Framework to Develop Precautionary Measures in Areas of Scientific Uncertainty

WHO/OMS

Draft for Review
NOT FOR FURTHER DISTRIBUTION
NOT FOR QUOTATION

For further information and comments contact:

Dr Emilie van Deventer
Radiation and Environmental Health
World Health Organization
Tel: +41 22 791 3950
Email: vandeventere@who.int

October 2004

TABLE OF CONTENTS

Preface

The World Health Organization (WHO) addresses environmental health threats that are uncertain and global in nature. Given the complexity of these risks, the need for timely preventive action, and, often, scientific uncertainty about the risks to health, it is important that WHO develop an approach for applying precautionary measures that is rational and practical, and consistent with public health values and its mission to promote and protect health.

As an international public health agency, WHO has always been cautious in its conclusions on health and safety issues, and has based its recommendations on sound and established scientific evidence. At the 1999 Conference of European Health Ministers, WHO was asked to take into account: "the need to rigorously apply the Precautionary Principle in assessing risks and to adopt a more preventive, pro-active approach to hazards." As a result, WHO has been promoting discussion and debate in this field through open scientific fora. A Workshop on "Precautionary Policies and Health Protection: Principles and Applications" was held in Rome, May 2001; a Symposium entitled "Environmental Exposures, Public Health, and the Precautionary Principle" was held in Vancouver, August 2002 to discuss case studies and review developments in the field. WHO also co-sponsored the October 2002 Collegium Ramazzini's international scientific conference, "The Precautionary Principle: Implications for Research and Prevention in Environmental and Occupational Health".

Finally a WHO Workshop on "Application of the Precautionary Principle", co-sponsored by the European Commission and US National Institute for Environmental Health Sciences, was held in Luxembourg 24-26 February 2003 to develop a common framework for application of the Precautionary Principle to health issues, in particular in the context of electromagnetic fields.

While WHO will continue to provide sound scientific advice on established health risk factors, this Precautionary Framework has been developed to assist Member States in incorporating precautionary measures into management of uncertain public health risks.

WHO encourages the use of rational, well thought-out precautionary measures based on scientific principles. These should be the driving force for the development of protective measures that restrict exposure to a given risk factor and should, in addition, indicate areas where practical measures can be identified that reduce any consequences to health..

Executive Summary

This section will be enlarged once the framework has been completed

1. Introduction

1.1 Objectives of this Framework

In the public health arena, priority is usually given to controlling those risks that are clear cut: that is, substantial, involving common diseases or widespread exposure, and well-established. However, changing societies and rapid technological developments produce an ever-increasing variety of agents and circumstances whose health consequences are difficult to predict and manage. Waiting for conclusive evidence of a health threat has sometimes had unfortunate consequences (Gee, 2001).

In this context, precautionary measures are used to prevent or limit exposures to agents or activities whose effects are not well understood, but which may nonetheless be harmful. Where an agent is ubiquitous or the potential harm great, it may be reasonable to apply precaution and act with foresight, before a cause-effect relationship has been established or robustly quantified. The object of precautionary measures is to minimize potential risks from new technologies or other potential risk factors but while still enjoying any potential benefits. However, these measures will have a cost, which must be offset against the value of the benefits gained. Precaution can be integrated naturally into existing public health policy and can complement conventional disease prevention actions, which are usually taken only after a cause-effect relationship has been established.

This Framework is intended to guide WHO Member States in the development of their public health policies and application of precautionary measures in the face of scientific uncertainty. The purpose is to provide a practical Framework for developing protection measures, aimed at optimising the overall benefit for society. The Framework is not a mechanical formula, generating instant answers or decisions. Rather, it provides clarification of processes and guidance in relation to how certain key issues should be considered. To that end, the Annexes include a set of case studies on several physical, chemical or biological agents with known or uncertain health risks, illustrating how the Precautionary Framework should be applied.

1.2 The Precautionary Principle

The Precautionary Framework detailed in this document is based on the application of the Precautionary Principle. This Principle has been advocated when there is scientific and/or public concern about exposure to an agent whose health impact cannot be fully assessed because scientific data are incomplete.

The Precautionary Principle lacks a clear and universally accepted definition (Foster et al., 2002) and actions by some countries suggest that there is confusion and debate about what the Precautionary Principle means and how it should be applied. Most existing definitions of the Precautionary Principle describe it in terms of situations in which inaction is not necessarily the appropriate response (Table 1). An alternative, stating when action should be taken, was recently proposed by the European Environment Agency (EEA) and is included in Table 1.

The Rio Declaration 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".*
Treaty on European Union (Maastricht Treaty), 1992
*"Community policy on the environment… shall be based on the **precautionary principle** and on the principles that preventive actions should be taken, that the environmental damage should as a priority be rectified at source and that the polluter should pay."*
Wingspread Statement
"*It is necessary to implement the Precautionary Principle: 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 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 the full range of alternatives, including no action."*
European Environment Agency, 2004
*"The **Precautionary Principle** provides a framework, procedures and policy tools for public policy actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act before there is strong proof of harm in order to avoid, or reduce, potentially serious or irreversible threats to health or the environment, using an appropriate level of scientific evidence, and taking into account the likely pros and cons of action and inaction"*
Table 1- The Precautionary Principle on some international treaties and agreements

2. Features of this Framework

2.1 Alternative descriptions of the risk management process

The Precautionary Framework is intended to facilitate integration of precautionary measures into existing public health policy. Most approaches to dealing with health risk employed throughout the world include the following basic steps:

- definition of the problem (what is the risk factor)
- science-based risk assessment (what is known about the risk)
- generation and selection of options (what are the options for dealing with the risk factor, and how to select the best one for implementation)
- action or implementation of the selected option, and
- monitoring and evaluation of actions undertaken.

In dealing with risk, the traditional paradigm has involved viewing these steps as a linear and unidirectional process consisting of risk assessment (RA), followed by risk management (RM), and then risk communication (RC), these different stages being often performed by different people (Figure 1(i)). Evolving from this view over the last decade is an improved paradigm involving an iterative circular process, which promotes two-way feedback and

stakeholder involvement at all stages (Figure 1(ii)). The Precautionary Framework developed here bases itself on this paradigm. From here on, risk "management" will refer to the overall circular process.

The US Presidential/Congressional Commission on Risk Assessment and Risk Management (Omen report, 1997) helpfully split this circular process into six stages, emphasizing the analysis of possible options, clarification of all stakeholders' interests and openness in the way decisions are reached. These steps are shown schematically in Figure 1(iii). This analysis of risk management in six stages is used as the basis for the WHO Framework, which extends it to uncertain risks.

2.2 Precaution as an overarching approach

In the traditional linear paradigm, the precautionary principle has often been linked to the risk management stage only, and has been regarded as an additional process, invoked or triggered only when a certain level of evidence is exceeded. The basic premise of the WHO Framework is that precaution should be viewed as an overarching philosophy for risk management which is to be applied to all aspects of managing an actual or potential health risk. The present WHO Framework sees the various stages as closely integrated, and precaution as an approach that informs every stage and for all risks rather than being triggered only sometimes. Each of the stages described by the Presidential/Congressional Commission is considered in the broader context of precaution rather than the narrower context of traditional risk management, as discussed further in section 3 below.

2.3 Relationship to other frameworks

The European Commission in its communication on the Precautionary Principle in 2000 provided a critical step in describing the purpose and use of the Precautionary Principle in European policy making (EC, 2000). It recommends that precautionary actions be proportionate to the degree of scientific uncertainty; the severity of possible harm; the size and nature of the affected population; and the cost of the actions. Where the evidence of danger is weak, regulation should usually be avoided. Continuing research may be an appropriate action to fill gaps in knowledge and ensure that the danger is not larger than what current understanding suggests. In addition, the Communication recommends transparent application of the process, and emphasizes the need for careful review of relevant scientific data. This Framework incorporates many of the guiding principles enunciated by the European Commission.

