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PRECAUTIONARY POLICIES AND HEALTH PROTECTION: PRINCIPLES AND APPLICATIONS

Report on a WHO Workshop

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ABSTRACT

Changes in society and rapid developments in technology are producing an ever-increasing variety of agents that may pose unknown risks to human health. Countries and international bodies call for a precautionary approach in making policy choices, and the precautionary principle has received increasing attention as a tool for decision-making in situations of scientific uncertainty. The rationale for applying precautionary policies in the environmental and public health fields is being debated, however, and criteria for developing specific policies remain controversial. WHO therefore convened a workshop:

- to clarify the concepts and principles of and the options for precautionary policies on the environment and health;
- to describe the current progress of the work in the field; and
- to identify the priorities and direction for further work, with special reference to exposure to electromagnetic fields.

The workshop started a process in which WHO would review and evaluate the precautionary principle and its application in public health matters. The participants urged that WHO pursue this task.

Keywords

ENVIRONMENTAL HEALTH
RISK MANAGEMENT
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CONTENTS

	<i>Page</i>
Opening	1
Scope and purpose.....	1
EMF	1
Specific aims	2
Meeting notes	2
What is the precautionary principle?.....	3
Why do we speak of the precautionary principle?	4
Language questions and cultural differences	4
Economic aspects.....	5
Political and policy aspects	5
Philosophical/ethical aspects.....	6
Application of the precautionary principle	7
EMF.....	8
Science and the precautionary principle.....	9
Risk assessment and management	9
Risk perception and communication.....	9
Public participation	11
Role of science	11
Science policy interface	11
Possible shortcomings of traditional scientific approach.....	12
Uncertainty.....	12
Precautionary principle and public health.....	13
Public health authorities and the precautionary principle	14
Conclusions and further steps.....	15

Opening

The meeting was opened by Dr Roberto Bertollini of the WHO Regional Office for Europe. Dr Bertollini welcomed the 23 participants and gave an overview on the scope and purpose of the meeting based on the previously circulated document, which is repeated here as introduction, and on a conference room paper with suggested questions to be answered. He emphasized the fact that no final product but rather some sort of preliminary conclusions was expected from this meeting.

Scope and purpose

Changing societies and fast technological development are producing an ever increasing variety of agents and circumstances that are partly unknown, difficult to predict, and that may pose risks to human health. While scientific knowledge advances, uncertainties on the health effects of many potential risk factors increase. More and more often, precautionary measures are called to prevent or limit exposures whose effects are not known or are poorly understood, but that may be harmful, and indeed precaution is included in the legislative reference framework of the European Union (EU). The importance of precautionary policies towards human health protection has been underlined also by the European Environment and Health Committee (EEHC), a body established by the European Region of WHO in collaboration with several European Member Countries. In particular, the EEHC has recently addressed the need for guidelines on implementation of the precautionary principle.

While the rationale for applying precautionary policies in public health and environmental fields is being currently debated, criteria for developing specific policies remain controversial, as demonstrated by the numerous cases where the adoption of preventive measures is called for. In many circumstances when dealing with potentially hazardous exposures, the need to exert caution is supported by all, but the choice of specific precautionary measures is controversial. Particular difficulties arise when there are calls for safety limits or standards to be established in the absence of adequate scientific evidence even on the presence of a risk, let alone the characterisation of an exposure-response relationship. This is the case for exposure to electromagnetic fields (EMF), which is of special interest in the workshop.

The overall objectives of the workshop are to clarify concepts, principles and options of precautionary policies on environment and health; describe the current progress of the work in the field; and identify priorities and direction for further work. All of these with reference to the implications in terms of adopting concrete precautionary measures in the environmental field. Special emphasis will be given to the case of EMF.

EMF

A specific objective of the workshop is to address EMF protection. The relationship between exposure to EMF and health is controversial. A variety of epidemiological studies have suggested that EMF, over virtually all the frequency spectrum, might be a risk factor for several health endpoints, including cancer and neurodegenerative disease. For extremely low frequencies (ELF) exposure and childhood leukaemia, epidemiological studies have shown reproducible

associations, recently re-evaluated through combined analyses that confirm elevated risks and indicate some consistency across epidemiological studies. These associations are not explained by any confirmed biological mechanism, and there are doubts as to their causal nature, as the available evidence is inadequate to make sound scientific conclusions. In addition even if the association was causal, the overall impact on public health (i.e., the number of cases attributable to ELF exposure) is likely to be very small. Against this background, it is proving difficult to identify and develop policies for protection of human health. Given the uncertainties surrounding the available evidence, precautionary measures are advisable, but the adoption of specific protective actions is controversial. Largely due to intense pressure from the public, the debate has widened, and certain interest groups express anxiety, possibly magnified by media attention and occasional sensationalism.

