

Draft for Review (2 May 2003)
Precautionary Framework for Public Health Protection

Summary

The Precautionary Framework is an overarching concept encompassing procedures to consider in managing risks that are either known (i.e. relatively established and certain) or uncertain. It is intended that the precautionary framework provides knowledge at all key stages and thus ensure a more comprehensive understanding of overall or aggregate risk. The Precautionary Framework also provides ways to develop options for reducing exposure to physical, chemical or biological agents, to assess and select the option or options most appropriate for the risk being considered, and facilitates implementation, evaluation and monitoring the chosen option(s).

Risk management within the Precautionary Framework is an iterative process and encourages the development of new information and understanding. By involving a wide range of stakeholders in the process, the Precautionary Framework requires clarification of stakeholder interests as well as transparency in the way decisions are made.

1. Introduction

Changing societies and rapid technological developments are producing an ever increasing variety of agents and circumstances whose consequences are sometimes difficult to predict, and yet may pose risks to human health and the environment. These risks may be difficult to manage because conventional methods to estimate risk are inadequate when the risk is new and the hazard unspecified.

More recently, precautionary measures have been used to prevent or limit exposures to agents or activities whose effects are not well understood, but may be harmful. By passing laws and promoting cautionary advice society tries to minimize potential risks from new technologies, while still enjoying the benefits. In making this risk-benefit trade-off society is guided by its culture, its traditions, its experience and its scientists. This arrangement works well when there has been time for knowledge and experience to accumulate. However, when the risk is new, its impact cannot be as fully gauged, and science cannot provide the data necessary for an informed decision, application of the Precautionary Principle has been advocated.

Precautionary Principle

By the Treaty on European Union (1992), the Precautionary Principle is the basis for European environmental law. A communication by the European Commission (EC, 2000) offers guidance for politically transparent application of the Principle, while emphasizing the need for careful review of relevant scientific data. However, precautionary decisions have been controversial, and the Principle itself lacks clear definition (Foster et al, 2000, Kheifets et al, 2001). Actions by some countries, in the name of the Precautionary Principle, suggest that there is widespread confusion about what the Principle means and how it should be applied.

The Precautionary Framework presented in this report addresses the issues raised by the Precautionary Principle. It is suggested that any implementation of the Precautionary Principle in jurisdictions where it is relevant should follow this Precautionary Framework.

Role of WHO

The World Health Organization (WHO) is increasingly interested in addressing environmental health threats that are uncertain and global in nature, in both developed and developing countries. Given the increasing complexity of these risks, the need for timely preventive action despite lack of proof, and the relevance of precaution under scientific uncertainty (and its potential misuse), it is important that WHO develop an overall approach to applying precaution, consistent with public health values and its mission to promote and protect health.

As an international public health agency, WHO has always tended to base its recommendations on health and safety issues on confirmed scientific evidence. However, in 1999 at the Third European Inter-Ministerial Conference on Environment and Health, 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 development in this field through a Workshop, “Precautionary Policies and Health Protection: Principles and Applications” (Rome, May 2001). A Symposium “Environmental Exposures, Public Health, and the Precautionary Principle” (Vancouver, August 2002) reviewed developments in the theoretical field as well as case studies. 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”. Most recently, a WHO International Workshop on "Application of the Precautionary Principle to Electromagnetic Fields", co-sponsored with the European Commission (EC) and US National Institute for Environmental Health Sciences, was hosted by the EC in Luxembourg 24-26 February 2003. This workshop addressed a framework for application of the Precautionary Principle to health issues.

Scope and purpose

The purpose of this report is to provide guidance on application of precautionary strategies that will improve preventive public health decision-making under conditions of complexity and uncertainty. A Precautionary Framework for public health protection is developed that will assist WHO Member States in the development of their public health policies and application of precautionary measures to address environmental health risks.

