Not all risks are equal

A commentary on 'Premises for Risk Management'

GEZONDHEIDSRAAD

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In the eighties, 'risk management' made its entry into Dutch environmental policy. The heart of this approach is the recognition that damage or loss as a result of human activity cannot be excluded and possible damage or loss as a result of varying types of activities must be dealt with and limited consistently. This approach has been set out in an appendix to the Indicative Multi-year Programme on the Environment 1986-1990 and later in the memorandum 'Premises of Environmental Risk Management', an appendix to the first National Environmental Policy Plan which appeared in 1989.

In 1991, I came to the opinion that, given the fact that the environmental risk management approach had been used in practice for some time, it was sensible to examine its basic principles and suppositions. In May of that year, I therefore appointed a committee whose task was to draw up an advisory report about the possibilities and limitations of an assessment system for the risks created by varying activities as proposed in 'Premises for Risk Management'. I also asked this committee to provide a reply to the request for a report - dated 28 October 1991, reference DGM/DS/S/MBS no. 23091005 - which was received from the Minister of Housing, Spatial Planning and the Environment.

In consultation with myself, the committee decided to record its findings in two advisory reports. The first of these has been completed. It contains the comments of the committee with regard to the environmental risk management approach and also responds to the request for a report from the Minister of Housing, Spatial Planning and the Environment. Having heard the Standing Committee on Toxicology, the Standing Committee on Radiological Protection and the Standing Committee on Environmental Factors and Health, I am pleased to submit this report to you.

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In addition, I would like to draw your attention to the following. The committee's reasoning is very abstract and is therefore of a general nature. In accordance with the angle of the environmental risk management approach, the committee assumed a very general definition of the concept of 'risk'. This immediately led to a problem: in 'Premises for Risk Management', the term 'risk' is used both as a concept and as a measure for that concept (the risk measures used are 'individual risk', group risk' and 'collective risk for ecosystems'). This could easily lead to confusion. I would therefore recommend that the terminology should be adapted in this respect in accordance with the committee's comments.

The general approach of the committee has another result. Cause-effect sequences - which provide an insight into the origin of risks - occupy a central position in the committee's reasoning. This approach means that measures or packages of measures which affect parts of these sequences - the measures implemented in the context of the dangerous substances policy, for example - could only be given limited attention since methods for risk assessment and management in the various policy areas and sub-areas will inevitably differ from each other. The Health Council has recently published - or will soon do so - a number of other advisory reports about risk assessment relating to, for example, substances. Allow me to refer you to the reports Uniform System for the Evaluation of Substances (1991/08, 1993/18), Setting Integrated Environmental Quality Objectives (1995/07) and Principles of Radiation Protection (1994/28).

I would wish to point out that it is true for every stage of cause-effect sequences that - even if the possible effects are caused by 'permitted' exposure to substances, radiation or other stressors - continuous attention needs to be paid to the quality of the production and labour processes. The heart of a risk assessment is, after all, uncertainty about the possible forms of damage to, or loss of, health, ecosystems and goods.

The committee notes that simplifications of the concept of risk are required for practical decision-making about the admissibility of risks. However, it warns against over-simplification which might possibly lead to decisions which are controversial or undesirable for society as a whole. I agree with this and would wish to emphasise that it is desirable for simplifications and their possible implications to be made as transparent as possible. This also provides opportunities to discuss on a higher level risk problems which are more complicated than was initially thought. On this higher level, decision-making procedures are generally in use which are more comprehensive in nature.

Finally, I would wish to make one comment about the questions in the request for a report from the Minister of Housing, Spatial Planning and the Environment. These questions take the principles laid down in Premises for Environmental Risk Management as given facts. However, the committee makes some critical observations about those principles. This did not make answering the questions any easier. However, the committee expects that its report and the answers to the minister's questions will provide openings for the further development of environmental risk policy. In its subsequent report, the committee will make further recommendations in this regard.

Signed

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Report of a committee of the Health Council of the Netherlands

to:

the Minister of Health, Welfare and Sports

the Minister of Housing, Spatial Planning and the Environment

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Executive summary

The environmental risk management approach

The policy document 'Premises for Risk Management' (OmR*) sent by the Netherlands Government to Parliament in 1989 as appendix to the National Environment Plan has been instrumental in moving environmental risk assessment and management into the centre of interest. The 'environmental risk management approach' described in the policy document offers numerical limits for possible harm caused by exposure of people and ecosystems to major industrial hazards, to ionising radiation and to substances. With these limits, termed maximally tolerable risk levels, the Government specified what possible harm was considered to be tolerable. In addition to the maximally tolerable risk levels the Government also established at what risk level it considers further reduction of risk was no longer worthwhile, the so-called negligible risk levels. The formulation and practice of this risk policy has stimulated research and discussion about the most effective method of risk management and at the same time has increased awareness of the influence of environmental factors on the health of people and ecosystems.

Between 1989 and 1994 the environmental risk management approach was modified. Emphasis was placed on maximally tolerable risk levels and on the balance between the costs of further risk reduction and its benefits (the so-called ALARA approach). Furthermore, activities that lead to norms for seldom occurring but serious

* OmR is the abbreviation of 'Omgaan met risico's', the title in Dutch of the policy document.

accidents being exceeded, are no longer automatically banned in situations in which other, major interests are involved. The basic policy principles - as far as human health is concerned, the establishment of norms based on individual mortality and, as far as ecosystems are concerned, the maintenance of species - were not affected by the public debate.

A committee of the Health Council discusses in this report the basis of the risk management approach in Dutch environmental policy. The report is one of a pair; in a follow-up report the committee will elaborate on the process of assessing and decision making as to risks. In the present report the committee also responds to the questions the Minister of Housing, Spatial Planning and the Environment has directed to the Health Council.

Risk and risk measures

The committee takes a view of the concept of risk much broader than that used in the OmR-document. It considers 'risk' as the possibility, with a certain degree of probability, of damage to health, environment and goods, in combination with the nature and magnitude of the damage. The causes of risk are action by man, natural events or combinations of these. In this report emphasis is placed on damage to health and damage to plants, animals and ecosystems. The proposed concept of risk is rather broad; possible detriment can take all kinds of forms, with respect to type as well as to magnitude, to time of occurrence as well as to duration and to possibilities of recovery.

Simplification of the concept of risk is unavoidable when decisions are made about the tolerability of risks and therefore about associated management actions. In the environmental risk management approach of the Netherlands Government, risk is interpreted in a much more restricted manner than it is by the committee. A description in terms of three risk measures is considered sufficient: individual risk, group risk and the collective risk for ecosystems. The first two measures relate to human health detriment, the third to the possibility of damage to species in ecosystems. According to the OmR-document it is possible to compare risks related to major accidents, to exposure to ionising radiation and to substances in the environment by applying these three measures.

The committee feels that this approach excludes consideration of several important characteristics of various risk problems. Effects on human health cannot always be expressed in terms of mortality: mortality is the effect used in the OmR-document in specifying individual risk and group risk. Furthermore, the judgement of the parties involved is determined by more than merely the chance of death and the chance of affecting species. In such a judgement process, voluntariness, confidence, dread, etc.

are important in addition to considerations related to the societal benefits of the particular action that causes the risk. These aspects are not sufficiently taken into account by the three risk measures presented in the OmR-document. It follows that risk assessment according to the Dutch environmental risk management approach is in certain instances inadequate, *i.e.* in those instances it does not provide an adequate basis for decisions on the tolerability of the risk and on risk management measures.

Numerical norms

In the Dutch environmental risk management approach decisions concerning the tolerability of risks are taken based on numerical norms established for the three measures. These maximally tolerable risk levels have an equal value for the probability of being killed due to an accident in a certain installation and for the probability of death from cancer due to exposure to radiation from a well-defined source and from cancer due to a specific carcinogenic substance: 1 in a million per year of exposure. The highest level at which exposure to a toxic substance is without effect is - in terms of policy - considered equal to this value. For the protection of ecosystems from damage by one of these agents it was established as norm that 95 percent of the species must not be affected. The committee is of the opinion that the introduction of equal numerical norms does not guarantee an equal degree of protection, contrary to the policy objectives. This is due to the importance, in a concrete situation, of risk attributes other than the three considered and because the elaboration of the measures proposed in the OmR-document can differ between cases.

It has been taken as a decision rule, that exceeding the norm established on the basis of the maximally tolerable risk level is not allowed. In principle, actions that cause exceeding of the norm value are not permitted. Exceeding of the norm because of earlier actions demands intervention. This is a rigid system that, in a formal sense, allows only very limited possibilities for considering the economic and social benefits of risk-bearing acts. The committee feels that more flexible decision rules and a differentiated system of norms can better do justice to the differences between varying forms of actions, activities and situations. This could lead to an improved set of priorities and to adequate levels of protection.

Group risk

In the OmR-document group risk is the probability of death of a group of ten or more persons within a short period of time due to an accident. This risk measure has been introduced to take societal disruption into account. The committee is of the opinion that societal disruption after a serious accident is expressed only to a very limited extent by the risk measure 'group risk', as is also *apparent* from a study performed at the request of the Department of Housing, Spatial Planning and the Environment. In addition to the number of victims, a.o., houses becoming unusable to live in and land becoming unfit for agriculture are relevant characteristics of societal disruption. The maximally tolerable level associated with group risk is specified in a form that is inversely proportional to the square of the number of victims that were fatally affected: the maximally tolerable probability of an accident with ten times the number of victims should be one hundred-fold smaller. Use of group risk aims at taking into account the possible number of victims; a characteristic that plays an important role when people decide about risks. The manner in which the norm depends on the number of victims is, however, not supported by empirical studies of risk perception. Finally, the committee feels that the delimitation of the area within which the victims are taken into account requires further attention, especially in case of risks association with non-stationary hazards like transport activities.

Risk management

Risk management that aims primarily at prevention of damage or loss involves in the first place a comparison of options, processes or techniques, the choice of the most suitable option, and, the creation of provisions to minimize inevitable damage, particularly in cases of serious accidents. Testing and comparing to numerical norms for, *e.g.*, a concentration of a substance, a radiation dose or an estimated probability of accidents of a certain type and magnitude play mainly a signalling or cautionary role and can provide an answer to the question: is the risk management system functioning properly? The committee feels that satisfying these kinds of norms is not an indication that a sufficient degree of risk reduction has been reached; this would imply a denial of the dynamic character of risk management and wrongly equate tolerating a given risk to accepting a certain damage. The committee further notes that exceeding a norm that has been established for prevention purposes, does not provide information on the possible damage.

Levels of scale

It was envisaged that the Dutch environmental risk management approach would also encompass other forms of environmental risks. The OmR-document mentions exposure to sound, odour and genetically modified organisms and also points to global climate change. This kind of objective requires that the stratification of the risk problems with respect to space and time, but also with respect to complexity should be better appreciated. Global climate change can be a target for risk analyses, but these analyses require a totally different set of attributes, measures related to these attributes and criteria to deal with the great uncertainties involved - than does the assessment of radiation levels in the street running along the x-ray room of a hospital.

Estimating risk

Risk assessment requires risk estimates. Risk estimation has qualitative and quantitative characteristics and involves models and expert judgement. The committee is concerned about the intention of the Government to impose the use of particular models. This could be acceptable for routine decisions, but there is the danger that for more complicated cases reality is adapted to model rather than *vice versa*. This is all the more a cause for concern because model uncertainty dominates the uncertainty in a risk estimate and rarely can be expressed in a quantitative form. The committee does support the desire by the Government to distinguish between 'good' and 'bad' models and to follow, as much as possible, a standardised approach when deriving model parameters. This is why the committee feels that each risk estimate should be accompanied by a discussion justifying the choice of model. In this connection, the committee notes in the Dutch environmental risk management approach, the lack of discussion about how to deal with uncertainties in risk estimates, in particular when numerical norms are derived and tested.

Developments elsewhere

In appendices to its report the committee discusses risk management approaches in the United States, the United Kingdom and Norway. The committee concludes that much can be learned regarding the further development of the risk management policy, from the views held elsewhere. This is particularly the case with respect to the integration of risk management awareness in all operations and the attention to the quality of the organisation, that has been specified in the Norwegian regulations for the off shore industry, and that are also being applied in other branches of industry.

In the US methods of ranking risks in a manner that is scientifically and socially acceptable ('comparative risk analysis') are being studied. Comparative risk analysis is intended to improve the setting of priorities by the regulatory agencies; in The Netherlands setting priorities is a key question too and was explicitly mentioned as an aim of the environmental risk management approach. In the US comparative risk projects the focus appears to shift from risk ranking to questions on the distribution of risk between socio-economic population groups (questions on 'environmental equity' or 'environmental justice'). Risk ranking as such is not sufficient in determining political priorities.

The 'tolerability of risk' approach of the British Health and Safety Executive shows strong similarities to that of the OmR-document. It is interesting that in this approach the norms for risk in terms of the probability of a certain effect only receives an indicative value. Norms for, e.g., exposure parameters derived from risk norms, must be 'practicable'. This implies that the derivation of a norm that is in agreement with the 'just tolerable' risk level can differ from that in line with a 'broadly acceptable' level. The British approach is therefore more flexible and can be applied more readily in different situations.

Questions of the Minister of the Environment

Chapter 6 of the report offers the replies to the questions asked by the Minister of Housing, Spatial Planning and the Environment. The replies refer to the comments made in the other chapters. The emphasis in the replies, and in the report in general, is on cautioning against too many simplifications which could possibly lead to socially controversial or undesirable decisions and thus do not work in the interest of public health and of the environment. It is important that simplifications are being made in an explicit way. The committee will elaborate further on these views in the report that is to follow.

Chapter 1

Introduction

1.1 Committee and charge

In May 1991, the President of the Health Council of the Netherlands invited various experts to join the Committee on Risk Measures and Risk Assessment (to be referred to below as the committee). In his letter, he asked the committee to evaluate the scientific basis of the assessment system for the risks involved in various activities, as had been proposed in the policy memorandum 'Premises for Risk Management' (TK89b). He believed that, now that the policy which had been set out in the memorandum (and its predecessor) had been in effect for some time, there was reason to submit the principles and assumptions to an appraisal. The committee started work in September 1991. The names of the members are listed in Annex B.

The President of the Health Council then received, in October 1991, a request from the Minister of Housing, Spatial Planning and the Environment for the Health Council's opinion about the 'environmental risk management approach'. In particular, the Minister wanted to hear the answers of the Council to ten questions. The President extended the charge of the committee to include the provision of a reply to this request.

The letter of invitation from the President of the Health Council, the request for a report from the Minister of Housing, Spatial Planning and the Environment, and the President's request for a reply to the Minister's request can be found in Annex A.

1.2 Procedure

At the request of the President of the Health Council, the committee will publish its findings in two separate reports. In the present report, it discusses the basis of the Dutch 'environmental risk management approach' and answering the questions posed by the Minister of Housing, Spatial Planning and the Environment. In its second report, the committee will discuss in greater detail aspects of the process of assessing and decision-making for risks to human and environmental health.

The present report from the committee is of a general nature: it contains discussions of the threat to human health as well as possible harm to flora and fauna and effects on the functioning of ecosystems. However, it does not discuss the damage mechanisms in detail. Many of the comments on risk management relate to the threat to human health. For a detailed discussion of the determination of the risks for ecosystems as a result of the presence of toxic substances in the environment, the committee refers to the report published by another committee of the Health Council in 1994 (GR94a).

The general nature of the report also means that certain parts of government policy which are oriented towards managing environmental risks are discussed relatively summarily. This is the case, for example, for the policy on exposure to chemicals as implemented on the domestic and international level. This also emerges from the selection of examples of risk analyses from outside the Netherlands. Here, the committee has concentrated on analyses of the *process* of risk assessment and risk management.

1.3 Design of the report

After a brief sketch of the background of the environmental risk issue in the Netherlands (chapter 2) and a discussion of the concept of 'risk' (chapter 3), the committee turns in chapter 4 and 5 to the Dutch environmental risk management approach as this has been set out in 'Premises for Risk Management' and later policy documents. Chapter 4 sums up the risk management approach, with chapter 5 being devoted to the comments of the committee. The central question for the committee is: is the policy memorandum based on a consistent foundation of concepts and ideas? The questions from the minister are answered in chapter 6.

In producing the report, the committee was aware that 'Premises for Risk Management' was not a scientific appraisal but a *policy* document. However, it does recognize that an attempt has been made to establish policy on a scientific basis.

Chapter **2**

Background

2.1 Decision-making and uncertainty

The environmental risk management approach can be seen as a response from the Netherlands Government to the debate about tolerable risk. This environmental risk policy is the Government's fulfilment of a constitutional duty: the protection of human health and protection of the environment. The risk management approach can be seen as a response to the question: what risk can be considered tolerable? It encompasses conditions for human behaviour which might possibly result in harm, with the ultimate aim of achieving a desired level of protection. This means that the Government is inevitably faced with the question: how can the requirements which must be imposed to protect health and the environment be balanced, in the short or the long run, against the achievement of other objectives, for example improvements in welfare and increased employment?

When deciding about the tolerability of certain risks and, therefore, about the tolerability of action which results in risks, the Government is bound to observe procedures laid down in law. Those procedures are intended to guarantee that the social actors involved can put forward their frequently conflicting interests and that these can be taken into account in an orderly way. An orderly decision-making procedure is also needed because deciding about the admissibility of risks amounts to choosing between uncertain outcomes. The core of the 'risk' concept it has adopted, as the committee will explain in greater detail in the following chapter, is that human activity can result in harm to human health and to the environment but that only uncertain statements can be made about *the nature, extent, and time of the harm.*

The core questions facing the government when deciding about the tolerability of risks and therefore of risk acceptance are:

- Does the social importance of activity which causes risks justify the nature and extent of those risks?
- What are the objects which need to be protected? What are they threatened by?
- What level of protection should be provided?
- How can this level of protection be achieved? What resources are needed to do so? Is it worthwhile to improve the level of protection?