As major breakthroughs in EMF research might not be imminent, decisions will necessarily be made on uncertain grounds for some time to come. Thus it is desirable to clarify current concepts and principles in the field of protection of human health from environmental hazards, when scientific knowledge suggests the potential presence of a risk, with large uncertainty. The WHO International EMF Project has, among its objectives, the aim of developing consensus documents and guidelines on precautionary policies on EMF. A recent WHO Background paper has discussed some of the available options. The document has been referred to by many people and perhaps unsurprisingly has been sometimes misinterpreted or distorted.

A possible explanation for the misunderstanding, the controversy and the lack of trust towards science expressed by some is that risk perception has not been thoroughly considered in some circumstances and its implications on how precautionary policies are acceptable to stakeholders might have been overlooked. In particular, the role and the relevance of cost-benefit type analyses should be put more clearly in the context of the decision-making process. While public health professionals are normally prepared to identify priorities through cost-benefit considerations, their view often clashes with reluctance by the public of accepting any risk, even of limited magnitude, especially when posed by involuntary hazards. Better elucidation of how issues of risk perception, equity, acceptability of risk, etc. concur to defining precautionary policies would therefore be beneficial.

Specific aims

- Review available options on precautionary approach.
- Present cases and examples of adoption of precautionary approaches worldwide.
- Identify gaps in the available methodology for developing and implementing precautionary policies.
- Develop guidance, recommendations and criteria for application of precautionary approaches on EMF.

Meeting notes

After this introduction the meeting elected Dr Raymond Richard Neutra as chair and Dr Gaudenz Silberschmidt as rapporteur.

This report does not try to summarize all the presentations, which will be published later. The report summarizes the discussions. For clarity of the report there is no chronological order of the views expressed; they have been rearranged around the broad topics addressed. The text is fully based on views expressed during the meeting, which does not imply that every participant agreed with all statements.

What is the precautionary principle?

There is no universally accepted definition of the precautionary principle, although one not legally binding definition of the Wingspread statement is broadly known:

When 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 this context the proponent of an activity, rather than the public, should bear the burden of the proof. The process of applying the Precautionary Principle must be open, informed, and democratic and must include potentially affected parties. It must also involve an examination of a full range of alternatives, including no action.

Art. 174 of the Amsterdam treaty of the European Communities, incorporating provisions already introduced by the Maastricht Treaty of 1992, fixes the precautionary principle to be used in the environmental context but does not define it. None of the Treaties where it is mentioned defines the precautionary principle; rather, it is defined by case law and commentaries and there are examples that can be used as definition. This is not uncommon, because in the United States context the legal principle of proportionality and in the European context subsidiarity are also mainly defined by case law.

In order to describe what is meant by the precautionary principle several examples and clarifications were mentioned:

One can delimit the precautionary principle by clarifying where to apply it:

- Ignorance – unknown impacts and probabilities of a given factor; a possible source of surprise.
- Precaution – where there are scientific uncertainties, which means that the possible impact is known, but its probability is unknown.
- Prevention – when risks are reasonably well characterized, which means that both the impact and its probabilities are known.

This means, when the causal relationship is established the precautionary principle is not any more relevant, while generally speaking it can not be used neither in an area where we do not have information, but only purely theoretical risk, which means that the hazard is simply not known.

The precautionary principle applies to intermediate areas, where possible consequences of a given factor are neither well assessed nor purely theoretical – therefore the precautionary principle tends to be provisional.

This is also reflected in the Communication on the precautionary principle of the European Commission asking for: “Preliminary objective scientific evaluation, reasonable ground of concern”.

The precautionary principle is seen by some as a simple extra reminder to be careful; others see it as a tool to avoid future harm. Views differ also with regards to whether the precautionary principle is to be used on the basis of scientific knowledge, or it can even undermine the efforts to produce reliable science-based information.

Why do we speak of the precautionary principle?

Politically the influence of precautionary principle is rapidly expanding, as it deals with the crucial question of comparing the consequence of action and non-action.

As presented in the forthcoming book of the European Environment Agency (EEA) “Late Lessons from Early Warning” there are many examples where things have gone wrong. For example, it took 15 years between the knowledge of the link between chlorofluorocarbons (CFC) and the destruction of the ozone layer and the political actions and even longer between first knowledge of health damaging effects of asbestos and its phasing out.

In Europe there is a growing public concern after the blood samples contaminated by AIDS, bovine spongiform encephalopathy (BSE) and dioxin crisis. The precautionary principle can be seen as a means of addressing more effectively these situations.

Language questions and cultural differences

There are many language and cultural differences to be clarified when speaking about the precautionary principle. These differences were apparent during this workshop.

What is a principle?

There were discussions on whether one should speak of a precautionary principle or rather on a precautionary approach, a precautionary set of procedural guidelines, or similar terms. The precautionary principle could be considered a principle in the legal sense. Indeed many legal scholars state it is at least at the edge of become a general principle of international law, which means that it should be applied even in a context where it is not explicitly mentioned in the contract at stake.