2. The Precautionary Framework: An Overarching Concept

To develop policies and actions that protect public health, it is necessary to know the WHO definition of **health**: *a state of complete physical, mental and social well being and not merely the absence of disease or infirmity*. Public health policies have always aimed at disease prevention **after** a causal relationship has been established. However, policies can be enacted to protect public health **before** risk factors have been causally established or where uncertainty remains. In this way, precaution can be naturally integrated into existing public health policy and actions.

The Precautionary Framework may be viewed as an “overarching” concept in the sense that it complements all stages of health risk management and is not something to be “invoked” only when it is considered that there is a lack of both scientific information and certainty about health consequences. Thus, this Precautionary Framework could be implemented whenever there is consideration of options and decisions about actions intended to protect public health.

There have been many differences in ways that the Precautionary Principle has been applied, and it has been subject to extensive debate that may have confused its usefulness for addressing public health issues. The Precautionary Framework is intended specifically to overcome many of the criticisms levelled against use of the Precautionary Principle.

Goal and Objectives of the Precautionary Framework

The overall goal of applying precautionary measures in the public health context, is to reduce the potential for health risks. If the risk is eventually found not to exist, it may be that any measures undertaken will not have protected health and some resources will have been spent unnecessarily. However, this outcome is often more acceptable than one where public health measures were delayed or neglected because a risk was thought not to exist, but was eventually shown to be both real and substantial. Of course the choice between inaction on the one hand, and precautionary action on the other, depends on the magnitude (to the extent that it can be determined) of the relevant risks. If a chosen action is not burdensome or costly, and if the risk in question is serious, precautionary measures would seem to be justified. In a precautionary framework, measures are taken even when there is no certainty of risk, as long as they are proportionate to the possibility of risk.

The Precautionary Framework has two objectives:

(i) To anticipate possible threats to health and respond appropriately in order to reduce exposures before introduction of an agent

Ideally, thinking within a precautionary framework involves shifting attention to addressing questions about risks as a priority before introducing an agent. For example, before asking, "What level of risk is acceptable?" or "How much contamination can a human or an ecosystem assimilate?" a proactive, precautionary strategy would first ask, "How much contamination can we avoid while still achieving our goals?", "What are the alternatives or opportunities for prevention?". These questions should be routinely asked before any evidence of harm is apparent.

The Precautionary Framework foresees risks from the initial proposal for the introduction of a new technology or agent through the decision on whether to proceed. It undertakes surveillance after implementation to monitor potential consequences. In this way the Precautionary Framework is integrated naturally within public health policy and actions, and ideally, enables informed decisions even when the available risk information is incomplete, and provides tools to comprehensively analyse and select from amongst a broad range of options, technologies and products to reduce exposures.

(ii) To address public concerns that a potential or perceived but unproven health problem is taken into account after introduction of an agent

The Precautionary Framework integrates societal and scientific perspectives. Risk perception is a complex social construct. Its many facets can lead to different responses by individuals and to diverse reactions by the various stakeholders to the proposed risk-management options. Choosing appropriate remedies may be complicated since it depends on the degree of scientific certainty, the potential severity of harm, the size of the affected population and an interplay between science and society.

The general public and scientists may differ in their willingness to make a mistake about the existence of risk. Scientists usually require considerable evidence embodied in

hypothesis testing studies before accepting that a risk is real. Typically, scientists will take a risk to be real if there is less than a 5% probability that evidence supporting it arose by chance. Thus scientists are generally careful not to say something exists when it does not. On the other hand, the public is often more fearful about uncertain and ambiguous situations. Citizens are typically more forgiving if something thought to exist is shown not exist than if something thought not to exist is shown to exist, irrespective of statistics. In other words, the public does not want a real risk overlooked.

Role of science

The Precautionary Framework recognizes perspectives based both on scientific evidence on social factors, values, and experience or observation, and provides a platform for each to be addressed. Science-based risk management relies on assessments of the peer-reviewed literature to evaluate the certainty and appropriateness of evidence for health risk assessment. Adding perspectives based on experience or observation, and recognizing the validity of people's values, helps to identify knowledge gaps and shortcomings in evidence that may elude scientific assessments. Because of this, the Precautionary Framework does not replace but instead enhances science-based risk management and attempts to incorporate whatever is known while evaluating what is not known or incompletely understood.