These questions raise a variety of sub-questions. For example: are we trying to protect the lives of individual citizens or of a certain social structure? If we are concerned with individual lives, are we trying to reduce the probability of death, to increase life expectancy or to increase the number of years of 'healthy life'? If we are trying to reduce the probability of death, should we make a distinction between more and less susceptible people and between people who benefit at the same time from the risk-bearing activity and people for whom this is not the case? The answers to questions of this kind are rarely straightforward, if only because the available knowledge is generally limited. This is, for example, the case with respect to the assessment of possible harm to ecosystems. The scientific knowledge is generally lacking for a sound translation of the wish to protect the structures and functioning of ecosystems into concrete measures (GR94a).

In the context of the environmental risk management approach, initial answers have been given to these questions. However, others remain unanswered and the final core question (is improved protection worthwhile?) has hardly been examined at all.

2.2 Risk estimates

The debate about 'tolerable risk' has been extended, widened and deepened since 1976 (see Vle90 for a concise review). The emphasis was initially on the analysis of the possible occurrence of serious accidents in industrial installations. The safety of nuclear power stations and of large industrial complexes such as those in the Rijnmond area in the Netherlands were important subjects of study. Central questions were: can the risk and nature of accidents be estimated and assessed in safety studies, how reliable are the results of analyses of this kind, how should the results be presented and are they suitable for assessment against norms? Dutch risk research did not concentrate exclusively on technical risk analysis. Using a sociological approach, attempts were made to determine how people perceive living and working near large-scale industry and how they assess the risks this involves (see, for example, Sch87).

Another subject of research and public discussion were the consequences for health of exposure to substances and radiation. The Health Council played an important role in recommending procedures for deriving health-based exposure limits for these agents (GR77, GR85, GR88). The recommendations of the Dutch Expert Committee on Occupational Standards (DECOS) constituted the basis for the exposure to substances in the workplace (MAC76, MAC78, MAC86).* Since the early seventies, the public discussion about radiation has been very much dominated by questions related to nuclear energy.

The Netherlands has also built up a tradition with respect to annoyance due to noise and odour exposure (GR94b, TK92c). 'Premises for Risk Management' states the ambition of including these 'agents' and their possible effects in the risk management approach. This has not happened as yet.

In addition, methods have been developed in the Netherlands for defining the risk posed by substances to ecosystems on the basis of ecological and ecotoxicological data. There is considerable international interest in these methods.

A number of reports from the Health Council which discuss the management of environmental risks have already been referred to here. The committee refers the reader to the following:

- Environmentally dangerous chemicals (GR82)
- External Safety (GR84a)
- Radiological Protection in the Netherlands (GR84b)
- Principles of Deriving Health Based Exposure Limits (GR85)
- Analysing the Risk of Toxic Chemicals for Ecosystems (GR88)
- Reassessing Nuclear Energy: Risk Analysis, Human Factors, Intervention Parameters (GR89a)
- Parameters for Ecological Standards in Water Management (GR89b)
- Ecotoxicological Extrapolation Methods (GR91a)
- Radiation Risks (GR91b)
- Uniform System for the Evaluation of Substances (GR93)
- Noise and Health (GR94b)
- Principles of Radiological Protection (GR94c)
- Setting Integrated Environmental Quality Objectives (GR95).

These documents were used in the formulation and elaboration of the environmental risk management approach.

* Since 1 January 1994, the DECOS has been a Health Council committee.

There was also debate outside the Netherlands about the safety of industrial installations and about the harm which radiation and substances can inflict on human health and the environment. In particular, the committee draws attention to developments in the United States of America, the United Kingdom and Norway. It describes some of these developments in Annexes C, D and E.

Chapter 3

Risk

Risk assessment and risk management can be seen as two stages of a process which aims to prevent or limit possible damage to, or loss of, health, the environment and goods. If this process is to be completed rationally, risks must be analysed, the scope of the risks must be estimated and the results of the analysis and estimation must be presented in such a way that they can be used to take policy decisions.

Risk

Risks are inevitably associated with human action, natural processes and combinations of the two. The committee defines risk as the possibility, with a certain degree of probability, of damage to health, the environment or goods, together with the nature and extent of that damage.

In order to be able to assess risks, cause-effect sequences are often considered (figure 1). From the scientific point of view, a sequence of this kind starts with human activity and natural processes - interacting or not - which influence material and energy flows. The present report primarily concentrates on the effect of human activity. Such activity can lead to harm and loss as a result of the action of stressors - stress factors - on people and the environment. The figure introduces stressors as an effect of changes in material and energy flows. Some of the stressors involved here are noise and concentrations of substances in water, soil and air which, given exposure, constitute a threat to or have an effect on health and the environment. Human activity can, as such, also be seen as threatening and have an influence on health in this way. In

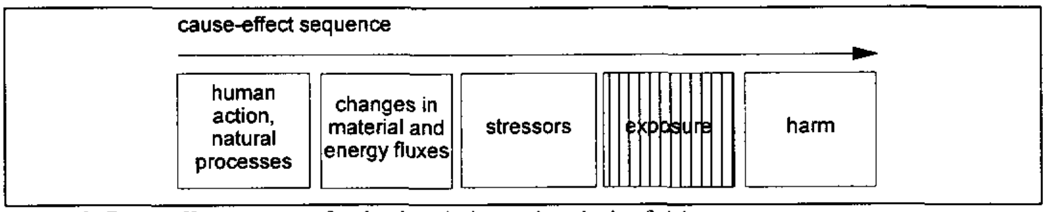

Figure 1 Cause-effect sequence for the description and analysis of risks.

that case, the activity itself is the stressor. Examples are technologically complex installations or traffic.

For various risk problems, it is necessary to consider the confluence of various cause-effect sequences, for example in the case of air pollution: a sequence for car traffic, a sequence for industrial emissions etc. Conversely, an analysis can benefit from breaking a sequence down into separate parts. For example, a power station generates noise and waste heat and the possible harm inflicted by each of these can be assessed separately. The committee sets out a few examples of cause-effect sequences in Annex G.

The committee believes that risk is a wide-ranging concept. Detriment can, after all, take various forms, in terms of not only nature and severity but also of probability. In addition, it is not possible to isolate cause-effect sequences or, therefore, risks and to consider them separately from the physical and social environment. For example, there is a difference between releasing hazardous substances into tropical or into arctic environments. Legislative systems and culture have an influence on the opportunities for, and effectiveness of, risk management measures and therefore on risks. Furthermore, the context of the activity and the evaluation of the usefulness of the activity also have an influence on the assessment of the risk by the various parties involved. Important, for example, is the degree of voluntariness of exposure to stressors and the degree to which the parties involved believe that the potential deleterious effects of the activity can be controlled.

Some aspects of risks can be expressed as measures and numbers, some not. Generally, it will be necessary to simplify the concept of risk by leaving certain aspects of it aside. The degree to which this is justifiable in the light of adequate risk management will differ from case to case. The advantage of a broad definition of the concept of risk is that it results 'naturally' in the creation of an understanding of the simplifications which are introduced.

Risk assessment and risk management

The aim of the Netherlands Government with the environmental risk management approach is to limit the risks associated with the influence of environmental factors*

Chapter **4**

Premises for risk management

4.1 Policy documents

In 1985, 'Premises for Risk Management' (TK85) appeared as an Annex to the 'Indicative Multi-year Programme on the Environment 1986-1990'. A new version of the 'environmental risk management approach' described in that Annex was published in 1989 as an Annex (TK89b) to the first National Environmental Policy Plan (TK89a). This document is discussed in this report and will be referred to below as the 'OmR memorandum'*. The memorandum 'Premises for Radiation Risk Management' (TK90) discussed the risk management approach as it applied to exposure to ionizing radiation. This document will be referred to as the 'OmRS memorandum'**. In later policy documents and in consultations with the Lower Chamber, the Government clarified the environmental risk policy. The committee draws particular attention to the following:

- the letters dated June 1992 (TK92a)*** and November 1992 (TK92b) from the Minister of Housing, Spatial Planning and the Environment to the Lower Chamber about the environmental risk management approach

* OmR is the abbreviation of 'Omgaan met risico's', the title in Dutch of the policy document.

** OmRS is the abbreviation of 'Omgaan met risico's van straling', the title in Dutch of the policy document.

*** This letter was sent by the Minister to the President of the Health Council "in view of the request for a report relating to 'Premises for Risk Management' " (letter DGM/SVS/11692004, dated 15 June 1992).

- the letter dated November 1993 (TK93a) from the Minister of Housing, Spatial Planning and the Environment to the Lower Chamber about the external safety policy
- the letter dated November 1993 (TK93b) from the Minister of Housing, Spatial Planning and the Environment to the Lower Chamber about the role of the negligible risk level in environmental policy
- the letter dated February 1993 (TK93c) from the Minister of Housing, Spatial Planning and the Environment to the Lower Chamber about setting quality standards for ionizing radiation at work and in the environment (follow-up to OmRS memorandum)
- consultations on 8 December 1993 between the Minister of Housing, Spatial Planning and the Environment and the Lower Chamber about the environmental risk management approach (TK93d).

Risk management has also been discussed in other policy documents and elaborated in detail in some areas. For this report, the quoted papers, memoranda and letters suffice. Some of these policy documents were also discussed in a recently published report from another Health Council committee about the basic principles of the radiation risk policy (GR94c). Here, a comparison was made with the recommendations of the International Commission on Radiological Protection.

4.2 Risk management approach

Objective

In the OmR memorandum, the Government works out a structural and coherent approach for tackling the increasing damage to the quality of the environment. The objective is to limit possible harm to health and to the environment. The aim of the memorandum is to provide a common framework for setting priorities and standards with respect to the reduction of the risks to humans and the environment caused by human activities. Figure 3 is a schematic representation of how this context was summarized in the National Environmental Policy Plan (TK89a).

The heart of the standard setting framework in figure 3 are the risk limits, some of which have been set out in the OmR memorandum. The risk limits indicate the minimum level of protection which the Government should maintain or strive after. It is possible, in principle at least, to derive exposure limits from those risk limits, for example in terms of radiation doses or the intake of particular substances. Requirements for, for example, food or drinking water can be derived in turn from these exposure limits. The exposure limits can also be translated into, for example,

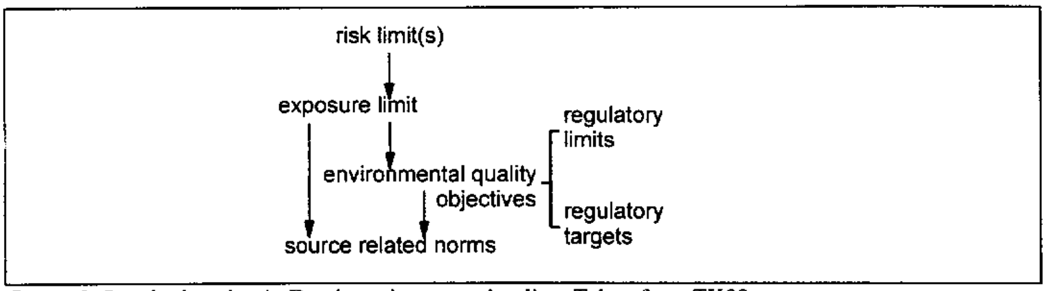

Figure 3 Standard setting in Dutch environmental policy. Taken from TK89a.

limits for emissions (source-oriented norms) and for concentrations in environmental compartments such as air, water and soil (environmental quality objectives). Environmental quality objectives are translated for regulatory purposes into limit and target values. The first of these should, in principle, always be met; the target values define the policy goals (progressive standard setting).

The OmR memorandum devotes a lot of attention to the possible consequences of major accidents with industrial installations ('external safety'). In effect, risk limits, exposure limits and environmental quality objectives coincide here, although it is not clear to the committee whether the policy documents indeed consider risk limits as environmental quality objectives.* Only one type of risk measure is used: the probability of death.

The OmR memorandum had high ambitions: the framework it proposed was not only intended to cover the risks resulting from accidents but also the risks involved in exposure to stressors such as chemicals, radiation, noise, odour and genetically modified organisms. As yet, in the memorandum, numerical standards for the risk limits and for the environmental quality standards (in the form of limit values and target values) derived from the risk limits are only worked out for external safety (possible harm as a result of accidents with industrial installations) and exposure to chemicals and ionizing radiation. For noise annoyance, a wide-ranging and differentiated system of numerical limits had already been developed which, in addition to health considerations, also takes other social interests into account. With the exception of annoyance caused by air traffic, these standards are set out in the Noise Nuisance Act (Tan89). Separate policy has been developed for the stressors 'smell' and 'genetically-modified organisms'. This will not be discussed in this report.

* The concept of 'environmental quality objective' involves problems when used in the area of 'external safety' since, in this case, the nature of the risk cannot be reduced to the 'state of parts of the physical environment'.

The basic assumption behind the approach in the OmR memorandum is that possible effects on health and the environment can be described using quantitative risk estimates and that this description provides a basis for limiting possible deleterious effects (in other words, for risk management). Attempts are made to achieve consistency by measuring, with a few measures, a range of risks caused by industrial activities, by exposure to hazardous substances and by exposure to radiation. Comparisons are then made between the risks and they are tested against corresponding numerical regulatory limits. According to the OmR memorandum, this makes it possible to set priorities. In this approach, one can also see the wish for legislation which provides equality before the law, transparency and predictability for those who initiate the activities causing the risk in question as well as for other citizens.

In the OmR memorandum, risk is defined as: 'the undesirable consequences of a particular activity linked to the possibility that these will occur'. Risk measures are then introduced in order to indicate in numerical terms what the risk is of a particular undesirable consequence of exposure to one stressor or to a group of these stressors. The memorandum provides regulatory limits based on these measures.

In the OmR memorandum, three risk measures are defined: *individual risk*, *group risk* and *collective risk for ecosystems*. The 'individual risk' risk measure is intended for individual people. In the memorandum, this risk measure is defined as 'the probability per year that a person can suffer a particular deleterious effect as the result of exposure to an agent'.*

The 'group risk' measure, next to the 'individual risk', is intended to describe the accident risk associated with industrial installations and to make it possible to establish numerical standards for those risks. It is the possibility that a group** of a minimum size (the memorandum refers to ten or more people) will be the victims of an accident. The group risk is expressed per year of operations. The measure was introduced in order to take account of what the memorandum refers to as 'social disruption' and describes more particularly as the simultaneous death of a group.

In accordance with the approach proposed in the OmR memorandum, the risk for ecosystems is assessed on the basis of the 'collective risk for ecosystems' risk measure. The measure is defined as the possibility that an ecosystem will suffer a deleterious effect because of exposure for a year to a particular substance.*** The type

* The committee discusses this definition in the following chapter.

** outside the site perimeter

*** The committee notes that the criterion chosen when deriving ecotoxicological exposure limits is an effect of a particular

Chapter 5

Comments

5.1 Policy memorandum

The OmR memorandum is a policy document in which strategic, political and socio-economic considerations have been set out. The proposed risk management approach with a limited number of risk measures and a simple set of risk limits has administrative advantages. The result of a quantitative risk analysis in the form of a more or less universal risk currency would seem to lend itself for use by interest groups and the public, just like other currencies have proved to be excellent for the expression of a concept as complicated as economical value. A simple system of risk limits provides, in principle, opportunities for standardized and, therefore, efficient policy implementation at a variety of administrative levels, with decisions being taken in the same way about a multitude of similar environmental problems.

An additional effect of the policy memorandum is that the concept of risk, the description and management of risks and the setting of regulatory risk limits have all been brought into the realms of political discussion and discussion in society as a whole. Furthermore, research into estimating, assessing and evaluating risks has received a stimulus. The result, in the opinion of the committee, is that the understanding of the risks associated with human activity and of the influence of stressors on human health and the environment has been considerably extended and deepened in the last decade. What is lacking is a grouping together of the available expertise as a basis for the development of a differentiated approach to risk management.

5.2 Characterizing risk

Range

When describing the possible hazards of activities or of situations on the basis of risk estimates, the assumption is that risk is essentially measurable and can ultimately be expressed in a verifiable way as a few figures. The committee has a number of reservations about this idea. There are problems even with the elaboration of the concept of risk. Risks can be expressed in quantitative terms in a number of different ways, for example as the probability of a specified undesirable event or as a probability distribution of all (predictable) undesirable events. In so doing, one can take a variety of effects into consideration such as death, illness, crop quality loss and reduction of the number of species in ecosystems. There are also consequences which are less easy to quantify. An example is the 'lack of supposed controllability' (see Vle90 for a review of definitions of risk).

The committee therefore sees risk as a wide-ranging concept with numerous dimensions or facets, some of which can be expressed as measures and numbers while others cannot (see chapter 3). The approach chosen in the memorandum, which assumes a description in terms of three risk measures, constitutes a considerable simplification of the risk concept. Whether or not such a simplification is justified depends on the objectives which one has in mind.

