Discussion

The Precautionary Principle in the Risk Management of Modern Biotechnology

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The precautionary principle is presumed to provide guidance when our scientific knowledge of the harmful effects of a proposed activity is significantly incomplete. In this paper, I will identify a three-part structure shared by every formulation of the precautionary principle. Second, the paper claims that the implementation of the precautionary principle has to deal with many currently open questions and problems. Third, I argue that two particular criticisms do not lead to abandonment of the principle.

Keywords: precautionary principle, modern biotechnology, risk management

Modern biotechnology has expanded rapidly. At the same time, there has been growing public concern over its potential adverse effects on the environment and on human health. The safe use of modern biotechnology has consequently become one of the most heated debates worldwide.

There seems to be general agreement as to the need to ensure the safety of biotechnology through effective risk assessment, management and communication. There are, however, differences in the ways risks and lack of certainty are perceived, assessed and valued. Some demand the application of sound scientific criteria as a basis for restricting the production and trade in products that pose a threat to the environment or to human health. Others, in contrast, argue for precautionary measures based on the precautionary principle, which allows policy action to be taken in the absence of full scientific certainty.

The precautionary principle (hereinafter, the PP) is becoming an ever more popular excuse, especially in Europe, to limit the introduction of new technologies. For instance, it is mentioned four times in Directive 2001/18/EU, which concerns the deliberative release and the placing on the market of genetically modified organisms. Few policies of risk management, however, have created as much controversy as the PP. There is extreme variability in its interpretation,

because of the many different formulations of the principle. Vanderzwaag and Environ (1999), for example, identified fourteen different formulations of the PP in treaties and non-treaty declarations. Thus, it seems "evident that there is no real agreement on what the precautionary principle means and how it should be applied" (Macilwain, 2000; see also Foster *et al.*, 2000). Moreover, there is also controversy concerning the scientific status of the principle.

In what follows, I will argue that different formulations of the PP have a common three-part structure and that two common criticisms of the PP are insufficient for the abandonment of this principle.

Background

The PP is presumed to provide guidance when our scientific knowledge of the harmful effects of a proposed activity is significantly incomplete. More precisely, it legitimises government intervention in the liberty of individuals and companies in order to avoid the threat of severe long-term or irreversible damage, even when strict scientific risk assessment cannot be fully completed. According to the *Wingspread Statement* (1998) on the PP, "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically".

In fact, the PP is very simple. All it actually amounts to is a piece of common sense: if we are embarking on something new, we should think very carefully about whether it is safe or not, and we should not proceed until we are convinced of its status. Thus, the PP embodies the folk wisdom, "better safe than sorry" or "look before you leap". Although such ideas have occurred in human thought for millennia, the recent history of the PP can be traced to the environmental debates of the 1970s. More precisely, the PP has its predecessor in the German principle of *Vorsorge*. According to the *Vorsorgeprinzip*, society should seek to avoid environmental damage by careful advance planning, blocking the flow of potentially harmful activities.

The PP was introduced in 1984 at the *First International Conference on Protection of the North Sea*. After the conference, the principle was integrated into numerous international conventions and agreements. It is best known in the context of the climate change, environmental protection and modern biotechnology. Probably the most influential statement of the PP is Principle 15 of the *Rio Declaration* of the *United Nations Conference on Environment and Development* (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.

Within the context of modern biotechnology, it is worth noting the *Convention on Biological Diversity* (1992) that is taken to be the first application of the PP to modern biotechnology and the *Cartagena Protocol on Biosafety* (2000), which reaffirms the precautionary approach contained in the *Rio Declaration*.

The *Cartagena Protocol* entered into force on 11 September 2003, and it is the first legally binding international agreement that regulates biotechnology and includes the precautionary approach as a key element. The objective of this protocol is "to contribute to ensuring an adequate level of protection" in the safe transfer, handling and use of living modified organisms (LMOs).[1] Governments who have ratified the protocol, are encouraged to take the precautionary approach to the domestic regulation of LMOs. It is also possible to refuse from individual shipments of LMOs from other countries if they are believed to be unsafe, even when the scientific evidence for this is insufficient.

The first applications of the precautionary approach concerned environmental risks, but since then it has extended its scope. An example of this is its adoption by the EU Commission (2000: 3) to deal more generally with risks to "the environment, human, animal and plant health". It should be mentioned that the extension of the PP to deal with food safety, in particular its use to regulate genetically modified (GM) food, has been highly controversial.

