Vattenfall Wind Power Ltd

Thanet Extension Offshore Wind Farm

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HSE
Health & Safety Executive

Reducing risks, protecting people

HSE's decision-making process

HSEBOOKS

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HSE's decision-making process

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Preface

We are pleased to present the document *Reducing risks, protecting people* revised in the light of comments on the discussion document.

The Health and Safety Executive (HSE) published the original discussion document *Reducing risks, protecting people* in May 1999. It set out how the statutory bodies responsible for the administration of the Health and Safety at Work Act 1974[1] ('the HSW Act') approached those decisions about the management of risk that are required of them under the Act. For the Health and Safety Commission (HSC) these include making arrangements to secure the health, safety and welfare of people at work, and the health and safety of the public, in the way undertakings are conducted – including proposing new laws and standards, conducting research and providing information and advice. HSE advises and assists HSC in its functions, including the preparation of draft regulations and Approved Codes of Practice. It has some specific statutory responsibilities of its own, notably for the enforcement of health and safety law, the licensing of nuclear power stations and dealing with a variety of safety case regimes etc. Local authorities also have statutory responsibilities for enforcement of health and safety law, mainly in the distribution, retail, office, leisure and catering sectors.

A major purpose of the document was to set out an overall framework for decision taking by HSE which would ensure consistency and coherence across the full range of risks falling within the scope of the Health and Safety at Work Act. This framework was based on the method which HSE applies to the control of risk at nuclear power stations, originally published in 1988 as *The tolerability of risks from nuclear power stations (TOR)*.[2]

Events since the publication of the discussion document have reinforced the need to publish a description of HSE's decision-making process. Over recent years, public concern over such matters as Bovine Spongiform Encephalopathy (BSE), railway safety and food safety has intensified the call for openness about how decisions are taken on the regulation of risks. The public is also more aware that, given few activities are without any risk, there must be a balance between the health and safety measures introduced to eliminate or control risks, and the costs arising or benefits forgone when the measures are introduced. Hence the recent lively debate about where that balance lies.

Not surprisingly, there was great interest in the discussion document. It was widely distributed both in print and electronically in a portable format. We received over 150 responses, many of them representing consolidated replies from a number of interested parties, and around 10 000 hits on the Internet site. We thank all those who have responded. Your comments have proved invaluable and the new version has taken them into account.

In fact most of the comments received were generally favourable. The concept of a single document explaining HSE's decision-making process was welcomed, as was the extension

of TOR beyond the nuclear industry. Moreover, the decision-making framework was accepted as being universally applicable, and no area was identified where the proposed criteria on tolerability would create difficulties. The majority of respondents also found that good practice had been given the right emphasis and supported the principles for conducting cost benefit analysis.

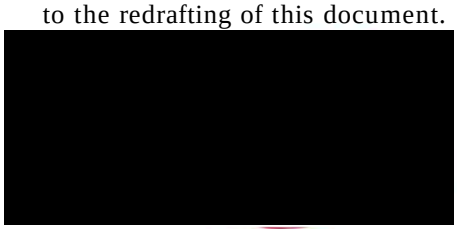
Nevertheless, the consultation has highlighted some points which could benefit from clarification. One of these relates to the status of the document. We would like to emphasise that the document is aimed at explaining the decision-making process in HSE rather than providing guidance to individual duty-holders on what they need to do. Such guidance is available in other documents and particularly *Management of health and safety at work regulations 1999. Approved Code of Practice and Guidance*.[3] The consultation process has shown that many duty holders, and others involved in occupational health and safety, would like to emulate HSE's approach to devising the control regime that should be put in place for addressing hazards at work. As the new document says, we welcome this as long as those who want to emulate the regulator recognise the different context in which HSE applies the framework and take this into account when applying our process to their own decisions. We have amended the text to make this distinction clearer.

We have also taken the opportunity to dispel any perception that we were moving away from a risk-based approach. The new version emphasises the role of risk assessment, both quantitative and qualitative, in the decision-making process and expands on the role of good practice in determining the control measures that must be put in place for addressing hazards. We also make clear that the philosophy and approach set out in the document operate within, and not as an alternative to, the principles of good regulation published by the Better Regulation Task Force.

In presenting this latest document we recognise there will be scope for further development and refinement. We shall revise it as necessary so that it remains a document attuned to current needs.

Improving health and safety requires attention to the assessment and management of risk. For this to be achieved, we need to raise public understanding of the issues involved and of our own understanding of the concerns of society and the values people employ when they consider matters of risk. Prompting a more informed public debate on how to handle risk is an essential part of this and we hope that publication of this document will help to stimulate this debate. We will certainly play our part in doing so.

Finally, we would like to thank all those, both in HSE and outside, who have contributed to the redrafting of this document.



Bill Callaghan
Chair
Health and Safety Commission

Timothy Walker
Director General
Health and Safety Executive

Introduction

This document is aimed primarily at stakeholders who want to know more about HSE's philosophy for securing the health, safety and welfare of persons at work and for protecting others against risks to health and safety arising from work activities, and the procedures, protocols and criteria underpinning the philosophy. It sets out the basis and criteria by which HSE, in complying with its functions, decides upon the degree and form of regulatory control that it believes should be put in place for addressing occupational hazards. It considers the way scientific evidence (or the lack of it) and uncertainties are taken into account and how the balance is struck between the benefits of adopting a measure to avoid or control the risks, and its disadvantages.

It is in three parts and has four appendices, as follows:

Part 1

- Sets out the aims of the document, namely the need to:
  - open to scrutiny HSE's approach to the regulation and management of risk, and the philosophy underpinning it;
  - make transparent the factors that inform our decisions on how risks should be regulated and managed, for example how account is taken of the scientific knowledge of the risks concerned, the technology available for controlling them, the resource implications of adopting the decisions, public attitudes towards the risks and the benefits they engender and show how these shape the form and content that our regulations and guidance take;
  - help reassure the public that risks to people from work activities are properly addressed, taking due account of the benefits of the activities giving rise to the risk. In particular to satisfy the public that industry, in taking advantage of technological advances and in responding to economic pressures, will not be allowed to impose intolerable risks on people;
  - let other regulators, whose responsibilities may overlap with those of HSC/E, know the basis for the management of health and safety risks from work activities and thereby help to promote consistency of decision-making amongst regulators. In this instance, consistency does not mean uniformity, it means the particular application of a coherent philosophy in a way suitable to the particular context.

- Mentions some of the difficulties inherent in meeting the above aims, particularly those involved in taking account of ethical, social, economic and scientific considerations and the preference values of society at large.

- Introduces the concept of tolerability which is central to the document. This concept (explained in greater detail in Part 3) refers to a willingness to live with a risk so as to secure certain benefits.

- Points out that the proper regulation of risks requires that both the individual risks and societal concerns engendered by a hazard must be addressed.

Part 2

- Reviews some of the developments that have influenced our approach to decision-making since the HSW Act was enacted. The developments examined include advances in knowledge on how people view risks; changes in the regulatory environment and on the industrial scene; and shifts in the values, preferences and expectations of our society.

- Describes the principles of good regulation that have evolved in adapting our approach to take account of the developments; namely:
  - the targeting of action: focusing on the most serious risks or where the hazards are less well controlled;
  - consistency: adopting a similar approach in similar circumstances to achieve similar ends;
  - proportionality: requiring action that is commensurate to the risks;
  - transparency: being open on how decisions are arrived at and what are their implications; and
  - accountability: making clear, for all to see, who is accountable when things go wrong.

- Notes some of the above developments which have been particularly important, ie:
  - the need for the meaning of risk to encompass more than physical harm by taking into account other factors such as ethical, economic and social considerations;
  - the recognition that, because the system for informing and reaching decisions is iterative, it is often very difficult to put a demarcation line between risk assessment and risk management;
  - a discussion by the Courts of the meaning of 'risk' in the HSW Act which implies that approaches for managing risks must ensure that anything in an undertaking presenting the possibility of danger (or what conceptually is regarded as a hazard) has to be properly addressed.

Part 3

- Describes the six stage iterative system adopted by HSE for reaching decisions on how risks should be regulated and managed, namely:
  - deciding whether the issue is primarily one for HSC/E;
  - defining and characterising the issue;

- ✦ examining the options available for addressing the issue, and their merits;
- ✦ adopting a particular course of action for addressing the issue efficiently and in good time, informed by the knowledge gained going through the six stage iterative system and by the expectation that as far as possible the course of action will be supported by stakeholders;
- ✦ implementing the decisions;
- ✦ evaluating the effectiveness of actions taken and revising the decisions and their implementation if necessary.

- Sets out the framework, known as the Tolerability of Risk (TOR),[2] for reaching decisions on whether risks from an activity or process are unacceptable, tolerable or broadly acceptable and its application in practice. In this context, 'tolerable' does not mean 'acceptable'. It refers instead to a willingness by society as a whole to live with a risk so as to secure certain benefits in the confidence that the risk is one that is worth taking and that it is being properly controlled. However, it does not imply that the risk will be acceptable to everyone, ie that everyone would agree without reservation to take the risk or have it imposed on them.

- The framework makes clear that:
  - ✦ both the level of individual risks and the societal concerns engendered by the activity or process must be taken into account when deciding whether a risk is unacceptable, tolerable or broadly acceptable;
  - ✦ the decision-making process and criteria adopted are such that action taken is inherently precautionary;
  - ✦ moreover, HSE starts from the position that, for every hazard, the law requires that:
    - – a suitable and sufficient risk assessment must be undertaken to determine the measures needed to ensure that risks from the hazard are adequately controlled;
    - – suitable controls must be in place to address all significant hazards, and
  - ✦ HSE also starts with the expectation that:
    - – those controls, at a minimum, must achieve the standards of relevant good practice precautions, irrespective of specific risk estimates;
    - – where there is no relevant good practice, or the existing good practice is considered by HSE to be insufficient or inadequate, the decision as to what control measures are suitable will generally be informed by further risk assessment;
    - – there are some risks from certain activities, processes or practice which are not tolerable whatever the benefits, i.e. they are unacceptable. Any activity, process or practice giving rise to risks falling in that region would be ruled out unless the activity, process etc can be modified to reduce the degree of risk so that it becomes tolerable;
    - – as control measures are introduced, the residual risks may fall so low that additional measures to reduce them further are likely to be grossly disproportionate to the risk reduction achieved, though the control measures should still be monitored in case the risks change over time;
  - ✦ HSE has proposed numerical criteria for informing decisions on the tolerability of risks only for very limited categories of risk, for example, those entailing fatalities either individually or in multiple fatality accidents.

Appendix 1

Sets out some of the conventions adopted for undertaking risk assessment. It points out that:

- more often than not, a risk assessment is done in relation to a hypothetical person (a hypothetical type of individual who is deliberately assumed to have some fixed relation to the hazard under consideration);
- the procedures adopted for handling uncertainty are in line with the precautionary principle and ensure that a lack of certainty is not a reason for not taking preventive action.

Appendix 2

Sets out:

- the architecture of health and safety law;
- the constraints that must be taken into account when introducing health and safety legislation;
- the procedures adopted for identifying the hierarchy of options for new regulatory measures.

Appendix 3

Examines some issues relevant to assessing risk reduction options, including:

- the implication of case law on 'reasonable practicability';
- the protocols and procedures adopted for conducting a cost benefit analysis and for ensuring consistency when comparing costs against benefits.

Appendix 4

Gives some statistics for comparing risks from different hazards.

Part 1

Overview of risk and risk management issues

Purpose of this document

1 Work activities give rise to many hazards which present risks to workers and the public. The HSC/E are responsible for regulating such risks. The aim of this document is to explain the basis for HSE's decisions regarding the degree and form of regulatory control of risk from occupational hazards, and in particular to:

- open to scrutiny our approach (eg when advising the HSC) to the assessment, management and regulation of risk and the philosophy underpinning it;
- make transparent the factors that inform our decisions on risks and show how these shape the form and content of our regulations and guidance. For example, how account is taken of the scientific knowledge of the risks concerned, the technology available for controlling them, public attitudes towards the risks, the benefits engendered by allowing the processes, events etc giving rise to the risk to take place;
- help reassure the public that risks to people from work activities are properly addressed, taking due account of the benefits of the activities giving rise to the risks. In particular to satisfy the public that industry, in taking advantage of technological advances and in responding to economic pressures, will not be allowed to impose intolerable risks on people;
- let other regulators, whose responsibilities may overlap with those of HSC/E, know the basis for the management of health and safety risks arising from work activities and thereby help to promote consistency of decision-making amongst regulators.

2 The central purpose throughout has, therefore, been on opening up our decision-making process rather than providing guidance to duty holders. The document is thus aimed at showing how our approach to the assessment and management of risk shapes the form and content of our regulations and guidance, and informs our compliance activities. The difference in emphasis is important. For example, as we point out in paragraphs 80-81 the boundaries that HSE applies in assessing and regulating risks are generally much broader than those we would expect duty holders to undertake in complying with the relevant statutory provisions.

Hazard and risk

Hazard and risk are used interchangeably in everyday vocabulary. Nevertheless, it has proved useful to HSE to make a conceptual distinction between a 'hazard' and a 'risk'

by describing a hazard as the potential for harm arising from an intrinsic property or disposition of something to cause detriment, and risk as the chance that someone or something that is valued will be adversely affected in a stipulated way by the hazard. HSE – as far as the health, safety and welfare of people is concerned – frequently makes use of the above conceptual distinction in its guidance by requiring that hazards be identified, the risks they give rise to are assessed and appropriate control measures introduced to address the risks. This reflects the fact that in most cases it makes sense to take account of the circumstances in which people and management systems interact with a hazard.

It is often possible to regard any hazard as having more remote causes which themselves represent the 'true hazard'. For example, when considering the risk of explosion from the storage of a flammable substance, it can be argued that it is not the storage per se which is the hazard but the intrinsic properties of the substance stored. Nevertheless, it makes sense to consider the storage as the basis for the estimation of risk since this approach will be the most productive one in identifying the practical control measures necessary for managing the risks, such as not storing the substance in the first place, using less of it or a safer substance, or if there is no alternative to storing the substance, using better means of storing it.

The term 'hazard' is absent in the HSW Act.[1] However, the Courts have ruled that as, far as section 3 of the Act is concerned, 'risk' means 'possibility of danger' rather than 'actual danger' (see paragraphs 41-42). Conceptually, HSE will therefore regard anything presenting the 'possibility of danger' as a 'hazard'. Moreover, since in any given workplace there would be a large number of hazards which duty holders could address, requiring duty holders formally to address them all would place an excessive and largely useless burden on them. So as not to impose unnecessary burdens on duty-holders, HSE will not expect them to take account of hazards other than those which are a reasonably foreseeable cause of harm, taking account of reasonably foreseeable events and behaviour. Whether a reasonably foreseeable, but unlikely, event – such as an earthquake – should be considered depends on the consequences for health and safety of such an event.

Why the need to explain decisions on the management of risk?

3 The risk of suffering harm is an inescapable aspect of living. Nevertheless, there has been tremendous progress in improving many aspects of the quality of our lives. We now live longer than at any time in history; products for use at home and at work are safer and more reliable than ever before. Although accidents at work still occur, the trend averaged over the years has been downwards and we have recently published our targets for reducing these further.[4]

4 This progress in the quality of our lives is readily acknowledged but, paradoxically, it has been accompanied by an increased expectation for a society free of involuntary risks. The

rapid technological developments of recent years have introduced new hazards but also enhanced the scope for controlling existing hazards. Though people accept that we should continue to take advantage of advances in science and technology, this is moderated by expectations that:

- those responsible for the hazards should ensure that adequate measures are taken to protect people from the harmful consequences that may arise from such hazards;

- the State should be proactive in ensuring that its arrangements for securing the protection of people from risks are adequate and up to date as distinct from reacting to events, and that those arrangements should address, as necessary, the concerns the hazards give rise to.

5 Such expectations are complemented in a free market economy by an underlying presumption that industry should be able to take advantage of new technologies, unfettered by undue State intervention.

6 It was such conflicting pressures that led the Government, in an initiative supported by all parties in the political spectrum, to undertake in the early seventies a fundamental review, under the Chairmanship of the late Lord Robens, of the way occupational risks are regulated and managed.[5] The result is that risks to health and safety arising from workplace activity in Great Britain are regulated through a single legal framework – the relevant statutory provisions which include the HSW Act – and by a single set of institutions – the Health and Safety Commission (HSC) and the Health and Safety Executive (HSE), (see the second paragraph of the Preface).

7 A fundamental principle underpinning the HSW Act is that those who create risks from work activity are responsible for protecting workers and the public from the consequences. Thus, the HSW Act places specific responsibilities on employers, the self-employed, employees, designers, manufacturers, importers, suppliers and people in charge of premises. Associated legislation places additional duties on owners, occupiers, licensees and managers.

8 Regulations have also been introduced clarifying these duties, requiring people such as employers and the self-employed to assess risks and to base their control measures on the results of the assessments. Where hazards entailing severe consequences are involved, the trend in recent years has been to amplify the duties for generic risk assessments to require the production of safety cases. These require duty holders to write down and submit to HSE the measures they have in place, or intend to introduce, to meet their legal obligations and ensure safe and healthy systems of work and the proper management of health and safety. This enables duty holders to demonstrate that they understand the hazards associated with work activities and how to control them.

9 In short, since 1974 the trend for managing risk at work has been to merge and centralise the authorities responsible for occupational health and safety and to clarify responsibilities in criminal law for managing risks in particular circumstances through the establishment of regulatory regimes whereby broad general duties are explicitly put on those who are best placed to do something about preventing or controlling the risks. The broad duties are supplemented by specific regulations. Many of these regulations place absolute duties

on duty holders. Others, however, like the broad general duties are qualified by expressions such as 'so far as is reasonably practicable' (SFAIRP) in order to avoid the imposition of duties that no one can fulfil – because absolute safety cannot be guaranteed – and in order to ensure that preventive and protective actions are commensurate with the risks. It is useful to note that SFAIRP is not the only qualification. There are other similar qualifications such as 'as low as reasonably practicable' (ALARP); 'as low as reasonably achievable' (ALARA).