Definition problems

The OmR memorandum uses the term 'risk' in two ways. On the one hand, it is used as a concept (the possible deleterious effect on the health of humans and of the environment) and on the other hand, it is used as a measure for that concept (individual risk, group risk, collective risk for ecosystems). The committee finds this confusing. The incorrect impression is created that, for example, the measure 'individual risk' represents the risk in its entirety, *is* the risk. The committee advocates the exact statement of the measures used, for example the probability of death resulting from a particular cause, the probability of a particular illness or disorder resulting from a particular cause, the reduction of life expectancy starting from the moment of exposure etc. The various risk attributes can be seen as dimensions of risk.

In the elaboration of the environmental risk management approach, the term 'risk' is used in a third way: to refer to a unit which serves as the derived measure for the risk, such as the concentration of a substance in the soil or the radiation dose. This usage has already emerged in table 1 for substances where the effects can be described using a threshold model. In addition, it will also be found in the derivation of limits for, for example, concentrations or doses which correspond to the risk standards as the maximally tolerable risk level. This usage also leads to confusion. The committee would wish to draw attention to the British approach in which a clear distinction is made between risk standards and standards for units which can be used as measures for risk. In the latter case, the terms which are used are 'basic safety limits' and 'basic safety objectives'. See Annex D.

The definition of individual risk in the OmR memorandum is incomplete. It is unclear whether it refers to an effect caused by a year of exposure or to an effect in a particular year. In addition, in the further elaboration of 'individual risk' for accidents, radiation and substances, there are discrepancies. For external safety, 'exposure' means possibly being affected by an accident in a particular installation or in any installation.* In the case of carcinogenic substances** and ionizing radiation, a study of the OmR memorandum and the OmRS memorandum shows that the basic assumption is the additional risk of death from cancer as a result of *lifelong* exposure. This risk is divided by average lifetime in order to establish a value per year. For non-carcinogenic substances, contrary to the definition, the individual risk is not related to the risk of death but to the occurrence of a toxic effect. Because, as is indicated by the OmR memorandum also, a threshold model is generally assumed when estimating the risks linked to these substances, the individual risk (in the sense of the risk of a toxic effect), given exposure below the threshold level, is always 0 and, given exposure above the threshold level, an uncertain value between 0 and 1. The memorandum refers to this as follows: "The risk limits [for substances to which the threshold model applies] cannot therefore be compared simply with the values referred to above for death."

Various health effects

The influence of stressors on the health of humans and on the environment can manifest itself in a multitude of ways which are difficult to assess using a single measure. In the OmR memorandum, no attempt has been made to define various dimensions of harm and to evaluate them as an inter-dependent whole. Instead of this, the risk concept is reduced to the *probability* of a *specified* undesirable consequence, mainly individual death and harm to species in ecosystems. This means that risk assessment primarily results in an estimate of the risk of a few effects. With the effects and measures selected at present, the ecological consequences of serious accidents, which can be of a very large-scale nature, are excluded from the assessment system.

* The OmR memorandum concentrates on consequences 'outside the perimeter'.

** When the committee uses the term 'carcinogenic substances', it means genotoxic carcinogens.

In the follow-up OmRS memorandum (TK93c), this issue is addressed insofar as it relates to possible effects on health. It is stated that, for the stressor 'ionizing radiation', the use of death as a criterion is preferable because of the availability of data and the clarity of the probability of death as a risk measure. Here, the committee would comment that risk of death can be expressed in more than one measure, for example the risk of death at a particular age, the probability of death after a particular age regardless of the point in time and the drop in life expectancy. A choice in favour of one measure or another has an influence on the system of limits and the results of standard testing (GR91b, GR94c). According to the OmRS memorandum and the OmRS follow-up memorandum (TK93c), setting environmental quality standards based on death adequately limits the risks of death and the effects on progeny linked to radiation. The committee is of the opinion that this position is primarily based on policy considerations. For example, one question which can be asked is whether, when deciding about the tolerability of risks for example, effects on progeny do not merit separate consideration in addition to illness or death in the present generation.*

With accidents in industrial installations, the story is similar. Here also, risk assessment is confined to determining the probability of death. Using the group risk, attempts are made to take into account what the memorandum describes as social disruption, that is to say the simultaneous death of ten or more people.

In the opinion of the committee, the OmR memorandum does not do enough justice to the wide-ranging nature of the risk concept. In the later discussion about the risk policy, especially with respect to exposure to radiation, the Government has indicated that it is aware of this. This does not alter the fact that it is, for the time being, maintaining the proposed measures and the numerical standards based on those measures (TK93c).

5.3 Comparing risks

Risks linked to human activities are often difficult to compare. They can vary in terms of the nature and extent of the undesirable consequences. Chances and probabilities can be of different natures. The quality of the data available for risk assessments is often very uneven. The comparison of risks is rendered more difficult because of the different positions which the social parties involved occupy with respect to risk-bearing activity. The judgement of the tolerability of risks given by groups in society at large is determined by a range of risk attributes (Vle90, Nor92, Roy92). Some of these can, at least in principle, be expressed in measures and figures,

* The committee indicated above that, for non-carcinogenic substances, the starting point is not death but a toxic effect which is to be specified in greater detail and which generally varies according to the substance in question.

examples being scale size (in space and time), numbers of casualties, ill people or people suffering from impediments, and recovery time. Other 'socio-cognitive' attributes which are important for the risk assessment are generally less suitable for quantification. Examples of this type of attribute are the supposed controllability of the risks linked to activities or situations, familiarity with the activity, the degree to which safety management inspires confidence, the unfairness and involuntariness of exposure to stressors.

The risks of activities which have no social usefulness are difficult to justify. The committee believes that a considered judgement of the risk therefore demands that those responsible for policy ('risk managers') should also take the social usefulness of the activity which causes the risks into consideration. There will therefore be a wish to express that usefulness in corresponding dimensions and units. As with the determination of the risk, questions therefore arise about the delimitation of the problem. Usefulness for whom? For those engaged in activities, for employees, for those living near an installation or for society as a whole? And within what length of time? Despite these difficulties, the committee considers the advantage which will accrue to society to be an important element which distinguishes one risk problem from another. When introducing a distinction of the kind, it will be necessary to bear in mind that more usefulness for some can involve more drawbacks for others: in many risk issues, risks are shifted onto other people or population groups elsewhere or onto later generations.

These questions will not require detailed answers for every risk problem. Partly on the basis of the benefits and drawbacks of activities, procedures can be established which do justice to the 'scope' of the risk problem (see proposals in Cla81, GR84a). Such distinct procedures can be found in current environmental legislation. An example is the obligation to draw up an environmental impact statement for certain activities.

In the characterization and classification (and therefore implicit comparison) of risks based on numerical values for only one (quantifiable) risk attribute, people will often act contrary to the *ceteris paribus** supposition. This is the case because links will be made between activities and situations which can have a variety of risk attributes and advantages on the basis of just one or just a few of those attributes. That attribute will not always be the most relevant for the assessment of the possible effect on the health of humans and the environment (Huy94).

In the opinion of the committee, the current version of the environmental risk management approach takes little or no account of the wide-ranging nature of the risk concept and of the advantages associated with human activities. The use of only a few

* *ceteris paribus*: other things being equal

risk measures suggests a non-existent homogeneity in situations which vary very widely in terms of the advantages, nature and seriousness of the risks and the perception of those risks by the people involved. This can negatively affect decision-making. The problem is not so much the simplification of the risk concept as such. This will be unavoidable in practice. What matters, in the opinion of the committee, is that every simplification must be justified by the nature of the risk issue. The approach in the OmR memorandum leaves hardly any room for this.

In determining the nature and the extent of the risk problem - who and what should be protected and against what? - choices must continuously be made. This is also the case when defining the undesired consequences and the quantitative risk measure, as well as when dealing with inherent uncertainties. Research results show that those choices can vary because 'risk' does not mean the same thing to everybody. People have, depending on differences in their psychological and socio-cultural backgrounds, different ideas about the usefulness of the activity or activities causing the risk and therefore about the tolerability of the risk (Vle90, Roy92, Huy94). Risk assessors will have to make it clear where such choices are involved and have to state how they are determined by the preferences of those who decide about risk-bearing activities and situations (see figure 2). An approach of this kind prevents the choices from being determined in obscure ways by the value judgements and social convictions of the risk assessors.

5.4 Risk acceptance through testing against numerical limits

Differences in nature of limits

The discussion in the previous two sections also leads to the conclusion that setting limits which are the same in numerical terms on the basis of the risk measures chosen for external safety, substances and radiation does not guarantee that the principle 'equal treatment for all' is actually implemented. The simplification of the risk concept does not always work out in the same way and the selected measures differ in the way they are implemented. For example, as the committee indicated in 5.2, the measure 'individual risk' has different meanings according to whether it is used for industrial accidents, carcinogenic substances and radiation or non-carcinogenic substances. That means that a numerically equivalent limit for individual risk, such as a maximally tolerable risk level for the individual risk for distinct stressors of 1 to one million per year (see table 1), does not logically mean that the level of protection will be the same for each of those stressors. It can also be concluded from this consideration that, in principle, the standard for, for example, the limitation of exposure to radioactive substances in the environment cannot be 'derived' from the limit for accidents with the large-scale landing of LPG*. Or *vice-versa*. Of course, the Government can opt for numerically equivalent limits on policy grounds.

Testing against numerical standards

According to the OmR memorandum, human activities must satisfy the principles of environmental policy such as integral environmental process management, energy extensivation and quality promotion. The memorandum indicates that these principles require further operationalization. The 'hard' criterion which remains for the assessment of activities and the ensuing situations is the testing of results of risk estimates against numerical limits. This leads to an unequivocal - but also rigid - procedure for deciding about the tolerability of risks and managing risks. The emphasis is on standard testing and not on the comparison of alternatives, that is to say not on the balancing of the economic and social costs and benefits of one option against other options. If the result of a risk estimate is above the maximally tolerable risk level, the approach makes it formally impossible to discuss the tolerability of the activity in the context of its social importance (including the benefits for the environment and public health). Departures from this rule require *ad hoc* decisions by those responsible for policy.** Some people see this as an advantage of the approach: only cases in which sufficiently 'serious' interests are at stake become the subject of discussion.

The rigidity of the approach is not located in the standard testing as such but in the rule which is linked to the standard: failure to meet the numerical limit means that the risk is intolerable. Other rules - for example, 'failure to meet the numerical limit means that extensive and detailed risk analysis is required' or 'failure to meet the numerical limit means that an explicit justification is required' - can lead to risk management in which more differentiation is possible than is the case at present. The altered view of testing against the maximally tolerable level for group risks is a step in this direction (TK93a). Local or regional authorities can permit activities which do not meet the requirements for group risk. In that case, a requirement is an explicit estimate (calculation) of the group risk and a justification based on the possibilities of intervention in case of accident, the social importance of the activity and the costs of management measures. In addition, some room for manoeuvre has been created by

* The proposed standard for the large-scale landing of LPG served as the basis for the value of the maximally tolerable individual risk level associated with the risk of accidents in industrial installations in general. The maximally tolerable individual risk level associated with exposure to ionizing radiation (and also, incidentally, with carcinogenic substances) was set at the same level. See Jul88, GR94c.

** An example are the less stringent limits for exposure to radiation of of family of patients treated with radioactive substances. The personal benefits for those exposed were used as an argument for the exceptions from OmR rules.

using numerical standards for individual and group risks in existing situations which are greater than the values for new situations which are set out in table 1. The cost issue played an important role in this policy decision.

In the OmRS follow-up memorandum, the Government stated that it accepts 'justification' as the guiding principle for permitting activities which result in exposure to radiation. It is suggested that justification means that the social and economic benefits of an activity offset the social and economic cost. But the follow-up memorandum then states that activities are justified if they can meet the requirements of testing against risk limits. This severely restricts cost-benefit analysis and perhaps even makes it impossible. Another Health Council committee has taken a closer look at this question (GR94c).

Developments in international recommendations in the field of radiation protection show a shift from the observance of exposure limits towards the objective of providing a level of protection which is 'as low as reasonably achievable' (see GR94c). In those recommendations, the main role of limits is now to protect individuals against unfair consequences (for the individual concerned) of ALARA considerations.* This shift is in line with what the committee proposes in 5.5 for risk management. The significance of the risk limits in the OmRS memorandum is much closer to the original significance of the exposure limits in radiation protection: the primary means of preventing intolerable effects on health.

Uncertainties

Risk estimates yield results which can include a considerable margin of uncertainty. The estimate of the risk must generally be based on sketchy information about the degree of exposure to the relevant stressor or stressors, about the course of exposure in time and about variation in exposure from place to place (scenarios). Furthermore, in many cases, knowledge is lacking about the (undesirable) consequences of exposure. Sometimes the information is simply not available; sometimes it is only partially relevant.** A major source of uncertainty which cannot generally be expressed quantitatively, are the models for risk estimation. Often, their representation of reality is only limited since the probability of harm to health frequently depends on environmental factors, human behaviour and cultural patterns which are difficult to

* An 'optimal' situation could be to allow just a few individuals to receive a relatively high dose instead of exposing a larger number of individuals to a lower dose. The individual dose limit is a pre-condition of the optimization process and ensures that the radiation load for individuals cannot become too extreme.

** For example, the accident with the Chernobyl nuclear reactor contains lessons for the safety of nuclear reactors made in the West. But it would seem to be improbable that those lessons will lead to other, or more precise, estimates of the risk in terms of the incidences of death or illness.

measure or to integrate into models and which also have an effect on health through other mechanisms. The validity of those models varies considerably, especially when they deal with a variety of activities or situations such as being exposed to dioxin in breast milk by comparison with living near an installation for the distribution of liquefied petroleum gas. Data about the validity of the models is lacking in many cases.

When testing the results of a risk estimate against a risk limit, it will therefore be necessary to determine how to deal with the - often quite large - margin of uncertainty in the estimate (for example: does one attempt to make the estimate as realistic as possible or does one err on the side of caution). The OmR memorandum does not provide guidance on this subject.

ALARA and the negligible risk level

The maximally tolerable risk level is of a conditional nature. Not only should the estimated risk be below the maximally tolerable risk level, but it must also be the result of an optimization procedure. According to the original OmR memorandum, there is, in the 'grey' area between the maximally tolerable and the negligible risk level (figure 4), a form of evaluation for which the abbreviation ALARA ('as low as reasonably achievable') is used. Later, the ALARA precept was extended to cover the entire area below the maximally tolerable risk level (figure 5; TK93a, TK93b, TK93c). Implicit in the ALARA principle is: to what extent can the risks be reduced? But another implication is: when can the efforts involved be considered to be excessive? The optimum is determined by comparing the benefits of additional risk reduction and the social and economic cost which they involve. This optimum is not pre-determined but is 'found' by means of an iterative process. Because of the scrapping of the notion of the negligible risk level as the ultimate objective of the ongoing process of setting environmental quality objectives, the ALARA principle has been reinvested with the usual meaning of optimization in the environmental risk management approach, at least in as far as the absence of a pre-determined result (in the long term) is concerned. The maximally tolerable risk level acts as pre-condition: a result of optimization above that level will not, in principle, be accepted. In practice, it has emerged that the Government no longer wishes to grant priority to the maintenance of the ALARA principle below certain risk levels. See the footnote in chapter 4 about the 'secondary risk level' and 6.9.

In the case of wide-ranging risk issues, application of the ALARA principle is not straightforward. What one party sees as the best achievable - *i.e.* optimal - result, can be described by the other party during the decision-making process as a poor compromise. In the case of issues which are less wide-ranging, the Government can demand that the result of the application of 'ALARA' should be below a certain risk level, the maximally tolerable level. Stating such pre-conditions or 'constraints' is currently recommended in the field of radiation protection (ICRP91; see also GR94c and Annex D).

In the field of radiation protection, among others, it has been argued that formal cost-benefit appraisal known as differential cost-benefit analysis should be used to determine what risk level should be considered to be 'as low as reasonably achievable'.*

In negotiations about allowing activities and the conditions in which they should take place, for example in the context of licensing, it has emerged that the ALARA principle is implemented in a completely different way. 'ALARA' is then often synonymous with the result of the negotiation process, and the balancing of the costs of protection against the benefits for health and the environment plays only an implicit role. The committee is of the opinion that, in this way, the ALARA principle may be eroded because decision-making about the tolerability of risks is no longer transparent.

For environmental exposure to chemicals, the negligible risk level has been retained and means a target level for limiting the risk associated with the possibility that one substance can enhance the action of another. Insofar as the Government also makes a link with sustainability here, the committee would point out that the negligible risk level has not been derived as a sustainability criterion. In recent policy documents, a substance-dependent adjustment of the negligible risk level has been proposed which is also linked to combined effects.

Level of the limits

The setting of norms, such as the assigning of numerical values to the maximally tolerable and the negligible risk level, is a policy issue. The level which is set does have consequences for the way in which risk management works out in practice. In this context, the committee would wish to draw attention to the following issues.

A maximally tolerable risk level cannot only be supported by health-based considerations such as the risk, extent and nature of harm to health. Examples of other relevant considerations are 'feasibility' (costs of risk reduction, technological possibilities) and the significance which is granted to the various risk management principles. In this way, feasibility played an important role in the discussion about the standards for exposure to noise which were finally set in the Noise Nuisance Act (Tan89). Feasibility issues also occupied a central position in the adjustment of the application of group risk standards (TK93a). As well as being a criterion for deciding

* This is no longer the case in the most recent international recommendations (see ICRP91).

whether activities which involve risk are tolerable or not, the maximally tolerable risk level is a hard pre-condition for the application of the ALARA principle. The optimal risk level which is the result of 'ALARA' can, after all, never exceed the maximally tolerable level. The stricter the numerical standard, the less room there is for 'ALARA'. This line of thinking implies that if one wishes the ALARA principle to play an important role, one arrives at a differentiated system of risk limits: limit values can be stricter for one form of activity or environmental factor than for another in order to achieve an effective system of risk management.