Other countries outside the European Union have incorporated precaution into their decision making processes, some in an informal way, and others using a formal approach. The Government of Canada has developed a "Framework for the Application of Precaution in Science-Based Decision Making About Risk". This Framework outlines guiding principles for federal regulatory activity to protect health and safety, as well as the environment and natural resources. In New Zealand, the Resource Management Act (1991) requires specific considerations of risks which are defined as "of low probability but high potential impact". In Queensland, Australia, the Precautionary Principle has recently been adopted by environmental legislation. In Switzerland, the Precautionary Principle is well established as an instrument of risk analysis. In cases where there is a lack of or insufficient scientific information the risk manager decides pro or contra taking action. Although there are no

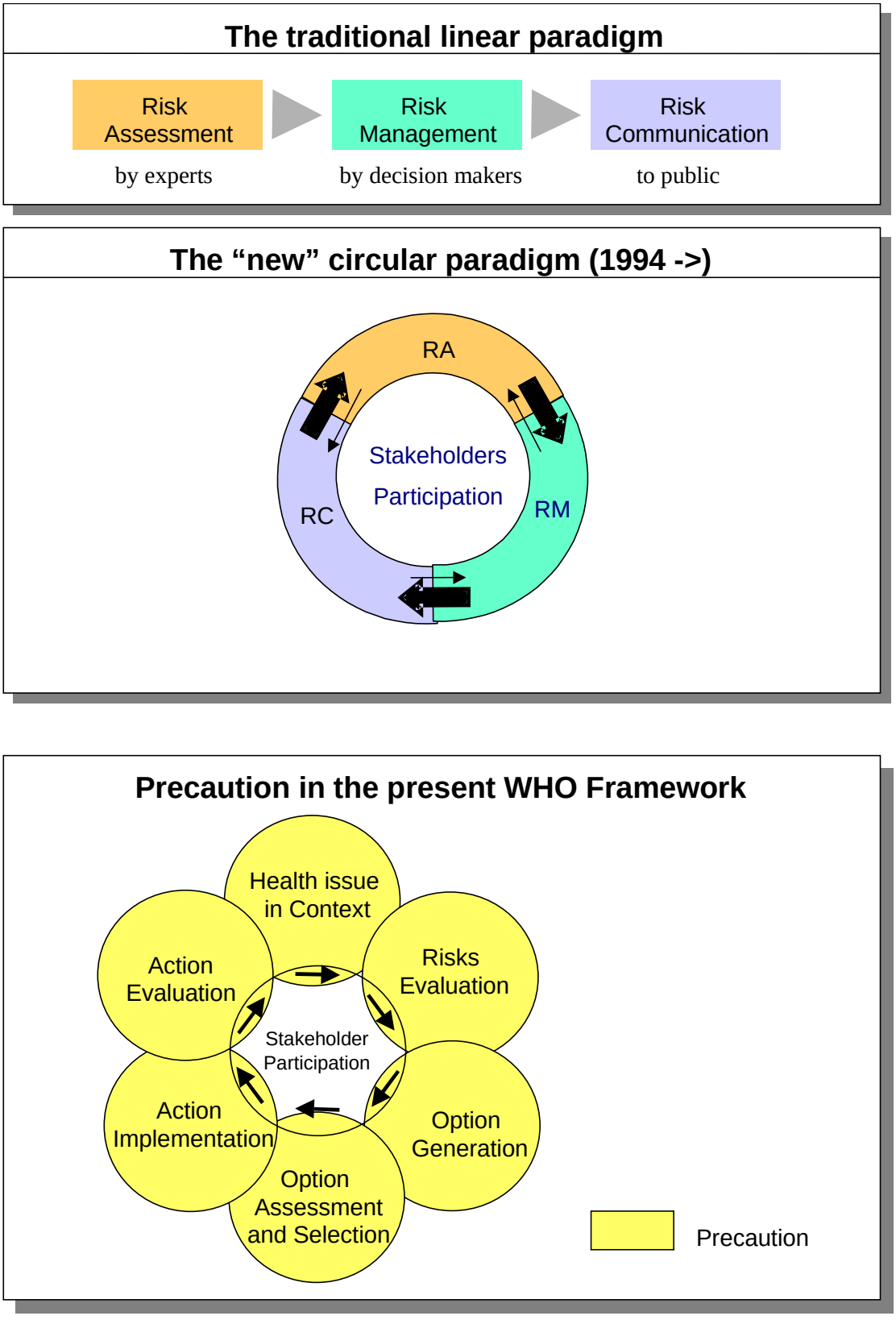

Figure 1- Dealing with risk: (i) the traditional paradigm as a linear process, (ii) the “new” paradigm as an iterative, circular process with 2 way feedback (adapted from the European Environment Agency), (iii) the circular process split into stages as in the Omen report.

fundamentally different viewpoints between different Federal Offices, the precautionary principle is regulated differently in law.

2.4 Science and Policy

Central to the Framework is the careful use of available scientific evidence. The Precautionary Framework extends rather than replaces science-based risk management.

Conventional scientific methods distinguish "established" from "uncertain" effects and take action only on the former. A high level of proof is required to establish a risk, which tends to generate false negatives (i.e. assuming that a risk does not exist when it actually does). By contrast, people in society as a whole are often more ready to accept a false positive (i.e. assuming that a risk does exist when actually it does not), because they do not want a potentially real risk overlooked.

This traditional dichotomy between "established" and "uncertain" effects can sometimes be unhelpful. For any effect or risk, a full scientific evaluation will identify some areas of knowledge, some areas of uncertainty, and even some areas about which there is no available information. The extent of knowledge and uncertainty varies over a continuum, from effects which are little more than hypothesised, through effects where there is some evidence but considerable uncertainty, to effects which would be regarded as "established" by conventional scientific standards. The role of science is not confined to the last group, "established" effects, but extends equally across the whole continuum, identifying clearly what is known as well as the uncertainties and gaps in knowledge.

The strength of scientific evidence concerning a potential risk is one of the factors considered in selecting appropriate actions. Other factors include technical feasibility, economic costs and benefits, and political realities. The Precautionary Framework also recognizes that perspectives based on theory, social factors, ethical values, and experience or observation provide valid input into policy recommendations.

3. Process Formulation

Figure 1.3 shows the basic steps of the Framework, as categorised by Omen (1997). Each of these six steps is described in detail in this section, and is further exemplified in the case studies. Consultation with stakeholders should be part of every step.

3.1 Health issue in context

Existing risk management frameworks deal mostly with established risks. Risks for agents that have not yet been fully assessed, if considered at all, are derived from a comparison with other agents of similar chemical, biological and/or physical properties for which the risks are known. The Precautionary Framework expands the scope of uncertain risks to include those where the scientific evidence is even weaker. In this paradigm, social, political and health contexts are also considered.

- From a social point of view, many societies have a heightened level of concern for vulnerable populations such as the infirm, the elderly and children because they may be

unable to take actions to effectively manage their own risk. Furthermore, many societies believe that the child and the foetus should be afforded an even higher level of protection because of their potentially increased vulnerability, greater potential for exposure over their lifetime and because they represent the future of the society. These issues may also raise ethical considerations.

- From a political point of view, attention is often directed at inequities in the distribution and magnitude of actual and potential exposures (individual and total) and consequent adverse health outcomes. Often, the distribution of benefits and risks are uneven across time and groups, and situations that could be viewed as inequitable need to be addressed appropriately.

- From a health point of view, special attention is paid to ubiquitous exposures because even a relatively small (and thus difficult to detect) health risk to many individuals may have significant public health consequences. The nature of the presumed health effect is also a factor in putting the health issue in context. Some diseases, such as cancer, are particularly dreaded. Other maladies, such as headaches and sleeplessness, are not life threatening and are often treatable, but can nevertheless have a profound influence on an individual's well being and productivity.

Another part of the context is the level of risk deemed acceptable by the society concerned, which depends on its nature. For involuntary exposures, for example, some countries have adopted a notional value of risk of 1 in 100,000 as a general threshold (with 1 in a million as an ideal goal) below which the risk is considered to be acceptable or impractical to improve on. For risks undertaken voluntarily, such as smoking or rock climbing, higher levels of risk are often more acceptable.

3.2 Risk evaluation

For normal science-based risk assessment:

- Overall evaluation is based on the weight-of-evidence. The science must be rigorous, with input provided by many specialized disciplines, and, other than in exceptional circumstances, based on publications in peer-reviewed journals.

- Uncertainties in the assessment of risk should be identified and clearly stated. Uncertainties can exist at every level of risk assessment: the existence of a hazard, the magnitude of exposure, and the relationship of dose to disease incidence or severity.

- Assumptions necessary for the proper assessment of risk should be identified and clearly stated. When direct evidence is limited, science-based assumptions or extrapolations are often used; for example extrapolating effects established at high exposures to possible effects at lower exposures.

The Precautionary Framework follows the same scientific principles but operates from a broader knowledge base than traditional risk assessment. It attempts to clarify what is not known in addition to what is uncertain. A description of where key scientific evidence (e.g. epidemiological or toxicological studies) is missing or inadequate is especially important. Scientists and decision makers should recognize that failure to demonstrate an adverse health effect does not rule out the possible existence of one since the test system used may not have

been sensitive enough to detect any effect[1]. Also, failure to demonstrate an adverse health effect in a limited timeframe does not rule out the possibility that there may be some consequence sometime in the future[2].