10 The general approach is to set out the objectives to be achieved and to give considerable choice to duty holders as to the measures they should put in place to meet these objectives. However, this is not universal. As explained later in this document, there are circumstances where the enabling powers of the HSW Act have been used to enshrine in regulations specific measures for ensuring that the risks from certain hazards are properly controlled – extending in certain circumstances to proscriptions or to the establishment of a licensing or permissioning regime for certain activities.

11 A similar trend towards centralisation of regulatory authorities and the adoption of non-prescriptive regimes is found in other areas, eg the environment.

12 For a non-prescriptive regime to work, duty holders must have a clear understanding of what they must do to comply with their legal obligations. It is therefore not surprising that HSE, as the regulator responsible for implementing the law on health and safety, is being pressed with increasing frequency for explanations of how risk issues are addressed, both in general and in particular circumstances, so that the risks are regarded as tolerable. In this context 'tolerable' does not mean 'acceptable'. It refers instead to a willingness by society as a whole to live with a risk so as to secure certain benefits and in the confidence that the risk is one that is worth taking and that it is being properly controlled. However, it does not imply that the risk will be acceptable to everyone, ie that everyone would agree without reservation to take the risk or have it imposed on them.

13 Providing such an exposition of the risk decision-making process is not an easy task. The process is inherently complex, with a variety of inputs. It has to be workable whilst allowing the use of judgement by the regulator and flexibility for duty holders. At the same time, it must reflect the values of society at large on what risks are unacceptable, tolerable or broadly acceptable. Any informed discussion quickly raises ethical, social, economic and scientific considerations, for example:

- whether certain hazards should be entertained at all;
- how to maximise benefits to society through taking account of advances in scientific knowledge and technology while ensuring that undue burdens with adverse economic and social impact or consequences are not imposed on the regulated;
- how to achieve the necessary trade-offs between benefits to society and ensuring that individuals are adequately protected;
- the need to avoid the imposition of unnecessary restrictions on the freedom of the individual.

14 The reform of the law relating to health and safety at work, set in train by the HSW Act itself, has proceeded over the past 25 years or so by taking such considerations into account. The approach has evolved – and is still evolving – through the formulation of regulations, Approved Codes of Practice and guidance spanning an enormous variety of industrial activity (see Appendix 2 for a fuller discussion of these regulatory tools). The evolution has taken place under many influences which need to be reviewed in order to set the approach in its full context. This review is the subject of Part 2 following, which leads on to a description in Part 3 of the approach to regulation designed to ensure that risks that are taken are tolerable in the sense already described.

Part 2

Review of developments that have influenced our decision-making approach

Developments and influences

15 The Robens Committee's diagnosis of the issues at stake when regulating for health and safety still holds good, namely that:

- health, safety and welfare at work could not be ensured by an ever-expanding body of legal regulations enforced by an ever-increasing army of inspectors;
- primary responsibility for ensuring health and safety should lie with those who create risks and those who work with them;
- the law should provide a statement of principles and definitions of duties of general application, with regulations setting more specific goals and standards.

16 Though the above diagnosis still underpins our approach for reaching decisions on the management and regulation of risks, the approach has also evolved to take into account developments that have arisen over the past 25 years. There is nowadays a better understanding of how people view risks. Changes have also taken place in the regulatory environment and on the industrial scene. Finally, within a generation, there have been some marked shifts in the preferences, values and expectations of our society. This review examines some of these developments – particularly those which have influenced the decision-making process and criteria described in Part 3.

Advances in knowledge on how people view risks

17 How people view risks and apply value judgements is perhaps the most challenging factor to take into account when developing an approach to the regulation of risk – not least because these views and value judgements are not static but change according to circumstances. Recent studies have shown that as mankind has evolved to cope with the dangers and uncertainty of life, we have all been provided with inbuilt mechanisms for dealing with risk – mechanisms that reflect our personal preferences and the values of the society in which we live.

18 We all recognise that, as an inescapable fact of life, we are surrounded by hazards – all with a potential to give rise to unwanted consequences. Less apparent is that whatever we do, however we occupy our time or even if we 'do nothing', we are taking some kind of risk. Even at home there are myriad risks – we could get hurt, for example, in a house fire

or when doing DIY jobs. If we did something else, we would be taking other kinds of risks. Some of the risks we face may be from naturally occurring hazards while others may arise from our lifestyle and are risks we take willingly to secure some wanted benefits, eg flying to go on holiday.

19 Moreover, everyday, consciously or unconsciously, we all view hazards and evaluate their risks to determine which ones we choose to notice, ignore or perhaps do something about. We may take the consequences of some risks for granted and, for others, consider that our own chances of being harmed may be either more or less than the average, depending on the apparent degree of control we have for taking or limiting the risks, eg whether we are more nimble, younger, have better sight and so on.

20 In short, the way we all treat risks depends on our perception of how they relate to us and things we value. It is only fairly recently that social scientists have examined in detail what factors affect people's perception of risk. They have found that there is a wide range of factors. Particularly important for man-made hazards are 'how well the process (giving rise to the hazard) is understood, how equitably the danger is distributed and how well individuals can control their exposure and whether risk is assumed voluntarily'.[6]

21 Other studies on perception of risk have led to a theory which considers that it may be simplistic to believe that it will be possible to derive a quantifiable physical reality that most people will agree represents the 'true' risk from a hazard. This theory argues that the concept of risk is strongly shaped by human minds and cultures. Though it may include the prospect of physical harm, it may include other factors as well, such as ethical and social considerations, and even the degree of trust in the ability of those creating the risk (or in the regulator) in ensuring that adequate preventive and protective measures are in place for controlling the risks. The logical conclusion drawn from the theory is that it is human judgement and values that determine which factors should be defined in terms of risk and actually made subject to analysis.[7,8,9,10]

22 The theory has been used to explain why, for many new hazards, high quality risk assessments by leaders in the field often fail to reassure people. Even using all available data and best science and technology, many risk assessments cannot be undertaken without making a number of assumptions such as the relative values of risks and benefits or even the scope of the study. Parties who do not share the judgmental values implicit in those assumptions may well see the outcome of the exercise as invalid, illegitimate or even not pertinent to the problem – as exemplified by the controversy surrounding the proposal to dispose of the Brent Spar oil platform in the middle of the ocean.

23 Social scientists have also proposed another theory for explaining why risks that are minor in quantitative terms at times produce massive reactions while major risks are often ignored.[11] Their social amplification of risk model suggests that the impact of a particular risk begins with the initial victims and diffuses outward to society at large. In that process, public response to the risk can be amplified or attenuated depending on how the reporting of the risk interacts with psychological, social, cultural, and institutional processes.

24 For example, awareness of the risk of air travel following an airline crash can be amplified by a large volume of information, scientific experts challenging one another, dramatisation

of the issue and use by the media of value-laden terminology and images. This perception can then be further amplified or attenuated depending on the effects of such media exposure on the community and society as a whole.

25 These and other studies have established that hazards give rise to concerns which can be put into two broad categories:

- **Individual concerns** or how individuals see the risk from a particular hazard affecting them and things they value personally. This is not surprising since one of the most important questions for individuals incurring a risk is how it affects them, their family and things they value. Though they may be prepared to engage voluntarily in activities that often involve high risks, as a rule they are far less tolerant of risks imposed on them and over which they have little control, unless they consider the risks as negligible. Moreover, though they may be willing to live with a risk that they do not regard as negligible, if it secures them or society certain benefits, they would want such risks to be kept low and clearly controlled.

- **Societal concerns** or the risks or threats from hazards which impact on society and which, if realised, could have adverse repercussions for the institutions responsible for putting in place the provisions and arrangements for protecting people, eg Parliament or the Government of the day. This type of concern is often associated with hazards that give rise to risks which, were they to materialise, could provoke a socio-political response, eg risk of events causing widespread or large scale detriment or the occurrence of multiple fatalities in a single event. Typical examples relate to nuclear power generation, railway travel, or the genetic modification of organisms. Societal concerns due to the occurrence of multiple fatalities in a single event is known as **societal risk**. Societal risk is therefore a subset of societal concerns.

26 Hazards giving rise to societal concerns share a number of common features. They often give rise to risks which could cause multiple fatalities; where it is difficult for people to estimate intuitively the actual threat; where exposure involves vulnerable groups, eg children; where the risks and benefits tend to be unevenly distributed – for example between groups of people with the result that some people bear more of the risks and others less, or through time so that less risk may be borne now and more by some future generation. People are more averse to those risks and in such cases are therefore more likely to insist on stringent Government regulation. The opposite is true for hazards that are familiar, often taken voluntarily for a benefit, and individual in their impact. These do not as a rule give rise to societal concerns. Nevertheless, activities giving rise to such hazards (for example, Bungee jumping) are often regulated to ensure that people are not needlessly put at risk.

27 In addition to the direct societal concerns about the impact of the hazards on those affected, there is also, and importantly, a concern that, in the wake of an event giving rise to such concerns, confidence in the provisions and arrangements in place for protecting people against risks to health and safety, and the institutions responsible for setting out and enforcing these provisions and arrangements, would be undermined, however remote was the chance of the event happening in the first place. The result would be a consequential loss of trust by the public not only in the duty holders with the primary responsibility for

reducing the risk, but also in the regulator and Government – even if current provisions and arrangements were very good. Consideration of how regulation should approach hazards of this kind to safeguard against such undesirable outcomes is intensely political and usually described on a case-by-case basis. A prime consideration is the amount of resources (time, money, etc) that should be devoted to introduce measures to control the hazard, relative to the total detriment suffered by society in the event of the hazard being realised.

Changes in the regulatory environment

28 We explore below some of the marked changes that have taken place in the regulatory environment since Robens.

The internationalisation of regulation

29 The regulation of risk is nowadays increasingly being undertaken at European or international level in the form of legally binding instruments on Member States – such as directives, treaties and conventions adopted in the wake of the creation of new global markets and new technologies. For some of the new risks, like those arising as a result of the release of genetically modified organisms, action will clearly have to be taken at international level to have any effect. Moreover, in other areas the technology is moving so fast that de facto international standards or practices are evolving all the time, eg in ensuring the safe use of computerised systems for controlling plant and machinery. Regulators, industry and pressure groups in many countries are calling for such technologies to be regulated at international level as the only effective way to prescribe appropriate standards.

30 The pressure towards the internationalisation of regulation requires innovative forms of regulatory co-operation which must take into account a host of other factors such as agreements for regulatory harmonisation, mutual recognition of standards and removal of barriers to trade – such co-operation is essential since the legal instruments used for that purpose (eg directives) take precedence over national legislation.

Increased complexity in the regulation of risk

31 Throughout the long history of legislation introduced to eliminate or minimise risks, the first areas to be regulated have always been the most obvious, often requiring little scientific insight for identifying the problem and possible solutions. For example, it was not difficult to realise that controlling airborne dust would reduce the risk of silicosis in miners and that making it mandatory to guard moving parts of machinery would prevent workers from being killed or maimed. In short, dramatic progress towards tackling such problems could be (and was) made without unduly taxing existing scientific knowledge or the state of available technology.

32 However, as the most obvious risks have been tackled, new and less visible hazards have emerged and gained prominence. Typical examples include those arising from technologies such as biotechnology, and processes emitting gases which contribute to global warming

and ozone depletion. One frequent characteristic of these new hazards is that it can be very difficult to define precisely the risks they may give rise to, even when scientific knowledge is pushed to the limit. The processes that may give rise to risks are only partially understood with the result that regulatory decisions must frequently be based on limited data and considerable scientific and technological uncertainties. The control measures required by regulation should reflect the nature of the uncertainties and err on the side of health and safety.

33 Moreover, whereas in the past, agreement about the action necessary could usually be reached on the basis of the degree of risk posed by a particular hazard as assessed by applying theories from natural sciences, engineering, logic and mathematics, this is no longer the case. This approach is no longer sufficient to counter the growing demand that regulation of some risks should take account of the quality (or attributes) of the hazard as distinct from objective assessment of the quantity of risk.

34 It has become a matter of course to request, for example, that taking into account undesirable consequences should include consideration of matters such as distributional or economic equity or ethical considerations[12,13,14] or, for those occupational risks that are often accompanied by secondary environmental risks, whether it is morally right to adopt policies without considering their effects on natural phenomena like the survival of species and the maintenance of ecosystems.[15] In short, the evaluation and management of hazards are evolving to include values that cannot readily be verified by traditional scientific methods. Techniques being produced for taking these values into account are at an early stage of development.

35 This has led to disagreements about the role that risk assessment should play in the regulation of risk – complicating matters still further. It has become a recent fashion by some to campaign against the use of risk assessment in the decision-making process, particularly for risks with widespread consequences. Many of the criticisms voiced about the role of risk assessments are based on mistaken beliefs about how such assessments are undertaken and applied. For example, it is often argued that an approach based on assessment of the risks:

- often underestimates the true impact of a problem overall. For example, a risk assessment is always undertaken for a specific purpose and with a specific population in mind and may therefore ignore risks to another population;
- is used capriciously to legitimise decisions, for example, to allow an unpopular development in one area but not in another;
- can be misused to present a particular problem as being primarily one of risk and could thereby undermine the adoption of a precautionary approach based on anticipating and averting harm;
- is inadequate since it often reduces the characteristics of what is in many instances a complex issue to a single number and is therefore weak in taking into account societal concerns or other important factors such as the degree of trust between regulators and their stakeholders (see paragraph 21).

36 However, the counter view – which we hold – is that there is overwhelming evidence that, properly used, the results of a risk assessment often provide an essential ingredient in reaching decisions on the management of hazards. Depending on the issue, the results of a risk assessment may be expressed in qualitative or quantitative terms, or both. The proper use of risk assessment also requires inter alia that:

- the risk problem is properly framed;
- the nature and limitations of the risk assessment are clearly set out and understood; and
- the results of the risk assessment are used to inform rather than to dictate decisions and are only one of the many factors taken into account in reaching a decision.

Clarification by the Courts on the meaning of risk

37 Arguments on the meaning that duty holders should attach to the concepts of 'hazard' and 'risk' when complying with their legal duties to ensure the health, safety and welfare may have contributed to the disagreements on the role that risk assessment should play in the decision-making process.

38 The concepts of hazard and risk are enshrined in our everyday vocabulary. When people say that they are prepared to take a risk they mean that in taking a particular decision they are willing to incur a chance of adverse consequences happening in the expectation of a probable benefit (ie a positive consequence). Intrinsic in that definition is that 'risk' should reflect both the likelihood that some form of harm may occur and a measure of the consequence. In everyday life though, we are more likely to pay attention to one than the other.

Regina vs Board of Trustees of the Science Museum, 1993

In the above judgement, the Court of Appeal ruled that as far as the use of risk in the HSW Act, section 3 was concerned, this should be interpreted as conveying the 'idea of a possibility of danger'.

'The starting point must be the ordinary meaning of the language of section 3(1). In our judgment the interpretation of the prosecution fits in best with the language of section 3(1). In the context the word 'risks' conveys the idea of the possibility of danger. Indeed, a degree of verbal manipulation is needed to introduce the idea of actual danger which the defendants put forward. The ordinary meaning of the word 'risks' therefore supports the prosecution's interpretation and there is nothing in the language of section 3 or indeed in the context of the Act, which supports a narrowing down of the ordinary meaning. On the contrary the preventive aim of sections 3, 20, 21 and 22 reinforces the construction put forward by the prosecution and adopted by the judge. The adoption of the restrictive interpretations argued for by the defence would make enforcement of section 3(1) and to some extent also of sections 20, 21 and 22 more difficult and would in our judgment result in a substantial emasculation of an essential part of the Act of 1974. The interpretation which renders those statutory provisions effective in their role of protecting public health and safety is to be preferred.

We have not lost sight of the defence submission that we ought to concentrate on the word 'exposed' rather than 'risks' in section 3(1). If the word 'risks' has the meaning which we consider it has, the point disappears. In that event exposure to a possibility of danger is sufficient. The word 'exposed' simply makes clear that the section is concerned with persons potentially affected by the risk… But the word 'exposed' cannot change the meaning of 'risks' from a possibility of danger to actual danger. On the principal points in this case the argument for the defence is really a red herring.'[16]

39 Nevertheless, it has proved useful to HSE to make a conceptual distinction between a hazard and a risk by describing a hazard as the potential for harm arising from an intrinsic property or disposition of something to cause detriment, and risk as the chance that someone or something that is valued will be adversely affected in a stipulated way by the hazard. HSE – as far as the health, safety and welfare of people is concerned – frequently makes use of the above conceptual distinction in its guidance by requiring that hazards be identified, the risks they give rise to are assessed and appropriate control measures introduced to address the risks. This reflects the fact that in most cases it makes sense to take account of the circumstances in which people and management systems interact with the hazard.

40 However, depending on the situation and degree of knowledge, the relative importance of likelihood and consequence in determining control measures may vary. HSE, for example, might attach a different weighting to the likelihood that harm will occur from the weighting attached to the consequences. In some circumstances, particularly where the consequences are particular serious or knowledge of the likelihood is very uncertain, we may choose to concentrate solely on the consequences so that, in effect, we are concerned only with the hazard.

41 However, the use of the latter approach by HSE has been challenged by some – perhaps because the HSW Act[1] makes reference to 'risks' but not 'hazards'. In that respect, a clarification by the Courts on the meaning of 'risks' in the context of the HSW Act is very relevant. The Court of Appeal in Regina vs Board of Trustees of the Science Museum, 1993,[16] ruled that, as far as the use of 'risks' in the HSW Act,1 section 3 was concerned, this word should be interpreted as conveying 'the idea of a possibility of danger'. We would interpret the use of 'risk' in other sections of the Act in the same way.

42 *The implication of this interpretation is that successful management of risk in the workplace must satisfy the premise that anything present in an undertaking which 'presents the possibility of danger' is properly addressed.* Conceptually, HSE will regard anything presenting the possibility of danger as a 'hazard'. As we shall see later, the processes and criteria described in Part 3, which include the use of risk assessment to determine the required control measures, meet this important condition. For example, they ensure that for hazards surmised to have consequences that may be irreversible and deleterious, there is an overriding need to introduce control measures to address the hazards. This is true when, or perhaps especially when, there is considerable uncertainty about the nature of the hazards and the likelihood of them causing harm.

