Framework
Guiding public health policy options in areas of scientific uncertainty

Dealing with EMF

WHO/OMS

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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 scientific uncertainty about the risks to health, it is important to 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".

A further 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 (EMF). In the framework of the preparation of the European 4th Ministerial Conference on Environment and Health, "The Future of Our Children", a workshop entitled "Dealing with uncertainty: how can the precautionary principle can help protect the future of our children?", co-organized by WHO and AFSSE (French Agency for Environmental Protection) was held in Paris, 11-12 September 2003.

While WHO will continue to provide sound scientific advice on established health risk factors, this Framework has been developed to guide Member States developing measures to manage uncertain public health risks.

WHO encourages the use of rational, cost-effective and well thought-out 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 as well as indicate areas where practical measures can be identified that reduce any consequences to health.

Ultimately we do not live in a "risk-free" world. As the consequences of known risks are reduced through sound public health policies, it makes good sense to reduce exposures to potential risk factors that are not well understood by use of acceptable, science-based precautionary measures and policies.

Executive Summary

This section will be enlarged once the framework has been completed

1. Introduction

In the public health arena, priority is usually given to controlling risks that are clearly established: that is, involving risks factors with a causal relationship to known diseases. However, changing societal values and rapid technological developments produce an ever-increasing variety of agents and exposure situations whose health consequences are difficult to predict and to manage.

Waiting for conclusive evidence of a health threat has sometimes had unfortunate consequences (Gee, 2001). Therefore, where an agent is ubiquitous (e.g. electromagnetic fields in the environment) or the potential harm great (e.g. SARS), it may be reasonable to apply precaution and act with foresight, before a cause-effect relationship has been established or robustly quantified. 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.

Policies based on precaution are increasingly being used to prevent or limit exposures to agents or activities whose effects are not well understood, but which may nonetheless be harmful. The object of precautionary measures is to minimize potential risks to health while allowing for economic development, sustainability and innovation.

Recognizing that uncertainties exist in the evaluation of health issues can lead decision makers to adopt a "culture of precaution". However, care must be taken to have a due process when establishing policies based on precaution, as indiscriminate use of precautionary measures may in turn promote large disparities between national policies and ultimately increase public anxiety, foster confusion for regulators and policy makers, and provide a challenge to the free flow of trade. These 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.

1.1 Guiding principles

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

- Precaution is to be included throughout the risk analysis and policy development process and should be seen as an overarching approach
- Science is the fundamental basis for application of this Framework in that it seeks to identify the level of uncertainty about the health consequences of exposure to an agent.
- Public concern may be a trigger for implementing public health policies, though the priority is the protection of health
- Communication and consultation with stakeholders should occur at all appropriate stages and the transparency of the whole process should be guaranteed.

1.2 Purpose and Scope

The purpose of the Framework is to provide practical guidance on a series of steps to assist WHO Member States develop their public health policies in the face of scientific uncertainty. This will involve developing exposure reduction strategies and protective measures aimed at optimizing the overall benefit for society.

This Framework addresses how precaution may be included in the process of decision making through the various stages of risk assessment and management. This Framework applies primarily to electromagnetic fields (EMF).

2. Features of this Framework

2.1 Risk analysis process

Most risk analysis approaches dealing with health risks include the following basic steps:

- risk profile or risk framing (characterization or prioritization of the risk factor within the overall public health context)
- risk assessment (scientific evaluation of the risk factor)
- risk management
    - o generation and selection of options (what are the options for dealing with the risk factor, and how to select the best for implementation)
    - o action or implementation of the selected option(s), and
    - o monitoring and evaluation of actions undertaken.

This paradigm involves an iterative process, which promotes feedback and stakeholder involvement at all stages. One such analysis is described in the US Presidential/ Congressional Commission on Risk Assessment and Risk Management (1997) which splits this process into six stages, emphasizing the analysis of possible options, clarification of all stakeholders' interests and openness in the way decisions are reached (Figure 1). This analysis is used as the basis for this Framework.

