International Journal of Occupational Medicine and Environmental Health, 2004; 17(1): 43—46

THE PRECAUTIONARY PRINCIPLE, SCIENCE AND HUMAN HEALTH PROTECTION

MARCO MARTUZZI and ROBERTO BERTOLLINI

World Health Organization
European Center for Environment and Health
Rome Office
Rome, Italy

Abstract. As technology advances rapidly, so do applications with potential adverse implications on human health. The possible threats include risks that can be substantial, far-reaching and irreversible, and currently available methods of investigation, designed to deal with direct exposure-disease associations, are not always suitable. Growing interest is being paid to health effects that may be the consequence of distal, "upstream" determinants. Considering the complex chain of events that links such determinants with health can be extremely difficult, and exposes severe limitations in science. Thus, there is often a mismatch between what is known and what would be required to inform rational, evidence-based decision making, which is increasingly called for. It has become apparent how production and use of scientific evidence in decision making must be accompanied by precaution, especially in those circumstances, more and more common in recent times, where there is an uncertain possibility that serious health consequences might take place. Several cautionary approaches have been proposed, but the Precautionary Principle (PP) has been the object of especially intense debate in recent years. Developed in the field of environmental health, the PP has been clarified, and has been applied or called for in several instances in public health. Although a unique definition is not available, the principle has been characterised, and criteria for its application have been proposed. However, many questions remain open on general as well as specific issues. In this paper, we address some of the questions that are relevant for the PP to support rational decision making in environment and health and more in general to strengthen its contribution towards human health protection.

Key words:
Epidemiology, Ethics, Health impact assessment, Precautionary Principle, Science-policy interface

THE PRECAUTIONARY PRINCIPLE: DEFINITIONS AND INTERPRETATIONS

What uncertainty?

The Precautionary Principle (PP) is a valuable tool for developing adequate course of action in situations where there is large uncertainty. Such uncertainty can derive from: patchy scientific evidence about the health effects of an agent; sporadic reports of episodical adverse effects, unconfirmed or not reproducible; or limited knowledge of the dynamics of complex systems, resulting in effective ignorance on a series of chain events. Uncertainty can be of different magnitude and degree, but essentially discussion around the PP has focused on elements and criteria that should be addressed when making decision under this kind of "undetermined" uncertainty, i.e., not easily measured or quantified. This contrasts with uncertainties linked to lack of accuracy, for example when a risk is established, but incomplete information about mechanisms of action, individual vulnerability, quality of exposure assessment and exportability of risk estimates from a population to another, to name a few, produce large confidence bounds, reflecting uncertainty on the relevant figures.

Notwithstanding the absence of an established definition, some consensus have emerged on key aspects of the PP,

Received: January 19, 2004. Accepted: January 30, 2004.
Address reprint requests to Dr M. Martuzzi, World Health Organization, ECEH Rome Office, Via Francesco Crispi 10, 00187 Rome, Italy (e-mail: mam@who.it).

which can help describe its role and relevance for public health protection: 1) the PP prescribes that uncertainty cannot be used as a pretext to delay action; 2) it suggests that the burden of proof might be reversed, from "recipients" to prove that an agent or technology is harmful to "proponents", to prove that it is innocuous; 3) it underlines the importance of switching the debate from arguments of acceptable risks to considering alternatives, preferably at early stages of the process; and 4) it recommends that the decision making process should be as transparent and democratic as possible, throughout its development.

THE PRECAUTIONARY PRINCIPLE IN ACTION

Consensus around these distinctive tracts has promoted the debate and has produced much progress in the field. However, given the fact that the PP remains effectively undetermined, there are many open questions, both theoretical and practical. Some argue that the PP is not a principle, in that it does not enunciate an explicit "statement", but rather reiterate consolidated ones, for example those in the Hippocratic oath. But for public health, the practical implications of how the PP translates into protective policies are of crucial importance.

