impacts of any future surprises will be smaller if there are several competing technologies that are being used to meet human needs, rather than just one global, near monopoly technology, as was the case with asbestos, halocarbons and PCBs. Diverse technologies and alternative ways of meeting needs can help deal with the seemingly intractable problem of 'societal ignorance' and attendant surprises.

What the PP is not

To avoid misunderstandings and confusions, it is useful to elaborate on what the PP is not. The PP is not based on 'zero risks' but aims to achieve lower or more acceptable risks or hazards. It is not based on anxiety or emotion, but is a rational decision rule, based in ethics, that aims to use the best of the 'systems sciences' of complex processes to make wiser decisions. Finally, like any other principle, the PP in itself is not a decision algorithm and thus cannot guarantee consistency between cases. Just as in legal court cases, each case will be somewhat different, having its own facts, uncertainties, circumstances, and decision-makers, and the element of judgement cannot be eliminated.

2. Precaution as ethical responsibility and legal norm

In this section the ethical basis and legal status of the PP will be reviewed. In section 2.1 the notion of ethical responsibility, equity issues, environmental protection, and democracy and the moral right to have a say will be discussed respectively. The role of ethical and legal principles in law, the issue of legally binding versus guiding, the relevance of a distinction between Precautionary Principle and precautionary approach, the ways in which the PP is introduced in international agreements and national legislation and the issue of liability and burden of proof are discussed in section 2.2.

2.1 Precaution as ethical responsibility

The PP has an ethical basis, and applications of the PP are value-sensitive. The working definition of the PP given in Box 2 talks about 'morally unacceptable harm'. Morality refers to beliefs and practices about good and evil that guide our behaviour. Ethics is the explicit, philosophical reflection on moral beliefs and practices.

One of the features of ethics that many people regard as problematic is the apparent great variety of ethical theories available. Some of these ethical theories, if applied consistently to a given case, might even yield contradicting moral obligations or moral prohibitions. This plurality seems to contradict the universal appeal of ethics and to the principle of universalism in ethics itself.

Yet, people who tend to disagree on abstract principles of moral thought, on religion, or ethical theory, very often manage to come to an agreement on the moral rightness or wrongness of particular actions for specific cases. This is because moral judgements are less subject to plurality and rest on a firmer basis than the ethical theories that one adheres to. This indicates that in spite of the plurality of ethical theories, ethical relativism is not the only option. In fact, the convergence of many moral judgements on specific problem-cases may be seen to reveal that there is a universal basis for ethics that is as yet only partially revealed by current academic theories of ethics.

When ethics is integrated into political and legal thinking, one should be careful to, on the one hand, acknowledge the diversity and plurality of ethical thinking and, on the other hand, strive for as much practical consensus on moral judgements as is possible. One way to do this is to deflect our thinking away from ethical theory and rather focus on more specific ethical principles and ethical values.

The notion of ethical responsibility

Ethical responsibility implies some freedom of choice in action. The notion that individuals (or firms, or States) are morally responsible for the choices they make is a crucial ethical basis of the PP.

Culpable ignorance and the PP

Culpable ignorance is one of the crucial ethical foundations of the PP. The concept has some tradition in ethics and law. It can be used in three ways. Firstly, it can be used in order to blame a person (or a firm or a State) for damage they have caused even if they did not know that damage would follow their action. This is because people have a moral responsibility to make an effort to find out whether their actions might lead to damage. Ignorance is considered blameworthy when an action is taken that is or could have been disastrous, even if, due to chance, no actual damage follows the action. What is blameworthy is not that one was ignorant, but that one did not make an effort to reduce that ignorance.

Secondly, the concept may function as an incentive to further investigation. If ignorance about possible consequences is great, one may delay action until more knowledge is available. Thirdly, the concept can be used as a reason for not acting in a certain way. A person may think that it is impossible to be more informed about possible harmful consequences of the action, and that it would be blameworthy to start the planned action on such a poor basis of information. This may be the case even if great benefits are forgone, that is the negative consequences of not acting are significant. This reflects an asymmetry between action and omission, which will be further explored below.

A key issue with culpable ignorance concerns the knowledge that one seeks or with which one is satisfied. In a situation of ignorance and uncertainty no reliable knowledge about future outcomes is available. Yet, ignorance is culpable only if one does not seek out and utilize other relevant information and knowledge, such as general knowledge about the type of situation that one may encounter. For instance, knowledge about the typical failures of an old car would mean one is morally responsible to have the brakes checked regularly. If failing to do so leads to an accident, one might be held accountable for it. Within the context of the PP one might point to parallels in complex environmental systems: even though one might be unable to reliably assess the risks, one might have enough knowledge to strengthen the general resilience of the system. Thus one may not be morally responsible for every possible consequence that one is not fully informed about, but one may still be morally responsible for acting to increase the resilience of the system to avoid possible breakdowns or catastrophes.

Actions and omissions

In decision theory, one of the courses of action that is always included in the calculus is not doing anything. Actions and omissions are treated on a par. In traditional ethics, however, one normally maintains that when facing quite risky decisions with the possibility of bad outcomes, one should refrain from doing anything, even if one's omission to act might cause greater harm. This position is directly coupled to one's moral responsibility: one is seen as more responsible for what one actually does than for what one fails to do. In medical ethics this moral attitude is common: the difference between causing a death and allowing a person to die is considered significant. The moral difference between actions

and omissions is also often reflected in criminal law: the failure to carry out an obligation is usually a lesser crime and never a greater crime than committing actions that violate prohibitions. There is a moral asymmetry between actions and omissions that is reflected in the degree of responsibility a person or an institution has.

Co-responsibility and special responsibilities

In many real-life situations responsibilities are shared: outcomes that matter result from my actions in combination with what other people do or do not do. Industrial or technological accidents, for instance, have seldom only one source of human failure; more typically they are the result of a chain of interrelated actions and systemic technological design.

In a moral context a person can only be made responsible for a certain outcome to the extent that their actions contributed to it. A person cannot be held responsible for factors that are beyond their control (or knowledge) but they do have some co-responsibility for certain outcomes to which they have contributed.

In some circumstances a person may hold greater responsibilities than most other people because they hold a role that is assigned greater responsibility. Ownership (for example of land) is one such special responsibility, being a guardian for a child another. Very often we assume special responsibilities as a consequence of the professional roles we hold. For instance, a priest may assume a special responsibility for the care and comfort of dying patients in a hospital, whereas a scientist may assume a special responsibility for informing the public about scientific matters. In the context of the PP, one may claim that, for example, scientists hold a special co-responsibility for disseminating information about the uncertainties involved in a specific decision. While very few of us are ever fully responsible for complex chains of events or decisions, many are co-responsible, and some may be especially responsible due to their professional or other role in regard to the situation.

Equity issues

The classic conception of sustainable development implies that the needs of present generations should be met provided they do not impair the ability of future generations to meet their needs. This implies an ethical balance between present and future generations. There is ample reason to say that as a moral norm inter-generational equity is not entirely new, but implied by traditional moral claims of universality and justice. The fact that it has been formulated in an explicit manner quite recently may be seen as the result of the recognition that many of our (technological and other) actions and decisions today have far-reaching consequences into the future (as, for example, storage of radioactive material).

Another reason to be explicit about inter-generational equity is that cost benefit analysis (CBA) tends to discount future interests and needs in such a manner that they have little value. In discounting it is assumed that in the future, incomes and welfare will have increased substantially, so that a dollar spent (or gained) in 50 years from now should weigh less than a dollar spent (or gained) today. Discounting in Cost Benefit Analysis (CBA) tends to favour activities that have short-term gains and long-term negative effects. It does not take account of how negative effects may be valued differently by the future generations who face them.

