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## **The precautionary principle and responsible risk management**

Report  
Committee on Culture, Science and Education  
Rapporteur: Mr Johannes RANDEGGER, Switzerland, Alliance of Liberals and Democrats for Europe

### *Summary*

Reducing risks for society without undermining the advancement of science or preventing innovation is a constant challenge for policy makers, who must find the appropriate balance.

In spite of being referred to in more than 15 international agreements there is no single definition of the precautionary principle.

The report suggests that the precautionary principle should allow, or in some cases justify, regulatory action in the absence of complete scientific evidence about a particular risk scenario. Action however should always be dependant on reasonable, albeit not complete, evidence of considerable potential risks.

**A. Draft recommendation**

1. Humanity has never before lived in a safer and securer environment than it lives in today. This is even more the case in the member states of the Council of Europe where we live a much longer and healthier life than our ancestors.
2. Paradoxically the perception of risk has increased and public opinion in Europe would wish to further reduce industrial and technological risks. Increasing references – including in international agreements - to the precautionary principle or to a precautionary approach are in line with that wish.
3. The lack of a single definition of the precautionary principle and of the conditions for its application make however the concept controversial, difficult to apply and sometimes ineffective. Therefore an agreement should be reached that would allow minimising risks without unduly restricting research and innovation.
4. The precautionary principle should allow, or in some cases justify, regulatory action in the absence of complete scientific evidence about a particular risk scenario. This does not mean that regulatory action is justified in the absence of **any** scientific evidence of risks. Action should always be dependant on reasonable, albeit not complete, evidence of considerable potential risks.
5. The precautionary principle should not however lead to forbidding a potentially risky product or activity until the proponent of such product or activity demonstrates that such product or activity pose no risks (or only limited risk). If this was to be the case, as some of those who defend the principle claim, scientific research and the advancement of science could be in serious danger. Furthermore “in the absence of complete scientific evidence” means that it is impossible to prove either the risk or the lack of it.
6. The Parliamentary Assembly supports most of the criteria set up by the European Commission in its communication of 2 February 2000 for the application of the precautionary principle: where action is deemed necessary, measures under the precautionary principle should be proportional to the chosen level of protection, non discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action and subject to review. The Assembly does not approve however assigning responsibility for producing scientific evidence to those against whom the principle is invoked.
7. Public authorities should respect freedom of research and accept taking risks in a responsible way. Public opinion needs to be informed in order to adhere to this. A culture of precaution should be encouraged. Efforts are needed both from public authorities in the field of education and from the scientific community and industry in the fields of transparency and communication. Furthermore the precautionary principle should not be used as a justification for trade protectionism.
8. In this context the Assembly recalls its Recommendation 1762 (2006) on academic freedom and university autonomy and its Resolution 1528 (2006) on student disaffection for scientific studies. The principle of academic freedom of researchers, scholars and teachers should be reaffirmed. Science, today more than ever before, should be part and parcel of general culture as it enables the maintenance of a sufficiently critical mind to remain impervious to the words of false prophets. Efforts to this aim are also a means of contributing to the defence of human rights which is the very role of the Council of Europe.
9. The Assembly therefore calls on the Committee of Ministers to prepare a recommendation which:
  - 9.1. asks governments in member states of the Council of Europe, to develop policies which:
    - 9.1.1. promote scientific education as from primary school;
    - 9.1.2. include ethical and precautionary thinking as an integral part of scientific studies;
    - 9.1.3. ensure communication on science in society;
    - 9.1.4. foster inter- and trans-disciplinarity in the field of research;

- 9.1.5. develop technology assessment (including participatory methods);
  - 9.1.6. regulate, whenever necessary, specific areas and sectors of applied research;
  - 9.1.7. review risk assessment and risk management related to research projects;
  - 9.1.8. communicate effectively the results of relevant risk studies.
- 9.2. calls on the academic world (public and private higher education institutions) :
- 9.2.1. to include ethical and precautionary thinking as an integral part of scientific studies, in order to promote a culture of precaution among scientists;
  - 9.2.2. to foster inter- and trans-disciplinarity in the field of research;
  - 9.2.3. to engage in dialogue with the various stakeholder groups;
  - 9.2.4. to communicate effectively the results of its activities;
- 9.3. calls on other research institutions and industry in the member states:
- 9.3.1. to consider possible negative outcomes and benefits of new products and activities;
  - 9.3.2. to suggest measures to prevent damages;
  - 9.3.3. to conduct risk assessment and risk related research and communicate effectively its results;
  - 9.3.4. to develop a culture of precaution among scientists;
  - 9.3.5. to engage in dialogue with the various stakeholder groups.
10. The Assembly also recommends that parliaments in member states:
- 10.1. to ensure that the principles of academic freedom of researchers, scholars and teachers and institutional autonomy of universities are properly guaranteed legislatively or constitutionally;
  - 10.2. to adopt, where this is not yet the case, parliamentary technology assessment procedures and relate to the European Parliamentary Assessment Network (EPTA);
  - 10.3. set the promotion of scientific education as a priority.

