Framework
Guiding public health policy options in areas of scientific uncertainty

With particular reference to EMFs

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Preface

The World Health Organization (WHO) exists to promote health, defined as:

"a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"

One aspect of the promotion of health is addressing environmental health threats. This Framework specifically considers health threats where there is significant scientific uncertainty. It presents an approach for applying precautionary measures that is rational and practical, that is scientifically based, and that is consistent with public-health values and the WHO mission to promote and protect health. It has been developed in the particular context of electromagnetic fields (EMFs) and the uncertainty as to whether these fields, produced by the use of electric power or by mobile phones and their base stations, might be harmful to health. It recognises the benefits new technologies bring to society, and the differing needs of developed and developing countries.

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.

Meetings that have assisted in the development of this work include:

- a Workshop on "Precautionary Policies and Health Protection: Principles and Applications" held in Rome, May 2001
- a Symposium entitled "Environmental Exposures, Public Health, and the Precautionary Principle" held in Vancouver, August 2002
- the October 2002 Collegium Ramazzini's international scientific conference, "The Precautionary Principle: Implications for Research and Prevention in Environmental and Occupational Health", co-sponsored by WHO
- a WHO Workshop on "Application of the Precautionary Principle", with particular reference to EMFs, co-sponsored by the European Commission and US National Institute for Environmental Health Sciences, held in Luxembourg 24-26 February 2003
- a Workshop entitled "Dealing with uncertainty: how can the precautionary principle help protect the future of our children?", co-organized by WHO and AFSSE (French Agency for Environmental Protection) held in Paris, 11-12 September 2003, part of the preparation of the European 4th Ministerial Conference on Environment and Health
- a Workshop on Guiding Public Health Policy in Areas of Scientific Uncertainty at the University of Ottawa, Canada July 11-13, 2005, in collaboration with the McLaughlin Centre for Population Health Risk Assessment, at which a draft of this Framework was discussed

1. Introduction to the Framework

> "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"
> WHO constitution

> "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"
>
> European Environment Agency, 2004
>
> (for other definitions, see section 1.4)

1.1 The need for the Framework

In the public health arena, priority is usually given to controlling risks that are clearly established: that is, involving risks factors with a clear causal relationship to known diseases. However, rapid technological developments produce an ever-increasing variety of agents and exposure situations whose health consequences are less clear, and societies increasingly wish to address these uncertain consequences.

Case studies
This Framework is illustrated with case studies principally concerning electric and magnetic fields (EMFs).

- Extremely low frequency (ELF) EMFs are produced by the generation and distribution of electricity in public electricity systems and its use in the home and elsewhere.
- Radio frequency (RF) EMFs are produced by all forms of wireless technology, including broadcast radio and TV and cellular communications system. The case studies used here concern mobile phones and the base stations which provide the mobile-phone networks.

Waiting for conclusive evidence of a health threat can have unfortunate consequences[1]. Therefore, where an agent is ubiquitous or the potential harm great or the possible effects are irreversible, it is sensible to consider taking precautions before a cause-effect relationship has been quantified or even established. Precaution can be integrated naturally into existing public-health policy and should complement conventional disease-prevention actions, which are usually taken only after a cause-effect relationship has been established.

However, care must be taken to have a due process when establishing policies based on precaution. Not all suggested health risks turn out to be true. Indiscriminate use of precautionary measures may mean that innovations with undoubted health benefits will not be developed, or the benefits they bring will be delayed. Further, it may lead to widely

[1] See e.g. Gee, 2001 in Further Reading

differing national policies, to increased public anxiety, and to restrictions on the free flow of trade.

Case study on the benefits of technology: EMFs
Practically all the technologies that produce EMFs 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). The benefits of a public electricity supply are obvious.

These competing factors have motivated WHO to build a framework for guiding public-health policy options in areas of scientific uncertainty using a rational and well-established process. This Framework gives clear guidance designed to prevent what could otherwise be confusion and excesses in either direction.

National Governments have responsibility for deciding whether and how to implement this Framework in their countries. This will happen to different extents depending on cultural, economic and political factors. Uncertain health consequences of technology may be more of a concern in developed countries, something to be worried about only when other more pressing health concerns have been reduced or eliminated. However, a precautionary approach to life has been a feature of some non-Western cultures, e.g. the Maoris in New Zealand, long before it became a preoccupation in the West.