Inter-generational equity demands that there are certain limits and restrictions on the

extent to which future needs and consequences can be discounted. The PP, being directly related to the principle of sustainable development, incorporates inter-generational equity in the sense that considerations of possible significant long-term and future harm provide enough reason to act now, even though present interests may not be threatened. The PP should embrace the principle of inter-generational equity.

But equity has also another dimension: intra-generational equity. The distribution of benefits and risks is not only due to individual behaviour and merit, but also due to systematic socio-economic differences among various groups of people and societies. In this way equity issues arise, most notably between developing countries and the industrialized countries. The dramatic and systematic differences in the distribution of wealth, health care, education, civil rights, welfare and other goods among countries is disquieting both from an ethical perspective and from the perspective of global political and economic stability.

Many people and many governments and international bodies (all UN bodies including UNESCO) recognize that truly positive social, political and economic development within a nation is not possible without the reduction of existing global inequalities. The principle of intra-generational equity does not require an equal sharing of benefits and risks across the globe, but that there be fairness with regard to the opportunities each person has to lead a meaningful life under conditions of economic, social and political security. The PP is built around the idea that the costs of human-made risks should not be externalized, neither to the local environment nor to the environment of other societies or nations. The PP should embrace the principle of intra-generational equity.

Environmental protection

There are different schools of thought about how we should value nature ranging from those that put humans at the centre of the world and assign priority, value and respect to humans and human concerns to those that claim that the environment and non-human lives have a value of their own, independent of their value to humans, and that they deserve respect and protection. Both views support the PP. Whether one considers that the health and integrity of ecosystems and the preservation of species is important for the well-being of humanity or because they have value in their own right, any potential harm from human activities that might jeopardize these is morally unacceptable. Since nature does not have a voice of its own the 'interests' of nature need to be taken care of in the decision-making process. Deliberations on the PP should explicitly consider the negative impacts that human activities may have on nature, even if these impacts do not pose direct risks for humans.

Democracy and the moral right to have a say

It is one of the ethical principles of modern democracies that parties affected by a decision should have their preferences taken into account when the decision is made. For instance, the *Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters* (Aarhus, Denmark, 25 June 1998) states in Article 7: 'Each Party shall make appropriate practical and/or other provisions for the public to participate during the preparation of plans and programmes relating to the environment, within a transparent and fair framework, having provided

the necessary information to the public. […] To the extent appropriate, each Party shall endeavour to provide opportunities for public participation in the preparation of policies relating to the environment.'

The ethical principle behind such statements is that decisions that affect parties other than the decision-maker should be consented to by these parties in conditions of transparent process and with freely accessible information. In cases where the consent of all parties involved cannot be obtained or assumed for practical reasons, or where there are conflicting views and a decision has to be made, one should go to great lengths to consult with these parties and let their views inform the relevant considerations of the decision-maker. This is normally done through participatory consultation processes. One of the main aims of such processes is to understand the conflicting values of the involved parties that may provide for different evaluations of possible outcomes. PP decisions should involve the participation of all those affected.

2.2 Legal issues

Despite the success of the PP in the fields of national, EU and international law, its outlines are far from clear from a legal point of view. According to diverse definitions in these legal orders and case law applications, the principle can in fact be understood in a variety of ways.

Ethical and legal principles

Ethical and legal principles are the foundation of the law that guides the application of norms relative to the object of protection. Their utility is based on three fundamental aspects. First, principles should be considered as one of the standards, among others, that allow the evaluation of the validity of a law. Second, principles have the potential to assist in the interpretation of other rules. And, third, principles have the capacity to fill legal gaps.

A principle can have different meanings in different legal orders. However, regardless of the legal system, principles are the central ideas, representing its logical, harmonic and coherent meaning. A principle is the central determinant of a specific legal system; it is its fundament that, because of its superior hierarchy, influences and resonates on all norms of the system and on the way to apply them.

While it is difficult to agree on fixed and precise rules at the international level, it is far easier to come to a public understanding about indefinite *principles* that can progressively be given more concrete form. Essentially the PP is an appeal to prudence addressed to policy makers who must take decisions about products or activities that could be seriously harmful to public health and the environment. For that reason, this emerging principle of international law does not offer a predetermined solution to every new problem raised by scientific uncertainty. On the contrary, the PP is a guiding principle that provides helpful criteria for determining the most reasonable course of action in confronting situations of potential risk.

Arguably, a strength of the PP being a principle is thus its open-endedness and flexibility, which creates a possibility and an incentive for social learning.

To what extent is the PP legally binding?

From a legal point of view, the question is whether precaution will become a legally binding principle

in customary international law and national law, rather than a guiding principle only. In the field of environmental law, such as the Cartagena Protocol on Biosafety, the PP seems to be on its way to become legally binding.

In the international context, it is frequently argued that Declarations of principles are not traditional sources of international law and are not binding for the member States of the organization that adopted them. It is also said that, due to this peculiarity, these international texts do not have the same legal force as international treaties and conventions. Strictly speaking, declarations of principles would just be 'recommendations', without binding force. However, this does not mean that these declarations of principles do not have legal relevance. Even if they cannot be considered as sources of new international law, they are at least legitimately capable of generating international norms. In fact, the strength of a Declaration depends on the degree of acceptability of the principle that it encompasses. Therefore nowadays nobody would dare to say, for instance, that sanctions might not be imposed by international organizations against countries that do not respect the Universal Declaration of Human Rights.

Declarations of principles, though not binding, can influence the elaboration, interpretation and application of the international laws of member States of the international organizations that conceived or endorsed the declarations. The reason is that, in joining an international organization, a State accepts a number of obligations. The State commits itself to the aims of the organization. Thus, when a State complies with a guideline or a policy of the entity it therewith accepts the rules of the constituent treaty of the organization. Often, the State has participated in the formulation of these guidelines or in the negotiations of international conferences. One cannot underestimate the influence that general principles exert on legal formulation, be it in the international context or in the internal legislation and jurisprudence of countries.

Indeed, all legal formulation is marked by two essential events: first, the recognition of a value by society as worthy of protection; and second, the provision of legislative tools in order to protect this new recognized value. International declarations of principles correspond necessarily to the first event in legal formulation. They are true inventories of values recognized by the international society as meriting protection. In practical terms, all subsequent formulation of both international and domestic laws then start to take due account of such principles.

Thus, in spite of not being obligatory and binding, principles of law constitute important tools for the crystallization of new concepts and values. In compliance with Article 38 of the Statute of the International Court of Justice, the general principles of law are also sources of international law (see Box 4).

Therefore, it seems incontestable that among the principles emanating from international declarations, the PP is legally relevant and cannot be disregarded, either by the countries in the international order, or by legislators, policy makers and courts in the domestic sphere. From the moment when the PP is recognized as an element of international law, it also becomes part of the general principles of environmental law, with undisputed legitimacy in guiding the interpretation and the application of all legal norms in force.

Precautionary principle/ precautionary approach

Although there is discussion about the meaning of the expressions *principle* and *approach* concerning

Box 4. Article 38 of the Statute of the International Court of Justice

Article 38 - The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:

(a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;

(b) international custom, as evidence of a general practice accepted as law;

(c) the general principles of law recognized by civilized nations;

(d) subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

precaution, in general *principle* is employed as the philosophical basis of the precaution and *approach* as its practical application. Therefore in most cases the terms will be closely related. Certainly, the phrase 'precautionary approach' has often been used in international settings to refer to the PP. The Rio Declaration, for instance, uses the word 'approach' in the English version, and the word 'principio' in the Spanish version. Where the PP has reached the status of a general principle of law or a customary rule of international law, those that prefer the term 'approach' sometimes deny such status to it.