Activities involving risks which exceed the maximally tolerable risk level should be brought to an end. If the risk standard is not met because of activities in the past, intervention is required. In this way, the numerical standard realizes an aim of environmental risk policy: the setting of priorities. But if the testing against limits results in a large number of interventions, supplementary criteria will be needed to arrive at 'feasible' priorities. In general, the level of the limit therefore determines the significance for setting priorities of testing against standards. Here also, solutions can be looked for in more sensitive decision rules, for example in order to obtain a better insight into the nature and extent of the risk by means of more detailed analyses and then to determine urgency in part on the basis of physical and social conditions (example: does the increased risk affect many or few people, or a small or large area). An approach like this can also be adopted for licensing factories or allowing chemicals onto the market. The level of the numerical standards will therefore depend on the presence of other criteria in the decision-making process. The system of criteria used by the Government in this respect will have to be subjected to the pre-condition of equal treatment in law for all the parties involved: all applicants for licences will be subject to the same rules.

The maximally tolerable risk level for the risk measure 'collective risk for ecosystems' is based on the assumption that 95 per cent of species will not suffer any adverse effects from substances present in an ecosystem. The concentration which corresponds to that risk level is derived using data about the vulnerability of individual species obtained from the results of a few tests. The concentration which corresponds to the negligible risk level is 100 times lower. The theoretical justification of this approach requires improvement. For example, the fundamental question of whether the approach also leads to the protection of the structure and functioning of an ecosystem cannot be answered on the basis of current knowledge (GR91a, GR93).

Prevention and intervention

Numerical standards such as those for concentrations of chemicals or radiation doses which correspond to the maximally tolerable risk level are preventive in nature: their aim is to protect. This is expressed in the way in which uncertainties are dealt with in the assessment of risks, in particular in risk estimates. The basic principle in the establishment of a preventive standard is, after all, that there should be a reasonable degree of certainty that harm to health will be prevented or, in any case, adequately limited. Incidentally, this also means that standards have to be adjusted in the light of new scientific advances, in particular when the effects on health of particular stressors are found to be more severe than was previously thought.

The committee would point out that, given the way in which preventive standards are derived, failure to meet such standards need not necessarily result in harm to health. It is principally a sign that the risk management system is failing and that an examination of the effectiveness of that system is needed.

As the committee pointed out above, more factors play a role in a decision to intervene (or decontaminate) than simple failure to meet a numerical standard which was originally intended to be preventive. A central position is occupied by the answer to the question of whether action is possible which will result in an improvement of the situation. In addition, the costs of the measures associated with 'decontamination' will have to be reasonable in terms of the 'benefit' which is achieved. Here also, the ALARA principle can be helpful in spending 'health and environment funds' as effectively as possible. Practical experience plays an important role here. It can be used as a basis for establishing intervention standards which will used as guidelines for the decisions which need to be taken (for example: intervention or no intervention, what type, sooner or later?).

Limit for group risk

The limit for group risk merits separate discussion. This standard was introduced to curb risks associated with serious accidents in industrial installations. In fact, group risk stands for a series of risk measures with the number of victims of an accident as a parameter. This series includes, for example, the probability that 10 people per year of operations will die as the result of an accident, the probability that 100 people will die, 500 people, 750 people, 10,000 people etc. In the OmR memorandum, the maximally tolerable group risk level is dependent on the number of fatal casualties. A quadratic relationship has been decided on: if the number of deaths increases by a factor of 10, the limit is made 100 times stricter. In this way, the Government wishes to do justice to the phenomenon of 'social disruption' which the memorandum defines further as the simultaneous death of ten or more people. According to the OmR memorandum, social disruption increases with an increasing number of fatal casualties within a short time and acceptance decreases more than proportionally.

The committee agrees with the idea that the number of victims which is recognizably the result of an accident, is linked to social disruption. But in addition, other factors are important which are inadequately represented by this attribute. A study of the University of Utrecht (Rav92) refers, among other things, to the number of houses which would be made unfit for habitation. This could serve as a measure for the scale of any evacuation. In the discussion about the admissibility of nuclear energy, the long-term unsuitability of land for residential and agricultural purposes (effect on environmental functions) has been put forward as a determining factor for social disruption (Smi83). In the opinion of the committee, not all of these facets of social disruption can be represented by the risk measure 'group risk' and they cannot therefore be accounted for by a 'quadratic' standard for group risk.

An argument in favour of the quadratic nature of the group risk limit was that people see accidents with large numbers of victims as being very much more serious than accidents with small numbers of victims. An example which is often quoted is road safety: a disaster with a ferry which results in more than 600 victims has a shock effect; many hundreds of traffic deaths spread across a period of time do not do so. It has emerged from risk perception research that the number of victims is certainly a measure for the 'severity' of the risk (the term for this is 'catastrophic potential'). As indicated in the table in Annex F, however, there are more factors which play a role in risk assessment. The extent to which the standard for group risk takes such factors into account in a sound way cannot be stated without justification using the results of research into people's assessment of the threat posed by the possibility of large accidents. An empirical basis of this kind is lacking.

Group risk was originally intended for activities with fixed installations at separate locations but it can also be applied to other types of activities such as transport. Here, the potential damage area can be very large, as with a national airport. Alternatively, large networks can be involved, as in rail transport. In such cases, the potential damage area has to be split up into sub-areas in order to trace relatively high risk areas. With railways, sections of routes would constitute sub-areas. The way in which such an area breakdown takes place will have an influence on the risk management measures which will need to be taken. Sub-areas can, for example, come under the jurisdiction of several authorities. It is also necessary to determine what the consequences of measures taken in one area will be in another. The committee therefore recommends additional vigilance when determining the group risk measure for activities of this kind.

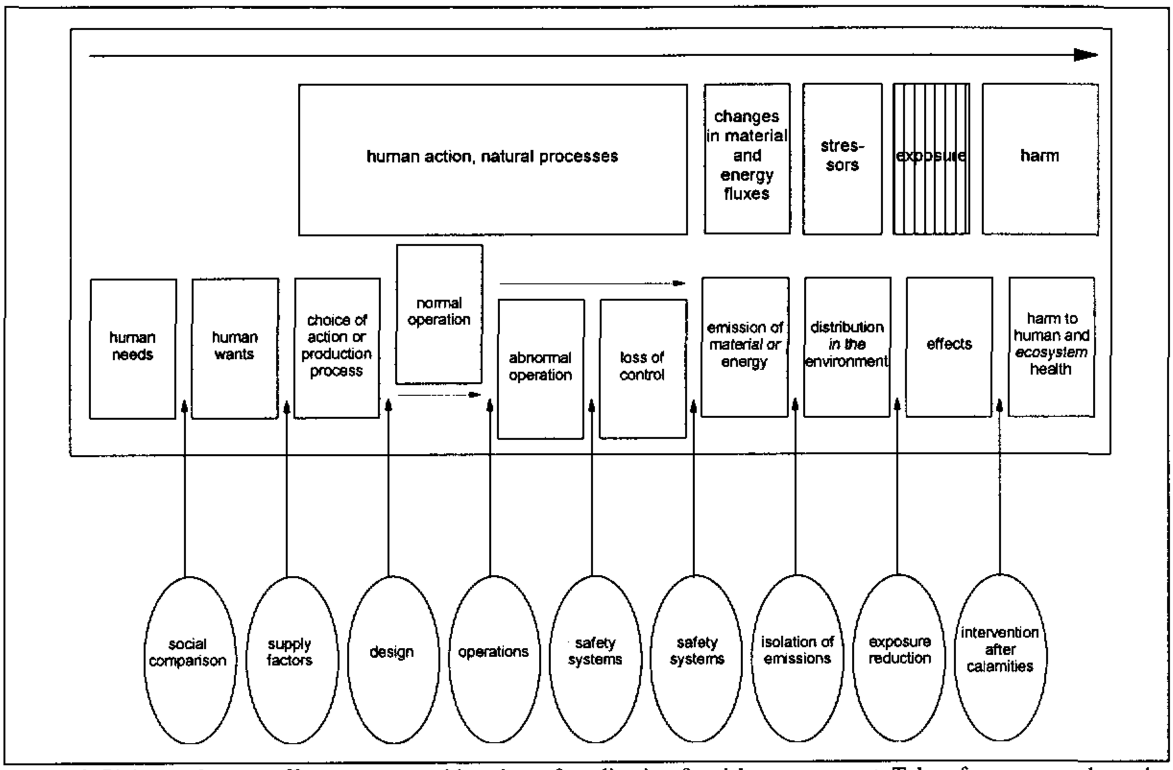

Figure 6 Elaborated cause-effect sequence with points of application for risk management. Taken from proposals made by Hohenemser et al. (Hoh83) and Stallen and Smit (Sta93).

5.5 Risk management as a dynamic process

Cause-effect sequences provide good opportunities for determining where to apply risk management measures. In figure 6, the sequence shown in figure 1 is extended and elaborated (Hoh83). A global indication of the resources which are available for risk management (Sta93) is given for the successive steps in the sequence. The figure makes it clear that general 'formulae' are only possible on a limited scale. Technological factors, environmental factors, individual expertise and the quality of social organization in which activities are situated play a role in the development of undesirable consequences. The multitude of factors which contribute to the presence of risk and the relationship between 'people and technology' create inherent uncertainty. Risk management must therefore be seen in this context as a dynamic process.

In figure 6, a distinction is made between 'normal operation' and 'abnormal operation'. The first refers to all the consequences of the activity, including the associated risks, which are considered to be 'normal'. Normal operation can include undesirable events. There will, in principle, be a wish to avoid such events but their occurrence is nevertheless seen as inevitable and, like the possible consequences, considered to be tolerable. By contrast, there will be a desire to limit as much as possible the frequency, duration and consequences of 'abnormal operation'. The risk management measures for abnormal operation, and in particular for rare events with major consequences, differ from those for normal operation.

Components of risk management include: the continuous improvement of the design and the operation of technical installations and systems*, adequate education and training for all those involved (with risk management as an integral part of the training), the identification of vulnerable components in the processes, the precise registration of accidents and near-misses and learning from them, the maintenance of an audit system and the development of criteria which will allow for the assessment of the quality of an organization (people and technology).

The committee is of the opinion that these elements play a role both in the case of measures directed towards the avoidance of serious accidents and in the case of limiting the risks of exposure to radiation, chemicals and other stressors. Here, the aim of the risk management process should not be confined to the reduction of emissions but also the development of alternatives so that, for example, the use of certain toxic substances becomes unnecessary.

The committee is, incidentally, aware that such an approach is less simple when managing risks which are caused by many individual activities, car driving for example. Components here are, in addition to technological advances, spatial planning measures, the provision of alternatives which involve lower risks and direct measures intended to alter patterns of behaviour. Equally complex is the counteracting of threats to ecosystems resulting from chemical environmental pollutants, whether or not in combination with other stress factors such as drought, acidification and manure pollution.

Fixed risk limits as proposed by the OmR memorandum can play a role in deciding about the tolerability of risks and as a point of reference for risk management ('are we going in the right direction with risk management?'). In practice, however, the main emphasis is on 'management', which includes risk management as an integral part. A task is reserved for the authorities in ensuring that the policy on which activities are based and the organization of activities are also directed towards reasonable risk limitation. A one-sided emphasis on the part of the authorities on meeting numerical standards can, in the opinion of the committee, be counter-productive. In addition, the committee would draw attention to the fact that, in the case of industrial activities, there are risks with consequences both 'inside' and

* This includes supervision and maintenance.

‘outside the perimeter’. These risks should be approached as an interdependent whole by company managers and authorities.

Prescribed quantitative risk estimates and associated limits relate poorly to the large variation in the conditions in which risks have to be dealt with. Standardization of models, as proposed in among other places external safety reports, can disregard essential differences which can exist in the risk attributes of different installations (a model is first extracted with difficulty from reality and then, in different situations, reality is squeezed into the model). Results of such ‘automated’ risk estimates meet (legal) regulations but are not an adequate representation of actual specific risk components in the processes or developments under consideration. Still less do they lend themselves to translation into practical measures for risk limitation.

The committee is aware that the Government’s attempts to standardize models for risk estimates also has positive aspects. It results in a separation of ‘the wheat from the chaff’: incorrect models are identified and their use is not permitted. This improves the quality of risk estimates and equality before the law in decision-making relating to risks. The committee is of the opinion that these benefits can be retained while avoiding the drawbacks it has referred to. All risk estimates will have to be accompanied by a justification of the suitability of the chosen model given the aim of the risk estimate, even when using ‘approved’ models. The requirements for such a justification will become stricter as models acquire a more special character. This approach means that the use of certain models cannot be prescribed as an obligation by means of legislation or regulations.

Finally, the committee would wish to draw attention to another facet of risk management which mainly emerges after serious accidents. An undesirable event of this kind, even if it had been accepted during the original risk assessment, almost always results in calls for supplementary risk management measures. In the committee’s view, this is partially a result of the fact that demonstrable damage, actual casualties for example, leads to a different risk assessment than the ‘anonymous’ results of risk estimates. In addition, classifying a risk as tolerable does not simply mean that the damage is thought to be acceptable. ‘Taking risk’ does indeed involve recognizing that risk management is not perfect and even that there will be a certain level of damage. However, when that damage actually occurs, it will generally not be accepted and certainly not if there is a belief that there are, in principle, possibilities for further risk management. In part, this is a learning process: the analysis of the event can lead to an understanding of the sources of risk and their management. However, care should also be taken not to combat ‘symptoms’ when this does not yield any actual risk reduction. Learning from experience means establishing the technological *and* the organizational *and* the individual human factors which led to the accident (see, among others, Gro92).

5.6 Accumulation of risks

The possible detrimental effects on health and the environment are, in a given situation, generally determined by a multitude of risk factors: in these cases, there is risk accumulation. The approach in the OmR memorandum only takes the accumulation of risk factors within certain population groups or ecosystems into account to a limited extent. For accidents, radiation and chemicals*, risk limits apply for the total (see table 1). The OmR memorandum does not elaborate on other stressors such as noise, odour or poor housing and possible forms of interaction between environmental factors. A complicating factor in the assessment of the role played by all these stressors is that the socio-economic status of those exposed, in combination with lifestyle and job, is also linked to health and often plays a dominant role (see, for example, Kun94, Mac94). Furthermore, a method is lacking for the joint appraisal of the risk for the population and for ecosystems. Partly as a result, a gap can develop between the way groups of the population see the risk which they run and the way in which the government wishes to manage that risk.

5.7 Differences in scale

In the development and management of risks, various types of aggregative levels can be distinguished. First of all, there are levels of scale in space and time: from individual (physical) to global and from 'today and tomorrow' to in the distant future or very long-term. Various decision levels can also be distinguished, such as the strategic, tactical and operational level with a correspondingly diminishing social scope. In addition, the level of complexity determines the uncertainties in the mapping out of causes, effects and measures for managing risks. These level classifications are closely inter-related.

The processes which lead to risks will vary at the different levels. For example, an individual activity such as excessive drinking primarily affects the health of the drinker. Other aspects of individual activities, such as air pollution as a result of car driving, generally only have a slight influence on the health of the individual driver but their cumulative effect becomes a threat for the collective (harmful air pollution)**. In this connection, the committee would also ask for attention to be paid to the problem of diversion. In the case of many forms of human activity, risks to 'humans and the environment' are diverted onto other parts of the world or onto the future. The existence of various levels and of these processes requires a differentiated risk policy

* Leaving to one side the variation discussed above in the meaning of 'individual risk' for the various stressors.

** This phenomenon, which plays a role in many environmental problems, is referred to as a 'social dilemma' (Vle93).

as a process of description, assessment, decision and management. This 'stratification' of health and environment risks, which was only partially brought out in the OmR memorandum, is recognized in the National Environmental Policy Plan (TK89a).

5.8 Premises for risk management

The committee would summarize its comments about the environmental risk management approach as follows:

- The environmental risk management approach, with its relatively simple system of limits, has given a strong impetus to interest in the influence of environmental factors, including industrial activities, on human health and on the structure and functioning of ecosystems.
- This has meant that the risks associated with human activity for the health of humans and the environment have entered into the centre of the political arena.
- The other side of the coin is that, as a result of simplification, the wide-ranging nature of the risk concept has been lost from view. This effect has in part been enhanced because of the range of meanings which have been attributed to 'risk' during the elaboration of the risk approach: risk as the possibility of damage, risk as the possibility of a particular effect on health and risk as a quantity, such as the concentration of a substance, for describing exposure.
- Deciding about the tolerability of risks on the basis of testing against numerical limits which are founded on a few quantitative measures requires justification based on the nature of the risk problem, since a limited range of numerical standards often fail to do adequate justice to a complex reality.
- Testing against generally applicable numerical standards in association with the rule 'failure to meet the numerical limit is not permitted or means that redevelopment is required' makes it formally impossible to include the assessment of economic and social benefits in deciding about the tolerability of risks. If one wishes to allow for this, the result will be a more differentiated system of standards which will sometimes be stricter or less strict than those currently in force.
- The link with the (dynamic) processes which are at the root of the development and management of risks is often weak. A stronger link would also result in a more differentiated system of standards, both in terms of decision rules and risk measures, with the application of the ALARA principle occupying a more central position.
- Meeting equal numerical limits for a risk measure like individual risk does not simply mean that the level of protection will be the same. This is because the risk measure does not adequately represent the risk in all cases and also because the

risk measure for non-carcinogenic substances, carcinogenic substances, radiation or the possibility of large accidents is worked out in different ways.

