

# Radiation Health & Safety Advisory Council

an advisory body to the CEO of ARPANSA, established under the ARPANS Act 1998

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## COUNCIL ADVICE ON PRECAUTIONARY APPROACHES IN RADIATION PROTECTION

### Introduction

The precautionary principle is an increasingly popular management tool used to deal with circumstances where there is risk and uncertainty. The precautionary principle can be considered in a structured framework similar to conventional risk management processes, which requires a balance of the risk and of the benefits and consequences of intervention. The precautionary principle is thus not an absolute construct, but is relative, where the emphasis is on precaution in the face of uncertainty. As a principle, it is used to guide policies, plans and actions. It is based on the premise that where there is uncertainty one should be cautious.

### Background

The precautionary principle has mainly been applied in environmental management, and it is becoming an increasingly important consideration in that field. It has appeared in several international declarations including the global summit meeting on the environment and development in Rio 1992, and in the EU treaty (Maastricht, 1992). Many countries have incorporated the precautionary principle into environmental protection legislation, particularly those in the European Community.

Australia was a signatory to the Rio declaration of 1992, which contains the following statement as Principle 15: *'In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be a reason for postponing cost-effective measures to prevent environmental degradation.'*

In February 1992 through an Inter-Governmental Agreement on the Environment, the Commonwealth, States and local governments agreed to follow the precautionary principle as part of a commitment to ecologically sustainable development.

*"Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be a reason for postponing measures to prevent environmental degradation."* The Precautionary approach has since been included in the Environment Protection and Biodiversity Conservation Act 1999, by requiring the Minister to consider the precautionary principle in making decisions.

The precautionary principle can best be considered in a structured framework of risk management, which requires a risk / benefit analysis of the particular situation before a decision is made to intervene (Tubiana). The EC communication on the precautionary principle (EC2000) also places the precautionary principle within the framework of conventional risk management, but where the scope has been extended to deal with uncertainty.

## **Trigger of the precautionary principle**

The precautionary principle is based upon a balance between the risk (dangers induced) from the problem, and of the consequences of any preventative intervention, both benefits, as well as adverse effects from restricting activity.

Although there is often uncertainty about the actual risks as complete an assessment as possible of risks is recommended. Risk aversion theory suggests that a major but infrequent risk is regarded as being more significant than a milder but more common risk. The decision on the degree of safety factor that is acceptable to the community is partly based upon science, but also based on societal perceptions and values. Judging what is an acceptable level of risk for society to trigger intervention is a political responsibility.

## **Elements of the Precautionary Principle**

In February 2000, the European Commission approved an important communication on the Precautionary Principle providing guidelines for its application.

It indicated that measures taken under the precautionary principle should be:

- proportional to the chosen level of protection.
- non-discriminatory in their application.
- consistent with similar measures already taken in equivalent areas in which all scientific data are available.
- based on examination of potential benefits and costs of action or lack of action.
- subject to review in the light of new scientific evidence.
- capable of assigning responsibility for producing scientific evidence for a more comprehensive risk assessment.

One of the important factors limiting the scope of the precautionary principle is the concept of proportionality. Proportionality means tailoring measures to the chosen level of protection and that the regulation must be as specific as possible to deal with the problem.

Another key element of the precautionary principle is the issue of who should bear the burden of uncertainty. The precautionary principle indicates that the onus is on those who wish to follow a particular behaviour. When any new process or development is introduced the onus is on the group that is undertaking the activity to demonstrate that the procedure is not hazardous prior to its introduction. It is however, impossible to demonstrate that an activity is completely safe prior to its introduction; such an expectation is unrealistic. What is required is that before accepting any new development there should be positive evidence that any risks are acceptably low, and not simply an absence of evidence that risks are unacceptably high.

There is a demand by the public for more transparency in decision-making processes. Openness in communication is important, particularly as the principle is being invoked because of uncertainty not because of hard scientific evidence. Tubiana recommended that whenever the precautionary principle is applied in the field of health care, the State should undertake actions based on fully open and undisguised decision making and provide as complete information as possible to the public.

The precautionary principle should be regarded as a mechanism for the development of further scientific evidence. As it may be invoked for uncertainty, efforts to resolve the uncertainty are important. Thus research into the problem area to provide additional data is often also an

appropriate action. Any measures that are implemented under the precautionary principle should be capable of being modified in the light of new data.

Intervention carries costs that have to be considered. The implementation of the precautionary principle in a way that is too strict may delay the benefits that new technology may bring. The aim should be to follow a policy that is acceptable to most people, which minimises the chance of adverse outcomes without unnecessarily stifling progress.

### **Problems associated with the precautionary principle**

One consequence of invoking the precautionary principle whenever uncertainty occurs, is that the further one is away from strong scientific evidence, the higher the probability that the hypothesis that triggered any proposed action under the precautionary principle will be wrong. The actual risk may be different from that perceived originally; also some proposed interventions may not alleviate the risk.