Changes on the industrial scene

Changes in patterns of employment

43 The regulatory environment now has to cope with the increasing trend in industry and elsewhere to outsource work and hence risks, with changes in patterns of employment and with the fragmentation of large companies into autonomous organisations working closely together. For example, there have been dramatic increases in self-employment and home-working; small and medium size firms are now a major force in creating jobs. Moreover, many monolithic organisations have become a series of separate companies, eg the railways now operate as separate companies with different responsibilities for operating the track, the rolling stock and the networks.

Polarisation of approaches between large and small firms

44 Some of these changes have blurred legal responsibilities for occupational health and safety, traditionally placed on those who create the risks or on those best situated to take steps to control the risks. In certain industries it is often no longer easy to determine who may be in such a position. Though case law has in many instances clarified the situation, the fact remains that for many sectors the above factors make it more difficult to co-ordinate the adoption of measures for controlling risks. Many more players are involved, some with little access to expertise. There has in consequence been a growing demand by small firms for a reversion to prescriptive regulation, running counter to the self-regulatory approach – a demand resisted by large firms because they do not face the same problems and are comfortable with the self-regulatory approach. This has resulted in greater emphasis being placed on the need for clarity of the status and content of the guidance element of the architecture of regulation (see Appendix 2).

Changes in the preferences, values and expectations of society

45 The preferences, values and expectations of society have never been static. Current shifts are linked in part to:

- the rapid rise in information technology which nowadays plays an important role in shaping perceptions by making it easier for people to have information on the risks that may affect them and the society (or indeed the planet) in which they live. This explosion in information technology has, for example, resulted in greater awareness of issues such as the Chernobyl accident, the toll of asbestos-related deaths, and the threats to the ozone layer. Unfortunately information about risks is frequently passed on in isolated bits by the mass media and without any critical examination or peer review – often resulting in the public getting confused or in some risks being amplified while others are attenuated;

- the increased pace in exploiting advances in scientific and technological knowledge, which has led to an increased focus on technological risks;

- greater affluence in society. The majority of people in industrialised countries no longer have to struggle at subsistence level. As a consequence, the acceptance of industrial activity to gain increased standards of living is no longer as readily given as when the fight against hunger and poverty overshadowed everything else.

46 These shifts in preferences and values result in:

A growing perception that risks imposed on people should be justified

47 There is a growing propensity to scrutinise benefits brought about by industrial activity against potential undesirable side effects such as the risk of being maimed or killed or of environmental pollution. This is particularly true for risks:

- which could lead to catastrophic consequences;

- where the consequences may be irreversible, eg the release of genetically modified organisms;

- which lead to inequalities because they affect some people more than others, such as those arising from the siting of a chemical plant or a waste disposal facility;

- which could pose a threat to future generations, such as toxic waste.

48 This has already resulted in industry having less discretion on matters on which they previously had considerable freedom to decide which course of action to adopt, eg plans for modifying their plant within their own boundaries, what raw materials and processes they should use, or how the waste generated (or the plant itself at the end of its useful life) should be disposed of.

An increasing reliance by the public on regulators that they trust

49 A heightened perception of risk has been accompanied by a recognition that modern society has evolved in such a way that it is virtually no longer possible for many of its individual members to:

- avoid risks that they would have preferred not to incur. For example, a person who does not want to travel by car or plane may find their employment or promotion opportunities severely restricted. A person wanting to avoid processed food because of their fear of additives would be able to do so only at great expense or by having a restricted way of life;

- assess for themselves the risks posed by many of the newer hazards arising from industrialisation. This often may be because the risk is not immediately obvious, eg the risks from new hazardous substances which do not cause immediate acute

effects and for which there might be long delays between first exposure and the manifestation of undesirable symptoms. People must rely instead on the opinion of experts. However, the trust placed in expert opinion as a source of reassurance is being continually eroded, particularly for those issues where the mass media seek to expose controversies surrounding such opinions or where the experts have had to frequently reassess the risks arising from certain hazards to take account of new knowledge etc.

50 The net result is that, increasingly, people are having to rely on authoritative bodies such as HSC/E as a source of reassurance about the arrangements in place for protecting people and the impartiality of those arrangements. These bodies for their part are acutely aware that they would not be able to provide reassurance unless they are trusted and that trust will not be bestowed but will have to be earned.

51 This is far from easy. There is often considerable pressure on regulators (and industry) to act quickly and decisively in a climate heavily influenced by perceptions of harm often based on graphic imagery. Regulating slavishly on such occasions is not the answer. Regulating to address concerns, which with hindsight turn out to be no more than transitory shifts in value preferences, carries heavy penalties.

Calls for greater openness and involvement in the decision-making processes

52 Perhaps the most dramatic shift in value preferences of society has been the pressure on regulators for greater clarity and explanation of their approaches to the regulation of risk. This is reflected in the broadly stated principles of good regulation published by the Better Regulation Task Force.[17] These require:

- the targeting of action: focusing on the most serious risks or where the hazards need greater controls;
- consistency: adopting a similar approach in similar circumstances to achieve similar ends;
- proportionality: requiring action that is commensurate to the risks;
- transparency: being open on how decisions were arrived at and what their implications are; and
- accountability: making clear, for all to see, who are accountable when things go wrong.

53 This need for clarity and explanation is entirely consistent with the Robens Committee's conclusion that real progress on health and safety is not possible without the agreement of those affected and the co-operation and commitment of those playing a role in implementing decisions.

54 Though all the developments described in this part have influenced our approach, the following have been particularly important:

- the need for the meaning of 'risk' to encompass more than physical harm by taking into account other factors such as ethical, economic and social considerations (paragraphs 17-27);

- clarification by the Courts on the meaning of 'risk' in the HSW Act which implies that approaches for managing risks must ensure that hazards present are properly addressed (paragraphs 37-42); and

- the need to explain how we apply the principles at paragraph 52 above.

55 The rest of this document sets out how we have taken these developments on board, building on our previous approach.

Part 3

Approach to reaching decisions on risk

System for informing and reaching decisions

56 In this part we build upon the developments described in the review in Part 2 to explain the approach that HSE adopts for reaching decisions on the degree and form of regulatory control of risk from occupational hazards. This includes both the system used for informing and reaching decisions and the criteria and philosophy adopted for deciding on what risks are unacceptable, tolerable or broadly acceptable.

57 Many systems have been developed for informing and reaching decisions, and some particularly pertinent to health and safety have been described.[18] The stages below characterise the system, governed by the principles set out in paragraph 52, that has evolved in HSE in the course of undertaking its own statutory responsibilities and in advising and assisting HSC, for example in implementing policies on modernising health and safety legislation.

58 The stages are:

- Stage 1: Deciding whether the issue is primarily one for HSC/E;
- Stage 2: Defining and characterising the issue;
- Stage 3: Examining the options available for addressing the issue, and their merits;
- Stage 4: Adopting a particular course of action for addressing the issue efficiently and in good time, informed by the findings of the second and third points above and in the expectation that as far as possible it will be supported by stakeholders;
- Stage 5: Implementing the decisions;
- Stage 6: Evaluating the effectiveness of actions taken and revisiting the decisions and their implementation if necessary.

59 However, it is worth emphasising four points. First, though the stages as listed above give the impression that they are distinct and independent of each other, in practice the boundaries between them are not clear-cut. We usually gather valuable information or perspectives while progressing from one stage to another, often requiring early stages of the process to be revisited. In short we find that going through the stages is an iterative process.

60 Secondly, we involve stakeholders at all stages in the above process with the aim of reaching a wider consensus. However, we are conscious that HSC must take, or propose to

Ministers, final decisions where consensus is not possible, for example, because different stakeholders hold opposite views based on deep-rooted beliefs.

61 Thirdly, as a corollary to the first point, how we proceed through the above stages will not be found in a single document because the process is reflected, for example, in the way we assist HSC and its Advisory Committees to go about their business, the research we commission to better understand the issue, the consultative documents that we publish, the responses to such consultation, and discussions that take place with our stakeholders, both formal and informal.

62 Finally, the system describes our current arrangements but some caution is necessary for those looking for their universal application in our past, present and future decisions. Because the system was developed over time, previous regulatory decisions may not be in full accord with them. Moreover, there are often many constraints which prevent the system from being applied fully. For example, as explained in Appendix 2, most health and safety at work legislation originates from the EC in the form of directives and their transposition may require, for example, regulations where otherwise we would use an Approved Code of Practice. Furthermore, the arrangements are also applied proportionately and with discretion. There may be times when the need to act quickly may circumvent some of the stages, and there may not be any need to go through all the stages if information and knowledge from past decisions can be transposed to inform new decisions.

63 We examine, in further detail below, what is involved at each stage.

Stage 1: Deciding whether the issue is one for HSC/E

64 The scope of the HSW Act is very wide and it will usually be self-evident that an issue or subject of concern is primarily one of occupational health, safety and welfare. These issues or subjects of concern can arise through many ways. The most important are:

- intelligence on new hazards for example from new technologies, or inadequacies in existing arrangements to cope with change, for example, in the pattern of employment;
- pressure of events and experience in terms of statistics of accidents and ill health and reports of investigations into particular incidents;
- public perceptions that there is a problem to be addressed;
- feedback that existing arrangements are not fit for purpose, for example in imposing unnecessary burdens on duty holders;
- political moves in Europe or internationally to which we have to respond.

65 It must always be borne in mind that the objectives of the HSW Act include not only the securing of the health, safety and welfare of people at work but also the protection of people not at work against risks to their health and safety arising out of work activities. The wide scope of the Act, together with its wide-ranging enabling powers to make regulations, often result in pressure on HSC/E to take the lead in protecting the public, because of the workability and effectiveness of the arrangements that can be put in place under health and safety legislation and/or its enforcement. Moreover, similar pressure may arise from the practical consideration that other institutions with relevant powers may not exist within the Government machine.

66 Such considerations have arisen particularly in the case of activities with minimal involvement of employees but with the potential to cause harm to the public and where the relevance of health and safety 'at work' legislation may not be obvious. Typical examples include golf courses, horse-riding establishments and pop concerts.

67 The wide scope of the HSW Act and its considerable enabling powers to make regulations have resulted in two other effects. Firstly, many of its provisions and regulations made under the Act overlap with other legislation which is the responsibility of other Government Departments. As a general rule, HSC/E wish to avoid duplication with other enforcing authorities and, where policy areas overlap, there are often demarcation agreements between HSE and other Departments on respective responsibilities covering many areas of potential risks to the public. In many areas of overlap, agreement has been reached that HSE should not attempt generally to enforce the requirements of sections 2 and 3 of the HSW Act, because public safety will be adequately guaranteed by the enforcement of the other legislation covering the risk in question.

68 Secondly, pressure on HSC/E is at times targeted at issues where health, safety and welfare is not a prime consideration but might be seen as a means of objecting to inequity between those who reap the benefits and those who are put at a detriment of some sort that may include a health and safety component, eg the loss of a visual amenity in the vicinity of a scenic spot or a fall in property values as a result of allowing a major installation, such as an airport, to be developed. In these circumstances, we may advise HSC:

- that public debate and discussion on the distribution and balancing of the benefits and detriments involved should take place in a wider context, and that it would therefore be better for the issue to be addressed and/or regulated through a more appropriate avenue in the political and democratic system; or

- to consider the issue but only with respect to the matters which are within its powers to consider ie the health, safety and welfare aspects entailed in the particular context. That is, to look at the appropriateness of the measures in place to protect workers and the public from the risks arising from the activity but leave wider aspects – such as whether the activity should be entertained in the first place – to be considered by the political and democratic system as per the first point above. For example, HSE has made it clear that in its consideration of the tolerability of risks from nuclear power stations, it has limited its analysis to the consideration of the safeguards that

should be in place and the way they should be exercised, and has left it for Parliament to weigh the benefits of nuclear power against the risks entailed.[2,19]

69 A quite different issue arises when a European directive is enacted under Article 137, the health and safety article of the EC Treaty. It is not always the case that matters covered by an Article 137 directive are interpreted as health and safety matters in Great Britain. Such a question arose when we had to advise HSC on whether the enabling powers of the HSW Act should be used to introduce regulations to implement an EC health and safety directive on working time. We (and HSC) were not convinced that all elements of the directive (eg paid annual leave) were primarily occupational health, safety and welfare issue and agreement was reached with Ministers that the enabling powers of the HSW Act should not be used to implement them.

70 In short, if an issue ends up being regulated under health and safety legislation, it should always be the result of careful consideration of all the factors involved, such as those described above.

Stage 2: Defining and characterising the issue

Defining the issue

71 In this stage we consider how the issue can be framed or described in terms of problems to be tackled and the means for tackling them.

72 For example, the rate of replacement of older rolling stock on the railways is an issue with two quite different dimensions:

- transport policy, regarding the public's willingness to use the system; and
- public safety policy, regarding the safety benefits of modern rolling stock.

The issue could be framed either way, giving rise to quite different problems to be tackled by different arms of the Government regulatory machine.

73 In framing an issue we shall therefore pay particular attention to whether:

- the action to be taken can be efficiently delivered by HSC/E acting within their powers and arrangements as discussed in paragraphs 64-70 above; and
- society at large will regard as valid the whole process that was adopted for reaching the decision on the most appropriate course of action for addressing the issue. This is because, as we have already seen, the way an issue is framed can have a considerable influence on judgements about whether risk is actually the crux of the issue and, if so, the effectiveness of the measures that should be put in place for addressing the risk.

74 Areas of particular contention arise when there is a divergence between public perceptions that there is an issue to be addressed and objective analysis of the associated problems in health and safety terms. There may then be a need for iteration between this stage and the first stage described earlier (paragraphs 64-70). We sometimes issue discussion documents as a means of seeking convergence towards a workable option.

Characterising the issue in terms of risk

75 The framing of the issue may point to it being one where a decision on proportionality of action requires information on the risks. In such cases, we need to characterise the risk quantitatively and qualitatively, to describe how it arises and how it impacts on those affected and society at large. Such information is needed in order to inform later consideration of options for risk reduction.

76 We usually undertake an assessment of the risks to achieve this. Assessing risks involves identifying the hazards associated with the risk issue, ie what in a particular situation could cause harm or damage, and then assessing the likelihood that harm will actually be experienced by a specified population and what the consequences would be.

77 The process of gathering and refining information on risks is underpinned by a great deal of research and the engagement of expertise both within and outside HSE. The systems devoted to establishing sound information and intelligence on risk account for around 25% of HSE's total resources notwithstanding the intelligence gathered by inspectors as part of day-to-day inspection/investigation activities. External expertise is engaged through research, often carried out collaboratively, and through the system of HSC Advisory Committees. The science underpinning HSC/E policies and practices is extensively exposed to the normal scientific process of peer review. There is, in addition, provision in our research commissioning arrangements for ideas generated independently to be considered for funding in order to bring fresh perspectives to bear. All told, the arrangements in place for incorporating science into the characterisation of risk require much deliberative activity between HSE and the science community at large.

78 We would be interested in assessing at this stage the individual risks and then identifying the associated societal concerns generated by the hazards and other issues such as whether a hazard should be entertained at all or should be regulated in particular way. But the extent to which each of these issues is considered in our assessment will depend on the nature and attributes of the hazard as well as the context of our intervention.

79 For example, many hazards in the workplace are well known, familiar, easy for people to gauge the actual threat they give rise to, have no stigma attached to them and would not cause society any significant concern if realised. We are likely in those cases to pay more attention to the level of residual individual risks after measures have been introduced rather than the societal concerns (if any) that they might engender. On the other hand, gauging the extent of the societal concerns caused by a hazard is likely to be a major consideration when considering whether regulations should be introduced for addressing a hazard that is new, unfamiliar and where its realisation would generate a socio-political response.

80 Moreover, in our role as a regulator and with powers of discretion, the assessment of risk that we undertake – for example when we propose options to the HSC for draft regulations – may, according to circumstances, be much broader than the one that we would generally expect a duty holder to undertake in complying with their duty to assess risks, for example, as required under the Management of Health and Safety at Work Regulations 1999.[3] The risk assessment performed under those Regulations would be confined in scope to the conduct of the undertaking and would usually concentrate on:

- looking at the prospect of harm to individuals and in some cases to society but, as far as the latter is concerned, limited to the extent to which HSC/E has stated in regulations, guidance etc how this should be undertaken;
- identifying, in the light of good practice, what needs to be done to comply with the law.

81 On the other hand, the assessments we carry out (at a much earlier stage):

- more often than not, have to probe in depth in order to develop standards of good practice for future application. In this way, good practice established by HSE is based on the risk assessment by HSE, and compliance with that good practice implicitly conforms to a risk-based approach to control;
- could go beyond the confines of the undertaking and look at the impact of our proposed action on society;
- would not necessarily be limited to the identification of control measures but could cover any matter which could be the subject of health and safety regulations as specified in section 15 of, and Schedule 3 to, the HSW Act;
- would in scope cover both individual risks and societal concerns as already mentioned at paragraphs 78-79 above (see also Appendix 3, paragraph 7).

82 Thus, we use a risk assessment essentially as a tool to inform our decisions by assisting in our understanding of the nature and degree of risk and for extrapolating, from available data, our experience of harm, or for representing a large amount of scientific information and judgement as an estimate of the risks. The policy process then couples the scientifically-based judgements about risks with policy considerations about the approach to their control. The latter (sometimes separately described as risk evaluation) includes such considerations as the relative weightings to be attached to likelihood and consequence as discussed in paragraphs 38-40, and the way that public perceptions of the risk should be taken into account.

83 For example, the risk assessment may show that the risks are such that individuals may not be unduly concerned because of the familiarity of the risks etc (see paragraph 79) and/or that the expectation of harm to any one individual is low. Nevertheless, the activity giving rise to the risks may need to be regulated further because of the numbers of people individually affected, and other possible detriments. For example, regulations have been introduced to make the wearing of hard hats compulsory on construction sites.

84 The proper characterisation of the risk is important to the effective application of the preferred risk control hierarchy promoted by HSC/E and the EU. The hierarchy actually covers controls on hazards as well as the resulting risks. At the top of the hierarchy, and consistent with the general duty to secure health and safety, is the consideration of measures or alternatives that will avoid the hazard in the first place. This might involve substitution or the adoption of processes that conform with principles aimed at ensuring that a design is inherently safer. Lower down the hierarchy is the consideration of measures that will reduce the risks, given that there are no viable alternatives to accepting the hazard.