In the debate aiming at clarifyng these practical aspects, there seem to be two main parallel views, somewhat conflicting but not necessarily mutually exclusive, on how the PP can help deal with decision making under uncertainties. According to some, the PP consists of a set of rules, considerations, evaluations, procedures that are applied when faced with a concrete decision, often of a dichotomous nature: can we go ahead with trading of GMOs? Should we ban beef imports? With this view, the debate tends to address the question of whether or not the PP is applicable, which would result in more or less stringent regulatory responses. For example, a recent report of the Health Council of the Netherlands on mobile telephones finds "no reason […] to apply the PP and lower the […] limits for partial body exposure" [1]. This approach, in other words, considers the available information and establishes if there are grounds to take "special", perhaps additional, action for health protection. Under this formulation, of applicability versus non-applicability, it is thus appropriate to develop criteria of application: indeed the EC has proposed, in an influential communication, several such criteria, for deciding on the PP applicability. Emphasis is given to consistency across different areas of application, and substantial weight is put on "proportionality" and adequacy of any action in terms of its costs to the society [2].

A different view seems to have developed in the debate that is mainly taking place in North America. Some authors refer to the PP as an "overarching principle" [3], i.e., a set of considerations, criteria, recommendations, guidelines to inform the whole process that goes from initial proposal of introduction of, for example, a new technology or industrial facility, through the decision on whether to proceed and even after implementation, to monitor potential consequences. In this view, emphasis is given to all steps of the process, and precaution must be applied throughout. Analysis of possible alternatives becomes prominent, clarification of all stakeholders' interests is essential, as well as openness in the way decisions are reached at all stages. In this framework, the PP is always applicable and applied, in that it should guide the entire course of action. Precaution should inspire all decisions that are to be made, and help identify the most pressing needs in terms of research.

Both views have advantages and disadvantages, and both can be valuable for human health protection. In the first of the two, the "European" approach, the PP is used to clarify the question of how much evidence is needed to take a certain action, typically involving large costs. Arguably, this is not a new question, and indeed the whole concept of prevention hinges around the same evaluation. However, the PP does provide an additional contribution: it suggests that, given the increasingly complex and far-reaching threats to health and the environment, we might need to "reset" such threshold, if one exists. On the other hand, there might be the danger that the PP is used, or rather misused, against technological development and scientific advancement. Although this is often an argument that is put forward by *a priori* critics of the PP, there are sometimes good reasons, because the PP is occasionally wielded as a definitive, irrevocable veto. These controversies might be explained by

the difficulty of conducting a democratic and transparent debate on a dichotomous question, with the inevitable polarisation of opinions. This tendency is probably the reason why the European way to the PP does not lend itself too well to resolve questions other than a yes/no type of decisions, but when a line must be drawn at some point along a spectrum, i.e., when quantitative protection standards must be defined. But again on the "pro" side, it is possible to specify coherent criteria of application, and ensure some kind of consistency in the way the PP is applied in different instances, an attractive feature for decision makers.

The "American" view, the second one described above, holds the PP as an overarching principle, which, among other advantages, might help adopt precaution earlier on. For example, there would be little scope in discussing about the PP when a technology is being introduced following large investments on the part of the industry (and hence of society). Similarly, evaluating the applicability of the PP at specific stages may mislead the debate onto treacherous terrains of cost-benefit considerations, where excessive credit may be given to weak scientific evidence. In other words, this view or use of the PP can be beneficial to raise and promote the public debate around the issues of real relevance. There is a shortcoming, however, in the necessary implication that the PP always applies, because it is not obvious what provision does the PP make exactly. It is very desirable that all steps, from hazard identification to risk assessment, from policy making to implementation and monitoring, are adjusted to allow for the extra degree of complexity that we face nowadays; but when a compelling case calls for extraordinary protection measures it might be difficult to invoke the PP to support such decisions.

Although this classification is somewhat over-simplistic, it is difficult to deny that a variety of open questions are raised in the frequent controversies arising in the area of environment and health. It might be useful to explore how the differences between these two approaches (and certainly others) to precaution have developed, as a function of the legal framework, the cultural environment, the political and public opinion response. Also, it might be beneficial to clarify ways in which different approaches can be reconciled and harmonized.

PP AND EVIDENCE-BASED POLICY MAKING

As previously discussed, the PP has emerged as a tool for dealing with uncertainty of an "undetermined" type, i.e,. where available knowledge indicate the potential occurrence of harm, but little is known about its likelihood and its magnitude. Although this is probably the most unfavorable circumstance for decision making, experience suggests that decision making is fraught with difficulties also when evidence is more robust. It should not be forgotten that rational decisions, and especially the development of satisfactory policies, is function of knowledge and science, as well as of societal and ethical values. Accommodating all these variables is a demanding exercise in complex democratic societies, even when information from science is exhaustive. In addition, the boundary between the region where scientific information is univocal and where it is equivocal or controversial is extremely blurry.

