Prudent precaution

Gezondheidsraad **President**
Health Council of the Netherlands

To the Minister of Housing, Spatial Planning and the Environment

Subject : Advice *Prudent precaution*
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Dear Minister,

In the European Union, the precautionary principle is now an important basis for policy. The goal is to provide the best possible protection for human health and for the quality of the environment. In practice, however, taking precautionary action is no simple matter. Accordingly, such measures regularly result in fierce controversies. Approval processes relating to specific products or technologies always involve conflicting interests.

Accordingly, I have formed a committee which has examined what the precautionary principle implies and what its meaningful application in policy entails. I hereby submit the resultant advisory report. It has been assessed by the Standing Committee on Medical Ethics and Health Law, the Standing Committee on Health and Environment and various members of the Council's other standing committees.

In its advisory report, the Committee stressed that use of the precautionary principle cannot be equated to the banning of activities, products or technologies – something with which it is frequently associated. There are various other possible courses of action, such as the imposition of restrictions, setting preconditions, developing alternatives or acquiring additional knowledge. Refraining from any action at all (on a permanent or temporary basis) is also an option.

When choosing from the range of available options, consideration is given to the anticipated beneficial and adverse, certain and uncertain consequences associated with each of them. In this context, special consideration is given to the interests of future generations. Once a decision has been taken, subsequent monitoring of the effects will continue to be needed, so that the policy can be adjusted as and when new knowledge makes it desirable.

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When applied in this way, the precautionary principle is a strategy for dealing with uncertainties in a careful and transparent fashion that is tailored to the situation at hand.

The commitment of key stakeholders remains essential throughout this process. They usually have to strike a difficult balance, which is not confined to facts and uncertainties alone - value judgments also play an important part. Participatory decision-making, however, is anything but simple. The Committee therefore urges that methods be developed and people trained with a view to improving this process.

All areas of public health policy are affected by uncertainty, from preventive and curative health care to nutrition, and from occupational health and safety to environmental management. The Committee feels that the precautionary principle is applicable to all these areas. It recommends creating a culture in which dealing with uncertainties in a careful and transparent way is the normal approach to take.

The relevance of this advisory report is not restricted solely to the policy domain for which you are responsible. Accordingly, today I have also sent copies of the report to your counterparts in the ministries of Health, Welfare and Sport, Agriculture, Nature and Food Quality, Social Affairs and Employment, and Economic Affairs.

Yours faithfully,
(signed)
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to:

the Minister of Housing, Spatial Planning and the Environment

No. 2008/18E, The Hague, September 26, 2008

The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare & Sport, Housing, Spatial Planning & the Environment, Social Affairs & Employment, Agriculture, Nature & Food Quality, and Education, Culture & Science. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

The Health Council of the Netherlands is a member of the European Science Advisory Network for Health (EuSANH), a network of science advisory bodies in Europe.

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The advisory report in brief

Which approach would be best in a situation where new technologies or products become available whose effects on human health or the environment cannot yet be predicted with any accuracy? Moreover, what action should be taken if doubts arise concerning the safety of products or technologies that are already on the market? Uncertainty about damage to health or to the environment calls for a policy in which precaution is the prime focus. However, that does not necessarily mean that these technologies or products should then be kept off the market or banned. The precautionary principle should rather be seen as a strategy for dealing with uncertainties in a way that is careful, transparent and tailored to the situation at hand. The outcome is not a foregone conclusion.

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Executive summary

Introduction

Does the disappearance of many animal and plant species threaten ecosystem functioning and human health? Is the cultivation of genetically modified crops a threat to people and the environment? Are people working in the cosmetics industry at risk from nanoparticles? Can variant Creutzfeldt-Jakob's disease be communicated in blood and blood products? Science cannot currently answer these and many other questions. However, the uncertainty that surrounds such issues does not mean that they can be relegated to the bottom of the political and policy agenda. In recent decades, there have been increasingly insistent calls for the precautionary principle to be applied in cases of scientific uncertainty, for the protection of public health and the environment. The European Union has incorporated the principle into its treaty and the environmental movement is constantly asking for the precautionary principle to be used to address potential hazards in our surroundings.

Application of the precautionary principle has, however, been the subject of considerable debate. Critics argue that the precautionary principle is vague and unscientific, promotes arbitrary decision-making and inhibits technological development and progress. The principle is also perceived by some to interfere with the efficient use of scarce resources. It is accordingly suggested that policy based on the principle is more likely to have a negative effect on public health than a positive one. The counterargument is that a precautionary approach is

often the only way of ensuring that modern technology does not cause serious irreversible harm.

Against this background, the President of the Health Council established a committee to carry out a scientific analysis of the precautionary principle and to make appropriate recommendations regarding its application. The committee was also asked to assess the significance of the principle for public health policy in its broadest sense, i.e. including the environmental protection, food safety, occupational health and safety and preventive and curative health care domains.

In this report, the committee explains what it believes the precautionary principle entails, identifies the types of issue to which it can be constructively applied and sets out the relevant considerations. The report concludes with a brief assessment of what can be achieved by application of the precautionary principle, as defined and in the manner proposed by the committee. The intention is that the report should serve primarily to guide policy-makers and politicians when considering application of the precautionary principle in government policy. Nevertheless, the committee hopes that the report will be helpful to everyone that is in some way involved in decision-making within the policy domains listed above.

What the precautionary principle entails

Numerous definitions of the precautionary principle can be found in policy documents, international treaties and other political and legal texts. Perhaps the best-known example is the definition given in the declaration issued at the conclusion of the 1992 United Nations Conference on Environment and Development in Rio de Janeiro (the 'Rio Declaration'):

> Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

More recently, a UNESCO committee defined the principle as follows:

> When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.

Recently, the European Environment Agency proposed the following definition:

> The precautionary principle provides justification for public policy actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act in order to avoid, or reduce,

potentially serious or irreversible threats to health or the environment, using an appropriate level of scientific evidence, and taking into account the likely pros and cons of action and inaction.

The various definitions differ in terms of the extent to which they imply action *must* be taken where uncertainty exists, and in terms of the nature of the action required. Hence, distinction is made between 'strong' and 'weak' versions of the precautionary principle. Proponents of the principle associate it with efforts to achieve sustainability. Many people take the view that the precautionary principle implies that, in situations characterised by serious uncertainty, more weight should be attached to the potential negative consequences of a human activity than to its potential positive consequences. This outlook is consistent with the ideas put forward by the originally German philosopher Hans Jonas. It also has echoes in the 'maximin' rule, which is often closely associated with the precautionary principle. This rule – one of many developed by decision scientists to facilitate decision-making in situations of uncertainty – requires that a course of action should be chosen solely on the basis of the potential negative consequences of the various options (the option likely to have the least serious undesirable effect being preferable). However, this rule is useful only in situations where there is little to be gained and a great deal to be lost. The many other available decision rules all have their own limitations. The committee does not therefore believe that any one rule is universally applicable in situations of great uncertainty.

The committee takes the view that greater weight should not *always* be attached to (potential) negative consequences than to (potential) positive consequences. Thus, the committee does not regard the precautionary principle as a decision rule. Foregoing benefits in order to avoid a particular risk can itself introduce other risks. If, for example, children were no longer vaccinated because of concerns about the possibility of neurological damage resulting from the presence of a mercury-containing preservative in vaccines, the risk of infectious disease would increase. The committee therefore sees no alternative to assessing the various possible courses of action and the associated (potential) positive and negative repercussions on their own merits, and weighing them up against one another in a careful and transparent manner. In this context, the precautionary principle may be regarded as a strategy for dealing with uncertainty in an alert, careful, reasonable and transparent fashion, which takes account of the particular situation. In the committee's view, applying the principle is by no means identical to banning activities, although this may be the preferable option in some cases.

Issues to which the precautionary principle is applicable

Decision-making is more challenging where the policy issue involved is characterised by ambiguity, uncertainty and/or complexity. Ambiguity exists where divergent values are involved. Distinction can be made between normative and interpretative ambiguity. The former involves differences of opinion as to what is ethically acceptable; the latter involves differences of opinion as to the significance of a given research finding (e.g. whether a given effect may be deemed to constitute 'harm'). Interpretative ambiguity is amplified more than normative ambiguity by the second challenging characteristic: uncertainty. Where the introduction of new technologies or products is concerned, uncertainty may exist regarding the hazard characteristics, the levels of exposure and therefore the nature and extent of the harmful effects that might occur, and the likelihood of their occurrence. Where harm has already occurred, uncertainty may exist regarding the possible cause(s). Sources of uncertainty include the variability of phenomena and lack of knowledge, which may entail anything from a measurement error to complete ignorance. Finally, complexity is an expression of the difficulty of developing a qualitatively and quantitatively clear picture of the consequences of a course of action on the basis of the available information. Complexity exists where there are a large number of possible causal factors and effects, and the relationships between them are unclear.

The three characteristics referred to above are interdependent and hard to distinguish from one another. High levels of complexity and uncertainty increase ambiguity, for example. Nevertheless, in principle, each of the characteristics requires a different approach strategy. Ambiguity is best addressed by means of consultation and debate, with a view to identifying common values, fostering understanding and seeking ways of enabling different groups to implement their own visions in practice. Uncertainty requires a strategy for dealing with the uncertain matters in an alert, careful and reasonable fashion, which takes account of the particular situation – in other words, for application of the precautionary principle. Finally, complexity should be tackled by (multidisciplinary) discourse amongst people with scientific and practical expertise, so that the best possible picture of the issue may be built up on the basis of all the available information.

The precautionary principle, therefore, is appropriate for use in connection with issues that are characterised by a degree of uncertainty sufficient to hamper decision-making. To warrant a precautionary approach, it must also be plausible that negative consequences will occur, or that a causal relationship exists. Plausibility needs to be judged by experts, who may apply standard scientific criteria.

In the assessment process, the role of non-experts is to make observations and pose critical questions in order to test and thus contribute to the quality of the experts' arguments. For their part, the experts should be open to such observations and questions, and candid about the extent of their knowledge. In general terms, an effect or correlation may be considered plausible if at least some recognised experts in the relevant field have concerns. Whether the degree of plausibility is sufficient to justify further action (and if so, what that action should be) is a policy decision that must be made on the merits of the individual case. In that context, consideration should be given to the interests at stake and extent to which the issue is liable to cause public disquiet. Most uncertain issues will also be characterised by a degree of ambiguity and complexity. Under such circumstances, it is advisable to formulate a customised approach that integrates the three specialised strategies.

All the policy domains with which the Health Council is concerned (preventive and curative health care, environmental management, occupational health and safety and food) are characterised by uncertainty. Therefore, the committee takes the view that the precautionary principle can usefully be applied in all these domains.

Developments in dealing with risk

Scientific and technological advances, population growth and globalisation are exposing large parts of the world to all sorts of 'new' risks, which it is increasingly difficult for the individual to fully understand or influence, or for experts and governments to specify and control. In parallel with this trend, thinking on how risk should be dealt with has gradually been changing in recent decades: the technical, natural science-based approach (with the focus on the nature, extent and likelihood of possible consequences and the role of mankind) has been broadened to take account of psychological and sociological factors that contribute to public perceptions of risk (control over the risk characteristics, extent to which exposure is optional, confidence in the authorities, etc). Finally, in line with developments in other fields of public administration, an approach referred to as risk governance was adopted, in which stakeholder groups are involved in the development and implementation of risk management policies, and openness and transparency are key principles. The advantages of such an approach are the input of knowledge, experience and views from a wider range of sources and the formulation of policies that are more likely to command general support. The successful involvement of stakeholders in assessment and decision-making is not easy to achieve, however. Factors such as the increasing availability of reliable

and unreliable information via the Internet and the greater assertiveness of private citizens and interest groups have resulted in metamorphosis of the high-trust society into a low-trust society. The committee therefore wishes to see the development of tools and the training of personnel with a view to enhancing implementation of the risk governance process. Although each party undeniably has a responsibility in this context, the principle of democracy requires that the government has ultimate decision-making authority with regard to public policy or defines the parameters within which other actors may decide matters. Depending on the issue in question, decisions may be made at the local, national or international level.

The governance of policy issues should be realised through an assessment and decision-making process divided into a number of steps, in which communication plays a central role (see Figure 1). The process needs to involve the exchange of information, making allowance for people's expectations, feelings and fears, promoting trust and a willingness to engage in debate about values. Specification of the process becomes more laborious and more challenging as the degree of complexity, uncertainty and ambiguity characterising the issue increases. This is particularly so where the participation of stakeholders is concerned. It is advisable that politicians and policy-makers involve scientists and researchers, as well as representatives of the business community, unions and NGOs, including consumers' and patients' groups and animal welfare or environmental lobby groups, in the process of assessment and decision-making on uncertain issues. It can be desirable to extend participation to include representatives of the general public (e.g. through citizens' panels), especially where an issue is also characterised by ambiguïty.

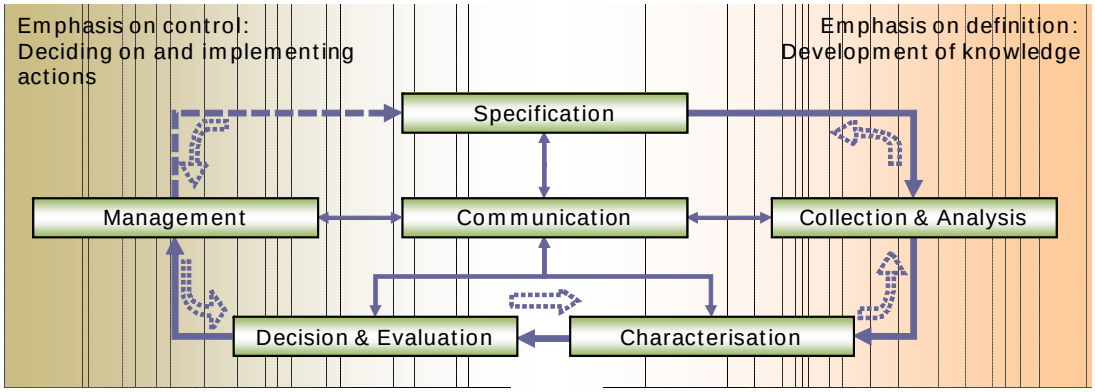

Figure 1 The assessment and decision-making process for policy issues.

Application of the precautionary principle

The Specification stage involves problem definition and demarcation. The decision situation is thoroughly examined and the degree of complexity, uncertainty and ambiguity involved in the relevant issue is established as accurately as possible. If it is concluded that the issue involves substantial uncertainty, application of the precautionary principle is advisable (if necessary in combination with strategies for ambiguity or complexity). Because the precautionary principle entails dealing carefully with uncertainty, precaution is exercised not only in the later stages of the process (Evaluation & Decision-Making and Management), as often suggested, but also in all the preceding stages. The risk-engendering activity is then examined, along with all possible alternatives; in this context, consideration is given to the positive and negative, certain and uncertain consequences of each option. The outcome has implications for the design of all subsequent process steps. It is also necessary to establish who the stakeholders are.

At the Collection and Analysis stage, the relevant data are collected and analysed, and the expectations, feelings, concerns and values of the various stakeholder groups are surveyed. The uncertainty characterising the issue means there is inevitably a risk that an inappropriate course of action is chosen, so it is necessary to build up a picture of the possible consequences (nature, extent, scenarios) of making the wrong decision (insofar as that is possible, given the level of uncertainty). To this end, consideration should be given to the possibility that a course of action subsequently proves to have been excessively cautious, and to the possibility that it proves to have been insufficiently cautious. The (often scarce) evidence for the potential consequences needs to be considered in the same way.

At the Characterisation stage, the available data are summarised and expressed in appropriate units to facilitate decision-making. In the interest of comparability, the consequences of both excessively and insufficiently cautious decisions should ideally be expressed in the same units. However, that is not possible in many cases, because of the dissimilar nature of the consequences. It is also important that assessment is not restricted to readily quantifiable and comparable effects (e.g. effects that can be expressed in monetary terms). If aggregated indicators, such as monetary value or DALYs, are used for comparison, care needs to be taken to ensure that other relevant information, such as the distribution of effects across population groups or between current and future generations, is given proper consideration.

During the Evaluation and Decision-Making stage, policy-makers reach a conclusion as to the course of action that is in society's best interest, in or following consultation with the relevant stakeholders. Arriving at such a decision tends to be a difficult process, because the various positive and negative implications of the various options are usually difficult to compare. Matters are further complicated by the uncertainty that surrounds (some) of those implications. Decision-makers need to take account not only of the scientific evidence, but also of the importance that people attach to the undesirable potential consequences of both excessive and insufficient caution.

The Management stage involves implementation of the chosen course of action. Because the decision-making process was characterised by uncertainty, the selection of that course of action is in principle provisional. It is important that the consequences are monitored, as a basis for policy review and realignment in the light of new information. Thus, assessment and decision-making guided by the precautionary principle is a dynamic and iterative process throughout.

Practical examples

Several years ago, the European Environment Agency (EEA) considered what lessons could be learned from the previous failure to heed early warnings on twelve policy issues (including asbestos, DES, PCBs and BSE), which had resulted in considerable environmental and health damage. In the preparation of this report, the committee has been guided partly by the EEA's findings. The committee has itself examined three issues, the policy on which is still under development and might yet therefore be improved. The issues in question are the possible toxicity of nanomaterials, the universal fortification of bread and bread products with synthetic folic acid for the prevention of neural tube defects, and intracytoplasmatic sperm injection (ICSI) using surgically harvested sperm in cases of male infertility. The committee has demonstrated how these issues should be assessed by outlining the potential implications of decisions based on over-optimistic and over-pessimistic assumptions. Policy development has progressed furthest in relation to ICSI. In the mid-1990s, a moratorium on the use of ICSI with surgically harvested sperm was introduced, because of concerns that the process could result in the birth of children with (epi)genetic defects. Apparently, less weight was attached to the possibility that some people would unnecessarily be denied the opportunity to have children that were genetically their own, than to the possibility of some offspring having serious genetic defects. Because more recent research has suggested that the earlier fears may have been

misplaced, the technique has now been cleared for controlled use in a research setting. If the results of the research tend to confirm the safety of the technique, the previously imposed moratorium will serve to illustrate that caution is not without its adverse consequences. However, provided that a cautious policy results from a careful evaluation process, it cannot legitimately be criticised.

Value of regarding the precautionary principle as a strategy

By calling for the precautionary principle to be regarded as a strategy for dealing with uncertainty in an alert, careful and reasonable fashion, which takes account of the particular situation, the committee has defined a procedural context for the principle. Although application of the principle does not direct decision-making or ease the unavoidable and difficult task of weighing up competing options, it does provide a reference framework within which policy-makers can work. By ensuring that uncertainty is actively taken into account, it serves as a valuable supplement to more traditional policy support tools, such as (classic) risk analysis and cost-utility analysis, and therefore provides a basis for better decisions. Hence, application of the precautionary principle is ultimately beneficial for human health and the environment. It prevents a situation where undue importance is attached to known or probable (and typically short-term) benefits, relative to the associated disadvantages, if these are less certain and likely to manifest themselves only in the long term. Such an approach provides better protection for future generations. While the precautionary principle cannot completely protect society from unpleasant surprises, it can make them less likely. Its application serves to encourage people to consider the potential negative impacts of new technologies right from the start of the development process. It promotes a dynamic and iterative process of policy formulation, monitoring and review, and thus reduces the danger of early warnings being overlooked or lightly discounted and enhances the prospects for early intervention. This in turn leads to the reduction of adverse effects (‘learning by restricted error’). Finally, adherence to the principle makes it clear that, in situations characterised by uncertainty, a choice needs to be made between the potential consequences of a policy that subsequently proves to have been very (or unnecessarily) cautious and the potential consequences of one that subsequently proves to have been (too) optimistic. Application of the principle promotes conscious and informed decision-making on such matters. General adoption of the precautionary principle would lead to the establishment of a culture in which uncertainty was consciously

addressed, as already happens in the field of radiological protection, guided by the ALARA principle*.

The committee believes that, if the precautionary principle is applied in the manner described, the criticisms that have been levelled at it cease to be valid. The proposed methodology does not encourage unduly pessimistic or optimistic assumptions; it utilises the available knowledge to the full without absolute reliance on scientific proof; and it guides technological progress without inhibiting it. The principle is defined in general terms, because that is a requirement for applicability in relation to a wide range of issues; detailed practical specification will be necessary on a case-by-case basis. Finally, the principle is more likely to lead to tailor-made solutions than to arbitrary policy, provided that all stakeholders work together in the context of a careful, government-supervised risk assessment and decision-making process to identify a reasonable way of accommodating the uncertainties associated with the issue in question, while heeding the interests of future generations.

Recommendations

The committee's recommendations may be summarised as follows:

- The precautionary principle should be regarded as a strategy for dealing with uncertainty in an alert, careful, reasonable and transparent fashion, which takes account of the particular situation.
- The precautionary principle should be applied in connection with issues that are characterised by a substantial degree of uncertainty, i.e. a degree of uncertainty sufficient to hamper decision-making. Where the introduction of new technologies or products is concerned, such uncertainty may relate to the hazard characteristics, the levels of exposure and therefore the nature and extent of the harmful effects that might occur, and the likelihood of their occurrence. Where harm has already occurred, the uncertainty may concern the possibility of a causal relationship with previously introduced products or technologies.
- The plausibility of a threat or an association should be judged by experts, who should be open to observations and critical questions from non-experts, and candid about what is uncertain. Whether the degree of plausibility is sufficient to justify action (and if so, what that action should be) depends on the interests at stake and the level of public disquiet.

* ALARA (as low as reasonably achievable): a principle intended to guide action to reduce exposure to harmful agents, such as ionising radiation.