On the other hand looking at the scientific, philosophical and ethical use of the word principle, there are good reasons not to speak of a precautionary principle.

In terms of ethics the precautionary principle is most likely a rule or a maxim deriving from the Principle of Beneficence, which is the moral obligation to act for the benefit of others, to prevent harm from occurring to others, and to remove conditions that will cause harm to others.

Difference between risk and hazard and other language barriers

It is important to distinguish between a risk and a hazard. A hazard is a factor or circumstance that may under some circumstances be harmful, while the risk includes the probability of harm, under specific conditions. Therefore one cannot conduct a risk assessment if the hazard is not known. Difficulties arise also from other languages. Latin languages such as French and Italian tend to use the same word for risk and hazard. Likewise in French the expression “cost benefit” means purely economic costs, while it can also have other meanings in English. The same problem can apply the other way round. In French one speaks of *une décision éminemment politique* to say that the decision is not to be taken by scientists but by policy-makers. If this is

translated into English to a political decision it has a connotation of being an arbitrary decision, which is not meant in French. Furthermore the German original word of Precautionary Principle is *Vorsorgeprinzip*. This should rather be translated to Foresight, or inventing a new word giving literally the German expression to Forecare Principle. *Vorsorge* in German has commonly a positive connotation while precaution in American English has a rather negative connotation.

Cultural differences

Beyond the pure language differences there are also important cultural differences. In the United States not many people have ever heard of the precautionary principle, nevertheless the concept has often been used in the United States, under another name. The United States legal system has a strong tradition of liability and financial compensation, which is weaker in continental Europe. One participant phrased it as “What is good for the US is not necessarily good for everybody”. This raised the question if different countries can choose different levels of protection through the application of the precautionary principle. In view of the cultural differences and different preferences, application of different standards or regulations in different countries is not necessarily problematic. However a closely interlinked world raises the issue of trade versus health protection and the fact that lower limit values in one country can make inhabitants of another country concerned about the protection of their safety and welfare.

Economic aspects

Economic considerations are important in the context of the precautionary principle but they cannot be the only criterion. Some ask that health aspects always be given more value than economic aspects. The economic aspects should not only be seen as a cost–benefit analysis, but also as cost effectiveness analysis.

It is important to define the costs of which outcomes are taken into account. As an example, the secondary benefits of a regulation based on the precautionary principle are rarely considered, such as the incentive for new innovations to replace the questioned technology.

The economic analysis can also be seen as a tool to help minimising the costs of being wrong. Another economic consideration is the question of how the necessary research is financed; if industry together with public authority would pay for more research where appropriate. It is also important to consider how scarce resources are allocated between known and not yet understood hazards in the sense that it can be dangerous to spend a lot of resources for a potential hazard if it is not expected to be very important while known hazards lack resources to be dealt with.

Political and policy aspects

The application of the precautionary principle is mainly a task of policy-makers and not of scientists or industry. It is the government not industry that fixes the level of protection for society. However the interface between the scientific and policy-making worlds, discussed below, is crucial. Policy-makers should be viewed in the broad sense of all those influencing the decision-making process and not just those responsible for political decisions.

Ultimately only society can decide on what is good for itself, and a collective informed consensus is needed.

Despite the fact that the precautionary principle in the legal sense is to be applied and, if so decided, enforced by policy-makers, “progressive” parties, including industry, can be inspired in its actions and decisions by the same concept.

The importance of the precautionary principle is high, but it should not be overestimated, since most decisions taken do not need the application of the precautionary principle.

A common view of all EU institutions is that the precautionary principle is not only applicable on environment matters but also on human, animal and plant health. The EU Commission Communication on the precautionary principle on the other hand is only binding for the Commission itself. However, given that other Community institutions endorsed the Communication, it could be expected that these institutions will also apply the guidelines contained in the Communication.

Regulatory decisions at any level need to be consistent, clear and decisive. This is a particular challenge because not only evidence but also a number of other things interfere in the decision-making process. Therefore it might be inconsistent to link the precautionary principle with a voluntary approach. Nevertheless voluntary activities such as prudent avoidance should be encouraged.

The precautionary principle is of particular relevance in the trade context where the question of whether its pretended application is really in the aim of protecting health or whether it is a measure of trade protection needs to be addressed. The World Trade Organization (WTO) plays a crucial role in this debate. In the recent case on hormones the WTO appellate body did not rule directly on the precautionary principle. Rather, the EU lost this case because there was no risk assessment and not because the agreement on Sanitary and Phytosanitary Measures SPS does not include elements of the precautionary principle.

In any case, both WTO and EU accept that sound minority scientific views have to be taken into account.

A comparison was made that the concept of the precautionary principle is familiar in the context of military defence. In fact even the proposed United States missile defence programme is investing large sums of money on a highly uncertain potential risk.

Philosophical/ethical aspects

The philosophy of public health is a relatively new field. It is in the so-called “middle ground” philosophy, which continues with practice. Therefore it should be distinguished from the high ground philosophy of philosophers and the low ground philosophy, which is ideologically following one particular school of thought.