- Group risk should express some of the multi-dimensionality just referred to, that is to say 'social disruption' following on from serious accidents as a result of the deaths of a certain number (more than ten) of people within a short time. However, the committee is of the opinion that this measure is an inadequate reflection of a complex phenomenon such as social disruption.
- The numerical limit associated with group risk, which changes according to the number of victims (inversely quadratic relationship with the number of victims) is not justified on empirical grounds. It is therefore unclear to what extent this standard takes perception factors into account.
- In the elaboration of the risk approach, it appears that the Government has a preference for carrying out risk estimates with a few models which it has 'approved'. This position fails to do justice to the variations which there will be in reality. The committee supports attempts to establish a 'quality hallmark'. However, the application of a particular model will always have to be justified in the light of the aim of the risk estimate.
- The risk management approach in its current form provides insufficient instruments for dealing with the phenomenon of risk accumulation.

Internationally, a variety of 'risk management approaches' are *en vogue*. The committee has taken a close look at approaches in the United States, the United Kingdom and Norway. This choice was principally based on the fact that information about these approaches was found in the literature, that it proved possible to obtain personal explanations of various aspects and that the approaches included aspects which fitted in with the nature of the committee's line of reasoning. It is certainly not the intention to suggest that there are, either beyond or within the borders of these three countries, no other ways of dealing with risks from which lessons can be learnt.

In the further development of the risk management approach in the Netherlands, elements could be adopted from approaches used elsewhere. An example might be the interest in the quality of the organization of human activity with risk management as an integrated part (Norway, Norwegian Petroleum Directorate, Annex E), the flexible link between risk limits and corresponding limit values for other units (UK, Health and Safety Executive, Annex D) and the classification of risks ('comparative risk analysis', USA, Environmental Protection Agency, Annex C).

Chapter **6**

Questions and answers

The request for a report from the Minister of Housing, Spatial Planning and the Environment has been included as Annex A. The questions posed by the minister fit in with the conceptual framework which was set out in the OmR memorandum and later policy documents concerning the environmental risk management approach. In the previous chapter, the committee set out a number of reservations relating to that conceptual framework. The answers to the minister's questions in this chapter should be seen in the light of those reservations.

6.1 Individual versus population (question 1)

Does the Council agree with the basic principle of the risk management approach, namely protection of humans on the individual level and of flora and fauna at the population level?

A direct answer to the question involves a policy decision which cannot be made by the committee. The committee therefore limits itself to the following comments.

In promoting public health and protecting the population against illness and premature death, the Government's efforts are directed towards individuals, population groups and the population as a whole. At the same time, it also bears the health of future generations in mind.* The basic principle of the environmental risk management policy, namely the protection of the individual, is rated highly in Western

* This is a constitutional duty. Important international documents in which these principles are laid down are the Declaration of Human Rights (Stockholm, 1972) and the report of the Brundtland Commission (WCDE87).

society, including the Netherlands. It is intended to prevent an inadmissible distribution of risks over individuals or population groups.

In addition, a question which can be asked here is whether, when describing risks, it is enough to use only measures oriented towards the individual such as the individual probability of death. The committee does not believe that this is the case and notes that, in the OmR memorandum also, individual protection is not seen as being adequate. It sees the introduction of a measure such as 'group risk' as an attempt to extend decision-making about risk acceptance in order to include other factors which are linked to the disruption of the functioning of society. When assessing the risk for the population associated with certain types of human activity, it will therefore generally be necessary to include risk attributes on the levels of both individual and population. These can include attributes which are particularly important for certain groups in society such as children.

For ecosystems, the basic policy principle is that the functions and structure of, as well as the processes in, the ecosystem must be protected. That basic principle has been translated into measures for protecting the populations of species in ecosystems. It has not been determined whether the method used in practice for working out the approach directed towards the protection of species also provides adequate protection for ecosystem functions and processes (GR88, GR94a).

In ecological and ecotoxicological circles, the question has arisen of the extent to which, in addition to effects which constitute a threat to the survival of populations, other effects must also be counteracted (GR93). The committee does not enter into any further discussion of this subject here.

6.2 Assessment criteria per agent (question 2)

Does the Council consider the current system of criteria for the risks for each agent and for the accumulation of risks associated with agents, as set out in Premises for Risk Management, to be adequate for the assessment of all the risks of environmental pollution as a result of human activity? For the answering of this question, I would be grateful if the Council were to assess the results of the research into supplementary criteria for social disruption.

The answer of the committee is: the criteria in the current risk approach are inadequate for deciding in all cases about the tolerability of the contribution of certain forms of environmental pollution to the (possible) effect on the health of humans and the environment. 'Environmental pollution' refers here both to permitted changes in concentrations of substances and energy (radiation, heat) and to changes caused by serious accidents. With respect to the latter, the committee believes that a simple criterion cannot do justice to a concept as complex as social disruption. This is illustrated by the study referred to in the question (Rav92). The study refers to the death of groups of people within a short time which occupies a prominent position in the OmR memorandum, and the possibility of housing becoming unfit for habitation, with the resultant temporary or more permanent evacuation. The committee certainly considers these things to be important aspects of 'social disruption' after an accident but not the only ones.

In chapter 5, the committee discussed the numerical limit which the Government has linked to group risk. It concluded there that the form of that limit, the relationship chosen between the limit of the frequency of an accident and the number of victims of that accident, is not justified on empirical grounds. Insofar as this relationship is intended to eliminate perception factors in the risk assessment, the committee stated that, because only the number of victims was taken into account, this had been achieved to only a very limited extent. It also recommended closer examination of the delimitation of the area in which victims are found, in particular in the case of the use of group risk for transport.

6.3 Assessment of human health effects (question 3)

For the time being, the choice made in the risk management approach has been for a single risk limit for one effect which can be caused by a variety of agents. The history - for example immediate death resulting from an accident as opposed to death after a period of time resulting from continuous exposure - is disregarded. It has also been decided to adopt a single method of assessment for various forms of serious harm to health. Does the Council believe that there is a scientific basis which is practical in the context of decision-making for introducing differentiation in assessment?

The desire to use equal numerical criteria in deciding about the tolerability of exposure to certain stressors originates in the wish to provide an equal measure of protection against the consequences of exposure to those stressors. The committee would repeat the conclusion it stated in chapter 5: equal numerical criteria for risk measures such as individual risk do not guarantee equal levels of protection.

Question 3 also relates to the comparison and comparative evaluation of a variety of effects on health. In scientific terms, the problem here is that different stressors cause different effects in different situations. In addition, the significance in terms of harm to health or to the environment is not clear for all the effects which are caused. This makes comparison and comparative evaluation difficult.

There are systems for the evaluation of effects on health for mapping out the state of health on the individual and collective levels. Some of these are structured along transparent lines and could also be used for the determination and assessment of risks. The committee emphasizes that the use of such systems requires a transparent and structured procedure in order to prevent inevitable personal value judgements from slipping in unnoticed.

An example of an evaluation system can be found in a recent report from the World Bank about health (WB93). In that report, the various groups of illnesses are evaluated in terms of death and that evaluation is integrated into a measure for the loss of 'healthy life years' (DALY - disability-adjusted life year). An approach of this kind makes it possible to compare the illness burden of populations and population groups. Another example is the estimate of the possible health effects linked to the inhalation or ingestion of radioactive substances (ICRP91). The radiation doses in the various organs are taken together after weighting derived from the estimated severity of the possible consequences linked to the irradiation of the organs.

The committee is of the opinion that the further development of such systems, also in conjunction with the assessment and management of risks, is sensible. It does not consider it possible to develop a system which is universally applicable to the management of environmental risks.

6.4 Death versus reduction in life expectancy (question 4)

The 'measure' for management for human health risk is the average individual risk per year for a critical group. Other risk measures are also possible, such as reduction in life expectancy. Does the Council believe that there are clear scientific advantages associated with the use of other measures? If so, are they suitable for use in practice?

In chapter 5, the committee pointed out that the 'individual risk' risk measure introduced in the OmR memorandum is used in a variety of senses. Among other things, there are differences in the way in which the factor 'time' is dealt with. When accidents occur, the effects can manifest themselves within a short time or at a later stage. Exposure to radiation increases the risk of cancer, but later on in life. With the 'collective risk for ecosystems' risk measure, the consequences of chronic exposure can vary very considerably in terms of the length of time before the effects on individual species and on the ecosystem as a whole become apparent.

A measure such as a reduction in life expectancy or a reduction in the expected number of healthy life years can account for such factors. The committee believes that it is sensible when assessing and managing risks to take the 'time' factor into account. It refers to its answer to the previous question. It also emerged there that the committee does not believe that it is possible to develop one measure which is based on a simple risk attribute such as the risk of death and which can be used for all problems.

Finally, the committee would make one comment with respect to the phrase 'average (...) for a critical group'. This phrasing closely resembles the terminology used by the International Commission on Radiological Protection (ICRP84). If it is to be associated with the conceptual framework used by the ICRP, it must be taken to refer to the group which is most exposed. The OmR memorandum uses the concept of 'risk group'. This is a group which consists of the people who are most likely to suffer adverse health effects, either because they are exposed more than others or because they are more susceptible to the influence of a particular agent than others or because of a combination of the two. The committee suggests adopting the term 'risk group' and defining it as the group which runs the greatest risk.

6.5 Risk perception (question 5)

Risks are sometimes perceived differently. Does the Council consider it possible to express the element of perception quantitatively or to make this element suitable for the decision-making process in a practical and sound way?

Research has shown that the following factors determine to a significant extent people's appraisal of the threat posed by certain activities or conditions (see review in Vle90, Vle93, see also Annex F):

- the harmful or fatal potential
- the inability to control the consequences with safety or rescue measures
- the number of people affected at one time
- the unfamiliarity of consequences and effects
- the involuntariness and unfairness of exposure and risk.

As the activity or situation scores for each of these criteria, people will assess risks in general as being more serious and will feel more threatened. In the report 'Reassessing nuclear energy: risk analysis, human factors, intervention parameters' (GR89a), the conclusion was drawn that the degree to which people feel threatened, in combination with the perceived inability to do anything about that threat, can be seen as a stressor and has an effect on health. The committee is of the opinion that ignoring this phenomenon when taking measures to manage risks can lead to significant tensions between citizens and government. Implementing measures solely on the basis of the possible additional risk of death (or reduction in life expectancy) will generally not cater adequately to the consequences of the sensation of being threatened. In principle, the factors referred to are objectively identifiable even though they are not quantifiable in all cases. As a result, they do not lend themselves to expression as numerical limits.

Including these factors in risk management inevitably means, therefore, that it is not enough to base decision-making on testing against limits for one or more risk measures (see also the answer to question 3). This particularly applies to issues involving major social interests and high levels of complexity. It is desirable, in conjunction with those interests and that complexity, to develop procedures for decision-making which involve 'parties' from society as a whole. The drafting of an environmental impact statement and a public discussion of the result is an example of such a procedure.

6.6 'Natural' agents (question 6)

Some environmental pollutants occurs naturally. Examples are heavy metals and radon. Other pollution does not have natural sources; DDT or ^{131}I, for example. Does the Council believe that it is desirable from a scientific point of view to make a different assessment of human activities which result in environmental pollution with substances which occur in nature (a stricter assessment, for example, given the background level) than of activities which may release substances which do not occur in nature? Against this background, should a threshold value - e.g. the background level - always be used for agents which occur naturally? Is it justifiable to take the added risk into account in this context and can the Council provide guidelines for deciding what can be considered to be an added risk for a source, particularly in the case of naturally-occurring contaminants?

Every organism finds elements in its surroundings which are absolutely necessary for its continued existence, as well as elements which constitute a threat to its health. Examples of the latter are ozone, dust, cosmic radiation, germs, predators and natural pesticides in food. The levels of exposure to those stressors often vary considerably in space and time and they have been and continue to be influenced by human activity. The definition of a natural background level is therefore difficult and will always be arbitrary to a certain extent.

The hypothesis that organisms have become adapted through evolution to 'background levels' is certainly not thought by the committee to be equally valid for all organisms and for all stressors. It is therefore incorrect to see in general the 'background level' of a particular stressor as a threshold below which no effects occur. The possible impact of stressors which are found in the natural environment will have to be estimated in the same way as other stressors.

In some cases, it would appear to be possible to deal separately with the various contributions made to (possible) effect of a particular stressor. This is, for example, the case for exposure to ionizing radiation and carcinogenic substances. For various substances whose effects lend themselves to description with a threshold model, this is not possible; natural and anthropogenic contributions to the exposure level should therefore be considered together.

The committee stated above that natural and anthropogenic contributions to the exposure level for particular stressors are difficult to separate. This does happen in the case of system-specific stressors, for example substances which occur naturally in the part of the environment under examination. If historical information is available about the exposure levels, then that information can be used as a reference for risk assessment, as happens in the case of chemicals in soil. The use as reference does not mean to say that historical exposure levels or the variations in space and time are harmless at those levels. No general statement can be made about the degree of harm inflicted; only specific research can clarify this question.

6.7 Historical pollution (question 7)

Can the Council indicate how background levels should be established if there is pollution which has sometimes been present for a long period of time (e.g. fallout from nuclear testing)?

Whether or not exposure to a stressor is of natural or human origin can be relevant to the risk assessment and the possibilities for taking risk management measures. However, the question is not significant in terms of the possible harm to health as a result of that exposure. See the answer to question 6. For example, we know that if heavy metals, polycyclic aromatic hydrocarbons and organic chlorine compounds remain in the soil for very long periods of time, this reduces their bioavailability. This fact has an influence on the result of the risk assessment for these substances in concrete situations.

In this context, the committee would put forward the example of the approach of the International Commission on Radiological Protection (ICRP91) which recommends making a clear distinction in policy terms between situations in which the risk can, in principle, be avoided by stopping or not allowing activities and situations in which intervention alone is possible, for example environmental pollution resulting from past activities. For the reduction of exposure to radioactive substances which are released during accidents ('Chernobyl', for example) and of exposure to radon in existing housing, the ICRP believes that the intervention approach is suitable: every step taken to reduce exposure must be 'beneficial' and the efforts which have to be made must be reasonable in terms of the health benefits which will be achieved (see also GR94c).

6.8 Ecotoxicological risk assessment (question 8)

In a letter dated 11 June 1991, reference U 3109/CB/mr/325-N, you submitted your advisory report relating to 'Ecotoxicological Extrapolation Methods'. Can the Council, in the light of the main conclusions in this memorandum, indicate on which elements, other than the statistical refinement of the method, the further development of the ecotoxicological risk assessment should concentrate?

For the answer to this question, the committee refers to the report 'Ecotoxicology on course' (GR94a).

6.9 Negligible level (question 9)

Does the Council believe that it is correct, from the point of view of the limits of precision with which calculations can be made, and of course from the point of view of the cost effectiveness of measures, to set a negligible level?

The decision to set a negligible level is one of policy. The committee therefore confines itself to indicating some considerations which are relevant to this decision. As the committee stated in chapter 5, the significance of the negligible risk level has changed in the course of time. The starting point which has now been decided upon by the Government, after consultation with Parliament, is a maximally tolerable level below which the aim is to achieve a risk level which is considered to be as low as reasonably achievable. The negligible risk level has only been retained in the case of substances as a target level in order to prevent harm to health as a result of the combined effect of substances.

The question states two possible arguments for the introduction of a negligible risk level below the maximally tolerable risk level: 'cost-effectiveness' and 'precision'. The committee would first of all wish to point out that any risk management measure must be cost-effective. This is certainly the case when costs are relatively high, something which is generally the case when relatively high risks are involved. In practice, in government policy, there can be a demand for a level which is so far below the maximally tolerable level that further risk management is below regulatory concern. The degree of certainty about the nature and extent of risks will play a role in determining the levels below which the government considers regulation to be unnecessary. However, the way this works out in practice will depend to a large extent on the policy principles which are followed. Consistent implementation of the precautionary principle, for example, will result in a strong emphasis on the prevention of even very small chances of uncertain harm to health.

The concept of negligible risk level is also interpreted in another way which is independent of the setting of a maximally tolerable risk level. The negligible level is in that case the ultimate aim of government efforts in the field of risk management. Here, in principle at least, considerations of cost-effectiveness play no role, or at most a very indirect one, in the establishment of a negligible level of this kind. Knowledge about the nature and extent of risks and the level of uncertainty of that knowledge do, of course, have a direct influence on what is defined as the ultimate aim of risk management.

Another report of the Health Council (GR95) discusses the interpretation of the negligible risk level in the management of the consequences of the combined effect of substances.

6.10 Uncertainties and standard setting (question 10)

Can the Council indicate in what way uncertainties in risk assessment (measurement, models, suppositions etc.) can be included in the process of standard setting?

The committee interprets this question in a general sense. Other committees have examined, for specified applications, the way in which uncertainties can be dealt with in specified situations. Examples are the reports 'Principles of standard setting' (GR85)*, 'Uniform System for the Evaluation of Substances (2)' (GR93) and 'Ecotoxicology on course' (GR94a).

Risk estimates are uncertain because the results of measurements are afflicted with errors. This results from the fact that there are doubts about the applicability of data and that the parameters of the models used are not known precisely enough. The margins which are associated with these types of uncertainty can often be expressed reasonably as measures and numbers. Among others, Dutch research in the Rijnmond area has provided indications that, for serious accidents in industrial installations, uncertainties of several orders of magnitude in both risks and effects are more the rule than the exception (GR89a). Uncertainties associated with the representativeness of the risk models used are much more difficult to express as measures and numbers. Many of the models have not been tested in practice; this is not always feasible. It is therefore impossible to indicate the extent to which the results provided by the models are significant in terms of the real situation.