1.2 Uncertainty in science

Precaution applies where there is uncertainty in the science.

Conventional scientific methods distinguish "established" from "uncertain" effects and take action mainly on the former by developing quantitative standards that limit exposure.

False positives and false negatives
Conventional science often requires a high level of proof to accept an effect. This minimises "false positives" (declaring that a risk does exist when subsequently it turns out not to) but tends to generate "false negatives" (declaring that a risk does not exist when in fact it does). By contrast, society as a whole may be more ready to accept a "false positive" rather than miss real risks. These different approaches stem from differing ethical value systems[2]. Precautionary approaches reflect this desire on behalf of society to "play safe".

However, no science is ever absolutely certain. There are different types of uncertainty:

- there may be uncertainty about some of the details of a known effect, for example the exact threshold or the resultant extent of harm. This type of uncertainty always exists to some degree even for "established" effects and is allowed for in conventional scientific methods, often by safety factors.
- there may be some evidence of an effect, but not enough to be sure whether it actually happens or not. The evidence can vary from little more than speculation up to almost enough evidence to regard the effect as established.

[2] see for example, Comba et al., 2004 in Further Reading

- there may be little evidence either way because the necessary research has not been done. This can be described as “ignorance” or an “unknown unknown”.

This Framework deals with situations where there is uncertainty of the second two types, that is, there is insufficient evidence to be confident there actually is any health effect. The role of science is not confined only to describing “established” effects, but also to identifying gaps in knowledge and uncertainties. This Framework is therefore firmly based on science.

1.3 Guiding principles of the Framework

This Framework has been developed using a number of guiding principles:

- **Science is the fundamental basis for application of this Framework**. Application of precaution requires a rigorous scientific assessment and the Framework in no way undermines traditional scientific approaches such as quantitative exposure limits.

- **Precaution is to be included throughout the risk-analysis and policy-development process and should be seen as an overarching approach.** Traditionally, separate processes are identified, such as risk identification, risk assessment, and risk management. Precaution 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 this 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 various stages are closely integrated, and precaution is an approach that informs every stage and for all risks, rather than being triggered only sometimes.

- **Decisions about precautionary measures should be rational and informed by proper consideration of the costs and likely benefits of any measures.** Factors considered should include the strength of the scientific evidence, technical feasibility, economic costs and benefits, and political realities.

- **Public concern may be a trigger for implementing public-health policies,** though the priority is the protection of health. In real circumstances, the debate on whether precautionary action is warranted, and if so what action is appropriate, often takes place when a potential, unproven risk factor is causing public concern. This is entirely legitimate as long as the decisions are made in accordance with the principles that underlie this Framework. However, when precautionary measures are selected and implemented without due process, or in an arbitrary way merely to placate public concern, greater and not less public concern can follow.

Case study on the role of public concern: RF EMFs
No health risk has been established for radio-frequency technologies, and suggestions of risks from scientific studies are weak. However, there is considerable public concern in many countries, and, particularly for mobile-phone base stations, it is largely public rather than scientific concern that drives precautionary considerations.

- **Perspectives based on social and cultural factors and ethical values constitute the context that ultimately determines the policy decisions**. A partnership approach between key stakeholders for all risk-management stages therefore needs to be developed. While public input may be difficult to achieve at every stage, decisions taken may lack credibility and acceptance if they do not involve interested and affected parties in the evaluation of risks and interventions. How this is done will vary from risk to risk, from stakeholder to stakeholder, and from country to country.

Case study on stakeholders: EMFs
For EMFs, stakeholders should include government, academics, citizen groups, other affected professionals such as planners and real estate professionals, and industry, including the electricity industry and appliance manufacturers for ELF EMFs and the mobile-phone manufacturers and telecommunications operators for RF EMFs.

- **The transparency of the whole process should be promoted through communication and consultation with stakeholders at all appropriate stages**. Within the regulatory process, precaution can, if poorly applied, reduce transparency and erode the link between evidence of potential harm and action. This should be avoided. All risk-management action should ensure the effectiveness of regulatory decisions, and seek to secure public trust.

- **The goal of protecting public health from uncertain, potentially far-reaching hazards must guide the process of decision making from the very beginning.** It is better to anticipate possible health problems than to mitigate adverse impacts after they occur.