- Most uncertain issues are also characterised by a degree of ambiguity and complexity. Under such circumstances, it is advisable to formulate a customised approach that integrates the precautionary principle and the specialised strategies for ambiguous and complex issues.
- In a given case, various possible courses of action should be assessed on their own merits, together with the associated (potential) positive and negative repercussions. The various options should be weighed up against one another in a careful and transparent manner.
- Proper consideration must be given to effects that cannot easily be quantified, and to matters such as the distribution of effects across population groups or between current and future generations.
- When choosing a course of action, account must be taken not only of the (sometimes limited) scientific evidence for each potential consequence, but also of the importance that people attach to the undesirable potential consequences of both excessive and insufficient caution.
- Appropriate stakeholder groups should be involved in the assessment and decision-making process associated with risk issues (risk governance). This will lead to the input of knowledge, experience and views from a wider range of sources, greater transparency and the formulation of policies that are more likely to command general support.
- Tools should be developed and personnel trained with a view to enhancing implementation of the challenging risk governance process.
- The outcome of implementation should be monitored as a basis for policy review and realignment in the light of new information, so that assessment and decision-making guided by the precautionary principle is a dynamic and iterative process throughout.
- The precautionary principle should be applied in all health-related policy domains: preventive and curative health care, environmental management, occupational health and safety and food.
- Make it common practice to apply the precautionary principle and create thus a culture, in which it is the norm for uncertainty to be addressed carefully.

Chapter 1

Introduction

1.1 Background

People have always had to prepare themselves against threats from the world around them. Natural forces, as well as one's own activities and those of other people, can all be hazardous to health and prosperity. Many external threats were once assumed to be under divine or supernatural control. Gradually, however, the perception grew that unwelcome events were not entirely manifestations of capricious fate or acts of God.[1] Yet proper explanations often remained elusive.

Lack of knowledge regarding the origins of danger and appropriate responses to its manifestation, coupled with uncertainty as to when and how 'fate' would strike, formed (and continue to form) the drivers for caution.

Over time, human understanding of the hazards that confront us and the best ways to control them has grown. However, the nature of the threats has been changing all the time, and never more so than in the last century, fuelled by developments in science and technology, together with the globalisation of economic and social activities. In many cases, insight into the causes of danger and the protective measures that may be taken is confined to a small group of experts. The average person therefore has little choice but to rely on these experts, and on the authorities that endeavour to protect the public against 'new' risks. Sometimes, however, these authorities prove to be ill equipped to perform this task.[3,4] So, for example, we have seen disasters at chemicals processing plants (Bhopal[5,6]), the contamination of food (mercury in fish[7]), the dispersal of disease

through global air traffic (SARS[8]) and the occurrence of unexpected adverse reactions to pharmaceutical products (Vioxx[9]).

Such events have helped to create an awareness of just how hazardous some activities can be. Consequently, there is for the most part general public support for risk control measures. Indeed, some people favour taking precautions wherever there is uncertainty regarding the nature and extent of a possible threat. Such an approach is advocated as preferable to waiting until the cause and effect relationships can be clearly defined, by which time the harm may already have been done. Intervention prior to the clarification of a causal mechanism has in the past saved many lives.[10]

A classic example is the removal of the handle from the water pump in Broad Street by the local authorities, on the advice of Dr John Snow during the second London cholera epidemic in 1854.[11,12] At that time, nothing was known about the spread of the responsible pathogen via the water supply. However, on the basis of his observations of other water sources, Dr Snow suspected that water contaminated with human waste was behind the epidemic. He considered the evidence sufficiently strong to justify removing the handle. This compelled people to make use of less convenient, but cleaner, sources of water. The local church authorities disregarded the health authorities' view (that the disease was due to air pollution) and followed Dr Snow's advice. Thus, although a causal link was suspected in 1854, it was another thirty years before scientists understood exactly how polluted water caused cholera.[13]

The proponents of early intervention in the event of illness or injury are essentially calling for the application of the precautionary principle. At the societal level, this also implies a careful approach to the development of new, potentially hazardous technologies.

The precautionary principle (*Vorsorgeprinzip*) was first adopted as a pillar of public policy in Germany and has since been incorporated into various international environmental treaties.[14-18] More recently, this principle has been embraced by the European Union[19,20] and has shaped the environmental policies of various countries, including France[21] and the Netherlands.[22] It is sometimes incorporated into local or municipal policy as well.[23]

Nevertheless, the precautionary principle remains a topic of debate at local, national and international level. Some commentators regard it as a sensible tool for the prevention of disaster, while others argue that it inhibits modernisation and progress. It is therefore pertinent to consider just what the principle implies, how widely applicable it is and how it should be applied in practice. Such deliberation gives rise to questions about the role of scientific knowledge. What course of action should we take if it has not yet been scientifically established

that something may be harmful? Against this background, it was decided that the Health Council should produce a report on the precautionary principle, with a particular focus on its use in public health policy.

1.2 The Committee's remit

The Health Council has a duty to promote public health by advising the Dutch government and parliament about public health matters, on the basis of the latest scientific knowledge. In the discharge of this duty, the Council has previously reported obliquely on the precautionary principle and on measures based upon it. The principle was considered, for example, in the reports on the influence of electromagnetic fields on health and on the safety of blood in connection with BSE and Creutzfeldt-Jakob's disease.[24-26] However, the Council has yet to examine this key principle in greater detail. In 2003, the President of the Health Council accordingly added the topic 'precaution and public health' to the Council's work programme. The Committee on Precaution and Health ('the Committee') was set up to address this issue on 3 February 2004. The requests for advice are contained in Annex A, while the committee members are listed in Annex B.

The Committee was given the remit of reviewing the application of the precautionary principle in public health policy. Although the precautionary principle is used mainly in the environmental and environmental health policy domains, the President asked the Committee to also consider its implications in the fields of occupational health and safety, health care and nutrition. The President posed the following primary questions:

1 How can the concepts 'precaution', 'precautionary principle', 'prevention' and 'prevention principle' best be defined?
2 How are the concepts 'precaution', 'risk' and 'uncertainty' related? Can a typology of risk assist decision-making in the context of a precautionary policy?
3 What similarities and differences exist in the way that a precautionary policy or the precautionary principle is applied in the fields of occupational health and safety, health care, the environment and nutrition?
4 What role does knowledge play in decision-making in the context of precautionary public health policy? What types of knowledge may be distinguished, where does the relevant knowledge come from, and by whom is its quality assessed?

1.3 Scope and methodology

Scope

The Committee has set itself the task of indicating what it believes the precautionary principle entails, and of identifying the types of issues to which it can be constructively applied. It also wants to offer a practical aid for the application of the precautionary principle in public health policy in the broadest sense of the term, i.e. for the policy domains of health care, working conditions, nutrition and environment. Finally, it attempts to clarify the issue of what the application of the precautionary principle can and cannot be expected to achieve.

In carrying out its task, the Committee has focused on government decision-making. It hopes, however, that the advisory report will be equally useful for local government bodies (at provincial and municipal level), knowledge centres (universities, research institutes, advisory boards), business and NGOs, in short all those involved in dealing with issues affecting the policy domains in question.

Methodology

In answering the question posed by the Council's President, the Committee has built upon the Health Council's earlier reports on dealing with risk.[27,28] It has also taken account of the findings of a background study into the legal demarcation of the precautionary principle, which was commissioned by the Council.[29] Naturally, the extensive body of literature on the precautionary principle provides a sound scientific basis for drawing up an advisory report with recommendations regarding the principle's application.

Because decision-making in this field must take account not only of scientific considerations, but also of value-based judgements, various community organisations were asked to provide information that could be of value to the Committee when formulating its advisory report. Details of that request and of the organisations that responded are listed in Annex C.

A draft version of the advisory report was reviewed by the Health Council's Standing Committee on Medical Ethics and Health Law and by the Standing Committee on Health and Environment. In addition, written feedback was obtained from representatives of the Council's other standing committees and a number of external experts, who are listed in Annex D. The Committee incorporated all the input and feedback into its final report as it saw fit.

1.4 Structure of this report

In chapter 2, the Committee sets out what the precautionary principle entails. This definition is based on an analysis of the main elements shared by the many definitions to be found in the literature. Particular attention is given to the issues of sustainability and establishment in law, to the relationship between the precautionary principle and other policy principles, and to the arguments put forward by proponents and opponents of the precautionary principle.

The central theme of chapter 3 is identification of the risk issues to which the precautionary principle may usefully be applied. The Committee begins by considering the concept of risk, before outlining developments in the management of risk, with particular reference to developments in governance. On the basis of several general characteristics of risk issues, it then provides an answer to the central question.

In chapter 4, the Committee considers how the precautionary principle can be applied to a specific issue, i.e. what the implications are for organisation of the assessment and decision-making process in a particular case.

In chapter 5, the Committee illustrates the use of its proposed approach with a number of practical case studies.

Finally, the Committee sets out direct responses to the questions posed by the President of the Council.

Chapter 2

A closer look at the precautionary principle

In this chapter, the Committee examines the precautionary principle more closely. To this end, an analysis is made of the main elements shared by the many definitions to be found in the literature. Attention is also given to the issues of sustainability and establishment in law, and to the relationship between the precautionary principle and other policy principles. Finally, the criticism generated by the principle's use is summarised.

2.1 Definition

List of definitions

Dworkin (cited in[30]) describes a principle as stating 'a reason that argues in one direction, but does not necessitate a particular decision'. Where the precautionary principle is concerned, the direction of the argument is towards a precautionary process of risk assessment and management, i.e. the anticipatory exercise of caution with a view to preventing something undesirable. It is worth considering what this means in practical terms.

A variety of definitions of the precautionary principle can be found in policy documents. Principle 15 of the declaration issued at the conclusion of the 1992 United Nations Conference on Environment and Development in Rio the Janeiro reads as follows:[31]

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

In the context of the principle's application within the European Union, the European Commission's communication on the precautionary principle is important[19] This document contains a detailed treatise on the principle's significance and use within EU policy, but does not provide a definition in the strict sense of the word. According to European jurisprudence, the precautionary principle implies the following:[32]

> Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.

For its part, Article 7.1 of the EC regulation laying down the general principles and requirements of food law states:[33]

> In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

In addition to this definition, there are numerous others in policy documents of varying degrees of formality,[34,35] in the publications of advisory bodies[36,37] and interest groups[38] and in the scientific literature.[39]

A recent definition that the Committee found particularly useful in its deliberations was that of the European Environment Agency:[40]

> The precautionary principle provides justification for public policy actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act in order to avoid, or reduce, potentially serious or irreversible threats to health or the environment, using an appropriate level of scientific evidence, and taking into account the likely pros and cons of action and inaction.

Constituent elements of the definitions of the precautionary principle

A number of authors have made more detailed comparative analyses of the definitions of the precautionary principle by reference to their constituent elements[41,42] The Committee follows Sandin in recognising four elements:[42]

- The element of threat
- The element of uncertainty
- The element of action
- The element of command.

The various definitions differ little with regard to the first two elements. They all refer to circumstances in which the harm to human health or the environment may be serious, but the precise nature, extent and likelihood of such harm remain uncertain. For the most part, it is implicitly assumed that the threats in question are plausible.

More difference exists where the element of action is concerned. Some definitions make clear requirements, relating to aspects such as cost-effectiveness, proportionality, provisionality or the comparison of options. Others state only that action must be protective.

The definitions also differ significantly with regard to the command element. Some make action a requirement, while others simply state that uncertainty regarding the existence of a causal relationship is not a valid reason for inactivity. On the basis of differences in terms of the obligation to act and the nature of the measures to be taken, the literature does in fact draw a distinction between 'strong' and 'weak' approaches.* Other authors make the point, however, that strength is ultimately dependent on the practical interpretation of all four elements,[44,45] with the definition being as strong as its weakest element.[42] As a result, strong and weak versions of the principle do not necessarily lead to different decisions in practice.

2.2 The moral context

The World Commission on the Ethics of Scientific Knowledge and Technology, a body set up by UNESCO, uses the following working definition of the precautionary principle:[46]

* In this context, Sandin prefers the terms *prescriptive* and *argumentative*, since the difference involved is one of kind rather than degree.[43,44]

Precautionary Principle, a working definition. When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm. *Morally unacceptable harm* refers to harm to humans or the environment that is – threatening to human life or health, or – serious and effectively irreversible, or – inequitable to present or future generations, or – imposed without adequate consideration of the human rights of those affected. The judgement of *plausibility* should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review. *Uncertainty* may apply to, but need not be limited to, causality or the bounds of the possible harm. *Actions* are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.

The UNESCO committee indicated that the precautionary principle has an 'ethical basis'.[46] Strictly speaking, precautionary action does not necessarily have such a basis. It could be based on something other than moral considerations. When deciding between different courses of action, application of the precautionary principle should prevent too little weight being given to plausible but uncertain repercussions which, should they occur, would be considered extremely undesirable or unacceptable by the individual or agency involved in making these choices. However, the principle is often used in the context of decision-making processes that are shaped, at least partly, by ethical considerations The UNESCO definition clearly assumes (as most of the other definitions implicitly assume) use of the principle in such a context. The precautionary principle may, therefore, be said to have an ethical basis. The object is to prevent insufficient weight being attached to the ethically undesirable or unacceptable consequences of policy options on account of them being uncertain (although plausible).

As the UNESCO definition indicates, a consequence is undesirable or unacceptable if it contravenes principles such as 'non-maleficence', 'justice' and 'respect for others' (including those as yet unborn). Naturally, it is important to recognise that application of the precautionary principle can also have an ethical cost. It may result, for example, in the rejection of policy options that have important potential benefits (that adhere to the principle of 'beneficence'). Such consequences are, of course, ethically relevant in the context of policy formulation as well. The precautionary principle does not imply a denial of this truth. Instead, in situations where there is uncertainty about morally undesirable or unacceptable outcomes, it seeks to ensure that such potential benefits do not determine events in advance.

The drive for participation, as expressed in the UNESCO definition, is in keeping with discourse ethics[47]. This states that every possible voice and interested party should engage in the debate on an equal footing, and that careful consideration should be given to each and every argument.

The precautionary principle and sustainability

In the late 1970s, prompted by a fear of the potentially serious consequences of ongoing technological developments, the German philosopher Hans Jonas formulated a new ethical imperative, which is also known as the 'ecological imperative'.[48] This states that no actions should be taken whose effects are inconsistent with the survival of human life on Earth. Almost all the authors who have written on this subject suggest that the precautionary principle is allied to this desire for sustainable development.[31,49-53] The principle may be seen as a policy response to serious threats to our environment.[54] 'Sustainability' became a topical concept following publication of the Brundtland Report in 1987, which defined it as:[55]

> development that meets the needs of the present without compromising the ability of future generations to meet their own needs.

According to the Brundtland Committee, sustainable development requires an integration of economic development, the tackling of social inequality and poverty, and the maintenance and protection of the natural environment.

Sustainable development programmes therefore tend to place considerable emphasis on ensuring that responsibility for the consequences of action is not shifted by individuals onto the group, by one group onto another or by the present generation onto future generations.[56,57] A recent declaration by the Council of the European Union also indicated that the precautionary principle is helping to shape concrete sustainable development objectives involving protection of the environment, the promotion of social equality and cohesion, economic progress, and the fulfilment of international commitments.[56,57]

In accordance with the notion of sustainable development, protection of the environment and of human rights are increasingly seen as complementary objectives, as illustrated by UNESCO's working definition of the precautionary principle.[46] So, for example, environmental protection policy – the cradle of the precautionary principle – has extended human rights to include environment-related rights such as the right to clean water and a clean environment and the right to access to safe food and water, which derive from the fundamental right to life. It may therefore be argued that the precautionary principle plays an indirect

role in the protection of human rights: if the precautionary principle is regarded as a tool for controlling an activity's potential to cause harm, it may also be seen as a tool for minimising the infringement of human rights that would arise from such harm. This view of the precautionary principle is acknowledged in the literature, where it is argued that human rights are inherently related to dealing with uncertainty and taking precautionary action and where the 'green' interpretation of human rights is advanced.[58*]

2.3 Establishment of the principle in law

The precautionary principle is increasingly becoming established in law. This development is apparent from the many declarations, resolutions and guidelines that now incorporate the principle. It is, for example, embraced by more than sixty important international agreements on environmental protection.[46] However, the breadth of the principle's validity and its practical import depend to a significant extent on the wording and interpretation of the relevant statutes and treaties. Differences of opinion apparently exist with regard to a number of legal points.[29]

Breadth of validity

There is disagreement in the international literature as to whether the precautionary principle should be regarded as a binding legal principle, or a guiding principle. In the EU context there is a greater degree of consensus, with most experts seeing the precautionary principle as generally binding, both within the environmental policy domain and elsewhere. This view is related to the European Commission's interpretation, as expressed in its communication on the precautionary principle[19] and the jurisprudence of the European courts[**].

The jurisprudence of the European courts showed that it is not only European institutions who can make use of the precautionary principle, individual member states can also use it as a basis for action.[***] Nevertheless, there is still a lack of

* See also Guideline 2 of the Precautionary Principle Project (an EU funded partnership between several NGOs exploring the application of the Precautionary Principle to sustainable development, biodiversity conservation and natural resource management) that favours a joint application of the precautionary principle with other principles and rights, such as human rights (www.pprinciple.net).

** See Case C180/96 (United Kingdom of Great Britain and Northern Ireland v. Commission of the European Communities) Jur. 1998, I-2265, Case C-157/96 (The Queen v Ministry of Agriculture, Fisheries and Food) Jur. 1998, I-2211.

*** See also Case C-236/01, *Monsanto Agricoltura Italia SpA et al. v. Presidenza del Consiglio dei Ministri et al.*, Jur 2003, I-8105.

clarity concerning the extent to which the various national legal regimes will permit the precautionary principle to be invoked. There is no general agreement as to the breadth of its legal validity in the Netherlands or Belgium, for example. Binding force is deemed to depend primarily on the principle's establishment in law. In the Netherlands, a number of legal experts have already made proposals to this effect. Nevertheless, the Dutch administrative courts currently appear to allow competent authorities to apply the precautionary principle when deciding whether to grant permits required under the Environmental Management Act. Belgium now has one federal law based upon the principle, namely the Marine Environment Protection Act. Jurisprudence indicates that the precautionary principle's legal validity is becoming ever broader in that country.[29]

Burden of proof

Many see it as inherent to the application of the precautionary principle that the burden of proof with regard to the safety of a product or activity rests with the entrepreneur or producer in question. This view is disputed, however, on the grounds that it is theoretically impossible to prove that something is harmless and that such an inversion would inhibit progress by placing an unreasonable burden on manufacturers. In practice, the Community courts do not currently place the burden of proof on the producer, but on the authority that has used or seeks to use the precautionary principle as a basis for action. If it is demonstrable that the risks have been scientifically assessed 'as thoroughly as possible', thus yielding 'sufficient' scientific evidence to support an objective scientific conclusion, the producer must provide counter-evidence sufficient to refute the authority's evidence if the precautionary action is to be stopped or prevented.[29]

Procedural principle

It is apparent from the literature and from jurisprudence that, legally speaking, the precautionary principle is regarded primarily as a procedural principle. This is reflected primarily in EU and national law. Viewed in this way, the precautionary principle implies that, when decisions are taken regarding potential hazards, all interests should be weighed up against one another, with a view to arriving at a conclusion that is consistent with the principles of good governance, such as proportionality, care, openness, the participation of interested parties, scientific objectivity and proper justification. Particular importance is attached to the way in which the underlying scientific advice is formulated and to the make-up of the scientific advisory bodies concerned. The job of the court is then to establish

whether the decision-making process provides the necessary procedural assurances and whether the authorities' decision has been arrived at reasonably.[29]

2.4 Relationship to other principles

The precautionary principle is not the only principle that plays a role in assessing and managing risks. For an overview of the principles that govern the management of environmental risks, the reader is referred to the books by De Sadeleer[59], Beder[60], and Backes[61]. In this section, the Committee considers two principles that are closely related to the precautionary principle: the prevention principle and the ALARA principle.

Relationship to the prevention principle

In the literature and in legal texts, the precautionary principle is often closely associated with the prevention principle. Both of these principles – and others – were cited in the Treaty establishing the European Community, and in all EC treaties since the Treaty of Maastricht,[62, 63] The principle that problems should be tackled at source may be regarded as a version of the prevention principle.[59] In the Netherlands, prevention at source has been introduced into the Environmental Management Act and into the Occupational Health and Safety Act.[64,65] Under these statutes, damage to health and to the environment has to be prevented wherever possible, rather than rectified afterwards.[66]

The prevention principle and the precautionary principle are often linked, since both are applied with a view to preventing harm, where possible by tackling problems at source. There is nevertheless an important difference between them. Preventive action entails acting to protect against real dangers whose associated risks are often easily quantified. In other words, prevention is characterised by the knowledge that, without counteraction, a hazard will manifest itself and harm will be done at the population level. By contrast, precautionary action involves taking protective action even though it may be unclear whether, without such action, harm will occur[67]. So, with precautionary action, there is always uncertainty about the need for – and therefore the efficiency of – the protective action, because it is not known how real the danger or risk is. Precautionary action may therefore also involve measures that are aimed at reducing uncertainty.

Application of the prevention principle requires that there is sufficient knowledge concerning the causes (i.e. the hazards in combination with the exposures) to be able to assess and manage the risks to people and the environment

associated with particular activities. The precautionary principle may be applied, however, if causality is merely plausible. Knowledge about causality is usually subject to more stringent requirements in the case of prevention than in the case of precaution. Accordingly, the prevention principle can be seen as less comprehensive than the precautionary principle.[59,66] However, precaution and prevention can also be seen as different stages in the process of tackling the risk involved. In practice, people undertaking preventive action often have little or no knowledge of specific aspects, as a result of which they resort to precautionary action. Conversely, the availability of new knowledge can cause elements of precaution to give way to prevention. Certainty and uncertainty are two ends of the same continuous scale. Accordingly, instead of being clear-cut, the boundary between preventive and precautionary action is a zone of gradual transition. Prevention and precaution lie at removed points on a continuum.