Recently, the PP has moved from a position primarly in science and legal realms to become more politicised. Environmentalists have appealed to the PP to justify worldwide bans on DDT and on GM foods and crops. Europeans have invoked the PP as a reason to ban US beef and genetically modified foods. At the same time, the US government is actively lobbying against precautionary actions by other governments.

The Structure of the PP and Problems of Implementation

What is the status of the PP? It is not a hypothesis, a theory or a methodological rule. Rather, it is a normative principle for making practical decisions under conditions of scientific uncertainty. The taking of precautions is an institution of governance; such institutions are the building blocks of society, serving as rules of the game used to make decisions. More simply, it is a regulatory tool. The PP is widely accepted at the national and international level. Many governments have accepted the principle as a basis for policymaking. Most of the national legislation contains at least implicitly the precautionary aspect. In many instances, the PP is also explicitly mentioned, for example in the forthcoming law on genetic engineering (*Geenitekniikkalaki*: paragraph 1) in Finland. According to the Commission of the European Communities (2000: 11), the PP is a general principle of international law.

Despite of the widespread support for the PP, it is often loosely defined and different formulations vary considerably. In most cases, formulations of the PP have been divided into the following two general categories (Morris, 2000: 1). According to the strong (or strict) form of the PP, one should not use a new technology unless its harmlessness is certain. In other words, the PP calls for absolute proof of safety before allowing new technologies to be adopted. Examples of the strong formulations are usually considered to be the *World Charter for Nature* (1982) and the *Wingspread Statement* (1998). Environmental and consumer organisations have typically employed

the strong form of the PP. Strong formulations are usually accompanied by the idea that proponents of a potentially hazardous technology must prove the safety of the technology.

The weak (or active) form states that lack of full scientific certainty per se is not a sufficient justification for preventing an action that might be harmful. In fact, appropriate precautionary measures may be taken even when it is uncertain that a new technology will cause harm. Moreover, if a hazard is likely but not certain, the lack of scientific certainty should not be used as an excuse for failing to mitigate the potential hazard. More simply, the need to be cautious should not prevent one from acting. Examples of the weak form are usually taken to be the *Rio Declaration* (1992) and the *Cartagena Protocol* (2000). Applications of the weak formulations usually include cost-benefit analysis and consequently they come close to outcome based moral doctrines, such as negative utilitarianism and maximin decision-making strategy (Häyry, 2004; Hansson, 1997). Governments have generally employed weak formulations of the PP. This generally means that the state is allowed to intervene only if it has a good reason to believe that there is a threat of severe hazard.

While it is certainly worth distinguishing the strong and weak form of the PP, in a closer analysis it becomes evident that different formulations vary in many respects. It is, thus, valuable to distinguish the structural elements of the PP according to which it is possible to evaluate the strength of different formulations. At the same time, the conditions of the application and criteria for implementation of the PP become explicit.

Structure, Application and Implementation of the PP

A review of statements of the PP indicates a general, three-part structure shared by every version (Manson, 2002: 264-270; Commission, 2000: 13-16; Tickner *et.al.*, 1998: 3-5). For example, the *Wingspread* (1998) definition of the PP has three elements: first, scientific uncertainty (i.e. knowledge condition); second, a threat of harm (i.e. damage condition); and third, precautionary action.

The first component of the PP is the knowledge condition which specifies the quality of evidence needed to trigger the PP. There is a considerable variety of formulations concerning the criteria for the knowledge condition. Neil Manson (2002: 267), for instance, lists the following degrees of the quality of evidence; threats can be possible, suspected, indicated by a precedent, reasonable to assume, not proven with certainty that it is not the case or not proven beyond a reasonable doubt that it is not the case.

The absence of sufficient evidence for a hazard is a necessary condition for the application of the PP. This, usually, refers to scientific uncertainty or scientific ignorance. The former refers to well defined outcomes (or hazards) to which no probabilities can be assigned. The latter refers to a situation where possible outcomes are unknown. In other words, completely unexpected hazards may occur in the state of ignorance.

Scientific certainty about long-term effects of new technologies is often impossible to attain. Most environmental future states, for example, cannot be forecast with any certainty because of the cumulative long-term effects that rise from a series of human actions and

processes of environmental change. According to O´Riordan and Cameron (2001: 9), however, uncertainties have recently been diminished because the risks of serious long-term harm have been increasingly identified by risk assessment.

The second structural element is the damage condition which specifies damage in virtue of which precautionary measures should be considered. What is the nature and extent of the potential harm that triggers precautionary actions? The criteria to activate the precautionary actions are variously stated. Examples of used criteria are harmful, serious, catastrophic, irreversible and cumulative hazards. It should be emphasised that a consistent application of the PP can be seen only in the light of the chosen level of protection.