1.4 Relationship to other frameworks

The definition of the precautionary principle used at the start of this Framework, from the European Environment Agency, is consistent with the many other definitions which are now in international treaties or law.

The Ministerial Declaration Calling for Reduction of Pollution (1987)
"In order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is addressed which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence"

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."*

United Nations Framework Convention on Climate Change (1992)

"The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effect. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefit at the lowest possible cost."

Convention on the Protection and Use of Transboundary Watercourses and International Lakes (1992)

The precautionary principle, by virtue of which action to avoid the transboundary impact of the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link between those substances, on the one hand, and the potential transboundary impact, on the other hand…"

Wingspread Statement [year?]

"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"*

A formal treatment of precautionary approaches by the European Commission was published in a Communication in 2000. This states:

"Where action is deemed necessary, measures based on the precautionary principle should be, inter alia:

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

This Framework incorporates many of the guiding principles enunciated by the European Commission.

A number of countries have incorporated precaution into their decision making processes, some in an informal way, and others using a formal approach[3].

- 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 Switzerland, the Precautionary Principle is enshrined in law and is a well established instrument of risk analysis.

2. Applying the Framework

The process of identifying, assessing and managing risks can helpfully be described in terms of a number of steps, although in reality, these steps overlap and merge into each other. One such analysis, used as a basis for this Framework, is described in the US Presidential/ Congressional Commission on Risk Assessment and Risk Management (1997)[4], though other descriptions are just as valid. This particular analysis splits the process into six stages, which are followed in an iterative way, with stakeholder involvement at each stage.

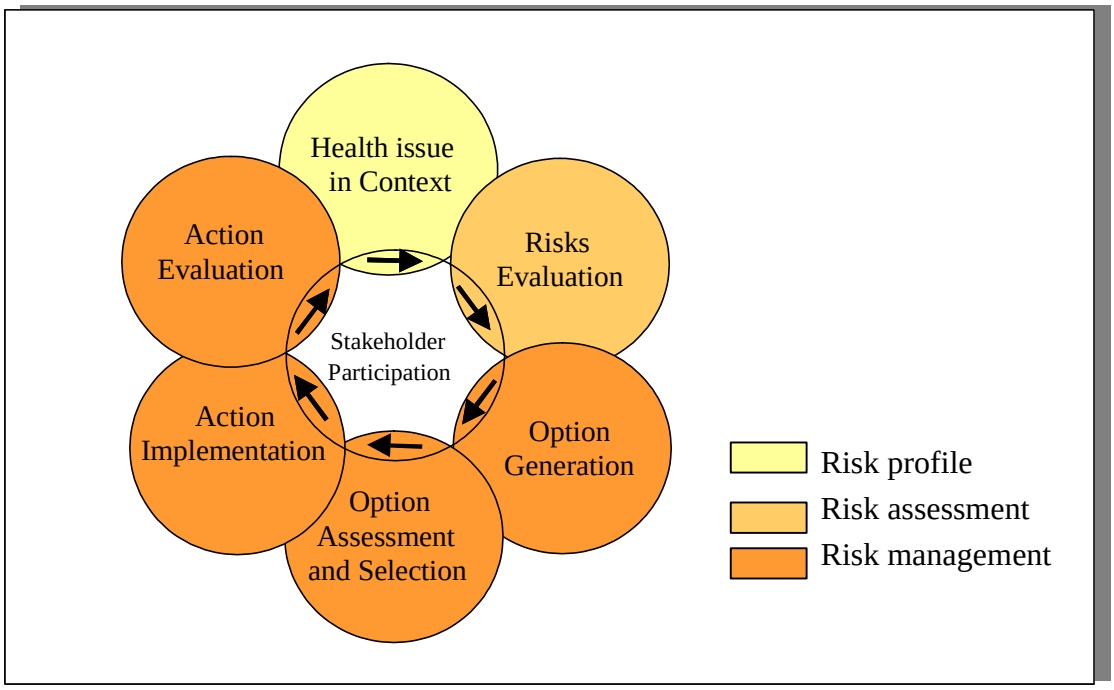

Figure 1 - Dealing with risk: A risk analysis process

This Framework takes each of the six stages and describes how that stage can be extended to uncertain risks.