85 An implicit presumption underlying the hierarchy is that it is not the case that any activity can be pursued simply because measures are available to control the risks it entails. This would be particularly true for activities where there are considerable uncertainties in the estimates of the risks attached to them. Indeed, in line with our earlier discussion on the meaning of risk at paragraphs 37-42, the regulation of health and safety is replete with examples where the potential severity of the consequences, rather than the probability of them occurring, is the dominant consideration. This is particularly true for hazards where there is considerable uncertainty on the nature and scale of the risks they give rise to, eg the release of genetically modified organisms. We therefore need to look at uncertainty in more detail.

Inherently safer design

Adoption of the principles of inherently safer design is particularly important where the consequences of plant or system failure are high. HSE will press for the incorporation of inherently safer design features, where these are possible, to reduce the reliance on engineered safety systems or operational procedures, to control risk.

For example, the concept of 'defence in depth', redundancy, diversity and segregation, the provision of multiple barriers and other good practices, as set out in HSE's safety assessment principles for nuclear plant[20], are fundamental to ensuring safety. These apply against a requirement to: firstly, avoid the hazard and maintain safe conditions through inherent and, where appropriate, passive design features; and, secondly, to minimise the sensitivity of the plant to potential faults as far as can be reasonably be achieved, by ensuring the plant response to a fault is as near the top of a hierarchy of: (i) produces no operational response or a move to a safer condition; (ii) passive or engineered safeguards, continuously available, make the plant safe; (iii) active engineered safeguards, brought into service in response to the fault, render the plant safe.

The RBMK type of reactor used at Chernobyl, for example, would not be licensed by HSE's Nuclear Installations Inspectorate for operation in Great Britain. The design of this type of reactor does not satisfy HSE's requirements because, under certain conditions, a change in the condition of the water coolant in the reactor core from liquid to steam could lead to a significant increase in the rate of nuclear fission. Such a change in coolant condition could occur either as a result of a mismatch between the rates of heat generation in the core and heat removal by the coolant, or as a result of a fall in coolant pressure. The increase in nuclear fission would exacerbate the situation, as the resulting rise in reactor power would increase the mismatch between the rates of heat generation and removal, leading to a runaway nuclear reaction. This

inherently unsafe aspect of the design was one of the main factors that led to the infamous accident at Chernobyl in 1986.

Handling uncertainty

86 The process of assessing risks needs to take account of the possibility of uncertainty. For example the science underpinning the assessment may be complex, ambiguous or incomplete and/or the necessary data may not be available.

87 We must first distinguish between uncertainty and ignorance. The latter refers to a lack of awareness of factors influencing the issue. This is a well-recognised weakness in risk assessment – that the identification of hazards may be incomplete. The measures needed to counteract ignorance are a wide engagement of different disciplines and communities of interest in the characterisation of the issue. Paragraph 77 describes the very broad base of expertise called into play by HSE in undertaking that task. A further measure is to practise openness to the greatest degree possible so that thinking can be exposed to alternative views at an early stage. This is a principal requirement in the guidelines issued by the Office of Science and Technology.[21]

88 Uncertainty itself is a state of knowledge in which, although the factors influencing the issue are identified, the likelihood of any adverse effects or the effects themselves cannot be precisely described. Uncertainty has many manifestations and they affect the approach to its handling. In summary:

- **Knowledge uncertainty** – This arises when knowledge is represented by data based on sparse statistics or subject to random errors in experiments. There are established techniques for representing this kind of uncertainty, for example confidence limits. The effect on a risk assessment is estimated by sensitivity analysis. This provides information relating to the importance of different sources of uncertainty which can then be used to prioritise further research and action, which is the only feasible way to address the uncertainty, though in some cases research may not be technically possible or cost-effective.

- **Modelling uncertainty** – This concerns the validity of the way chosen to represent in mathematical terms, or in an analogue fashion, the process giving rise to the risks. An example is the growth of a crack in the wall of a pressure vessel. The model would postulate the way the growth rate is affected by factors such as the material properties and the stress history to which the vessel is exposed in service. The model will provide prediction of failure in terms of time and the nature of the failure. It will inform intervention strategies such as the material specification, in-service monitoring and mitigation measures. All these factors may be modelled in many ways with the assumptions for each one open to question. The rigour of the peer review process and openness to alternative hypotheses are the main safeguards. However, the most intractable problems arise when it is not practical or physically possible to subject the alternative hypotheses to rigorous testing. In such cases, the exercise of expert judgement is paramount and confidence depends on the procedures adopted for selection of the experts and the management of bias (or appearance of bias).

- **Limited predictability or unpredictability** – There are limits to the predictability of phenomena when the outcomes are very sensitive to the assumed initial conditions. Systems that begin in the same nominal state do not end up in the same final state. Any inaccuracy in determining the actual initial state will limit our ability to predict the future and in some cases the system behaviour will become unpredictable.

Precaution in the face of uncertainty

89 However, our risk assessment and risk management procedures have a number of safeguards to ensure that our approach is inherently precautionary and in line with the precautionary principle. Included though not defined in the EC Treaty, the precautionary principle has been defined, for example, by the United Nations Conference on the Environment and Development (UNCED) in 1992 as: ***'where there are threats of serious or irreversible environmental damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent degradation.'***

90 Thus, the precautionary principle describes the philosophy that should be adopted for addressing hazards subject to high scientific uncertainty, and rules out lack of scientific certainty as a reason for not taking preventive action. Although originally formulated in the context of environmental protection, particularly in connection with 'global' environmental issues (eg climate change, ozone depletion), the precautionary principle has been applied more widely.

91 Our policy is that the precautionary principle should be invoked where:

- there is good reason, based on empirical evidence or plausible causal hypothesis, to believe that serious harm might occur, even if the likelihood of harm is remote; and

- the scientific information gathered at this stage of consequences and likelihood reveals such uncertainty that it is impossible to evaluate the conjectured outcomes with sufficient confidence to move to the next stages of the risk assessment process.

92 Good reason to believe that serious harm might occur could be demonstrated by showing that an activity, product or situation is similar to others which are known to carry a substantial adverse risk; or by adducing a sound theoretical explanation (tested as necessary by peer review) as to how harm might be caused.

An example of a qualitative assessment of risks

Crowd Safety at Pinner Fair

Estimates of risk are often qualitative rather than quantitative, and are frequently based on systematic observation. An example is the assessment of crowd safety risks at an annual fair in Pinner on the north-west outskirts of London.

Pinner Fair was established by Royal Charter in 1337. Each year it attracts about 50 000 people to the central streets of Pinner, where the restricted space contrasts with the increasing size and complexity of modern fairground rides.

In a study in 1993 by HSE, observation of the setting up, running and dismantling of the fair, together with an analysis of the safety management, formed the basis for hazard identification and risk assessment. The hazards included overcrowding during the fair and dismantling rides while crowds were still present. Comparisons were made with standards in codes of practice and guidance, and with good practice for comparable events. Opinions voiced by local residents, the local authority and the police were also taken into account. It was shown that straightforward changes in the organisation and layout of the fair could eliminate some hazards and substantially reduce the risks from others. To prioritise the improvements needed the risks were ranked qualitatively using a five point scale from 'very low' to 'very high'.

The findings of the risk assessment were discussed with interested parties, including the local authority, the emergency services and the Showmen's Guild of Great Britain, who decided to adopt a series of measures to improve crowd safety. HSE evaluated the effectiveness of the action taken in a follow up study in 1994 when significant improvements were already apparent.

Further information: Fairgrounds and amusement parks: guidance on safe practice.[22]

93 Though the precautionary principle is invoked for hazards where, because of the uncertainty involved, it is not possible to apply the conventional techniques of risk assessment to assess the risks involved whatever the circumstances, it is possible in practice, to use such techniques for operationalising the principle. Uncertainty is overcome by constructing credible scenarios on how the hazards could be realised and thereby making assumptions about consequences and likelihood. The credible scenarios can range from a 'most likely' worst case to a 'worst case possible' depending on the degree of uncertainty. For example, by assuming that exposure to a putative carcinogenic chemical will cause cancer the chemical becomes subject to a very stringent control regime. Though such risk assessments made on scenarios are inevitably narrower in scope than a full blown risk assessment, this may not be a serious limitation if the scenarios are carefully chosen to reflect what could happen in reality.

Quantitative risk assessment

As indicated in a previous example, estimates of the likelihood that a hazard will be realised are often qualitative rather than quantitative, and in general duty holders under occupational health and safety legislation adopt authoritative good practice to address the significant hazards arising from their work activities.

Some sectors of industry, however, have used the tool of quantitative risk assessment (QRA) as part of their consideration of the safety of plant and operations. QRA is a powerful tool in showing the relationship between different subsystems and the dependencies within the overall system. QRA is frequently used to estimate the risk from plant, as designed and operated. However, care needs to be taken to avoid numerous pitfalls that can trap the unwary. For example, in estimating the likelihood of an event by looking back at historical accident or incident data, care needs to be taken in selecting:

- *the accident/incident sample – too small a sample or too narrow a scope can mislead; too wide a scope may result in the inclusion of accidents/incidents that developed differently from the event in question;*

- *the time period – too short a period may lead to the omission of representative accidents/incidents; too long a period may again result in the inclusion of accidents/incidents that developed differently from the event in question. Whatever time period is chosen, the assumption of a constant relationship between accident/incidents and time needs to be questioned in the light of changes in technology and in public expectations;*

- *the statistical method – historical accident/incident data may not include the cause, and selective use of data and/or choice of model can result in numerical figures that do not properly reflect actual history.*

The process of undertaking a QRA can lead to a better understanding of the important features contributing to risk and weaknesses in the systems as well as allowing a numerical estimate of the residual risk to be derived. The quality of the modelling and the data will affect the robustness of the numerical estimate, and the uncertainties in it must always be borne in mind when using the estimate in risk management decisions. The use of numerical estimates of risk by themselves can, for several reasons including those above, be misleading and lead to decisions which do not meet adequate levels of safety. In general, qualitative learning and numerical risk estimates from QRA should be combined with other information from engineering and operational analyses in making an overall decision.

94 In addition to invoking the precautionary principle as above there are many other ways in which our approach is inherently precautionary. For example our risk assessment procedures:

- do not take 'absence of evidence of risk' as 'evidence of absence of risk', although they recognise that persistent absence of evidence of risk, notwithstanding appropriate and thorough efforts to find it, may be indicative;

- require that the effects of the assumptions made to cover gaps in knowledge be tested through recognised methods, eg sensitivity analysis;

- build safety factors into the assessment process where appropriate, eg in assessing toxic substances, safety factors are used depending on the quality of data, severity of effect, and whether data from animals or *in vitro* experiments are being extrapolated to humans;

- attach more weight to consequences where a hazard has attributes which makes it likely that it will give rise to societal concerns, such as the potential to affect future generations, or the potential for severe detriment, eg a major explosion in a built-up area;

- make use of comparative risk assessment for novel hazards that bear a similarity with existing hazards, requiring a stringent control regime for reducing risks to tolerable levels.

95 All the above show that assessing risks is far from being a straightforward exercise. At times the risk assessment will be a simple process based on observation and judgement, while at the other extreme it can also require the use of complex techniques such as quantified risk assessment. In practice it cannot be carried out without adopting certain conventions or protocols. We examine some of these at Appendix 1.

Stage 3: Examining the options available and their merits

Identifying options

96 Once the problem has been characterised we then identify the options available for managing the risks. These can range from doing nothing to introducing measures (whether non-regulatory or regulatory) to get rid of the cause of the problem altogether, or to reduce it to one which people are prepared to live with so as to secure certain benefits and in the confidence that the risk is one that is worth taking and that it is being properly controlled.

97 The courses of action available are similarly many and varied, for example:

- providing more information and guidance to duty holders to enable them to fulfil their responsibilities;
- publicity campaigns to create awareness, for example the 'Good Health is Good Business' campaign and the publicity given to the poor maintenance of domestic gas heating installations;
- engaging the assistance of intermediaries in the health and safety system (eg safety representatives, consultants);
- stronger enforcement of existing legal provisions;
- exerting pressure for heavier penalties on transgressors;
- developing the line to be taken in negotiation of European directives to reflect the issue as it manifests itself in Great Britain;
- targeting action on those who should be controlling the risks;
- improving the available knowledge base through research; and
- proposing new measures that are commensurate with the risks to be addressed, eg new law.

98 For example, the following illustrates some of the options that are available for preventing or controlling exposure to a particular substance:

- banning the use of the substance altogether;
- requiring the use of technology to prevent the substance being released into the workplace or the environment;
- introducing new law, eg licensing regimes to limit the exposure of people to the substance while ensuring that they use best practice to prevent accidental exposure to the substance;
- educating/informing the public on the steps they can take to prevent exposure (eg on the need to service gas appliances to prevent carbon monoxide poisoning); or
- doing nothing because the substance does not pose a significant risk at the level at which it is present.

Adopting decisions: setting occupational exposure limits

Occupational exposure limits (OELs) are important risk management tools that regulate the extent of personal exposure (via inhalation) to substances hazardous to health. The procedures for setting OELs illustrate the involvement of the stakeholders in consensus decision-making in an area where risk assessment is complex and where account has to be taken of uncertainty and socio-economic factors. The procedures also illustrate the use of dose as a necessary surrogate for risk and the importance of openness.

Under the framework in the Control of Substances Hazardous to Health Regulations (COSHH), there are two types of OEL – an occupational exposure standard (OES) and a maximum exposure limit (MEL). Both are expressed as airborne concentrations of a hazardous substance averaged over a period of time.

An OES is set at a level at which, based on current scientific knowledge, it is judged that there is minimal risk to the health of the workforce if exposed via inhalation to the substance day after day. MELs are normally set for substances which may cause health effects such as cancer or occupational asthma where it is not possible to identify reliably a threshold of exposure on which to base an OES. MELs are also set for substances for which 'safe' thresholds may be identifiable, but control to these levels is not reasonably practicable.

OESs and MELs are set on the recommendations of the HSC's Advisory Committee on Toxic Substances (ACTS) and its Working Group on the Assessment of Toxic Chemicals (WATCH). The role of WATCH is to consider all the scientific evidence; the role of ACTS is more to take into account socio-economic factors in balancing risks to health against the cost and effort of reducing exposure. Both groups comprise appropriate representatives of the stakeholders, eg employers and employees, together with scientific experts.

The process starts in WATCH which decides for each substance whether an OES can be established, and if so at what level it should be set, using assessment or uncertainty factors to reflect, eg the quality of the data, the nature of the toxic effect and the need to extrapolate from animal data to effects on people. If, however, WATCH decides that a MEL is appropriate, consideration of the level passes to ACTS. ACTS makes recommendations on the basis of the level that can be achieved by application of good occupational hygiene practice, taking into account socio-economic factors (in practice WATCH or ACTS may recommend separate levels for 8 hour time-weighted average and 15 minute reference periods). If the recommendations are endorsed by the Commission, proposals are published for public consultation, together with criteria documents summarising for each substance the toxic effects, typical exposure levels, measurement levels and the basis for the proposed exposure limit – including for a MEL, a cost benefit assessment.

After public consultation the Commission may approve a new OES or a new MEL.

Further information: Health and Safety Executive guidance booklets EH40, Occupational exposure limits[23] *and EH64,* Summary criteria for occupational exposure limits, *both published annually.*[24]

Fairhurst S, *'The uncertainty factor in the setting of occupational exposure standards'.*[25]

99 We can often build on our experience to identify options that are likely to work in certain circumstances. For example, we identify at Appendix 2 the options that should be considered when introducing new regulations or guidance and the order in which they should be examined.

100 In looking at options, we would be particularly interested in examining:

- **possible good practice** for addressing the hazards identified, and evaluating whether it is relevant and sufficient. If specific good practice is not available we would also examine the merits of good practice that applies in comparable circumstances if we believe that this is directly transferable or can be suitably modified to address the hazard;

- **possible constraints attached to a particular option**; for example whether the option is technically feasible; or whether there are legal constraints on its adoption. As shown in Appendix 2, the general principle is that the option adopted will improve or at least maintain standards of health, safety and welfare;

- **any adverse consequences associated with a particular option**. Very often adopting an option for reducing one particular risk of concern may create or increase another type of risk. For example: banning a particular solvent may increase the use of a more hazardous one; reducing airborne concentration of substances in the workplace by exhaust ventilation may increase risk in the community or vice versa. Therefore for each option having adverse consequences we examine the trade-off between reducing the target risk and the increase in other risks. Appendix 3 gives an indication of how far and how deeply this exercise is carried out;

- **how much uncertainty is attached to the issue under consideration** and as a consequence **the precautionary approach** that should be adopted to ensure that decisions reached are in line with the precautionary principle (see paragraphs 89-94). As we shall see later, though HSE adopts a framework (see paragraph 121-127) for reaching decisions which intrinsically ensures that the treatment of uncertainty is biased towards health and safety to take account of uncertainty, this bias reflects a proper judgement of the degree of caution needed in the circumstances of the decision. The framework achieves this by ensuring that, as the degree of uncertainty increases, and depending on certain other characteristics attached to a particular hazard (eg whether the risk, if realised, could result in consequences that are irreversible or could detrimentally affect future generations), there is an increasing shift towards requiring more stringent measures to mitigate the risks. Moreover, in cases where the benefits cannot justify the risks, the framework requires that consideration is given to banning the activity, process or practice giving rise to the hazard;

- **how far certain options should be constrained** so that the problem remains within the boundaries that we have set in Stage one. For example, when considering options for improving health and safety on the railways and in particular whether a railway operator should introduce investments, we cannot consider the question whether the resources could be better spent on the National Health Service as this would be an issue for the Government to address;

- **how far the options succeed in improving (or at least maintaining) standards** in line with section 1(2) of the HSW Act. Though there is a duty on the HSC to adopt this principle when proposing the modernising of legislation predating the HSW Act, the same principle permeates HSC/E's policies and approach to the regulation and management of risks;

- **the costs and benefits** attached to each option by looking at what is required to implement each option and the degree of risk reduction it is likely to achieve. Since this is one of the factors taken into account to inform decisions (the next stage in the process), it is examined in greater detail below;

- **what is the most appropriate regulatory instrument** in the range available to HSC/E (see Appendix 2) for achieving its objectives for managing the risks in question.