To function effectively and add value to decision making, the *Risk Evaluation* will need to recognize and evaluate the factors which affect the perception of risk. Such factors include:

- whether the risk is voluntary or involuntary
- what measure of control over the risk the subject has
- the personal, social or economic benefits associated with the risk
- whether the consequence is likely to be immediate or delayed
- whether the subject is familiar or unfamiliar with the risk
- whether the risk is well-characterised by science or not
- the severity of the consequences (including whether the consequences are common or dread)
- the size, nature or special characteristics of the group exposed to the risk
- whether the effects are chronic, cumulative or catastrophic in nature
- the distribution of the risk across sub-groups
- the effect on future generations
- whether the hazard is encountered occupationally
- whether it affects `average' people or only special sub-groups
- whether there is likely to be potential for misuse
- whether the consequences are reversible
- whether the subjects know if they have been exposed to it.

3.3 Option generation

In existing risk management frameworks, options designed to protect health are often based on an exposure limit or guideline. Other options may emphasize reducing exposure by engineered solutions, driven by technological feasibility. Further options based on education, voluntary initiatives, and market incentives are also possible.

The WHO Framework encourages consideration of the full range of options to respond to uncertain health risks, not restricted to a specified statutory or guideline level, and including options involving individual choice such as behaviour modification, information and risk communication. Where efforts aimed at reducing the exposure are not feasible, options to minimize the seriousness of the health outcome (e.g. increased medical surveillance) should be evaluated. Examples of options are given in the inset below.

[1] Animal systems that are designed to provide information for regulatory issues generally emphasize identifying hazards. In contrast, many published studies are both limited and uncertain with respect to their ability to describe how the incidence or severity of the effect caused by a hazard changes with different environmentally-relevant doses. This is because dose-response relationships are often inferred from doses that are very high and environmentally-irrelevant. For some hazards, laboratory animal studies cannot be conducted at the high doses necessary to detect an effect with confidence and still comply with ethical guidelines, or be technically feasible.

[2] An inability to demonstrate the existence of an adverse health effect in epidemiological or laboratory studies is sometimes taken to show that a causal relationship to the agent of concern is unlikely. However, long latency (the time between the initial exposure and evidence of the effect) is characteristic of many diseases and will limit for many years our understanding of the potential for a new exposure to cause harm.

EXAMPLES OF OPTIONS

- A **decision to take no formal action** may be an appropriate response in cases where the risk is considered very small or the evidence is very weak.
- **Research** is an appropriate response to fill gaps in knowledge, help identify potential problems, and to allow for a better assessment of risk in the future.
- A **formal monitoring process** provides transparency in monitoring the results of research and measurement and the decisions being made by standard-setters, regulators, and others.
- **Consultation, communication and engagement programmes** can be used to help people voice their concern, understand the issues, become involved in the process and make their own choices about what to do.
- **Labelling** can sometimes be used to alert people to the exposure level from a device or technology and allow people to choose lower exposure option.
- Methods designed to produce **reductions in exposure** or, in the extreme, banning the source of exposure altogether are options to be used when the degree of certainty of harm is high, when the costs of limitations or bans are low, or both. Reducing exposure might include, for example, industry codes of practice, or economic incentives.
- **Technical options (mitigation)** normally involve making engineering or other technical changes to reduce exposure
- **Voluntary behavioural change** may be chosen to avoid or reduce exposure, if easily achievable.
- **Numeric standards** are formal steps taken by government to limit both the occurrence and consequences of potentially risky events. These may be imposed with defined methods of showing compliance, or they may state the objectives to be achieved without being prescriptive.

3.4 Option assessment and selection

Option assessment

In risk management frameworks, option assessment for known risks is based on scientific, economic and technical information. Priority is given to preventing known risks, wherever possible, not just controlling them (e.g. the polio eradication campaign). Option assessment for known risks can be undertaken according to either a cost-benefit analysis (an economic method for comparing the costs and benefits of particular options) or a cost effectiveness analysis (an economic method to identify the least costly way to achieve a particular exposure reduction or health protection goal). Further discussion on these types of economic analysis is provided in Appendix A.

Option assessment within the WHO Framework extends the same principles to uncertain risks. The nature of the assessment will depend on the strength of evidence for a risk:

- Where, for example, the International Agency for Research on Cancer (IARC) or a body with equivalent status classifies an agent as "possibly carcinogenic" or that there is a possibility of causing other diseases, the benefit-cost analysis can be reasonably quantitative and objective, similar to that for a known risk.

- Where the classification is less than this (e.g. insufficient evidence, IARC Group 3), the option assessment will inevitably be less objective, less satisfactory and less supportable. In this case option assessment may be sensibly restricted to only those options with very low costs. However, no matter how low the apparent cost of an intervention, at least a rudimentary cost-benefit analysis should be undertaken to ensure that an apparently "low cost" option really is low cost yet effective in achieving its intended benefit.

Option selection

In the WHO Framework, the option that is expected to provide the best outcome for society should be selected, balancing health protection against intrusion and cost. Scientific evidence influences option selection: stronger evidence, particularly of a pervasive, severe or irreversible health effect, supports more intrusive actions. However, evidence that does not meet conventional scientific criteria as proof of cause, particularly for a pervasive, severe or irreversible health effect, may still support selection of less intrusive actions.

At one extreme, selecting the action of banning an agent or activity may depend on whether or not an alternative is available. If so, the implications of the alternatives for potential health effects, costs and benefits must be evaluated. Where no alternative is available and reduction of exposure is not feasible, the evaluation needs to compare the benefits provided by the agent or activity with its potential detrimental effects.

At the other extreme, taking no formal action is often assumed to be the most benign option. However, taking no formal action should also be evaluated employing a similar methodology, including any costs due to public opposition or increased anxiety, which itself is detrimental to mental and social well being.

The weight of political, environmental, social, economic and other factors will need to be made explicit when selecting actions on the basis of precaution. Transparency is key to the commitment and trust of stakeholders. Their active participation is necessary for successful implementation of any chosen action.

3.5 Action implementation

In traditional risk management frameworks, implementation often involves statutory or regulatory requirements. In the WHO Framework, the selected options may include voluntary as well as mandatory measures. While mandatory measures can be implemented the "traditional" way, implementation of voluntary measures may require further resources to inform, explain and promote these new measures through appropriate communication strategies.

A broader range of stakeholder involvement is required for implementation when the benefits of the action become less favourable and costs, financial or otherwise, become more burdensome.

3.6 Action evaluation

Evaluation of actions developed for a known health risk generally concern compliance and enforcement. In the WHO Framework, actions not requiring measurable compliance may be

harder to evaluate relative to the objectives of exposure reduction, reduced scientific uncertainty or reduced public concern.

Action evaluation is not the final step in the risk management process within the WHO Framework. Rather, the process is iterative and intended to be responsive to newly available information and to changing society values. Actions, especially those selected under emergency situations, should be subject to periodic review to determine their effectiveness and relevance in the context of prevailing scientific uncertainty and public concern. As new information becomes available it should be incorporated into the assessment under the precautionary framework.

4. Discussion

4.1 Quantitative limits and guidelines

Guidelines setting quantitative limits on human exposures to environmental agents are normally introduced only on the basis of consistent, reproducible data, confirmed by different laboratories and clearly establishing the levels of exposure to physical, biological or chemical agents thought to be harmful to humans. In addition, exposure limits generally incorporate safety factors that allow for uncertainty in any identified thresholds for established effects. Such approaches remain central to the WHO Precautionary Framework; guidelines should not be undermined by additional, arbitrary exposure reductions in the name of "precaution", since this would devalue their scientific credibility.

4.2 Consultation strategies

The emphasis on consultation acknowledges that the acceptability of risk is ultimately at least as much about political and societal values and judgements as it is about scientific information. A partnership approach between key stakeholders for all risk management stages needs to be developed because of the clear need to modify the traditional separation between the approaches used to assess risks and those used to reduce them. Many risk management failures can be traced to a failure to involve stakeholders in decision-making at the appropriate time. While public input may be difficult to achieve at *every* stage, it is recognized that without involving interested and affected parties in the evaluation of risks and interventions, decisions taken may lack credibility and uptake.