In the philosophical sense of the word principle, the precautionary principle can be fitted with other existing principles. One view was that it is an expression of the Best Principle, which asks to make the best possible choice when confronted with different alternatives. Or it can be seen as a moral principle on its own. In any case the precautionary principle as moral responsibility and procedure supporting decision-making is coherent with different schools of thought. It can be found in Aristotelian ethics as soundness of judgement and fits well with a utilitarian approach, except that the utilitarian framework has no solution to the fact that each stakeholder has a

different conclusion of the analysis. If there is a small group of people bearing the costs of the society at large, this can be overlooked in a utilitarian perspective, but it is unacceptable in other approaches. It should be accepted that some adopt a more result- and others a more duty-oriented ethic. For example, a company can say that what they are concerned about is the safety of their customer and make a safer product. The duty ethicist requires that they be truthful about their motivation, and would fault them, if they took this action only to avoid litigation. In contrast, the results oriented ethicist would be satisfied that the product was safe as a result.

We are at the beginning of development on the precautionary principle and on the philosophy of public health. As often the beginning of such a process is rather vague. It implies a shift from “hard” science and “soft” values, to “softening” facts and “hardening” values as well as more humility and less hubris from the side of the scientists.

Application of the precautionary principle

Beside these more general considerations the difficulties lie as so often in the details, which means also in the practical application of the precautionary principle. The important question of uncertainty is discussed in a separate chapter. Some are asking for consistency in the application of the principle, others pay attention to the fact that public health is often inconsistent in its application, in the sense that public health action cannot purely reflect the priorities that emerge from epidemiological evidence. So when should the precautionary principle be used, when should it not be used? There are several underlying philosophical, economical, and societal questions. Do we tolerate dealing with one criminal even though we cannot deal with another criminal doing the same thing because we don't get a hand on him or cannot proof his guilt? In other words, how to reach the optimal balance between sensitivity and specificity?

The application of the precautionary principle is not just the “yes or no” question whether it has to be applied at all. There are different possible answers when examining a potential application of the principle. These answers range from do nothing, conduct research or inform the public to a full ban.

There can be an immediate response followed by a second stage perhaps including analyses aiming at more refined action. Action should also include looking for alternatives. Since it is an action under uncertainty and evolving knowledge, the policy framework should be regularly reviewed.

Such an approach might not be necessary if the world is seen as a “machine” or a deterministic structure, but can be needed if the world is seen as a complex organism. The precautionary principle cannot be applied mechanically, as it is more concerned with the question of what should be done than on how much we know.

Anything new is potentially subject to precautionary action. The precautionary principle is justified where the potential hazard has been clearly identified. The word potential is important because once the hazard and the causal relationship are clearly shown it is not a case for the precautionary principle any more. Therefore the precautionary principle is not only to be considered in cases where the results can be quantified, but also when there are only qualitative appreciations of the potential hazard. We should more often nest quantitative analyses of the parts where it is possible in overall qualitative studies.

As mentioned earlier, industry can inspire its own policy by the spirit of the precautionary principle (where it is not strictly speaking an application of the precautionary principle, because it is done voluntarily and not in response to a requirement in the face of moderate confidence that a hazard might exist). From an industry point of view these cautionary approaches include scientific research, public health practice, good business practice, government action and litigation. If one can persuade business people that there is a return on investment, they are ready to invest resources in research and in changes of practices.

In fact, the mandatory implementation of the precautionary principle is not really needed with this progressive business inspiring its own practice by similar concepts, but rather with “dinosaurs”, i.e., enterprises only looking for profit and ignoring known and potential external negative effects of their activities. But will the precautionary principle really change the practice of these dinosaurs? The example of the unified front of the fossil fuel industry concerning climate change within the Global Climate Coalition (GCC) in 1992 and how companies like Shell and BP have left the GCC and changed both policy positions and practices (by diversifying into investments in renewable energy) suggest that such changes in strategy might be possible.

EMF

Due to the very intense discussions around the precautionary principle in general the discussions concerning the specific case studies concerning electromagnetic fields EMF were much shorter. There is a lot of political pressure to apply the precautionary principle on questions concerning EMF. This is linked to the fact that the EMF question fulfils many of the factors known to exacerbate risk perception and attracting public concern.

However, there are inconsistencies between this concern and real risk, for example mobile phones base stations cause about 1000 times less exposure than handsets. While for low frequency fields there are studies showing a link with childhood leukaemia, there are fewer and less consistent studies on risks from high frequency fields. Some hypotheses on the relation of radio frequencies with childhood leukaemia have been however put forward. Therefore the regulations adopted for example by Italy and Switzerland are inspired to a precautionary attitude towards low and high frequency fields, although this rationale has been questioned.