By including additional information not normally part of an evidence based assessment, the Precautionary Framework addresses the needs of stakeholders whose own experiences form a reasonable and intelligent basis for understanding a problem. Even without scientifically authoritative information, observations and experiences can be suggestive and informative and are therefore an appropriate part of the analysis. Enhanced perspectives based on science and on experience or observation can also help in evaluating the effectiveness of options and ensure avoidance of unintended consequences. Post-market surveillance conducted using the Precautionary Framework may effectively identify early warnings as well as vulnerable sub-populations, countries or regions that need special attention.

Precautionary Framework and guidelines

In the absence of complete scientific information, the Precautionary Framework

- is not a basis for **replacing** existing science-based guidelines All international and many national guidelines limiting human exposures are supported by health effects research results that are consistent, reproducible, confirmed by different laboratories, and clearly identify levels of exposure to physical, biological or chemical agents that are harmful to humans. In addition, exposure limits incorporate safety factors that allow for uncertainty in any identified thresholds for established effects. Such approaches to health protection remain essential within the Precautionary Framework.
- is not suited to **extending or developing** guidelines. Where established guidelines exist, it is important that their scientific basis not be undermined by using the Precautionary Framework to support arbitrary reductions in the exposure limits.

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 and 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.

3. The Precautionary Framework Process

A risk management process adapted from the US Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997 (<http://www.riskworld.com>) is shown in fig.1(a). It illustrates the risk management cycle for known risks wherein analysis of possible alternatives becomes prominent, and clarification of all stakeholders' interests as well as openness in the way decisions are reached. For uncertain risks, the risk management cycle retains the attributes of the management cycle for known risks and enhances them with attributes of precautionary vision is shown in fig 1(b). The overarching Precautionary Framework, as shown in Fig. 2 is the synthesis of the risk management processes for both known and uncertain risks.