Although it is impossible to assign objective probabilities to some hazards (because of uncertainty), it is possible to use epistemic criteria, such as coherence, analogy and precision, to distinguish plausible ones. For example, the requirement of coherence entails that the hypothesis of hazard should be supported by and consistent with our background theories and knowledge. Thus applying the PP is not fundamentally a fallacy of *argumentum ad ignorantiam*. Arguments of this form assume that since something has not been proven false (safe), it is therefore true (hazardous). In order to constitute a rational argument for hazard further evidence is needed. Among others David Resnik (2003: 337-341) has argued that epistemic criteria can be used to determine whether a threat is plausible.

The third component of the PP consists of precautionary action. There is an important distinction between the decision as to whether to act and the nature of the action ultimately taken (Commission, 2000: 15-16). Applying the PP is a combination of the threat of harm and of scientific uncertainty. Thus, the damage condition and the knowledge condition predetermine when precautionary measures should be taken. If precautionary measures are applied, they may be for example preventive, anticipatory or postponing.

A formulation of the PP should contain criteria for implementing different kinds of precautionary measures. In other words, plausible formulations of the PP should include criteria for reasonable precautionary measures. Reasonable response to a credible threat should be effective and it should be proportional to the nature of the threat. It should be cost-effective and consistent with the chosen level of protection. Resnik (2003: 341-342) also suggests that this kind of practical considerations can be used to determine whether a response to a threat is reasonable.

In sum, it is possible to distinguish three structural elements in every formulation of the PP: scientific uncertainty or ignorance, a threat of harm and precautionary action. Second, the application of the PP implies a hazard beyond the chosen level of protection and the absence of scientific certainty. Third, the implementation of the PP presupposes a chosen level of protection, criteria for the knowledge condition and criteria for precautionary measures. Lastly, a plausible formulation of the PP must include criteria for credible threats and reasonable precautionary measures.

Problems in the Implementation of the PP

Currently, it is unclear how to draw a specific action from the PP in concrete cases. *Communication* from the EU Commission (2000) is an important and influential contribution intended to eradicate the arbitrary use of the PP. According to the *Communication*,

> [w]here action is deemed necessary, measures based on 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 (--); subject to review, in the light of new scientific data; and capable of assigning responsibility for producing the scientific evidence (--).

Despite its general directions, however, clear guidelines about the weight of evidence needed to trigger the PP and for deciding which of the precautionary measures should be applied to new technologies, are still lacking. Article 4 of Directive 2001/18/EU, for example, states that "[m]ember States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs". The question is how the PP can be taken into account when implementing the directive in concrete cases.

In applying the PP to modern biotechnology the following questions have to be critically considered. First, what standards should be used to measure harm? Second, how severe risks are acceptable? This is necessarily an ethical issue. Finally, what kind of precautionary action should be taken? This consideration must pay regard to the consequences of risk distribution and its fairness.

There are also important issues related to the burden of proof on showing the harmlessness of a new technology. The burden of proof is usually determined by the knowledge condition. According to the *requirement for a reversal of the burden of proof*, the state does not have to prove that a product or a technology is hazardous. Rather, the proponent of a potentially hazardous technology must provide evidence that the technology is not hazardous. This requirement is often accompanied with strong formulations of the PP. The *Wingspread Statement* (1998), for example, states: "the proponent of an activity, rather than the public, should bear the burden of proof".

In typical scientific practice, it is common to prefer minimizing false positives (type-I error), i.e. to conclude wrongly that a new technology is unsafe and thereby to increase the risk of accepting false negatives (type-II error), i.e. to conclude wrongly that no hazard will result from using a new technology. Accordingly, there is a greater burden of proof on the individuals or collectives who postulate some, rather than no, severe effect. Currently it is unclear whether we should minimize either type-I errors, i.e. false assertions of harm or type-II errors, i.e. false assertions of no harm. In cases of uncertainty both cannot be avoided. Minimizing type-II errors would place the burden of proof on risk imposers rather than risk victims. (See Belt and Gremmen, 2002; Lemons *et.al.*, 1997.)

Discussion about the PP involves several ethical issues. The degree to which we are prepared to take precautionary

action is related to the values we attach to nature, society, human well-being and social equality. Since the use of the PP implies redistributing costs, the way the PP is applied has clear social impacts. What kinds of distributions of costs and benefits are just and democratic? Applying the PP to modern biotechnology will also redistribute risks. On what conditions is the distribution of risks fair and just? These kinds of questions raise new challenges for democratic decision-making processes.