## **B. Explanatory memorandum by Mr Randegger, Rapporteur**

### **I. Introduction: The main question**

1. In its Order 566 (2000) the Assembly, referring to its Recommendation 1468 (2000) on biotechnologies and considering the importance of the precautionary principle mentioned in this text, invited its Committee on Science and Technology, together with other committees concerned, to draft a report elaborating measures to be applied when defining the precautionary principle<sup>1</sup>.

2. In January 2006 several Assembly members tabled a motion (Doc. 10812) with a view to tackling the general question of the meaning and application of the precautionary principle. The present report attempts to do this.

3. The challenge to regulators is to be cautious without preventing innovation in a way that would deprive future generations of novel solutions to pressing problems. Extreme caution - staying on the safe side - may often appear to be the most attractive alternative. However, in many cases, a conscientious risk-benefit analysis may reveal that this alternative has serious disadvantages which outweigh the benefits.

4. The European Union endeavours to enhance capabilities for research and innovation through its Lisbon Policy of 2000. In the 2003 update on progress in achieving the Lisbon targets, the Commission summarizes: *“Achieving an innovation performance that makes the European Union a world reference for innovation represents an enormous opportunity that can translate into raised living standards over the coming years. Progress towards such a more innovative European economy is however proving tentative and fragile. Enhancing innovation is a cornerstone of the strategy to meet the target agreed by the European Council in Lisbon in March 2000 of the Union becoming the most competitive and dynamic knowledge-based economy by the end of the decade.”*

5. Achieving these targets is not only a question of providing research capabilities. It also depends on the support of innovation and the introduction of new products and services in the societal, political and regulatory context. Neither unchallenged research, nor a zero-risk mentality will provide the stimuli for the desired economic development and for developing answers to unresolved problems future generations face.

6. In this context a constructive application of precaution in research and innovation is particularly important. This concerns all actors in the research and innovation arena and those with political responsibility, but also media and enterprises. The question is whether the precautionary principle is the appropriate tool to achieve this and if so how should it be applied.

7. The aim of this report is to provide guidance in the application of precaution in particular in the fields of research, innovation and the introduction of new products. This will be done in a spirit that respects the rights to academic freedom and to university autonomy as well as providing guidance for precaution and consideration of ethical issues.

8. The report:

- explains the difference between the principle of prevention and the precautionary principle for products and services;
- gives a short summary of the present regulatory understanding of the precautionary principle and defines the key elements of a precautionary approach (“What is the precautionary principle and how it should be understood and applied to products and services?”);
- reviews the nature of research and innovation (“Research and Innovation”);
- discusses the “challenges of applying the precautionary principle to research”;
- proposes a “culture of precaution” as a means to research and innovate responsibly but without undue restrictions.

9. The issue of whether, when and how to use the precautionary principle has given rise to much debate and to a host of different and often contradictory views. Decision-makers are constantly faced with

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<sup>1</sup> I would like to thank Kaspar Eigenmann, Klaus Peter Rippe, Sergio Bellucci, Hans-Peter Bernhard, Georg Diriwächter, Thomas Epprecht, Rainer J. Schweizer and Mathis Brauchbar who helped me in the preparation of this report

the dilemma of balancing risks and benefits. It is their responsibility to find an adequate balance which is proportionate, non-discriminatory, transparent and coherent.

10. In the last twenty years public policy has focused on the application of the precautionary principle in the development and application of products and processes that, through their volume of application and their properties, can have adverse effects on the environment, human, animal or plant health. The precautionary principle was applied mainly in environmental policy and public health policy. Whether and if so, how the precautionary principle should also be applied in scientific research, is another and yet unresolved question.

11. In scientific research the main challenge for regulators consists in adopting a responsible approach to innovation without restricting the academic freedom and without restricting innovation in a way that deprives future generations of opportunities to develop novel solutions to pressing problems.

## **II. The difference between prevention and precaution**

12. There is a need to differentiate between the precautionary approach and the 'Vorsorgeprinzip' or 'principle of prevention', which is, for instance, an important element of German environmental legislation. The principle of prevention is applied to situations with a known cause-effect relationship and therefore a clearly defined risk. A prominent example of the application of the principle of prevention is the restriction imposed on the use of CFCs after they had been identified as a cause of ozone depletion. The precautionary approach, on the other hand, addresses situations of scientific uncertainty. A current example is the issue of endocrine disruptors.