Relationship to the ALARA principle

In some publications, the ALARA principle is referred to as an expression of the precautionary principle[68,69] The acronym ALARA stands for 'As Low As Reasonably Achievable'. Generally speaking, the principle implies that action should be taken to reduce a risk, unless the expectation of action would be unreasonable. Whether it is reasonable to expect action depends on the cost relative to the benefit likely to accrue from the reduction of risk. Reasonableness therefore depends not only on economic factors, but also on societal considerations concerning the risks and the risk-engendering activity. The principle - which is established in Dutch environmental and occupational health and safety legislation - is examined in more detail in Annex E.

The ALARA concept originates from the field of radiological protection. It was developed on the assumption that there is no threshold level of exposure to ionising radiation below which there is absolutely no risk of cancer or inheritable health impairment. From its radiological origin, the concept was adopted in the management of industrial accident risk, particularly in the Netherlands and the United Kingdom.[70-72] In both fields, ALARA may be seen as a mechanism for dealing with the uncertainty associated with plausible, serious threats, albeit in situations where the risks were believed to be quantifiable with reasonable confidence. However, uncertainties about the risks involved make it difficult to find an appropriate relationship between the cost of risk-reducing measures and the benefits of possible risk reduction. In the field of radiological protection, therefore, the principle has evolved from a cost-benefit consideration into a collection of practical methods that have been developed within a culture of awareness of,

and concern for, possible adverse consequences for people and the environment.[68,73]

Hence, it follows that there is a difference between the ALARA principle and the precautionary principle. ALARA usually applies in the context of activities that are considered to be justified because of their potential benefits to society, even though they may also have disadvantages. In other words, an assessment of the relevant activities and a decision regarding their implementation has already been taken.

2.5 Debate regarding the advantages and disadvantages

Although the precautionary principle has entered use in many parts of the world and in various policy fields, considerable disagreement persists regarding its value and utility. In this section, the Committee briefly summarises the main criticisms levelled at the principle.

Arbitrariness

Some commentators regard the precautionary principle's establishment in jurisprudence and policy as a worrying development.[74,75] They argue that this development opens the way to arbitrary decision-making, because the principle is not clearly defined. As things stand, the precautionary principle is often applied on an *ad hoc* basis, rather than in the context of a structured decision-making process.[76] There are no clear criteria for its application.[77] When is there sufficient evidence to justify application of the principle, or, conversely, to decide that the principle does not have to be applied? The same applies to the potential threat. When is it sufficiently serious to necessitate action, and what form should such action take? Other authors have responded by arguing that all decision-making entails such problems, whether the precautionary principle is applied or not[42] Nevertheless, it is generally recognised that the process of putting the precautionary principle into effect would benefit from its further specification by reference to the elements referred to above (threat, uncertainty, action and command).[42,44]

Unscientific thinking

It has also been suggested that the precautionary principle promotes unscientific or even antiscientific thinking: application of the principle is liable to lead to the displacement of science by the perceptions (or misperceptions) of people who lack appropriate expertise, or by forms of belief.[78-80] Opponents of the principle

fear that it may be abused to constrain trade in situations where there is no scientific basis for believing that there is any risk to health or the environment.[81] In this context, the disagreement between the EU and the USA regarding the use of hormone preparations in livestock farming to increase meat production is often cited as an example.[82]

Proponents of the precautionary principle endorse the view that its use should be conditional on some evidence of possible harm. In this connection, the European Commission's communication on the precautionary principle speaks of 'well-founded reasons'.[19] Proponents of the principle stress the benefit of an approach that recognises the uncertainties and gaps in scientific knowledge. History, they argue, has shown that activities that appear to entail negligible risk at the outset can ultimately lead to substantial environmental and health damage.[13] The mistakes made in the past, when early warnings that certain activities might be harmful were disregarded as 'scientifically unproven', should not be repeated.

In this context, it is important to distinguish between two types of mistake that can be made in scientific research. First, researchers may conclude that a particular phenomenon or effect is liable to occur, when that is not in fact the case. This is known as a false positive result or a type-I error. Second, a genuine phenomenon or effect may be overlooked. This is called a false negative result or a type-II error.

Researchers often tend to concentrate on avoiding false positive results, even though this is liable to increase the risk of false negatives.[43] The reason being that scientists seek to generate 'genuine' knowledge, and therefore set themselves high evidential standards. However, in the context of societal decision-making, policies based on false negative results are at least as undesirable. Allowing a harmful substance onto the market, because research has failed to detect or prove that it is harmful, is clearly undesirable. Asbestos and thalidomide are cases in point. Some therefore argue that the burden of proof should be placed on the entrepreneurs in question. Those looking to market a product should be expected to prove that it is safe.[83,84] Even the proponents of such an approach nevertheless accept that a very strict 'guilty-until-proven-innocent' principle would be unworkable; rather, what they want to see is an obligation that the safety of a given practice should be convincingly demonstrated.[83]

Societal stagnation

In view of the considerations outlined above, it is suggested by some that application of the precautionary principle results in risk-averse decision-making and therefore in unnecessary stagnation. The fear is that the restraint of technical

progress for fear of perceived threats is liable to lead to societal inertia and thus to genuine harm.[74,85,86]

The argument runs that innovation is a societal necessity that inevitably entails risk, and that such risk is a normal part of the societal learning process.[74,87] The precautionary principle is accused of taking no account of the benefits of certain developments, or of the direct and indirect cost of precautionary action (the assumed 'health-health trade-offs' of regulation). In consequence, it is not seen as a basis for meaningful cost-benefit analysis.[88]

In support of this line of reasoning, it is often pointed out that the ban on DDT has led to a rise in malaria problems in developing countries.[89,90] Those who are critical of the precautionary principle also emphasise that the allocation of resources to protection inevitably has implications for the availability of resources for other activities.[91]

The counterargument is that the precautionary principle actually promotes innovation, because its application obliges people to find less harmful ways of meeting society's needs.[92] For example, with reference to the precautionary principle, President Sarkozy of France recently said:[93]

> Proposer sa suppression au motif qu'il briderait l'action repose à mes yeux sur une grande incompréhension. Le principe de précaution n'est pas un principe d'inaction. C'est un principe d'action et d'expertise pour réduire l'incertitude. Le principe de précaution n'est pas un principe d'interdiction. C'est un principe de vigilance et de transparence. Il doit être interprété comme un principe de responsabilité.*

The principle's advocates accordingly argue that it is not sufficient to demonstrate that a risk is acceptable. In their view, the precautionary principle can be used to favour those technological developments that result in the least harmful products and services.

2.6 The Committee's view of the precautionary principle

The Scientific Council for Government Policy (WRR), has described the precautionary principle as a normative concept that is motivated by risk avoidance in situations of great uncertainty.[94] The word 'risk avoidance' suggests that, in situ-

* Proposals to abolish this on the grounds that it would curb activity are, in my view, based on a serious misconception. The precautionary principle is not a principle of inactivity. It is a principle that implies activity and the deployment of expertise with a view to reducing uncertainty. Nor is the precautionary principle a principle of prohibition. It is, rather, a principle of alertness and transparency. It should be seen as a principle that emphasises responsibility.

ations of great uncertainty, the precautionary principle requires that more weight should be attached to the possible adverse consequences of human action than to their benefits. That is also the message of Jonas's *Prinzip Verantwortung* which firmly contents that possible adverse consequences should weigh more heavily than any positive ones (designated as the heuristics of fear).[48] The most extreme example in this regard, is the Maximin rule of classical decision theory. This is just one of the many decision rules that can be used if uncertainty makes it impossible to assign probabilities (chances of occurrence) to effects. This decision rule is often associated with the precautionary principle. It stipulates that the decision should only be based on the possible adverse consequences, and that no heed should be paid to the benefits. The preferred course of action should be the one that has the least adverse impact. This approach is regarded as very pessimistic. It is considered to be especially useful for decisions where there is a great deal to lose and relatively little to gain.[95]

In the view of the Committee, however, there is no element of risk avoidance in the precautionary principle, at least not in the sense that risks – by definition – should carry more weight than benefits, and certainly not in the sense that risks should be avoided at all costs. Indeed that is not possible, as abandoning benefits to avoid particular risk may entail yet other risks. For instance, failing to vaccinate children due to concerns about possible neurological damage caused by the mercury-containing preservative thimerosal in vaccines results in an increased risk of infectious diseases.[96] The Committee therefore feels that the only course of action in situations where a decision is required is to assess all the viable options (together with their certain and uncertain consequences) on their merits and to consider which choice, on balance, is best for society. An ever-present challenge in this regard is the problem of achieving a fair distribution of costs and benefits across the different population groups.

It goes without saying that, if the potential loss is catastrophic while the potential gain is more or less limited, then more weight should be assigned to the risks than to the benefits, even if the latter are considered more likely. That is not because risks outweigh gains by definition, but simply because of the difference in scope or severity. In that sense, therefore, the Committee sees the precautionary principle less as a decision rule and more as a strategy for dealing with uncertainties carefully, reasonably and flexibly (i.e. in a way that is tailored to the situation in question).

This interpretation is very much in keeping with the legal perspective of the precautionary principle that has already been outlined here (see section 2.3). It also matches Steele's view, which is that the precautionary principle can best be understood as a broad guideline for formulating or specifying a decision prob-

lem. She sees it as a supplement to decision theory, rather than an alternative. It emphases aspects which, in real-world decision-making, are often neglected.[53]

Gardiner is critical of this interpretation of the precautionary principle, which he refers to as the 'purely procedural precautionary principle' (PPPP).[97] He describes it as empty, as - in his view - it provides no direction in decision-making. It neither facilitates the process nor leads to better decisions. It does nothing to resolve the shortcomings of policymaking on the basis of cost-utility analysis nor, most importantly, does it have any benefits in terms of protecting the environment. The Committee does not concur with this criticism. Even if a precautionary principle of this kind neither provides any clear direction in decision-making nor facilitates the inevitable and difficult process of weighing up the pros and cons, it nevertheless offers some guidance in determining the way forward. If all-out efforts are made to identify uncertainties and attempts are made to deal with these in a careful and reasonable way, then this must be reflected in better and more transparent decisions. It avoids situations in which benefits that are confidently expected to accrue in the short term too easily outweigh drawbacks that are considered to be less likely and which often involve effects that are only evident in the longer term. What is needed is a culture in which uncertainties are dealt with alertly, carefully and flexibly – such as the one that is emerging in the area of radiation protection under the influence of the ALARA principle (see Annex E). Although this will not entirely protect society from unpleasant surprises, it will make them less likely, while also ensuring that intervention occurs at an earlier stage, thereby limiting any damage.

The Committee takes the view that this interpretation of the precautionary principle invalidates much of the criticism (cited in the previous section) that has been levelled against the principle. The Committee discusses the specific details of its implementation in chapter 4. First it explores the question of what constitutes a risk and which risk issues lend themselves to the application of this strategy.

2.7 Conclusions

The definitions of the precautionary principle are many and varied. They mainly differ in terms of the requirements that apply to actions against plausible threats and the extent to which an obligation to act is implied.

Numerous definitions of the precautionary principle are in use. Analysis of these definitions based on four common elements indicates that they are quite similar with respect to the elements of threat and uncertainty. The precautionary princi-

ple always relates to serious, plausible threats, whose nature, extent and likelihood of manifestation are uncertain. The definitions mainly differ in terms of the extent to which an obligation to act is implied and the requirements that apply to such action. None of the definitions specifies the nature of the action to be taken to any significant degree. The Committee regards the definition of the precautionary principle formulated by the European Environment Agency (EEA)[40] as particularly useful.

The principle is often applied in a context where moral and legal considerations play an important role.

The precautionary principle is often associated with sustainability and, increasingly, with human rights as well. In law, the precautionary principle is seen primarily as a procedural principle, which finds expression mainly in EU law and national law.

Two related principles are the prevention principle and the ALARA principle. They cannot be clearly distinguished from the precautionary principle.

In addition to the precautionary principle, policymakers use other principles to prevent damage to human health, the environment or goods. Foremost among them is the prevention principle, which differs from the precautionary principle in that it is concerned with known threats, where the causal mechanisms are adequately understood. The dividing line between prevention and precaution is blurred, just like the one between certainty and uncertainty. The ALARA principle serves to reduce exposure to (potentially) harmful influences, insofar as reasonably possible. Because of the cautious approach taken to uncertainty in the application of this principle, it has over the years evolved from a cost-benefit analysis principle into a range of tools that can be flexibly applied to give shape to a tacit precautionary principle.

The Committee sees the precautionary principle as a strategy for dealing with uncertainties in an alert, careful, reasonable and transparent fashion, that is tailored to the situation at hand.

Much criticism has been levelled at the precautionary principle. It is perceived in some quarters to be too vague and to promote arbitrary decision-making, to be unscientific and – due to its focus on risk avoidance – to inhibit progress. How-

ever, the Committee takes the view that the precautionary principle does not necessarily cause more weight to be attached to risks than to benefits. In that sense, therefore, it does not view this principle as a decision rule. In accordance with the legal perspective, the Committee sees the principle more as a strategy for dealing with uncertainty in an alert, careful, reasonable and transparent fashion. This view negates many of the cited criticisms. As a result, it matters little exactly what definition is used.

Chapter 3

Selection of relevant risk issues

Which risk issues lend themselves to application of the precautionary principle? This question forms the main focus of this chapter. First, the Committee outlines the main developments in dealing with risks. It then classifies risk issues on the basis of various characteristics and identifies issues to which the precautionary principle may usefully be applied in order to guide the processes of assessment and decision-making.

3.1 New ways of dealing with risk

Risks

The concept of risk grew in prominence during the twentieth century. The term is used in various senses, amongst which there is considerable overlap, both in everyday life and in scientific disciplines such as epidemiology, psychology and economics.[98] Almost all definitions of the concept make reference to potential and to consequence or harm (i.e. a negative consequence). Rosa proposed the following very general definition of risk, which covers the spectrum of perspectives:[99,100]

A situation or event in which something of human value (including humans themselves) has been put at stake and where the outcome is uncertain.

The uncertainty may include both the nature of the outcome and the probability that it will occur.* Rosa's definition stresses that risk exists only if something of value is at stake.

Risk arises when there is exposure to a hazard, or the possibility of such exposure. A hazard is a characteristic of, for example, an appliance, product, working method, procedure, animal, plant or natural phenomenon, which is inherently threatening, i.e. capable of causing harm under certain circumstances.** In other words, risk may derive from natural processes, human activities or a combination of the two. The mechanism of harm may involve an accident or an undesirable (and often initially unsuspected) side-effect of a process that operates according to plan. Examples of the latter include the discharge of substances and energy (heat) into the environment by power plants and processing industries, and the development of resistance to antibiotics or pesticides.

Over the years, scientific and technological developments, population growth and globalisation have changed the nature of the risks to which people are exposed. Many 'new' risks are not confined to particular places or times, but affect large areas of the Earth. Furthermore, the associated damage is often irreversible, or very difficult to reverse. In the face of such risks, traditional responses, such as insurance and liability, are often found wanting.[101] Risks that come under this heading include the greenhouse effect, the 'hole' in the ozone layer, urban air pollution, hormone disruption and BSE.[102]

Technological development and the associated risks have come to shape relationships in our 'risk society'.[3] At the same time, it has become harder for the general public to fully understand the nature of the threats that they face. Indeed, governments and 'experts' find it increasingly difficult to specify and manage such risks. As a result, people have less faith in the bodies that have the job of protecting public health and safety. It is worth noting, however, that the inevitable presence of hazards and risks within society is not purely negative: they also provide an incentive for innovation and technological development.

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* The literature sometimes distinguishes between the concepts of 'risk' (in the strict sense: known effects with known probabilities), 'uncertainty' (known consequences with unknown probabilities) and 'ignorance' (unknown consequences with, of course, unknown probabilities).[13] The term 'risk', as used by the Committee, combines these three concepts.

** Hazard classifications, such as the IARC classification system for carcinogenic agents, retain a degree of uncertainty and can reveal gaps in knowledge.

After the Second World War, human activity became an increasingly important determinant of risk, as the products of science and technology entered general use at an ever increasing rate and on an ever increasing scale.[103] This led to a growing need for ways of estimating the likelihood of a risk manifesting itself and the nature and seriousness of the consequences.

Quantitative risk analysis is a technique that was developed in response to this need. It makes use of cause-effect chains to describe how material and energy can be released and how harm can be done to human health and the environment.[27,104] In the Netherlands, a system of standards and testing was developed, with a view to providing the business community with legal certainty and providing the public with a uniform minimum level of protection.[105]

This approach appeared to provide scientifically-based certainty. Furthermore, the results of the analyses appeared to provide a basis for the comparison of risks of various kinds. They also facilitated rational decision-making about the acceptability of apparently hazardous activities, and about the nature and extent of the action needed to keep the risks within acceptable bounds. Quantitative risk analysis became established not only in the environmental policy domain, but also in the field of occupational health and safety and the field of food safety.

In recent years, it has become clear, however, that quantitative risk analysis has its limitations. First, it is concerned purely with the probability of health damage and material damage occurring, and with the nature and extent of such damage. Because risk estimation inevitably involves a degree of uncertainty, a raft of methods has been developed in order to provide ‘certainty’ about such uncertainties, including methods for using the opinions of experts to build up a picture of (and reduce the uncertainties or gaps in) knowledge.[106,107] The perspective of risk analysis is such, however, that it is inevitably confined to a small part of the entire body of information about risk, i.e. to that information which scientists consider sufficiently reliable and which is to some degree quantifiable. This has led to criticism of the quality of risk analyses and reduced scope for using the results as a basis for policy development and decision-making in the management of risk.[108]

Furthermore, psychological research has demonstrated that the way people view a risk-engendering activity and, therefore, the risk itself is shaped by more than simply the likelihood and extent of the associated adverse consequences. That includes the ability to influence the consequences, the person’s confidence in the willingness and ability of government and the business community to accept responsibility, and the individual’s degree of choice regarding exposure to

risk.[109-111] Opinion is also shaped by the degree of familiarity with the risk-engendering activity and the extent of personal involvement. It is not so much a lack of understanding of the nature and causes of a risk which determines the significance that people attach to these other aspects.[112,113] In today's 'risk society'[3] the acceptance of a risk policy and of decisions concerning risk-engendering activities depends on the existence of a reliable system of *risk governance* (see below).[114,115] In such a system, the way uncertainty is dealt with[108,116] is accorded particular importance, scientists and other experts recognise the limitations of their expertise[52,102], and the concerns of ordinary people regarding their surroundings are not quieted by a simple reassurance from an expert.

Governance as a vision of modern risk policy

The government increasingly seeks to arrive at policy decisions in consultation with stakeholders. The manifestation of such governance[117] in the regulation of risk is referred to as risk governance. In this context, the Committee adheres to the definition given in the recent Health Council advisory report on nanotechnology:[118]

> By governance, it [the Committee that produced the report on nanotechnology] means the structures and processes for collective decision-making, which involves government as well as private-sector institutions and bodies.[114] These include companies for example, or sector umbrella organisations, employer and employee organisations, professional groups, consumer and patient organisations and organisations concerned with wildlife, the environment and animal welfare. This all reflects the fact that decisions in modern society are no longer taken by governments in a 'top down' fashion. Instead, they are arrived at in networks incorporating all the parties concerned. The application of such ideas to risks and risk-related decision-making is termed risk governance.

The introduction of the concept of governance into the domain of public administration is an acknowledgement that many of the issues facing society are complex, that there is uncertainty concerning many cause-effect relationships and that the cooperation of a variety of actors is required to arrive at solutions that will be generally accepted. Certain universal values are also important in this context, such as inter-individual equity and the right to development of future generations.[31,119] Within the United Nations, associated criteria for *good governance* have been defined: good *governance* is participative, lawful, transparent, demand-led, consensus-seeking, fair and open, effective and efficient, and publicly accountable.[120,121]

The benefits of stakeholder-participation include greater support for the decisions that are made, better-quality assessment and decision-making processes and thus better-quality decisions, and stronger democracy. Participative or interactive assessment and decision-making may be realised by various methods. In this context, the Committee would like to highlight a study by the Scientific Council for Government Policy[122], reports on the various case studies carried out for the Trustnet programme[123], and a report on risk characterisation by the US National Academy of Sciences.[124] Various methods have been systematically described in the form of a users' manual by the viWTA in Flanders[125] and the Netherlands Environmental Assessment Agency (MNP).[126]

The vision of governance set out above ties in with the working definition of the precautionary principle produced by the UNESCO body referred to earlier (see section 2.2), which stipulates that precautionary action should be decided upon by means of a participative process.

3.2 Obstacles to – and strategies for – dealing with risk issues

Three challenges involved in dealing with risk issues

For policymakers, it would be helpful to identify specific issues to which they can usefully apply the precautionary principle. In order to provide such information, it is necessary to first identify the characteristics that can complicate the assessment of a risk issue and the associated decision-making process to such an extent that a routine, purely rational-analytical approach ceases to be sufficient. The Committee follows Renn[114] in believing that three characteristics are particularly challenging in this context:

- ambiguity
- uncertainty
- complexity.

Ambiguity is a result of divergent and contentious views on the justification, severity or broader significance of a given threat.[114] In everyday usage, the term can have different meanings, but in relation to *risk governance* it means 'giving rise to several meaningful and legitimate interpretations of accepted risk assessment results.' Renn distinguishes between normative and interpretative ambiguity.[114] The first form relates to different views about what is acceptable from an ethical perspective, for example with regard to the quality of life or the distribution of benefits and risks throughout the population. The second relates to differing interpretations of identical research results. For example, should changes in

receptor densities within the brain or in certain immune parameters be seen as harmful? What value can be attached to the results of toxicology studies in animals when the issue essentially relates to human health? Any differences in interpretation and value allocation in this regard largely derive from a lack of knowledge about the significance of molecular changes to the health of the organism and about the extent to which data from experimental animal studies can be extrapolated to humans. Accordingly, the Committee believes that interpretive ambiguity represents a transitional area between normative ambiguity and uncertainty.