Stakeholders will need to be consulted for their views at two levels: firstly, prior to its finalisation, on the content and form of the Framework itself, and secondly, on the assessment of particular risks and on the analysis of possible interventions to manage those risks. The public will, for example, expect to contribute to the formulation of criteria to determine what risks are ‘negligible’ or ‘acceptable’. Without establishing its *bona fides* in this way, public trust and confidence (so essential to the credibility of recommendations arising from the methodology) will be difficult to secure. While there will not always be consensus on such issues, the position taken should be transparent, evidence-based and able to withstand critical scrutiny.

The public and other stakeholders will also expect to be consulted when the Framework is used to consider particular public health risks. There will need to be flexibility as to who gets consulted, at what stage(s) and what type and level of consultation is appropriate. This will vary from risk to risk and from stakeholder to stakeholder.

4.3 Communication strategies

Some societies or sections of society are reticent to adopt precautionary measures in case this is seen as an admission that the health risk is real. In part, this concern relates to public perception of the issue. This concern can be ameliorated, though not necessarily completely removed, by sensitive communication.

The need for and content of a communication strategy should be considered at an early stage, particularly if assessment of a risk is to proceed beyond the preliminary analysis stage. These strategies may need to be reviewed and revised as the process continues.

4.4 Human rights

Certain concepts in the present framework relate closely to international human rights law in terms of focusing upon access to information, participation and ensuring positive impact on human rights including the right to health. The precautionary principle is implicated to the extent that consideration of activities which raise threats to harm human health, even if cause and effect relationships are not fully established scientifically, is necessary to protect the right to health. The participation of the population in all health-related decision-making at the community, national and international levels also constitutes an important component of the realization of the right to health.

4.5 Legal context of using of precautionary measures

Adopting precautionary measures may also generate a legal concern, i.e. it could be construed as an admission of liability; it might be taken to imply responsibility for similar exposures prior to taking precautionary action; and it may put the person, national authority or company taking such action in the position of having to justify, in a legal arena, why they took the actions they did, why they had not taken actions earlier, and why they did not go further.

It should be expressly acknowledged that in implementing precautionary measures, persons, national authorities or companies are not to be taken to be admitting liability for any consequences of not having taken precautionary measures earlier; or to be even acknowledging that the precautionary measures imposed are either necessary or appropriate.

4.6 Case studies

Generic case studies for ELF magnetic fields and radiofrequency fields are given in Appendices B and C. Further case studies will be added as they are completed.

Glossary (to be expanded)

Adverse effect: (add from EPA glossary)
Agent: (add from EPA glossary)
Cost-benefit analysis: an economic method for assessing the benefits and costs of achieving alternative health-based criteria (e.g. a risk of 1 in a million) with different levels of health protection
Cost effectiveness analysis: an economic method to identify the least costly way to achieve a particular exposure reduction goal
Disability-adjusted life years (DALYs):
Endpoint (add from EPA glossary)
Known risk: A risk is known if its existence has been established by evidence generally accepted as proof of cause according to conventional scientific standards.
Health: a state of complete physical, mental and social well being and not merely the absence of disease or infirmity (WHO Constitution)
Precautionary principle: a concept that allows flexible approaches to identifying and managing possible adverse consequences to human health even when it has not been established that an activity or exposure constitutes harm to health
Precautionary Framework: an overarching approach encompassing procedures in managing human health risks that are either known or uncertain.
Public health: the health of all of - (a) the people, or (b) a community or section of such people
Public health risk: an activity, arrangement, circumstance, event, occurrence, phenomenon, process, situation, organism (including micro-organisms) or substance that is, in the ordinary course of events, an actual or potential cause or source of an adverse effect on public health
Risk: the combination of the magnitude of an adverse effect and the probability of its occurrence (add from EPA glossary)
Significant public health risk: a public health risk which may result in or has caused a person or persons to suffer death, disease, injury, hospitalisation as an in-patient, permanent disability or impairment, or, a life threatening episode
Stakeholder (add from EPA glossary)
Uncertain risk:

Appendix A: Technical considerations for cost-benefit and cost-effectiveness analysis

Assessment of costs

Costs are not just financial but include other consequences as well. Costs can be broken into three components: initial cost (actual cost of implementing the intervention), ongoing costs (any recurring costs directly created by the intervention or required to keep the intervention in place), and consequential costs (costs created as a consequence of the intervention, for example if the intervention causes people to modify their behaviour in some way).

Assessment of benefits

In option assessment, the putative benefit or effectiveness of an exposure reduction or other option ***to prevent or reduce the adverse health effect*** is evaluated.

Outcomes need to be clearly reported, as different answers might be obtained if the outcome is defined as number of fatalities, as opposed to disease incidence, or years of life. Effectiveness can be measured in terms of disability-adjusted life years (DALYs) gained by the option[3]. National governments may choose to emphasize other measures of the outcome.

In principle, it is necessary to evaluate the impact that an intervention might have on the pattern of exposures across the population. In practice, this is not possible, simply because full information is never available. However it is important to avoid assuming that the consequences can be adequately expressed in terms of a single number representing a reduced exposure. Assessment should include various effects relating to different aspects of exposure (risk offset), re-distribution of exposures among people or populations (risk transfer), or creation of new risks (risk transformation).

Comparison of costs and benefits

To permit comparison with costs, the value of a health benefit is expressed in monetary terms, derived either from an observation of how much money a society is prepared to spend, or from the effect of health on economic productiveness. Benefits need to be expressed in units that make clear whether it is per person affected, per member of some sub-group or the whole population.

The value a society places on the reduction of risk or disease arising from a particular agent, technology or intervention assumes the reduction would actually occur, i.e. there is a known risk. Where the risk is uncertain, it will be necessary to adjust this figure.

While some costs will arise only once, others are on going as, in general, are the benefits. The applied costs and benefits must therefore be discounted using an appropriate model.

There will always be uncertainties, in the assessment both of the costs and the benefits. All significant uncertainties should be explicitly recognised.

[3] WHO World Health Report 2002, p.106

The cost-benefit or cost-effectiveness analysis should be performed at the level of a whole society. It will therefore encompass all costs regardless of who might bear them, be it industry, taxpayers or others. Costs always have consequences, not least through the established association between disposable income and health. On the other hand, actions often lead to unanticipated benefits. The proper application of the WHO Framework should address those consequences.

Incorporation of social factors

The utilitarian approach to cost-benefit or cost-effectiveness analysis would be to reduce exposure until the cost of the last reduction equals its benefit. However, the WHO precautionary framework stresses the importance of recognising social factors whereby society may wish to err on the side of caution and incur greater costs, in excess of the expected benefit. This can be accomplished either by making the test for comparing costs and benefits "not grossly disproportionate" rather than "equal", or at the earlier stage of deriving a value for the uncertain adverse health effect prevented.

Appendix B: Case study on ELF electric and magnetic fields

One of the environmental agents which falls within the purview of the present Framework is the case of exposure to extremely low frequency (ELF) fields from the generation, transmission or use of electricity. The International Agency for Research on Cancer (IARC) has classified ELF magnetic fields as an agent that is "possibly carcinogenic" to humans (classification 2B); such classification embodies in itself the uncertainty of the health risk to the population, and is therefore a good candidate for the application of the present Framework.

Health Issue in Context

"ELF EMF" encompasses power frequency electric and magnetic fields. The evidence that ELF EMF causes cancer was evaluated by IARC in 2001. IARC classified magnetic fields as 2B, "possibly carcinogenic", and electric fields as 3, "unclassifiable". The 2B classification for magnetic fields was based on the evidence for childhood leukaemia. For other types of childhood cancer and for all adult cancers, the evidence as assessed by IARC would not have been sufficient to warrant a 2B classification.

Non-cancer endpoints have not been formally classified by any WHO-recognized body. WHO itself will classify them in 2004 and will also revisit the IARC classification. It is assumed here that childhood leukaemia will remain at 2B and that no other health outcome will warrant a 2B classification. Should this change, the following assessment will need revision.

Thus we have:

Childhood leukaemia and magnetic fields	2B carcinogen Under the WHO Precautionary Framework, warrants a thorough consideration of precautionary measures including detailed cost-benefit or cost-effectiveness analyses
Other childhood cancers Adult cancers Other health outcomes (provisionally) Electric fields	Evidence weaker than for 2B Under the WHO Precautionary Framework, a presumption that the evidence would not be strong enough to justify precautionary interventions with significant costs. Detailed cost-benefit analysis not required. Consideration limited to low-cost interventions, if any, and more rudimentary cost-benefit analysis

For the one health outcome warranting full cost-benefit analysis of possible precautionary measures, childhood leukaemia:

- The disease affects children
- The disease is perceived with dread
- The exposure is largely involuntary

- There is evidence that in some situations the exposure burden may fall disproportionately on lower socio-economic status groups

Under the WHO Precautionary Framework, all these factors argue for adopting greater rather than lesser protection.