[3] See Further Reading
[4] See Further Reading

Applying the Framework in practice

Before starting to apply this Framework in a particular country, it is useful to determine:

- What is the legislative framework that provides for the process to commence?
- Which department, agency, or other group has the responsibility?
- Who are the appropriate scientific experts, government or agency representatives, and other stakeholders?
- Is there funding to complete the whole process?

2.1 Health issue in context

Existing risk management frameworks deal mostly with "established" risks. This Framework expands the scope to include risks where there is greater uncertainty. In this paradigm, social, political and health contexts are central alongside scientific issues. The public will expect to contribute to the formulation of criteria to determine how seriously risks are regarded. In particular, many societies will treat situations as more serious[5]:

- if the risks affect **vulnerable populations** such as the infirm and the elderly or the economically deprived. The child and the foetus are often afforded an even higher level of protection because of their increased vulnerability, greater potential for exposure over their lifetime, and because they represent the future of the society.

- if the distribution and magnitude of risk and consequent adverse health outcomes are **inequitable**, particularly where risks fall on groups who are already less privileged.

- if exposures are **ubiquitous**, because even a health risk that, for an individual, is relatively small and thus difficult to detect, may have significant public-health consequences if it affects many people.

- if the nature of the health effect causes **particular dread**, such as cancer. 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.

- if risks are **poorly understood** or outside normal experience.

- if the risks are **involuntary** or outside the control of the individual exposed. Societies generally tolerate higher risks if they are voluntary.

More acceptable and less acceptable risks

- Smoking or rock climbing are examples of risks which are voluntarily adopted and are largely within the person's own control: higher risks are accepted
- Driving a car brings an obvious benefit and some, albeit limited, control over the risk: higher risks are accepted
- Travel in trains or aeroplanes are voluntarily adopted risks but largely outside the individual's control (and may harm many people at once): regulators usually require the risks to be lower

[5] See Slovik 1987 in Further Reading

Case study on acceptability of risks: EMFs

Power-frequency magnetic fields are classified as "possibly carcinogenic". The evidence that led to this classification was primarily epidemiological evidence concerning one disease in particular, childhood leukaemia.

- The disease affects children.
- The disease is one attracting particular dread in many societies.
- The exposure (eg from power lines) is largely involuntary.
- There is evidence that in some situations the exposure burden may fall disproportionately on lower socio-economic status groups.

Under this Framework, all these factors argue for seeking greater rather than lesser protection.

Exposure from mobile phones is largely voluntary, and brings clear benefits to the user, but societies are nonetheless still likely to be particularly concerned about exposure to children. Exposure from base stations, although attracting less scientific concern, is largely involuntary.

2.2 Risk assessment

For traditional risk assessment:

- The overall evaluation is based on the weight-of-evidence. The science must be rigorous, with input provided by many specialized disciplines, and mainly 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 assessment of risk should be identified and clearly stated. When evidence is limited, science-based assumptions or extrapolations are often used; for example, extrapolating known effects at high exposures to possible effects at lower exposures.

This Framework follows the same scientific principles but with greater emphasis on identifying the uncertainties, including considering what is not known in addition to what is known but uncertain. A description of where key scientific evidence (e.g. epidemiological or toxicological studies) is missing or inadequate is especially important. Also, the relevance of the available evidence to real-life exposure situations needs to be carefully scrutinized .

The use of scientific evidence

Three things to remember:

- An abundance of data does not automatically mean a high degree of knowledge.
- Failure to demonstrate an adverse health effect does not rule out its possible existence, since the test system used may not have been sensitive enough to detect any effect

- 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

Case study on evidence and the absence of evidence: RF EMFs
Mobile-phone use has increased dramatically over the last decade. Few people have been exposed for more than about ten years. The available evidence is broadly reassuring in not having identified major health risks from mobile-phone use. But until more people have used them for longer, it is not logically possible to rule out the possibility of a major health problem. A low probability, but of a large public-health consequence, can still justify action.

2.3 Option generation

Options for precautionary action are not limited to traditional quantitative exposure limits, and all the alternatives should be identified in the decision-making process. If this is done at the initial stages of a potential problem, for example when a new technology is proposed, it is more likely that alternative courses of actions can be identified that preserve societal benefits while averting any potential health problem.