Uncertainty refers to the lack of scientific certainty concerning hazards, levels of exposure and therefore risk, and consequently the nature and extent of the harmful effects that might occur, or the likelihood of their occurrence. Various sources of uncertainty can be identified.[127] Firstly, uncertainty can arise from variability in the phenomena in question. These include variability in natural phenomena, in the behaviour of individuals, in social phenomena, and in technological developments and their effects. This kind of uncertainty is referred to as ontological uncertainty.

Secondly, uncertainty can arise from the limitations of our knowledge. This kind of uncertainty is termed epistemological uncertainty. This can take various forms, ranging from measurement errors, lack of observations or measurements, and contradictory research results, to irreducible ignorance. In the latter case, this involves processes (or interactions between them) which are too complex for us to grasp.

Finally, complexity is an expression of the difficulty of developing a clear picture of the risk on the basis of the available information. There may be numerous possible causative factors and a variety of specific observed effects.[114] Causal relationships may be difficult to discern or quantify – due, for example, to interactions between the various causes, long delays between cause and effect, the hidden development of effects, inter-individual variation or other complicating factors. In many cases, the involvement of various scientific disciplines is necessary for the proper definition of an issue.

The dividing line between complexity and uncertainty is far from sharp, like that between uncertainty and ambiguity. Moreover, the three characteristics are not necessarily independent of one another. Uncertainty often results from the failure to reduce or eliminate complexity when modelling cause-effect chains. In turn, great complexity and uncertainty provide scope for differences of interpretation and valuation, thus facilitating the emergence of ambiguity (although they are not a necessary precondition for this process). Conversely, ambiguity can give rise to uncertainty.

Three strategies

Each of the three identified characteristics requires a separate approach, featuring a specific level of stakeholder participation.[114,128] Where there is ambiguity, a consultation and debate-based strategy is required. The challenge here is accommodating people with different beliefs, different ideas about what is worth protecting and different views on what constitutes a good life and a healthy society. Questions such as 'Should everything that is possible be permitted?' and 'How far do we want to go?' need to be explored. In a pluriform society like ours, such questions provoke considerable debate, as we have seen in the past in connection with nuclear power, agricultural biotechnology, the creation of human embryos as a source of stem cells, and reproductive technology. Issues that are characterised by ambiguity require the most comprehensive form of participation, involving not only direct stakeholders, but also the general public. The object of consultation should be the definition of common values, the promotion of mutual understanding for divergent views and the identification of options that enable people to realise their own visions without compromising those of others.

As the Committee contended in the previous chapter, application of the precautionary principle is the best strategy for dealing with substantial uncertainty. The existence of plausible but uncertain threats, while the actual dimensions of the risk are unknown, calls for caution. It is useful to distinguish between two different starting points here, those in which a problem already exists, and those in which a problem is anticipated.[94] In the first case, the impossibility of obtaining absolute certainty about causes and effects could lead to inaction and a lack of initiative. The precautionary principle breaks that deadlock by recognising that, despite the uncertainty, appropriate action is needed. In the second situation, the precautionary principle dictates that a product or technology should be introduced in small steps. This approach makes it possible to stop or even retrace these steps should new knowledge so require or if initial, unacceptable adverse effects start to become apparent. This approach makes it possible to learn from small-scale mistakes. The primary driver is the desire to prevent serious and potentially irreversible harm. With this end in mind, consultation with stakeholders is a very important means of gathering relevant knowledge reflecting as many different perspectives as possible. Stakeholder consultation also facilitates the striking of an appropriate balance between the need to avoid excessive restraint and the need to avoid recklessness.

Finally, complexity requires an approach that is based on risk information. Such an approach should involve consultation (or multidisciplinary consultation) regarding the available knowledge, with a view to characterising the risk under

consideration as accurately as possible. This consultation may involve representatives of government, universities, the business community or citizens' groups, subject to the understanding that they are able to provide new or supplementary knowledge.

Categories of risk issue

On the basis of the dominant characteristic, Renn distinguishes four categories of risk issues[114,128]:

- ambiguous risk issues
- uncertain risk issues
- complex risk issues
- simple risk issues.

The latter category covers those risk issues in which ambiguity, uncertainty or complexity play no significant part. The Committee feels that a categorisation of this kind is not particularly useful, as most risk issues involve all three characteristics to a greater or lesser extent, and would therefore fall into multiple categories. By way of illustration, consider the issue of the use of genetically modified agricultural crops. This issue is characterised by both ambiguity and uncertainty. It is ambiguous insofar as it is not obvious what normative principles apply. Some people believe that 'messing' with genes from different species is unnatural or amounts to 'playing God'; they argue that humanity should not go down that path. Others see genetic modification as opening the way for the prevention of starvation and suggest that it would be wrong to ignore such opportunities. The issue also involves various scientific uncertainties, regarding matters such as the possibility of adverse health effects for consumers or livestock, the possibility of genetic crossover to related wild species and the potential for ecological damage. In addition, there are undoubtedly complex aspects to the issue.

Reproductive cloning is another issue with both ambiguous and uncertain characteristics. Some people are fundamentally opposed to the process on religious or moral grounds. They regard reproductive cloning as degrading to human dignity, they fear the breakdown of parenthood and society or they believe that children born as a result of the process may suffer developmental problems.[121,129] Others have no objection in principle, provided that uncertainties concerning the health and life expectancy of the children can be reduced to acceptable levels.

Accordingly, it is more sensible to ascertain which of the above features are exhibited by a given issue. It is then a matter of applying the associated strategies

simultaneously and integrating them to produce a single strategy that is tailored to the issue in question.

Society is constantly changing, under the influence of technical and scientific developments, and in social and ethical terms. That which is acceptable today will not necessarily be acceptable tomorrow. As a result, the character of a risk issue is also liable to change with time, and the associated levels of ambiguity, uncertainty or complexity can increase or decrease. In a previous advisory report on nanotechnology, the Health Council classed the matter of privacy as a 'simple issue', for example.[118] However, it was also stressed that growing concerns about terrorist threats created an increasing need to weigh up privacy considerations against security considerations. Such reappraisal may lead to value conflicts and thus to ambiguity. Another example is the risk assessment of substances. New discoveries concerning chemicals' mode of action (e.g. endocrine disruption, epigenetic effects) could increase scientific understanding of their potential to cause harm. That could raise renewed doubts about the safety of some applications that were hitherto considered safe. The classification of risk issues therefore needs to be reviewed periodically and the assessment and decision-making processes adjusted accordingly.

3.3 Issues that lend themselves to the application of the precautionary principle

The Committee sees the precautionary principle as a strategy for dealing with uncertainty in an alert, careful, reasonable and flexible fashion. It follows from this that the principle is the appropriate strategy for those risk issues where the level of uncertainty is so large that it makes decision-making substantially more difficult. In cases where damage has already been done, that uncertainty may relate to the possible causes. Where the introduction of new technologies or products is concerned, such uncertainty may relate to hazard characteristics or to levels of exposure, and therefore to the nature and extent of the harmful effects that might occur, and the likelihood of their occurrence.

Classical decision theory has various decision rules for choosing the most suitable course of action in uncertain situations of this kind. For example, the Maximin rule dictates loss minimisation, while the Maximax rule is aimed at maximising profit. However, each of these decision rules has its own shortcomings.[53] Which one is best depends on the situation in question and on the decision-maker's fundamental attitude to risks in general.[95] The precautionary principle, in itself, provides no solution in such cases. After all, the Committee does not consider it to be a decision rule. What it adds is an emphasis on aspects of good deci-

sion-making that go beyond formal decision theory and which are often neglected in everyday decision-making: a thorough exploration of the issue, taking account of all the possible consequences of an activity, and of any alternatives, not just the consequences that have been established scientifically.[53]

The foregoing assumes that the threat involved (i.e. the possibility of harm) is plausible. If damage has already occurred, then there must be a plausible link to a possible cause. A threat may be deemed plausible if, taking all the available information into account, the threat is a genuine and serious possibility. If that's not the case, then it is doubtful whether there is indeed any significant uncertainty. In other words, plausibility is a precondition for uncertainty.

The degree of plausibility of a threat or of a causal link can be determined on the basis of criteria that are routinely used in science to determine the status of a hypothesis or theory. This involves criteria such as coherence, explanatory capacity, analogy, precision, simplicity and the existence of precedents.[95] This is, in fact, a job for the experts. By asking critical questions and making observations, non-experts can test and challenge the experts' reasoning, and broaden their horizons in the process. In this way, they contribute to the quality and transparency of the assessment. The experts would do well to be receptive to this process and endeavour to pay due deference to the limits of knowledge. On the basis of the available information, it is not possible to state objectively when a possible threat may or may not be deemed sufficiently plausible to warrant further action. However, the problem of subjectivity is not peculiar to assessment in the context of the precautionary principle; if the policy were to take risk-reducing measures only in cases where it is justified by adequate scientific evidence, a similarly subjective decision would need to be made as to whether the criterion for action had been met.[43,130] Policymakers must decide this on a case-by-case basis in, or after, consultation with the stakeholders. The entire context of the issue has a part to play in this. In general, the greater the perceived severity of a threat, the fewer the requirements imposed on plausibility. The explanatory notes accompanying the UNESCO working definition of the precautionary principle referred to earlier (section 2.2) suggest that the implications of a threat may be deemed serious if the following criteria are met:

- life-threatening or health-threatening;
- irreversible in practice;
- unfair to the present or future generations;
- infringement of human rights.

The following could also be added:

- the consequences can affect many people

- the harm is not immediately apparent and also affects later generations;
- the cost of reversing the harm or, if that is not possible, compensating for it is potentially overwhelming.

The social unrest generated by the issue also plays a part. Furthermore, the less benefit an activity or product provides to society, the more inclined people will be to control any associated uncertain risks by taking action. The availability of alternatives is also an important factor. If the same societal benefits are obtainable from another activity or product, which carries no uncertain risks, the alternative will be regarded as preferable, even if the plausibility and severity of the uncertain risk associated with the former activity or product is limited.

Finally, there is also the nature of the measures involved. A lower level of plausibility or severity will generate less drastic measures than a higher level of plausibility or severity. So there is no single threshold level of plausibility or severity above which taking action in line with the precautionary principle is appropriate, and below which it is not. Accordingly, the decision can only be made on a case-by-case basis. In the next chapter, the Committee explores in greater depth the question of how the precautionary principle should be applied.

3.4 Conclusions

A purely scientific and quantitative estimation of risk does not provide a basis for risk policy that commands general support.

Scientific and technological developments, population growth and globalisation have in recent decades significantly altered the nature of the risks associated with human activity (both on its own and in combination with natural processes). At the same time, people's attitudes to managing risk have changed. As a result, a modern risk policy cannot be based exclusively on scientific, quantitative estimates of risk. Unquantifiable factors and the general social context have to be taken into account as well. Risk governance is a more suitable approach. This implies recognising that the estimation and control of risk in a technologically dynamic modern-day society is a complex matter, which is liable to involve numerous uncertainties. Accordingly, effective and transparent decision-making requires the involvement of a variety of actors.

The characteristic features of risk issues are ambiguity, uncertainty and complexity.

Three characteristics complicate the decision-making process in risk issues: ambiguity (differences in value judgments), uncertainty (usually a lack of knowledge) and complexity (through a tangle of cause-and-effect chains). These characteristics each require their own specific strategy in order to reach decisions, namely consultation and debate, application of the precautionary principle and multidisciplinary consultations on the basis of risk information. Risk issues often involve all three characteristics to a greater or lesser extent. For this reason, a categorisation of risk issues on the basis of these characteristics is not particularly useful.

The precautionary principle applies to risk issues that are characterised by substantial uncertainty.

Use of the precautionary principle is the best strategy for dealing with issues that are characterised primarily by a degree of uncertainty which hampers decision-making. In issues where damage is not yet manifest but might be expected, the uncertainty involves the severity and extent of possible damage, and the probability of occurrence. With regard to issues in which damage has already come to light, the uncertainty relates to the possible causes. Use of the precautionary principle is subject to the condition that a plausible threat or plausible causal relationship is involved. However, there is no general threshold level of plausibility above which application of the precautionary principle is appropriate and below which it is not. That depends on the context of the whole issue (the seriousness of the possible damage, the benefits at stake, the availability of alternatives for the activity associated with the risk in question, and the level of public disquiet) and must be decided either on a case-by-case basis or following consultation with experts and stakeholders.

Issues that involve substantial uncertainty are usually also characterised by ambiguity and complexity. In cases such as these, the three specific strategies must be integrated into a single strategy that is tailored to the issue at hand.

Chapter 4

Application of the precautionary principle

In this chapter, the Committee outlines the various stages of the assessment and decision-making process associated with risk issues. It describes the consequences for the practical implementation of each step, when an issue has been classed as 'uncertain' and the precautionary principle is, therefore, adopted to guide the organisation of the process as a whole.

4.1 Elements of the assessment and decision-making process

Various stages can always be recognised in the proces of dealing with risk issues. A variety of systems have been put forward for structuring the activities involved in the *governance* of risk. In Figure 1, the Committee presents a flowchart based partly on a proposal contained in a recent report produced for the *International Risk Governance Council* (IGRC)[114] and partly on earlier Health Council reports.[27,28] The system it illustrates is consistent with proposals made in other quarters.[131*]

'Specification' involves examination of the nature and extent of an issue and its definition. The Specification stage is a prerequisite for proper organisation of the assessment and decision-making process. The next stage in the process, 'Collection and Analysis', consists of determining what benefits an activity provides,

* see also a recent flowchart prepared by the European Environment Agency (EEA)[217]

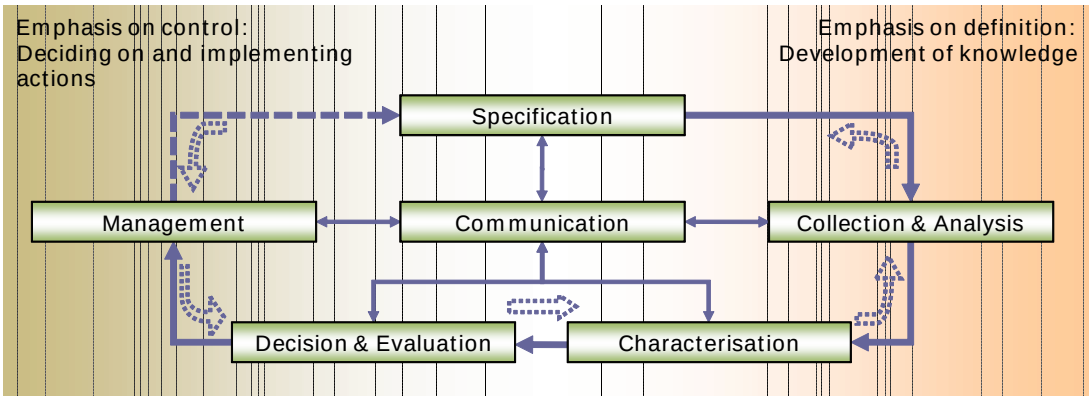

Figure 1 Flowchart illustrating the successive stages in the process of dealing with risk issues.

what hazards, exposure levels and risks are (or may be) associated with it, and to what extent alternatives are available. Identification of people's concerns and perceptions regarding the relevant risk-engendering activity and the associated risks also forms part of this stage. This stage is followed by 'Characterisation': definition of the issue in terms that are relevant for the decisions to be taken. The final two stages are 'Evaluation and Decision-Making' (deciding what should be done) and 'Management' (implementation of the chosen policy).

At each stage, new questions may arise, which require further analysis. The preceding steps should then be revisited. This form of feedback, which can take place at each stage of the assessment and decision-making process, is illustrated in Figure 1 by the dotted arrows.

At the centre of the flowchart is 'Communication'. This is particularly important in connection with the broad and complex issues involved. Communication is crucial if the process is to be transparent and efficient, precisely because of the numerous parties involved in such cases.

In the stages shown in the right-hand section of the flowchart, the emphasis is on the collection and interpretation of knowledge, whereas in the stages on the left it is on decision-making and action. However, there is no sharp dividing line between the knowledge domain and the control domain.[28]

The process illustrated in the flowchart is suitable for all types of risk issue. Detailing of the various stages will be relatively straightforward where simple risk issues are concerned, but will become more laborious and demanding as the associated complexity, uncertainty and ambiguity increase. This principle has found expression through concepts such as the 'risk management escalator'[114] or 'risk ladder'[115]. Depending on the type of issue involved, this flowchart will have

to be applied either in a domestic or an international setting. The form and content of each stage that are appropriate when addressing uncertain risk issues, for which the process is guided by the precautionary principle, are described in the following sections.

4.2 Specification

The Specification stage is the lead-in to the process of assessment and decision-making; it is not the trigger for that process. Specification is preceded by agenda forming: it is developments and processes in wider society that place a risk issue on the policy agenda.[132] The 'alarm bell' may initially be sounded by the scientific community (as with certain forms of ICSI), or special interest groups may speak out against certain developments (as with nuclear power), parliament may push an issue forward, or a systematic research and assessment programme may bring or return a topic to prominence (as with climate change). An issue's societal profile is what sets the assessment and decision-making process in motion and what drives problem demarcation.

The main steps in this first stage are as follows:
- determining the characteristics of the risk issue and the organisation of the process;
- problem definition and demarcation;
- identification of stakeholders;
- definition of starting points for analysis.

In other words, it is at this stage that a tentative decision is made as to the applicability of the precautionary principle. The four steps are described in more detail below.

Determining the characteristics of the risk issue and the organisation of the process

In the 'Specification' stage a start is made on the practical implimentation of the assessment and decision-making process. The most suitable approach depends on the presence of ambiguity, uncertainty and complexity. Accordingly, it must initially be determined which of these challenges characterises the risk issue in question. In this chapter, we have assumed that substantial uncertainty, at least, has been identified. This means that the risk assessment and decision-making process is based on the precautionary principle, with a view to ensuring that the

identified uncertainty is carefully and reasonably accounted for. The conclusion drawn at this stage regarding the issue type is in fact provisional, insofar as the outcome of subsequent stages may lead to reclassification of the issue in consultation with the relevant parties. Any reclassification naturally has implications for the design of the remainder of the risk governance process. The Specification stage may therefore be regarded as a form of pre-assessment.[114] If the risk issue is to be approached effectively, it is very important that all relevant parties endorse the issue classification.

Problem definition and demarcation

A risk issue acquires a general definition when it first appears on the policy agenda. However, at the Specification stage, it has to be defined in more detail, if necessary through consultation with stakeholders and experts. The precautionary principle requires that the entire decision situation be thoroughly mapped out. This means that the activity associated with the risk is taken into consideration (together with all feasible alternatives), giving details of the certain and uncertain consequences associated with each of these options. Conceptual health models, such as that used by the RIVM for public health status reporting and forecasting[133] and the compact version used by the Health Council,[34] can be helpful in this context. So too can systems for calculating indicators of the relationship between health and environment, such as the European Environment Agency's DPSIR* model [135] and the WHO's DPSEEA** model.[136] In the field of occupational health and safety, models have been developed to simulate the interaction of physical, social and background factors, which can also provide structure for the analysis.[137,138]

The scope of the issue is a central point. The licensing of novel foods serves as a good example in this regard: There is a substantial difference between a process that is concerned only with the possibility of a novel food having an adverse effect on health, and a process that is also concerned with the veracity of the health benefits claimed for that food.[139,140]

The time horizon needs to be specified as well. In line with the sustainability principle, the time horizon is normally linked to the period into the future for which repercussions of the risk under consideration may be felt. When considering the consequences of exposure to ionising radiation, great weight has tradi-

* DPSIR stands for *drivers, pressure, state, impact* and *response*.
** DPSEEA stands for *drivers, pressure, state, exposure, effects* and *actions*.

tionally been attached to the potential impact on future generations; indeed, this was originally the decisive consideration in the definition of standards.[141]

Problem definition and demarcation are crucial to the conduct and outcome of the assessment and decision-making process. If interested parties are explicitly or implicitly working according to divergent definitions of the risk issue, difficulties will inevitably arise later in the process.

Identification of stakeholders

A careful stakeholder analysis is essential to the smooth running of the risk assessment and decision-making process. The breadth of stakeholder participation that is appropriate depends on the nature of the issue.[114] Where uncertain risk issues are concerned, it is desirable to involve experts from relevant government agencies, research organisations and consultancies. In view of the uncertainty surrounding the issue, it is important that an appropriate balance is achieved between the risk of overprotection and the risk of under-protection. To this end, it is necessary to secure input from the business community and from representative organisations (consumers' and patients' organisations, environmental groups and animal welfare organisations, unions etc) with a direct interest. If substantial ambiguity is also involved (concerning, for instance, major differences of opinion as to what is worthy of protection) then it is worth involving representatives of the general public (e.g. through citizens' panels) in the process.[114]

There are no verified methods for identifying stakeholders. However, two methods are described in a guideline document published by the Netherlands Environmental Assessment Agency: press cutting analysis and the snowball approach. This latter involves conducting telephone interviews with identified stakeholders, who are asked to suggest other parties who might have a different view on the matter, so that the consultation process snowballs.[126,142]

Definition of starting points for analysis

The final step in the Specification stage is making a preliminary assessment of the available information. From the scientific perspective, that implies selecting suitable protocols, models, research methods and so on.

Assessment rules – which are typically associated with the models to be used – have to be defined as well.[114] Model selection for the assessment of substance-related risk is illustrative in this regard: a decision has to be taken as to whether it may be assumed that a threshold exists, below which exposure may be expected to have no adverse effect.[143] Another example is the convention of not assuming

that all the effects that a xenobiotic substance or a form of radiation has on an organism are adverse to its health.[24,143] It is also necessary to select concepts and variables for use in the definition of risks and benefits. The Committee will return to this question in the 'Characterisation' stage.

It is important that such conventions are explained and discussed during this first stage of the process, in the context of consultation between experts and stakeholders. Otherwise there is a danger that disagreement with - or misunderstanding of - the conventions will disrupt the process later on. Even if consensus cannot be reached, at least it is clear early on where and why opinion is liable to be divided later. Modelling and other conventions can be given further attention during the 'Collection and Analysis' stage and the 'Characterisation' stage of the process, provided that they are on the agenda from the outset.