The size of risk potentially involved, e.g. of the order 1 in 2000 lifetime risk for childhood leukaemia, is unlikely to be regarded as negligible by any society.

The exposures that are associated with childhood leukaemia in epidemiological studies come primarily from electricity, used by society, flowing either in transmission and distribution circuits owned by electricity companies, or in wiring within buildings such as homes and schools. Other contributions to exposure come from domestic appliances, mobile phones and electric transport systems.

Risks Evaluation

For childhood leukaemia, the epidemiological evidence suggests a relative risk of approximately 2 applying to children living in homes where the long-term average field (24 hours or longer) over the general volume of the house (i.e., specifically, not close to domestic appliances) is 0.4 μT or more.

There is uncertainty in whether the epidemiological evidence reflects causality or not. This uncertainty stems partly from the likelihood that bias may be present in the effect estimate, where there is a possibility that confounding, misclassification and selection bias may be present. Uncertainty also arises from the absence of reliable supporting evidence from in vivo or in vitro experiments and consideration of mechanisms. All these uncertainties are already captured by the IARC 2B classification as “possibly carcinogenic”.

If magnetic fields are a cause of childhood leukaemia, the chief uncertainties in assessing the risk are:

- Uncertainty as to the relevant aspect or metric of exposure. Long-term time-weighted average exposure in the home has been used in epidemiology partly for pragmatic reasons and may be a marker for some other aspect of exposure.
- Uncertainty as to exposure-response relationship. If long-term average is indeed the correct metric, it is not known whether there is a threshold (at 0.4 μT or any other value) or a smooth function, and if a smooth function, what shape.
- Uncertainty as to the aetiologically relevant period and duration-response relationship

In view of these uncertainties, WHO recommends:

- a working assumption that measures that reduce any aspect of average exposure across the population would indeed reduce the risk if there is one (this is equivalent to ruling out concepts such as exposure “windows”; a measure that reduces some aspect of exposure can be assumed not to increase any risk, though it may not be as effective as hoped)
- a recognition that any specific measure that reduces exposure is unlikely to reduce precisely the relevant aspect of exposure. Under the WHO PF this extra uncertainty must be included in any cost-benefit analysis.

Options Generation

Possible precautionary measures for ELF EMF will vary from country to country. WHO suggests the following categories as a guide and an aid to further discussion but expects each country to modify this list as appropriate:

Do Nothing

- Take no formal action; maintain the status quo

Research

- Enhanced research to remove uncertainties in the science
- Further research on sources and distribution of exposure in different countries to allow more informed decision making

Communications

- Increased provision of information to the public, particularly information on sources of exposure and ways of reducing exposure by individual lifestyle choices, to make it easier for members of the public to adopt individual precautionary approaches if that is their choice

Engineering measures

- Enforcement of existing approved wiring practices in distribution systems and buildings to reduce magnetic fields (this possibility arises because a major source of magnetic fields is ground currents, and ground currents sometimes arise from incorrect wiring)
- Changes to distribution wiring practices to reduce ground currents (not all ground currents are accidental, many arise from the legitimate multiple grounding of neutral conductors which is a feature of wiring practices in many countries, but which could be changed)
- Other engineering changes to distribution or transmission systems (it is possible to reduce fields by raising ground clearances, split-phase designs, undergrounding, etc)
- Changes to design of domestic appliances to reduce magnetic fields

Planning measures

- Changes to planning procedures to reduce exposures from high-voltage overhead lines (this includes changes to procedures for assessing the need for and siting of new lines, and changes to planning regimes that affect homes and schools already situated or proposed near existing power lines)

Exposure limits

- WHO believes exposure limits should be based on effects conventionally regarded as established and are not an appropriate mechanism for implementing precautionary approaches. Therefore WHO does not recommend including exposure limits based on the childhood leukaemia data as an option.

Cost-based options

- A method of delivering reduced exposure may be to specify a certain sum of money or a certain percentage of the cost of a project to be spent on field reduction, subject only to a test that a certain level of field reduction is achieved by spending that money. This is

philosophically less attractive as the direct weighing of costs and benefits is lost, but may be practical in creating an onus to reduce exposures without constraining the method.

All options may need considering separately for retrospective and prospective application.

Option Assessment and Selection

Under the WHO PF, national governments should perform cost-benefit or cost-effectiveness analyses of these possible measures and any others they may identify. Cost-benefit analysis compares the cost of a measure with a notional figure expressing the value the society places on preventing a fatality or case of disease. Cost effectiveness analysis compares the effectiveness of a measure with alternative ways of achieving a similar benefit. Under the assumption that societies behave rationally, the two approaches will reach the same conclusions.

As detailed in the WHO PF, the cost-benefit/cost-effectiveness analysis should incorporate:

- the uncertainty that magnetic fields actually cause childhood leukaemia
- the uncertainty as to the relevant aspect of exposure to reduce
- the greater store that societies will typically set on reducing the risk of a dreaded disease, affecting children, with involuntary exposure
- the full range of costs of each measure, including both financial and non-financial costs and any redistribution of the burden of exposure
- The incidence of childhood leukaemia in the country concerned and the fraction potentially attributable to magnetic fields
- the number of children a given measure would affect

An indication of the factors that will need considering for each option is given in the following table, but is not exhaustive.

Option	Relevant factors in considering benefits	Relevant factors in considering costs
Do nothing		No possibility of reducing burden of disease and no progress towards removal of uncertainties and better knowledge in future
Research	Ability to remove uncertainties and allow better decisions in future. Removal of possibility (albeit currently low) that a high-prevalence disease may be caused by ELF EMF with much higher public health burden than for childhood leukaemia Opportunity to discover other risk factors and thus reduce disease burden	Opportunity cost of research into other risk factors not carried out

Communication	May have limited effectiveness where exposure is not easy to understand or is involuntary and hard to avoid	Possibility of creating undue alarm or concern. Note: WHO accepts this factor is in principle relevant, but considers it is often overstated
Remove wiring errors	May have safety benefits	A significant part of the cost may be in identifying the instances
Changes to grounding practices	Existing grounding practices have evolved partly for cost reasons but partly for safety reasons, specifically, reducing injury due to electric shock. Any increased risk of actual harm from other reasons such as shocks should be set against the possible benefits from reducing magnetic fields	Expertise on costs rests largely within electricity utilities. Governments should draw on this expertise but should audit it suitably. Costs are likely to vary greatly when comparing new installations with changes to existing installations.
Other engineering changes	Reduction of exposures should be assessed for real electricity systems not idealised ones, e.g. with realistic levels of imbalance	Ditto
Changed appliance design	Of the various possible aspects and sources of exposure, domestic appliances are less clearly linked to the measure implicated by epidemiology, and therefore any benefit should be reduced appropriately to reflect this uncertainty	Increased cost (or increased size or weight) of appliances is a factor. But this may be offset if presented as a consumer choice in combination with suitable information
Changed planning regime	Might facilitate building of new facilities and thus save money	Costs may include sterilisation of land, devaluation of property, and compensation payments, but these are highly dependent on the existing regime in place in each country
Specified sum of money	Clear and simple leading to potentially greater take-up	As there is no direct comparison of benefits with costs, runs the risk of money being spent disproportionate to any actual benefit

In accordance with the WHO PF, costs should be considered at the level of the society as a whole and all costs should be included, whether born by industry, taxpayers or others.