Assessment of risk reduction action

101 We sometimes need to carry out formal analyses of costs and risk reduction to help with judgements on the benefits of each option and the costs involved in reducing the risks. These analyses may be of varying sophistication and complexity, and might in some cases include a cost benefit analysis (CBA). CBA is often a useful tool for judging the balance between the benefits of each option and the costs incurred in implementing it. CBA aims to express all relevant costs and benefits in a common currency, usually money. This in principle requires the explicit valuation of the benefit of reducing the risk. However, such a valuation may not always be possible or practicable – in these circumstances we rely on qualitative estimates. And, in any case, we apply common sense when reviewing the results. Moreover, explicit valuations may not always be necessary because:

- as we shall see later, most safety provision for day to day hazards is in terms of the adoption of good practice or the voluntary pursuit of best practice, taking advantage of technological advances; and

- it may be possible to compare the difference in costs from switching from one option to another against the gains so achieved in terms of avoidance of harm.

102 Nevertheless, we do carry out explicit valuations in support of policy proposals that would require duty holders to make major investments in safety measures, or when introducing new regulations.

103 When an option produces the benefit of preventing fatalities, this requires putting a monetary value on achieving a reduction in the risk of death. For example, for the purpose of conducting CBAs, we currently take as a benchmark that the value for preventing a fatality (VPF) is about £1 000 000 (2001 figure). As is made clear in Appendix 3, VPF is **not** the value that society, or the courts, might put on the life of a real person or the compensation appropriate to its loss. This figure derives from the value used by the Department of Transport, Local Government and the Regions (DTLR) for the appraisal of new road schemes. However, we regard higher values as being appropriate for risks for which people appear to have a high aversion (the practical use of the VPF is discussed in Appendix 3).

104 There will of course be many options where potential benefits are not concerned with a reduction in the risk of death, for example avoiding deafness or dermatitis or a major injury. Very often in these cases, we place monetary values on the risk reduction by comparing how society rates the risks of harms such as a major injury relative to the risk of death. In addition, there may be non-monetary benefits of a regulatory option such as improvement in the sense of well-being or security. There may also be potential benefits in terms of not having to take measures, such as food bans, evacuations etc, which otherwise would be needed to reduce the effects on health and safety following an incident.

105 Expected costs for an option may also be non-monetary as well as monetary. Typical examples of monetary costs include those associated with the development and application of technology, training, clean-up etc. Non-monetary costs include loss of things that people value, such as convenience or a reduction in choice for consumers and businesses, for example if a product or process is banned.

106 We give further information on our approach for appraising options at Appendix 3, including the use of the results of CBA for assessing the cost-effectiveness of the options identified. However, as will be clear from the next stage, cost-benefit analysis is only one of a number of factors that are taken into account in deciding whether to pursue any particular course of action.

107 This approach means that the cost for preventing a fatality (CPF) of a particular measure adopted might reasonably be very different from the value of preventing a fatality (VPF) used for the purpose of conducting a cost-benefit analysis (see Appendix 3 for a fuller discussion).

108 Eventually we reach a point where we have to make a judgement about whether enough information has been collected and analysed to enable us to proceed to the next stage. This

avoids us falling into a mode known as 'paralysis by analysis' where the need for additional information is used as an excuse to avoid or postpone the adoption of a decision.

Stage 4: Adopting decisions

109 This is the stage where we review all the information gathered in the previous stage with a view to selecting the most appropriate option for managing the risks. The key to success depends to a large extent on ensuring as far as possible that interested parties are content with the process for reaching decisions and, hopefully, also with the decisions themselves. They will have to be satisfied, for example, about:

- the way uncertainty has been addressed, the plausibility of the assumptions made; and
- how other relevant factors such as economic, technological and political considerations have been integrated in the decision-making process.

110 Meeting these conditions is not always easy to achieve, particularly when parties have opposing opinions based on differences in fundamental values or confine themselves to a single issue. Nevertheless, we tackle the first condition by:

- finding out and focusing on the uncertainties that matter;
- explaining why a particular method was chosen, in preference to others, for estimating the risks; and finally
- being open on the science, assumptions and other critical inputs that have contributed to the value or judgement obtained from the risk assessment exercise.

111 Addressing the second condition above (ie how economic, technological and political considerations have been integrated in the decision-making process) is more difficult. Success lies in adopting decisions which most accurately reflect the ethical and value preferences of society at large on what risks are unacceptable, tolerable or broadly acceptable, and how far we have been successful in involving stakeholders in the decision-making process. At times, to take account of uncertainty and the need to adopt a precautionary approach, this might require focusing more on the consequences of harm occurring from a hazard than on the likelihood that the hazard will be realised (see paragraphs 37-42).

The importance of societal concerns: Adventure activities

The regulatory controls put in place on adventure activities (eg certain caving, watersport or climbing activities) show how societal factors can sometimes dominate considerations of individual risk and cost benefit.

In 1993 four young people lost their lives in a canoeing tragedy at Lyme Bay. At the request of Ministers, the Health and Safety Commission published a consultative

document (CD) seeking views on proposed new regulations to license commercial providers of certain adventure activities. The proposed controls took the form of a statutory licensing system even though (as the CD noted):

- *the historic risk of fatalities was low;*
- *formal licensing systems are normally reserved for activities which, if not properly managed, would pose high risks to large numbers of people (eg manufacture and storage of explosives, operation of nuclear installations, or certain work with asbestos).*

Public consultation confirmed the desire for new controls along the lines proposed – a reflection of societal concerns. Such concerns might perhaps be summarised in the view that society expects a very high standard of care of organisations which provide activities that aim to develop young people by enabling them to experience a sense of achievement in overcoming challenges they would not otherwise meet. The Adventure Activities Licensing Regulations came into force in April 1996.[26]

Note: Although made under the Activity Centres (Young Persons' Safety) Act 1995,[27] *the requirements of the 1996 Regulations are enforceable as if they were relevant statutory provisions under the Health and Safety at Work etc Act 1974,*[1] *and the licensing authority has to report annually to the Health and Safety Commission.*

112 We shall examine in more detail later how the criteria that we have developed on the tolerability of risks address these issues.

Stage 5: Implementing the decisions

113 When we have reached a decision on the degree to which a risk should be controlled, we have to decide how the decision can be implemented in practice using the regulatory tools at our disposal, eg recommending new legislation, inviting new guidance or taking enforcement action (see Appendix 2 for a fuller discussion of this process). As explained in paragraphs 7-8, the responsibility for measures for controlling a risk will usually fall on the person who creates it or who is in a position to do something about preventing or minimising it.

114 When constructing the regulatory tool we apply, our approach:

- is exposed to the checks and balances inherent in HSC's arrangements for dealing with occupational health and safety matters, thus ensuring fundamental principles (eg the strategy and targets set out in the 'Revitalising Health and Safety' programme agreed by the Government and HSC) are not compromised and that societal concerns are taken into account properly;
- involves consulting our stakeholders, and requires communicating effectively the outcome to stakeholders;
- takes place in the context of legal requirements which include the Management of

health and safety at work Regulations (MHSWR)[3,28,29] and so requires those who have to introduce measures for managing risks to:

- enlist the co-operation and involvement of those affected and those able to assist, such as safety representatives, by pointing out that this is crucial for the proper management of health and safety. For example, the involvement of safety representatives in health and safety management can help duty holders considerably to fulfil their legal obligations and achieve high standards of health and safety. Moreover, employers are unlikely to achieve the proper control of risks in their workplace without the help of their employees;
- introduce procedures that foster a culture disposing everyone involved to give of their best. For example, in the workplace this may mean getting a commitment, at every level of the organisation, to adopt high health and safety standards and work to them. It also calls for the establishment of well-considered and articulated safety policies where responsibilities are properly defined and allocated and organisational arrangements set out to ensure control and promote co-operation, communication and competence;
- have a plan for taking action by looking ahead and setting priorities for ensuring that risks requiring most attention are tackled first, based on the risk assessment which they are legally required to undertake under the MHSWR[30] and other specific legislation;
- set up a system for monitoring and evaluating progress, eg by identifying potential indicators for evaluating how far the control measures introduced have been successful in addressing the problem;
- comply with well-established principles on the hierarchy of measures for the prevention of risks, e.g. eliminating risks, combating the risk at source, generally applying sound engineering practice such as inherently safer design and applying collective protective measures rather than individual protective measures;

- takes account that employees also have duties imposed on them (eg by virtue of section 7 of the HSW Act[1] and Regulation 14 of MHSWR[30]) to:
  - take reasonable care of their own health and safety and of other persons who may be affected by the employees' acts or omissions at work;
  - cooperate with their employers as necessary to enable the latter to comply with their statutory health and safety responsibilities.

Stage 6: Evaluating the effectiveness of action taken

115 Finally, our process for ensuring that risks are properly managed would not be complete without procedures to review our decisions after a suitable interval to establish:

- whether the actions taken to ensure that the risks are adequately controlled resulted in what was intended;

- whether decisions previously reached need to be modified and, if so, how; for example, because levels of protection that were considered at the time to be good

practice may no longer be regarded as such as a result of new knowledge, advances in technology or changes in the level of societal concerns;

- how appropriate was the information gathered in the first two stages of the decision-making process to assist decisions for action, eg the methodologies used for the risk assessment and the cost benefit analysis (if prepared), or the assumptions made;

- whether improved knowledge and data would have helped to reach better decisions;

- what lessons could be learned to guide future regulatory decisions, improve the decision-making process and create greater trust between regulators, operators and those affected by, or having an interest in, the risk problem.

116 We regard such evaluations as an ongoing process which we need to plan carefully to ensure, for example, that we can tap the data that we have encouraged risk managers to obtain by suggesting they set up a system for monitoring and evaluating progress (paragraph 114). Since there might be some time before the full impact of risk reduction measures can be monitored, we might first focus on the extent of our success in getting risk managers to introduce appropriate measures before concentrating on the success of the decisions as a whole.

117 The importance of the evaluation stage should not be underestimated. For example, we shall see later that the criteria we adopt for deciding the degree to which risk should be controlled rely heavily on good practice being adopted or alternatively the introduction of measures achieving a similar or better level of protection. Evaluation provides a good opportunity to assess whether such 'established standards of good practice' are out of date. New developments such as better knowledge of the risks involved and advances in technology may indicate that a higher standard would be more appropriate to control the risk.

Criteria for reaching decisions

118 Though all six stages of the decision management system just described are important, getting Stage 4 right (the one concerned with reaching decisions) is crucial. Achieving this will not only help to reach decisions that are likely to be supported and implemented but, because of the iterative process inherent in the health and safety management system, it will also help to get the other stages right as well. Getting it right depends to a large extent on the criteria adopted for deciding whether a risk is unacceptable, tolerable or broadly acceptable. It is, therefore, not surprising that a lot of effort has been spent in developing such criteria.

119 Research analysing the criteria used by regulators in the health, safety and environmental field has shown that, in general, the criteria can be classified according to three 'pure' criteria. Regulators have either used these 'pure' criteria on their own or have used them as building blocks to create new criteria. They are:

- an **equity-based** criterion, which starts with the premise that all individuals have unconditional rights to certain levels of protection. This leads to standards, applicable to all, held to be usually acceptable in normal life, or which refer to some other premise held to establish an expectation of protection. In practice, this often converts into fixing a limit to represent the maximum level of risk above which no individual can be exposed. If the risk estimate derived from the risk assessment is above the limit and further control measures cannot be introduced to reduce the risk, the risk is held to be unacceptable whatever the benefits;

- a **utility-based** criterion which applies to the comparison between the incremental benefits of the measures to prevent the risk of injury or detriment, and the cost of the measures. In other words, the utility-based criterion compares in monetary terms the relevant benefits (eg statistical lives saved, life-years extended) obtained by the adoption of a particular risk prevention measure with the net cost of introducing it, and requires that a particular balance be struck between the two. This balance can be deliberately skewed towards benefits by ensuring that there is gross disproportion between the costs and the benefits;

- a **technology-based** criterion which essentially reflects the idea that a satisfactory level of risk prevention is attained when 'state of the art' control measures (technological, managerial, organisational) are employed to control risks whatever the circumstances.

120 Though there are many circumstances where these criteria work well on their own, their universal application has been found wanting. For example, it has been argued that:

- an equity-based criterion may often, in practice, require taking decisions on worst case scenarios bearing little resemblance to reality. In such cases, the decisions reached are inevitably based on procedures which systematically overestimate risks, causing undue alarm and despondency among the public or resulting in benefits achieved at disproportionate costs;

- a utility-based criterion tends to ignore that there are ethical and other considerations than just achieving a balance between costs and benefits. For example, some people believe that certain hazards should not be entertained at all because they are morally unacceptable. At the other extreme, utility-based criteria do not impose an upper bound on risk, whereas we believe that there are risks that society regards as unacceptable because they entail too high a likelihood that harm will actually occur to those exposed or the consequences are too extreme, however small the likelihood of the risk being realised, to countenance exposure to the hazard;

- technology-based criteria often ignore the balance between costs and benefits. They would, for example, require wood furniture manufacturers to adopt the state-of-the-art technology developed for keeping, clinically clean, factories, manufacturing medicines – hardly a realistic proposition.

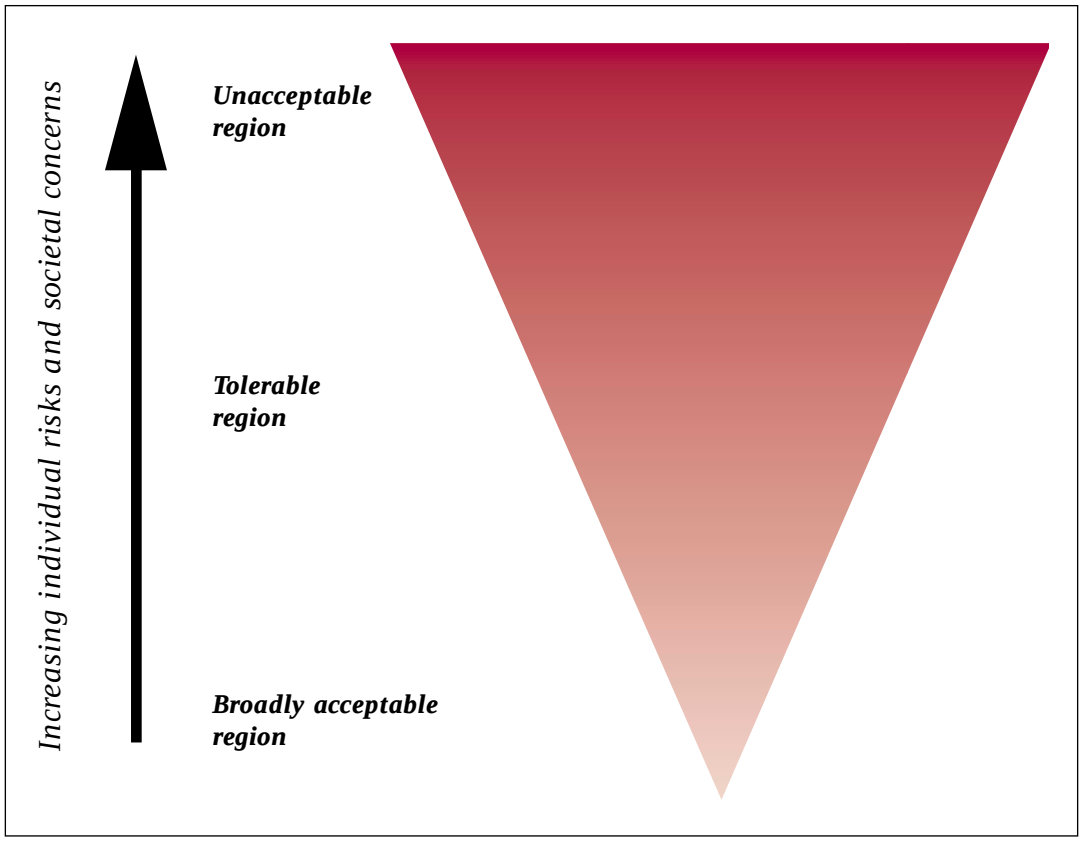
121 However, as already mentioned above, there is of course no reason why the above three pure criteria should be regarded as mutually exclusive. Indeed, the criteria that HSE has

adopted in the form of a framework, known as the tolerability of risk (TOR), accommodate all three criteria. The strength of the framework lies in:

- its ability to capitalise on the advantages of each of the above 'pure criteria' whilst avoiding their disadvantages; and

- the fact that the main tests that are applied under it for reaching decisions on what action needs to be taken are very similar to those people apply in everyday life. As already mentioned, in everyday life there are some risks that people choose to ignore and others that they are not prepared to entertain. But there are also many risks that people are prepared to take by operating a trade-off between the benefits of taking the risks and the precautions we all have to take to mitigate their undesirable effects.

Figure 1: HSE framework for the tolerability of risk



122 The framework is illustrated in Figure 1. The triangle represents increasing level of 'risk' for a particular hazardous activity (measured by the individual risk and societal concerns it engenders) as we move from the bottom of the triangle towards the top. The dark zone at the top represents an unacceptable region. For practical purposes, a particular risk falling into that region is regarded as unacceptable whatever the level of benefits associated with the activity. Any activity or practice giving rise to risks falling in that region would, as a matter of principle, be ruled out unless the activity or practice can be modified to reduce the degree of risk so that it falls in one of the regions below, or there are exceptional reasons for the activity or practice to be retained.

123 The light zone at the bottom, on the other hand, represents a broadly acceptable region. Risks falling into this region are generally regarded as insignificant and adequately controlled. We, as regulators, would not usually require further action to reduce risks unless reasonably practicable measures are available. The levels of risk characterising this region are comparable to those that people regard as insignificant or trivial in their daily lives. They are typical of the risk from activities that are inherently not very hazardous or from hazardous activities that can be, and are, readily controlled to produce very low risks. Nonetheless, we would take into account that duty holders must reduce risks wherever it is reasonably practicable to do so or where the law so requires it.