Rejection of Two Criticisms

Opponents of the precautionary approach argue that the PP is a risk-aversive rule that can stifle progress, change and growth. Taking precautionary measures when we have no good reason to do so can waste time and resources and deprive us of important benefits. In what follows, I will consider two influential criticisms of the PP.[2]

According to one of the most common criticism, the PP is a highly rigid principle since it takes the form of categorical denials and bans. Holm and Harris (1999), for instance, state that "[t]he PP will block the development of any technology if there is the slightest theoretical possibility of harm". More simply, according to the PP, we cannot take any action unless we are certain that it will do no harm, and nothing can be certain. In other words, it is logically possible for any action to lead to a catastrophe (Hansson, 1997: 300).

In criticism of this view, it should be noted that inaction too can logically have catastrophic consequences. Furthermore, this kind of criticism applies only to the strong formulations of the PP. As noted before, the weak formulations require early but proportionate response to a threat. This is explicitly supported by the EU (European Commission, 2000; European Council, 2000). In contrast, there is the strong form of the PP, sometimes called as the abstention rule; this demands the prohibition of any new activity, product or technology that might potentially generate a risk, until scientific proof of its safety is obtained. Consequently, only the strong formulations provide justification for 'zero risk or do nothing' approach. Also, according to Olivier Godard (2003: 2), there is the wrong but common idea that not applying the PP requires proof of the absence of risk (Manson, 2002; Räikkä, 2003).

According to another common criticism, the PP is unscientific (Tickner *et.al.*, 1998; Resnik, 2002). As pointed out before, whether or not to invoke the PP is a decision exercised where scientific information is uncertain and where there are indications that the possible effects on the environment or on human health may be potentially dangerous and inconsistent with the chosen level of protection. It should be noted that if there is certainty about cause-and-effect relationships then acting is no longer precautionary, although it might be preventive. If we have enough data to assign a degree of probability to the threat, we can use another approach to the decision, such as traditional risk assessment and risk management. In cases where the PP is applied, we have a threat to which no probability can be assigned. Consequently, critics can insist that the principle is not based on sound science. Because of the uncertainty, it is difficult to accommodate precautionary measures with the values of a given society. If we

do not know the level of risk, we cannot choose acceptable risk-taking measures.

To answer this criticism, it is important to notice that all decision-making strategies are non-scientific in the strict sense. They cannot be derived from scientific knowledge. In other words, it is always logically improper to deduce a normative conclusion from a claim describing the world. There are two well-known forms of the naturalistic fallacy. The definitional or Moorean form involves an illegitimate identification of values with facts. The derivational or Humean form involves an illegitimate derivation of norms from facts. Thus, there is no point to claim that the PP is a scientific principle in the strict sense. Secondly, there seems to be no significant difference between the PP and other decision rules: both are value based but to the same extent (Sandin *et.al.*, 2002). Thirdly, the application of the PP, as well as other risk management practices, is based on scientific risk assessment. Actually, precautions merely expose uncertainty and admit the limitations of science, particularly in risk assessment. It has been argued that there is a significant problem in risk analysis. According to Michael Pollan (2001: 1), for instance, risk assessment has not been successful in predicting the ecological and health effects of many new technologies (see Resnik, 2003: 333-335; Tickner *et al.*, 1998: 14-16). Consequently, researchers and research institutes increasingly contend that the current framework for the regulation of new biotechnologies is inadequate because it fails to cope efficiently with the scientific uncertainty and emphasise the invocation of the PP as a solution (Myhr and Traavik, 2003: 228; Food Ethics Council, 2003: 4, 12-13).

Conclusion

Nearly twenty years after its introduction, there is still heated debate over the status of the PP and its application. In this paper, I have argued that every formulation of the PP has in common a three-part structure, consisting of a damage, of scientific uncertainty or ignorance and of a precautionary action. Second, it is unclear how to derive specific action from the PP in concrete cases. Implementation of the PP has to deal with many currently open questions and problems. In addition, I have claimed that two particular criticisms do not lead to the abandonment of the PP. It should be stressed that I have not argued that some other or additional criticism might not be reliable.

Acknowledgements

I would like to thank Juha Räikkä, Veikko Launis, Helena Siipi, Krister Talvinen, Kaija Rossi and Susanne Uusitalo for helpful comments.

Notes

1 *Cartagena Protocol on Biosafety* to the Convention on Biological Diversity (2000), article 1. The PP is mentioned explicitly in Article 10, paragraph 6.3.

2 For different kinds of criticisms see Tickner *et al.*, 1998: 16-17.

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