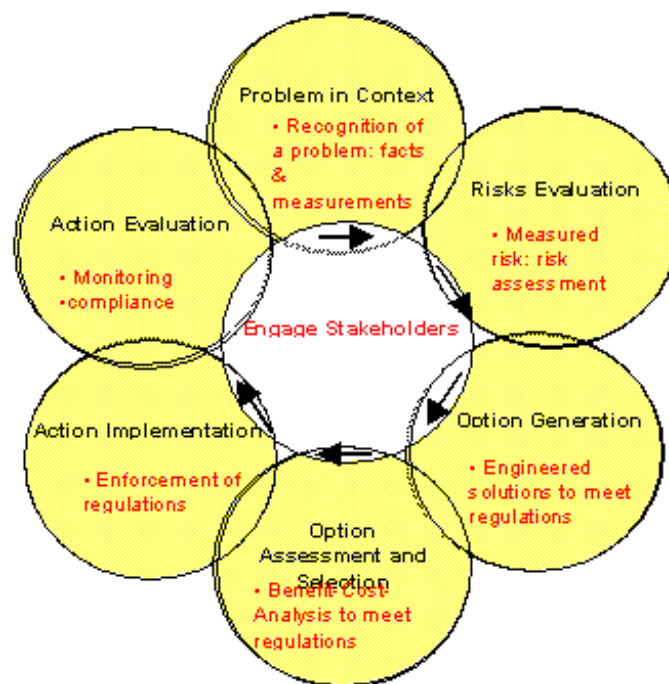


Figure 1a. Risk Management Framework for Known Risks

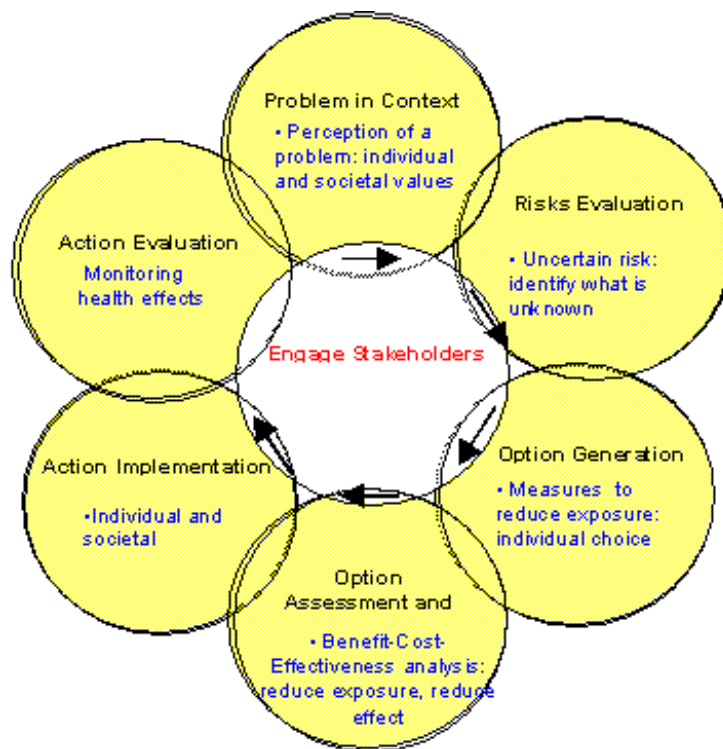


Fig. 1b. Risk Management Framework for Uncertain Risks

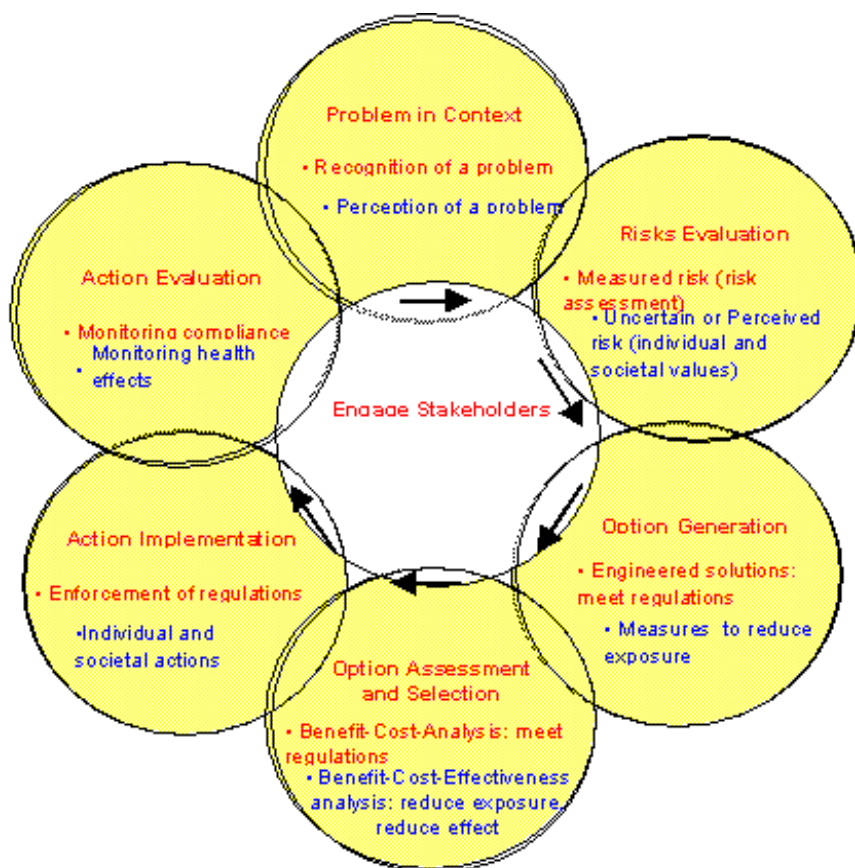


Fig. 2 Precautionary Framework for Public Health Protection

Problem in context

Existing risk management frameworks deal mostly with known risks. They identify a problem and put it into context on the basis of facts (evidence) and measurements. Guidelines or limits may be set following a benefit-cost analysis. Once statutes, regulations or guidance are in place, the problem is seen to exist when there is lack of compliance, based on measurements, to those standards. Possible problems (i.e. those without a known risk) are considered if there is an underlying basis, such as similar chemical or physical properties of an agent to those of an agent known to be hazardous.