PP in international agreements and national legislation

Nowadays, the PP abounds in declarations, resolutions and guidelines enacted in different international settings. Recently, international lawmakers have been endorsing the PP in most major agreements related to environmental protection (more than 60 international agreements). Despite its wide recognition in international treaties, international courts (ICJ, ITLOS, WTO Appellate Body, ECHR) have nevertheless remained reluctant to accept the PP as such.

The PP is frequently introduced in framework conventions. Although this strategy is widely used in international environmental law, it is merely a first step in elaborating more precise rules at the international level fleshing out that principle. Furthermore, in a number of international agreements, the PP is worded in such a way that it is deprived of immediate and autonomous applicability. Use of terms such as 'form a basis for', 'inspire', 'endeavour', etc. imply that the principle is merely intended to prepare States to implement their international obligations. Only the repeated use of State practice and consistent *opinio juris* are likely to transform precaution into a customary norm.

Many EU policy programmes, political statements, strategy documents and White and Green Papers refer to the PP. Given the non-binding

nature of these instruments, the PP is somewhat deprived of a legal effect because it does not constrain the EU institutions to act in a strictly determined manner. The PP is nevertheless enshrined in the EU Treaty and is encapsulated increasingly in secondary law (directives and regulations, in particular those applying to environmental issues, Genetically Modified Organisms and food safety).

As autonomous norm, the PP enshrined in national legislation may produce concrete results mostly at the level of administrative jurisprudence (Australia, Belgium, France, Germany). In other words, it is, above all, at the level of litigation that the principle comes into play.

Liability and burden of proof

A precautionary approach would be favoured if liability were to be given better shape in international policies. Liability is the obligation of a person under the applicable law to provide compensation for damage resulting from an action for which that person is deemed to be responsible. The PP requires that the main burden of providing evidence for safety rests on the proposers of a new technology or activity. Levels of proving the absence of risk should be inversely related to the extent of liability of actors: reduced burden of proof for prospective actors should translate into stricter liability.

3. Complexity, risk and cost benefit analysis

The PP applies to a special class of problems that is characterized by: (1) complexity in the natural and social systems that govern the causal relationships between human activities and their consequences and (2) unquantifiable scientific uncertainty in the characterization and assessment of hazards and risks. The existing decision-support tools to cope with risks in a rational way, such as probabilistic risk assessment and cost benefit analysis, have limited value under these conditions. Some of these issues may be well-known to scientists, but one cannot assume that all relevant decision-makers recognize the implications of them for the PP. Therefore a brief excursion into the basic characteristics of these issues will follow.

3.1 Complex systems, robustness and resilience

There is a growing awareness that the behaviour of natural and social systems is more complicated than scientists had previously believed. In particular, the dynamics of these systems may not be regular (with conditions today following closely upon the conditions of yesterday), but characterized by thresholds or non-linear behaviour where conditions today may bear little resemblance to conditions of the immediate past.

In these complex systems, then, periods of relative stasis (conditions remaining largely the same) can suddenly give way, and the system can 'lurch' towards another fundamentally different state. Some examples include the large-scale ocean circulation that currently transports heat on the Northern hemisphere from the mid latitudes to the high latitudes (known as the "Thermohaline Circulation"), which geological analysis and model experiments suggest can be on or off, with drastic changes for the environmental conditions of Western Europe between the two states. To give another example, cultures can be open to external influences, or more insular and can, on long time scales, oscillate back and forth between these two states.

Systems that can suddenly cross thresholds or flip to a new state give rise to different policy and management challenges than do systems that respond more gradually to changes (always returning to the same stable configuration each time they are perturbed away from it), not the least because care must now be exercised to avoid states of the system that are undesirable, or to access or remain in states that are desirable. At the same time, it must be recognized that systems that are characterized by these non-linear behaviours can be, at times,

difficult to 'steer' – management policies and interventions may themselves give rise to unexpected outcomes. In such systems, experimentation and adaptation are critical components of effective management strategies. And evidence is accumulating that these state flips are pervasive, and management and policy approaches must rise to the challenge of their existence.

Several complementary research projects and bodies of scientific literature have dealt with the existence of multiple stable states and their implications for policy and management, including resilience, robustness, adaptive management, sustainability science, vulnerability science, and complex adaptive systems more generally. We will briefly elaborate on the concepts 'resilience' and 'robustness' because these concepts provide ways to cope with complex systems in a more responsible way.

Resilience is the capacity of a system to tolerate disturbance without collapsing into a qualitatively different – usually undesired – state. For instance, a resilient ecosystem can withstand shocks and rebuild itself when necessary. Resilience in social systems includes the capacity of humans to anticipate and plan for the future, and to adapt to inevitable unanticipated conditions. Humans depend on ecological systems for survival and their actions are continuously impacting ecosystems from the local to the global scale. Resilience is a property of these linked social-ecological systems. Resilience has three characteristics: (1) the amount of change the system can undergo and still retain the same controls on function and structure, (2) the degree to which the system is capable of self-organization, (3) the ability to build and increase the capacity for learning and adaptation. The first two are also the focus of vulnerability science (see also section 4.1) and fostering of the third should be a central element of any precautionary governance.

The concept of robustness can be understood in different ways. In scientific risk assessment, a robust finding is one that holds under a variety of approaches, methods, models, and assumptions and one that is expected to be relatively unaffected by uncertainties. Robust findings should be insensitive to most known uncertainties, but may break down in the presence of surprises. On the level of risk management the concept is also useful: a robust risk management strategy is one that is relatively insensitive to over- or underestimates of risk. That is, should the problem turn out to be less serious or more serious than foreseen, the policy would still provide a reasonable way to proceed.

The research developments from 'simple science' (characterized by the mono-causality of laboratory experiments under controlled and idealized conditions) towards 'systems science' (accounting for complex non-linear interactions of open systems under un-controlled conditions) have obvious consequences for applications of the PP. First of all, complex systems that can flip between multiple states and their accompanying non-linearity provide a special challenge to our ability to predict future states. There is an inherent uncertainty in these systems, an uncertainty that typically cannot be avoided by more research. Secondly, the wise management of such systems, especially those that may enter very undesirable states, seems to call for a precautionary approach that does not strain the limits of the system. Thirdly, robust precautionary strategies to manage such systems may focus on building up the resilience of the system. Thus, precautionary action may include a variety of scientifically based strategies.

3.2 Multiple dimensions of uncertainty in scientific assessment

The science involved in issue-driven risk assessments differs significantly from the science of curiosity-driven laboratory practice. Risk assessment regarding, for instance, anthropogenic climate change, Genetically Modified Organisms, or endocrine disruptors, involves uncertainties of many sorts, not all of which can be resolved. The task of risk assessment is further complicated by the fact that it typically takes place in a context of hard political pressure, disputed values, and high decision stakes. In such a situation the classic mode of scientific analysis in the form of puzzle solving within an unquestioned framework or 'paradigm' is unfeasible. However successful this approach is in mono-disciplinary research, it meets its limits when society is confronted with the need to resolve trans-disciplinary policy issues regarding transnational and trans-generational risks. For these no unquestioned frameworks exist yet. Risk assessments tend to be dominated by models, scenarios, and assumptions. Hidden values tend to determine the problem frames, indicators, and assumptions of these models and thereby may colour the outcomes.