13. Different countries may judge differently on a specific topic. While for the US authorities the effect of carbon dioxide emissions as a cause of global warming is not proven, European countries tend to believe that there is a sufficient body of evidence for such a cause-effect relationship. Therefore, the United States would take measures under the precautionary approach, while the European countries would apply a preventive approach.

## **III. What is the precautionary principle and how it should be understood and applied to products and services**

14. The precautionary principle was introduced in the 1980s as a tool in pro-active environmental protection and management. At the international level, the precautionary principle was first recognised in the World Charter for Nature, adopted by the UN General Assembly in 1982. One of the earliest international agreements that use a precautionary approach is the Ministerial Declaration of the Second Conference on the Protection of the North Sea, issued in London in 1987. It states that *"in order to protect the North Sea from possibly damaging 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 reason"*.

15. In the 1992 "Treaty of the European Union" of Maastricht, the European Community mentions in Art. 174 that *"the Community policy on the environment should be based on the precautionary principle and on the principles that preventive actions should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay"*. There is no definition of the precautionary principle in the Treaty, and it occurs only once with respect to environmental protection.

16. In the White paper on food safety the European Union introduced the precautionary principle into public health policy. According to the "Communication from the Commission on the precautionary principle" from 2.2.2000, the precautionary principle is not restricted to environmental policy. Its scope is much wider and the opportunity remains open to apply the precautionary principle outside the field of environmental policy. But it is not clear if this extends only to the regulation of products and their application or could cover also the regulation of activities such as scientific research.

17. The Parliamentary Assembly of the Council of Europe has acknowledged the importance of the precautionary principle as an element of policy-making. It supports the development of a rational framework for its application in situations of scientific uncertainty. In its Recommendation 1468 (2000) on

biotechnologies<sup>2</sup> the Assembly recommended that the Committee of Ministers “ask the relevant steering committees to adopt the precautionary principle as a common tenet of decision-making, once its scope has been clearly defined”. The present report fulfils this task emphasizing the difference between the activity of scientific research and the development of products.

18. The above mentioned EU Communication says the precautionary principle is to be applied, when “preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal and plant health may be inconsistent with the high level of protection chosen for the Community” and when for the “potentially dangerous effects” arising from “a phenomenon, product, or process” the risk cannot be assessed “with sufficient certainty”. According to the EU communication, measures taken on the basis of the precautionary principle should be, inter alia:

- *proportional* to the chosen level of protection,
- *non-discriminatory* in their application,
- *consistent* with similar measures already taken,
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- *subject to review*, in the light of new scientific data, and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.

19. We have to emphasize two important aspects:

- Firstly, different societies – and different individuals in each society - prioritize and perceive given risks in different ways. An affluent society perceives minor food safety risks considerably differently than a society where there is food scarcity. Societies have the right to choose a specific level of protection;
- Secondly, in applying the precautionary principle, we have to examine not only the potential costs but also the potential benefits. It would have severely negative consequences for society as a whole if certain opportunities were missed.

20. Generally, the precautionary principle is used to regulate “potentially dangerous effects” arising from a phenomenon, product or process. The Second Conference on the Protection of the North Sea speaks in 1987 of “damaging substances”. In food policy the precautionary principle is applied to meat, meat products (hormones) and food additives, in biotechnology to genetic modified organisms and in public health policy for example to new drugs and nanoparticles. In the areas where it is applied, it usually deals with dangers evolving from products.

21. In spite of being referred to in more than 15 international agreements there is no single definition of the precautionary principle. One Swedish author, Per Sandin, lists 19 formulations, often individually vague and mutually contradictory. The most commonly used definition is contained in the 1992 Rio Declaration:

*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.*

22. Another popular definition derives from an environmental meeting held in the United States in 1998 in Wingspread, Wisconsin. It states:

*When an activity raises threats to the environment or human health, precautionary measures should be taken, even if some cause-and-effect relationships are not fully established scientifically. In this context, the proponent of an activity, rather than the public, should bear the burden of proof (of the safety of the activity).*

23. One of the more rigorous analyses of the meanings of the precautionary principle has been put forward in work by Wiener and Rogers. They argue that there are three different formulations of the precautionary principle. These are:

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<sup>2</sup> See also the report by Mr J-F. Mattei (Doc. 8738) of 5 May 2000.

Version 1: *Uncertainty does not justify inaction*. In its most basic form, the precautionary principle is a principle that permits regulation in the absence of complete evidence about the particular risk scenario. [Lack of full scientific certainty shall not be used as a reason for postponing measures to prevent environmental degradation - Rio Declaration].