The Precautionary Framework includes problems defined in terms of uncertain risks. Although all risks are to some degree uncertain, in this text uncertain refers to a risk that has not been established according to conventional scientific standards and where there is uncertainty, not only in the magnitude but also whether or not the risk exists. That harmful effects may occur derives from evidence based on experience or observation alone, by analogy with another activity, product or situation which has unacceptable risk, by showing that there is a reasonable theoretical explanation (tested as necessary by peer review) as to how harm might be caused or by identifying substantial scientific unknowns. Here experience, inference and perception play key roles. Uncertain risks also may have an evidence basis that is deemed insufficient, inconclusive or imprecise for defining a known risk. When considering precautionary actions, accounting for uncertain risks must be recognized as a critical issue especially in circumstances where the factual evidence of risk is weak and/or subjective.

The Precautionary Framework is not meant to concentrate on a subset of the risks. Control of one risk, for example, might increase another risk; the Precautionary Framework is meant to be applied in a way that is focused on overall risk.

Prior beliefs and societal values such as protection of vulnerable populations, inequity of exposures, as well as the characteristics of both the disease and exposures, are important considerations in defining uncertain problems. Many societies have a heightened level of concern for older people as well as for children since both groups may be unable to take actions to manage their own risk effectively. Furthermore, many societies believe that the child and the fetus should be afforded a higher level of protection because of their potentially increased vulnerability, increased potential for exposure over their lifetime and because they are the future.

The distribution and magnitude of actual and future exposures (individual and total) are factors determining potential public health impact and also contribute to the uncertainty of a problem. They should therefore be considered within the Precautionary Framework. Special attention is paid to ubiquitous exposures because even a relatively small (and thus difficult to detect) exposure to many individuals may have significant public health consequences.

Involuntary exposures, particularly if they could be viewed as inequitable or unjust with respect to the distribution of risks and benefits over time, space and social status could impact on how risks should be dealt with within the framework. Particular concern should be devoted to risks potentially faced involuntarily by disadvantaged members of society.

The nature of the presumed health effect can also be a factor in defining a perceived problem. Actions undertaken within a Precautionary Framework are intended to prevent adverse health effects. Some diseases, such as cancer are particularly dreaded. Other end-

points, such as headaches and sleeplessness although not particularly severe and often reversible, can nevertheless have a profound influence on an individual's well being and productivity and should be considered.

The Precautionary Framework distinguishes known risks from uncertain risks as they are afforded different weights when considering appropriate remedial options.

Risks evaluation

Existing risk management frameworks focus on what is known; science plays a key role. The science must be rigorous and multi-disciplinary and its evaluation based on the weight-of-evidence. However, uncertainties and assumptions necessary for the proper evaluation of risk must also be identified. Uncertainties can exist at every level of evaluation: the existence of a hazard, the magnitude of exposure, and the relationship of exposure to disease incidence or severity. When scientific studies are less than compelling, assumptions or extrapolations from other evidence are used. It is appropriate to offer ranges of anticipated effects where this is feasible.

The Precautionary Framework at its best is pre-emptive and thus attempts to illuminate what is unknown or uncertain. In this way the Precautionary Framework extends traditional evidence-based assessments of known risks. A description of gaps in relevant knowledge is especially important when key evidence (e.g. epidemiological or laboratory studies) is missing. The evaluation of both boundaries and existing gaps of our current knowledge can and should be determined by the science. Identifying what is unknown does not mean that policy should be developed for any and all activities and exposures.