Important observations about uncertainty include:

- Uncertainty is more than statistical error or inexactness of numbers: it is increasingly understood as a multidimensional concept involving quantitative (inexactness) and qualitative dimensions (think of unreliability stemming from the limitations of the assessment methods used; ignorance; the use of assumptions; and limited social robustness of findings and methods). Uncertainty can manifest itself in different parts of the risk assessments (for example: context, system boundaries, indicator choice, model structure, parameters and data). Most present day uncertainty methodologies and practices focus only on quantitative uncertainty in model parameters and input data. Methods to address qualitative dimensions of uncertainty are absent or in an early stage of development. Uncertainty in, for example, model structure, model assumptions, and model context require more attention;
- More research does not necessarily reduce uncertainty. It often reveals unforeseen complexities and irreducible uncertainty;
- High quality science does not require low uncertainty;
- In problems that are characterized by high system uncertainties, knowledge gaps, and high decision stakes, unquantifiable dimensions of uncertainty may well dominate the quantifiable dimensions.

Many actors have vested interests in how a given risk is interpreted, be it food safety, global warming or electromagnetic fields from mobile phones, and therefore are not necessarily averse to exaggerating or downplaying scientific uncertainty. Just as science is often strategically used (for instance, through selective and biased use of sources to favour one's policy agenda) by different actors in policy debates, scientific uncertainties are sometimes magnified and distorted, sometimes neglected and played down. The uncertainty question can be (and is) actively used as a strategy to undermine the role of scientific assessment, either to achieve the postponement of measures, or to achieve a ban on a new technology.

Often we find ourselves in a situation where the available scientific evidence allows for more than one tenable interpretation. Scientific

consensus about the truth of many contemporary risks is unlikely to be achieved given the complexities and uncertainties faced. Consequently, science cannot be expected to provide ultimate authoritative answers about causality, nature, magnitude and probability of many contemporary risks. Society might have to learn to live with radical uncertainty and pluralism in scientific assessment of risks.

A better awareness of the limits of science in relation to the risk analyst's task of providing a scientific basis for policy debate and a widening in focus from 'reducing uncertainties' to 'coping with irresolvable uncertainties and complexities' can help to avoid misunderstandings and undue expectations of the role and competence of science.

3.3 Risk

Risk means chance or possibility of loss or bad consequence. It refers to the possibility, with a certain degree of probability, of damage to health, environment and goods, in combination with the nature and magnitude of the damage. The classic formula for quantifying risk combines magnitude of damage and probability:

Risk = *Probability* x *Damage*.

Risk denotes a possibility that an undesirable state of reality (adverse effects) may occur as a result of natural events or human activities. This means that humans make causal connections between actions (or events) and their effects, and that undesirable effects can be avoided or mitigated if the causal events or actions are avoided or modified.

Several authors have argued that the implementation of the PP demands a clear functional separation between those responsible for the scientific evaluation of the risk (risk assessment) and the decision-makers responsible for taking the final decision (mainly goal and strategy formulation and implementation) and requires the involvement of all those having a direct interest in the issue, such as consumer groups and representatives of the industry. Others see the assessment and management activities as interwoven since the design of assessments cannot be kept in strict isolation from qualitative value assumptions.

People consider a number of dimensions or risk attributes when they judge risks and decide whether or not they consider a given risk acceptable or not. The degree to which people consider a risk acceptable or not depends not only on the magnitude of the damage and the probability that damage will occur, but on other risk dimensions as well. A given risk tends to be seen as less acceptable if the (perceived) controllability of consequences is lower; if the nature of the consequences is unfamiliar and dreadful; if one is exposed to the risk involuntarily; if the benefits of the activity are less clear and smaller; if the effects are more acute and more nearby in space and time; if risk and benefits are unfairly distributed; and if the likely harm is intentional.

Attitudes towards risks vary from person to person and across cultures. Some people have a risk-seeking attitude whereas others have a risk-averse attitude. Environmental risk attitudes tend to correlate with the way that people view nature. Those that see nature as robust tend to be risk-seeking, those that see nature as fragile tend to be risk-averse. In between are those that have a risk-regulating attitude, corresponding to a view of nature as 'robust within limits', and those that are indifferent to risk, corresponding to a view of nature as capricious or risk as fate. One should further be

aware that being risk-averse to ecological risks is not the same as being risk-averse to economic risks.

The cultural plurality in risk attitudes implies that the question of how society ought to deal with risks can only be answered in public debate – a debate in which people will necessarily discuss their perception of risks and risk management from different points of view and different conceptual and ethical frameworks.

Risk and decision-making

Decision theory purports to study human decisions descriptively and provide a normative framework for rational decision-making. The elements of decision theory are quite simple: a choice between different courses of action; some knowledge about different outcomes or consequences of these options; and, finally, an evaluation of each outcome, that is a value attached to every consequence based on preferences. Generally four types of practical decision problems can be distinguished: a decision under certainty; a decision under risk; a decision under uncertainty; and a decision under ignorance. In the case of certainty we know the outcomes of different choices and the only challenge is to be clear about one's preferences. In the case of risk we know the outcomes (benefits and adverse effects) and the probability of various outcomes. In the case of uncertainty we know the possible outcomes but have no objective ground to estimate their probability. In the case of ignorance we do not even know what adverse effects to anticipate or we don't know their magnitude or relevance and have no clue of their probability.

When both the utility and the probability of the various outcomes of a decision are known, maximizing expected utility is generally advocated as a rational decision rule. However, this is not the case with the PP, which applies to decisions under uncertainty.

Risk management based on quantitative risk assessment and the setting of quantitative norms and standards for acceptable risk for different activities has become the dominant paradigm in the risk policies of many nation-states. This approach is often regarded as scientific, because it draws on empirical evidence. It is, however, not a purely objective endeavour because it employs normative assumptions about the types of harms that should be addressed; the level of risk that is acceptable; the choice of a limited set of risk dimensions that are considered in the judgement of acceptability; the implicit choice to consider the unquantifiable as well as the distribution of benefits and harms to be irrelevant.

The usefulness of this quantitative approach is further limited by lack of agreement about the utilities or indicators to be used in the risk assessment to compare outcomes for different decision options (for example dollars lost/saved, lives lost/saved, species lost/saved, years of life lost/gained, etc.) and how to weigh them if different indicators are used simultaneously. Finally, scientific uncertainties and knowledge gaps that hamper the ability to reliably assign probabilities to the various outcomes.

Different rational decision strategies have been developed for decisions where the probability of outcomes is unknown. What approach is the best depends, however, on one's attitude towards risk, that is whether one is for instance risk-averse, risk-tolerant, or risk-seeking.

For instance, *maximin* is the strategy that chooses the option that has the best (that is: the least severe) worst-case scenario. It makes sense if

we have little to win and a great deal to lose, but it tends to prevent us from taking advantage of opportunities. Such a strategy seems the only rational course when we are gambling with outcomes that affect not only us, but also others. It would be unjust to let others suffer unnecessarily from our unlucky choices. One may note that the maximin strategy already contains the seeds of precaution. Closely related to maximin is the *difference principle*: one society is better off than another if the worst-off members of the former do better than the worst-off of the latter. Maximin allows the most disadvantaged members of society to be harmed if the overall society benefits; the difference principle would forgo an overall benefit to the society if it harmed the most disadvantaged members.

Arguing from an ethical point of view, one may say that in certain types of situations the use of decision theory prescribes the course of action that is both rational and ethical. One could even say that decision theory not only may, but also should be used in ethics. People who have moral goals, should seek to realize them rationally. If the goals should be achieved, then rationality should control the relationship between means and ends. There is, however, an important proviso to this claim: some important types of situation demand close attention to morally relevant aspects and facts that are not routinely captured in decision theory.