Even for the low frequency 50/60 Hz fields there is a difficulty. How should one avoid harmful exposure if we don't know what the relevant exposure metric is and therefore which factor should be regulated? Some avoidance measures (like rephasing lines) deal with only some aspects of the EMF mixture, others (like greater distances from the lines) deal with all hypothesized aspects of the EMF mixture. Since the studies showing effects were done on high voltage power lines, Denmark plans to invest a billion of dollars to dig power lines into the ground. In the public's perception, power lines are a big problem for those living close to them, but not a large public health problem, in quantitative terms, compared for example with ozone depletion. Should policy try to protect small percent of the population (that numbers in the tens of thousands) or should it compare the potential lives saved for investments for the total population, the most good for the most people at the least costs. Thus, many disagree with the attitude of those governments that have set limits which are 100 times lower than the limits set by other governments.

The International Commission on Non Ionising Radiation Protection (ICNIRP) bases all its recommendations on the conventional scientific approach of requiring more than 90% confidence before any possible effect is taken into account. Therefore these widely accepted recommendations do not address the possibility of applying the precautionary principle, which would mean going beyond these recommendations in considering evidence with a lower degree of confidence on its precision.

EMF is an intensely studied subject. The large amount of studies and literature has been seen by some as an indicator that since no clear effects have been shown, the real magnitude of the risks is limited or negligible. On the other hand, it can be questioned if these studies have asked the right question.

Science and the precautionary principle

This next chapter groups different questions concerning the link between science and the precautionary principle starting with some general considerations. As mentioned earlier the precautionary principle is mainly a tool for policy-makers and it should not be confused with the cautious interpretation of science. In fact these two tendencies are even going in opposite directions, since the well established cautionary practice in the scientific community means that scientists prefer not to state a possible effect as long as they do not have enough confidence in the result.

Although scientists should not apply the precautionary principle when evaluating the findings of their work, it is highly relevant how scientific evidence is summarized. There is no scientific justification to privilege some studies in the line of caution. Nevertheless some biases historically responsible for several missing or late applications of the precautionary principle in the 20th century should be kept in mind. The precautionary principle has to do with a long-term view, whereby all of us, whether politicians, businesspersons or scientists have many short-term priorities.

There is an important latency lacuna, that the effects take a long time between exposure and scientific detectability. The Pensioner Party Fallacy is the fact that those currently alive and available to be studied are those who have survived a hazard. The power of the current paradigm is very strong in the scientific community going sometimes even to the effect of shooting the messenger.

Risk assessment and management

The precautionary principle can be described as an option in risk management. However if risk management is purely based on classical quantitative risk assessment it can be difficult to see how the precautionary principle fits in, especially when exposure limits are only based on established and quantifiable effects.

Risk perception and communication

The precautionary principle is closely linked to risk perception and risk communication. As policy-makers are subject to all sorts of pressure, the question of the perceived risk will co-determine if they choose to apply the precautionary principle to a specific question.

To some extent risk communication should be replaced or at least extended by decisional communication, not only including the communication on a risk but also on why and how a decision concerning the issue is taken and how this decision can be influenced.

There are different steps of communication from the scientists to the policy-makers, from policy-makers to the public but also from scientists directly to the public. These communications should frame the issues and to some extent try to simplify complexity. The notion of risk communication at the end of a process is wrong, because it cuts the public out of the process. Indeed it should be an integral part of the process and involve stakeholders throughout. However sometimes there is a danger that risk communication makes things worse. But there are different notions of what the aims of risk communication to make things better are: a better consensus or more rational resource use?

Something is only perceived as a risk if people care about it. Together we create risk out of natural facts.

There are some important lessons learnt from risk communication experience, such as:

- risks are multidimensional;
- many people are oversensitive to small risks and under sensitive to large risks;
- experts speak a different language;
- trust is an extremely important dimension (much easier to destroy than to build);
- there is no value free risk communication;
- once people frame a risk issue, it is very difficult to change their mind. Technical risk assessments are largely irrelevant to people;
- people live in a knowledge rich society (competition for attention);
- how information is presented matters;
- values should be made explicit;
- the process is part of the message.

Risk communication is a societal communication, which has to be designed around how people are (cognitive creatures) and not around our models. Often scientists do not address the question the public is asking.

The public concern and size of effect cannot directly be linked to the precautionary principle, because the application of the precautionary principle should be based on sound science. However the public can be very distrustful towards science, for example when there are potential conflicts of interest.

One could even take a long-term view where this public distrust complies very well with scientific criteria. In the early post war period the public had the hypothesis that whenever scientists say that a technology does not represent a danger they were right. This hypothesis has been falsified by many examples like the Chernobyl accident, the ozone depletion by so-called harmless substances, and more recent scandals like the BSE crisis. Therefore the public has changed its views and a reassurance from scientists that there is no danger is severely scrutinised.

The period where scientists say how things are is over.