Thus, although the PP "specializes" in informing decision making under uncertainty, it appears advantageous to clarify its role and relevance in the wider context of the science-policy interface. Other lines of work endeavor to support and shed light to the mechanisms that underlie the translation of scientific evidence into policy making, and it seems likely that taking a wider perspective might help clarify the contribution of the PP, and of other approaches, to this complex issue.

THE ETHICAL FRAMEWORK

The ethical values and principles are a crucial component of the question, which is occasionally overlooked by exchanges of opinions on whether the PP applies or not. It has been described by several authors that several alternative ethical frameworks can be used in decision making: utilitarian, libertarian, distributive [4]. The choice of one of these frameworks, often done implicitly, has implications on the value and relevance of available scientific information, and can determine different courses of action. It has been compellingly stated that it is crucial that these values are made explicit [5], however discussion around the PP is sometimes scanty of open acknowledgments

in this respect. In particular, criticism is often made of decisions taken applying risk assessment and cost-benefit analysis, on the grounds that these methods fail to consider interactions in complex systems, or that instability in the available evidence prevents meaningful results. Although legitimate, such criticisms do not always address another important aspect, i.e., that most cost-benefit analyses are based on a utilitarian criterion, aiming at maximizing the average "common good", while controversies might stem from unequal distribution of exposures. This omission is potentially dangerous: by keeping the focus of the discussion on the issue of whether science is strong enough to warrant a cost-benefit analysis, divergence of opinions tends to be ascribed only to different assessment of the scientific literature. Thus, while the debate is seemingly about what level of protection is warranted by the weight of the evidence, given the practical constraints, a more fundamental difference in terms of what ethical framework is applied might explain the controversy.

HEALTH IMPACT ASSESSMENT

Health impact assessment (HIA) is a set of tools and procedures for assessing the health consequences of policies, developments and plans, typically implemented outside the health sector [6]. Since it has become apparent how such policies are key health determinants, HIA addresses "upstream" factors and characterizes their likely health implications. HIA is a special case of other kinds of impact assessments, and in particular it builds on environmental impact assessment. HIA has become a recognized tool for supporting policy making in some European countries over the last decade. Examples of application include the creation of local industrial facilities, urban development schemes within cities, regional transport policies and agricultural, food and nutrition policies at the national level. These exercises are normally very difficult, because attempts are made to identify and analyze all pathways through which health can be affected as a result of changes in policy or social organization that can have a very wide spectrum of consequences, very often mediated by socio-economic mechanisms. In addition, HIA is based on the WHO's view of health, that is, it is concerned not only with disease occurrence, but also with well-being and quality of life. Thus HIA's mandate is to study detrimental health effects as well as beneficial consequences of policies.

Even from a summary description of HIA, it should not be surprising that HIA shares several features with the PP. Given HIA's interest in complex chains of events, from non-health policies to health effects in modern society, uncertainty is a recurrent theme. HIA, however, takes a proactive approach, where, despite all uncertainties, health is put at the center of the debate, in order to support the identification and development of policies that take health into high consideration. Among its distinctive characteristics, HIA is based on an open and transparent process, where all relevant stakeholders should be involved. HIA is most effective when several policy options are being analyzed, and is valuable in identifying possible mitigation strategies.

Thus, three of the four elements that characterize the main "definitions" of the PP, described above (i.e., taking action in the face of uncertainty, transparency of the process, analysis of alternatives), are also central to HIA. It seems therefore of interest to explore better how these close connections can be mutually beneficial and ultimately enhance the science-policy interface.

REFERENCES

1. *Mobile telephones; an evaluation of health effects.* The Hague: Health Council of the Netherlands; 2002.
2. *Communication of the Commission on the Precautionary Principle.* Brussels: European Commission; 2000.
3. Raffensperger C, Schettler T, Myers N. *Precaution: belief, regulatory system, and overarching principle*. Int J Occup Environ Health 2000; 6(4): 266–9.
4. Shrader-Frechette K. *Risk and Rationality.* California: University of California Press; 1991.
5. Botti C, Comba P. *Ethical considerations concerning the regulation of human exposure to electromagnetic fields*. Epidemiology 2000; 11(2): 225–7.
6. Lock K. *Health impact assessment.* Br Med J 2000; 320: 1395–8.