For some an inability to demonstrate the existence of disease in an epidemiological or laboratory study is 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 disease) is characteristic of many diseases and can limit for many years our understanding of the potential for a new exposure to cause such harm. Failure to demonstrate a disease outcome in a limited timeframe may not rule out the possibility that the disease will occur sometime in the future.

Similarly, failure to demonstrate a disease outcome in laboratory animals may reflect the insensitivity of the test system rather than the absence of an effect. Animal studies designed to inform regulatory issues generally emphasize identifying hazards. Many published studies are limited and uncertain with respect to their ability to describe how the incidence or severity of the hazard changes with different environmentally-relevant doses. Dose-response relationships are often derived from extrapolations from very high doses that are environmentally-irrelevant. This has been the case for exposure to many chemicals, where the dose-response relationship at low doses is very important for health, but has had to be extrapolated from much higher exposures. For some hazards, studies cannot be conducted at the high doses necessary to detect an effect with confidence and still comply with ethical guidelines for laboratory animal studies.

Option generation

In existing risk management frameworks, options designed to be protective of health are normally generated to meet a statute or guideline developed as a result of a risk assessment. The overall objective is to reduce exposures to below a specified level known to be protective against established health effects. Here option generation emphasizes reducing exposure by engineered solutions or clean-up, and is driven by technological feasibility. Education, enforcement compliance, pollution taxes, and market

incentives may also have a role in generating options. To the extent that it is effective, the least intrusive and least costly approach should ordinarily be chosen to address highly speculative risks.

The Precautionary Framework adds options that are developed to respond to uncertain risks. Here the goal is to identify ways to reduce exposure but generating possible options should not be restricted to meeting an already specified target level. Therefore, options involving individual choice such as behaviour modification are considered along with engineered or technological solutions.

The Precautionary Framework generates response options ranging from minimal to stringent. The degree of certainty and the severity of harm are two important factors in deciding the type of actions to be taken. A range of risk management options is given in the box below.

Risk Management Options

- **Decision to take no formal action** is an appropriate response in cases where the risk is considered very small, or the evidence is insufficient to support formal actions.
- **Research** fills gaps in our knowledge, helps to identify problems, and allows for a better assessment of risk in the future.
- **Watchful waiting:** monitoring the results of research and measurement and the decisions being made by standard-setters, regulators, and others.
- **Communication programmes** can be used to help people understand the issues, become involved in the process and make their own choices about what to do.
- **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.
- **Regulations** are formal steps taken by government to limit both the occurrence and consequences of potentially risky events. Regulations can take many forms. They might include, for example, economic incentives to discourage activities or processes that create risk, or to encourage activities or processes that do not create risk. Regulations might also include programs designed to ensure efficient reductions in risk. Numerical standards may be imposed with defined ways to show compliance or they may state objectives to be achieved without being prescriptive.
- **Technical options (Mitigation)** involves making engineering changes in the system to reduce exposure and ultimately, known or perceived risk. Mitigation may mean redesigning the system, installing shielding or introducing protective equipment.
- **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.

At one extreme, banning an agent or activity will 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, the evaluation needs to focus on the benefits provided by the agent or activity against its potential detrimental effects.

At the other extreme, the option of doing nothing should also be evaluated employing a similar methodology. Although ‘doing nothing’ is often assumed to be the most benign option, it can incur substantial costs. Increased public concern and anxiety can produce both adverse health consequences and higher economic costs.

Between these extremes, a range of other actions and interventions needs to be considered. Some measures will carry minimal costs, and therefore would require less evidence than would be needed for more costly actions. The Precautionary Framework calls for proportionality in responses – the greater the evidence, the greater the justification for considering stronger responses or actions.

Option assessment and selection

Option assessment should take place when there is "good reason" that harmful effects to people might occur even though the likelihood of harm is remote. "Good reason" can be based on scientific evidence, belief based on experience or observation alone, or a plausible causal hypothesis. Option assessment within the Precautionary Framework depends not only on what options are available, but also on the nature and strength of the evidence for a known or uncertain risk. The size of the exposed populations is obviously important here. Strong objective scientific evidence supports consideration for a more severe remedial action (option) than weak scientific evidence or evidence based on experience or observation alone; evidence that a health effect is pervasive or severe supports consideration of more severe options than evidence that a health effect is limited in scope and mild.