This Framework encourages consideration of the full range of alternatives and options. It includes options involving individual choice, behaviour modification, education, voluntary initiatives, and market incentives. Where removing or reducing the exposure is not feasible, options to minimize the seriousness of the health outcome (e.g. increased medical surveillance) should be evaluated.

Examples of policy options

- A **decision to take no formal action** may be an appropriate response in cases where the risk is considered small or the evidence is weak.
- **Research** is always 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. This provides an early warning measure.
- **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.
- **Voluntary behavioural change** may be chosen to avoid or reduce exposure, if easily achievable.
- **Special measures** may be appropriate for vulnerable populations or groups.

- **Numeric standards** are formal steps taken 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.

Case study on available options: ELF EMFs

Possible precautionary measures for ELF EMFs 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:

- Take no action
- 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 if the justification were strong enough)
  - 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
- Land-use and planning measures
  - Changes 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 rules on land use that affect homes and schools in proximity to power lines)
- Exposure limits
  - WHO believes exposure limits should usually be based on established effects and are not an appropriate mechanism for implementing precautionary approaches for EMFs.

Options may need considering separately for retrospective and prospective application.

Case study on available options: RF EMFs

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:

- Take no action

– 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 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.

- 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 (eg to make them a “fashion statement”), particularly to young people

– Improved design to make use easier, eg 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 usually be based on established effects and are not an appropriate mechanism for implementing precautionary approaches for EMFs.

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

The role of quantitative limits

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 establishing the levels of exposure to physical, biological or chemical agents that are harmful to humans. Exposure limits generally incorporate safety factors that allow for uncertainty, eg in identifying thresholds. Such approaches, where justified by the scientific data, remain central to this Framework. It is rarely if ever appropriate to implement precaution by additional, arbitrary reductions to exposure limits, which devalues their scientific credibility.

Case study on quantitative limits: EMFs

For EMFs, there are international exposure guidelines published by ICNIRP[6]. These have been determined on the basis of known health effects, using scientific criteria established over many decades. ICNIRP state that the evidence for EMFs causing cancer or other health effects at lower levels is insufficient to set exposure limits. Quantitative exposure limits at e.g. 0.3 or 0.4 μT are not appropriate because:

- There is too much uncertainty in the interpretation of the epidemiological studies to be confident that these are indeed the appropriate levels
- Simplistic application of limits at these low levels is likely to have costs disproportionate to any benefit
- They could undermine the consistent international adoption of the ICNIRP guidelines.

WHO therefore advocates alternative options for precautionary approaches on EMFs.

2.4 Option assessment and selection

Option assessment

Option assessment for known risks is based on scientific, economic and technical information. Priority is given to preventing the risks, wherever possible, not just controlling them (e.g. the polio eradication campaign). Sometimes there is a requirement to remove or to reduce a risk to a specified level regardless of cost. More usually, however, option assessment for known risks is undertaken using a health-economics analysis to identify the most efficient way to achieve a particular exposure reduction or health protection goal.

Option assessment within this Framework extends the same principles to uncertain risks.

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, including a diversion of risk management resources from one set of activities to another).

Assessment of benefits

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

Outcomes need to be clearly reported, for example as number of fatalities, disease incidence, or years of life. Effectiveness can be measured in terms of disability-adjusted life years (DALYs) gained by the option. 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, 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

[6] See ICNIRP 1998 in Further Reading

reduced exposure. Assessment should include any increase in a different aspect 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

Cost-effectiveness analysis assesses the costs of different methods of achieving the same health benefit. Where different options produce different health benefits, a cost-benefit analysis is performed instead: the value to society of the 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.

The value a society places on the reduction of risk or disease assumes the reduction would actually occur, i.e. that there is a known risk. Where the risk is uncertain, as in this Framework, the benefit from removing the exposure must be reduced accordingly.

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

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 Framework should address those consequences.

The analysis should recognise social factors whereby society may sometimes wish to err on the side of caution and incur greater costs, in excess of the expected benefit.

Case study on assessing costs and benefits: ELF EMFs

An indication of the costs and the benefits that will need considering for each option is given in the following table.