Public participation

Public participation is an important aspect for the precautionary principle, because the decision-making process involving the application (or non-application) of the precautionary principle should have as full as possible stakeholder involvement and be transparent. One should be careful not to reinvent the wheel on public participation but to learn from the experience gained in other fields with public participation. In general, public participation in the field of health seems to be less developed than in the field of the environment.

Role of science

The discussions at the workshop lead to the question of what is the role of science concerning the precautionary principle. It became clear that it is not up to the scientists to apply the precautionary principle but rather to give to the policy-makers the information allowing them to decide if and how it should be applied. Methods for decision analyses are not purely scientific as they involve value judgments and the interpretation of the scientific results is also seen as a policy-making activity. The initial thought of “precautionary science” cannot be retained, since science should try to be as objective as possible even though the scientists’ work is value laden. Scientists should not pre-empt the value judgement, since this is the role of policy-makers.

The misunderstanding that the precautionary principle is detrimental to science needed clarification. Basing policy decision on the precautionary principle needs rather more science than less science and to some extent a different approach of science and a different presentation of scientific results. When a lack of data is openly noted, there is a need to actively look for and search this data, even if this is technically difficult.

There is a role of values in interpretation of data by scientist. This is unavoidable and there should be more awareness of these involved values. We need much more debate on what sound science is.

We have to accept that there is no such thing as a right policy, only the best given a set of beliefs and values. This leads to the important relation between science and policy-making.

Science policy interface

Scientists very rarely use the word proof, policy-makers do use it. The question what is an acceptable risk for society is a political decision (in the French meaning of political) and not a scientific one. At the end of the day the decision-makers have to decide to act or not to act.

We should use the fact the precautionary principle exists to think about how science can best serve public policy-making. Scientific bodies have to provide input and support without interfering in the political process.

In fact, we cannot clearly separate science and policy-making. In small countries this is not only the case for content but also for persons, because there are not enough experts for both worlds. The difference between science and policy-making can be compared to farming and cooking, where what you get on the table depends both on the ingredients and on how they are prepared.

Possible shortcomings of traditional scientific approach

Overstating the need for rigorous scientific evidence might hamper precautionary decision-making. Given examples of science seen as limiting precaution include:

Conservative hypothesis formulation (tendency to refine understanding of old problems rather than investigating new ones); nearly exclusive preference for quantification as scientific methodology; therefore problems lacking quantitative treatment cannot be studied, and the complexity of systems that is not captured by available quantitative methods is ignored. We tend not to study whole systems including interactions and cumulative effects, but rather parts of the system. We need more, better and more complex science to be able to provide the information policy-makers need to decide whether to apply the precautionary principle.

For academic scientists there is a reward structure that tends to penalize “false positives”, more than “false negatives”.

As a consequence, science can be slow to establish and describe new hazards.

Also, often scientists are reluctant to adopt transparency, as this would put further strain on their work. Furthermore scientists tend to choose research questions where they have a reasonable chance to deliver results in time and they tend to avoid questions which might be too complicated. Thus, scientists can occasionally have a tendency towards defensive or even patronizing stances. In fact, studies show that science professionals are as bad in probabilistic reasoning as other people.

Uncertainty

The precautionary principle comes into play when there are uncertainties. Therefore it is of crucial importance how uncertainties are presented.

A 100% certainty is rare in scientific language. Traditionally scientists require more than 90 or 95% confidence in a positive result to accept a relation. The precautionary principle is not involved in this reasoning. It should somehow be read backwards: If we don't need a proof (i.e. 100% fully established certainty), how much certainty do we need before a given action is warranted? In other words: What is the minimal amount of evidence needed to act?

For example, the Stewart report on mobile phones and health used a balance of evidence as used by the Intergovernmental Panel on Climate Change (IPCC) experts in their second assessment report (only just above 51% of probability).

The English language is not always precise in characterizing different degree of evidence. Nevertheless the third assessment report of the IPCC has developed a language by using the following words to indicate judgmental estimates of confidence: *virtually certain* (greater than 99% chance that a result is true); *very likely* (90-99% chance); *likely* (66-90% chance); *medium likelihood* (33-66% chance); *unlikely* (10-33% chance); *very unlikely* (1-10% chance); *exceptionally unlikely* (less than 1% chance).

In the example of the International Agency for Research on Cancer (IARC) the classification of carcinogenicity of substances and exposures is 1 = carcinogen; 2a = probable carcinogen; 2b =

possible carcinogen, 3 = non-classifiable 4 = non-carcinogen. The classification is done by a vote of a group of experts.

The question on whether to apply the precautionary principle will probably mostly be asked in the range from very unlikely to medium likelihood. However the level of uncertainty is not the only criteria applied.

Given an epidemiological association, if consistency is met but biological plausibility is not present, a scientist whose rationale is guided by effectiveness will not recommend any action, another scientist with precautionary-based values could recommend some action because of the reproducibility.

One further approach is the decision analysis, where effects with less than 50% of confidence would not be put out of the equation, but weighted as possible effects with the appropriate degree of confidence even if low.