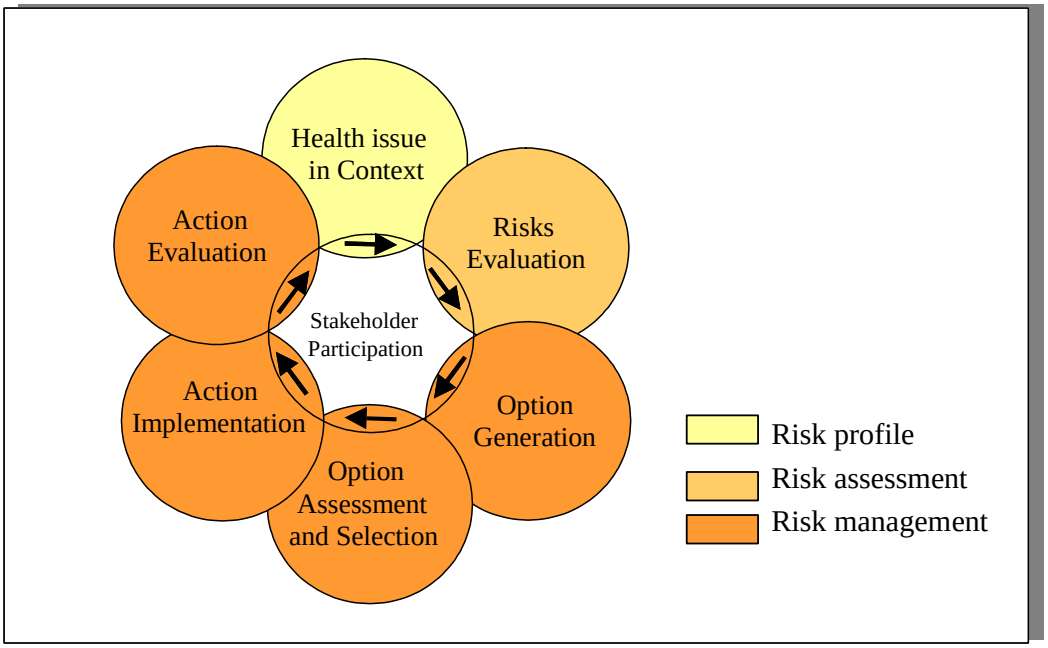

Figure 1: Iterative process for the Framework

2.2 Precaution as an overarching approach

Policy action aimed at attaining high levels of health and wellbeing for current and future generations is the ultimate goal. Precaution is among the criteria to be used as a guide to pursue such a challenging objective. It 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 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 is discussed further in Section 3 below.

2.3 Relationship to other frameworks

Since the early 1980's, European policy-makers have progressively adopted precautionary approaches. The European Commission has provided a critical step in describing the purpose and use of the Precautionary Principle in European policy making through a communication document (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 enshrined in law as is a well established 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.

2.4 Legal context

In several countries, precaution has been incorporated in primary legislation as a way of managing risks to human health or the environment. Policy decisions based on precautionary measures should be taken by accountable elected representatives, and not in an ad hoc reactive manner.

Governments should provide the legal framework that provides their departments with the mandate to develop and implement policies that are mindful of the health implications, including uncertain ones. This should also be extended to encouraging companies to act in a

precautionary way. Within the legal framework, companies should not increase their liability for using precautionary measures, or that acting in a precautionary way does not imply that such measures are necessary to protect health, but are implemented in case future research suggests health consequences may occur.

Application of precautionary action should be relevant, effective, workable, socially acceptable and legitimate. Moreover, it should strengthen legal certainty and legal predictability. Policy measures should include any views on liability for implementation of precaution based on risk from the basic science. This should be explained clearly in any policy advice to implementation bodies. This clarifies the source of the decision and the litigation route. 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.

Where precautionary action is deemed necessary, measures should:

- Be provided for and carried out in accordance with the law
- Not be drafted or imposed arbitrarily, i.e. in an unreasonable or otherwise discriminatory manner.
- Be proportional to the chosen level of protection,
- Be no more restrictive than necessary to achieve the intended purpose,
- Be subject to systematic review
- Be consistent with similar measures already taken
- Be based on an examination of the potential benefits and costs of action or lack of action
- Be subject to review, in the light of new scientific data
- Be capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

There is no single recipe for precaution, nor does precautionary action guarantee against mistakes. Using precautionary measures is a powerful tool for managing risks, but its application, without proper control can lead to negative unintended consequences. Within the regulatory process, it can, under certain circumstances, reduce transparency and erode the link between evidence of potential harm and government action. If misguided, this process might increase administrative discretion and can undermine legitimacy. It may also reduce the effectiveness of regulatory decisions, and hence damage public trust.

2.5 Science and Policy

Central to the Framework is the careful, ethical use of available scientific evidence. This Framework extends rather than replaces the notion of science-based risk management, in that it recognizes the overarching nature of the considerations and tools that are necessary for dealing with uncertainty.

Conventional scientific methods distinguish “established” from “uncertain” effects and take action mainly on the former by developing standards that limit exposure. 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, society as a whole is 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. The conflicting ethical value systems underlying such discrepancy have been described in the literature (for example, Comba et al., 2004).