Version 2: *Uncertainty justifies action*. This version of the precautionary approach is more aggressive.

Version 3: *Uncertainty requires shifting the burden and standard of proof*. This version of the precautionary principle is the most aggressive. It holds that uncertain risk requires forbidding the potentially risky product or activity until the proponent of the product or activity demonstrates that it poses no (or acceptable) risk.

24. The two first versions, which are in agreement with most definitions, can be accepted by most and many of those who oppose the principle oppose in fact only the third and most aggressive version of it. In spite of the fact that the two first versions are able to cover most of the cases for which the precautionary principle has been invoked, many papers on the precautionary principle (including the above mentioned Wingspread definition) mention the shifting of the burden of proof as a central component of the principle, fuelling therefore the controversy. This concept however is liable to unduly restrict or even put an end to research and innovation, which is unacceptable. Furthermore in a situation of lack of full scientific certainty it would be impossible to prove either the risk or the lack of it.

25. The Parliamentary Assembly should therefore make it clear that the precautionary principle should allow, or in some cases justify, regulatory action in the absence of complete scientific evidence about a particular risk scenario but that it should not lead to forbidding a potentially risky product or activity until the proponent of such product or activity demonstrates that it poses no risk (or limited risk). In other words the shifting of the onus of proof to the proposer of the new product or activity cannot be accepted.

26. The Assembly should therefore support the following key elements for the application of the precautionary principle on products and services:

- *Cost-benefit analysis*: The implementation of a precautionary approach always has to start with a broad cost-benefit analysis of the challenged activity or product and of the consequences of applying the precautionary principle: abandonment or substitution. The science-based cost-benefit analysis includes a risk assessment and also an assessment of economic, social, environmental and health impacts on society (benefits and risks). This analysis has to be based on scientific knowledge and consider the degree of uncertainty. It should also take into account the fact that not only an action or a product can be associated with risks and costs but also inaction and avoidance. The responsibility for conducting such an analysis is generally shared between industry, which has to provide the data and tests, and the authorities, which have to provide an external review and assessment. On the parliamentary level this is the object of technology assessment.
- *No proof of absence of risks*: The application of the precautionary principle should not be understood as implying that industry has an obligation to prove that a product or process is «risk-free». As referred before, if the provider had to prove the complete absence of any risk associated with a specific product or service, there would be an end to innovation, as such a level of proof can never be achieved in any human activity. If reasonable doubt exists to justify the application of the precautionary approach, then reasonable evidence should be sufficient to suggest that the suspicion is unjustified.
- *Legal framework*: The precautionary approach has to be implemented within an established legal framework, providing a process that is transparent to all stakeholders and allows legal redress under international, Community and national law. Clear administrative procedures should be put in place, enabling decision-makers to apply the precautionary approach in a transparent and coherent manner. Early involvement of all stakeholders is essential for achieving an efficient and effective process.
- *Adequacy of measures*: Any measures based on a precautionary approach must be in proportion to the potential risk and the objective / level of protection to be achieved. Restrictive measures are to be taken only if it is established that less restrictive ones cannot achieve a similar result in terms of the protection of health, safety and the environment.

- *Provisional character of measures:* The measures based on the precautionary approach have to be provisional. They should be limited in time and subject to regular scientific and judicial review. The application of the precautionary approach should trigger the opportunity for further scientific research. A mechanism has to be set up to integrate new evidence and scientific data in a timely fashion.
- *Principle of non-discrimination:* The application of the measures should be coherent and non-discriminatory. The principle of non-discrimination means that comparable situations should not be treated differently. On the other hand, different situations are not to be treated identically. In this context the precautionary approach should not be used as an obstacle to trade.
- *Decision Process:* If applied the precautionary approach should lead to a stepwise, systematic and transparent process to support decisions that have to be taken in conditions of scientific uncertainty. But this will not resolve all the questions that face politicians and regulatory authorities when they take decisions on new products, processes and technologies. In a pluralistic society with free exchange of information there will always be scientists who advocate controversial positions. Decision-makers will therefore always have to take decisions on the basis of the best available science and of existing regulations. This responsibility cannot be avoided.

#### IV. How do we understand “Research” and “Innovation”?

27. If we apply the precautionary principle to research, we do not apply it to a product but rather to a process or an *activity*, which by its very nature demands a different strategy and a different approach.

28. *Research* can be defined as the methodical process of inquiry aiming at the improvement and enlargement of human knowledge via discovering, interpreting and understanding facts or theories. Even if scientific research is characterized by a certain methodology, it would be false to reduce it to a linear goal-oriented quest. New insights are often unintended by-products of scientific research, are a result of luck or serendipity. Serendipity is characterised as discovery by accident and sagacity. A good example of serendipity is the discovery of penicillin. Fleming was cleaning up his laboratory when he noticed that one of his old experiments had become contaminated. The identification of the source of contamination was a result of sagacity: Fleming had been investigating the antibacterial properties of common substances for several years and thus had the experience that allowed him to understand and adequately assess what he saw.