The PP has arisen from unresolved problems of the existing decision support approaches outlined above. When the bounds of the possible outcomes are not known and no credible ground exists for the quantification of probabilities, and ethical dimensions of inter- and intra-generational equity are at stake, the other decision principles fail to satisfactorily address these problem characteristics. For exactly these cases, the PP offers a rational alternative. Because the PP applies to those cases where serious adverse effects and surprises can occur with an unknown probability, it is rational to follow a 'better safe than sorry' strategy. Failing to take precautionary measures in a timely manner could result in devastating and irreversible consequences. Such consequences might have been avoided by proactive and anticipatory interventions whose costs are justifiable in comparison to the damages and losses that could occur.

3.4 Considering costs and benefits

The regulation of risky activities, such as the introduction or implementation of new technologies, always involves some form of consideration of costs and benefits. Considering the positive and negative effects of an activity is also important in the PP. The potential harm resulting from certain activities should always be judged in view of the potential benefits they offer (compare this to the proportionality criterion in the EU approach to the PP). Similarly, the positive and negative effects of potential precautionary measures have to be considered. Some way of systematically assessing negative and positive effects is therefore necessary, but – as explained in the chapter on ethical issues – not necessarily sufficient, in order to arrive at a balanced decision on complex ethical problems.

Cost benefit analysis (CBA) is one of the most widely used formalized methods that aim to support decision-makers in weighing the costs and benefits of different policy options. In theory the potential and scope of CBA are quite large. In practice CBA is often applied in ways that make it difficult to assess the distant, uncertain, or irreversible harms that characterize situations requiring the PP.

When CBA is applied and used without a full understanding of its possibilities and limits, a variety of important issues may be sidelined, which are briefly discussed here. For example, the tendency of CBA to focus primarily on economic aspects means that issues of equity, morality and public acceptability often will be neglected. Cumulative impacts, irreversibility and irreplaceability are also issues that can be neglected. For example, it is debatable whether CBA can take account of the fact that the decision to preserve an area is reversible, whereas the decision to develop an area may be irreversible. Whereas profits can be made from a variety of activities, the loss of environmental quality cannot be so easily replaced.

CBA relies on quantification of all aspects that one wants to consider in the analysis. Often this occurs in monetary terms or in terms of expected utility. When environmental values are converted into monetary terms in a CBA, it implicitly assumes that environmental 'goods' are interchangeable with manufactured goods and replaceable without overall loss of welfare. The methods for quantification and monetarization are highly disputed. Environmental values such as the value of clean air and water, unspoilt wilderness areas, ecological balance, and diversity, and social values, such as community feeling and a sense of security, are difficult to quantify and some say they cannot or should not be measured. Such values differ from person to person and across cultures, and their valuations will include economic, ecological, aesthetic and ethical components.

CBA does not deal with who gets the benefits and who suffers the costs. CBA typically favours a risky activity as long as the sum of the benefits outweighs the sum of the costs, even if a small group of people get the benefits and a whole community suffers the costs. Thus aggregation of costs and benefits may obscure ethical issues of fairness and equity.

Given the limits of CBA, its use should always be interpreted with caution and should be complemented by other methods that may be better suited to tackle the thorny political, social and ethical issues that frequently characterize situations where the PP applies. These methods can include public and transparent debate on options, particularly when phenomena are difficult to quantify and values are at stake. Nevertheless PP discussion needs to take account of economic and other costs and benefits.

3.5 Conclusions

In summary, the PP applies when the following conditions are met:

- there exist considerable scientific uncertainties;
- there exist scenarios (or models) of possible harm that are scientifically reasonable (that is based on some scientifically plausible reasoning);
- uncertainties cannot be reduced in the short term without at the same time increasing ignorance of other relevant factors by higher levels of abstraction and idealization;
- the potential harm is sufficiently serious or even irreversible for present or future generations or otherwise morally unacceptable;
- there is a need to act now, since effective counteraction later will be made significantly more difficult or costly at any later time.

In Box 5 these conditions are illustrated using the example of xenotransplantation.

Box 5. Conditions under which the PP applies: the example of xenotransplantation

Xenotransplantation is the transplantation of organs from animals to human beings, for instance the heart of a pig. 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.

Conditions 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 Precautionary Principle. Thus, precautionary measures might be indicated in this case.

4. Application issues

The introduction of the PP in risk governance and national and international law has implications for several institutions and actors. In the following, the implications for science (4.1), policy and governance (4.2), industry and trade (4.3) and finally, social and cultural implications (4.4) will be discussed. Recommendations are given to promote effective implementation of the PP.

4.1 Implications for science

The PP asks for a number of changes in scientific culture and in the way in which risk assessment is performed. These are discussed below.

Coping with uncertainty

The PP requires a science that better reflects uncertainty and complexity in the assessment of risks. Both qualitative and quantitative dimensions of uncertainty need explicit treatment. Uncertainties along with the key assumptions on which knowledge claims on risks are conditioned need to be made explicit and communicated clearly to the various actors involved in the discourses on these risks. This requires the further development and dissemination of multidisciplinary and multidimensional uncertainty analysis, which enables the delivery of policy-relevant quantitative information on risks together with the essential warnings about its uncertainties, limitations and pitfalls. The PP imposes a clear need to improve communication and reflection on various levels and types of uncertainty in scientific assessment.

Enhance the role of vulnerability science: systematic search for surprises and ways to constrain them

The *Late Lessons form Early Warnings* study (Harremoës et al., 2001) has shown many examples of unanticipated adverse effects of new technologies. Given the absence of adequate methodology to assess surprise, a systematic search for examples of surprises and non-linear system behaviour from the past might be the prelude to a search for possible future surprises. Other strategies that can help us to anticipate surprise include focusing on the underlying principles of surprise and systematically 'thinking the unthinkable' by imagining unlikely (undesirable) future events or future states of the environment, followed by the construction of plausible scenarios by which they might be realized.

From such an analysis it may be possible to identify precautionary interventions that constrain the possibilities of the system developing towards potential undesired states. For instance, the global

change research community has become more and more aware of the irregular aspects associated with humanity's transformation of the planetary environment. A growing body of evidence produced by paleo-scientific studies reveals that major dynamic patterns, complex interactions, and feedback loops in the total Earth System can be flipped to different modes of operation by internal and external perturbations. Revealing the mechanisms that bring about such 'extreme events' in the coupled nature-society system is a major scientific challenge.

Novel approaches – taking full advantage of the recent progress in non-linear dynamics and complexity theory – will be needed. A key challenge here is the advancement of *vulnerability science*, which is able to identify those directions that represent a catastrophic risk to the system at stake by modelling responses of systems to multiple perturbations and stresses.

Enhance the role of monitoring and empirical research

One of the difficulties in understanding complex environmental systems is that short-term observations (even of decades or a century) may be too short to reveal the full range of possible behaviours of the system. Scientists cannot use observations to demonstrate the existence of an alternative state that has not, for instance, appeared in the observational record. Therefore, the PP requires further development of models of integrated social-ecological systems that exhibit complex behaviours on a variety of spatial and temporal scales. These models, which may reveal the existence of undesirable states and give some indication of the warning signals of change from one state to another must be accompanied by a more intensive effort in monitoring. By placing a greater emphasis on direct measures to systematically monitor observable effects on occupational, public or ecosystem health, a precautionary approach offers a way to be more responsive to harm when the first signals of it manifest themselves in the real world, however ambiguous these first signals may be. History has shown many cases (asbestos, benzene, etc.) where this kind of monitoring could have permitted much earlier avoidance of what eventually came to be recognized as serious impacts on human health or the environment.

Likewise, more strenuous efforts might be made to conduct research into outstanding questions or anomalies in our understanding of particular hazards. By enhancing both scientific research and environmental and health monitoring and by an active search for early warnings, one can hope to significantly reduce society's exposure to uncertainty and ignorance.