4.3 Collection and analysis

In the second stage of the process, information about the issue is collected and analysed. Information collection has to be systematic, and has to allow stakeholders to put forward material and sources of material and to see how that material and those sources are utilised. The Committee believes that the analysis of information is primarily a task for scientific experts, but that the perspective described by De Hollander and Hanemaaijer[115] (drawing on other authors[102,144-146]) has particular merit:

> Broadly speaking, science is about 'systematic analysis', 'scepticism', 'peer review', 'impartiality' and 'transparency', 'accountability', and 'learning from experience'. It is not the holy, value-free 'truth', but these, generally more procedural attributes of science which are of particular value in the assessment and management of environmental risks.

The Committee takes the view that this is equally the case with other risks that have implications for public health.

Benefits and risks

The information that needs to be collected and analysed is, first of all, that which sheds light on the benefits that the activity or product under consideration can potentially bring. It also concerns the hazards, the exposure (voluntary of otherwise), the risks, and the potential harm that it can cause. Does this harm represent a threat to human health or life? Does it damage the environment? Are its effects persistent or practically irreversible? Is it liable to affect many people? How are

its effects distributed across the different population groups? Can it affect future generations? The best possible picture must be built up of the uncertainties that exist regarding such matters. To this end, bandwidths or damage scenarios should be drawn up, so that the need for precaution may be gauged.

In addition, the likelihood of harm needs to be estimated or, if harm has already been done, the strength of the evidence for a causal relationship between the activity and the harm needs to be assessed. In this regard, it can be helpful to focus on the assessment points highlighted by Hill: strength, consistency, specificity, sequentiality, biological gradient, plausibility, coherence, experiment and analogy.[147] In this connection, consideration should be given to the fact that several sub-causes are usually involved in the development of disease.[40]

When evaluating empirical research, special consideration should be given to possible errors. Poor test or study design can generate effects that not occur in reality (false-positive results). Alternatively, it can cause real effects to be missed (false-negative results). The experimental design should have a sufficiently high probability of detecting real effects, which are large enough to be relevant from an human health or ecological perspective. Any such errors made at the Collection and Analysis stage cannot readily be corrected later in the assessment and decision-making process.[130] Confidence intervals shed more light on the degree of uncertainty inherent in research findings than simple statements as to whether an observed effect is or is not statistically significant.[53]

Possible courses of action and costs

By examining scenarios that feature different policy measures designed to protect health (and manage other risks), it is possible to compare various options for implementing a risk-engendering activity*. One of the options that may be considered is a temporary or indefinite prohibition on the activity in question. There are many other options, however: the Committee certainly does *not* regard application of the precautionary principle as necessarily amounting to a prohibition on certain activities.

Various authors have indicated that the comparison of options should be integral to application of the precautionary principle.[92] The object of such comparison is to identify a sustainable way of providing for society's needs. When analysing options, it is important to consider divergent views, including the concerns and perceptions of stakeholders.[148]

* Environmental impact assessments (EIA) already require a comparison of the options.

Particular attention should be given to the costs and benefits of intervention. In addition to the direct costs of risk control measures and the direct benefits, it is necessary to take account of opportunity costs or alternative costs: what useful policies will be compromised as a result of the allocation of resources to control of the risks associated with the issue under consideraton?[28,149]

Also relevant in this regard are the risks associated with the intervention measure itself.[150] Such risks can be difficult to estimate, even on a qualitative basis. Consider, for example, food irradiation. Some people argue that this procedure should not be allowed. However, a ban on irradiation could result in higher prices for some products. This could mean that these products would be either less accessible, or totally inaccessible, to certain members of society. Would that impair the diet of the people affected and thus create health risks? That question cannot be answered with confidence; furthermore, any effect would depend partly on the value patterns of the people concerned and would be almost impossible to quantify. Some authors have suggested that such situations are liable to give rise to risk migration. They point out that the risks associated with a given measure may not become apparent for some time as was the case with bromine-containing flame retardants. These substances were widely introduced to a variety of product types with a view to reducing fire-related death and injury, but it has since come to light that they may disrupt the hormonal system.[151]

On the other hand, action can also have 'secondary' benefits. For example, reducing the use of fossil fuels to combat climate change can also deliver direct benefits to human health.

With many policy issues, the emphasis is on determining and comparing the utility of the various options, particularly in relation to the cost. However, various authors have argued that this utility analysis approach is inappropriate or, at least, requires modification, partly because of aspects such as the distribution of costs and benefits, which utility analyses do not always account for to the satisfaction of the stakeholders.[152-154] The Committee also considers it a drawback that a utility analysis is a predominantly quantitative activity, given that there tends to be a paucity of reliable quantitative data on issues to which the precautionary principle applies. DeKay *et al* have nevertheless demonstrated that application of the precautionary principle and the use of utility analysis for option comparison are not necessarily incompatible.[153] The approach may also provide insight into the costs and benefits of additional scientific research as a form of intervention; this value-of-information analysis can indicate whether the extra cost of acquiring new information is justified by the anticipated benefits, e.g. better decision-making regarding the direction to be pursued.[150] Therefore, while recognising the drawbacks referred to, the Committee takes the view that, when designing the

assessment and decision-making process, serious consideration should be given to the use of this approach.

With each of these elements, questions have to be asked concerning the quality of the available information. The RIVM and the Netherlands Environmental Assessment Agency have accordingly devoted considerable attention to this point in recent years.[142,155-158] The Committee believes that the methods these organisations have developed have considerable potential for use outside the environmental policy domain. Their strength lies in clear demarcation between the roles of experts and stakeholders. The proposed interactive process provides a structure for ensuring that both social and scientific considerations are taken into account in the identification of uncertainties. In other words, there is an arsenal of methods that can be useful for weighing up risks in relation to anticipated benefits. In places, it is often possible to make use of quantitative risk analysis methods, although care needs to be taken to ensure that this does not result in more weight being attached to well-understood quantifiable dimensions of risk, than to more elusive and qualitative dimensions.

4.4 Characterisation

Various approaches have been proposed for organisation of the information collected. In this context, the Committee would highlight the RIVM's *Framework for decision making in the field of environment and health*: a workable system with which experience has now been gained in the Netherlands.[159] In practical terms, the RIVM framework brings together the findings of the Specification, Collection and Analysis and Characterisation stages, thus providing a sound basis for the Evaluation and Decision-Making stage. The Committee nevertheless takes the view that various matters need more explicit attention within the assessment framework in question than is currently the case. This involves the aims and benefits of the risk-engendering activity under consideration, the alternatives to that activity, and information about the data's quality and inherent uncertainty.

In general, decision-making requires synthesis of all the available information. Synthesis in turn implies data selection and the choice of appropriate variables for expression of the benefits and risks. This process is inevitably subjective, to some extent: decisions about what matters most reflect not only the information and its quality, but also the stakeholders' value judgements.[28]

In an advisory report on environmental risk policy, the Health Council called for the definition of a risk profile for the risk issue under consideration.[28] The Committee believes that risk profiles could be useful when addressing issues in

other policy fields as well. A risk profile should at least cover the following: an estimate of the nature and extent of the potential short-term and long-term harm, preferably featuring scenarios; conclusions regarding the probability of harm or the strength of the evidence for a causal relationship; options for risk reduction; the cost of, and risks associated with, possible risk-reducing measures; the desirability of additional research; the implications of a false positive conclusion (false alarm) compared to those of a false negative conclusion (overconfidence), preferably expressed in the same units; the social context. In the previous section, the Committee indicated the importance of assessing the quality of available data. The results should be reflected in the risk profile. Again, the Committee would highlight the work being done at the RIVM and the Netherlands Environmental Assessment Agency.[157]

The selection of variables for the formulation of a risk profile is an important part of the process. The expression of a threat's potential consequences in numbers of patients or deaths may lead to a very different conclusion from that suggested by a statement of impact expressed in terms of the collective reduction in life expectancy (measured in DALYs, or disability-adjusted life years).[160] Utility scores, which are usually expressed in monetary terms, are another option. In this context, the aggregation of information can help with the retention of an overview, but can also result in important facets being pushed into the background. It is therefore very important to exchange ideas with stakeholders. Finally, it is recommended that the risk profile not be restricted to those effects that are easy to quantify.

Once all the data have been organised, matters should be reviewed to determine whether the original, provisional conclusion reached in the Specification stage, that the issue under consideration is characterised by substantial uncertainty, was correct. If so, the process can continue on its existing path and its remaining stages can be guided by the precautionary principle.

4.5 Evaluation and decision-making

The ultimate decision concerning the policy to adopt with regard to the risk-engendering activity under review is based on the description of the activity developed in the previous stage. Where uncertain and often complex risk issues are concerned, it is not normally possible to reach a simple 'yes/no' decision. In most cases, the government will define parameters, within which different groups in society may decide whether or not to go ahead with a given practice. Such conditions need not pose an obstacle to developments in the longer term. The marketing of pharmaceutical products is a case in point. The strict authorisa-

tion systems that exist in industrialised countries may be seen as expressions of the precautionary principle. With such a system in place, the introduction of a given product takes on the character of a 'simple' risk issue: an operational question which does not require a comprehensive, fresh assessment and decision-making process. Because an element of risk remains, such an authorisation procedure requires periodic review, usually in the light of incidents.

In principle, it would seem sensible to distinguish between established and new practices in the context of the decision-making process. If something is 'new', it is likely to be easier to do without it, and to satisfy the societal need it is intended to meet in some other way. Where established practices are concerned, the avoidance of possible further harm is the objective.

The Committee considers this distinction particularly important for decisions of a more operational character. The system for ensuring protection against ionising radiation requires, for example, that new radiation applications must meet certain safety standards, while with existing forms of radiation exposure (e.g. exposure to radiation from the ground or from building materials) it is difficult to achieve reductions and their regulation is based mainly on an assessment of the costs and benefits of protective action.[161] The distinction is less clear cut, however, where issues to which the precautionary principle applies are concerned. In such cases, intervention consists mainly of guiding technological development. The nature of such intervention will, however, depend on the phase of development. With a technology that is in an early phase of development, prudent adaptive further development is possible, whereas later intervention is liable to involve a more fundamental change of course. The efforts now being made to reduce greenhouse gas emissions serve as an example of a fundamental course change in relation to an established technology, while the establishment of a licensing regime for functional foods is an example of early intervention designed to direct subsequent development.

Decision rules

Decision scientists have proposed various rules to guide decision-making, even in situations of complete uncertainty. The relevant literature contains various suggestions regarding the most appropriate decision rules for use in connection with the precautionary principle.[97,162,163] The Maximax rule requires that all courses of action be ranked on the basis of their most favourable possible outcome, and that the option be selected which leads to the largest most favourable outcome. This rule, which seeks to maximise profit, is extremely optimistic. It does not take possible negative consequences into account, which means that it is

only useful in situations where there is a lot to gain and little to lose. The Maximin rule is quite the opposite. It requires that the available courses of action be ranked on the basis of their most adverse possible consequences, and that the option be selected which leads to the most favourable outcome of that most adverse possible consequence. By endeavouring to minimise losses, this decision rule can be described as very pessimistic. It is particularly unattractive when there is an alternative course of action which offers much greater chances of making a profit with only a minimal additional risk. Accordingly, the Maximin rule is best suited to situations in which there is relatively little to gain by making a decision, and a great deal to lose. These are by no means the only decision rules, however. There are many others, some of which take a more balanced stance between beneficial and adverse potential consequences. Each of these, however, has shortcomings of its own.[53, 95] As a result, all that remains is to tailor the decision strategy to the situation at hand, and to the individual's fundamental attitude towards risks in general.[95]

The precautionary principle does nothing to simplify decision-taking. It does not stipulate in advance which aspects should weigh more heavily and which less so. It gives no indication of which direction to follow. As previously stated, the Committee does not see it as an alternative decision rule. Instead it takes the view that this is a strategy which ensures that uncertainty will be dealt with in a careful and reasonable way. To this end, consideration should be given to all realistic courses of action (the activity under discussion, together with all possible alternatives), and including their beneficial and adverse, certain and uncertain, but plausible consequences.

It is important to find a good balance between the risk of excessive restraint and the risk of undue recklessness.[114,164] An essential factor here is the balance between the severity of the effects produced by these two possible errors.[43,165] In the past, the possibility of undue recklessness (a false-negative result) in particular was often underestimated.[13] An additional difficulty is that the range of potential positive and negative effects resulting from the various courses of action often cannot be easily measured on the same yardstick.[162]

The nature of the decision that is ultimately arrived at is not in any way prescribed by the precautionary principle It may be that the activity under discussion is allowed to proceed, possibly subject to certain conditions. Alternatively, it could be temporarily or permanently prohibited. The latter option is made all the more attractive by the availability of alternatives which deliver the same benefits but at lower (uncertain) risks. An explicitly temporary decision – favouring one side or the other – can be linked to an instruction to examine matters further. This is especially useful if one expects to obtain (relatively quickly and inexpen-

sively) additional information that can lead to a better decision (i.e. one with less chance of false positive and false-negative results) in the relatively near future. One example of this is the moratorium on ICSI using surgically obtained sperm cells (see chapter 5).

Decision-making in, or following, consultation with stakeholders

Evaluation and Decision-Making can be regarded as a focus of the governance process, since it is this stage that frames the characteristics of good governance (see section 3.1)[120,121].

The government is ultimately responsible for making decisions on issues of the kind dealt with in this report. The locus of decision-making should be formal and democratic in nature, rather than a multi-stakeholder process. That is certainly true in the case of broader sustainability issues, where the decisions taken will also affect future generations. Representative democracy is specifically designed to do justice to, or strike a balance between, all the interests at stake. Accordingly, this would include those interests which are not specifically represented by any of those involved in the process.[94]

That does not mean, however, that the government has to rule on every detail of the activities associated with application of the precautionary principle. Where such issues are concerned, it is important to arrive at a policy that is accepted by all stakeholders or, at least, by as many as possible. To this end, it can be helpful in some cases if the government establishes a system under which the relevant actors make decisions at their own levels. A system of this kind has recently been set up for the control of substances in the EU.[166] A new directive defines parameters, within which producers are responsible for the safety of the substances that they introduce to the market.

Even though decision-making responsibility is in the government's hands, it does not follow that the stakeholders have no say in those decisions. That 'say' has already been discussed in the context of earlier stages of the process – in relation to the examination and demarcation of the risk issue ('Specification'), the provision and interpretation of (typically scarce) information ('Collection and Analysis') and the 'Characterisation' of the risk in socially relevant terms. As the provisional end point of such a participative process, this decision-making stage will benefit from stakeholder cooperation. The exact form that such cooperation should take will depend on the nature of the risk issue in question. Sometimes, joint decision-making will be desirable, in which case it will be important to ensure that the co-decision-makers are representative. For other issues, it will be more appropriate to consult the relevant parties about the decision parameters

and about proposals for their implementation. Once this process is complete, the government will define the parameters in question.

Various methods are available - and in use - for organising participation in the Decision-Making phase. In this context, the Committee would highlight a handbook published by the Flemish Institute for Science and Technology Assessment.[125] It is important – and not only at this stage in the governance-process – to have clarity regarding the way decisions will be arrived at and regarding the roles and responsibilities of the participants.

Provisional nature of decisions

Decisions are taken in conditions of uncertainty, so there is a risk that they are based on false-positive or false-negative results. Accordingly, decisions taken within the framework of the precautionary principle are, in theory, provisional in nature. According to the Committee that is something that cuts both ways, i.e. whether a given activity is being permitted or prohibited. The European Commission too has stressed that decisions taken in the context of the precautionary principle initially have a provisional character. This remains the case until such time as an increase in knowledge, resulting from monitoring for example (see 'Management' step) enables a better informed decision to be made.[19, 29,167] This gives the whole assessment and decision-making process an iterative nature.

In this context, the Committee makes the following observations. First, it is questionable whether enough will ever be known to allow many of the relevant issues, e.g. climate change, to be reclassified to simpler risk categories.[167,168] Nevertheless, uncertainty can be reduced by the manifestation of consequences, such as a rise in sea level due to higher average temperatures. Furthermore, the nature of an issue can change under the influence of the action taken. Following the prohibition on the use of antimicrobial growth promoters in livestock farming in Europe, for example, will anyone still be willing to try to demonstrate that these products are in fact harmless? [169] It is more likely that new technologies and methods will be developed to maximise yields within the restrictions.[150] A recent report on the impact of European legislation suggested that this may already be happening. In many cases, the cost of alternative technologies ultimately proves to be significantly lower than initially suggested.[170] Nevertheless, a decision may very well include provision for review, partly on the basis of the results of a monitoring programme. In that case, the timing and nature of the necessary evaluation and reassessment should be specified in the context of the original decision.

Reconsideration does not necessarily have to be linked to scientific advances, however: changes in the societal context or in people's outlook can also make it appropriate to return to an issue.[94,167]

4.6 Management

At the Management stage, the decision is implemented. Many of the debates regarding the precautionary principle have tended to focus on whether a given practice should or should not be prohibited. As previously stressed, the Committee does not believe that it is right to portray assessment and decision-making led by the precautionary principle as a prohibition process. That is not to say that such assessment and decision-making processes will not sometimes result in a prohibition or moratorium. Indeed, this has happened in the past, in the cases of certain forms of ICSI (see chapter 5) and of ozone-depleting chlorofluorocarbons.

It is important to indicate who should direct any supervision and reassessment processes. Bodies such as the RIVM could play a role in this context, as could the knowledge centres that are being set up in many fields, such as the Netherlands Centre for Occupational Diseases. Expertise is concentrated in such centres, which also have a role in highlighting important developments.

In the Committee's view, management implies general monitoring and the supervision of implemented measures. The first task might, for example, involve the creation of a monitoring programme along the lines of the post-marketing surveillance system for pharmaceutical products. This system allows society to benefit from a given pharmaceutical product while minimising the risks associated with it, even if uncertainties exist regarding possible adverse effects. In the repeatedly cited Health Council advisory report on nanotechnology, it was suggested that a committee made up of people from a wide range of disciplines should monitor and evaluate the development of nanotechnologies.[118] That committee would have to identify and weigh up potential threats and, by doing so, shape judgment-making and decision-making under the precautionary principle. In support of a monitoring programme, indicators that can be used in the context of reassessment may be formulated in consultation with the stakeholders.

One problem affecting risk reducing actions taken under the precautionary principle is that there will be uncertainty regarding the need for – or the effectiveness (and therefore the efficiency) of – such actions. Nevertheless, the findings of earlier risk assessments can help to shape any measures that are taken. In keeping with the systematic reasoning that the Committee has put forward, attention may be given to underlying risk determinants.[137] Broadly speaking, such

determinants relate to *design*, *conduct* and *organisation*. For example, the failure to include watertight hold bulkheads in the roll-on-roll-off ferry concept when it was introduced proved to be a determinant of the extent of the Herald of Free Enterprise disaster (design). Lack of collaboration between different NASA centres contributed to the failure to correct a rocket design fault that caused the *Challenger* spacecraft to explode (organisation).[171] And special provisions need to be made in hospitals and other institutions to allow for near accidents to be reported without fear of adverse repercussions for the whistleblower in question (conduct).

Given the potential benefits of the risk-engendering practices under discussion, selection of the 'best' option should in most cases preferably be followed by controlled incremental implementation, with an impact review after each step. In this way, it is possible to meet society's needs, while maximising the opportunity to respond promptly to undesirable developments. A study by the European Environment Agency has shown that such an approach is not always easy to follow in practice, however, since it is liable to be at odds with short-term economic interests.[13]

Work is being done in the Netherlands and elsewhere with a view to developing a system of controlled incremental implementation. In this context, the Committee would highlight the direction and guidance of technology development by means of *constructive technology assessment* (CTA).[172,173] Constant dialogue between stakeholders and reflection on the outcome of each development step can facilitate the satisfaction of society's needs and the early identification of risks. Such an approach, which is also proposed in the Health Council's report on nanotechnology[118], requires the cooperation of all interested parties and input from the government to promote research and create conducive economic conditions.[172] The latter point is important, because the prevailing economic order does not encourage investment decisions to be made primarily on the basis of what society needs. The Committee believes that the CTA approach is consistent with assessment and decision-making based on the precautionary principle, as described in this report.

4.7 Communication

In accordance with the system put forward in the IRGC *White Paper on Risk Governance*[114] the Committee has included 'Communication' as the central element of its risk assessment and decision-making process (see flowchart, Figure 1). Communication - regarding risks and benefits, regarding risk control options, regarding the views and concerns of stakeholders, regarding the out-

come of the process and regarding the action to be taken - forms the connecting and coordinating element of the entire assessment and decision-making process.

A great deal has been written about risk communication in recent years. According to some authors, the primary purpose of risk communication is to provide 'objective' information about potential adverse effects and the likelihood that they will occur.[174] This view is consistent with the concept of risk as a collection of adverse effects and their probabilities, and the belief that risk-related decisions should be made on the basis of the acceptability of combinations of such consequences and probabilities. As indicated in chapter 3, however, the Committee takes a broader view, based on the idea that risk cannot be viewed in isolation from the societal context, such as the benefits of risk-engendering practice, or from the values held by stakeholders.[174,175] Moreover, risk perceptions are the product of both rational and affective mechanisms.[176] Risk communication needs to be adapted to this reality, certainly in the case of issues to which the precautionary principle is considered applicable.

It is communication that facilitates the participative aspects of the assessment and decision-making process. Good information exchange and debate among interested parties necessitate openness, honesty, legitimacy, responsiveness and mutual trust. More technical aspects of communication are also important: the aims of communication should be defined, messages should be brief and accessible, understanding for and adaptation to the sometimes very different capacities and perspectives of other participants should be promoted, regular contact should be maintained with the appropriate parties, all stakeholders' views should be taken into account and the results of communication activities should be reported to all participants in good time.