29. An *innovation* is generally understood as the introduction of a new product, process or service, a significant improvement in products, processes or services or a new way of handling a product. Frequently, the concept of innovation is confused with the concept of invention. *Inventions* represent one type of innovations, but not all innovations are inventions. This differentiation is important because only inventions are patentable. Patents are protective rights granted only for a new solution to a technological problem with commercial applications. Inventions include products and processes. They must be novel, non-obvious, and commercially applicable (useful) in order to be patentable. Innovations that cannot be patented are, for example, the use of an existing tool in a new way or a new accounting method. A result of a scientific research can be an invention, but very often it is a discovery. A *discovery* is a new increment to the body of knowledge. Paradigmatic for a discovery is the observation and description of previously unknown natural phenomena.

30. Often innovation is used as a (value-laden) concept. According to this concept innovations are not only new, but they are also an improvement benefiting the general public. Innovation occurs in this sense when someone generates new products, processes or services that are of benefit for citizens and consumers and improve their quality of living.

31. The common distinction between “basic research” (aiming at discoveries – the advancement of knowledge for its own sake) and “applied research” (trying to solve specific, practical questions) is misleading. For one, it erroneously equates the intention of the researcher (aiming at discoveries vs. aiming at practical applications) with the content of research (fundamental scientific questions vs. practical questions); for another, it presupposes a linear progression from discovery of abstract principles to their practical application. History of science has shown that abstract principles are found while researchers are trying to solve specific practical questions and that practical questions are answered by research aiming at the general advancement of knowledge.

32. Thus, innovation:

- is not predictable;
- can occur all the time and in nearly all types of scientific research, sometimes with intent, and sometimes by chance; and it
- is a complex and not a linear process.

33. But there is scientific research where the probability for an innovation is smaller than in other research. Therefore, we can define types of scientific research that are differentiated by the increasing strength of their connection to innovation (see Table 1, column 5). Classifying types of research in this way will be helpful for the integration of precaution in scientific research processes.

34. Table 1 (appended) should not be read as a description of a linear process. Scientific research does not necessarily start with research on fundamental questions (types 1 -3), then goes on to answer specific practical questions relevant for the development of specific goods and services (type 4 and 5) and finally produce innovations. The discovery of restriction endonucleases by Werner Arber, which was honoured with the 1978 Nobel Prize in Physiology or Medicine, for example, started as a by-product of a specific research project on radiation effects on living organisms. This research was a part of the development of nuclear technology in Switzerland (type 5). Studying the nature of radiation damage to genetic material and its repair, Arber went back to fundamental questions on the mechanisms of host-controlled modification of genetic material (type 2), which was the basis for future technical possibilities using genetic modifications (type 4). Arber's research is a good example of how discoveries can occur at all levels of scientific research.

## V. Challenges of the application of precaution to research

35. A precautionary approach is a tool to protect the environment and human, animal or plant health. But scientific research has impacts not only on the environment and human, animal or plant health. If we look at the possible negative effects of scientific research (in addition to its possible positive effects), we also need to consider specific "ethical consequences"<sup>3</sup>. Scientific research may affect values, such as human dignity or the integrity of non-human organisms. Furthermore, research may conflict with the rights of individuals or groups. Eventually, scientific research confronts the scientific community and the public with new ethical questions, e.g. what is the moral status of stem cells or human body parts? Is it morally permitted to enhance human nature (neuro-enhancement)? Is it morally wrong to build cyborgs or to create synthetic life (synthetic biology)? There is a widely shared concern about scientific research that is connected rather to ethical risks than to environmental and human, animal or plant health risks.

36. A precautionary approach should cover all possible "harm", including undesired societal consequences as discrimination or eugenics. However there is usually no broad general consensus on ethical questions. Even in risk analysis there are often discussions on whether a certain effect is beneficial or harmful (for example, an effect on so-called "pest plants"). In the field of ethics this problem exists to a much wider extent.

37. Society formulates minimum consensus on ethical questions in legal standards. In scientific research academic freedom is restricted by these legal and ethical constraints. But very often scientific research confronts society with ethical dilemmas for which there are no consensually shared answers, as exemplified by stem cells, neuro-enhancement, cyborg technology, and synthetic biology mentioned above.

38. Scientific research has inter alia the societal effect of forcing our society to develop and formulate adequate ethical and legal policies.