Usually the amount of uncertainty should be decreasing over time. Sometimes however more research can mean more uncertainty. A lot of studies do not mean that we know enough. A pile of 5000 studies can provide a right answer to the wrong question. Therefore assessments are never complete or full, but can be better, more comprehensive, more integrated and assessments do not always have to be quantitative or need a majority of scientists. In 1959 most scientists had not any knowledge about the mesothelioma risk following asbestos exposure. In 1964 most not industry paid scientists knew about the link.

Finally it is important to provide full information about scientific uncertainty around a given issue and to develop methods to better characterize and communicate uncertainties from multiple sources.

Apart from uncertainty, effects that are just possible or potential do matter. In the field of genetically modified organisms (GMO) and health, for example, there is no degree of evidence for the time being, but potential consequences can be exceptionally severe.

Precautionary principle and public health

An important new aspect in the workshop was the relation of the precautionary principle with public health. Discussion around the precautionary principle has developed concerning international law on environmental issues, but how does it apply to public health policy? Initially the view was expressed that the precautionary principle is nothing new in public health; it has always been applied using other words. In environmental science speaking of precaution means avoiding possible future harm, but by the time epidemiological data confirm the presence of a problem, harm has already occurred, even if we are not yet certain about it. This led to a discussion on the difference between prevention and precautionary principle. Preventive action is mainly done when the cause-effect link is already well established, while precautionary actions are taken in the presence of uncertainty about this link. The level of evidence will distinguish between precaution and prevention. With a different perspective one can also place precaution as a subset of prevention saying that both are done with similar motivations, it is always a preventive activity but it is only precautionary in the cases where there is still uncertainty on the cause-effect link. Application of the precautionary principle is done in a preventive aim, but by far not all preventive actions are applications of the precautionary principle. Public health has

traditionally done a lot of preventive actions when there was a lot of evidence, what is new is to act when there is less evidence but a potentially serious harm. With endocrine disruptors, for example, it would take a very long time if we wait until level of evidence is high.

Public health has been using precautionary approaches since the 19th century, in many fields. Somehow the approach was born in public health in 19th centuries and elaborated in the environmental world in the 20th century while public health having more evidence on many fields turned its attention to those issues where most uncertainty was overcome. The clear line drawn earlier between scientists and policy-makers, does not take into account the fact that there are people called public health professionals who do science and policy.

One should be careful that the precautionary principle does not divert resources from other public health priorities. However often the required actions are outside of the public health field.

Discussions on the precautionary principle are also challenging traditional public health practice. The instincts of epidemiologists, for example, are “conservative” in the sense that it takes a long time to challenge established hypotheses. We do not consider enough the balance in having a false positive and having a false negative in health. Training as epidemiologist and physician did neither prepare for this challenge nor for the conflicts with different stakeholder. We are at the beginning of a journey leading to curriculum, which should better prepare public health professionals for such questions.

Public health authorities and the precautionary principle

Public health authorities have roles going beyond those of public health professionals. They therefore merit being discussed separately in relation to the precautionary principle. The most prominent public health authority is the World Health Organization (WHO), but several issues raised for the role of WHO also apply for other public health relevant international agencies and national health authorities. Like public health professionals, WHO has often the tendency to be “conservative”, i.e. maximizing specificity of intervention, sometime at the expense of sensitivity.

WHO is somehow in-between science and policy-making and should pursue further the question of balance between these two aspects. Traditionally WHO does not advise adopting policies beyond established scientific knowledge. One reason why WHO had been criticized is that it takes a long time until it makes a statement and then all member countries support it. On the question if policy advice is in the tasks of WHO there are different views. Many participants felt that WHO should take a more active role on the precautionary principle but it should also be careful that its actions are relevant for all WHO countries.

One way of preserving WHO’s reputation could be by clearly indicating that a given recommendation is based on the precautionary principle and therefore subject to later changes and possible even withdrawal. In that way it would then be up to the countries to decide if they adopt the recommendation based on the traditional scientific approach with a high level of confidence or the recommendation based on the precautionary principle.

A further institutional aspect discussed was the possibility of some kind of “yellow flag committee”. This would be an independent body with a broad stakeholder involvement, hosted by WHO, United Nations Environment Programme (UNEP) or an interagency collaboration

between them and others, having a mandate to evaluate based on the available knowledge if there is a scope for the application of the precautionary principle in particular cases.

Conclusions and further steps

This workshop was a start for a process of review and evaluation in WHO on the precautionary principle and its application in public health matters. The workshop has confirmed the assumption that the role of the precautionary principle in public health and of public health professionals and agencies in the precautionary principle needs clarification. This assumption was confirmed and first steps towards such clarification taken. The proposal submitted to the European Environment and Health Committee (EEHC) in November 2000 of considering the elaboration of WHO guidelines on the implementation of the precautionary principle could be based on the discussion of the workshop and be modified into a proposal of WHO guidelines on how public health bodies should present data where there is a low level of evidence. This would reflect the fact that scientists and scientific bodies have to present available knowledge and policy-makers have to take the policy decisions based on this knowledge. It could also clarify the languages to be used in such science – policy interaction.