One of the tools developed to implement this participatory approach in practice is the RISCOM model. In Belgium, for example, it was used in connection with the issue of the above-ground storage of nuclear waste.[177] It aims to achieve transparency in decision-making processes that are governed by the precautionary principle. It requires a participatory communication process that incorporates tests and challenges in the areas of scientific justification, legitimacy (relevance in the context of societal interest) and authenticity (honesty of expertise). This is done by a specially designated individual or organisation, the 'stretcher', through public participation, or the involvement of community stakeholder organisations. This is driven by the need to influence decision-making as effectively as possible. In this context, the role played by a suitable and efficient regulator who is as independent as possible (the process guardian) is truly indispensible.[178-180]

Local partnerships in nuclear waste disposal projects, as discussed by Laes[181] and coordinated in the European COWAM* network have also been explored.

In other words, the Committee sees communication primarily as a bidirectional process of information exchange, rather than a one-way information dissemination process. It believes that this is an essential for effective decision-making on the basis of the precautionary principle. That is not to suggest that information dissemination and education have no role in the assessment and decision-making process described here. Such communication activities should be open and discrete. They should also be comprehensive (e.g. should include information about the uncertainties that exist) and should clearly state the relevant arguments and reasoning.[102] In this context, valuable guidance can be gained from knowledge about (and experience with) the efficacy of communication regarding risks and scientific issues in general. The reader is referred to a recent publication by the US National Academy of Sciences, to a Health Council advisory report, and to the publications cited in those two sources.[182, 183] The dissemination of risk information should be geared to the needs, perceptions and comprehension level of the target audience. Unfortunately, however, information about such matters is often unavailable.[184]

4.8 Conclusions

The precautionary principle serves to guide implementation of the assessment and decision-making process.

Any risk issue may, in theory, be approached using the same, more or less iterative risk assessment and decision-making process, consisting of five stages: ‘Specification’, ‘Collection and Analysis’, ‘Characterisation’, ‘Evaluation and Decision-Making’, and ‘Management’. These steps are relatively straightforward where ‘simple’ risk issues are concerned, but become more involved and difficult to implement as the complexity, uncertainty or ambiguity of the risk issue under consideration increases. The precautionary principle serves to guide the risk assessment and decision-making process when dealing with ‘uncertain’ risk issues. In the Committee’s view, the precautionary principle has implications for both the form and the content of the latter process, but it does not impose any real decision rules. Therefore, the outcome of the assessment and decision-making process is not defined by application of the precautionary principle.

* Community Waste Management, see www.cowam.com

Precaution needs to be integrated into all stages of the risk assessment and decision-making process.

Use of the precautionary principle involves great care when dealing with uncertainties. Therefore, the principle strongly influences the way in which each stage of the process is shaped. The steps below include details of those elements that are essential in this context:

- 'Specification': a participatory (i.e. consultative) problem definition and demarcation process
- 'Collection and Analysis' consideration of the anticipated benefits of the activity under consideration, of the seriousness and plausibility of the associated risks (damage scenarios), of the availability of alternative ways of securing the benefits sought and of the perceptions of interested parties, as well as consideration of the available scientific and other quantitative and qualitative information, of the associated uncertainties and of the potential for false-positive and false-negative results.
- 'Characterisation': the summarisation, structuring and expression of the information in terms judged appropriate in, or on the basis of, consultation with stakeholders, as well as proper characterisation of the uncertainties and the consequences of false-positive and false-negative results.
- 'Evaluation and decision-making': the selection, in or on the basis of consultation with stakeholders, of suitable actions that take proper account of the benefits sought, the seriousness and plausibility of the associated risks, the availability of alternatives and the uncertainties, as well as the striking of a good balance between the risk of false alarms and the risk of overconfidence
- 'Management': monitoring, on the basis of agreed indicators, of the consequences of actions undertaken, and policy adjustment in line with new information or changes in the societal context.

Chapter 5

Practical examples

In a recent report by the European Environment Agency, entitled ‘Late lessons from early warnings’, an attempt is made (on the basis on an analysis of twelve case studies, including those on asbestos, PCBs, DES and BSE) to learn from previous mistakes arising from the neglect of uncertainties.[13] The approach outlined in the previous chapter is largely based on these lessons. In this chapter, the Committee attempts to illustrate this approach on the basis of several specific examples which are still very topical in the policy arena and which might, therefore, still be amenable to improvement. These are issues on which the Health Council has previously issued advisory reports, and which involved some discussion of precaution or of the precautionary principle. The Committee briefly discusses the issues and indicates (in the accompanying tables) what form the staged assessment and decision-making process described in the previous chapter might take. The Committee does not intend to use these discussions as a means of providing fresh advice on these issues. It simply wishes to indicate how use of the precautionary principle might shape the decision-making path. Depending on the type of issue involved, the government has already explored this route to a greater or lesser extent.

5.1 Application of the precautionary principle in relation to the risks associated with free, persistent nanoparticles

In recent years, researchers have become increasingly adept at manipulating the shape and size of materials at the nanometre scale.* This creates an opportunity to study and exploit the particular properties demonstrated by materials with dimensions in the nanometre range. Such study and exploitation are the aims of nanoscience and nanotechnologies. A wide range of nanomaterials – materials that measure less than 100 nm in at least one dimension – has now been developed for a variety of applications.

Many nanomaterial-based products are still at the developmental stage, but the number of products that have reached the market is increasing very rapidly indeed.[185-187] These products offer potential benefits in many areas, including public health and environmental quality.

Recently, however, people have become increasingly concerned about the possible downsides of this development. Chief among these concerns is the fear that the very properties that make nanomaterials so technologically attractive – such as their high reactivity and ability to penetrate barriers – could make them harmful to people or the environment. In this regard, attention has focused particularly on nanomaterials that could be released from products at a given point in their life-cycle (production, use, or disposal) in the form of free particles. Workers in the nanotechnology industry currently run the greatest risk of coming into contact with nanoparticles of this kind.

This issue became the focus of attention during a scientific meeting of the British Royal Microscopical Society in 1999.[188] In 2002, it moved into the political fast lane when a Canadian environmental organisation called for a moratorium on the commercial production of nanoparticles, on the basis that they might well be the 'asbestos' of the future.[189] Since then, the issue has been high on many countries' policy agendas. Government institutions have published numerous reports on this issue, both in the Netherlands and elsewhere.[190]

The Health Council has placed the issue of the possible toxicity of persistent, free nanoparticles in the 'uncertain risk issues'[118] category. This reflects our lack of knowledge about how these particles' special properties affect their behaviour in the environment, their uptake by (and distribution throughout) the body, and their ability to cause or aggravate disease symptoms. At the end of 2006, the Dutch government published a vision paper on nanotechnologies, confirming the

* One nanometre (nm) is one billionth of a metre; the diameter of a single atom is from 0.1-0.2 nm.

importance of the issue.[191] The Minister of Housing, Spatial Planning and the Environment recently made a written statement to parliament, communicating her intention to address the risks associated with nanoparticles in a rational, careful and precautionary manner.[192] Also, the body representing European trades unions has advocated that nanoparticles be dealt with in accordance with the precautionary principle.[193] This approach is consistent with a code of conduct for responsible nanoscientific and nanotechnological research recently adopted by the European Commission.[194]

The risk issue is currently being addressed at national level by various government and quasi-governmental bodies.[195-199] The Dutch observatory on risks of nanotechnology (KIR-nano) was set up at the RIVM in 2007. This centre's role is to highlight and monitor developments in the risks associated with nanotechnology, to collect relevant scientific information and to advise the government accordingly. In addition, the Netherlands contributes actively to international initiatives under the auspices of organisations such as the OECD and ISO. Preparations for consultations with the business community and with community stakeholder organisations are also underway. In line with the European Commission's code of conduct, the Dutch government is committed to transparent political decision-making.[192] In Table 1, the Committee indicates what form the various stages in the assessment and decision-making process might take.

Table 1 Developing the various stages in the assessment and decision-making process on the issue of the possible toxicity of nanomaterials.

Stage	Development
Specification	
Characteristics	Substantial uncertainty about how the special properties of nanoparticles will affect their behaviour in the environment, their uptake by (and distribution throughout) the body, and their ability to cause or aggravate disease symptoms. Relatively little is known concerning the nature of their potential effects; there are a potentially large number of victims (initially workers and consumers in particular). On the basis of epidemiological data on the effects of natural and accidentally produced nanoparticles and on the basis of the toxicological testing of synthetic particles (both existing and new) it has been shown that there is a plausible risk. An approach based on the precautionary principle would seem to be indicated.[118]
Participation	Policy officers at the relevant ministries; personnel at relevant government and quasi-governmental bodies (e.g. RIVM, TNO, Food and Consumer Product Safety Authority, Institute of Food Safety, Board for the Authorisation of Plant Protection Products and Biocides, Medicines Evaluation Board, Dutch Standardisation Institute NEN), independent experts (e.g. at universities), the business community (e.g. employers' organisations, bodies representing relevant industries, unions) and NGOs (e.g. consumers' organisations, patients' organisations, environmental organisations, international government bodies (EU) and organisations (OECD, ISO).
Demarcation and data relevance	Determine which types of nanoparticles and which applications should be taken into consideration, which research methods are usable and what quality criteria apply.

Collection & Analysis	
Benefits	Potentially wide ranging and diverse, they also offer many opportunities for gains in health and environmental quality; enormous economic importance; implemented only to a limited extent, but there are a growing number of products on the market.
Risks	Gain an impression of the potential health and environmental damage that could be caused by free synthetic nanoparticles, on the basis of toxicological testing and epidemiological research; data is still scarce, more is rapidly becoming available (see, for example [200]); draw parallels with data from research on naturally occurring particles (asbestos, fine particulates) and using data from pharmacological studies on nano-sized drug delivery systems. Collect data on their behaviour in the environment (persistence, aggregation, mobility); life cycle analysis of products needed, measure or estimate exposure via different routes; scenario analyses are an appropriate tool; data still scarce. Estimate the risks on the basis of knowledge about hazards and exposure; may vary considerably from one application, product, or population subgroup to another.
Perceptions	There is still relatively little public knowledge and disquiet[190,201-203]; all stakeholders are concerned about the lack of knowledge concerning the risks of introducing products to market, government, and industry also fear an adverse public attitude which would have an inhibiting effect on development of nanotechnology, which would affect the economy and the realisation of benefits.
Risk management options	Various optional courses of action could be implemented concurrently: 1. measures to reduce uncertainties (encouraging the development of nomenclature, measurement and analysis techniques, techniques for the physical characterisation of nanoparticles, adapting existing occupational hygiene measures, and existing toxicity tests); 2. changes in laws and regulations, such as adjustments in REACH for nano-applications of certain materials; 3. Impose conditions on production processes; impose restrictions on specific applications or products in terms of space or time, or other constraints.
Characterisation	Indicate the benefits and risks of all risk control options (with the associated uncertainties) using selected units, report perceptions.
Evaluation & Decision-Making	Consider which measures are appropriate, given benefits and risks at stake, consider the uncertainties involved when weighing up the pros and cons; strike a balance between risk of overprotection (needless loss of benefits) and underprotection (environmental and health damage); agreement on the desirability of more research is probably relatively easy, harder when it comes to legislation, hardest of all in terms of specific applications; the balance can vary widely from one application to another, such as springy tennis rackets based on carbon nanotubes, anti-bacterial silver particles in washing machines or iron particles in the treatment of brain tumours.
Management	Dutch observatory on Risks of Nanotechnology KIR-nano at RIVM designed to collect scientific data, to identify and monitor developments, and to advise the government, other institutions also involved (including Food and Consumer Product Safety Authority, Medicines Evaluation Board, Board for the Authorisation of Plant Protection Products and Biocides); Labour Inspectorate designs compliance policy on the basis of an inventory listing the use of nanoparticles in the workplace and the various protective measures.

5.2 Application of the precautionary principle in relation to the fortification of bread and bread-replacement products with folic acid

In the Netherlands, 35 per cent of women who are planning a family take synthetic folic acid (400 µg per day) in tablet form for the recommended period (from four weeks before conception to eight weeks after) in order to reduce the risk of having a baby with a neural tube defect. Currently, about 120 babies are born with a neural tube defect each year. The number of foetuses that develop such defects would be lower if more women took extra synthetic folic acid around conception. However, this approach would not prevent those cases that are unrelated to folic acid deficiency.

The Health Council's Micronutrients Committee recently examined the problem of how best to optimise the provision of folic acid to the Dutch population in general, and to women who are planning a family in particular.[204] It urges that efforts be made to improve the provision of public information concerning the use of folic acid tablets in the weeks before and after conception. This would involve the systematic targeting of information at groups that are difficult to reach, particularly less well educated women and women from ethnic minority backgrounds. In combination with more extensive preconception care in GPs' practices, the use of synthetic folic acid in the critical weeks preceding and following conception could rise from the present level of 35 per cent to 86 per cent. The above-mentioned Committee has calculated that the annual number of cases of neural tube defects would decline by 20 to 26, if 80 per cent of women were to take folic acid tablets during the critical period.

The Micronutrients Committee proposes an additional means of improving the supply of folic acid to difficult to reach groups of women. This would involve fortifying all bread and bread-replacement products with synthetic folic acid. At present, the voluntary fortification of foods with synthetic folic acid is permitted. Folic-acid-containing supplements (such as vitamin preparations) are also commercially available. As a result of this situation, it is hard to control the folic acid intake of the general population. The suspension of voluntary, unmanaged fortification, combined with the universal fortification of bread and bread-replacement products with a low level of synthetic folic acid (150 µg per 100 g flour, equivalent to an extra intake of 100 µg per day) would ensure that folic acid intake would reach an adequate basic level in almost all women, including those who were not planning a family, but were nevertheless liable to become pregnant. The low level of fortification is intended to ensure that certain population subgroups, with specific consumption patterns, do not ingest excessive amounts of synthetic

folic acid. This measure should reduce the number of foetuses developing neural tube defects by up to 15 cases per year.

Such a move would be of no direct benefit, however, to the vast majority of people who would be exposed to synthetic folic acid. Furthermore, there are uncertainties regarding the possibility of adverse effects, particularly at high intake levels. That is particularly true with regard to the effect of synthetic folic acid on the risk of cancer, especially colon cancer. Due to the major uncertainties involved, the Health Council's Micronutrients Committee took no account of the possible link between folic acid and cancer in its quantitative risk-benefit analysis. In the advisory report, however, it did indicate that – given the lack of clarity – it might be useful, or even desirable, to adopt a strategy based on the precautionary principle with regard to fortification options.[204]

There may also be ambiguous aspects to the universal fortification of bread and bread-replacement products with folic acid. It might be argued, for example, that such a measure might compromise the autonomy of the individual citizen. A second issue is whether it is reasonable to expose the entire population (more or less compulsorily) to synthetic folic acid in order to reach a relatively small, specific target group (poorly educated and non-western women who are planning families).

With regard to preconception care and to public information concerning the use of folic acid tablets, the Minister for Health, Welfare and Sport recently embraced the Micronutrients Committee's advisory report. However, he has yet to issue a ruling on the fortification of bread and bread products with synthetic folic acid. In or following consultation with all stakeholders and, if desired, representatives of the general public, the Minister will have to decide what action is appropriate, given the benefits and risks (including uncertain risks) outlined by the Council. It is important to find a good balance between the risk of excessive restraint with regard to folic acid use (possibly resulting in additional cases of neural tube defects) and the risk of excessive use (possibly resulting in additional cases of cancer). That depends not only on the available evidence for each of these relationships (folic acid – neural tube defect; folic acid – cancer), but also on the weight that people ascribe on both possible effects. Table 2 provides details of the various stages in the assessment and decision-making process, which do justice to the application of the precautionary principle.

Table 2 Developing the various stages in the assessment and decision-making process on the issue of the folic acid fortification of bread and bread-replacement products.

Stage	Development
Specification	
Characteristics	Evidence that both a deficiency of natural folic acid and excessive intake levels of synthetic folic acid can promote the development of cancer from precursor stages or that it can adversely affect the course of existing cancers[204-206]; the strongest evidence of such promotion has been found in association with colorectal cancer; there is insufficient evidence to draw firm conclusions: there is substantial uncertainty. An extremely large number of people are being exposed as a result of the universal fortification of bread. Plausible risk, based on folic acid's mechanism of action: this substance is essential for the synthesis of both DNA and RNA; especially important where there is rapid cell division (in the fetus, but also in cancer); cancer cells express increased numbers of folic acid receptors in their cell membranes; methotrexate (a folic acid antagonist) inhibits the growth of tumours. An approach based on the precautionary principle would seem to be indicated.[204] Possible ambiguity: infringement of civil autonomy; everyone is exposed in order to reach a small target group.
Participation	Policy officers at the relevant ministries (Ministry of Health, Welfare and Sport; Agriculture, Nature and Food Quality); government and quasi-governmental bodies (RIVM, TNO, Food and Consumer Product Safety Authority, Institute of Food Safety, Netherlands Nutrition Centre); universities (various disciplines); the business community (supplements industry, umbrella organisations for the baking industry, food industry), health insurers, consumers' and patients' organisations; possibly the general public.
Demarcation and data relevance	Relevant data: intervention studies in humans weigh most heavily, followed by observational epidemiological studies, and studies in experimental animals
Collection & Analysis	
Benefits	Proven benefits: the prevention of neural tube defects (NTD) in newborns; the prevention of anaemia caused by severe folic acid deficiency; insufficient evidence of other benefits (reduced risk of stroke or cancer).
Risks	At low intake levels, synthetic folic acid may protect against cancer. However, there is some evidence that it may actually promote certain forms of the disease at intakes five times greater than normal dietary levels of folic acid. The issues of whether there really is a tipping point and, if so, what precise intake level is involved, have yet to be resolved. There is no data concerning a possible dose-response relationship, observational studies and studies in experimental animals suggest that people with undiagnosed precursor stages of certain types of cancer are at increased risk relative to those without such precursor stages, but even this is uncertain.
Perceptions	In connection with the possible universal fortification of bread and bread-replacement products, determine the extent to which people are willing to take folic acid in the interests of a specific group even though they stand to gain no personal benefit from doing so, how people feel about this more or less forced curtailment of their freedom of choice, and how important they consider the uncertain cancer risk that is involved; determine whether the producers and importers of other foods that are voluntarily fortified with synthetic folic acid are prepared to withdraw these from the market if the universal fortification of bread products is implemented; bakers fear that bread's image as a natural product will suffer if additives are used.
Risk management options	Various risk management options could be implemented concurrently: 1. Improved information on the use of folic acid tablets (400 µg per day) by women around the time of conception, focusing specifically on less well educated women and women from ethnic minority backgrounds; preconception care in GPs' practices can boost the use of tablets to 86% (currently 35%); if 80% of women take extra folic acid in good time, this can result in 20-26 fewer cases of NTD per year (of a total of 120). 2. Possible supplementary measures: universal fortification of bread and bread-replacement products with synthetic folic acid (150 µg per 100 g flour, equivalent to an extra intake of 100 µg per day): should result in 15 fewer cases of NTD per year; condition: other voluntarily fortified products should be removed from the market (throughout the EU). 3. ultrasound scan 20 weeks after conception, with the option of terminating the pregnancy.
Characterisation	Indicate the benefits and risks of all risk management options (with the associated uncertainties) using selected units, report perceptions.

Evaluation & Decision-Making	Decide what action is appropriate, given the benefits and risks involved, consider the uncertainties involved when weighing up the pros and cons; find a good balance between the risk of excessive restraint with regard to folic acid use (additional cases of neural tube defects) and insufficient protection (possible additional cases of cancer); balance may turn out differently for distinct population subgroups; consider the distribution of benefits and risks throughout the population, apply the principle of subsidiarity (less drastic measures – e.g. with respect to infringement of civil autonomy – preferable to more radical approach), weigh up the cost involved (e.g. per QALY); feasibility 2nd option dependant on the practicability of removing other products that are fortified with synthetic folic acid from the market.
Management	Implementation of selected options; the following should be monitored in all cases: folic acid intake, the occurrence of neural tube defects, the masking of vitamin B12 deficiencies, stroke and cancer (including colorectal cancer); evaluation of results at agreed intervals or earlier if the data indicates that this is appropriate.

5.3 Application of the precautionary principle in relation to intracytoplasmic sperm injection (ICSI) with surgically obtained sperm

About 10 per cent of men who wish to have children but are unable to do so are azoospermic.[207] This means that there are no sperm in the ejaculate. The causes of azoospermia are divided into two categories. In obstructive azoospermia, spermatogenesis is normal, but there is a problem with the delivery of the sperm. This may be due, for example, to a congenital absence of seminal tubes, inflammation of the epididymis or a failed surgical attempt to reverse an earlier vasectomy. Most commonly, however, azoospermia has an unobstructive cause. In unobstructive azoospermia, the problem is not with the delivery of sperm, but with its production (spermatogenesis). This can result from a genetic abnormality or from damage (e.g. following chemotherapy), but the cause is usually unknown.

Intracytoplasmic sperm injection (ICSI) was introduced to the Netherlands in 1994 and has revolutionised the treatment of male subfertility.[207] It is a form of *in vitro* fertilisation (IVF), involving the injection of a single sperm cell into an egg cell. The procedure makes it possible for men whose sperm quality is substantially below normal to father children that are genetically their own.