124 The zone between the unacceptable and broadly acceptable regions is the tolerable region. Risks in that region are typical of the risks from activities that people are prepared to tolerate in order to secure benefits, in the expectation that:

- the nature and level of the risks are properly assessed and the results used properly to determine control measures. The assessment of the risks needs to be based on the best available scientific evidence and, where evidence is lacking, on the best available scientific advice;
- the residual risks are not unduly high and kept as low as reasonably practicable (the ALARP principle – see Appendix 3); and
- the risks are periodically reviewed to ensure that they still meet the ALARP criteria, for example, by ascertaining whether further or new control measures need to be introduced to take into account changes over time, such as new knowledge about the risk or the availability of new techniques for reducing or eliminating risks.

125 Benefits for which people generally tolerate risks typically include employment, lower cost of production, personal convenience or the maintenance of general social infrastructure such as the production of electricity or the maintenance of food or water supplies.

126 As such the framework can be seen as essentially applying an equity-based criterion for risks falling in the upper region, while a utility-based criterion predominates for risks falling in the middle and lower regions and technology-based criteria complement the other criteria in all three regions.

127 It must be stressed that Figure 1 is a conceptual model. Moreover, the factors and processes that ultimately decide whether a risk is unacceptable, tolerable or broadly acceptable are dynamic in nature and are sometimes governed by the particular circumstances, time and environment in which the activity giving rise to the risk takes place. For example, standards change, public expectations change with time, what is unacceptable in one society may be tolerable in another, and what is tolerable may differ in peace or war. Nevertheless, the protocols, procedures and criteria described in this document should ensure that in practice, risks are controlled to such a degree that the residual risk is driven down the tolerable range so that it falls either in the broadly acceptable region or is near the bottom of the tolerable region, in keeping with the duty to ensure health, safety and welfare so far as is reasonable practicable.

Tolerability limits

128 The TOR framework just described can in principle be applied to all hazards. When determining reasonably practicable measures for any particular hazard, whether the option we have chosen to control the risk is good enough or not depends in part on where the boundaries are set between the unacceptable, tolerable or broadly acceptable regions in Figure 1. As will be clear from earlier discussions, the choice will be the outcome of much deliberation and negotiation in the course of policy development, reflecting the value preferences of stakeholders and the practicability of possible solutions.

Tolerability limits for risks entailing fatalities

In practice the actual fatality rate for workers in even the most hazardous industries is normally well below the upper limit of a risk of death to any individual of 1 in 1000 per annum for workers and of 1 in 10 000 per annum for the public who have a risk imposed on them 'in the wider interest of society' (see paragraphs 131-132).

For example, in 1999/00 the annual fatality rates for agriculture, hunting, forestry and fishing (but not sea fishing); construction; and mining and quarrying (including offshore oil and gas) were 1 in 12 984, 1 in 21 438, and 1 in 14 564 respectively. In traditionally less hazardous industries the annual risk of death for workers is lower still; for example in the service sector in 1999/00 it was 1 in 388 565.

Similarly the actual risk of death per annum for the public from work activities is usually very much lower than the figure of 1 in 10 000. For example, during the period 1994/5-1998/9 the annual risk of death to the public from the use of gas (fire, explosion or carbon monoxide poisoning), averaged over the entire population of Great Britain, was 1 in 1 510 000 – in other words below the limit of what is often regarded as broadly acceptable. Gas incidents, however, continue to give rise to societal concern, particularly where the incidents occur because unscrupulous landlords seek to avoid the cost of simple safety checks on their gas heating systems and so put those who rent the accommodation (often young people) at greater risk. In effect such societal concerns override averaged numerical considerations. HSE has responded by firm enforcement action where appropriate, and by targeted publicity emphasising the importance of annual safety checks on gas appliances.

Further Information: Appendix 4 gives other examples of the magnitude of different risks. Further information is available in Health and Safety Statistics *published annually by the Health and Safety Commission.*

129 As a result what is unacceptable, tolerable or broadly acceptable in specific circumstances is often spelled out or implied in legislation, ACOPs, guidance, etc or reflected in what constitutes good practice ie there is no need to set explicit TOR boundaries. However, HSE on the basis of its wealth of experience accumulated over the years in engaging its stakeholders subscribes as a matter of policy to the following indicative criteria, as to where these boundaries lie, for risks in a limited category, namely those entailing the risk of individual or multiple deaths. We must also stress that these criteria are merely

guidelines to be interpreted with commonsense and are not intended to be rigid benchmarks to be complied with in all circumstances. They may, for example, need to be adapted to take account of societal concerns or preferences.

Example of good practice enshrined in law

Substances hazardous to health and genetically modified micro-organisms

Some basic principles of good occupational hygiene practice are enshrined in the Control of Substances Hazardous to Health Regulations (COSHH). Control of exposure to substances hazardous to health, for example, must be achieved by:

- *prevention (eg by avoiding use altogether, or by substituting a less hazardous substance), or where this is not reasonably practicable;*
- *control measures (eg engineering controls such as containment or local exhaust ventilation), or where this is not reasonably practicable;*
- *personal protective equipment.*

Sometimes application of good practice is made a specific requirement in law. For example, in setting down standards of human health and environmental safety the Genetically Modified Organisms (Contained Use) Regulations 2000[31] require application of 'the general principles of good microbiological practice and of good occupational safety and hygiene' (14 well accepted principles are then listed). Societal concerns over the risks from genetically modified micro-organisms are reflected in a high standard of control and, in the developing area of micro-biological safety, a legal requirement which demands application of accepted good practice in step with evolving scientific knowledge and technological developments.*

**These Regulations implement Directive 90/219/EEC, as amended, on the contained use of genetically modified micro-organisms, which includes the same wording.*

Boundary between the 'broadly acceptable' and 'tolerable' regions for risk entailing fatalities

130 HSE believes that an individual risk of death of one in a million per annum for both workers and the public corresponds to a very low level of risk and should be used as a guideline for the boundary between the broadly acceptable and tolerable regions. As is very apparent from Tables 1-4 at Appendix 4, we live in an environment of appreciable risks of various kinds which contribute to a background level of risk – typically a risk of death of one in a hundred per year averaged over a lifetime. A residual risk of one in a million per year is extremely small when compared to this background level of risk. Indeed many activities which people are prepared to accept in their daily lives for the benefits they bring, for example, using gas and electricity, or engaging in air travel, entail or exceed such levels of residual risk.

131 Moreover, many of the activities entailing such a low level of residual risk also bring benefits that contribute to lowering the background level of risks. For example, though electricity kills

a number of people every year and entails an individual risk of death in the region of one in a million per annum, it also saves many more lives, eg by providing homes with light and heat, operating lifts, life support machines and through a myriad of other uses. Indeed, it is the combined effect of many activities involving such low levels of residual risks that contributes to the wealth of the nation and leads to improvements in health and longevity.

Boundary between the 'tolerable' and 'unacceptable' regions for risk entailing fatalities

132 We do not have, for this boundary, a criterion for individual risk as widely applicable as the one mentioned above for the boundary between the broadly acceptable and tolerable regions. This is because risks may be unacceptable on grounds of a high level of risk to an exposed individual or because of the repercussions of an activity or event on wider society. Indeed, it would be quite unusual for high levels of individual risk not to engender societal concerns, on equity grounds, for example, as we have already argued. The converse is not, however, true – society can be seized by hazards that pose, on average, quite low levels of risk to any individual but could impact unfairly on vulnerable groups, such as the young or the elderly or particularly susceptible individuals. Furthermore, exposure to an activity may result in a low level of average risk to any one individual but the totality of such risks across the affected population would not be acceptable as judged by the socio-political response to a particular event such as a railway disaster. Nevertheless, in our document on the tolerability of risks in nuclear power stations, we suggested that an individual risk of death of one in a thousand per annum should on its own represent the dividing line between what could be just tolerable for any substantial category of workers for any large part of a working life, and what is unacceptable for any but fairly exceptional groups. For members of the public who have a risk imposed on them 'in the wider interest of society' this limit is judged to be an order of magnitude lower – at 1 in 10 000 per annum.

133 However, these limits rarely bite. As we have already pointed out, hazards that give rise to such levels of individual risks also give rise to societal concerns and the latter often play a far greater role in deciding whether a risk is unacceptable or not. Secondly, these limits were derived for activities most difficult to control and reflect agreements reached at international level. In practice most industries in the UK do much better than that.

Risks giving rise to societal concerns

134 Developing criteria on tolerability of risks for hazards giving rise to societal concerns is difficult. Hazards giving rise to such concerns often involve a wide range of events with a range of possible outcomes. The summing or integration of such risks, or their mutual comparison, may call for the attribution of weighting factors for which, at present, no generally agreed values exist as, for example, the death of a child as opposed to an elderly person, dying from a dreaded cause, eg cancer, or the fear of affecting future generations in an irreversible way.

135 Nevertheless, HSE has adopted the criteria below (some of which are currently under review) for addressing societal concerns arising when there is a risk of multiple fatalities occurring in one single event. These were developed through the use of so-called FN-curves

(obtained by plotting the frequency at which such events might kill N or more people, against N). The technique provides a useful means of comparing the impact profiles of man-made accidents with the equivalent profiles for natural disasters with which society has to live. The method is not without its drawbacks but in the absence of much else it has proved a helpful tool if used sensibly.[32] Moreover, the criteria are based on an examination of the levels of risk that society was prepared to tolerate from a major accident affecting the population surrounding the industrial installations at Canvey Island on the Thames. Reports on the risk from the installations at Canvey Island were discussed in Parliament, and (after improvements) the risk was deemed by Ministers to be just tolerable. The limit was subsequently endorsed by the HSC's Advisory Committee on Dangerous Substances in the context of major hazards transport.[33] These criteria are, however, directly applicable only to risks from major industrial installations and may not be valid for very different types of risk such as flooding from a burst dam or crushing from crowds in sports stadia.

136 Thus, where societal concerns arise because of the risk of multiple fatalities occurring in one event from a single major industrial activity*, HSE proposes the following basic criterion for the limit of tolerability, particularly for accidents where there is some choice whether to accept the hazard or not, eg the risk of such an event happening from a major chemical site or complex continuing to operate next to a housing estate. In such circumstances, HSE proposes that the risk of an accident causing the death of 50 people or more in a single event should be regarded as intolerable if the frequency is estimated to be more than one in five thousand per annum. See reference 32 for a discussion of techniques available for extrapolating this criterion to other numbers of casualties and their frequency.

* Here a single major industrial activity means an industrial activity from which risk is assessed as a whole, such as all chemical manufacturing and storage units within the control of one company in one location or within a site boundary, a cross-country pipeline, or a railway line along which dangerous goods are transported.

137 A different situation arises altogether when giving advice to planning authorities in connection with proposed developments in the vicinity of major hazard chemical plants. Since the developments have not yet received planning permission, not allowing them because of the putative societal risks to which would-be occupants would have been exposed by living next to a chemical plant, is relatively inexpensive when compared to the costs entailed in requiring existing developments with similar risks to introduce remedial measures. HSE's criteria for advising against a development because of the societal risks that it may engender are based in the first instance on the level of individual risk per year calculated for a hypothetical person (see Appendix 1) receiving a dangerous dose, or worse, together with certain characteristics of the development.

Occupational exposure limits for substances hazardous to health and the TOR framework

In a previous example we explained that occupational exposure limits (OELs) determine the extent of exposure (by inhalation) of people at work to substances hazardous to health; an OEL can be of two types – an occupational exposure standard (OES) or a maximum exposure limit (MEL).

In principle an OEL ought to be set using data on all the effects on health produced by the substance at different levels of occupational exposure. In practice, however, absence of data and lack of a clear understanding of the biological processes involved means it can be difficult to relate occupational exposure over time to a probability of

specific harm, particularly for chronic effects such as cancer, occupational asthma or dermatitis. (One exception is chrysotile asbestos, for which the relationship between the risk of death from lung cancer and occupational exposure has been estimated.) Alternative approaches are, therefore, normally adopted. Nevertheless, the general TOR framework (Figure 1) still applies, and illustrates the application of the different types of OEL, the role of legislation in sometimes setting out what is intolerable, and the use of good practice in setting limits.

The conventional approach is to decide whether or not the hazardous properties of the substance have a threshold, and if so to seek to derive from the available data an overall no observed adverse effect level (NOAEL). Using suitable assessment or uncertainty factors (see Example Box on page 37) the NOAEL is then translated into an OES – a level of exposure at which, based on current scientific knowledge, it is judged that there is minimal risk to the health of the workforce. An OES is, however, only set if the level can be met by the application of good practice, and foreseeable excursions above this level are not associated with serious health effects.

In contrast, MELs are normally set for substances for which it is judged that there is no identifiable threshold of exposure and the health effects produced are of serious concern. (A MEL may also be set for substances for which it may be possible to identify a 'no-effect' level, but control to the corresponding exposure level is not reasonably practicable.) A MEL is set at the level which is reasonably practicable to achieve for the work activity where control of exposure is most difficult.

Under the Control of Substances Hazardous to Health Regulations (COSHH), exposure must not exceed the MEL and must be reduced to a level which is as low as is reasonably practicable below the MEL in accordance with good practice. In effect, MELs are at the boundary between the unacceptable and tolerable regions of exposure (Figure 1); exposure above the MEL is deemed intolerable.

On the other hand, control of exposure to an OES represents a level of risk that is close to or even within the broadly acceptable region. The permitted excursions are in the tolerable region provided exposure is restored to the OES as soon as is reasonable practicable (as required by COSHH).

Note: however, that whilst MELs and OESs fit within the framework of Figure 1, the levels at which they are set do not correspond with the numerical limits of risk in paragraphs 129-131. (OELs are, of course, set substance by substance; they do not usually relate to end points of death; and they are not expressed in terms of probability of harm.)

Further Information: The role of occupational exposure limits in the control of workplace exposure to chemicals.[34]

138 Thus in the case of most housing developments, for example, HSE advises against granting planning permission for any significant development where individual risk of death for the hypothetical person is more than 10 in a million per year, and does not advise against granting planning permission on safety grounds for developments where such individual risk is less than 1 in a million per year. (Somewhat different criteria are applied to sensitive

developments where those exposed to the risk are more vulnerable, e.g. schools, hospitals or old people's homes, or to industrial or leisure developments, reflecting the different characteristics of the hypothetical person used to assess individual risk).

139 Cases of proposed housing development where the individual risk of death per annum is between 1 and 10 in a million per year are scrutinised more closely, taking into account a more detailed assessment of the individual risk, the area of the development, the number of people involved, their vulnerability and how long they are exposed to the risk. Further information is available on the risk criteria presently applied by HSE in land use planning, including the criteria applied for different categories of development, for developments in the vicinity of major chemical plants, and for development of new plants.[35]

Applying the (generalised) TOR framework

140 Our general thrust in applying the framework is aimed at ensuring that our approach for addressing hazards is inherently precautionary and leads to control regimes that improve or at least maintain standards, while retaining the principles of proportionality, consistency, etc as mentioned in paragraph 52.

141 Thus when we apply the framework to policy formulation, regulatory development and enforcement activities, we:

- take into account that societal concerns are often absent for a wide range of hazards, for example, this is often the case for those hazards that are familiar or where the risks they give rise to are generally accepted as being well controlled. As we have pointed out in paragraph 26, hazards giving rise to societal concerns have a number of well known features and such concerns are often absent for many routinely encountered occupational hazards. This means that when determining where the hazard falls on the TOR triangle (as described in paragraph 122) we can, as a general rule, for most occupational hazards, focus on the individual risks (generally assessed in relation to a hypothetical person using conventional risk assessment techniques – see Appendix 1). We would weigh up the extent (if any) to which societal concerns are taken into account according to the degree that they are pertinent to the circumstances under consideration;

- decide, from the information gathered in going through the decision-making process, how precautionary our approach will be when determining where the individual risk and societal concerns ie on the TOR geometry;

- concentrate on ensuring that duty holders must have in place suitable controls to address all significant hazards arising from their undertakings;

- start with the expectation that those controls should, as a minimum, implement authoritative good practice precautions (or achieve similar standards of prevention/protection), irrespective of specific risk estimates.

142 In this context we would:

- regard a hazard as significant unless past experience, or going through the decision-making process described earlier, shows the risk from it to be extremely low or negligible when compared to the background level of risk to which people are exposed, and the hazard does not give rise to societal concerns;

- consider as authoritative sources of relevant good practice those enshrined in prescriptive legislation, Approved Codes of Practice and guidance produced by Government. We would also consider including as other sources of good practice, standards produced by Standards-making organisations (eg BS, CEN, CENELEC, ISO, IEC, ICRP) and guidance agreed by a body representing an industrial or occupational sector (eg trade federation, professional institution, sports governing body). Such considerations would take into account that HSE is a repository of information concerning good engineering, managerial and organisational practice, and would also include an assessment of the extent to which these sources had gained general acceptance within the safety movement.

143 The next stage is to distil from the information gathered at Stages 2 (characterising the problem) and 3 (examining options and their merits) on individual risks and societal concerns and, by applying the tests at Appendix 3 and the criteria in paragraphs 118-139 above, decide whether adoption of authoritative good practice precautions is an adequate response to the hazards. Our experience suggests that in most cases adopting good practice ensures that the risks are effectively controlled.

144 One consequence of linking the required control regime to relevant good practice (or measures affording similar levels of protection) is that the control measures so derived apply regardless of the length of exposure. In most circumstances, we would expect control measures to be in place at all times. For example, if good practice requires that accidental contact with the moving parts of a machine should be prevented through the fitting of a guard, the guard will need to be in place, however short the period the machine is being used.

145 There will be, however, cases where existing good practice:

- was not identified as an option at Stage 3. This will be particularly true for hazards that are new or not well studied, or where the circumstances in which people interface with the hazard are untypical or exceptional;

- is found to result in inadequate control of risks.

146 In these circumstances we have to examine (again by adopting the procedure set out at paragraph 58 above) whether any of the other options identified at Stages 2 and 3 would reduce the risks to the degree HSE considers appropriate. If one is found we would advocate its adoption. However, as we go through this iterative process of examining options, there will be occasions when we may find that no option is available for reducing the risks to a tolerable level. This will be the case for risks from activities:

- that are so high and their control inherently so difficult that it is not possible to find reasonable control measures that one could feel confident would work in practice; or

- where it is not possible to allay the societal concerns about the risk. For example, though experts may regard available control measures as adequate for controlling a particular risk, that view may not be shared by society as a whole, as established through existing democratic processes and regulatory mechanisms, either because the majority of people believe that the measures will not always be observed or that they have doubts that the risks should be entertained at all.