In many risk estimates, the uncertainties in the result are not discussed explicitly. The committee considers this to be incorrect. Every risk estimate should be

* The Health Council is working on a revision of this report.

accompanied by a discussion of the uncertainties and, when possible, their quantification. In some cases, a sensitivity analysis can be very useful in this respect.

The uncertainty associated with risk estimates also involves a problem in terms of choice, especially when the margin of uncertainty cannot be expressed as a measure and in numerical terms. Does one opt for a value which, as far as is known, will certainly not be an underestimate of the risk? Or does the risk problem require 'the best estimate'? To make such decisions, it is necessary to understand the nature of the risk problem as well as the policy principles of the risk manager. There is therefore no general formula for 'dealing with uncertainties' in the context of risk estimates. However, one can demand that the decisions taken should be indicated clearly as a part of the estimate.

The Hague, 20 April 1995
Signed, on behalf of the committee,

Dr WF Passchier, scientific secretary	drs AEM de Hollander, scientific secretary	ir WC Reij, chairperson

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A Charge

B The committee

C Developments outside The Netherlands: United States of America

D Developments outside The Netherlands: United Kingdom

E Developments outside The Netherlands: Norwegian

F Risk perception factors

G Cause-effect sequences

Annexes

Annex **A**

Charge

1 Invitation from the President of the Health Council

With his letter U2314/dH/mr/346-B the President of the Health Council invited experts to join the committee that prepared the present report. The President wrote:

Several Health Council reports concern the quantitative assessment of risks in the fields of external safety, radiological protection or protection against chemicals. These reports primarily deal with possible detrimental effects of human activity on human and ecosystem health.

Related to these Health Council activities I asked Professor CAJ Vlek to prepare a background paper 'Deciding on risk acceptance' (A90/10), which was published in 1990. Vlek's study lists several definitions of risk and discusses the problems associated with estimating and assessing risks, the pitfalls of risk comparisons and the principles of decision-making on the acceptability of risky activities.

The Government set out its policy on risky activities in the document 'Premises for Environmental Risk Management', the latest version of which was published in 1989 as an annex to the National Environmental Policy Plan. To attain equality before the law and transparency of the decision making process, assessing risky activities with different 'costs' for man en the environment should be performed in a similar way, according to the document. Quantitative risk analysis is proposed as an assessment tool using, as far as possible, an uniform risk measure.

Although 'Premises for Environmental Risk Management' is generally considered as an important forward step, is has also been criticised. In his study Vlek lists several drawbacks, such as the limited, rather technological definition of risk, the neglect of the benefits of risk generating activities and the lack of decision rules for balancing costs and benefits, the unavoidable reduction of the real world in applying quantitative risk analysis, the neglect of the social-psychological dimensions of risk and risk communication and the fact that risk management is a dynamic process, not a static decision problem.

At present the approach outlined in 'Premises for Risk Management' plays an important role in the environmental policy of the Netherlands Government. However, the approach has several limitations. This is a sufficient reason to evaluate the scientific basis of the policy, following the discussion in the above mentioned study 'Deciding on Risk Acceptance'.

I would like a committee of the Health Council to prepare a report for the ministers of health and of the environment on the possibilities and limitations of a risk assessment system, as proposed in the policy document.

2 Request from the Minister of Housing, Spatial Planning and the Environment

In his letter of 28 October 1991 (DGM/DS/S/MBS nr. 23o91005) Minister Alders of Housing, Spatial Planning and the Environment asked the President of the Health Council to report on 'Premises for Risk Management'. The minister wrote:

The ultimate goal of the environmental policy is sustainable development in which man, fauna, flora and goods are sufficiently protected.

The environmental risk management approach has been developed to assess, in as far as possible, the harmful effects and the probabilities of these effects in a systematic and transparent way, to relate standards to such assessments, to set priorities, to be able to compare the environmental profits of different management options and to provide insight in the different methods of risk estimation (standard tests, model calculations, extrapolation factors, etc.) by providing one measure for different environmental problems.

The environmental risk management approach was published for the first time in the 'Indicative Multi-year Programme on the Environment 1986-1990' (Tweede Kamer, 1985-1986, 19204) and was further detailed in an Annex to the National Environment Policy Plan (Premises for Risk Management; Tweede Kamer, 1988-1989, 21137 nr. 5). The approach was elaborated with respect to radiological protection in the policy document Premises for Radiological Risk Management (Tweede Kamer, 1989-1990, 21483, nr. 2). The ecotoxicological risk assessment has been amplified in a letter to the Lower House (Tweede Kamer, 1990-1991, 21.137, nr. 74). Both the Upper and the Lower House have formulated written and oral questions on the documents Premises for Risk Management (Tweede Kamer, 1990-1991, 21137, nr. 5) and Premises for Radiological Risk Management (Tweede Kamer, 1990-1991, vaste commissie voor milieubeheer, UCV van 11 maart 1991).

I envisage adding again an annex on the risk management policy to the next National Environmental Policy Plan.* Therefore I would like to receive a report from the Health Council on the environmental risk management approach, *especial with respect to the following points.*

1. Does the Council agree with the basic principle of the risk management approach, namely protection of humans on the individual level and of flora and fauna at the population level?

2. Does the Council consider the current system of criteria for the risks for each agent and for the accumulation of risks associated with agents, as set out in Premises for Risk Management, to be adequate for the assessment of all the risks of environmental pollution as a result of human activity? For the answering of this question, I would be grateful if the Council were to assess the results of the research into supplementary criteria for social disruption.

3. For the time being, the choice made in the risk management approach has been for a single risk limit for one effect which can be caused by a variety of agents. The history - for example immediate death resulting from an accident as opposed to death after a period of time resulting from continuous exposure - is disregarded. It has also been decided to adopt a single method of assessment for various forms of serious harm to health. Does the Council believe that there is a scientific basis which is practical in the context of decision-making for introducing differentiation in assessment?

4. The 'measure' for management for human health risk is the average individual risk per year for a critical group. Other risk measures are also possible, such as reduction in life expectancy. Does the Council believe that there are clear scientific advantages associated with the use of other measures? If so, are they suitable for use in practice?

5. Risks are sometimes perceived differently. Does the Council consider it possible to express the element of perception quantitatively or to make this element suitable for the decision-making process in a practical and sound way?

6. Some environmental pollutants occurs naturally. Examples are heavy metals and radon. Other pollution does not have natural sources; DDT or ^{131}I, for example. Does the Council believe that it is desirable from a scientific point of view to make a different assessment of human activities which result in environmental pollution with substances which occur in nature (a stricter assessment, for example, given the background level) than of activities which may release substances which do not occur in nature? Against this background, should a threshold value - e.g. the background level - always be used for agents which occur naturally? Is it justifiable to take the added risk into account in this context and can the Council provide guidelines for deciding what can be considered to be an added risk for a source, particularly in the case of naturally-occurring contaminants?

7. Can the Council indicate how background levels should be established if there is pollution which has sometimes been present for a long period of time (e.g. fallout from nuclear testing)?

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* This intention did not materialize.

8. In a letter dated 11 June 1991, reference U 3109/CB/mr/325-N, you submitted your advisory report relating to 'Ecotoxicological Extrapolation Methods'. Can the Council, in the light of the main conclusions in this memorandum, indicate on which elements, other than the statistical refinement of the method, the further development of the ecotoxicological risk assessment should concentrate?

9. Does the Council believe that it is correct, from the point of view of the limits of precision with which calculations can be made, and of course from the point of view of the cost effectiveness of measures, to set a negligible level?

10. Can the Council indicate in what way uncertainties in risk assessment (measurement, models, suppositions etc.) can be included in the process of standard setting?

Given the time period needed for the preparation of the second National Environment Policy Plan I would like to receive your report before the end of 1992.

The Minister of Housing, Spatial Planning and the Environment,

signed JGM Alders

3 Request of the President of the Health Council to respond to the letter of the Minister of Housing, Spatial Planning and the Environment

In his letter of 17 February 1992 the President of the Health Council wrote to the committee:

The Minister of Housing, Spatial Planning and the Environment has asked the Health Council to report on 'Premises for Risk Management' (letter DGM/DS/S/MBS nr. 23o91005 d.d. 28 oktober 1991). The Health Council secretariat provided you with a copy of the minister's letter (committee document 346-22). I herewith request you to respond to the questions of the minister in the report you working on at present. At the start of your second meeting I suggested a way in which you might take the questions of minister Alders into account.

signed professor dr L Ginjaar

The President refers in his letter to the second meeting to the committee. The minutes of that meeting state:

According to mr Ginjaar the main question that the committee should answer is: what is the significance of the policy document *Premises for Risk Management*, what are the limitation of the proposed risk management approach, and what are its shortcomings? Also, the committee should indicate what are the limitations and shortcomings of alternative approaches. In commenting on these questions the committee could respond to the request of the minister of the environment.

Annex **B**

The committee

- ir WC Reij - *chairperson*
  public works engineer, Voorschoten
- prof dr HAJ Struyker-Boudier - *vice-chairman*
  pharmacologist, Rijksuniversiteit Limburg, Maastricht
- dr WFJPM ten Berge (from 3 January 1992)
  industrial toxicologist , DSM, Geleen
- dr ir W Biesiot
  nuclear physicist, Rijksuniversiteit Groningen
- prof dr LA Clarenburg
  chemist, Rijksuniversiteit Utrecht
- dr HJP Eijsackers
  ecotoxicologist, Speerpuntprogramma Bodemonderzoek, Wageningen
  and Rijksinstituut voor Volksgezondheid en Milieuhygiëne, Bilthoven
- prof dr ir JDF Habbema
  medical decision analyst, Erasmus Universiteit Rotterdam
- ir ChrJ Huyskens
  radiation physicist, Technische Universiteit Eindhoven
- dr ir G de Mik
  toxicologist, Rijksinstituut voor Volksgezondheid en Milieuhygiëne, Bilthoven
- dr WA Smit
  physicist, Universiteit Twente, Enschede

- ir WP Smit (from 1 March 1992 untill 1 January 1993)
  chemical engineer, AKZO NV, Arnhem
- dr PJM Stallen
  biochemist/psychologist, Arnhem
- dr ir JP Visser
  chemical engineer, Shell, Den Haag
- prof dr CAJ Vlek
  psychologist, Rijksuniversiteit Groningen
- drs AEM de Hollander - *scientific secretary*
  Rijksinstituut voor Volksgezondheid en Milieuhygiëne, Bilthoven
  and Gezondheidsraad, Den Haag
- dr WF Passchier - *scientific secretary*
  Gezondheidsraad, Den Haag

The President op the Health Council participated in some of the meetings of the committee.

Ms AMC van Kan, ms MFC van Kan and ms MJ Roskam served as secretaries to the committee. Mr AB Leussink assisted in editing the report.

The SAB concluded in each report that the ranking on the basis of relative risk differs from that of the public and the policymakers. Communication and instruction should increase the knowledge of the nature of risk problems and might be affective in reducing the difference. The conclusions were formulated in terms of ten commandments for the EPA:

- EPA should target its environmental protection efforts on the basis of opportunities for the greatest risk reduction
- EPA should attach as much importance to reducing ecological risk as it does to reducing human health risk
- EPA should improve the data and analytical methodologies that support the assessment, comparison, and reduction of different environmental risks
- EPA should reflect risk-based priorities in its strategic planning processes
- EPA should reflect risk-based priorities in its budget process
- EPA - and the nation as a whole - should make greater use of all the tools available to reduce risk
- EPA should emphasize pollution prevention the preferred option for reducing risk
- EPA should increase its efforts to integrate environmental considerations into broader aspects of public policy in as fundamental a manner as economic concerns
- EPA should work to improve public understanding of environmental risks and train a professional workforce to help reduce them
- EPA should develop improved analytical methods to value natural resources and to account for long-term environmental effects in its economic analyses

The report of the SAB-EPA has stimulated the discussion on risk assessment and comparative risk analysis in the US. It was received well by EPA and by other parts of the federal administration. Economists, ecologists and public health officials all thought to strengthen there position by means of risk assessment and risk comparison. The opinions of politicians and environmentalists were mixed. Several of them preferred political principles above technical analysis.

3 Comparative risk analysis in California (Cal94)

In 1994 the final report of the 'California Comparative Risk Project' was published. It contained the result of a two year study and presented recommendations for California's environmental policy. The project coordinators took account of the results of evaluations of similar projects in other US States. They made serious efforts to involve the public in the comparative risk analysis process and to pay more attention to social-economic health differences then elsewhere (environmental equity).

The authors of the report define risk as the probability that some activity, situation or event causes loss or damage. Loss or damage is the result of exposure to stressors; a stressor is a chemical, material, organism, radiation, temperature change or any activity that threatens health, environment or the quality of life. Health damage is expressed in the probability of a disease or handicap. Ecological damage relates to the detonation of the structure and function of the ecosystems.

The aims of the projects were:

- to assess and rank environmental threats to human health, ecological health, and social welfare
- to critique the risk-ranking model and explore other models for environmental protection and priority-setting, outlining their values and implications
- to incorporate public input in the discussion of the diverse issues that contribute to environmental priority-setting
- to seek consensus among the many perspectives and identify those issues for which their is a lack of consensus.

Three committees assessed risks and ranked them with respect to human health, social welfare and ecosystem health. Three other committees discussed questions of education and communication in the field of occupational and environmental hygiene, the unequal distribution of environmental resources and environmental pollution over the various social-economic population groups and the role of economical considerations in environmental policy. Representatives of the state authorities constituted the advisory panel. The committees reported their findings to the 'Statewide Community Advisory Committee'. The latter committee, composed of representatives of environmental and social organizations, local councils, business, agriculture and academia, formulated policy recommendations. The project was supported by the staff of the California Environmental Protection Agency. The public could express its views in several hearings.

Human health

In ranking human health risks the following questions were discussed:

- what are stressors?
- what is the relationship between exposure and response or effect?
- what is the exposure?
- how can the risk be expressed?
- how does the risk compare with other risks?

The human health committee used two criteria to rank risks: the severity of possible damage and the number of affected persons. Risks were categorized in six classes: high (H), medium (M), low (L), insufficient data (IN), not considered (NR), no problem (NP). On top of the committee's list figured the different types of air pollution, such as particulate matter, ozone, environmental tobacco smoke and lead (see table 2). The committee noted that some population groups run special risks due to increased sensitivity or due to accumulation of environmental pollution. It also pointed to the necessity of a just distribution of risk over population groups and the developments of methods to predict future health effects.

Ecosystem health

The assessors of ecological risk considered several environmental routes. In ranking risk they used as criteria:

- intensity measures - the ecological severity of the effect and ranges from non-lethal effects on organisms to complete destruction of ecosystems
- extent measures - the proportion of the ecosystem affected and ranges from less than one to 100 percent
- reversibility measures - the time required for the system to recover and ranges from less than one year to more than 70 years (which is 'unrecoverable')
- uncertainty/probability measures - the certainty that the effect will occur or the probability that the event producing the stressor will occur and ranges from no direct evidence to documented evidence it will occur.

The ecological health committee put the different types of air pollution in top of its list (table 2). However, the committee also identified urbanisation as a significant threat due to urban runoff and urban sprawl. The committee recommended an extensive system of physical planning to manage, also ecologically, building activities and infrastructural works. It also asked for protection of ground water and groundwater supplies.

Social welfare

The definition of the protection objective: improving social welfare, is not easy. According to the social welfare committee it is related to good health and health care provisions, personal safety, useful work, sufficient income, an adapted environment, adequate services, possibilities for recreation, good education facilities, local social structure and sufficient control of the own environment. To this list the committee

Table 2 Ranking of environmental factors (stressors).

Human health	**Social welfare**	**Ecological health**
High	*High*	*High*
Environmental tobacco smoke	Alteration of aquatic habitats	Alteration of aquatic and wetland habitats
Inorganics	Alteration of terrestrial habitats	Alteration of terrestrial habitats
Persistent organochlorines	Environmental tabacco smoke	Inorganics
Ozone	Greenhouse gases	Non-native organisms
Particulate matter	Lead	Ozone
Radionuclides (natural sources)	Ozone	SO_x and NO_x
Radon	Particulate matter	
Volatile organics	Pesticides-agricultural use	
	Pesticides-non agricultural use	
	Radionuclides	
	Stratospheric ozone depletors	
	Volatile organics	
Medium	*Medium*	*Medium*
Carbon monoxide	Asbestos	Alteration of acidity, salinity, or hardness of water
Lead	Inorganics	Greenhouse gases
Microbiological contaminants	Microbiological contaminants	Lead
Pesticides-agricultural use	Non-native organisms	Persistent organochlorines
Pesticides-non agricultural use	Oil and petroleum products	Oil and petroleum products
	Persistent organochlorines	Pesticides-agricultural use
	Radon	Pesticides-non agricultural use
	SO_x and NO_x	Total suspended solids, biological oxygen demand, or nutrients in water
Low	*Low*	*Low*
Alteration of acidity, salinity, or hardness of water	Alteration of acidity, salinity, or hardness of water	Microbiological contaminants
Radionuclides (anthropogenic)	Carbon monoxide	Particulate matter
SO_x and NO_x	Thermal pollution	Volatile organics
Total suspended solids, biological oxygen demand, or nutrients in water	Total suspended solids, biological oxygen demand, or nutrients in water	

adds possibilities for self fulfilment and guarantees for the welfare of future generations. The committee measured risks in terms of:

- number of people exposed
- number of people impacted
- severity of impact
- irreversibility
- involuntariness
- uneven distribution
- potential for catastrophic impact
- lack of detectability.