The following factors will apply to any such analysis:

- childhood leukaemia is a relatively rare disease
- taking the epidemiological evidence at face value, only a small fraction of the population is exposed at the levels associated with a significantly increased risk
- there are many uncertainties as to whether any intervention would be effective or not, including the uncertainty as to whether magnetic fields are causal or not and the uncertainty as to which aspect of exposure is the relevant one to reduce

In view of these factors, and even after fully allowing for the legitimate desire by society to err on the safe side, it seems likely that only very low-cost measures will be justified. Specifically:

- exposure limits set at 0.4 μT or similar levels seem unlikely to be justifiable. WHO considers that exposure limits for EMF should continue to be based on science conventionally regarded as "established"
- any measures involving changes to engineering practice seem unlikely to be justifiable, unless they bring other benefits as well, such as greater safety, or unless local circumstances mean they of particularly low cost.
- it seems unlikely that a precautionary approach to EMF alone could justify a change to distribution grounding practices, but EMF should be considered alongside safety, reliability and economics when changes are contemplated
- appliance manufacturers should investigate whether magnetic fields could be reduced at low cost, and whether offering consumer choice of low-field appliances could be an advantageous marketing strategy
- enforcing existing wiring codes so as to reduce unintentional ground currents must be sensible, but high costs in proactively seeking out and identifying existing errors are unlikely to be justifiable
- the costs of changes to planning regimes for high-voltage power lines are dependent on national circumstances, and no generalisation is possible. However, procedures may be adopted which require efficient reduction of exposure for each new project
- continued and enhanced research programmes are desirable to remove uncertainty in the future
- communication to the public allowing informed decision making seems eminently sensible and justifiable

For suggested health effects where the evidence is less than required for a "2B" classification, WHO PF calls for a simpler assessment, including only low-cost options. These options would seem to be:

- research
- communications
- changes to grounding practises IF there are other reasons for such changes
- changes to appliance design IF this can be made a matter of consumer choice
- changes to planning regime for high-voltage power lines DEPENDING on the particular circumstances of each country

Action Selection and Implementation

In the light of the analysis conducted of the various options, national governments or their agencies will select and implement appropriate options. The exact way this is done will be specific to the particular country. In general, for options selected for precautionary reasons, voluntary codes, encouragement and collaborative programmes rather than rigid enforcement will be appropriate.

The WHO PF calls for implementation of precautionary measures to be free from legal connotations, particularly since ELF EMF has already seen litigation in several countries. Specifically, the chosen measures should be implemented in such a way that:

- an individual or company acting to reduce exposures under the WHO PF is not taken to be admitting legal liability for such exposures
- the decision to reduce an exposure is not taken as evidence that such an exposure is in fact dangerous

WHO PF encourages involving a broad range of stakeholders. For ELF EMF, stakeholders should include government, academics, citizen groups, other affected professionals such as planners, school officials and real estate professionals, and industry, including the electricity industry and appliance manufacturers.

Action Evaluation

As detailed in the WHO PF, the actions chosen should be re-evaluated periodically, and in particular, when new scientific understandings emerge.

Appendix C: Case study on RF electromagnetic fields

One of the environmental agents which falls within the purview of the present Framework is the case of exposure to radio-frequency (RF) electromagnetic fields from broadcast transmissions and cellular communications, including, particularly, mobile phones. No health risk has been established, and suggestions of risks from scientific studies are weak. On the other hand, there is considerable public concern in many countries and there has been a rapid growth of exposures over a relatively short time. The combination of little scientific evidence but large potential consequences and large public concern make this a challenging but important test of application of the WHO Precautionary Framework (WHO PF).

Health Issue in Context

"RF EMF" encompasses radio-frequency electric and magnetic (or equivalently, electromagnetic) fields. It is helpful to recognise some broad groupings of exposure to such fields.

Sources of RF EMF	Relevant characteristics of exposure
Broadcast transmissions Radio and TV broadcasts at frequencies from roughly 100 kHz to 100 MHz, at relatively high power from a small number of fixed locations	Virtually all the population exposed, at relatively low level, continuously, for many decades
Cellular communications infrastructure transmissions Principally for mobile phones, at frequencies from 400 MHz to 2 GHz, but also including a growing range of other cellular systems. Produced at low power from a large (and rapidly growing) number of locations each serving a small area	Virtually all the population exposed, at relatively low level, continuously though at varying strengths, with exposure growing from zero to present values over roughly one decade
Cellular communications handsets Principally mobile phones. Usually operated in close proximity to the body, but only intermittently	Relatively high exposure, principally to the brain, approaching (and in earlier years probably sometimes exceeding) ICNIRP exposure limits, but only intermittently (during use of the device)
Occupational sources of RF EMF	
Other miscellaneous sources	

Exposure to broadcast RF EMF has been present in most societies for decades, whereas exposure to cellular communications RF EMF is relatively recent, of the order of a decade or so. Neither the motor car, nor the television set, nor any other invention in the history of mankind has been so quickly and universally accepted or has achieved such a rate of growth as mobile telephony.

Human experience over a century of broadcast exposure may give comfort for the more recent exposure to cellular communications. On the other hand, there is the possibility that

cellular communications RF EMF may be biologically different from broadcast RF EMF, because of the generally higher frequencies and, particularly, more complex modulations including pulsing at frequencies of tens or hundreds of Hz. This issue is scientifically unresolved, and therefore, in the spirit of the WHO PF, health evidence from broadcast RF EMF should be considered when assessing cellular communications but should not be regarded as decisive. In any event, the exposures to members of the public from mobile phone handsets is unprecedented by anything in broadcast technologies; prior to the widespread use of mobile phones, comparable exposures were limited to occupational use of walkie-talkies and the like.

Neither IARC nor any other body of comparable status has yet evaluated RF EMF, though there have been good reviews by reputable national bodies (e.g. IEGMP, NRPB, Zmirou, Canada). The following summary of the scientific position should therefore be reviewed following any evaluation by IARC or WHO.

- Laboratory evidence, broadly, does not support health effects of RF EMF. In particular, animal toxicology experiments have not identified effects. There are suggestions of effects, e.g., on cognition, but these are not regarded as "established".

- Epidemiological evidence from broadcast RF EMF is sparse and uninformative, but such evidence as there is has not identified effects. There has been, to date, essentially no epidemiological evidence from cellular communications infrastructure.

- Epidemiological evidence from mobile phones is, so far, of questionable quality. There have been suggestions of effects, but not from reliable studies. Most importantly the technology is relatively new, thus most studies have not had sufficient latency. Additionally exposure assessment in the RF area is still in its infancy,

Thus, on the one hand, the scientific evidence currently available is broadly reassuring and has certainly not identified any risk that would justify a classification on the IARC scheme of 2B or higher. On the other hand, widespread exposure to RF EMF, particularly from use of mobile phones by the general population, is too recent, and the available scientific evidence too uncertain, to give confidence that there is no such effect.

If there is a health risk from RF EMF, it seems less likely to come from cellular base stations, where the exposure to the public is low and comparable to broadcast exposures which have been present for many decades without adverse effects being identified. The most likely source of any health effect is from mobile phones, which produce exposures, particularly to the brain, of a level and type not previously experienced by people. There is some basis for considering that children may be particularly vulnerable, because of their developing nervous system, though there is little actual evidence for this. However, in the WHO PF, it is legitimate to aim for a higher level of protection for children than for adults.

If there is a risk, it seems less likely to be an acute effect or a disease with a short latency, which would be more likely to have been already identified. In the absence of specific evidence, the possibilities which occasion most concern are cancers of the brain or other parts of the head, and neurodegenerative disease, memory loss or loss of mental faculties, all resulting later in life from exposures accumulated earlier in life.

Under the WHO PF, the fact that the available direct scientific evidence is reassuring argues for less need for precautionary measures. The fact that widespread exposure to certain types of RF EMF is too recent for effects with long latency to have been discovered argues for greater precaution. The possibility that children are particularly affected also argues for greater precaution but is not strong.

Practically all the technologies that produce RF EMF bring considerable benefits to society. Broadcast radio and TV bring cultural, educational and democratic benefits; cellular systems bring specific safety benefits and undoubtedly save lives, as well as the general benefits of improved communication (though like any technology they can also be used for destructive as well as constructive purposes).

In many societies, there is great public concern about RF EMF. This usually centres on base stations for mobile phones, with less concern about mobile phones themselves. This distribution of public concern is understandable, as base stations are perceived as involuntary exposure, which the public have little control over and do not perceive a direct benefit from. It is, however, contrary to the scientific assessment. The WHO PF recognises that public concern is a legitimate factor to consider, both as an expression of societal priorities in a democracy, and as representing a different but equally legitimate value system from traditional scientists. In particular, part of the public concern stems from the knowledge that on previous occasions when a new exposure has been introduced across a society it has sometimes led to unpredicted, widespread and serious consequences. This is an important perspective on this issue under the WHO PF. However, the WHO PF requires assessments to be based on science, and therefore where public concern appears to be contradictory to science, as with the differing concern about phones and base stations, it should not be allowed to override the science.

In many societies, the issue of health concerns around base stations is inextricably tied up with the issue of siting of base stations, aesthetics, planning systems, and general amenity. WHO recognises that these issues are important and will affect decisions reached by national authorities, but they are not within the scope of the WHO PF or this case study. Similarly, mobile phones cause annoyance when employed improperly in public places and put lives at risk by their use while driving. Societies may well wish to act on both these, but they are outside the scope of this case study.