Be more realistic about the role and potential of science in assessment of complex risks

Precaution entails a greater degree of humility or realism over the role and potential of science in assessment of risks. Scientific and technical evidence and analysis remain essential. However – under a precautionary approach – scientific analysis is seen as a necessary, rather than a sufficient, basis for effective policy choices.

More realism is also needed in the level of precision and confidence with which findings of risk assessment are expressed. The present focus on the quest for hard evidence rather than on the relative likelihood and plausibility of risks needs revision. Scientists are not bound to remove uncertainty – at least this may not be their primary task – but they can inform society about possible risks, on the background of what may be relevant for their

audiences. Instead of a one-sided focus on 'hard evidence', plausibility requires scientific reasoning in order to explain certain observations or hypotheses so they make sense to both expert and non-expert audiences and appeals to their understanding of the problem.

Scientists need to play down the unachievable ambition of reliably quantifying all risks and need to shift towards a more modest ambition of characterizing the underlying hazards. In the chemicals field, for instance, there is growing recognition that serious or irreversible hazards are often better addressed in terms of qualitative 'intrinsic properties' (such as carcinogenicity, mutagenicity and reproductive toxicity), than in terms of elaborate – but sometimes seriously misleading – quantitative dose-response or exposure-based modelling.

Knowledge partnerships for precaution and sustainable development

The PP implies a need for trans-disciplinary approaches to science and policy. Science for policy in the face of uncertainty requires new trans-disciplinary contacts and integration (internal extension of the peer community) on the one hand, and new contacts with policy makers, non governmental organizations (NGOs), industry, media and the public (external extension of the peer community) on the other hand to meet the challenges of quality control in the assessment of complex risks.

Because of the many uncertainties, traditional science is not able to sufficiently support drastic steps that may sometimes be needed to deal with complex risks. The traditional dominance of 'hard facts' over 'soft values' has been inverted: hard value commitments may have to be made – even in the course of research design –, based on soft facts. The assessment of risks and the setting of policy should therefore encompass public agreement and participation.

The knowledge and perspectives of stakeholders can bring in valuable new views and relevant information on that problem. Stakeholders can contribute to knowledge on local conditions which may help determine which data are strong and relevant or which response options are feasible. They may provide personal observations on the risk and its effects, which may lead both to new foci for empirical research addressing dimensions of the problem which were previously overlooked, and to creative thinking about mechanisms and scenarios through which different sectors of society may be affected.

Scientific and technical discourse can benefit from inclusion of non-specialist knowledge, wisdom, and perspectives of stakeholders on the problem at hand. Making full use of this reservoir of extra knowledge requires the establishment of an extended peer community not only in the phase where response options are debated, but also in the problem-framing and risk assessment processes that precede it.

New platforms need to be established that bring together stakeholders, scientists working on evaluating risks, and scientists working on options for risk reduction and more sustainable alternatives for the risky technology or activity. However, these types of collaborations are the exception rather than the rule and are often frowned upon by funding agencies, government authorities, and professional societies.

To contribute to a more precautionary scientific culture it is desirable that opportunities are created for scientists to think about their methods, tools, and the implications of the research they do. It is advisable to stimulate scientists to step back from everyday practice and think about

whether their work could more effectively support precautionary policies. The question of finding an adequate language for the purpose of communication with new communities may be crucial. Case studies and examples might provide one such vehicle for communication.

Increase protection of whistle-blowers

Vested interests and the high stakes involved in new technologies can lead to tendencies to hide uncertainties and evidence that may indicate risks because public knowledge of these risks might hamper the further competitive development of that technology. In the globalized knowledge economy, scientific and technical knowledge is less and less freely shared and is often subject to procedures to obtain intellectual property rights. A significant part of advanced research is conducted in private R&D laboratories of large companies that have no tradition in freely sharing their knowledge.

These types of mechanisms confront us with a new type of ignorance, which we may call 'imposed ignorance'. This is when one party has knowledge relevant for public policy, but prevents others, especially competitors and the public, from sharing it. There are two variants of this. It could be that others are aware that the knowledge exists; that is, that they are aware of their imposed ignorance. They may then take measures to obtain that knowledge, perhaps using legal procedures to get access to the knowledge. Considering the importance of some of that knowledge for public policies, one might have to reconsider parts of the legal framework in order to widen the possibilities of gaining access to such knowledge.

The more serious case is when parts of the public or the relevant authorities are ignorant that the knowledge exists; they are ignorant of their ignorance. Often, such knowledge comes to the attention of the public through the actions of some whistle-blowers. Blowing a whistle means typically to set aside organizational loyalties towards one's employer for the sake of the greater good of society. However, all too often the whistle-blower faces severe lawsuits and risks to personal welfare. This poses a dilemma to public policy that is sometimes dependant on the courage of whistle-blowers. On the other hand, there is no doubt that institutions have to rely on the loyalty of their employees; but a public servant, is first and foremost a servant of the common good, not of his boss. The real threat of whistle-blowing may increase the willingness of an institution to create mechanisms in which concerns can be voiced before they are brought outside. One does not want to encourage disloyal behaviour in general or when it is unjustified, one does on the other hand want to provide for sufficient protection and security in the cases of justified concern. Therefore one may conclude that the ethics and the legal frameworks of whistle-blowing need more careful attention than is currently the case.

4.2 Implications for policy and governance

Putting the PP into practice requires a framework for action where several actors are called upon to contribute. It may typically require institutional change, new collaborations and new regulatory and other policy measures. Some of the typical challenges in this area are listed below.

Breaking through administrative cultures

While problems of precaution occur in a specific sector that is typically the responsibility of one

jurisdiction and one administration, the application of the PP asks for consideration of the problem on a wide and inclusive basis. More specifically, this implies, for example, that though a problem appears to be technical at the outset, the evaluation of precautionary action includes many other areas, like social, economic, environmental issues, on a regional, national and possibly international level.

Typically government administrations are not designed to cover considerations of this great variety. Thus, in order to handle precaution adequately, one branch of administration must liaise with relevant other branches. Ministries need to get used to inter-ministerial cooperation, as do government officials at other levels of administration. This kind of cooperation is still the exception rather than the rule in most countries. Ministries foster their own ministerial 'culture' that is often not in tune with other ministerial 'cultures'.

Actually this kind of institutional challenge is already required to achieve sustainable development, but it is even more accentuated in the application of the PP. Cooperation must take place not only horizontally, but also vertically, for example linking the regional with the national and the international spheres of administration. Working out how to build up administrative structures with this kind of flexibility is a great challenge for most States. It also implies awareness building among its professional staff.

Harmonizing PP for several sectors

A precondition of breaking through administrative barriers and cultures is the development of a common understanding of the PP across various sectors. In many States one can see that one sector works with one understanding of the PP that is markedly different from that of another sector. For example, those working with preserving biodiversity may have a very different understanding of precaution than those working with the utilization of natural resources or trade. Inconsistencies of this kind tend to undermine the PP in the long run and to diminish its basis in society.

Finding relevant expertise

In the dynamics of policy formation, the search for relevant expertise is often one of the first crucial elements of action. Experts are asked by a decision-maker or government official to provide assessments of the policy options. Two pitfalls are particularly relevant here. First, there is a temptation by the one commissioning the advice to be overly specific in outlining (and thereby constraining) the assessment task. There is sometimes a tendency to frame the issue at hand in a manner that would split up the issue into several compartments and subcompartments, possibly to be addressed by several such advisory groups. Yet, in real life several parts of a problem area are typically connected to several other parts. Responses to one subproblem have reverberations on the possibility and effectiveness of other responses to other subproblems.