Intolerable risks: I

There are relatively few examples in health and safety legislation of processes or activities that have been banned because the risks they entail are so high and their control inherently so difficult that it is not possible to find any control measure that one could feel confident would work in practice (paragraph 146(i)).

The examples below are historical and reflect judgements on the risks from two particularly hazardous substances. The bans, however, have been continued into modern legislation because the risks are still real and, notwithstanding modern control measures, the judgement of the Health and Safety Commission (confirmed in public consultation) remains that, in the light of accepted good practice in using alternatives, the effort required to control the risk would be disproportionate.

The manufacture and use for any purpose of 2-naphthylamine and its salts was banned under the Carcinogenic Substances Regulations 1967[36] because its combination of physical (sublimation) and chemical (potent carcinogen) properties means that control of exposure is very difficult and the potential ill-health effects severe. The ban was continued under an EC Directive now implemented by the Control of Substances Hazardous to Health Regulations 1999 (COSHH).[37]

The Control of Lead at Work Regulations 1998 (CLAW)[38] continue a prohibition on the use of certain glazes in pottery manufacture first introduced more than 40 years ago. The requirement bans any glaze unless it is 'leadless' or 'low solubility' (terms which are defined).

Historically the use in pottery manufacture of glazes containing raw lead compounds resulted in unacceptably high levels of lead poisoning. The problem was resolved by the development of glazes containing reduced amounts of lead, or by 'fritting' the lead compounds (ie fusing and quenching to form a glass, and then granulating) to produce glazes with much reduced lead bioavailability. Adoption of these glazes became accepted good practice and their use was made a legal requirement.

Levels of exposure of workers to lead in the pottery industry are now relatively low, and there are very few cases where workers have to be suspended from work with lead because their blood lead levels are above prescribed limits.

Intolerable risks: II

Presently there are very few examples in health and safety at work legislation of processes or activities that have been banned outright on the basis of societal concerns (paragraph 146(ii)). One concerns the employment of young people (under 18 years) in certain work activities where there is potential for exposure to high levels of lead.

The Control of Lead at Work Regulations 1998 (CLAW)[36] rationalise and continue certain historical restrictions on the employment of young persons and women of reproductive capacity in specific activities where there is potential for high exposure to lead. Historically these restrictions were imposed mainly on the basis of ethical considerations. The provisions of CLAW expressly provide for a high level of protection for women of reproductive capacity, as the foetus is now known to be at greater risk from exposure to lead than adults. Nevertheless, public consultation on CLAW when still in draft form confirmed that there were continuing societal concerns over the employment of youngsters in such work activities, and the Regulations expressly ban the employment of young persons, as well as women of reproductive capacity, in a list of specified activities involving work in lead smelting and refining, and in lead-acid battery manufacture.

147 We would conclude in such circumstances that we are dealing with activities located in the upper, 'unacceptable' region of the framework. In our experience, activities or processes where the above conditions apply are relatively rare. There may be several reasons for this. First, as noted above, advances in technology mean that most risks can now be controlled. Secondly, we are aware that as regulators we can often allay societal concerns by giving reassurance that risks are being properly controlled through the introduction of progressively more stringent regulatory instruments, such as the use of guidance, ACOPs, or prescriptive legislation, culminating if necessary in the introduction of process regulations such as notification or licensing systems (see Appendix 2).

148 Nevertheless, in situations where Intolerable risks I and II are found to apply, we shall give consideration to banning these activities or processes. For existing risks where banning would be an incomplete solution because the hazard is already widespread, remedial action of some kind has to be undertaken – removal of asbestos prior to demolition of buildings is a case in point.

149 We must stress that we use the above criteria and framework flexibly and with commonsense. For example, addressing certain hazards from existing situations may require that certain activities be undertaken which would fall into the intolerable region for a short period of time, eg when the emergency services are engaged in saving life. Our decision-making process provides the necessary flexibility. Thus in the above example of the emergency services, as we go through the iterative stages of the decision-making process, we should be able to gauge the best option overall for ensuring that measures are introduced so that health and safety standards are not compromised.

Appendix 1

Some of the conventions adopted for undertaking risk assessments

Actual and hypothetical persons

1 Though a risk assessment can be done (and is sometimes done) to assess the risk to an actual person – ie the risk to an individual taking full account of the nature, extent and circumstances in which the exposure arises – there are three problems which limit the usefulness of such an approach for managing risks generally. First, the implications of the case law mentioned in paragraph 41, means that we do not need to wait for people to be actually exposed to a hazard before taking decisions about whether the risk they entail should be incurred at all or the degree to which it should be controlled. Secondly, the approach could be very resource intensive. Exposure to most hazards is seldom confined to one person. It would be necessary to carry out a risk assessment for each person exposed since individuals are affected by risk differently depending, amongst other things, on their physical make up, abilities, age, and the circumstances giving rise to their exposure. Thirdly, it would be very difficult to extract and distil useful information from all the individual assessments.

2 In practice therefore, assessment of the risks to an actual person has rather limited uses such as checking whether a generic measure introduced is suitable for a particular person. What is done instead is to perform the assessment in relation to an hypothetical person. An hypothetical person describes an individual who is in some fixed relation to the hazard, eg the person most exposed to it, or a person living at some fixed point or with some assumed pattern of life. For example, occupational exposure to chemicals, entailing adverse consequences after repeated exposure for long periods, is often controlled by considering the exposure of an hypothetical person who is in good health and works exactly forty hours a week.

3 To ensure that all significant risks for a particular hazard are adequately covered, there will usually have to be a number of hypothetical persons constructed. For example, for each population exposed to the hazard, there will usually be an hypothetical person specifically constructed for determining the control measures necessary to protect that population.

4 Relating assessments to an hypothetical person has several advantages. Persons actually exposed to the risks can compare their own circumstances to those associated with the measures deemed necessary to control the risks found for the hypothetical person, and decide whether they or their family incur a greater or lesser risk and therefore whether the measures in place are adequate in their circumstances. Furthermore, those who have a duty to assess risk and introduce appropriate measures can also reach similar conclusions in respect of those they have to protect. Moreover, the approach allows all relevant factors to be taken into account in the assessment of the risks, for example, human factors where relevant.

5 In addition the concept of hypothetical person has the considerable advantage that it allows the risk of a certain process, activity, situation etc to be assessed meaningfully and independently of

the exposure of persons actually exposed to the risks. This is because in applying the concept, it is assumed that exposure to the hazard is for the time period that was fixed when the credible scenario for the exposure of the hypothetical person was agreed upon.

6 Accordingly, its use:

- limits claims that, in particular circumstances, it is not necessary to introduce control measures for addressing a hazard entailing a significant probability of adverse consequences because the exposure to persons exposed to the hazard is actually low as they interface with the hazard for a short time. Attempts to justify such a claim could be made if, for example, persons interfacing with the hazard were periodically dismissed and replaced with others, thereby ensuring that exposure of any person to the hazard is short;

- deals elegantly with the phenomenon that exposure to many hazards is not uniform but comes in peaks and troughs. This, if present, must be factored in when determining the exposure of any exposed population by creating as necessary one or more hypothetical person to take this into account. For example, the period of exposure of the hypothetical person could be time-weighted and/or more than one hypothetical person could be constructed to deal with the various attributes of the exposure to the hazard.

- helps to improve (or at least maintain) standards by encouraging risks to be assessed (and therefore controlled) in an integrated manner by taking account of the way people interface with the hazard giving rise to the risk. A particular hazard might pose a risk of immediate traumatic injury and/or long-term health effects and affect the various population exposed differently, (eg pregnant women as opposed to male workers). A particular work activity might give rise to a number of hazards which could occur at different stages of the activity. Hazards might arise as a direct consequence of the work activity or incidentally to it (eg traffic at road works). The same hazard may be found in the different locations of a duty-holder's undertaking (eg hazards occurring on the railway system). There will usually be a need for more than one hypothetical person to be constructed to capture all these factors when assessing risks.

Hypothetical persons in the assessment of risk from nuclear plants

The procedures for assessing risks from nuclear plants illustrate how careful use of the concept of 'hypothetical persons' can reduce uncertainty and increase confidence in the outcome of the assessment.

When establishing the radiation risk to those outside a nuclear site three different hypothetical persons are used to ensure that the control measures built into the plant and incorporated in its operational procedures cater both for normal operation and for all reasonably foreseeable faults and accidents. To ensure that any calculations do not underestimate the risk, these hypothetical persons are assumed to have lifestyles that would result in the highest realistically conceivable doses from exposure to:

- *direct radiation from normal operation of the plant itself;*

- *routine emissions to air, water, etc;*

- *direct radiation and intakes of radioactivity in the event of a fault or accident.*

The definition of each hypothetical person would have to be justified in the light of the nature and environment of the plant. For the points above respective examples might be:

- *a child present continuously in the nearest dwelling to the site*
- *someone whose diet includes regular consumption of the greatest plausible quantity of a locally produced food likely to be most affected by the maximum allowable discharges from the plant (see note);*
- *someone who remains at the position of highest dose for the duration of a release of radioactive material occurring in weather conditions that resulted in the greatest exposure.*

Further information: Health and Safety Executive Safety assessment principles for nuclear plants.[39]

Note: In England and Wales discharges to the environment are regulated by the Environment Agency (in Scotland the Scottish Environment Protection Agency); food safety is the responsibility of the Food Standards Agency.

7 Our approach is to provide a 'full picture' of the risks generated by a hazard by creating enough hypothetical persons to enable control measures to be put in place to protect all those exposed from all the undesirable consequences of the hazard, taking account of the different populations exposed and the circumstances of their exposure (see paragraph 3). This technique has the merit of preventing risk being underestimated by making clear whether a generic assessment of the risks on its own is adequate, or whether it should be supplemented by other assessments pertaining to:

- particular groups of persons interacting with the hazard in a certain way or who are particularly vulnerable to it;
- a slice of time;
- particular locations.

8 In practice, when assessing compliance, it will also be necessary to check whether actual persons exposed to the risks fall within the profile of the hypothetical person(s) adopted for the assessment of the risk. If the preventive measures adopted for controlling risks to the hypothetical person are found not to be adequate to protect actual persons, more stringent measures may need to be introduced.

Standards

9 The results of assessments done in relation to hypothetical persons are also used for the

adoption of standards. Standards can be regarded as generic control measures that must be applied to eliminate or reduce the risks for a particular hazard. The scope of the standard is set by specifying the circumstances in which the hazards give rise to the risk. One feature of using standards is that once adopted they may be regarded as applying to the hazard rather than to the risk in the sense that they are applied to control risks whatever the circumstances, for example, however short the actual exposure to the hazard.

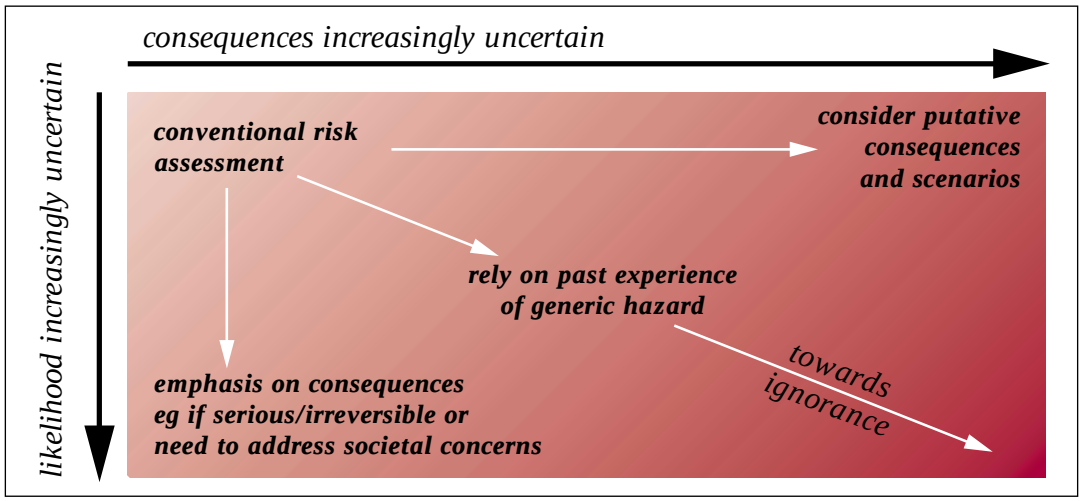
Procedures for handling uncertainty

10 The procedures adopted for handling uncertainty are illustrated in Figure 2. The vertical axis represents increasing uncertainty in the likelihood that the harmful consequences of a particular event will be realised, while the horizontal axis represents increasing uncertainty in the consequences attached to the particular event.

11 At the upper left hand corner, a risk assessment can be undertaken with assumptions whose robustness can be tested by a variety of methods. However, as one moves along the axes increasingly assumptions are made that are precautionary in nature and which cannot be tested.

12 For example, at the bottom of the vertical axis where there is a high degree of uncertainty about likelihood, it is assumed that the event will be realised by focusing solely on the consequences, while on the far right of the horizontal axis, where there is a high degree of uncertainty surrounding the consequences, putative consequences are deliberately assigned to the hazard.

Figure 2: Procedures for tackling uncertainty when assessing risks



13 It is also worth noting that though more information frequently leads to a decrease in uncertainty, it does not necessarily change the probability of an event. For example, though frequent inspections of a critical component may reduce the uncertainty regarding the probability of the component failing within a period of time, the inspections do not reduce the probability of the component failing unless action is taken to remedy the situation.

Appendix 2

Identifying and considering options for new regulations, Approved Codes of Practice and guidance

1 When considering a specific risk problem, HSC/E are often confronted with the question as to how they should use the powers conferred on them by the HSW Act to clarify how duty holders should comply with their legal duties under the Act, or to extend those duties in particular cases. In these circumstances, in our role in advising HSC, we need to decide whether the new measure is really necessary and, if it is, what form this should take so that the decisions reached take due account of the framework in Part 3 of this document, the architecture of our health and safety law, and the fact that there may be constraints in pursuing certain options. How we tackle this question is explored below.

Architecture of health and safety law

2 The HSW Act puts a range of regulatory instruments at HSC's disposal in its role as guardian of occupational health, safety and welfare. These include making proposals to the Secretary of State for new legislation, and issuing Approved Codes of Practice (ACOPs) and guidance. The Act also allows for modernising health and safety law according to a particular architecture. Our policy is to ensure that regulations, like the Act itself, should, so far as possible, express general duties, principles and goals with subordinate detail set out in ACOPs and guidance. As such the architecture is designed to keep the need for intervention by the regulator to a minimum.

3 The architecture takes the following form:

- **the general duties** on employers, self-employed persons and others in the HSW Act. They amount to a statutory (criminal law) enactment of common law duties of care. They are comprehensive in coverage – of people, places, activities and other sources of hazard. They are qualified by 'so far as is reasonably practicable' (SFAIRP). An exception is Section 7, under which employees have a duty to 'take reasonable care' of their own and others health and safety;

- **regulations**, some of which clarify particular aspects of the general duties and are mandatory; others may introduce particular requirements for specific hazards, sectors etc. They do not add to the scope of the general duties, but regulations may impose a higher standard of duty ('practicable' or absolute requirements). Of special mention is the Management of Health and Safety at Work Regulations 1999 (MHSWR).[32] These require employers and self-employed people to assess the risks in their undertakings so as to identify the measures they need to have in place to comply with their duties under health and safety law. As such, the assessment provisions of

MHSWR permeate all other workplace health and safety legislation including the general duties in the HSW Act;

- **ACOPs**, which clarify particular aspects of the general duties and regulations, and are HSC's way of spelling out their implications. ACOPs have a special guidance status. If employers are prosecuted for a breach of health and safety law, and it is proved that they have not followed the relevant provisions of the Approved Code of Practice, a court can find them at fault unless they can show that they have complied with the law in some other way. Accordingly, the HSC agreed in 1996, following consultation, that it would limit the use of guidance having the status of an ACOP to cases where four conditions were met. These are when:
  - there is clear evidence of a significant or widespread problem;
  - the overall approach being taken to an area of risk is by amplifying general duties in the HSW Act or preparing goal-setting regulations (see paragraph 4);
  - there is a strong presumption in favour of a particular method or particular methods that can be amplified in an ACOP in support of the general duties or goal setting regulations to give authoritative practical guidance;
  - the alternative is likely to be more prescriptive regulation;

- **guidance**, which is not law but gives advice on measures available and what is good practice.

4 Regulations broadly take three forms:

- **'process' regulations** concerned with what has to be done to manage the control of risks. These include requirements to assess risks, set out management approaches, draw up safety cases, notify hazards, keep records etc. and may include some form of permissioning, eg licensing. Many of the requirements are derived directly from what is implicit in the general duties, eg the need to assess risks. They deal with matters where there is a need to demonstrate that risk is subject to careful, explicit control;

- **goal-setting regulations** which set out the objectives to be achieved but leave considerable freedom on how these objectives are to be met. Goals or targets to be met in such regulations are often qualified by 'reasonable practicability' and thus demand from both regulator and duty holders some matching of response to risk and of cost to benefit;

- **standard-setting regulations** which prescribe what constitutes an appropriate response to a hazard.

5 These forms are not mutually exclusive, ie a set of regulations could contain all three.

Constraints

6 The regulation of health and safety risks from work activities is subject to certain constraints, some voluntary and others which we must take into account. In the latter

category we would include:

- the fact that most health and safety legislation these days originates from the European Union, mainly in the form of European Community directives (some legislation may originate in International Conventions). Once adopted, the UK has to transpose the provisions of the directive into national legislation. Though the framework described in Part 3 of this document will be most useful to inform the line that should be taken in negotiation of directives, compromises reached during the negotiations may result in measures for managing risks which do not fit completely in either the framework or the above architecture. If the enabling provisions of the HSW Act (as is often the case) are subsequently used to implement the directives into UK law, these 'misfits' will inevitably be reflected in the implementing legislation;

- the need, when modernising legislation preceding the HSW Act, to maintain or improve standards of health, safety and welfare.