The committee deemed the results of its deliberations as preliminary. It pointed out that there are no accepted methods to measure the impact of environmental factors on social welfare. This is especially true for a complex system as the State of California. The committee's rankings are presented in table 2.

The committee recommended to include social welfare in risk assessment. The opinions of local communities and the general public are essential factor sin this aspect.

Recommendations

The Statewide Community Advisory Committee accepted the recommendations of the various committees. It stated that in environmental policy decision making assessing and ranking risks are important elements, especially where priority setting is concerned. However, nature and magnitude of the risk are not the only factors that determine the final policy decisions. Economical considerations, public preferences, feasibility to prevent pollution, the unequal distribution of environmental pollution and possible future threats to the environment are of importance as well.

The Statewide Community Advisory Committee pointed to so called hot spots: population groups or ecosystems that are exposed to stressors in an elevated way. The identification of such groups and ecosystems were considered to be of importance. It cautioned not to exclude 'low' risks fully from consideration and recommended to study the extent to which the 'low' score was due to limited exposure to the stressor, to the effectiveness of the regulations or to a lack of data.

The Statewide Community Advisory Committee finally concluded that comparative risk analysis should be a structural part of the planning mechanisms of the state authorities. The ranking obtained should be reviewed regularly, for example every three or five years.

Comment

Comparative risk analysis appears to develop in the US into a process to define an environmental policy, this is supported by the various groups in society. That is demonstrated by the attention paid to the social aspects of environmental pollution's such as the distribution of the pollution across the various social, economic and ethnic population groups. In ranking risks experts do play a role, but on the same footing as the representatives of social interest groups. It is interesting that risks are expressed quantitatively and that the associated uncertainties are discussed. The risk ranking itself, however, is a process of negotiation using predefined criteria.

Not withstanding the positive overall conclusion of the State Wide Community Advisory Committee the project will not have a follow-up*. The reason given is that social aspects are still underdeveloped.

* According to the report of a meeting of the Risk Assessment and Risk Management Commission of the American Industrial Health Council on 12 and 13 February 1995.

Annex **D**

Developments outside The Netherlands: United Kingdom

The Tolerability of Risk approach of the UK Health and Safety Executive*

TOR-document

In the report of the Sizewell B Public Inquiry** (1986) it was recommended that the Health and Safety Executive (HSE) should "formulate and publish guidelines on the tolerable levels of individual and societal risk to workers and the public from nuclear power station". As a first step HSE "should publish a document on the basis of which public and Parliamentary opinion could be expressed". In this way discussion on the extent of risk and especially on its tolerability - a notion introduced for the first time - should not remain a pastime for experts.

In 1988 HSE produced the first version of the 'The tolerability of risk from nuclear power stations' (HSE88). In the report HSE described its risk management approach and also compared the risk from the operation of nuclear power stations with other risks. This so-called TOR-approach was reconfirmed in 1992 in a revised version of the 1988-document. It has become the cornerstone of the UK risk management policy, not only in the field of nuclear power, but also as far as protection against other major hazards, both from fixed installations and from the transport of hazardous materials, is concerned (HSE92a, Har94).

* This annex is based on the report of a visit of WF Passchier in February 1995 to R Pape, F Campbell and C Nussey of the Health and Safety Executive, Bootle, Merseyside, Engeland. The report of the meeting has been edited by the British hosts.

** 'Sizewell B' was, at that time, a proposed pressurised water reactor, the first nuclear power plant of that design to be built in the UK.

Principles

The guiding principle in the UK to ensure the safety of workers and the public is that 'operators' must do whatever is *reasonably practicable* to reduce the risk from work activities. This so-called ALARP*-principle has been incorporated in the TOR-approach, which considers:

- whether a risk is unacceptable so that the activity causing the risk should be refused
- whether a risk is so small that no further precaution is necessary
- whether a risk, that falls between these two states, has been reduced to a level 'as low as reasonably practicable'.

These principles are visualised in figure 10. The 'risk reduction triangle' also symbolises that according to the ALARP-principle operators are expected to spend proportional more resources on risk reduction at higher risk levels than at lower risk levels.

The TOR-approach encompasses existing activities and proposed ones. Especially in the latter case the authorities can define benchmarks for requirements that are considered to be readily achievable for plants at the design stage with modern technology and analysis techniques. This does not imply that an operator should not try to reduce risks any further. However, exceeding the benchmark level is thought to be quite unlikely and would require serious justification to show that a higher level is indeed 'ALARP'.

For nuclear power plants HSE has further developed the general principles in the form of 'safety assessment principles' or SAPs (HSE92b). SAPs are used as guidance for HSE staff** for assessing an operator's safety case. They reflect the HSE's judgement of what constitutes the best modern practices in engineering and science. Safety assessment principles are not enforceable as such, but operators would need strong arguments not to comply with the criteria based on these principles.

It should be mentioned that the UK regulations take as a starting point that the operator is responsible for the safety of all operations under his control. Thus the operator generally produces his own criteria, taking account of the SAPs, and uses these criteria in making a safety case for submission to HSE.

* as low as reasonably practicable
** Nuclear Installations Inspectorate or NII

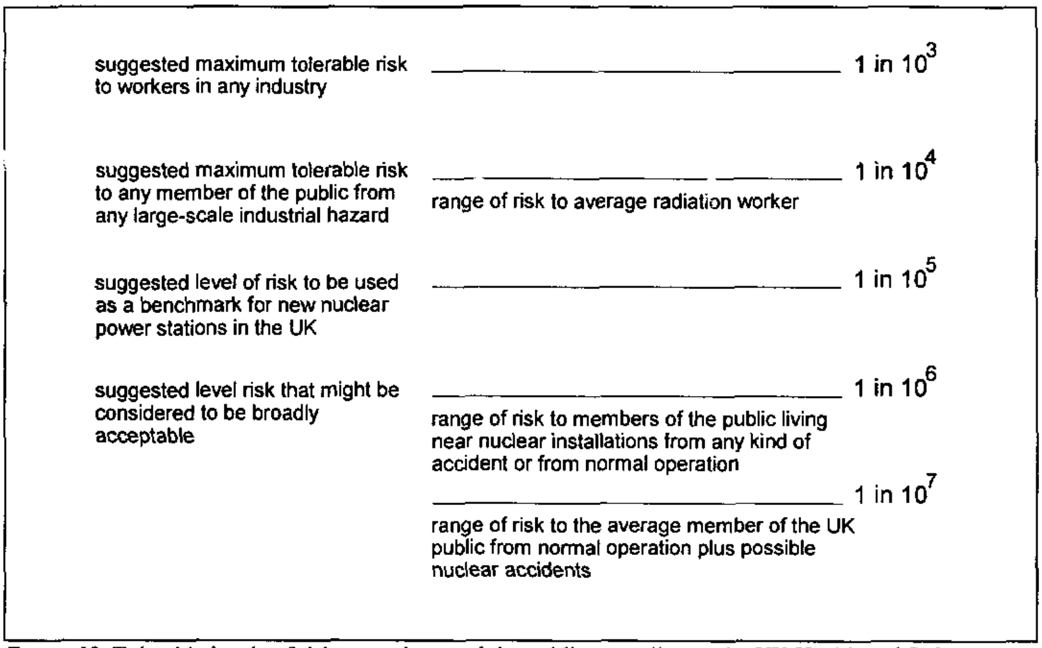

Figure 12 Tolerable levels of risk to workers and the public according to the UK Health and Safety Executive (HSE92a). The numbers pertain to the probability of attributable death from one year of operation. In between the lines: estimated levels of risk to UK workers and the UK public.

risk region. If the exposed population group would contain a relatively large proportion of highly susceptible people a value of 1 in 10 000 000 per year may be considered to be more reasonable.

Also risk criteria for land planning uses have been specified. Quantitative criteria apply for the individual risk, which is now defined as the probability of receiving a 'dangerous' dose. A dangerous dose of an agent like a toxic gas, heat, pressure wave or radiation, is the amount of exposure that would cause death to susceptible people and severe stress or injury to the remainder of a typical cross section of the national population. The just tolerable level, which applies to the siting of houses, is 1 in 100 000 per year. The upper bound of the broadly acceptable region is 1 in 1000 000 per year, unless higher proportions of highly susceptible people are present, in which case a level of 1 in 3000 000 per year is thought to be more reasonable. For the siting other buildings it is suggested to consider shops, pubs and restaurants with a possible 100 people at peak hours, or a hotel with a capacity of 25 people as equivalent to 10 houses. In actual decisions* societal risk is also taken into account, but in a more qualitative way. For example HSE would suggest to aim at individual risk levels in case of multi-storey buildings at 1 in 3 million per year.

* In the UK HSE makes recommendations to local planning authorities who take the spatial planning ('zoning') decisions. HSE does have the right to appeal such a decision in court.

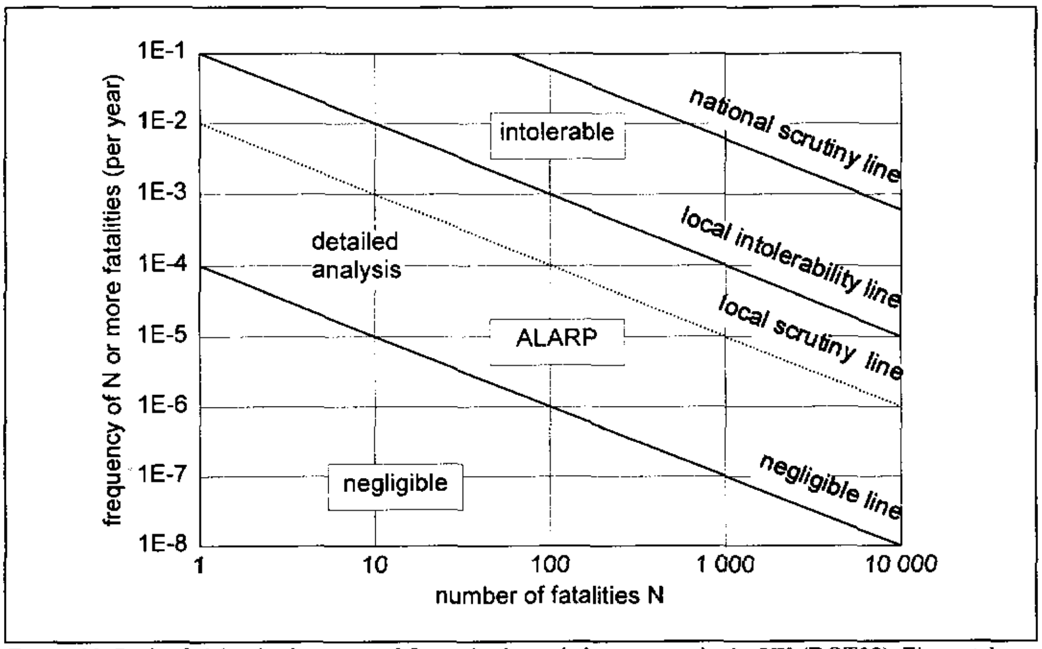

Figure 13 Societal risk criteria proposed for major hazards in transport in the UK (DOT88). Figure taken from HSE92a, *Figure D1*.

In a study of major transport hazards, criteria for societal risk in terms of the annual frequency with a given number of fatalities or more versus that number have been proposed. These criteria, that follow the TOR-approach, are reproduced in figure 13.

For nuclear plants in normal operation, using criteria in terms of the probability of attributable death is not always practicable. The HSE has recognised this and proposes to translate the just tolerable risk level and the upper bound of the broadly acceptable risk region into, respectively, basic safety limits and basic safety objectives (HSE92b). These quantities are not just derived from the corresponding risk level by applying risk coefficients, but also involve judgements to obtain practicable values. An example is given in figure 14, which presents the basic safety limits and basic safety objectives for exposure to ionising radiation due to the normal operation of a nuclear power plant. Whereas the ratio between two individual risk levels is of the order of magnitude of 100 (figure 12), to be practical the ratio of the basic safety limit and the basic safety objective for exposure to ionising radiation at nuclear installations is a factor of 10 for workers and a factor of 50 for members of the public.

For accident frequencies the safety assessment principles specify basic safety limits and objectives that differ with the order of magnitude of the individual radiation dose (HSE92b; figure 15). These safety targets are consistent with TOR in terms of individual risk, but they may also be interpreted as representing societal risk and are

effective dose in a year to:		basic safety limit millisievert	basic safety objective millisievert
persons working with ionising radiations	maximum	20	2
	average	10	1
other workers on site		5	0,5
members of the public		1	0,02

Figure 14 Basic safety limits and basic safety objectives specified by the UK Health and Safety Executive for normal operations of nuclear power plants (HSE92b).

maximum effective dose in millisievert	total predicted accident frequency per year	
	basic safety limit	basic safety objective
0,1 - 1	1	10^{-2}
1 - 10	10^{-1}	10^{-3}
10 - 100	10^{-2}	10^{-4}
100 - 1000	10^{-3}	10^{-5}
> 1000	10^{-4}	10^{-6}

Figure 15 Basic safety limits and basic safety objectives specified by the UK Health and Safety Executive for accident frequencies of nuclear power plants (HSE92b).

based on an inverse linear relation between effect size and frequency, similar to figure 13. Also, basic safety limits and objectives have been specified for the frequency of accidental releases of given amounts of radioactive iodine (iodine-131) and radioactive caesium (caesium-137). These too are interpreted as being criteria for societal risk.

Evaluation

This annex describes the 'tolerability of risk'-approach of the UK Health and Safety Executive. It should be added that the HSE places a strong emphasis on sound engineering millisievertpractices in designing, constructing, operating and decommissioning nuclear power plants (and other complex industrial installations). An installation's safety case should demonstrate that such practices have been applied, in addition to the use of probabilistic safety analyses to estimate risks. Part of that demonstration is that risk levels are as low as reasonably practicable. Furthermore, the safety or risk analysis will often identify targets for further improvement.

The TOR-approach is also a means of setting priorities for the supervisory activities of the HSE and its Nuclear Installations Inspectorate. If the outcome of a risk analysis falls high in the ALARP-region stronger arguments are required from the operator to justify his operations than in the case of an outcome near or in the broadly acceptable risk region.

As is visualised by figures 10 and 11 the just tolerable risk level and the upper bound of the broadly acceptable risk region are not absolute criteria. However, it would be very unlikely that a plant that would generate risks in the intolerable region would be licensed or would be allowed to continue to operate. Likewise, the HSE would generally not put further requirements on an operator if risks were shown to be broadly acceptable, although the operator might consider it his responsibility to spend resources on further risk reduction.

The HSE acknowledges that factors such as size of accidents, voluntariness of risk exposure and being acquainted with the harmful agents, determine the extent to which people accept activities that generate risks. However, the basic safety limits and objectives do not reflect the degree of risk aversion of the public. Emphasis on sound engineering and the requirement of a management control system (quality assurance system) in all phases of plant operation (including design, construction and decommissioning) taking ALARP as the guiding principle is thought the most adequate approach.

The aim of the original TOR-document was to make risk management policy the subject of public debate. An underlying aim was that this would lead to decisions that would have more public and political support. The extent to which the TOR-approach has really gained public support is doubtful. The comments on the 1988-document (HSC88), have lead to a revised document, in which the approach was essentially unchanged. It has been accepted in later public inquiries which might be a proof of political support.

Comparison with OmR

The TOR-approach of HSE has much in common with the environmental risk management approach ('OmR') of the Netherlands Government. Both can be considered as top-down approaches: objectives are defined for risk levels and risk reduction which are translated into targets that can be used as operational criteria. A major difference is that, at least originally (TK85, TK89b), the pair of risk levels in the OmR-approach are considered to be absolute criteria, whereas in the TOR-model, at least in principle, more flexibility is allowed as individual risk values will be interpreted more as order of magnitudes. This is demonstrated by the ratio between the two levels. In the TOR-approach this ratio may vary, depending on the operational quantity considered, whereas in OmR a factor of 100 is always maintained*.

In terms of the probability of attributable death ('individual risk') the TOR-values are two order of magnitude higher than those of OmR. The HSE did not specify numerical criteria for societal risk in terms of the probability on given effects. However, for nuclear plants, criteria have been derived as safety assessment principles, some of which may be considered to represent societal risk. These criteria have an inverse linear relationship with accident frequency, whereas those of the corresponding OmR 'group risk' have an inverse quadratic relationship with accident frequency.

Documentation

The following references provide further information on the 'tolerability of risk'-approach of the UK Health and Safety Executive: DOT88, Har94, HSC88, HSE88, HSE92a, HSE92b.

* At present, in the case of hazardous substances, possibilities for differentiation of the ratio are studied.

Annex **E**

Developments outside the Netherlands: Norge

Regulations for off-shore activities*

The Norwegian Government has since 1985 introduced new regulations with respect to safety management in the petroleum industry on the Norwegian Continental Shelf. The main characteristics of these regulations are:

- a change from a prescriptive to a goal-setting philosophy
- using risk analysis as a tool for identifying and reducing possible losses of human life, of environment values and functions and of economic values
- defining safety objectives and risk acceptance criteria is a responsibility of the operators
- the supervision of the performance of operators is centralised in one authority, the Norwegian Petroleum Directorate.