Precautionary option for ELF EMFs	Relevant factors in considering benefits	Relevant factors in considering costs
Take no action	No immediate costs incurred	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 cost of research into other risk factors not carried out
Communication	May have limited effectiveness	Possibility of creating undue

Precautionary option for ELF EMFs	Relevant factors in considering benefits	Relevant factors in considering costs
	where exposure is not easy to understand or is involuntary and hard to avoid	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 as well	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, eg with realistic levels of imbalance	
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 land-use regime		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

Case study on assessing benefits: RF EMFs

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 result in increased emissions from base stations and vice versa. Such effects should be included in the assessment of benefits as consequences of the proposed intervention. However, the possibility of adaptive power control is not a reason for inaction unless there is good evidence it prevents the desired effect.

The complexity of the assessment of costs and benefits should 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 equivalent for non-cancer health outcomes), the analysis should be reasonably quantitative and objective, as far as the data permit, similar to that for a known risk but including allowance for the uncertainties.

- Where the classification is less than this (e.g. insufficient evidence, IARC Group 3), the option assessment will inevitably be less quantitative and less satisfactory. In this case, option assessment can 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.

Case study on complexity of cost-benefit assessment: EMFs

- Power-frequency magnetic fields are classified as "possibly carcinogenic" (IARC 2B carcinogen) on the basis of the evidence on childhood leukaemia. The evidence linking power-frequency magnetic fields to other health outcomes, and the evidence on power-frequency electric fields, is weaker than the IARC 2B classification.
- Therefore, under this Framework, magnetic fields and childhood leukaemia warrants a full cost-benefit analysis, but for other health outcomes, there is a presumption that only no-cost or very low-cost options would be justifiable, and the assessment is less detailed. Cost-benefit or cost-effectiveness analysis should therefore primarily be based on childhood leukaemia.
- Radio-frequency EMFs have not been formally classified by WHO. However, in view of the dramatic spread over the last decade of mobile-phone technologies and the accompanying exposures, examination of no-cost and low-cost options as a minimum is justified under this Framework.

There will always be uncertainties, in the assessment both of the costs and the benefits. All significant uncertainties and assumptions should be explicitly allowed for and declared in any cost-benefit calculation.

Case study on uncertainties: ELF EMFs

There is uncertainty in whether the epidemiological evidence reflects causality or not. This uncertainty stems from:

- the likelihood that some amount of bias may be present
- the possibility that confounding may be present
- the absence of reliable supporting evidence from in vivo or in vitro experiments
- limited plausibility derived from 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 but in part 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 0.3 - 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; but
- a recognition that any specific measure that reduces exposure is unlikely to reduce precisely the relevant aspect of exposure.

Option selection

An appropriate option or options should be selected, on the following basis:

- Based on an examination of the potential **benefits and costs** of action or lack of action, using cost-benefit or cost-effectiveness analysis as discussed above.
- Allowing for **social and cultural factors** which lead society to regard some risks as more serious than others.
- **Proportionate** to the level of protection desired in society in general, recognising that risk can rarely be reduced to zero.
- **Consistent** with similar measures already taken for other health risks.
- **Non-discriminatory** in their application, treating comparable situations in comparable ways.
- **Subject to review**, in the light of new scientific data.

Scientific evidence influences option selection: stronger evidence, particularly of a pervasive, severe or irreversible health effect, supports more intervention. Weaker evidence tends to support selection of less interventionist actions. Where there are low-cost or no-cost options that reduce exposure, they can be implemented with little further debate. As the cost of the option being considered increases, the importance of an analysis of the cost-effectiveness increases.

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. All evaluations need 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.

Case study on option selection: ELF EMFs

For power-frequency magnetic fields and 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 is 0.3 - 0.4 μT or more. It would be proportionate to the general level of protection in society and consistent with other measures to act to reduce such a risk if it were known to be causal. However, childhood leukaemia is a rare disease, the prevalence of these exposures is low, and there is considerable scientific uncertainty as to whether a risk exists or not. 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 0.3 - 0.4 μT or similar levels are not scientifically justifiable. WHO considers that for EMFs, exposure limits should continue to be based on effects scientifically regarded as "established" and recommends against setting exposure limits as a precautionary measure.
- 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 are of particularly low cost.
- it seems unlikely that a precautionary approach to EMFs alone could justify a change to distribution grounding practices, but EMFs 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
- planning and land-use regimes for high-voltage power lines can incorporate genuinely low-cost options, but the costs and consequences of changes to existing regimes is so dependent on national circumstances that no generalisation is possible
- continuing 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

Case study on option selection: RF EMFs

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 there is a presumption that only interventions with correspondingly low costs are likely to be justified
- The potential consequences of any health risk are large, because of the ubiquitous exposure, so where low-cost ways of reducing exposure are available they should be adopted
- The technologies producing RF EMFs bring substantial benefits to society; any reduction in these benefits as a consequence of a precautionary measure, eg 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. However, EMFs should be considered alongside the beneficial aspects of public consultation and reducing public concern when considering changes to licensing regimes or planning policy.