39. In its Recommendation 1762 (2006), the Assembly reaffirms, in accordance with the Magna Charta Universitatum, the right to academic freedom and university autonomy, which comprises the following principles: academic freedom in research and in training should guarantee freedom of expression and of action, freedom of disseminating information, as well as freedom of unrestricted inquiry in the pursuit and distribution of knowledge and truth.<sup>4</sup> If a society wants the benefits of innovation (in the value-laden meaning) it has to allow scientists to research freely and independently. For this reason it would be an illegitimate

<sup>3</sup> **The Convention on Human Rights and Biomedicine** of the Council of Europe (4.4.1997) and the Additional Protocol concerning **Biomedical Research** (25.1.2005) address this aspect for Biomedical Research.

<sup>4</sup> **Academic freedom and university autonomy**, Rapporteur: Mr Josef Jařab, Czech Republic, Doc. 10943 (2 June 2006).

violation of academic freedom and the freedom of research to mandate that research has to stop until scientific evidence shows that damage will not occur (apart from the general impossibility to prove absence of risk).

40. Research and innovation have been and are key drivers for improving the standard of living and for resolving pressing challenges of mankind. Society needs to be aware that lost opportunities in innovation can represent risks equivalent to those that might be avoided by an unreasonable application of precaution to innovation.

## **VI. A culture of precaution: recommendations**

41. There are means other than the precautionary principle to adhere to the spirit of precaution. It is more adequate to foster a precautionary culture that fits the nature and the impacts of the specific scientific research, combined with a timely public debate of ethical questions implied by results of scientific research.

42. Public policy has to respect freedom of research. But it is no violation of the autarchy of science if public policy measures try to assist the scientific community in building a culture of precaution.

43. Each scientist and the research community in general have the responsibility to consider possible negative outcomes of research. Therefore, it has been and continues to be part of the responsibility of science to foster a culture of precaution. The public policy of the member states should assist the scientific community in creating tools to improve such a culture of precaution. The assistance will be more effective if it creates different tools for the different types of research. The following proposals refer to the different types of research, as proposed in Tables 1 and 2.

44. In all forms of scientific research (types 1 – 5) innovation is possible, but not predictable. Scientists have the responsibility to:

- communicate with transparency;
- take an interdisciplinary approach;
- initiate and/or participate in a general discussion on ethical aspects and societal effects of science;
- consider responsibly both positive and negative implications of their research activities;
- adhere to legal standards.

Responsibilities of the state, therefore, consist in:

- enforcing communication on science in society;
- fostering inter- and trans-disciplinarity;
- promoting scientific education (ethical and precautionary thinking, risk assessment and risk communication)

45. Scientists are trained to focus on the objective facts. One of the problems arising from this concentration is that scientists, not schooled in discussion of ethical problems, often try to delegate these problems to the general public. Another problem is that all precautionary approaches need anticipative and translateral thinking, that is, the capacity to consider possible developments and risks at a time when only few facts can be interpreted from a purely scientific point of view. It is a responsibility of the state to encourage and promote programs that complement the current traditional scientific training.

46. Transparency, i.e. open communication of research projects and research results by scientist and the research community, is a basic requirement for a culture of precaution, in particular in types 1 and 2. Without such transparency no critical review, neither by other scientists nor by society, is possible, and public debate will not be productive. Scientists that behave in a transparent manner are open about all conflicts of interest and reveal fully and in good time mistakes and unfavourable developments.

47. In scientific research where innovation is possible (types 3 – 5); the scientists have the specific responsibility to:

- consider possible negative outcomes and possible benefits;
- suggest measures to prevent damages;
- conduct risk assessment and risk related research;
- foster the public debate on chances and risks of science.

Responsibilities of the state are to:

- foster the public debate on chances and risks of science;
- initiate and finance anticipative technology assessment-studies that aim at elaborating possible scenarios arising from current research.

48. Regarding research on specific questions relevant for the development of specific goods or services (type 4), scientists have the responsibility to:

- assess, manage and communicate the risks and benefits; and
- engage in dialogue with the various stakeholder groups.

Responsibilities of the regulators are:

- technology assessment ;
- regulation of specific areas/sectors.

49. In research projects that apply innovation in practice (type 5), scientists and corporations have a responsibility for:

- risk assessment, risk management, risk communication (“product stewardship”);
- stakeholder dialogue.

Scientists have a further duty to a responsible transfer of know-how and to facilitate or participate in spin-offs.

Responsibilities of the regulators are:

- regulation of specific areas/sectors;
- review of risk assessment and risk management;
- technology assessment (especially participative methods);
- communication of the results of relevant risk studies.

## VII. Perspectives

50. The Council of Europe and its bodies are invited to address the issue of precaution on two levels, the level of the products and the level of scientific research as an activity.