Tubiana (2001, 2000) summarised some of the problems associated with the precautionary principle. The following are quotations from the abstracts of his papers:

*"The pitfalls include the opposition to progress and the refusal of innovation, ever greater bureaucracy with highly restrictive administrative procedures, and the waste of funds in the pursuit of the utopian goal of "zero risk". Other drawbacks are more insidious. The precautionary principle could contribute to a general feeling of anxiety and unease in the population. It could be used by campaigns to manipulate public opinion in favour of a particular commercial or ideological interest. Furthermore, policy makers could be led to make choices not dictated by a search for the optimal solution, but rather one based on expediency designed to relieve pressure and protect them from future accusation.*

*Nevertheless, the precautionary principle can have advantages, such as that it requires decision-makers in the public or private sector to explain the rationale behind their decisions, to quantify the risks and to provide objective information."*

### **The precautionary principle and radiation**

The model of the precautionary principle has been extended to health and the issue arises as to how these concepts apply in the radiation field.

Many of the elements of the precautionary principle are similar to those that have been used for many years in radiation protection, to deal with risk. In ionizing radiation the data about radiation effects are much stronger and the risk can be better quantified, enabling a risk management strategy to be applied. It is usually sensible to encourage work practices that minimise the possibility of exposure to radiation and thus a precautionary approach is often used in codes of practice.

At very high doses of ionising radiation there is the hazard of serious consequences in the short term, which are directly related to dose (deterministic effects). For lower doses there is also the hazard of an increased probability that an effect such as cancer may occur many years after exposure (stochastic effects). The radiation dose limits in legislation with measures to prevent over-exposure are designed to minimise those risks.

Although there is direct epidemiological evidence of stochastic effects at doses above 100 mSv, no such evidence exists at the low doses that may be received as a consequence of occupational exposure. The ICRP has taken the conservative, precautionary approach of assuming that risk of stochastic effects extends to zero dose. Thus, at radiation doses below the limits a policy

called ALARA (an acronym for “As Low As Reasonably Achievable”) is usually applied. It is a policy used to minimise known risks by keeping exposures as low as is reasonably possible, taking into account risks, benefits to public health and safety, economic factors, technology and other societal factors (ICRP 1991). In ionizing radiation the limits are set at a level where there is a calculable risk which is deemed acceptable. Even below those limits it is believed there is a low risk of stochastic health effects, and ALARA is designed to minimise that risk. ALARA can thus be considered to be a form of the precautionary principle.

A related policy called prudent avoidance was initially developed as a risk management strategy to deal with concern about possible effects from extremely low frequency (ELF) electromagnetic fields from high tension power lines (reviewed by Nuttall et al 1999). Prudent avoidance has evolved to mean taking simple, easily achievable, low cost measures to reduce exposure to electromagnetic fields, even in the absence of a demonstrable risk. In most countries where it has been implemented, prudent avoidance refers to adopting measures, at modest cost, to reduce public exposure to electromagnetic fields at levels below the recommended limits.

The precautionary principle has been extended to the RF field. The RF limits are designed to protect against known harmful effects of heating and muscle and nerve stimulation, but uncertainty exists about effects at low exposure levels, particularly from long term exposure. There has been concern about cancer, but current evidence suggests that cancer is unlikely, although longer follow up and more data is required. Other possible effects from long term exposure remain uncertain. Because of the uncertainty, particularly in relation to concern about long-term effects from RF, there have been proposals to apply the precautionary principle to issues such as the use of mobile phones and the siting of telecommunication towers. Usually proposals for such matters are couched in terms of voluntary recommendations.

## Recommendations

It is recommended that the terminology and concepts of the precautionary principle be reaffirmed in the radiation field particularly in areas below the regulatory limits in both ionising and non-ionising fields.

It is recommended that ARPANSA should monitor the use of precautionary approaches in radiation protection with other agencies and the community, with the aim of reconciling the use of the precautionary principle in environment protection and radiation protection.

## References

Commission of the European Communities. Commission adopts communication on precautionary principle. Brussels 2 Feb 2000.

<http://europa.eu.int/rapid/start/cgi/guesten.ksh> DN:IP/00/96 Date 02/02/2000

ICRP Publication 60 1991. 1990 Recommendations of the International Commission on Radiological Protection, *Annals of the ICRP*, vol. 21, no. 1-3.

Nuttall, K., Flanagan, P., J., Melik G. 1999, Prudent avoidance guidelines for power frequency magnetic fields. *Radiation Protection in Australasia*, vol. 16, no. 3, 1999 pp 2-12.

Tubiana M. Conclusions. The precautionary principle: its advantages and risks. *Bull Acad Natl Med* 2000; 184:969-93

Tubiana M. The precautionary principle: advantages and risks. *J Chir* 2001; 138:68-80.