WHO Framework for Developing Health Protection Measures in Areas of Scientific Uncertainty

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INTRODUCTION

The World Health Organization (WHO) increasingly deals with health threats that are uncertain and global in nature, especially in developing countries. Traditionally WHO conducts formal health risk assessments of physical, chemical or biological agents and bases any public health actions on what has been established from this process, i.e. on what is known and can be prevented. However, there are many agents having risks to health that may be complex (e.g. electromagnetic fields (EMF) that have a wide range of frequencies with different interaction mechanisms in tissues) and their consequences difficult to predict. In such cases it may be important to take public health measures before a cause and effect relationship has been scientifically established. In this way, precautionary measures can be integrated naturally into existing public health policy and can complement actions taken for disease prevention after a cause and effect relationship has been established.

In this light, WHO is developing a practical framework for applying precautionary measures to address concerns in areas where there is uncertainty about risks to health, i.e. where the science is not yet adequate for rigorous risk assessments. However, central to the framework is the science. Without the use of accumulated scientific knowledge, even though it may be limited, precautionary measures could certainly be inadequate or cost-ineffective. Science can be used to identify:

1. established health risks that can be prevented by measures such as exposure limitation, and
2. uncertain health risks that can be dealt with through precautionary measures.

FEATURES OF THE PROPOSED FRAMEWORK

The basic premise of the WHO framework is that precaution should be applied to all aspects of managing an actual or potential health risk. In this framework it is not necessary to "invoke" precautionary measures at a given predefined level of scientific uncertainty or possible health outcome, as implied when considering actions under the Precautionary Principle. Rather the framework has precaution as an overarching philosophy, from evaluating the risk and generating options to dealing with uncertain risks, to implementing actions to reduce possible health risks and monitoring the effectiveness of the actions taken. This is shown schematically in Figure 1.

In the risk management process for known risks developed and described by the US Presidential/Congressional Commission on Risk Assessment and Risk Management,
prominence is given to the analysis of possible options, clarification of all stakeholders’ interests, as well as openness in the way decisions are reached. This is one of the bases for the WHO framework which additionally incorporates a precautionary vision of risk management when dealing with uncertain risks. Thus, the framework combines the attributes of risk management for both known and uncertain risks into a single, enhanced risk management process.

Each step within the framework should involve all stakeholders. These steps are:

1. Identifying the agent that could have health consequences and putting the health issue and risk into context.

2. Conducting a scientific risk assessment to identify what is 'known' (what the science identifies as an established risk) and what is 'unknown or uncertain'. Different individuals or societies may have differing views on what they consider is an acceptable risk. This may
need to be taken into account when considering the level of acceptable risk or the possibility that a health effects may occur.

3. Generating options for known and uncertain risks. Measures to reduce known risks usually include limiting exposure below a given level through engineering or technical solutions to meet regulations or standards. However for uncertain risks, various other measures could be used to reduce exposure to levels commensurate to the possibility of risk to health. Examples of options that could be considered are given in the box below