**Products:** Where there are reasonable grounds for dangerous effects on the environment, human, animal or plant health the states have to taken measures on the basis of a precautionary approach: Measures under the precautionary approach should be established in a transparent process, based on an examination of the potential benefits and costs of action or lack of action, proportional to the potential risk and the chosen level of protection, non discriminatory in their application, subject to review, if new knowledge is available, and consistent with similar measures already taken. This should, however, not lead to assigning responsibility for producing scientific evidence to those against whom the principle is invoked.

**Research activities:**

The best way to a responsible and proactive approach to scientific research is to foster a culture of precaution in scientific research. This includes especially enforcing communication on science and society, to foster inter- and trans-disciplinarity, to encourage and promote a complementary education and training of scientists in ethics, in precautionary and translateral thinking and to initiate and finance early recognition of ethical issues and anticipative technology assessment-studies.

51. The scientific community can contribute to a culture of precaution through integrity, transparency, and interdisciplinarity, as well as by supporting early recognition of potential risks or ethical dilemmas, by addressing such issues and risks through dedicating specific research to their resolution, and by engaging in public debate on controversial developments early on.

52. This is a way to protect society from possible harms of scientific research without restricting the academic freedom in an illegitimate way and without restricting innovation in a way that deprives future generations of chances to develop novel solutions to pressing problems.

**Table 1: Types of scientific research**

Type	Description	Connection to innovation	Predictability of an innovation	Discovery vs. invention	Main Locations	Example
1	Research on fundamental theoretical questions in a field where no goods and services are developed	Very loose	Very low probability	Discoveries	University	Einstein's Theory of Relativity
2	Research on fundamental theoretical questions in a field where goods and services are developed (life sciences etc.)	Loose	Innovation uncertain (the generation of ideas)		University	Research to understand the neurological basis of colour vision
3	Research on theoretical questions of known relevance for the development of goods and services	Weak	Possible, but low probability (idea generation, establishing the principle of an innovation)		University, Industry	Research on biological factors influencing the disposition for depression
4	Research on specific practical questions relevant for the development of specific goods and services	Strong	Higher probability (Search for application of an idea)	Inventions	Industry, University of Applied Sciences	Development of an animal model for depression
5	Research as an integral part in the development of specific goods and services	Very Strong	Research projects to apply innovation in practice		Industry, Hospitals	Clinical trials testing a new medication for the treatment of depressive moods
6	Introduction of new products and services into the markets	Very Strong	Application of innovation in practice		Industry, Markets	Introduction of new medication for the treatment of depressive moods

**Table 2: Practical measures for establishing a culture of precaution**

Type (not to be confused with a step in a linear development)	Recommended precautionary approach	Responsibility of the scientific community	Responsibility of the corporation	Responsibility of the state
1 Research on fundamental theoretical questions in a field where no goods and services are developed	Culture of Precaution	<ul style="list-style-type: none"> <li>○ Adhere to legal standards</li> <li>○ Initiation of and/or participation in general discussion on ethical aspects and societal effects of science</li> <li>○ Transparency</li> <li>○ Interdisciplinarity</li> </ul>	<ul style="list-style-type: none"> <li>○ Support the approach of the scientific community</li> </ul>	<ul style="list-style-type: none"> <li>○ Fostering inter- and transdisciplinarity</li> <li>○ Promotion of scientific education (precautionary thinking, risk communication)</li> <li>○ Enforcing communication and dialogue on science and society</li> </ul>
2 Research on fundamental theoretical questions in a field where goods and services are developed (Life Science etc.)	Culture of Precaution			
3 Research on theoretical questions of known relevance for the development of goods and services	Culture of Precaution	<ul style="list-style-type: none"> <li>○ Consider possible negative outcomes and possible benefits</li> <li>○ Suggest measures to prevent damages</li> <li>○ Risk assessment and risk related research</li> <li>○ Foster the public debate on chances and risks of science</li> </ul>		<ul style="list-style-type: none"> <li>○ "Research Assessment"/</li> <li>○ Anticipative "technology" assessment</li> <li>○ Fostering the public debate on chances and risks of science</li> </ul>
4 Research on specific practical questions relevant for the development of specific goods and services	Culture of Precaution  But also application of the precautionary principle (risk and benefit), if applicable	<ul style="list-style-type: none"> <li>○ Assessment, management and communication of risks and benefits</li> <li>○ Stakeholder dialogue</li> </ul>	Risk assessment, risk management, risk communication ("product stewardship")	<ul style="list-style-type: none"> <li>○ Technology Assessment</li> <li>○ Regulation of specific areas/sectors</li> </ul>
5 Research as integral part in the development of specific goods and services	Application of the precautionary principle (risk and benefit), if applicable  Culture of Precaution	<ul style="list-style-type: none"> <li>○ If applicable see responsibility of corporation</li> <li>○ Responsible know-how transfer to and participation in spin-off's</li> </ul>	<ul style="list-style-type: none"> <li>○ Risk assessment, risk management, risk communication ("product stewardship")</li> <li>○ Stakeholder dialogue</li> </ul>	<ul style="list-style-type: none"> <li>○ Regulation of specific areas/sectors</li> <li>○ Review of risk assessment and risk management</li> <li>○ Technology assessment (esp. participative methods)</li> <li>○ Communication of results of relevant risk studies</li> </ul>
6 Introduction of new products and services	Application of the precautionary principle	<ul style="list-style-type: none"> <li>○ Responsible for know-how transfer</li> </ul>	Responsible for the application of the precautionary principle	