System

The Norwegian Government has restricted the exploration and production activities on its Continental Shelf. Companies (hereafter called 'operators') need a license for such activities. Up till 1985 the legislation that outlined the requirements for licensed operators was prescriptive in nature. The authorities defined the safety objectives en prescribed how those objectives were to be met. This approach followed the one that was and still is common in the shipping industry and in many other types of industry:

* This annex is based on the report of a visit of WF Passchier in August 1994 to M Ognedal, Norwegian Petroleum Directorate, Stavanger, and T Aven, Rogaland University Center, Stavanger. The report of the meeting has been edited by the Norwegian hosts.

based on past experiences constructions and procedures are specified in detail; following those specifications is made obligatory.

Although this system was deemed to ensure an acceptable level of safety, it was unsatisfactory in several respects. Inherent to the system is a large degree of inflexibility. This might hamper technological progress or, in any case, picking the fruits of such progress. Not incorporating the results of technological innovation into safety management would be counterproductive to the ultimate safety goal of reducing the possible losses of human life and environmental and economic values as far as possible. Also, striving for a comparable level of safety in all situations, requires introducing different measures to prevent possible losses; circumstances in the offshore industry may differ from place to place and from time to time.

These considerations led to the introduction in 1985 of a new Petroleum Act (Petroleumslov) and a new supervisory structure. In that structure the Norwegian Petroleum Directorate (Oljedirectoratet) was given a central and co-ordinating role in order to avoid confronting the operators with conflicting regulatory decisions (see figure 16). A new set of regulations with binding objectives and indicators of how such objectives were to be met, were to be issued under the auspices of the NPD, as well as guidelines and publications that might help operators in setting up operations in accordance with the new legislation.

In 1985 the regulations on the internal control system entered into force. These regulations require that operators have an appropriate form of management structure which would ensure that they can accommodate the legal requirements on a 'round the clock' basis. The regulations do not only require an internal control system for operators, but for their contractors and subcontractors as well. It is the responsibility of the operators to verify that contractors and subcontractors follow the regulations in this respect. These regulations did not drop from out of the blue. Already in 1979 operators were required to produce a document on their internal control organisation and from 1981 up to 1986 this document, or a revised version, was used as a basis for supervision by the NPD.

In the new system risk analysis is considered to be a key tool for identifying hazards and deciding on measures to avoid those hazards or to reduce the possible loss of human health and environmental and economic values in which those hazards might result. The regulations on the application of risk analysis entered into force in 1991 and replaced earlier NPD-guidelines of 1981. The regulations require the operator to set safety objectives and risk acceptance criteria. The former approach, in which only accident probabilities were quantified and were deemed acceptable by the authorities as the probability was below 1 per 10 000 per operational year, was abolished. The general philosophy of the regulations is that operators should strive for continuous improvement of the level of safety.

- the protection of the external environment
- the protection of economic values.

The risk analyses regulations provide the framework and tools for ensuring an adequate level of safety. The regulations relate the concept of risk to accidental events. An accidental event is defined as an:

uncontrolled event which may lead to loss of human life, personal injury, damage to the environment and loss of assets and financial interests

and clearly reflects the meaning given to safety. Risk is the

expression of the probability and the consequences of an accidental event.

The risk analysis regulations specify that an operator is required to:

- define safety objectives
- define risk acceptance criteria.

The safety objectives should aim at avoiding and withstanding accidental events. Although the operator is free to set his own objectives, the guidelines attached to the regulations list elements that would normally be reflected in the objectives. The elements are:

- accidental events must be avoided
- the risk level must be as low as possible
- attempts shall be made to reduce risk level over time.

The first element reflects that the goal is to reach an ideal (and thus unattainable) level of safety. However, the objectives should provide a driving force to improve the safety level over time (third element). Here the notion of risk comes into play. The operator should be able to demonstrate that he has reduced the risk as low as possible at each point in time, which also means that as technology progresses the risk level should be reduced. The expression 'as low as possible' is interpreted by the NPD as requiring an optimisation of the level of safety, which includes a consideration of the costs of safety or risk reducing measures. With this interpretation 'as low as possible' is, for all practical purposes, equivalent to the concept of ALARP ('as low as reasonably practicable') used in the regulations of the British Health and Safety Executive and to the concept of ALARA ('as low as reasonably achievable') used, for example, in health and safety regulations in The Netherlands.

Risk analysis is considered to be a tool for identifying accidental events that may occur and their consequences.* The operator is free to choose his preferred method, as long as it is adequate. A Norwegian standard on risk analysis is in preparation. The results should be presented is such a way that they can be used for deciding on risk reducing measures. Such decisions are to be based on risk acceptance criteria that are to be set by the operator before the analysis is carried out. The operator has considerable freedom in setting criteria, which may be of a quantitative or of a qualitative nature, depending on the nature of the risks to be assessed en the methods use for the risk analysis. In case of quantitative risk analysis the criteria should refer to the uncertainties associated with the results of the analysis. The risk acceptance criteria and the risk analysis should be reviewed and updated in the course of time as part of a systematic risk management effort.

The guidelines associated with the regulations clarify that the acceptance criteria express a standpoint with regard to risk connected to loss of human lives, to personnel injury, to damage to the environment and to damage to assets and financial interests. 'Zero risk' is not considered to be a valid criterion, as it is deemed impossible to eliminate all risk in offshore activities. The guidelines continue to state that the risk of an accidental event may be accepted, but the actual occurrence not.

The procedure specified by the regulations is as follows. The operator sets acceptance criteria, performs a risk analysis, identifies those accidents that do not pass the criteria (so-called dimensioning accidental events), develops risk reducing measures and has to demonstrate that this measures lead to an acceptable risk level that is also as low as possible (this is as a matter of fact the iterative process mentioned above).

Emergency preparedness

Although reducing the probability of accidents should be a first priority, an emergency preparedness organisation is required for offshore activities on the Norwegian Continental Shelf. The emergency preparedness regulation, one in a series of detailed regulations issued by the NPD, sets out requirement for such an organisation. This regulation follows the same structure as the other, more general ones. It provides a framework; the operator should analyse what is required given the nature of the accidents that appeared from the risk analysis. The emergency preparedness organisation and provisions should be an integral part of the whole operation and be subject to the same internal control as all other parts of the operation.

The requirement of emergency preparedness measures demonstrates that in the Norwegian approach the results from the risk analysis do not automatically generate

* Another important function of quantitative risk analysis, the comparison of options, is not mentioned in the regulations and the guidelines. Of course operators have every freedom to use risk analysis in this way, but in the end they have to estimate the absolute risk of the chosen option and compare the estimate with the acceptance criteria.

decisions. Even if the risk is acceptable, further provisions are needed to mitigate the consequences. A case in point is the 'man overboard' situation. The emergency preparedness organisation for rescuing people would further lower the risk, if expressed in terms of the probability of life lost.

Epilogue

The Norwegian system for regulating the offshore industry appears to be a promising approach for reducing risks that are inevitably associated with exploration and production activities. It takes full account of the dynamic nature of the risk management of complex installations. A condition for its success is the existence of highly qualified supervisory authorities.

One may wonder if a similar approach is effective in other industrial branches. This report is not the right place to answer this question. However, it should be stressed that in the offshore industry one deals with a limited and controlled number companies that have large resources at their disposal, also in the field of risk analysis and risk management. This situation may be quite different in other branches of industry. As mentioned before, contractors and subcontractors are also subject to the internal control system and risk analyses regulations. The safety management approach of the offshore petroleum activities will therefore also affect other branches of industry.

Documentation

The following references provide further information on Norwegian regulation of the offshore petroleum industry: NPD85, NPD90, NPD92a, NPD92b.

Annex **F**

Risk perception factors

During the 70s, 80s and 90s the risk perception has been extensively studied in Western Europe and Northern America. Recent reviews of the relevant literature have been presented in Vle90 and Dro91. The studies consistently show that many factors affect personal risk assessments. A list of factors is given in table 3 (Sjö94). Often some of those factors can be aggregated into a smaller number; cf. *inter alia* Vle90.

Table 3 Factors commonly used to explain perception of risk (Sjö94).

factor/dimension	hypothesized condition for high perceived risk or risk rating
factors related to the type of hazard:	
catastrophic potential	able to cause a concentration of fatalities/injuries in time, or, relation to one single event, in contrast to 'normal' risks
voluntariness	involuntary
controllability	uncontrollable
familiarity	unfamiliar to the subject
scientific uncertainty	little known, or unknown, to science
controversy	uncertain; different judgements of the risk exists
dread	terrible; the type of consequences are feared
history	reoccurring; previous occurrence of accidents
onset of effects	sudden; lack of prior warning of large immediate effects
reversibility	irreversible; consequences cannot be adjusted or healed
factors related to the social context:	
fairness	based on unfair distribution of risks and benefits
benefits	uncertain with respect to benefits
trust	handled, or estimated, by distrusted experts or authorities
media attention	highly exposed, and emotionally presented, in mass media
availability of information	information is perceived as lacking or untrustworthy; rumours increase in importance
involvement of children	affecting children or foetuses
future generations	affecting coming generations in an unfair or irrevocable direction
victim identity	causing harm to a known or likeable person
factors related to context of risk judgements or ratings:	
risk target	ratings of risk to others than oneself
risk definition	emphasis on consequences in contrast to probabilities
contextual framing	closely related in time to a negative personal experience, or in a situational setting inducing negative mood
factors related to individual characteristics:	
gender	women express higher perception of risk than men
education	people with low education often give higher estimates
age	older persons often give higher estimates
income	people with low income usually give higher estimates
psychological sensitivity	more anxious persons usually give higher estimates
personal skill	people with little or no risk relevant training or ability give higher estimates

Annex **G**

Cause-effect sequences

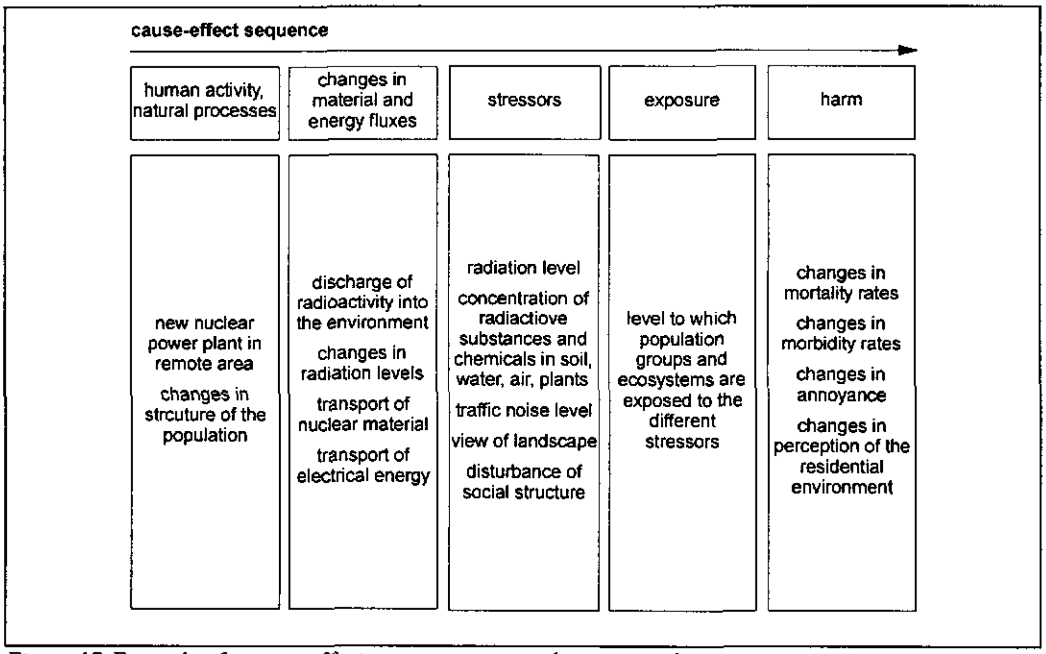

Figure 17 Example of a cause-effect sequence: new nuclear power plant.

The cause-effect sequence of figure 17 illustrates the health detriment generated by a nuclear power plant. The construction of the plant is a response to the electricity need of the population. The operation of the plant causes discharges of radioactive

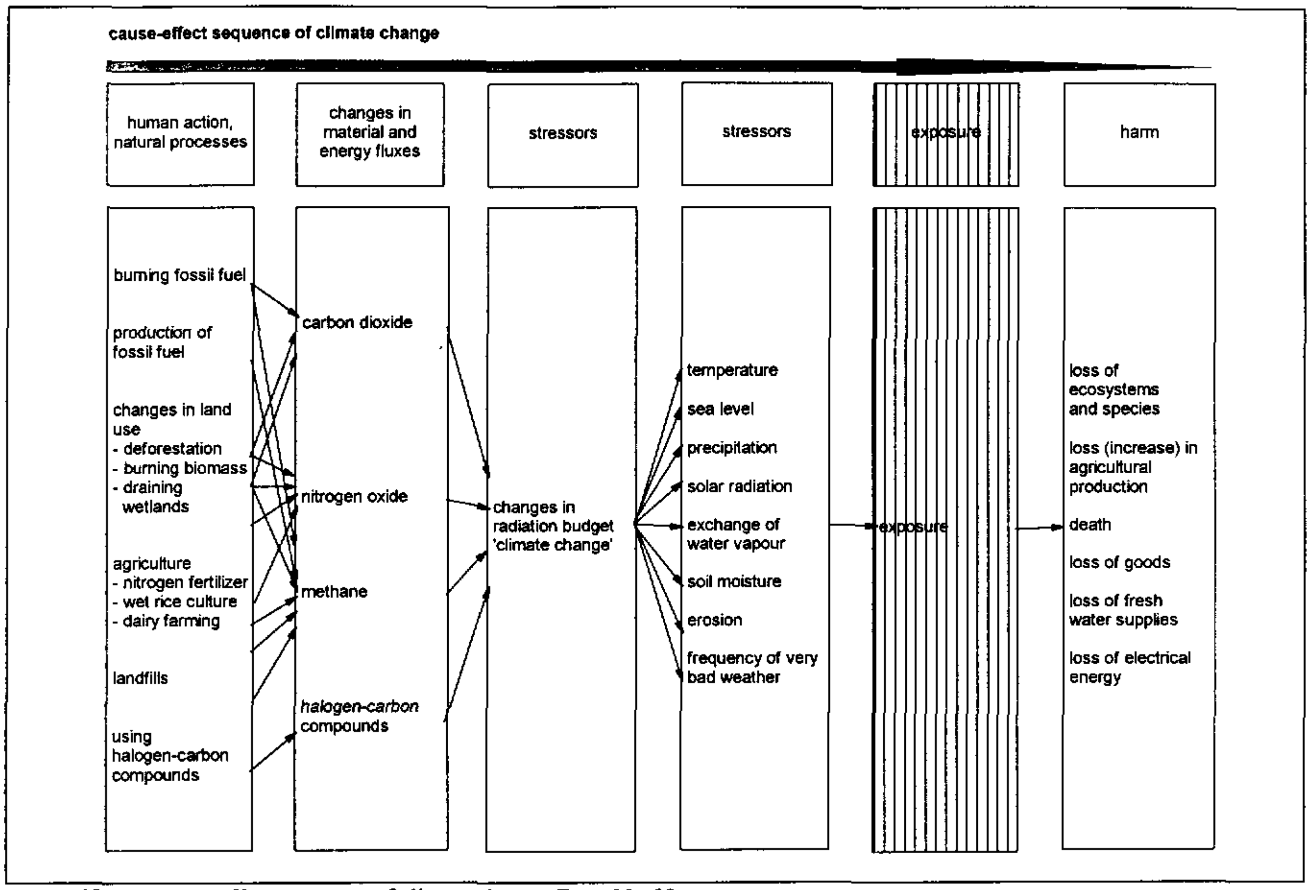

Figure 18 The cause-effect sequence of climate change. From Nor92.

substances and chemicals into the environment. Discharge is more or less continuous at low emission levels, with possible (infrequent) changes due to small or large accidents. The operation of the plant also necessitates the transport of nuclear materials and radioactive waste. High voltage lines transport the electricity to other areas. The social structure of the region around the plant will change; as the local labour market often can not satisfy the needs of the plant. The plant operation also increases the environmental levels of physical stressors, such as the concentration of radioactivity in plants and in the water. The increased traffic generates noise and the construction of roads may disturb local ecosystems (not mentioned in figure 17). The presence of the power plant in itself may affect health and is to be considered to be a psychological stressor (not mentioned in figure 17). Human and ecosystem health is or may be harmed in so far they are exposed to these stressors. The nature and measure of the possible health effects depends on the amount of exposure.

Nordberg-Bohm and colleagues constructed a cause-effect sequence for a global environmental problem: climate change with the change in radiation balance as a stressor (figure 18; Nor92). That stressor is a composite of stressors like average temperature, sea level, amount of precipitation, etc. These stressors are generated by human activities, like burning of fossil fuel, deforestation, drainage of wetlands, agriculture and production and use of fluorocarbons. Human and ecosystem health detriment is caused in a direct way by increased exposure of man, animal and plant to ultraviolet radiation and, indirectly, for example floods and loss of fresh water supplies.

Both examples demonstrate that the structure of cause-effect sequences may be quite complex. Each of the 'links' is composed of several components that affect the next link in different ways. Using cause-effect chains for analyzing and managing environmental risks has its limitations. The influence of the 'outside world' on the effects of human actions is modelled in a simplified way. Furthermore, the diagrams of figure 1 in the main report and of the figures 17 and 18 in this annex only have one 'direction': from cause to effect. Within a chain feedback's may occur that affect the magnitude of the possible effects.

A cause-effect sequence is preceeded by human needs and wants. Influencing human wants and needs offers an additional opportunity for risk management (figure 6).