Risks Evaluation

As with any agent where the mechanism of any interaction is unknown, the correct metric or aspect of exposure is also unknown. The known effects of RF EMF at higher levels, basically heating, are appropriately assessed through the specific absorption rate (SAR). If there are currently unknown effects which turn out to be also heating effects, albeit at lower levels than are currently believed possible, it is reasonable to suppose that the SAR would still be appropriate. If any effects are not heating effects, SAR might be irrelevant. However, in the absence of any basis for choosing an alternative metric, WHO recommends a working assumption that the relevant aspect of the radiation to reduce is related to the power deposited in the body, and specifically that for a constant exposure geometry, the relevant aspect is monotonically related to power density.

For reasons discussed under "the risk in context", no real quantitative assessment of possible risks is feasible; there is too little evidence at this point, as many important studies are yet to be done. The following qualitative statements apply:

- The probability that exposure from mobile phone handsets causes diseases of the brain, either cancer or effects on mental functioning, is probably small, but cannot be completely eliminated

- If there are such effects, the global burden of disease could be enormous, with a significant fraction of the world population potentially affected

- The probability of risks from broadcast RF or from the infrastructure for cellular communications is probably even lower.

Options Generation

Under the WHO PF, assuming that the evidence for health effects from RF EMF falls below the level of an IARC 2B classification, consideration should only be given to very low cost or no cost interventions. The assumption is that the probability of there actually being a health risk is too small to justify any interventions with significant costs. Detailed cost-benefit analysis is not appropriate but costs and benefits should still be compared in a simple way.

Possible precautionary measures for RF EMF will vary from country to country. WHO suggests the following categories as a guide and an aid to further discussion but expects each country to modify this list as appropriate:

Do Nothing
- Take no formal action; maintain the status quo. Note that under existing trends in mobile phone technology, this would in fact probably lead to more people using phones for longer, but experiencing lower exposures from them, whereas it would probably lead to increasing exposures from base stations.

Research
- Enhanced research to reduce uncertainties in the science

Communications
- Increased provision of information to the public, particularly information on sources of exposure including power emission levels for individual models of mobile phone, and ways of reducing exposure by individual lifestyle choices, to make it easier for members of the public to adopt individual precautionary approaches if that is their choice

Measures relating to mobile phone base stations and other fixed infrastructure
- Prohibition of base stations within populated areas, suitably defined. This would probably lead to poorer-coverage networks and possibly higher power transmitters elsewhere
- Prohibition of base stations close to specified areas of particular sensitivities, or where children are known to be present, such as schools, hospitals etc.
- Limiting the period that a mast may operate from a given location may be a method of 'sharing the pain'. If the public were to know that a mast could only operate for a

maximum of 7 to 10 years from a given location and that no replacement mast could be sited within 800 metres for a further 7 to 10years might be a strategy worth considering. This may make it easier to obtain permission to build masts and reduce public opposition. It would also average out long term public exposure to phone mast fields Measures relating to mobile phone handsets

- Hands free kits. Hands free kits as currently available reduce the maximum exposure to the brain. They may also increase exposures to the abdomen, if that is where the phone is then held during operation, and possibly to the face and jaw. The latter could be eliminated by simple design changes to the hands free kit, and neither increase is to the level of exposure to the brain removed by the hands free kit. Other consequences of use, such as ear infections, need assessing but are probably small. The cost of production is low, and if bundled with new phones would be a very small incremental cost.
- Use of hands free kits could be increased by:
  - Compulsory bundling of hands free kits with new phones
  - Design and marketing of hands free kits so as to increase attractiveness (e.g. to make them a "fashion statement"), particularly to young people
  - Improved design to make use easier, e.g. ways of reducing the inconvenience caused by the wire, including Bluetooth technology (which although wireless is much lower power).
- Mobile phone use, particularly among young people, could be discouraged by marketing, advertising, and public information campaigns; but experience suggests the effectiveness of these is likely to be limited.

Exposure limits

- WHO believes exposure limits should be based on effects conventionally regarded as established and are not an appropriate mechanism for implementing precautionary approaches. ICNIRP exposure limits for RF EMF already include a reduction for the general public of a factor of 5, which allows for uncertainty in the scientific evidence relating to established heating effects.

All options may need to be considered separately for retrospective and prospective application.

Option Assessment and Selection

In accordance with the WHO PF, costs should be considered at the level of the society as a whole and all costs should be included, whether born by industry, phone users, taxpayers or others.

In comparing costs and benefits in order to decide on appropriate precautionary actions, the following factors will apply:

- The probability that there actually is a health risk is low, so under the WHO PF there is an assumption only interventions with correspondingly low costs are likely to be justified
- The potential consequences of any health risk are large, so where low-cost ways of reducing exposure are available they should be adopted
- The technologies producing RF EMF bring substantial benefits to society; any reduction in these benefits as a consequence of a precautionary measure, e.g. through delayed availability of cellular communications, is likely to outweigh any benefits

It therefore seems unlikely that precautionary interventions related to mobile phone base stations would be justified unless supported by other reasons, such as changing the licensing

regime or the planning policy to provide greater public consultation or to increase separation from sensitive areas and thereby reduce public anxiety.

With mobile-phone handsets, however, there are more possibilities with apparently genuinely low costs. It seems likely that, subject to any factors specific to national or local situations, the following would be justified:

- Greater availability of phone emission levels, e.g. clear display at point of sale, to allow greater informed consumer exercise of individual precaution
- Encouragement of continued reduction of power levels involved in mobile phones (this merely reinforces a trend driven by other concerns, e.g. improved battery life)
- Improvement in the design of hand-free kids, as well as greater provision of and encouragement of use of hands-free kits

The way in which mobile phone networks operate means there can be interplay between power levels of different parts of the system, often known as "adaptive power control". Broadly, in the interests of prolonging battery life, power is reduced to the lowest level that is still effective. This means that some measures to reduce exposures might be ineffective if the phone increases its power as a result. Further, measures that affect the exposures from handsets could conceivably result in increased emissions from base stations and vice versa. Under the WHO PF such effects should be included in the assessment as consequences of the proposed intervention. However, WHO recommends that they should be accorded their due weight and no more; the possibility of adaptive power control is not a reason for inaction unless there is good evidence it prevents the desired effect. Further, on the assumption that higher exposures are likely to be worse, a measure that reduces exposure from handsets at the cost of increasing exposures from base stations is still worthwhile.

Action Selection and Implementation

In the light of the analysis conducted of the various options, national governments or their agencies will select and implement appropriate options. The exact way this is done will be specific to the particular country. In general, for options selected for precautionary reasons, voluntary codes, encouragement and collaborative programmes rather than rigid enforcement will be appropriate. However, experience suggests that mere recommendations may not always be followed, e.g. the continued marketing of phones to children and the difficulty of finding SAR values, both in the UK following recommendations of the IEGMP.

The WHO PF calls for implementation of precautionary measures to be free from legal connotations. Specifically, the chosen measures should be implemented in such a way that:

- a company acting to reduce exposures from mobile phones under the WHO PF is not taken to be admitting legal liability for such exposures
- the decision to reduce an exposure is not taken as evidence that such an exposure is in fact dangerous

WHO PF encourages involving a broad range of stakeholders. For RF EMF, stakeholders should include government, academics, citizen groups, other affected professionals such as planners, school officials and real estate professionals, and industry, including the operators of cellular and broadcast networks, providers of sites, and manufacturers of handsets.

Action Evaluation

As detailed in the WHO PF, the actions chosen should be re-evaluated periodically, and in particular, when new scientific understandings emerge. This is particularly important for RF EMF as technologies for cellular communications change rapidly.

References

A Canadian Perspective on the Precautionary Approach/Principle http://www.dfo-mpo.gc.ca/ccpa/HTML/pamphlet_e.htm

Abelson PA. Risk assessment of low level exposure, *Science*; 265: 1507 (1994).

Adams MD. The precautionary principle and the rhetoric behind it. *Journal of Risk Research*; 5(4): 301-316 (2002).

Ames BN, Gold LS. Environmental pollution, pesticides and the prevention of cancer. *Faseb J*; 11: 1041-52 (1997).

Arrow KJ, Cropper ML, Eads GC, *et al*. Is there a role for benefit – cost analysis in environmental, health and safety regulations? *Science*; 272: 221-22 (1996).

Ashford NA. Implementing a Precautionary Approach in Decisions Affecting Health, Safety and the Environment: Risk Technology Alternatives and Tradeoff Analyses in The Role of Precaution in Chemicals Policy. Freytage E, Jakl T, Loibl G, Wittmann M (eds.) Diplomatic Academy, Vienna, 128-140 (2002).