Second, decision-makers often have a tendency to choose advisory bodies with narrow views on the needed expertise, or to draw experts from the same source as advised on earlier decisions. Precaution is, however, often of a controversial nature, and what constitutes relevant expertise is often debatable. The challenge is actually two-fold: to employ expertise of a wide variety (for example including the social sciences and humanities) and to employ expertise that is varied within one field of expertise (for example to actively seek out alternative or dissenting expert views).

Utilizing participatory instruments

Precaution involves taking a stand on value-sensitive issues and strategies. The weighing of possible overall costs and benefits always reflects the weight the analyst puts on the individual values and these are affected by the analyst's choices. Individual willingness to accept risks and risk-aversion differ widely in a population and can likewise be seen as expressing varying value stances. The choices made between a variety of different possible precautionary actions reflect values and beliefs. Good decision-making processes therefore require finding a way to capture and take seriously the plurality of relevant values and interests.

Experts may be authorities on the facts that enter the deliberation, but they are not necessarily experts on how different values have influenced the weighing of the options. This indicates the need to supplement the decision-making process with participatory measures of various sorts to capture the plurality of viewpoints and values that are prevalent in a society. Various such participatory instruments have already been successfully tried (for example, in technology assessment). They need to be utilized on a much broader basis and they need to be improved and supplemented by other instruments designed for specific purposes.

Making governments accountable

Governments typically last for one or several terms of office. Those in government are often tempted to think first of all in terms of actions that may show positive results within their term of office. This is a natural consequence of the desire of a government to retain power and to have their mandate renewed at the next election. Also, new governments may often be tempted to revise or overthrow the decisions of the previous government in order to mark clear differences for the electorate. However, precaution typically implies a long-term thinking that extends beyond a term of office, sometimes far into the future.

The implication of this dynamic seems to be that it is advisable that precaution should not be based on small margins of parliamentary majority and against strong social opposition. Rather, precaution seems to work best when based on a wide consensus, both within the political parties and within the social groups and partners that are affected by the policy. To strive for such consensus may be time-consuming and may not always pay off in terms of political support for the government in place. This implies the need for a change of attitude amongst political decision-makers. It needs to be recognized that all parties, whether in power or in opposition, share a common responsibility for the long-term good of society and that support for precautionary actions cannot fully be realized within a framework of power- and party-politics. Decision-makers need to contribute to and be made accountable for decisions and these decisions need to be justified in terms of the common good, independently of office and world view.

The most effective solution is not always the simplest one. Banning an activity is sometimes a 'panic' reaction by government, which even if based on the PP can have considerable negative side effects. If not accompanied by a mechanism to ensure long-term compliance, it tends to lead to unmonitored activities that supposedly should not take place but will take place anyway. Governments sometimes hide behind a ban while activity continues. Also such a formal ban is often perceived by government to be the cheapest 'solution' to international or internal pressure because it does not need to impose a management regime.

Building up capacity and monitoring systems

States need to recognize that modern technology and industrialization necessitate a strong independent sector of public experts and watchdogs that can give governments early warnings about potential harm or dangerous developments. To the extent that decision-makers grow more and more dependent on expertise that is institutionally or economically dependent, the independence of those experts is threatened and their credibility is undermined. There is thus a social responsibility for governments to maintain a largely independent sector of expertise, or a sector of counter-expertise, that can counteract bias in the assessment of risks and harms. This is usually achieved through publicly funded research. There is also a need to let new activities, for example new technology applications, be followed by appropriate monitoring and learning activities that provide performance data on a continuous basis.

4.3 Implications for industry and trade

It has been mentioned several times in this report that the PP implies new knowledge partnerships. Business corporations, as well as labour unions, are obviously an important part of these partnerships. If the idea of precaution is to make headway, then private industry has to take on co-responsibility for precautionary management. This implies a number of points:

Transparency and knowledge sharing

While scientific knowledge has long been considered to be public knowledge, this assumption cannot be made in the case of scientific knowledge developed by industry and business where specialized knowledge is often kept secret within the bounds of the company in order to gain a competitive advantage. Yet with products and activities that may pose a public, health or environmental risk, such an attitude is no longer viable. Industrial knowledge may be crucial for sound assessments, and the transparency and openness of these knowledge sources are crucial to enable the community to be able to trust the industrial operator. Companies need to become partners with the public and the administration, and they thus need to adopt a principled attitude of transparency and knowledge sharing.

Product development strategies

New technologies typically need long and costly development phases before they are ready to enter the market. The more a company has invested in terms of time and money in the development of a certain product, the less flexible it will be to adjust the product to new demands or wishes. Yet, precaution typically involves public consultations, deliberations and hearings that may focus on selected side effects or possible harms. Such consultations are often deemed avoidable and obstructive by business. Yet product development strategies that do not take account of community values will often place the company in the position of having to defend risky products. The call for precaution is then seen as anti-industrialist, anti-innovation and anti-technology. Yet, several companies now realize that this can be avoided if their product development is made more flexible and responsive to outside input from the very beginning.

Various choices are made during the development of every product that shape the special features of the end-product. To the extent that companies manage to integrate the spectrum of

outside concerns at an early stage, they stand a better chance to come up with products that are widely seen as good solutions. Some companies have therefore started to use participatory procedures, scenario analysis and other instruments to make their product development more reflexive and responsive to outside concerns.

Freedom and fairness in international trade
It is sometimes claimed that that the PP can be used as a front for a nation to impose trade barriers against other nations, and thus hampers socio-economic progress. This criticism is based on the assumption that the PP can be based on all kinds of non-scientific considerations and therefore can be used as a form of protectionism when there are no reasonable grounds for concern about harm. This report, however, argues that the PP cannot be based on purely non-scientific concerns. Precaution needs always a basis in science. However, uncertainties are indisputable parts of science and they need to be managed sensibly given the values that are at stake. Societies may differ considerably, to the extent that what is acceptable in one society may not be acceptable in another. Standards of safety, priorities of needs, as well as capacities to implement or monitor an activity or product, may thus legitimately differ between societies.

The goal of free trade needs to be constrained by a mutual respect for differing values concerning safety and needs. The fact that a nation may occasionally misuse the PP to protect their short-term economic interests is not a good enough reason to dismiss the more important priority that each nation should be able to democratically decide the level of protection that is acceptable and apply the PP to achieve this. Precautionary measures should in any case be judged transparently on a case-by-case basis, and be subjected to scrutiny from many parties.

4.4 Social and cultural implications

The use of the PP in any practical setting will always reflect a larger cultural context and tradition. The prime reason for this is that knowledge and values are always culturally embedded, and this finds expression in the different legal cultures and cultures of public administration that exist in various States and societies. Even though States may adhere to the PP as a common principle for the management of uncertainty and risks, the PP may be administered differently within the bounds of different cultures.

Recognition of different cultural contexts
In order for the PP to fulfil precautionary tasks within different cultural settings and contexts one needs to recognize basic cultural differences that are reflected in different political cultures. One such difference is the utilization, role and function of scientific knowledge as an element of due process in preparing administrative and other decisions. What counts as admissible and what as mandatory in decision-making of this kind, including the scope of what is regarded as 'scientific knowledge' is seen differently within different cultural frameworks.

Some of the political difficulties surrounding the incorporation of the PP into international treaties and negotiations may be due to the fact that countries fail to see their own way of integrating scientific knowledge into the PP. The general point has been exemplified with regard to different principles of good administration. It implies that not all conflicts around the PP deal with the complex issue

of science and values, but rather manifest conflicts about political and administrative culture.