If the ejaculate contains few (strong) sperm cells (oligospermia), sperm cells can be extracted from the ejaculate for use in the IVF procedure. If the man is completely azoospermic, sperm cells must be surgically isolated from the epididymis or testis. In men with obstructive azoospermia, sperm cells can usually be harvested from the epididymis. Initially, the sperm was obtained by a microsurgical procedure (MESA), but this practice has been superseded by a dermal puncture procedure (PESA). In cases of unobstructive azoospermia, sperm cells will be absent from the epididymis, but can sometimes be found in the testis. These

can be isolated by means of a surgical procedure (TESE). Extracted sperm cells can be used in an ICSI procedure the same day, or frozen for later use.[207]

In 1994 and 1995, articles appeared in the scientific press, suggesting that the sperm cells used in ICSI could have genetic abnormalities, thus giving rise to questions about the possible consequences for the health of the resulting children.[208,209] In response to questions in the Lower House of the Dutch Parliament[210, 211], the Minister of Health, Welfare and Sport replied that, because of the experimental nature of the procedure, she favoured a cautious approach. She also indicated that she planned to consult the relevant professional groups, that she was asking the Health Care Inspectorate to investigate the scale of the procedure's application and that she had asked the Health Council to report on the current level of knowledge concerning ICSI. The issue's ambiguities, such as the question of how important it is to have a child that is genetically one's own[212] did not apparently motivate the request. Utrecht University Hospital had meanwhile declared its intention to stop using ICSI in combination with MESA, because of safety concerns.

In 1996, the Health Council's 'Review of the IVF Planning Decree' Committee concluded that further clinical application of MESA and TESE was irresponsible, and advocated the introduction of a moratorium. Its view was based mainly on theoretical grounds, as virtually nothing was known about the potential risks at that time.[213] ICSI with ejaculated sperm was, however, deemed acceptable, subject to strict conditions, such as the careful selection of sperm (good morphology and motility), effective follow-up of the descendants, and the provision of good information to the parents. In anticipation of a ministerial decision, gynaecologists and clinical embryologists decided to declare a voluntary moratorium on ICSI with surgically obtained sperm cells. Freya, the group that represents people with fertility problems, questioned the need for such a moratorium, as this was already a routine procedure in other countries. The Minister endorsed the Council's opinion, however, and embraced the professions' voluntary moratorium. In 1998, it enacted into law as the *In Vitro* Fertilisation Planning Decree.[214] This meant that the Netherlands was the only country in the world where this treatment was prohibited. As a result, the moratorium remained at the centre of an ongoing debate. In addition, many patients responded by seeking treatment abroad, mainly in Belgium and Germany.[207]

By the year 2000, however, a body of reassuring data had became available from experimental animal research, from sperm cell research, and from clinical practice abroad. Accordingly, the decision was taken to allow ICSI treatments in combination with MESA/PESA to take place in a research setting, i.e. in a lim-

ited number of clinics, with follow-up for the patients and their children. In 2007, the same applied for ICSI in combination with TESE.[207]

The developments described above illustrate that relatively strict regulatory controls implemented in accordance with the precautionary principle can later be eased, as new, reassuring research data becomes available, thus reducing the level of uncertainty regarding the risks. In fact, this involved running through the entire assessment and decision-making cycle again, several times. Each time new amendments were made to the policy. It may be expected that the clinical research now in progress will in due course contribute to a further reduction of uncertainty in this particular field.

By opting for a moratorium on the application of ICSI with surgically obtained sperm cells, the Health Council, the professions, and the government have indicated that they are less concerned about the consequences of false-positive results (which would unnecessarily deprive some patients of the opportunity to have a child that was genetically their own) than about the consequences of false-negative results (which could result in children with genetic defects or other problems). Freya, the patients' association, took the opposite view, with the provision that there would be effective follow-up for the children in question.

Should the applications of ICSI in combination with MESA and TESE that are currently taking place in a research setting establish that such techniques are actually safe, then the moratorium on ICSI with surgically obtained sperm cells will have served to show that caution, which is dictated by false positive results or expectations, also comes at a price. There is nothing wrong with that, as such, provided that those involved are fully aware of the fact. It is the price that has to be paid for the exacting requirements placed on the safety of medical interventions. Table 3 illustrates how the various stages in the assessment and decision-making process have been shaped by the precautionary principle.

Table 3 Developing the various stages in the assessment and decision-making process on the issue of ICSI using surgically obtained sperm cells (MESA/TESE).

Stage	Development
Specification	
Characteristics	In the mid-1990s, there was considerable uncertainty about whether ICSI treatment with surgically obtained sperm cells was safe for the offspring. There was a lack of certainty about the nature and severity of the potential health effects, especially in the longer term, which included the possibility of genetic or epigenetic defects. Number involved: technique had already been introduced into clinical practice: up to 1995 there were 1500 ICSI treatments in 11 IVF centres (2100 were planned for 1996, in 12 centres); seven centres also performed ICSI in combination with MESA or TESE, 85-90 times. Risk at that time was deemed plausible (mainly on theoretical grounds) in the scientific literature; Utrecht University Hospital suspended ICSI in combination with MESA. The Minister of Health called for restraint in using the technique due to uncertainty about the associated health effects and the experimental nature of the technique. There is also some ambiguity here: how important is it for people to have a child that is genetically their own?
Participation	In 1996, the Minister consulted with the relevant professional groups: the Netherlands Association for Obstetrics and Gynaecology (NVOG) and the Association of Clinical Embryologists (KLEM). In view of the uncertainties involved, she also requested an advisory report from the Health Council. The Council, in turn, consulted bodies such as FREYA, a group that represents people with fertility problems.
Demarcation and data relevance	The request for advice made by the Minister relates to ICSI in general; relevant data: epidemiological research (ICSI children cohort), *in vitro* research and studies in experimental animals, genetic and morphological research on sperm cells.
Collection & Analysis	
Benefits	This procedure makes it possible for men whose sperm quality is substantially below normal to father children that are genetically their own. About 18 to 25 per cent of all treatment cycles started result in fertilisation and subsequent pregnancy.
Risks	In 1996, the Health Council concluded that largely unknown health risks might derive from a link between some forms of male infertility and certain hereditary conditions, the use of old or immature sperm, the absence of sperm cell selection of the kind involved in natural fertilisation, and the mechanical perforation of the egg cell. Clinical introduction was not preceded by studies in experimental animals, due to the lack of a suitable animal model. Following the evaluation of large numbers of ICSI pregnancies, no significant risks have come to light. However, the descendants in question are still very young. In the case of ICSI with ejaculated sperm, the risk of using old or immature sperm is lower than in the case of MESA or TESE, provided that the sperm cells are carefully selected on the basis of their external characteristics. ICSI with MESA of TESE has not been sufficiently widely used to enable any conclusions about safety to be drawn.
Perceptions	In 1996, a Heath Council committee considered the use of MESA and TESE to be irresponsible and called for a moratorium. Studies in experimental animals were required in order to understand the risks involved. The Committee saw ICSI with ejaculated sperm as a method of last resort, which was only acceptable under strict conditions. In 1996, NVOG and KLEM announced a voluntary moratorium for ICSI with MESA and TESE. They wanted to see whether it was possible to conduct these treatments in a research setting, and to review the options for studies in experimental animals. Freya did not consider ICSI to be experimental, and saw no reason for the moratorium. It did, however, stress the need for follow-up studies.
Risk management option	Encouraging the use of alternative treatments is not an option. There are few, if any, alternative treatments of proven efficacy. Artificial donor insemination (ADI) can provide a couple with a child, but it will be the genetic offspring of the mother only. Adoption is also an alternative to IVF treatment, but the child is not then the genetic offspring of either parent. Possible courses of action: approve, subject to strict conditions or impose a moratorium and encourage further research until there is greater certainty about the safety of the technique.
Characterisation	The Health Council's advisory report can be seen as a characterisation of the issue, even though it does not incorporate the views of the patients' association.

Evaluation & Decision-Making	In 1996, the Minister of Health, Welfare and Sport largely endorsed the Health Council's position. [215] She was satisfied with the voluntary moratorium imposed on the clinical application of ICSI with MESA and TESE by the professions involved, pending the results of experimental animal studies. She asked the centres involved to modify the statutory IVF protocols relating to ICSI accordingly. The professionals involved also largely agreed with the conclusions and recommendations put forward by the Health Council.
Management	In 1998, the requirement for IVF centres to observe the moratorium on ICSI with MESA and TESE was enacted into law as part of the *In Vitro* Fertilisation Planning Decree[214]. Patients sought treatment abroad[207]. By 2000, there was adequate data from experimental animal studies, sperm cell research, and data on ICSI with MESA/PESA from other countries to establish the safety of the technique. The professionals involved advocated that the technique be used in a research setting approved by the Central Committee on Research Involving Human Subjects. The Minister for Health, Welfare and Sport amended the Planning Decree. ICSI with MESA/PESA was once again available in the Netherlands, albeit on a limited scale[207]. In 2003: Freya called for the wider availability of ICSI with MESA/PESA, and approval for ICSI with TESE[216] In 2007: reassuring data from other countries concerning ICSI with TESE. The professions involved advocated that the technique be used in a research setting approved by the Central Committee on Research Involving Human Subjects. ICSI with TESE was once again available in the Netherlands, albeit on a limited scale.[207]

Chapter 6

Concluding deliberations

In this final chapter, the Committee summarises its findings and makes a few comments. In doing so it also responds to the questions posed by the President of the Council.

6.1 What does the precautionary principle involve?

Definitions

A principle is a reason that argues in one direction, but does not necessitate a particular decision. In the case of the precautionary principle, that action involves implementing a process of assessing and managing risks. The direction is towards the anticipatory exercise of caution with a view to preventing something undesirable. A variety of definitions of the precautionary principle can be found in policy documents and scientific literature, most of which feature a variation on the following structure: if there is a threat(1), which is uncertain(2), one may/should(3) act(4). The numbers in brackets identify the four key elements that are common to the definitions referred to. The various definitions differ little with regard to the first two elements: most stipulate that the threat must be serious *and* plausible. More difference exists with regard to the third and fourth elements: the degree of obligation to act and the conditions that any action must meet. Variants of the precautionary principle that state that action is necessary (the third key element) and which advocate the use of predominantly stronger actions are

described as ‘strong’, while those that state that action is merely acceptable are termed ‘weak’.

The Committee does not, however, consider the distinction particularly important in the context of this report. The Committee does not see the precautionary principle as a decision rule, in the sense that it requires that risks carry more weight than benefits. Accordingly, it provides no direction in decision-making. The Committee sees the principle more as a strategy for dealing with uncertainty in an careful, reasonable, transparent and flexible fashion. The nature of the decision that is ultimately arrived at is not prescribed by the precautionary principle. As a result, the exact wording used is less important.

Divided opinion

Although the precautionary principle has now been embraced by the European Union and is enshrined in many international environmental treaties, it has been widely criticised. Opponents regard it as an obstacle to progress, as vague and unscientific or even anti-scientific, and as leading to arbitrary and risk-averse policy. However, the Committee takes the view that it has shaped the principle in such a way (as a strategy for dealing with uncertainty in an alert, careful, reasonable, flexible and transparent fashion) that these criticisms no longer apply.

The difference between precaution and prevention

The precautionary principle is often associated with the prevention principle, since both preventive action and precautionary action are intended to prevent harm. There is nevertheless an important difference between them. Preventive action entails acting in the knowledge that, without counteraction, a hazard will manifest itself and harm will be done, at least at the population level. That damage is usually also easy to quantify. So, with precautionary action, there is always uncertainty about the need for protective action, because it is not known how real the risk is. If harm is already manifest and the cause known, targeted preventive action can be taken to prevent further harm. If the cause is merely suspected, one may take precautionary action against the suspected cause; however, whether by doing so one prevents further harm will depend on the actual role of the suspected cause. There is no advance certainty concerning the effectiveness of the measures. Just as there is a gradual transition from certainty to uncertainty there is also a gradual transition from preventive to precautionary action. In practice, a policy will often involve a mixture of preventive action and precautionary action.

6.2 Which risk issues on the environmental, occupational health and safety, nutrition and health care policy fields lend themselves to application of the precautionary principle?

Precaution in risk issues that are characterised by substantial uncertainty

The Committee sees the precautionary principle, in fact, as a strategy for dealing with uncertainty in a sensible and transparent fashion. This can arise due to gaps in knowledge. With regard to the introduction of new technologies or products, the uncertainty may involve the possible hazards, the risks, the severity and extent of any adverse consequences, and the likelihood that they will occur. In the case of damage that has already been reported, it may relate to the possible causes. Uncertainty is not the only characteristic that can complicate the decision-making process in risk issues: others are ambiguity (differences in value judgments) and complexity (involved cause-effect relationships). There are no clear lines of demarcation between each of these three characteristics, and they do influence one another, nevertheless each one requires a different individual approach. In the case of ambiguity, that would be a strategy based on consultations about value judgments. As previously stated, the approach for uncertainty is based on the precautionary principle, while complexity involves an approach based on consultation about all risk information. Based on these three characteristics, risk issues can be classified into four categories: ambiguous, uncertain, complex and simple. In the latter category, none of the three obstacles are involved to any significant extent. The Committee questions the usefulness of such a classification, however, as many issues exhibit all of these characteristics to a greater or lesser extent. Accordingly, the precautionary principle is applicable to risk issues in which decision-making is hampered by substantial uncertainty. Often, however, ambiguity and complexity will also be involved. Such issues require a strategy that integrates all three category-specific approaches.

Plausibility and seriousness

If uncertainty is to be deemed a sufficiently important obstacle to the decision-making process associated with a given issue to warrant application of the precautionary principle, then - when all the available information is taken into account - there must be a credible threat. In other words, a plausible risk must be involved. Without plausibility, there can be no significant element of uncertainty.

Determining the degree of plausibility is primarily a job for the experts. The role of non-experts is to contribute to the quality of the judgement by testing and challenging the reasoning used, and - where necessary – by broadening the experts' horizons. The experts should be encouraged to be receptive to this process, and to pay due respect to the limits of knowledge. One could argue that there is some plausibility if at least a number of acknowledged scientists active in the relevant field have serious concerns about the threat in question.

Details of the exact plausibility threshold at which action is justified, and of the type of action involved, need to be judged in consultation with stakeholders on a case-by-case basis. However, this problem is not peculiar to assessment in the context of the precautionary principle; if action had to be based on firm evidence, it would be equally difficult to decide whether the criterion for action had been met. The answers to these questions are context dependent and are determined by a range of factors. These include the severity and extent of possible damage, the social disquiet which gives rise to the risk, the benefits to society that are at stake, the potential availability of alternative ways of deriving the same benefits, and the costs involved.

General applicability of the precautionary principle

Precaution is a strategy for dealing with uncertainty. The Committee therefore takes the view that the precautionary principle can be applied to any risk issue in which decision-making is hampered by uncertainty. Accordingly, it believes that the principle could be applied to all areas of public health policy, namely health care, the environment, nutrition, and occupational health and safety. Its usefulness even extends to the field of economics, for example, which can also involve uncertain risk issues. Use of the precautionary principle is currently confined mainly to the domains of the environment and of nutrition. Furthermore, the key actors differ from domain to domain, and each domain has its own traditional ways of controlling risk and dealing with uncertainty. Where pharmaceutical products are concerned, for example, the responsibility for demonstrating efficacy and safety lies with the industry, subject to review by the government and a post-marketing surveillance system for reporting any adverse effects of licensed products. The system may be regarded as an expression of the precautionary principle, even though it was not described as such at the time of its introduction. Another example is the management of occupational risk. In this context, a system of advice and responsibility has grown up, involving employers, employees, company doctors, occupational hygienists and safety experts. Within this system, decisions are made about uncertain risk issues, although no explicit reference is

made to the precautionary principle. Some examples are measures to counter work-related complaints to the arms, shoulder or neck (RSI) and psychological problems (burn-out).

6.3 How should the precautionary principle be applied in these policy domains?

Precaution in five steps

As detailed in chapter 4, risk issues are addressed in the context of an five-stage assessment and decision-making process. This process is in principle the same for all types of risk issue, although exactly what each process stage entails depends on the nature of the issue: the stages are relatively straightforward where simple risk issues are concerned, but become more involved and difficult to implement as the complexity, uncertainty or ambiguity of the risk issue under consideration increases. In the case of substantial uncertainty, the strategy for dealing with it (the precautionary principle) needs to shape all five stages, rather than merely the last two ('Evaluation and Decision-Making' and 'Management') as is commonly believed. Both the design of the stages and the activities involved should reflect the principle.

During the first stage ('Specification'), policy makers provisionally determine that the decision-making process is complicated by substantial uncertainty and application of the precautionary principle would appear to be appropriate. Of particular importance are participative problem definition and demarcation. In the Collection and Analysis stage, the available risk control options – including the option of taking no action at all – are examined. The risks and benefits associated with each option are analysed on the basis of all the available information. The social context, such as the concerns and perceptions of stakeholders, is also taken into account. The precautionary aspects of this stage include the mapping of all uncertainties and ensuring balanced consideration of the possibility of false positive and false negative results. At the process's Characterisation stage, when all the information has to be properly summarised and organised, a definite decision has to be taken as to whether the issue does indeed involve an uncertain but plausible threat justifying a precautionary approach. If the provisional conclusion is confirmed, the 'Evaluation and Decision-Making' stage will involve deciding on a course of action in accordance with the precautionary principle. To this end, the option that offers the most favourable balance between risks and benefits has to be selected, in or following consultation with all interested parties. When making the selection, the distribution of costs and benefits across the different popu-

lation groups and across current and future generations needs to be taken into account. Greater precaution can often be exercised in the regulation of new practices than in the regulation of established ones, because of the more favourable cost-benefit relationship involved.

The uncertainty, which is often associated more with the risks than with the benefits, should be incorporated into this evaluation process. In this uncertain situation, it is important to find a good balance between the risk of excessive restraint and the risk of excessive optimism. What constitutes an appropriate balance depends on the weight that one attaches to the consequences of each type of error. Excessive restraint can lead to the unnecessary loss of societal benefits (possibly in the form of health or environmental benefits). Excessive overconfidence may result in serious harm (typically to human health or the environment). Finally, in the 'Management' stage, the selected course of action is put into effect. Given the uncertainty involved, the consequences of the selected policy are monitored over time. If relevant new information comes to light, a renewed assessment and decision-making process be put in motion, as in the case of ICSI using surgically obtained sperm cells.

The role of knowledge

Scientific knowledge plays an important role in the entire process. Hence, the Committee rejects the suggestion that the precautionary principle is unscientific or anti-scientific. In fact, the available scientific information is handled in just the same way as if greater certainty existed. The only difference is that decision-making is guided more by plausibility than by certainty. The notion that objectivity depends on a large degree of certainty is a misconception.[53]

An uncertain risk issue is characterised by a lack of knowledge, combined with uncertainty regarding such knowledge as is available. The role of knowledge in the assessment and decision-making process is therefore necessarily limited. Partly for this reason, the Committee advocates making use of all possible forms of knowledge: not only knowledge from scientific research, but also experience-based expertise possessed by the relevant actors. Assurance of the quality of scientific knowledge is primarily the responsibility of the scientific community, which performs this task through the peer review system. However, actors' enquiries regarding the significance of scientific debates make a valuable contribution as well. In general, communication in the context of the assessment and decision-making process should be geared to promoting and assuring the quality of all the knowledge and expertise that informs the deliberations.

The role of value judgements

Value judgements are a feature of all science and – alongside factual knowledge – inevitably play a major role in scientifically informed risk assessment and decision-making.[130] This is especially true in the context of risk issues that are characterised by ambiguity, which by definition involve differences of opinion amongst different groups within society about what warrants protection. However, it is also true where all other types of risk issue are concerned, not least those involving substantial uncertainty. Even if agreement can be reached as to what warrants protection (human health, environmental quality, biodiversity), there may still be differences of opinion on numerous other issues. When may a threat be deemed plausible? What degree of plausibility is sufficient to justify action? To what lengths are we prepared to go in order to reduce a risk? How can one weigh up the relative importance of dissimilar benefits and risks? What constitutes a fair balance between pleasure and pain, or between overcautiousness and an inappropriate lack of caution? These questions cannot easily be answered on the basis of the available knowledge.

The precautionary principle is used when a choice has to be made, in situations which almost always involve moral considerations. As such, it touches on the relationship between the principles of beneficence and non-maleficence and implicitly involves concepts such as respect for others and fairness. If our actions are to be considered fair, we must take account of the risks that a practice entails not only for us, but also for others, such as people in the developing world or future generations. People will inevitably differ in their views on what is appropriate in this regard; some are risk-averse by nature, while others are risk-inclined; some have a libertarian philosophy, while others have a more welfare-based vision of the government's role.

Participation of stakeholders

Because value judgements play such an important role in the analysis, assessment and decision-making process, the Committee believes that interested parties must be involved throughout the process of risk governance. Such an approach is a corollary of the principle of respect for others, which implies a respect for their views. Various practical arguments can be put forward here. One is that stakeholders can add their own forms of expertise, thereby contributing to the quality of the decisions. Another is that policies which enjoy broad societal support are more likely to be successful than those that do not. This approach also bolsters confidence in institutions and procedures.[52] A crucial element in our

democratic system is that the ultimate decision-making authority rests with the government. Alternatively, the government determines the framework within which other parties have a say in decisions. This is important because multi-stakeholder consultations never include all of the interested parties. This applies, for example, to future generations. Moreover, this helps to even out the sometimes considerable power disparities between those stakeholders who are involved.

The various interested parties play different roles in the risk assessment and decision-making process. Independent experts, together with those from the relevant government bodies, take the lead in collecting and interpreting knowledge (the 'Collection and Analysis' and 'Characterisation' stages). Stakeholders provide input and express their perceptions. Policy-makers and politicians have ultimate responsibility for formulating a decision and therefore come to the fore at the 'Evaluation and Decision-Making' stage and the 'Management' stage. In keeping with the governance concept, the objective is to reach a decision that enjoys the widest possible support. The stakeholders' main contribution is made at the boundary between the scientific and policy domains, where value judgements are most important, namely at the Specification stage, in the context of problem definition and demarcation, and at the 'Evaluation and Decision-Making stage, in the context of evaluation of courses of action.