Ashford NA. A Conceptual Framework for the Use of the Precautionary Principle in Law. In Carolyn Raffensperger and Joel Tickner (eds.), *Protecting Public Health and the Environment: Implementing the Precautionary Principle*. Washington: Island Press, (1999).

Barrett K and Raffensperger C. Precautionary Science. In Carolyn Raffensperger and Joel Tickner (eds.), *op. Ci, (*1999).

Breyer S. Breaking the vicious circle: towards effective risk regulation. *Harvard University Press* (Cambridge, Mass, USA) (1993).

Cameron J and Abouchar J. The precautionary principle: a fundamental principle of law and policy for the protection of the global environment, *Boston College International Comparative Law Review, XIV* **1**, 1–27 (1991).

Cranor CF. Asymmetric Information, The Precautionary Principle, and Burdens of Proof. In Carolyn Raffensperger and Joel Tickner (eds.), *op. Cit* (1999).

Cross FB. Paradoxical perils of the precautionary principle. *Washington and Lee Law Review;* 53: 851-925 (1996).

Dekay ML et al. Risk-based decision analysis in support of precautionary policies. *Journal of Risk Research*; 5(4): 391-417 (2002).

European Commission (2000), Commission of the European Communities, Communication on the Precautionary Principle, Brussels 02 February 2000. See http://europa.eu.int/comm/off/com/health_consumer/precaution.htm

Foster K, Vecchia, P and Repacholi MH. Science and the precautionary principle. Science

Gee D. Late Lessons from Early Warnings. *European Environmental Agency* (2001). http://reports.eea.eu.int/environmental_issue_report_2001_22/en/Issue_Report_No_22.pdf

Godard O. The precautionary principle: matching economic axiomatics and reasoned heuristics to tackle collective risks. 4th Journées Green-Cirano "Environmental and resource economics", Montreal November 17-18 2000 (2000).

Goklany IM. The Precautionary Principle. Washington DC: The Cato Institute (2001).

Goldstein BD. Editorial: The precautionary principle and scientific research are not antithetical. *Environ Health Perspectives*; 107: 594-595 (1999).

Gollier C, Jullien B and Treich N. Scientific Progress and Irreversibility: An Economic Interpretation of the 'Precautionary Principle'. *Journal of Public Economics*; 75(2): 229-53 (2000).

Graham JD and Wiener JB. Risk vs. Risk: Tradeoffs in Protecting Health and the Environment, Cambridge, MA: *Harvard University Press* (1995).

Graham JD and Hsia S. Europe's precautionary principle: promise and pitfalls. *Journal of Risk Research;* 5(4): 371-390 (2002).

Howard J. Environmental "Nasty Surprise" as a window on Precautionary Thinking. *IEEE Technology and Society Magazine*; 21(4): 19-22 (2002/2003).

Klinke A, Losert C, Renn O. The Application of the Precautionary Principle in the European Union. Report from the Workshop on "The Application of the Precautionary Principle", held in Herrenberg/Stuttgart, Sept. 2001.

Kourilsky P, Viney G. Le principe de précaution. Rapport au Premier Ministre, Odile Jacob, Paris (2000).

Lave LB. Benefit-Cost Analysis: Do the Benefits Exceed the Cost in Risks, Costs and Lives Save, Getting Better Results from Regulation. Robert W Hahn Editor, Chapter 6: 104-122 *Oxford University Press New York* (1996).

Lave LB. Hormesis: implications for public policy regarding toxicants. *Annu Rev Public Health;* 22: 63-67 (2001).

Lemons J and Brown DA. The Role of Science in Sustainable Development and Environmental Protection Decision making. In John Lemons and Donald A. Brown (eds), *Sustainable Development: Science, Ethics and Public Policy*. Dordrecht (Netherlands): Kluwer Academic Publishers (1995).

Margolis H. Dealing with Risk, Why the Public and Experts Disagree on Environmental Issues. *U of Chicago Press*, Chicago (1996).

Matthews RAJ. Facts versus Factions: The Use and Abuse of Subjectivity in Scientific Research. In Julian Morris (ed), *Rethinking Risk and the Precautionary Principle*. Oxford: Butterworth Heinemann (2000).
Morris J. Defining the Precautionary Principle. In Julian Morris (ed), *op. cit.* (2000).

O'Brien M. Making Better Environmental Decisions: An Alternative to Risk Assessment *MIT Press*, Boston (2000).

Ozonoff D. The Precautionary Principle as a Screening Device. In Carolyn Raffensperger and Joel Tickner (eds.), *op. cit.* (1999).

Pearce D. The Precautionary Principle and Economic Analysis. In Tim O'Riordan and James Cameron (eds), *Interpreting the Precautionary Principle*. London: Earthscan Public (1994).

Petrini C and Vecchia P. International Statements and Definitions of the Precautionary Principle. *IEEE Technology and Society Magazine*; 21(4): 4-7 (2002/2003).

Porta M. Biologic plausibility in causal inference. *Am J Epidemiol*; 150: 717-718 (1999).

Precautionary Policies and Health Protection: Principles and Applications; Rome Italy May 2001. See: http://www.euro.who.int/document/e75313.pdf

Presidency Conclusions – Nice European Council meeting 7-9 Dec. 2000, Annex III – Council Resolution on the precautionary principle.

Quinn S. Precautionary Behavior and Informed Decisions in the Information Age. *IEEE Technology and Society Magazine*; 21(4): 28-31 (2002/2003).

Rachel's Hazardous Waste News, No. 339, May 27 1993 (1993).

Raffensperger C and Tickner J. Protecting Public Health and the Environment: Implementing the Precautionary Principle. *Island Press*, Washington DC (1999).

Rosen G. A history of public health. *John Hopkins Univ. Press*. Boston (1993).

Rubin CT. Asteroid Collisions and Precautionary Thinking. In Julian Morris (ed), *op. cit.* (2000).

Sandin P et al. Five charges against the precautionary principle. *Journal of Risk Research*; 5(4): 287-299 (2002).

Slovic P. Perception of risk. *Science;* 236: 280–285 (1987).

Sunstein CR Risk and Reason. *Cambridge University Press* (2002).

Swedish Environmental Protection Act. International Digest of Health Legislation 21 (1971), p. 180. (1969).

Swiss Federal Office of Public Health: "The Precautionary Principle in Switzerland and Internationally", (August 2003)
http://www.bag.admin.ch/themen/weitere/vorsorge/e/synthese.pdf

Tickner J. ed. Environmental Science and Preventive Public Policy. Washington, DC: *Island Press* (2002).

Tickner J, Raffensperger C, and Myers N. The Precautionary Principle in Action: A Handbook. Windsor (North Dakota): *Science and Environmental Health Network* (1999).

Treaty of Maastricht. *International Legal Materials* 31 (1992).

Tubiana M. Actual and virtual risks. In: Technology and health. Proceedings of 13th Convocation Caes-Cadas, *Institut de France, Paris*, 133-164 (1999).

United Nations. United Nations Conference on Environment and Development: Convention on Biological Diversity, Preamble (1992a).

UK Interdepartmental Liaison Group on Risk Assessment, "The Precautionary Principle: Policy and Application", 2002, http://www.hse.gov.uk/dst/ilgra/pppa.pdf

United Nations. United Nations Conference on Environment and Development: UN Framework Convention on Climate Change, Article 3 (3) (1992b).

United Nations. United Nations Conference on Environment and Development: Rio Declaration on Environment and Development, LFNCED document A/CONF, 151/5/Rev. 1, June 13 (1992c).

U.S. Congress, General Accounting Office. Environmental Protection Agency: Use of Precautionary Assumptions in Health Risk Assessments and Benefits Estimates. Washington (2000).

VanderZwaag D.J. Env. Law and Practice, 8, 355 (1999). See also http://www.ec.gc.ca/cepa/ip18/e18_00.html.

VanderZwaag D. The precautionary principle and marine environmental protection: Slippery shores, rough seas, and rising normative tides. *Ocean Develop. and Int. Law*; 33(2): 165-188 (2002).

Von Moltke K. The Vorsorgeprinzip in West German Environmental Policy, in Twelfth Report of the Royal Commission on Environmental Pollution, Annex 3, p. 57. London: H.M. Stationery Office (1987).

Weed D. Is the Precautionary Principle a Principle? *IEEE Technology and Society Magazine*; 21(4): 45-48 (2002/2003).

Wiener JB, Rogers MD. Comparing precaution in the United States and Europe. *Journal of Risk Research*; 5(4): 317-349 (2002).

Wilson R. Precautionary Principles and Risk Analysis. *IEEE Technology and Society Magazine*; 21(4): 40-44 (2002/2003).