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 kits, as well as greater provision of and encouragement of their use.

2.5 Action implementation

In traditional risk-management frameworks, implementation often involves statutory or regulatory requirements. In this Framework, the selected options may include voluntary as well as mandatory measures. While mandatory measures can be implemented in 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.

Some societies or sections of society are reluctant to adopt precautionary measures in case this creates concern by giving the impression that the health risk is real. This concern can be reduced, though not necessarily completely removed, by sensitive and appropriate communication.

The need for and content of a communication strategy should be considered at an early stage. These strategies may need to be reviewed and revised as the process continues. The International EMF Project has published a booklet[7] entitled "Establishing a dialogue on risks from electromagnetic fields" that provides considerable information on how to better understand people's concerns about risks and how to communicate in a way that will be most effective.

Case study on communication strategies: EMFs

Codes of practice on procedures for stakeholder dialogue have been developed in both the UK and in Australia[8] in responding to public concerns over the siting of radio base stations. These codes utilise a range of different engagement techniques in recognition of the variety of stakeholders, issues and local contexts within which such dialogue is required. Experience has demonstrated that early dialogue with stakeholders such as homeowners, tenants, local

[7] See Further Reading [add it]
[8] [add references]

residents, or parents of school children is essential to respond effectively to potential concerns. In the UK, the procedures were developed by mobile-phone operators in conjunction with local and central government, they have been independently audited and reviewed. In Australia, precautionary measures for mobile-phone network deployment under the Australian Communications Industry Forum (ACIF) code of practice have been formalised to include required methods of notification, consultation, and dialogue with local communities.

The legal framework within which precautionary measures are implemented will differ from country to country. The adoption of precautionary measures is not intended to provide a basis for determining the legal liability of any person or entity. If taking precautionary action is perceived to increase the legal liability of the person or company taking it, this is likely to be a disincentive. Such legal consequences should therefore be avoided, but without providing unfair protection from liability either.

Legal liabilities

In the legal context, implementation of precautionary measures to reduce an exposure should not be taken as:

- evidence that the exposure is in fact harmful
- evidence that the person or company reducing the exposure has legal liability for it
- evidence that the same exposure could or should have been reduced earlier

Case study on legal liability: ELF EMFs

- Some electricity companies have been reluctant to adopt precautionary policies on EMFs, thinking that to do so would be seen as an admission that there was a health risk and that this might increase their legal liability.
- Other electricity companies have come to the opposite conclusion: that adopting precautionary measures shows that the company is behaving responsibly, and therefore reduces legal liability.

This Framework encourages the latter view.

Policy should be produced in a form as free as possible from jargon so that there is less scope for misinterpretation by the implementing agency, in the courts or indeed by any of the stakeholders.

2.6 Action evaluation

Evaluation of actions developed for a known health risk generally concern compliance and enforcement. In this Framework, actions not requiring measurable compliance may need evaluation in more flexible ways, including their effect on public perception.

Action evaluation is not the final step in the risk management process within this Framework. Rather, the process is iterative and intended to be responsive to newly available information and to changing societal values. Actions should be subject to periodic monitoring and review to determine their effectiveness and relevance in the context of prevailing scientific knowledge. As new information becomes available, the policy measures should be reconsidered.

3. Further reading

3.1 Precautionary approaches internationally and in different countries

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

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

3.2 Case studies of relevant health issues

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3.3 Discussion of particular aspects of precautionary approaches

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

3.4 Further reading on EMFs

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ICNIRP (International Commission on Non-Ionizing Radiation Protection), Guidelines for limiting exposure to time varying electric, magnetic and electromagnetic fields (up to 300 GHz). Health Physics 74(4), 494-522, 1998. (http://www.icnirp.org/)

WHO International EMF Project (http://www.who.int/emf)