The successful involvement of stakeholders in assessment and decision-making is not easy to achieve, however. Complex assessments of incomprehensible technical and scientific information need to be made by the stakeholders, who often differ markedly in terms of their levels of knowledge and views. Moreover, partly because of the increasing availability of information (of varying degrees of reliability) through the Internet and the growing empowerment of citizens and stakeholders, society is gradually changing from a 'high trust' to a 'low-trust' community. There is, therefore, a pressing need for people who are capable of supervising or directing the process of governance. To this end, appropriate training should be included in the curricula of various disciplines. Tools for use in the implementation of the process are also required. Some already exist, such as the aforementioned RISCOM model[177, 178,180], a stakeholder participation support tool developed by the Netherlands Environmental Assessment Agency (MNP)[126], a method for dealing with uncertainties (from the same institution)[142, 157]. Furthermore, experience has been gained with local partnerships.[181] It is advisable that these tools be further improved, and that new ones be developed. Indeed, this is already happening in various scientific disciplines, such as environmental economics, health economics, policy science and decision science. However, inter-

disciplinary barriers stand in the way of a structured and efficient approach. Hence, research programming is advisable.

Carefulness and reasonableness

The involvement of a variety of parties, each with their own expertise and their own outlooks and values, makes the assessment and decision-making process more involved, but also contributes to its quality. When dealing with uncertainties, carefulness and reasonableness have to be assured by adhering to the system of governance. A careful broad-based assessment and decision-making process is the best way of avoiding the problems highlighted by critics of the precautionary approach, such as disregard for the benefits of new technologies or for the risks associated with the precautionary action itself. A collective decision must also be reached as to what action is reasonable in light of the seriousness and the likelihood of the potential threat. Contrary to what is sometimes suggested, such action may encompass a great deal more than simply the prohibition of certain practices or products. Application of the precautionary principle does not necessarily imply draconian restriction.

Guilty until proven innocent or innocent until proven guilty? The Committee takes the view that, when it comes to the wide-ranging question of public health, the most reasonable approach is a middle course between the presumption of guilt and the presumption of innocence. The side to which a policy should lean depends on the consequences of an inappropriate decision that one is most anxious to avoid: those that are liable to result from overcautiousness or those that are liable to result from inappropriate lack of caution. The Committee therefore believes that application of the precautionary principle does not mean that the burden of proof is borne entirely by the entrepreneur or producer in question. Rather, it implies striving to find an appropriate balance. The Committee does, however, share the view that people have a moral duty to investigate the harm that can potentially result from their activities. Failure to conduct proper investigations to that end is morally culpable in the Committee's eyes. The exact interpretation of 'proper' in this connection will have to be reviewed in consultation and on a case by case basis.

Arbitrary or tailored decision-making?

Precaution is a basic human instinct that serves to protect us in situations where we face uncertain but plausible and potentially serious threats. It is a higher order principle, which is intended to guide the formulation of more specific laws and

government policies. Because it needs to be applicable in the most varied circumstances, it can only be defined in general and rather abstract terms.[53] Further clarification is only possible in a given context.

Every risk issue is different and involves different actors with different values. The Committee sees nothing arbitrary about a carefully organised and government-supervised risk assessment and decision-making process that involves all interested parties collectively seeking to identify – and negotiate on – precautionary action that is reasonable in view of the seriousness and plausibility of a given threat, and of the benefits that are at stake. Rather, the Committee regards such a process as a form of careful, tailored decision-making.

Can a procedural precautionary principle prevent harm?

As the Committee previously indicated, some people are sceptical about the usefulness of a procedural application of the precautionary principle. The Committee believes, however, that it does indeed lead to better decisions, that it can complement instruments such as classical risk analysis and cost-utility analysis and, most importantly, that it can improve the protection of human health and the environment. Dealing with uncertainties in an alert, careful, reasonable and transparent fashion, which takes account of the particular situation, avoids undue importance being attached to known benefits that are expected to materialise in the short-term relative to uncertain disadvantages, which often manifest themselves only in the long term. Such an approach also provides better safeguards for future generations. While it is true that a precautionary principle of this kind will not entirely protect society from unpleasant surprises, it will make them less likely. It helps to ensure that the focus on possible adverse effects keeps pace with the development of new technologies. It promotes a dynamic and iterative process of policy formulation, monitoring and review, and thus reduces the danger of early warnings being overlooked or lightly discounted, while enhancing the prospects for early intervention. This in turn restricts any damage. Finally, adherence to the principle makes it clear that, in situations characterised by uncertainty, we must decide in advance, consciously and as well informed as possible, which consequences are most acceptable to us, those resulting from excessive restraint or those resulting from excessive optimism. The Committee hopes that general adoption of the precautionary principle will increasingly lead to the establishment of a culture in which uncertainties are consciously addressed. Similar developments are now taking place in the field of radiological protection, guided by the ALARA principle.

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A Request for advice

B The committee

C Consultations with community stakeholder organisations

D Experts consulted

E The ALARA principle

Annexes

Annex **A**

Request for advice

Primary questions

1 How can the concepts ‘precaution’, ‘precautionary principle’, ‘prevention’ and ‘prevention principle’ best be defined?

2 How are the concepts ‘precaution’, ‘risk’ and ‘uncertainty’ related? Can a typology of risk assist decision-making in the context of a precautionary policy?

3 What similarities and differences exist in the way that a precautionary policy or the precautionary principle is applied in the fields of occupational health and safety, health care, the environment and nutrition?

4 What role does knowledge play in decision-making in the context of precautionary policy aimed at protecting public health? What types of knowledge may be distinguished, where does the relevant knowledge come from and by whom is its quality assessed?

Subsidiary questions

a When applying the precautionary principle, is it necessary to distinguish between existing and new practices, furthermore should particular risk groups and the number of people at risk be taken into account?

b How does the distribution of costs and benefits across different groups influence the way that the precautionary principle is applied?

c Does application of the precautionary principle place specific requirements on the various actors involved?

d Does scientific knowledge have a special position, as one of several relevant forms of knowledge, within a precautionary policy?

e How can dissimilar health risks be weighed up against one another in the context of the decision-making process?

f Can codification of the precautionary principle in Dutch law contribute to the improvement of public health?

Annex **B**

The Committee

- Professor C.A.J. Vlek – *chairman* (until 29-8-2007)
  professor emeritus of environmental psychology and behavioural decision research, University of Groningen
- Professor J.A. Knottnerus – *chairman* (from 6-9-2007)
  president of the Health Council, The Hague
- Professor W.E. Bijker
  professor of technology and society studies, Maastricht University
- Professor D.D.M. Braat
  professor of obstetrics and gynaecology, Radboud University Medical Centre, Nijmegen
- Professor G. Eggermont
  visiting professor of radiation protection and nuclear waste management, Vrije Universiteit, Brussels
- Professor M.H.W. Frings-Dresen
  professor of work-related disorders, Academic Medical Centre, Amsterdam
- Professor L.J. Gunning-Schepers – *advisor* (until 14-4-2006)
  professor of social medicine and board of directors Academic Medical Centre, Amsterdam
- Professor J.C.S. Kleinjans
  professor of environmental health science, Maastricht University

- Professor E. Lebret,
  RIVM, Bilthoven and professor of environmental health impact assessment, IRAS, Utrecht University
- Professor P. Leroy
  professor of political sciences of the environment, Radboud University, Nijmegen
- Professor E.G. Schouten
  professor of epidemiology, Wageningen University
- Professor D.R.M. Timmermans
  professor of risk communication and patient decision-making, EMGO Institute, VU Medical Centre, Amsterdam
- Professor S.P. Verloove-Vanhorick (until 7-9-2004)
  TNO Quality of Life, Leiden and professor of preventive and curative health care for children, Leiden University
- Professor E.I.L. Vos,
  professor of European Union Law, Maastricht University
- N.M. van Kuijeren – *scientific secretary* (until 31-12-2006)
  Health Council, The Hague
- Professor W.F. Passchier – *scientific secretary* (until 24-8-2007, from then on *advisor*)
  Health Council, The Hague and special professor of risk analysis, Maastricht University
- Doctor H.F.G. van Dijk – *scientific secretary* (from 1-1-2007)
  Health Council, The Hague

The Health Council and interests

Members of Health Council Committees – which also include the members of the Advisory Council on Health Research (RGO) since 1 February 2008 – are appointed in a personal capacity because of their special expertise in the matters to be addressed. Nonetheless, it is precisely because of this expertise that they may also have interests. This in itself does not necessarily present an obstacle for membership of a Health Council Committee. Transparency regarding possible conflicts of interest is nonetheless important, both for the President and members of a Committee and for the President of the Health Council. On being invited to join a Committee, members are asked to submit a form detailing the functions they hold and any other material and immaterial interests which could be relevant for the Committee's work. It is the responsibility of the President of the Health Council to assess whether the interests indicated constitute grounds for

non-appointment. An advisorship will then sometimes make it possible to exploit the expertise of the specialist involved. During the establishment meeting the declarations issued are discussed, so that all members of the Committee are aware of each other’s possible interests.

Annex **C**

Consultations with community stakeholder organisations

The President of the Health Council invited thirty community stakeholder organisations to contribute relevant information during the process of drafting the advisory report (see attached letter). The following organisations responded to this request, either verbally or in writing.

- Dutch Consumers' Organisation (Consumentenbond), The Hague
- Employers' Organisation and Trade Association for the Technological-Industrial Sector (FME-CWM), Zoetermeer
- Netherlands Association of Community Health Services (GGD-Nederland), Utrecht
- Royal Dutch Association for the Advancement of Pharmacy (KNMP), The Hague
- Monitoring Network Health and Environment (MNGM), Bunnik
- Royal Association of Small and Medium Enterprises (MKB Nederland), Delft
- Federation of Patients and Consumer Organisations in the Netherlands (NPCF), Utrecht
- Association of Dutch Innovative Pharmaceutical Industry (Nefarma), The Hague
- Dutch Crop Protection Association (Nefyto), The Hague
- Dutch College of General Practitioners (NHG), Utrecht
- Dutch Food Industry (VAI, now FNLI), Rijswijk
- Confederation of Netherlands Industry and Employers (VNO-NCW), The Hague

Letter dated 21 November, 2003, from the President of the Health Council to thirty community stakeholder organisations (reference U1781 NvK/mz 661):

To whom it may concern,

The Health Council is currently preparing an advisory report on the concept of precaution and its implications for public health policy in the Netherlands. To this end, the Committee on Precaution and Health was established. The advisory report identifies four areas of policy, each of which is linked to public health. These are occupational health and safety, health care, the environment and nutrition. The purpose of the advisory report is to provide the Dutch government with avenues for the implementation of precautionary action. In its advisory report, the Committee will address the following questions:

- How can the concepts ‘precaution’, ‘precautionary principle’, ‘prevention’ and ‘prevention principle’ best be defined?
- How are the concepts ‘precaution’, ‘risk’ and ‘uncertainty’ related? Can a typology of risk assist decision-making in the context of a precautionary policy?
- What similarities and differences exist in the way that a precautionary policy or the precautionary principle is applied in the fields of occupational health and safety, health care, the environment and nutrition?
- What role does knowledge play in decision-making in the context of precautionary policy aimed at protecting public health? What types of knowledge may be distinguished, where does the relevant knowledge come from and by whom is its quality assessed?

In addition to scientific data, the Health Council wants to incorporate information from community stakeholder groups in the advisory report. In that context, I would like to invite you to bring to the Council's attention such relevant information as might be important for the scientific analysis.

With this in mind, the following questions might provide a useful guide:

1 What do you understand the ‘precautionary principle’ to mean?
2 What, in your view, is the significance of the precautionary principle?
3 Do you believe that the precautionary principle is of practical use in terms of public health policy in the Netherlands?
4 Do you think that the precautionary principle is of use in all of the areas mentioned (occupational health and safety, health care, the environment and nutrition)?
5 What are the major obstacles to the use of precaution in Dutch public health policy?

Please send in your written response as soon as possible, but **no later than Monday, December 15, 2003** to the scientific secretary of the Committee on Precaution and Health.

Annex **D**

Experts consulted

In addition to the members of the Standing Committee on Medical Ethics and Health Law and of the Standing Committee on Health and Environment, the following experts have commented on the draft text (or parts thereof) of the advisory report:

- Professor C.H.C.M. Buys
  professor of human genetics, University of Groningen
- Doctor D. Gee
  European Environment Agency, Copenhagen
- Professor L.J. Gunning-Schepers
  professor of social medicine and board of directors Academic Medical Centre, Amsterdam
- F.A.C. Jaspers
  Board of directors, University Medical Centre, Groningen
- Professor G.J. Kok
  professor of applied psychology, Maastricht University
- Professor N.J. Leschot
  professor of clinical genetics, Academic Medical Centre, Amsterdam
- Professor P.J. van der Maas
  professor of public health, Erasmus Medical Centre, Rotterdam
- Professor J. van der Noordaa
  professor emeritus of virology, University of Amsterdam

- Professor D. van Norren
  professor of ophthalmic physics, Utrecht University
- Doctor G.C. van Rhoon,
  physicist, Erasmus Medical Centre, Rotterdam
- Professor P.J.J. Sauer
  professor of paediatrics, University Medical Centre, Groningen
- Professor E. Schroten
  professor of Christian ethics, Utrecht University
- Professor H.A. Verbrugh
  professor of clinical microbiology, Erasmus Medical Centre, Rotterdam
- Professor C.A.J. Vlek
  professor emeritus of environmental psychology and behavioural decision research, University of Groningen
- Professor J.W. Wladimiroff
  professor of obstetrics and gynaecology, Erasmus Medical Centre, Rotterdam

The following have contributed to the creation of the practical case studies in chapter 5:

- Doctor W.J. Dondorp, Health Council, The Hague (ICSI)
- Doctor RM Weggemans, Health Council, The Hague (Folic acid)

Annex **E**

The ALARA principle*

In some publications, the ALARA principle is referred to as an expression of the precautionary principle[1,2] The acronym ALARA stands for 'As Low As Reasonably Achievable'. Generally speaking, the principle implies that action should be taken to reduce a risk, unless the expectation of action would be unreasonable. Whether it is reasonable to expect action depends on the cost relative to the benefit likely to accrue from the reduction of risk. Reasonableness therefore depends not only on economic factors, but also on social considerations concerning the risks and the risk-engendering activity.

Radiation protection

The ALARA concept originates from the field of radiological protection.[3] It was a response to the problem that exposure to ionising radiation increases the risk of cancer, but it is not possible to say when or in whom the disease will manifest itself; in other words, a form of stochastic risk exists. Although the research data and the accepted theories indicate that, as exposure decreases, the risk of cancer must also decrease, it is not possible to identify a threshold level, below which exposure has no influence on the carcinogenic process.[4,5]

The ALARA principle finds expression in the optimisation requirement, one of the three pillars of the generally accepted system of radiation protection. The other

* This annex is based on a piece by Commissioner G. Eggermont.

two pillars are the justification requirement and compliance with individual dose limits. The justification requirement implies that applications that may involve exposure to ionising radiation have to be justified, i.e. do more good than harm. That applies both to applications in general – the use of X-rays for radiodiagnostics and the use of radioactive sources in radiotherapy – and to individual procedures – whether a particular patient should undergo radiodiagnosis or radiotherapy and, if so, using which modality. As explained below, these forms of justification can also be seen as expressions of the ALARA principle. Radiation dose limits are intended to ensure that individuals are afforded adequate protection. It should be noted that they do not apply to the radiation risk from the main forms of exposure experienced by the population at large – exposure to radiation from substances in the ground or in building materials, from outer space and from medical equipment.

The system of radiation protection outlined above is based upon recommendations made by the International Commission on Radiological Protection (ICRP).[3,6] It is the basis for international Basic Safety Standards.[7] It has also been embraced by the EU in the context of the Euratom treaty which affords the European Council harmonised powers to impose a system of radiation protection on member states by issuing directives.[8] The ALARA principle is enshrined in article 6 of Directive 96/29/Euratom, of 29/6/1996, and has therefore been implemented in Dutch law.[9]

The ALARA principle is based on the assumption that any dose of radiation increases the risk of cancer . Furthermore, it is assumed that, in the low exposure range for which observational data is lacking or surrounded by uncertainty, the relationship between exposure and cancer risk is linear.[4,5] This linear non-threshold (LNT) relationship was recently reconfirmed by the ICRP[3] by reference to sources such as the reports published by United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).[5] The LNT relationship in the low exposure range is a simplified assumption made to facilitate operational decision-making in accordance with the ALARA principle.* The precise nature of the actual relationship and whether sensitivity differences exist between, for example, people in different phases of life or people with different genetic make-ups is not clear. Nor is it known whether the LNT relationship constitutes an underestimation or an overestimation of the true risk, although it is possible to distinguish both to some degree.[10] **

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* When deriving a relationship between the extra risk of cancer and radiation exposure, on the basis of data on the effects of high radiation exposures, the assumption is also made that the range of low exposures and exposure tempos involves an additional risk reduction factor of 2.

** New research sometimes causes greater uncertainty, as it may reveal evidence of new mechanisms causing previously unsuspected effects.[4,11]

The uncertainty that exists regarding the consequences of exposure to low levels of ionising radiation may be deemed to justify application of the precautionary principle. For applications of radiation sources that are felt to bring sufficient benefit to society (i.e. that meet the justification requirement) and are therefore approved by the authorities, at least in principle, the optimisation requirement and the ALARA principle provide a framework for implementation of the precautionary principle in specific situations.[1,2]

The first step in application of the ALARA principle is the justification of specific instances of exposure to ionising radiation. This places a responsibility on all the relevant actors (operators, medical practitioners, experts, etc.) to weigh up all the advantages and disadvantages and to consider all the alternatives. Because of the uncertainties that exist regarding the consequences of radiation exposure, the selection of a preferred option is difficult to describe in quantitative terms and goes beyond classic technical-scientific risk analysis. Hence, the award of a permit for a particular radioactive application may to some extent reflect political, economic, social or cultural considerations, as well as perceptions communicated in the context of consultations with workers or local people. A doctor should be able to justify a radiological procedure on the basis of comparison against the alternatives, and a safety officer should be able to justify the choice of a system for filtering radioactive substances out of ventilation air. The licensing or supervisory authority can define rules – in the form of, for example, equipment quality requirements and dose constraints – to apply the ALARA principle[3]. However, the most important thing is that the party using the radiation source applies the ALARA principle in a systematic way.

Optimisation on the basis of the ALARA principle has in recent years made a difficult but successful evolution from a simple cost-benefit expression, which was hard to implement in practice due in part to uncertainties regarding the consequences of low exposures, into a practical methodical system for managing exposure to radiation.* The promotion of understanding of stochastic risk through training and motivation and establishment of the associated safety and ALARA culture (i.e. a culture characterised by the prioritisation of safety or radiation protection by the individual or organisation) have proved critical to successful risk management. Procedures and quality assurance play an important role.

Optimisation approaches based on the system outlined above are now entering use in medicine, where the levels of exposure experienced by patients can be considerable and there is substantial scope for reduction. Optimisation begins with referral

* See also the European ALARA Network (EAN): www.eu-alara.net

practices within radiodiagnostics (e.g. referral for CT scans). Patients can experience considerable exposure in the context of radiodiagnostic procedures, but with the help of hospital physicists the levels of exposure can be substantially reduced. Intervention radiology in paediatrics serves as another example.[12] In the technologically increasingly complex field of radiotherapy, the adoption of suitable quality control guidelines that integrate radiological protection principles is also important for the prevention of incidents and the reduction of secondary tumour risk.[13]

Having originally been developed to address the risks associated with higher radiation doses, the ALARA principle has, on account of the careful approach to uncertainty that it implies, gradually developed into a flexible methodology expressing the (albeit rarely explicitly mentioned) precautionary principle.[14]

Other fields

The ALARA principle has begun to enter use in other fields as well, but nowhere is it developed to the degree that it is in the field of radiological protection. One could make a good case for adopting a similar approach in the regulation of exposure to genotoxic carcinogens, since there is uncertainty about the consequences of low levels of exposure to these substances and the LNT approach is used in the estimation of risk.[15,16] However, scientists and policy makers are reluctant to apply the ALARA principle in this field, since it is felt that this might deflect attention from the substances that bring the greatest risks.[17]

In the Netherlands, the ALARA principle was introduced to environmental risk policy in the 1980s.[18-20] Partly because of uncertainty about the consequences of exposure to environmental factors such as chemicals, radiation and industrial accidents, the government considered that exposure to risks that exceeded a particular maximum level was unacceptable. Hence, risk reduction was considered desirable, but not at any price; in this context, the ALARA principle therefore applied. It is worth noting that application of this principle can, over time, lead to the reduction of maximum permissible risk levels (progressive standard setting).[30] While it has not proved possible to apply this principle to all sources of environmental risk,[21,22] the ALARA principle has certainly become one of the pillars of Dutch environmental policy.[23] The risk reduction requirement contained in the Environmental Management Act (Article 1.1) is qualified by the phrase ‘insofar as can reasonably be expected’ and may therefore be regarded as an expression of the ALARA principle.[24] The Occupational Health and Safety Act uses a similar approach (Article 3).[25] Adoption of the principle does raise an important enforcement question: how

does one determine whether it is reasonable to expect a particular course of action? In practice, ‘reasonableness’ is normally judged by comparison with what is normal in similar situations and by taking account of the technological options.[26] Nevertheless, by no means all legal experts are convinced of the value of the ALARA approach.[2,27]

The question is, to what extent can the ALARA principle be regarded as an expression of the precautionary principle? The precautionary principle was not explicitly referred to in the development of the regulations, either in the Netherlands, or in the United Kingdom (where, at about the time of the ALARA principle's adoption in the Netherlands, the same principle was adopted, albeit dubbed ALARP (As Low As Reasonably Practicable). However, the approach has the same motivation – disquiet regarding ‘environmental risks’[28] – as that which has driven introduction of the precautionary principle. Thus, the retrospective interpretation of the ALARA principle as a version of the precautionary principle is not unreasonable.[1,2] Nevertheless, it will be apparent that the ALARA principle is not identical to the precautionary principle. As developments within the radiation protection domain demonstrate, the ALARA principle comes into play only if the assessment and decision-making process has led to the conclusion that an activity that constitutes a ‘serious plausible threat’ is permissible. This also means that specific applications require further justification.

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