It is important to recognize that there are different types of uncertainty

- Insufficient data (gaps in knowledge which can be filled by targeted research)
- Uncertainty within data (experimental and statistical ambiguities and biases)
- Ignorance (areas of potential risk, which are not on the radar screen, also called "unknown unknowns").

The extent of knowledge and uncertainty varies from effects for which there is some evidence but considerable uncertainty to effects regarded as “established” by conventional scientific criteria. The role of science is not confined only to determining “established” effects, but also to identifying gaps in knowledge and uncertainties. In this case science provides a basis for the degree of precaution that could be taken.

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. This Framework also recognizes that perspectives based on social and cultural factors, ethical values, and experience or observation constitute the context that ultimately determines the policy decisions.

3. Applying the Framework

The basic steps of the Framework are shown in Figure 1, and are described in detail in this section. Consultation with relevant stakeholders should be sought at every step of the process.

3.1 Getting started

Dealing with uncertainty is a challenging task, which is becoming increasingly required. Ideally, the goals of maximizing good health and protecting it from uncertain, potentially far-reaching hazards, must guide the process of decision making from the very beginning. An approach aimed at anticipating possible health problems, rather than mitigating any adverse impact, is preferable.

There are questions that need to be addressed before using this Framework:

- Is there a legislative framework that provides for the process to commence?
- Is there a mandate and an approval process for a particular department or agency to lead the process of developing policy or measures? If not this should be sought prior to commencing the process.
- Are there appropriate scientific experts and government or agency representatives to form a committee from which the process can evolve and be managed?
- Is there funding to complete the whole process?

Once the administrative basis has been established, a committee should be formed of responsible government agencies, scientists who can advise on the issue and other appropriate stakeholders. A strategy should then be developed for using the Framework to guide the committee's work.

3.2 Health issue in context

Existing risk management frameworks deal mostly with established risks. This Framework expands the scope of uncertain risks to include those where the scientific evidence is weak or lacking. In this paradigm, social, political and health contexts are central.

- 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 increased vulnerability, greater potential for exposure over their lifetime and because they represent the future of the society.

- From a political viewpoint, 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 in time and across groups, and situations that could be viewed as inequitable need to be addressed.

- From a health viewpoint, 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.

Also relevant is the level of risk deemed acceptable by the society concerned, which depends on its nature. For involuntary exposures 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. These considerations become particularly problematic when dealing with uncertain health impacts.

Putting the health issue in context or risk profiling may also need to recognize and evaluate factors that include:

- whether the consequence is likely to be immediate or delayed
- whether the consequences are reversible
- whether the effects are chronic, cumulative or catastrophic in nature
- the severity of the consequences
- whether or not the risk is well-characterized by science
- the size, nature or special characteristics of the group exposed to the risk
- the distribution of the risk across sub-groups
- the effect on future generations
- whether the hazard is encountered occupationally

3.3 Risk assessment

For traditional science-based 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 effects at high exposures to possible effects at lower exposures.

This Framework follows the same scientific principles and also 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. Also, the relevance and informativeness of available evidence with respect to real-life exposures needs to be carefully scrutinized. It is possible to mistake an abundance of data for a high degree of knowledge. 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].

3.4 Option generation

As part of the anticipatory nature of the approach to dealing with uncertainty, it is important that efforts are made to carry out a thorough, rigorous analysis of the alternatives available to the decision making process. If such analysis 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. If such win-win strategies can be identified and supported by all or most stakeholders, then a low level of proof on the health effect is required. While this optimal situation is rarely achieved, there are examples of success stories that can be used as model. In fact, such analysis of alternatives, fully resonant with fundamental values in medicine and public health, should be seen as a central element of precautionary action.

This Framework encourages consideration of the full range of alternatives and options to respond to uncertain health risks, is not restricted to a specified statutory or guideline

[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.

exposure level, and includes options involving individual choice such as behaviour modification, information and risk communication. Further options based on education, voluntary initiatives, and market incentives are also possible. Where efforts aimed at removing or 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 box below.

EXAMPLES OF POLICY 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 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.
- **Technical options (mitigation)** normally involve making engineering or other technical changes to reduce or avoid exposure
- **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 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.

3.5 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). Option assessment for known risks can be undertaken according to a cost-benefit analysis because the benefits are know, 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 this type of economic analysis is provided in Appendix A.

Option assessment within this 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.

As a guide, if there are low or no cost options that reduces exposure, they should be implemented as soon as possible. As the cost of the option being considered increases, an analysis of the cost-effectiveness needs to be considered. For example, in the EMF area, cost-effectiveness considerations suggest implementing exposure reduction measures for new facilities rather than applying them retroactively to facilities already constructed. Examples of such measures adopted for new rather than old facilities can be found on the California Department of Health home page at: http://www.dhs.ca.gov/ps/deodc/ehib/emf/general.html.