Implementation of the PP needs to accommodate various cultures of risk regulation and administrative regimes, while still addressing the basic tenets of the PP (uncertainties, science, values, transparency and participation, etc.).

Countries choose their own level of acceptable risk

Countries choose their own level of acceptable risk and find their own balance between the PP and other issues and principles. Local circumstances may justify a deviation from the PP. For instance, regulations that allow the introduction of experimental new medicine for AIDS that have unknown but possibly deadly side effects, may not be considered to be in accordance with the PP, but for countries facing an AIDS epidemic that will kill many anyway, such an action can be justifiable. Implementation of the PP can vary from country to country because the chosen level of protection may vary, the socio-economic context is different, and priorities may differ.

Recognition of alternative knowledge sources

The scope of what counts as scientific knowledge may vary across cultures. It may be restricted to natural science in some parts of the world, while it may include social science and humanities in others. Yet knowledge is not necessarily restricted to academic disciplines. One needs to recognize the importance of traditional knowledge alongside scientific knowledge. Traditional knowledge captures what is sometimes also described as indigenous knowledge, folk knowledge or the like. All of these are very culture-specific. The value of these knowledge sources is increasingly being recognized, as they tend to supplement scientific and technological knowledge rather than necessarily competing with it.

When making decisions at a local level close attention needs to be paid to existing traditional knowledge and to incorporate it among the relevant considerations. For the practice of implementing the PP, this has several consequences. Firstly, the scientist assessing the possible harm of a certain practice within a given location should incorporate traditional knowledge, especially in understanding the ecology of a given location, and pursue its implications. Secondly, though ultimately it is scientific evidence that triggers the implementation of the PP, traditional knowledge may have much to offer in designing workable strategies to contain the potential risk or reduce it. Thirdly, integration of traditional knowledge may be necessary to communicating precautionary measures to an involved public. The integration of traditional knowledge into a precautionary regime of managing uncertain risks is an important step towards increasing the quality and effectiveness of this regime.

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Annex 1.

Practical guidance: frequent questions about the precautionary principle

What is the goal of the PP?

The goal of the PP is to protect humans and the environment against uncertain risks of human action by means of pre-damage control (anticipatory measures). The PP provides a rational approach to the satisfactory and ethically justified management of uncertain risks to public health, society or environment. It aims to use the best of the 'systems sciences' of complex processes to make wiser decisions. The PP is to supplement, but not necessarily replace, other management strategies that fall short of being able to handle large-scale scientific uncertainty and ignorance: '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'.

What conditions trigger the consideration of the PP?

Generally speaking, the PP applies when there is plausible evidence of possible harm but scientific uncertainty and ignorance makes it impossible to reliably quantify and characterize the risks. More specifically, one needs to check whether:

- there exist considerable scientific uncertainties or even ignorance about the anticipated harm;
- there exist scenarios (or models) of possible harm that are scientifically reasonable (that is, based on some scientifically plausible reasoning);
- it is currently impossible to reduce the uncertainties without at the same time increasing ignorance of other relevant factors by higher levels of abstraction and idealization;
- the potential harm is indeed sufficiently serious or even irreversible for present or future generations or otherwise morally unacceptable;
- there is a need to act now, since effective counter-action later will be made significantly more difficult or costly at any later time.

What actions are consistent with the PP?

The PP calls for measures that either are likely to prevent the possible harm from occurring or are likely to contain or reduce the possible harm should it occur. In principle, there will always be a range of possible strategies that would satisfy this requirement. One may impose certain constraints on the range of such measures. One may, for example, require that the actions be:

(a) non-discriminatory in their application, i.e. similar situations are treated similarly,
(b) consistent in scope and nature with comparable measures from equivalent areas,
(c) proportional to the chosen level of protection and the scope of the harm,
(d) chosen with due consideration of positive and negative consequences (including non-monetary costs and benefits) and with an assessment of the moral implications of both action and inaction,
(e) subject to continuous review and monitoring, and that the main burden of providing evidence for safety rests on the proposers of a new technology or activity.

Even under these conditions a variety of possible precautionary actions may remain, ranging from simple restrictions upon a practice, strengthening the resilience of the system, the development of effective controlling (remediating) technologies, to a total ban of the activity. The final choice will always be value-based.

Who decides on the PP?
What is an appropriate decision procedure?

Since the application of the PP involves the explicit consideration of values that are affected by it, since values differ in society, the processes leading up to a final choice of action should be largely participatory and inclusive. The cultural plurality in risk attitudes varying from risk-aversion to willingness to take risks implies that the question of how society ought to deal with risks can only be answered in public debate – a debate in which people will necessarily discuss their perception of risks and risk management from different points of view and different conceptual and ethical frameworks. Only if decisions can acquire some robustness in terms of social and political acceptability do they stand a chance of being effective over time.

What makes a reasonable ground for concern?

A mere fantasy or crude speculation that an activity or new technology causes harm 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).

Some form of scientific analysis is mandatory. The hypothesis that an activity can cause harm should be consistent with background knowledge and theories. If a hypothesis requires one to reject widely accepted scientific theories and facts, then it is not plausible. The hypothesis should posit causal mechanisms or processes, or if no causal mechanism is known, there should be some evidence of a possible statistical correlation. However, if a hypothesis posits radically new and unfamiliar mechanisms and processes, it is not plausible. Further, obscure and complex hypotheses are not as plausible as simple and straightforward ones.

Under what conditions is the PP not the best way to go?

Generally speaking, there are three classes of cases where the PP should not be used. The first class is when the scientific uncertainties can be overcome in the short term through more research, or when the uncertainties are simply understood as low probability of harm (in that case it is only a question of the chosen level of protection). However, in some cases the potential consequences can be of a nature and magnitude that makes them morally unacceptable even if the probability is very low, for instance, extinction of mankind. The second class is when the potential harm is not morally unacceptable, e.g. when the harm is restricted to individuals who voluntarily engage in the activity and are informed about the possible consequences. The third class of cases is when the harm is reversible and it is likely that effective counter-action is not becoming more difficult or costly, even when one waits until the first manifestations of the harm eventually occur. In this case a 'wait and see' strategy might be used.

Some say that the PP does not provide clear guidance/ is not a good administrative principle. Is that a problem?

The PP provides a rational framework for managing uncertain risks. However, the PP in itself is not a decision algorithm and thus cannot guarantee consistency between cases. Just as in legal court cases, each case will be somewhat different, having its own facts, uncertainties, circumstances, and decision-makers, and the element of judgement cannot be eliminated. In this respect it resembles other ethical and legal principles. Principles of law constitute important tools for crystallization of new concepts and values. A strength of the PP being a principle is its open-endedness and flexibility, which creates a possibility and an incentive for social learning. Different areas of application and different legal frameworks may lead to more specific guidance and regulations. The repeated use of State practice and consistent *opinio juris* are likely to transform the PP into a customary norm. Among the principles emanating from international declarations, the PP is legally

relevant and cannot be disregarded by the countries in the international order, nor by legislators, policy makers and courts in the internal sphere. Precautionary measures should in any case be judged transparently on a case-by-case basis, and be subjected to scrutiny from many parties.

Annex 2.

COMEST
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Division of Ethics of Science and Technology of UNESCO

The Division of Ethics of Science and Technology reflects the priority UNESCO gives to ethics of science and technology, with emphasis on bioethics. One objective of the medium-term strategy of the Organization is to "promote principles and ethical norms to guide scientific and technological development and social transformation".

Activities of the Division include providing support for Member States of UNESCO that are planning to develop activities in the field of ethics of science and technology, such as teaching programmes, national ethics committees, conferences and UNESCO Chairs.

The Division also ensures the executive secretariat for three international ethics bodies, namely the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC).

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