Where risk assessment identifies a hazard, option assessment is undertaken according to a benefit-cost analysis (i.e. an economic method for assessing the benefits and costs of achieving alternative health-based criteria (e.g. a risk of 1 in 10^6) with different levels of health protection) and an effectiveness-cost analysis (e.g. an economic method to identify the least costly way to achieve a particular health protection goal). These, and other aspects of option assessment and selection for this situation are described in detail in the Report of the Presidential Commission (<http://www.riskworld.com>).

Where risk assessment identifies an uncertain health hazard, the options chosen must still be proportional to the possible risk, and in principle this is achieved by a benefit-cost analysis. Where, for example, the International Agency for Research on Cancer (IARC) or a body with equivalent status classifies an agent as “possibly carcinogenic” or “possibly” a cause of other forms of ill health, the benefit-cost analysis can be reasonably quantitative and objective, similar to that for a known risk. Where the scientific evidence is less than this, the benefit-cost analysis will inevitably be less objective, less satisfactory and less supportable. Therefore, a benefit-cost analysis 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 benefit-cost analysis should be undertaken to ensure that an apparently “low cost” option really is low cost.

Benefits Assessment

In the first stage of option assessment, the benefit in exposure reduction of an intervention is evaluated. This can be complex as an intervention may have effects on different aspects of exposure (risk offset), or may re-distribute exposures among other people or populations (risk transfer). If a precautionary intervention leads to exposure to new risks, that situation should be taken into account. In principle, it is necessary to compile a complete picture that an intervention has on the pattern of exposures across the population. In practice, this is never really possible, simply because all needed

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.

In the second stage, the benefit of the exposure reduction to reduce the severity the health effect under consideration should be assessed. In those circumstances where efforts aimed at reducing exposures are not feasible, options to minimize the seriousness of the health outcome should be evaluated as alternatives.

Benefits need to be expressed in units that make clear whether it is per person affected, per member of some defined affected population, or applies to the whole population. In addition, the outcome of interest needs to be clearly specified: for instance, different answers will be obtained if the outcome is defined as number of fatalities, as opposed to disease incidence, or years of life lost as opposed to years with disability. Benefit can be measured in terms of disability-adjusted life years (DALYs) gained by the intervention [WHO World Health Report 2002, p.106]. National governments however may choose to put the emphasis on other measures of the health outcome.

While it is difficult to place an actual financial value on a human life or on disease, when societies are faced with competing priorities for health care budgets, they have to employ some measure for assessing and prioritizing specific proposals. Therefore it is necessary to assign a notional figure to allow comparisons and decisions. The outcome can be quantified in various ways, for example, value of a fatality prevented. Because the value of a fatality prevented normally stems from the money that societies may be prepared to spend to save a life, it varies with the circumstance. Societies exercise value judgements and may be prepared to spend more on preventing fatalities where the person concerned has no choice in being exposed to the risk, where the potential fatality affects children, and where the fatality arises from a particularly dreaded disease, such as cancer. More difficult is the evaluation of subjective outcomes such as headaches and sleeplessness. These outcomes are not only difficult to study; their costs to society and individuals are also highly uncertain.

Accounting for risk uncertainty is an important aspect when assessing the option within the Precautionary Framework. The figure derived for the value a society places on the reduction of risk or disease arising from a particular intervention, assumes the reduction would actually occur, i.e. from an established risk. If the risk may not actually exist, it may be necessary to adjust this figure. Conceptually, it becomes necessary to derive a figure for the likelihood that the exposure causes the disease. This likelihood could then be incorporated in the analysis in various ways; the simplest being to reduce the benefit of the intervention proportionately to possibility that the exposure causes disease.