The question on if and how the topic should be brought to the ministerial conference in Budapest 2004 should be raised again in the EEHC.

It was proposed that WHO should give input to the elaboration of the EU white paper on governance.

WHO should take the lead, in the context of interagency cooperation. The European Environment Agency (EEA) has kindly offered to co-finance next steps.

The main conclusion was a broad consensus that there should be a follow up to this beginning work on the precautionary principle and public health.

Annex 1

SUGGESTED QUESTIONS TO BE ADDRESSED AT THE WORKSHOP

The following questions were tabled at the beginning of the meeting. Due to the dynamic discussions not all of them could be addressed to the meeting, but they represent areas of work for further development:

1. Precautionary Principle: most definitions share some main aspects: (i) taking action in the face of scientific uncertainty; (ii) reversing the burden of proof; (iii) openness; and (iv) analysis of all alternatives. See, for example, the Wingspread statement.¹

Do these characterize the Principle well enough for public health? Do we need another definition?

In particular:

- (a) Does the Principle only apply to qualitative questions (e.g., yes/no to a new technology, how it can be introduced etc), or can it be applied where quantitative standards or guidelines are invoked?
 - (b) Does “taking action” necessarily include regulatory and legislative measures?
2. Criteria for application of PP: are for example the EC’s guidelines applicable and satisfactory for public health?
 3. The role of public health professionals in the issue needs clarification. PH people may approach the question with conflicting views, e.g., the utilitarian standing (based on cost-benefit type reasoning) and “social justice” standing (based on equity), and reconciling the two can be problematic. A number of roles can be envisaged, see e.g. a list by R Neutra below.²
Should PH practitioners be involved in the decisional process that includes (i) evaluating the scientific evidence; (ii) evaluating the social aspects, e.g., perception, acceptability of risks, equity; and leads to recommendations on public health policies? What should WHO’s role be?

¹ “When 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 this context the proponent of an activity, rather than the public, should bear the burden of the proof. The process of applying the Precautionary Principle must be open, informed, and democratic and must include potentially affected parties. It must also involve an examination of a full range of alternatives, including no action”.

² 1) The “unbiased” explainer of possible health effects expected from optional courses of action with either (a) a very high burden of proof to avoid calling wolf or (b) a lower burden of proof to avoid letting the wolf into the village.

2) The “unbiased” explainer of ethical implications of various courses of action particularly if health consequences fall unequally on different segments of the population because of unequal exposure, unequal vulnerability or unequal ability to cope with illness.

3) Since the WHO definition is holistic, to be an advocate for a holistic view of environmental health problems and policy dilemmas and the convenor of interested parties in reaching a holistic, transparent and fair resolution to the policy dilemma.

4) The effective advocate for protecting health regardless of the size of the risk or the cost of achieving it.

5) The effective advocate that the health consequences, and the ethical dimensions of the health consequences are not forgotten in the policy discussion.

6) The unbiased explainer of the state of the science and the uncertainties that surround the issue.

7) The voice of warning to alert the community of a public health danger.

8) The voice of reason to calm down an alarmed community.

4. The rationale underlying the development of precautionary approaches (which took place in the environmental field) is based on general principles that include the recognition of the complexity of the systems involved: environment at large, populations, multi factorial effects etc. As science is ill equipped to describe such complexity, precaution is increasingly called for when considering potentially far-reaching hazards. Focusing on human health, and consider only the last ring of the complex chain of events from environmental degradation to all its consequences, may therefore conflict with the need of taking a holistic view. Also, application of precautionary approaches in public health, for hazards that are partly known, may result in actions that can potentially undermine the scientific component of decision-making (see also question 7) below.
Is there a scope for pursuing the debate on precautionary approaches *specifically in public health*?
5. EMF. Is the PP applicable to EMF and public health?
6. Prudent avoidance has been suggested as a suitable option for EMF protection. However, voluntary measures or “non-aggressive legislation” (as suggested by NIEHS) may have different degrees of effectiveness in different countries, depending on the quality of social and welfare structures, participation, accountability etc. In addition, as someone put it “talk is cheap”.
How can these objections be taken into consideration?
7. Some countries (e.g., Italy) have recently set exposure standards (quantitative limits) to protect the public from potential undemonstrated effects. The choice of numerical values, given the uncertainty, have a high degree of arbitrariness, but can give the impression of being “safe” limits in the same way as those that protect from established acute effects.
Is this a problem of communication, or quantitative standards are intrinsically at odds with precaution (see question 1 above)?
8. **How should public concern be taken into consideration when deciding what precautionary approach is appropriate?**
9. **What are the most urgent open questions that should be addressed?**

Annex 2

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