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<th>Examples of WHO PF Risk Management Options</th>
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<td>• Decision to take no formal action is an appropriate response in cases where the risk is considered very small, the evidence is insufficient to support formal actions, or an appropriate option is not available.</td>
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<td>• Enhanced research effort is an appropriate response to fill gaps in our knowledge, help to identify problems, and allow for a better assessment of risk in the future.</td>
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<td>• Watchful waiting: monitoring the results of research and measurement and the decisions being made by standard-setters, regulators, and others.</td>
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<td>• Communication and engagement programmes can be used to help people understand the issues, become involved in the process and make their own choices about what to do.</td>
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<td>• Compensation is sometimes offered in exchange for accepting higher exposures in a workplace or environment. People may be willing to accept something of value in exchange for accepting increased exposure.</td>
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<td>• Technical options (Mitigation) involves making engineering or other technical changes to reduce exposure and ultimately, known or uncertain risk.</td>
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<td>• Regulatory controls may involve both self-regulatory measures or formalised government controls to limit both the occurrence and consequences of potentially risky events. Regulations can take many forms. Numerical standards may be imposed with defined ways to show compliance or they may state objectives to be achieved.</td>
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<td>• Limiting exposure or 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. Performance standards, in the form of exposure limits, are often preferred to design standards, because they leave more flexibility in achieving health and safety goals without being prescriptive. Limiting exposure might include, for example, industry codes of practice, economic incentives to discourage activities or processes that create risk, or to encourage activities or processes that do not create risk. It might also include programs designed to ensure efficient reductions in risk.</td>
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4. For known risks, a cost-benefit analysis is usually performed to ensure that the cost of implementing standards limiting exposure has a net benefit to health. On the other hand, it is important to identify the most cost-effective precautionary alternative for reducing exposure.
to uncertain risks. If there are several ways of achieving a precautionary goal, the least expensive and most effective way should be chosen. Precautionary approaches should be undertaken only after balancing both costs and benefits. If the costs of certain precautionary actions are extremely high, they should be avoided unless there is reason to believe that the risk of harm is also extremely high. If the costs of precautionary measures are low, these measures could be taken even if the risk seems small or low. Precautionary measures should favour low-cost measures for reducing poorly understood risks. Once an option or options have been chosen for dealing with both known and uncertain risks, all costs associated with the selected options need to be fully assessed.

5. Implementing the chosen options is important to ensure that the exposure to the agent is reduced. For known risks this will involve enforcement of standards or regulations. For uncertain risks, depending on the possibility of there being a risk to health, precautionary actions taken by individuals or societies need to be assessed.

6. Monitoring implementation of selected actions is essential to ensure the desired outcome is being achieved. For known risks the compliance with standards is the usual measure. For measures taken to reduce exposure to some health risk, monitoring of the level of the supposed health effect or outcome in the population is a valid indicator. If precautionary measures to reduce exposure do not lead to a reduction in some health effect, a reassessment of the precautionary actions should be taken. The whole process is iterative.

The framework also incorporates many of the guiding principles enunciated in the Communication by the European Commission in February 2000. This Communication recommends that precautionary actions be proportional to the degree of scientific uncertainty; the severity of possible harm; the size and nature of the affected population; and the cost taken to protect public health (EC, 2000). 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 current understanding suggests. In addition, the Communication recommends transparent application of the process, and emphasizes the need for careful review of relevant scientific data.

DISCUSSION

Case studies
1 WHO is currently applying this framework to several environmental health risks and developing
2 generic case studies for a number of agents. The case studies are generic by nature since it is up
3 to individual countries to choose the extent and type of precautionary measures for their citizens.
4 One of the environmental agents which falls within the purview of the present framework is the
5 case of extremely low frequency (ELF) fields. Indeed, the International Agency for Research on
6 Cancer (IARC) has classified extremely low frequency (ELF) magnetic fields as an agent that is
7 “possibly carcinogenic” to humans (classification 2B). Such classification embodies in itself the
8 uncertainty of the health risk to the population, and is therefore a good candidate for the
9 application of the present framework.
GUIDELINES

The WHO framework does not provide a basis for replacing science-based guidelines. International guidelines limiting human exposure are supported by established health effects studies that are consistent, reproducible, confirmed by different laboratories and that clearly identify when exposure is thought to be harmful. In addition, exposure limits generally incorporate safety factors that allow for uncertainty in any identified thresholds for established effects. Guidelines protect against know health effects and should be made mandatory. They remain as an essential component of the WHO framework.

LEGAL CONTEXT OF USING OF PRECAUTIONARY MEASURES

Some societies or sections of society are reticent to adopt precautionary measures in case this is seen as an admission that the health risk is real. In part, this concern relates to public perception of the issue. This concern can be ameliorated, though not necessarily completely removed, by sensitive communication. In part, however, the concern is legal: that adopting precautionary measures could be construed as an admission of liability; that it might be taken to imply responsibility for similar exposures prior to taking precautionary action; and that it may put the person, national authority or company taking such action in the position of having to justify, in a legal arena, why they took the actions they did, why they had not taken actions earlier, and why they did not go further.

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

REFERENCES