Cost or Cost Efficiency

The costs for proposed interventions need to be assessed. 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).

While some costs will arise only once, others are on-going as, in general, are the benefits. The applied costs and benefits must be assessed. Options should be selected in terms of their ability to decrease health risks, both known and uncertain and associated costs and

consequences. Full account should be taken of all the uncertainties in the assessments of both benefits and costs.

Once measures of the benefits and costs of each candidate intervention are obtained, they can be compared in a benefit-cost and/or efficiency-cost analysis to assess which interventions are justified. The utilitarian approach would be to reduce exposure until the cost of the last reduction equals its benefit. However, society may wish to err on the side of caution and incur greater costs, in excess of the expected benefit. This may be the case for all risks, but is particularly relevant as an insurance policy against a small risk of a serious consequence, or to circumstances involving involuntary exposure, exposures of children, and to risks of certain diseases. This is a value judgement and can either be taken into consideration at this stage by making the test for comparing costs and benefits “not disproportionate” rather than “equal” or at the earlier stage of deriving a value for a fatality prevented.

Assessing the benefit-cost and benefit-cost effectiveness of each option

The first step is to develop a method for effectiveness analysis that can model the potential impact of any option and calculate the long and short term cost of implementation. The effectiveness of each option then needs to be separately identified and assessed. Different considerations apply to the various options. Likewise, application of an option to a new situation needs separate assessment. It is important to develop a *standard* approach as this will offer a valuable basis from which reasonable comparisons can be made, be it at a national or regional level.

It is assumed that the final assessment of the benefit-cost analysis will be performed at the level of a whole society, ideally by Government. It will therefore encompass all costs regardless of who might bear them, be they on industry, taxpayers or others. Costs always have consequences, not least through the established association between disposable income and health. The proper application of the Precautionary Framework should address those consequences.

Criteria for Option Selection (EC 2000)

The option selection should be:

- ***proportional*** to the desired level of protection
- ***non-discriminatory*** in their application
- ***consistent*** with the measures already adopted in similar circumstances or using similar approaches
- ***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 of review***, in the light of new scientific data
- ***capable of assigning responsibility*** for producing the scientific evidence necessary for a more comprehensive risk evaluation

Option Selection

Option selection can include a number of criteria, whose weighting can be given flexibility to reflect differences in risk factors and diseases as well as cultural differences. The EC Communication on the subject has defined several such criteria for the application of the Precautionary Principle (see inset above).

Option Implementation

At this stage of the Precautionary Framework risk management cycle, decision- and policy makers will have been presented with a broad range of policy options and perhaps a recommendation for selecting one or more of those options. The audience to receive those options and the responsible party or parties for implementation will be different for different options. However, the active participation of a broad range of stakeholders is necessary for successful implementation of any chosen option. These stakeholders should include, but not be restricted to participants of the previous steps of the Framework.

The timing of implementing an option will depend on information gathered during the process including the ubiquity of exposure, the severity of the demonstrated or perceived health effect, and the availability of a readily applicable option. More detail and a broader range of stakeholder involvement is required for implementation when the benefits of the response option become less favourable and costs, financial or otherwise become more burdensome.

Option Evaluation

Options developed for a known problem with existing guidelines, regulations or statutes generally are evaluated with respect to compliance. A finding that there is lack of compliance brings new information to the process and can re-initiate the risk management cycle. Options developed for an uncertain risk are harder to evaluate. However some measures, such as increasingly successful deployment of a low-exposure technology can indicate an option's success.

Within the Precautionary Framework there exists the need for additional information from studies appropriate for successful risk management. New information to determine whether an uncertain risk is a real risk redefines the perspectives within the Precautionary Framework processes and would likely lead to generating new and more appropriate options.

Ultimately the success of the risk management process will be the demonstration that public health has been improved or at least it hasn't deteriorated as a result of implementing options.

Option evaluation is not the end of the risk management process within the Precautionary Framework. The process is iterative and intended to be responsive to changing information available and changing values of societies.

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