Option selection

The European Commission has provided guidance on the selection of precautionary measures in its report (EC, 2000). Such measures include:

- *Proportional* to the chosen level of protection: Risk can rarely be reduced to zero, but incomplete risk assessments may greatly reduce the range of options open to risk managers. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk.
- *Non-discriminatory* in their application: Comparable situations should not be treated differently, and that different situations should not be treated in the same way, unless there are objective grounds for doing so. For example, measures for mobile phone base stations should not be treated differently from radio or television transmitters.
- *Consistent* with similar measures already taken: Measures should be of comparable scope and nature to those already taken in equivalent areas in which all scientific data are available.
- B*ased on an examination of the potential benefits and costs* of action or lack of action: Comparing the overall cost to the Community of action and lack of action, in both the short and long term. This is not simply an economic cost-benefit analysis: its scope is much broader, and includes non-economic considerations, such as the efficacy of possible options and their acceptability to the public. In the conduct of such an examination, account should be taken of the general principle and the case law of the Court that the protection of health takes precedence over economic considerations.
- *Subject to review*, in the light of new scientific data: Measures should be periodically reviewed in the light of scientific progress, and amended as necessary.

Scientific evidence influences option selection: stronger evidence, particularly of a pervasive, severe or irreversible health effect, supports more intrusive actions. Evidence that does not meet conventional scientific criteria as proof of cause, particularly for a pervasive, severe or irreversible health effect, tends to 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.

3.6 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.

3.7 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 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 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 uncertainty. As new information becomes available, the policy measures should be reconsidered.

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 identified thresholds for established effects. Such approaches remain central to this Framework; guidelines should not be undermined by additional, arbitrary exposure reductions in the name of precaution, since this would devalue their scientific credibility.

For the example of EMF, exposure limits in international guidelines (ICNIRP) have been determined on the basis of known health effects, using scientific criteria established over many decades. The reasons for adoption of international standards by national authorities are given below.

- The limits provide protection from known effects and so exposures well above these limits are known to produce adverse health consequences
- Any new technology producing EMF exposures above international limits should not be allowed because the science has established that they may be unsafe
- Arbitrary reductions in the international limits will have increased compliance costs since manufacturers normally test their products against international standards, but not against others. National authorities will have to bear the increased compliance cost, or products in their country will be more expense to cover the compliance cost, for no known health benefit.
- National limits well below those in international standards could prevent highly beneficial technologies being introduced, for no known health benefit.

4.2 Public concern

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. However, as noted in the guiding principles for this Framework, public concern may be a trigger for implementing public health policies, though the priority is the protection of health. This should be interpreted to mean that the precautionary options selected should use the criteria identified in section 3.5.

It should also be noted that there is mounting evidence to suggest that 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 is generated.

4.3 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 acceptance.

Stakeholders will need to be consulted for their views 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 public trust and confidence (so essential to the credibility of recommendations arising from the methodology) it will be difficult to secure acceptance of measures finally adopted. While there will not always be consensus on such issues, the position taken should be transparent, evidence-based and able to withstand critical scrutiny.

There will need to be flexibility as to who is 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.

4.4 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 an appropriate 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. The International EMF Project has published a booklet entitled "Establishing a dialogue on risks from electromagnetic fields" that provides considerable information on how to better understand peoples concerns about risks and how to communicate in a way that will be most effective. For further information see: www.who.int/emf.

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 recognized.

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

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

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.

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 Framework stresses the importance of recognizing 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 encompasses power frequency electric and magnetic fields. The evidence that ELF 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 Framework, warrants a thorough consideration of precautionary measures including detailed cost-effectiveness analyzes
Other childhood cancers Adult cancers Other health outcomes (provisionally) Electric fields	Evidence weaker than for 2B Under the 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-effectiveness analysis

For the one health outcome warranting full cost-effectiveness 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 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 Framework this extra uncertainty must be included in any cost-effectiveness analysis.

Options Generation

Possible precautionary measures for ELF 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 Framework, national governments should perform cost-effectiveness analyzes of these possible measures and any others they may identify. Cost effectiveness analysis compares the effectiveness of a measure with alternative ways of achieving a similar benefit.

As detailed in the Framework, the 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 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 sterilization 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 Framework, 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 generalization 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, the Framework 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 Framework calls for implementation of precautionary measures to be free from legal connotations, particularly since ELF 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 Framework 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

The Framework encourages involving a broad range of stakeholders. For ELF, 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 Framework, the actions chosen should be re-evaluated periodically, and in particular, when new scientific understandings emerge.

Further reading

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