*Reporting Committee:* Committee on Culture, Science and Education

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*Draft recommendation adopted by the Committee on 08.12.2006 with two abstentions.*

*Members of the Committee:* Mr Jacques **Legendre** (Chairman), Baroness Hooper, Mr Josef Jařab, Mr Wolfgang **Wodarg** (Vice-Chairpersons), Mr Hans Ager, Mr Toomas **Alatalu**, Mr. Kornél Almássy, Mr Rony Bargetze, Mrs Marie-Louise Bemelmans-Videc, Mr Radu-Mircea Berceanu, Mr Levan Berdzenishvili, Mrs Oksana Bilozir, Mrs Maria Luisa Boccia, Mrs Margherita Boniver, Mr Ioannis Bougas, Mrs Anne **Brasseur**, Mr Osman **Cořkunođlu**, Mr Vlad Cubreacov, Mr Ivica Dačić, Mrs Maria **Damanaki** (Alternate: Mrs Eleonora **Katseli**), Mr Joseph Debono Grech, Mr Stepan Demirchyan, Mr Ferdinand Devinsky, Mrs Kaarina Dromberg (Alternate: Mrs Sinikka **Hurskainen**), Mrs Åse Gunhild Woie Duesund, Mr Detlef Dzembitzki, Mrs Anke Eymmer, Mr Relu Fenechiu, Mrs Blanca Fernández-Capel, Mrs Maria Emelina **Fernández-Soriano** (Alternate: Mr Iřaki **Txueka**), Mr Axel Fischer, Mr José **Freire Antunes**, Mr Eamon **Gilmore**, Mr Stefan Glăvan, Mr Luc Goutry, Mr Vladimir Grachev (Alternate: Mr Igor **Chernyshenko**), Mr Andreas **Gross**, Mr Kristinn H. Gunnarson, Mrs Azra Hadžiahmetović, Mr Jean-Pol Henry, Mr Rafael **Huseynov**, Mr Fazail Ibrahimli, Mrs Halide İncekara, Mr Lachezar Ivanov (Alternate: Mrs Aneliya **Atanasova**), Mr Ali Rashid Khalil, Mr Serhiy Klyuev, Mr József Kozma, Mr Jean-Pierre Kucheida, Mr Guy Lengagne, Mrs Jagoda Majska-Martinčević, Mr Tomasz Markowski, Mr Bernard Marquet, Mr Ruzhdi Matoshi, Mr Andrew **McIntosh**, Mr Ivan Melnikov (Alternate: Mr Alexander **Fomenko**), Mrs Maria Manuela de **Melo**, Mrs Assunta Meloni, Mr Paskal Milo, Mrs Christine Muttonen, Mrs Miroslava **Němcová**, Mr Jakob-Axel Nielsen, Mr Edward **O'Hara**, Mr Andrey Pantev, Mrs Antigoni Pericleous Papadopoulos, Mrs Majda Potrata, Mr Duřan Proroković, Mr Lluís Maria **de Puig**, Mr Johannes **Randegger**, Mr Zbigniew Rau, Mrs Anta Rugāte, Mr Pär-Axel Sahlberg, Mr André **Schneider**, Mr Vitaliy Shybko, Mrs Geraldine Smith, Mrs Albertina Soliani, Mr Yury Solonin (Alternate: Mr Anatoliy **Korobeynikov**), Mr Valeriy Sudarenkov, Mr Mehmet Tekeliođlu, Mr Ed van Thijn, Mr Piotr **Wach**, Mrs Majléne Westerlund Panke, Mr Emanuelis Zingeris.

N.B. : The names of the members who took part in the meeting are printed in **bold**

*Head of the Secretariat:* Mr Grayson

*Secretaries to the Committee:* Mr Ary, Mr Dossow