7 Voluntary constraints include:

- adhering to the general principle that standards of health, safety and welfare should be maintained, even when this is not mandatory, for example, when replacing legislation or guidance introduced after the Act;

- ensuring that, wherever possible, regulatory measures adopted domestically fit as far as possible with the architecture described above.

Hierarchy of options

8 Based on our wealth of experience in applying the framework and while taking account of the above constraints, the following procedure has evolved for identifying options most likely to work for new regulatory measures and the order in which they should be considered:

- reliance on the general duties and the Management of Health and Safety at Work Regulations. These would be judged as sufficient unless:
  - past experience shows enforcement of the above duties does not succeed;
  - there is a high level of uncertainty about what is required;
  - EC Directives (or International Conventions) require more specific or different legislation to be introduced domestically;
  - societal concerns require that some explicit form of action is needed (politically or to allay public fears).

- use of guidance. This may help to deal with some of the above, but could be insufficient if:
  - EC Directives (or International Conventions) require more;
  - the need to address societal concerns requires more;
  - the current compliance record suggests guidance will not be effective, or will leave

too large a gap between average and poor compliance;
- statutory regulation is required to ensure a level playing field for the risk creators;
- the general view of stakeholders is that guidance alone leaves too much discretion to duty holders and/or HSW Act inspectors, eg in interpreting 'reasonable practicability' and measures necessary to reduce risk 'as low as reasonably practicable' (ALARP).

- ACOPs. These may help to overcome some of the above, whilst still allowing scope for alternative, equally good, ways of controlling hazards and reducing risks. They would be considered particularly effective if:
  - there is rapidly developing technology offering new ways of achieving good practice;
  - there is high diversity of circumstance best dealt with by allowing different approaches;
  - the industry is highly organised, homogeneous and capable of a fair degree of self-regulation;
  - the ACOP can be used, in effect, to define reasonable practicability (or other legal standard, as appropriate) and hence prevent over-response by industry, over-enthusiasm by enforcers and over-selling by intermediaries – and the converse (under-response etc).

- But an ACOP is likely to be regarded as insufficient if:
  - the hazard requires an absolute and/or prescribed duty to deal with it;
  - EC Directives (or International Conventions) allow no alternative approaches;
  - there is not a sufficiently strong statutory 'peg' on which to hang requirements in an ACOP (since ACOPs are not to be used to introduce higher duties by the back door);
  - the need to address societal concerns requires more.

- goal-setting regulations. These may help to amplify general duties in ways which overcome most of the above. But these may still be insufficient if:
  - EC Directives (or International Conventions) require specificity or prescription;
  - HSC has decided that adequate control of the risk from a particular hazard requires that specific standards have to be met;
  - a 'level playing field' requires duty holders to do the same thing as well as to achieve the same results;
  - uncertainty needs to be reduced to the minimum (including allowing minimum discretion to the regulator);
  - the need to address societal concerns requires more, such as the introduction of process regulations.

- specific or prescriptive regulations. These may be justified to:
  - deal with manifest hazards and/or those hazards entailing high risks or societal concerns;
  - deal with new hazards so as to ensure consistency of action;
  - secure a step-change in behaviour in known areas of bad practice (including changes that will reduce the 'spread' of performance and bring bad performers up to generally acceptable levels);

- define and eliminate uncertainty by providing a generic assessment of risk and a suitable response which can help cut costs;
- secure standardisation and fair competition;
- meet the requirements of EC Directives (or International Conventions);
- allay worker and public concern by transparent measures and accountability;
- cut down duty holders and/or inspectorial discretion;
- ban a specific activity or process in line with the criteria adopted for stage four of the decision-making process.

9 If specific or prescriptive legislation needs to be introduced then process regulations will generally be used as a last resort because they tend to be resource intensive. Nevertheless, this course of action will be adopted if process regulations are found to be the best way of ensuring that adequate measures are put in place for controlling the particular hazard under consideration. Such regulations could require (in ascending order of stringency) the notification of the hazard; the drawing up of safety cases for demonstrating that the risks from the hazard are adequately controlled; or establishing a licensing system that stipulates specific conditions for ensuring health and safety.

Appendix 3

Some issues relevant to assessing risk reduction options

1 When deciding how to regulate hazards and their concomitant risks, HSE can consider a broader range of factors than those which the HSW Act and its relevant statutory provisions require duty-holders to take into account when they manage risks at work (see paragraphs 80-95). However, HSE must operate within the framework provided by the HSW Act and the existing case law – it cannot propose a regulatory regime which places requirements on duty-holders to reduce risks at work which does not fit within this legal framework. The framework though is very wide.

2 The enabling powers of the Act to make regulations (section 15) and the subject matter that may be covered in regulations (see Schedule 3) are very broad in scope. Health and safety legislation made under the Act may be absolute or qualified by expressions such as 'practicable' or 'reasonable practicability'. The latter expressions provide duty holders with a defence against a duty. They are therefore used for instances where HSC/E would like duty holders to have such a defence, for example when the lack of the qualification would result in bad law by imposing duties that cannot be fulfilled because absolute safety cannot be guaranteed. Paragraphs 3-9 are a discussion of the implications of case law when regulating through the imposition of duties qualified by the concept of 'reasonable practicability'. Paragraphs 10-22 discuss the factors taken into account by HSE when comparing risks and costs in the context of undertaking a cost benefit analysis before regulating.

Implications of case law on 'reasonable practicability'

3 Because, ultimately, it is a matter for the courts to decide whether or not duty-holders have complied with such duties, considerable attention must be paid to how the courts have interpreted the above qualification. Case law on duties qualified by 'so far as is reasonably practicable' (SFAIRP) makes it clear that the courts will look at all relevant circumstances, on a case by case basis, when reaching decisions on the appropriateness of action taken by duty-holders in meeting this qualification.

4 Of particular importance in the interpretation of SFAIRP is *Edwards v. The National Coal Board (1949)*.[40] This case established that a computation must be made in which the quantum of risk is placed on one scale and the sacrifice, whether in money, time or trouble, involved in the measures necessary to avert the risk is placed in the other; and that, if it be shown that there is a gross disproportion between them, the risk being insignificant in relation to the sacrifice, the person upon whom the duty is laid discharges the burden of proving that compliance was not reasonably practicable.

5 In seeking to apply this case law, when regulating or producing guidance on compliance with duties qualified by all injunctions embodying the concept of 'reasonable practicability' such as SFAIRP, ALARP (as low as reasonably practicable), ALARA (as low as reasonably achievable), HSE believes that such duties have not been complied with if the regime introduced by duty holders to control risks fails the above 'gross disproportion' test. Moreover, HSE believes that in making this compliance assessment, the starting point for determining whether risk has been reduced as low as reasonably practicable, should be the present situation in the duty holder's undertaking. However, in certain circumstances, it will not be possible to assess options in this way. In such situations, the starting point should be an option which is known to be reasonably practicable (such as one which represents existing good practice). Any other options should be considered against that starting point, to determine whether further risk reduction measures are reasonably practicable.

Risks taken into account in regulating

6 HSE would not normally impose duties on duty-holders which required them to consider risks other than those which:

- arise out of reasonably foreseeable events and behaviour. For example, the risk of a well designed, properly built and well maintained building collapsing would not be regarded as a reasonably foreseeable event (unless signs such as subsidence, cracked walls or falling roof tiles suggest otherwise). This is because the risks were considered and taken care of by the building designers, contractors and maintenance engineers and the building is unlikely to collapse unless it is affected by an external event such as a severe earthquake, itself very unlikely. In contrast, the risk of a building collapse during its demolition would be regarded as reasonably foreseeable. However, in some circumstances, we would consider very unlikely risks (ie 'foreseeable' but not 'reasonably foreseeable') because of the extent of the consequences should those risks be realised. For example, it would be proper to consider the effects of a severe earthquake in the case of major hazard industries because it could trigger an even greater catastrophic event;

- are under the control of the duty-holder. This is in line with the regulatory structure provided by the HSW Act, which for example requires employers to ensure the health and safety of their employees and members of the public who may be affected by the conduct of the employers' undertakings. When determining what is reasonably practicable, HSE will take into account that the risks which an employer needs to consider are limited to those present in the conduct of his undertaking and which he is in a position to eliminate or control.
  ✦ For example, a railway operator would not need to consider whether increasing their fares would put more people at greater or less risk overall because they suspect that some people might be inclined to choose to travel by inherently less safe modes of transport (eg using their own motor cars). What determines such choices is very complex and depends on many elements. Though the operators might be able to control one of those elements (the price of their fares), they have no way of

controlling the other elements. Nor for the same reasons would they in practice be able to reach a view on the impact of their proposed fare increases on the level of risk overall. On the other hand it would be quite proper for Government (as opposed to HSC/E) to consider such matters;

- are not trivial or arising from routine activities associated with life in general, unless the work activity compounds those risks, or there is evidence of significant relevance to the particular work activity.

7 In regulating and assessing risks, HSC/E considers both individual risks and societal concerns, including societal risks. Therefore, where hazards give rise to societal concerns, HSC/E may require duty holders to take these into account. Duty holders action on societal concern is limited to instituting the measures set out by HSC/E in the control regimes which are required by regulations enacted to address the hazard concerned, and in associated guidance.

8 Within these constraints, HSE when regulating attaches great importance to risks being assessed in an integrated manner as described at Appendix 1, paragraph 7. Here again, HSE's approach in deciding the control regime that duty holders should adopt would initially be to require the introduction of generic control measures to eliminate or control the risk for the full range of hypothetical persons identified at the risk assessment stage. However, if these are not sufficient to control the risk, HSE will consider whether it is appropriate to require control measures specifically tailored for risks which may occur at particular locations or in a slice of time, or for particular groups.

9 If, due to unusual circumstances, some actual persons exposed to the risks fall outside the profile adopted for the hypothetical person(s) used for assessing the risks (see Appendix 1, paragraphs 3-8), then HSE will expect that the control measures adopted for protecting the hypothetical person(s) are modified by the duty holder to ensure that the actual persons are protected. For example, control measures may need to be adapted to cater for people with disabilities such as colour blindness, if the need to distinguish between colours is a health and safety requirement, or if the employees lack a particular skill that the hypothetical person is assumed to have, such as the ability to read or understand instructions.

Use of cost benefit analysis in the decision-making process

10 As discussed in paragraphs 101-108 cost benefit analysis (CBA) offers a framework, widely used in Government, for comparing the benefits of reducing risks against the costs incurred for a particular option for managing risks. HSE uses CBA to informs its decisions when regulating and managing risks. It does this by expressing all relevant costs and benefits in a common currency – usually money. It is normally undertaken for options falling within the tolerable region in Figure 1. In practice, a CBA cannot be done without the adoption of certain technical conventions. Those used generally by Government have been published in guidance from HM Treasury.[41]

11 The Treasury rules are meant to cater for a wide range of circumstances and as such are inevitably broad brush. We examine below in more detail (but still in general terms) the policy rules that we consider particularly relevant for assessing the relationship between the cost and benefits of occupational health and safety measures.

Valuation of benefits

12 A suitable and sufficient assessment of cost and risk can often be done without the explicit valuation of the benefits, on the basis of common sense judgements while, in other situations, the benefits of reducing risk will need to be valued explicitly. The latter is far from easy because the health and safety of people and their societal concerns are not things that are bought and sold, and yet a monetary value has to be attributed to matters such as the prevention of death, personal injury, pain, grief and suffering.

13 Where the benefit is the prevention of death, the current convention used by HSE, when conducting a CBA is to adopt a benchmark value of about £1 000 000 (2001 prices) for the value of preventing a fatality (VPF).* This is the VPF adopted by the Department of Transport, Local Government and the Regions for the appraisal of road safety measures. It may well be the case that individuals' willingness to pay for risk reduction – measured in aggregate by the VPF – will vary, depending on the particular hazardous situation. Thus, the particular hazard context will need to be borne in mind when a VPF figure is adopted. Currently, HSE takes the view that it is only in the case where death is caused by cancer that people are prepared to pay a premium for the benefit of preventing a fatality and has accordingly adopted a VPF twice that of the roads benchmark figure. Research is planned to assess the validity of this approach.

* VPF is often misunderstood to mean that a value is being placed on a life. This is not the case. It is simply another way of saying what people are prepared to pay to secure a certain averaged risk reduction. A VPF of £1 000 000 corresponds to a reduction in risk of one in a hundred thousand being worth about £10 to an average individual. VPF therefore, is not to be confused with the value society, or the courts, might put on the life of a real person or the compensation appropriate to its loss.

14 Moreover, it is also important to note that when HSC/E regulate, VPF is not the only factor in balancing costs against risks since a CBA informs, but does not determine, the decisions on measures that should be adopted to control the risk. As already explained, the final decision may take into account wider political and equity considerations as to whether costs are grossly disproportionate to benefits.

15 Once a decision has been adopted on the control regime that should be introduced to control the risk, the cost of the measures required can be assessed to derive a value for the 'cost of preventing a fatality' (CPF), by dividing the total final cost by the (putative) total fatalities prevented. Comparison of CPF with VPF may well reveal a difference between the two values.

Discounting of costs and benefits

16 When preparing formal CBAs, it is customary to discount future costs and benefits to reflect the fact that people, on balance, prefer to have benefits now and pay for them later. Thus they value a benefit in the present more highly than the same benefit received some

time in the future. Similarly, a health and safety measure paid for in the present is considered more costly than if it is paid for at some future date. Conventional economic theory is that such preferences are reflected in the rate of interest paid by borrowers or to savers for capital.

17 For most public policy applications, a real rate of return of 6% a year is used currently to discount costs and benefits. This assumes that all monetary costs and benefits are expressed in real terms (constant prices). The value that individuals place on safety benefits tends to increase as living standards improve, so the future values applied to such benefits should be uprated to allow for the impact on well-being of expected growth in average real income. On the basis of past trends and Treasury guidance, HSE regards an uprating factor of 4% a year as appropriate on the benefits side of the comparison.

18 However, when costs and benefits accrue far into the future, the assumptions underlying these discounting conventions may need to be re-examined. Special considerations may be needed for specific cases.

Costs taken into account in regulating

19 HSE adopts the following principles when it make judgements about costs in assessing possible regulatory options:

- the costs to be considered are those which are incurred unavoidably by duty-holders as a result of instituting a health and safety measure. In other words the costs that should be considered are only those which are necessary and sufficient to implement the measures to reduce risk. Where duty holders incur additional costs for other reasons, these should not be counted. So, for example, extra costs incurred by the duty holders adopting 'deluxe' measures where 'standard' ones would serve just as well should be excluded;

- for any particular measure, it will be proper to include the cost of installation, operation, maintenance and the costs due to any consequent productivity losses resulting directly from the introduction of the measure. In general, these should be estimated on the basis of the value of the economic resources involved. This will usually be the same as the financial costs to the duty-holder, but there may be cases where alternative estimation procedures are necessary.

- monetary gains accrued from the introduction of a health and safety measure should be offset against the costs. This is because measures for managing risk often have the effect of reducing costs. Typical examples are the reduction of losses (eg damage to property, lost production) resulting from decrease in accidents or incidence of ill health, and savings made from any productivity gains resulting directly from the introduction of the measure. However, costs should be offset only against those productivity savings which can actually be realised, ie unit cost reductions. The following should not be offset:
  - potential savings/gains, which may depend upon the state of the market, such as

the profits which would result from selling on the increased production made possible through improved productivity;

- gains which would accrue from an improved commercial reputation;
- indirect savings such as those resulting from reduced insurance premiums* or civil damages.
- the ability of the duty holder to afford a control measure is not a legitimate factor in the assessment of costs. This ensures that duty holders are presented with a level playing field.

* In some cases, insurance companies may link reduced premiums directly with the introduction of health and safety measures, in which case the reduction should be used to offset costs.

Comparison of risk against costs

20 In comparing cost against risks HSE, when regulating, will be governed by the principles that:

- there should be a transparent bias on the side of health and safety. For duty holders, the test of 'gross disproportion' implies that, at least, there is a need to err on the side of safety in the computation of health and safety costs and benefits. HSE adopts the same approach when comparing costs and benefits and moreover, the extent of the bias (ie the relationship between action and risk) has to be argued in the light of all the circumstances applying to the case and the precautionary approach that these circumstances warrant (see paragraphs 89-94);

- whenever possible, standards, should be improved or at least maintained.

21 In practice, as noted in paragraphs 140-141, HSE when regulating will consider that normally risk reduction action can be taken using good practice as a baseline – the working assumption being that the appropriate balance between costs and risks was struck when the good practice was formally adopted and the good practice then adopted is not out of date. However, there will be cases where some form of computation between costs and risks will form part of the decision-making process. Typical examples include major investments in safety measures where good practice is not established.

22 Moreover, HSE may decide that certain hazards would be best regulated through a safety case regime requiring an explicit demonstration in the safety case that control measures introduced conform with the ALARP principle. Though HSE expects that this requirement can often be met by just showing that the control measures adopted represent good practice there will, nevertheless, be certain occasions where HSE will expect duty holders to show (not necessarily by a full cost benefit analysis) the comparisons made between the costs of introducing particular options and the risk reduction thereby achieved.

Appendix 4

Some statistics for comparing risks from different hazards

1 Comparing the degree and probability of the various risks we run is not an easy task. Different kinds of risks have to be compared in different ways. Some kinds of risk, such as being killed by lightning or in a road accident or by some other violent cause, are borne by large numbers of people or even by all of us all the time, so it is reasonable to give the chance per million per annum, even though some of us would have a better chance than others.

2 However, some kinds of risk need to be compared in a way that takes account of the extent to which the risk is being run. For example, to compare the risks of death from travelling by air, road or rail we need to express it as a proportion of the number of kilometres or the number of journeys travelled.

3 Estimating the annual chance of certain major events occurring also presents difficulties. In Great Britain, estimates of this kind can sometimes be based on direct or historical experience. We know for example how many major fires occur each year and we can expect the same trend to continue, more or less. Sometimes, however, these estimates represent no more than a complex set of expert judgements based on a variety of factors such as the known rate of failure of engineering components. Some others, such as estimating the chance of an aircraft crash represent a scaling down of world experience. As a result, all of them are subject to large margins of error, particularly in translating the probability of accidents occurring in developing countries to more industrialised ones. Moreover, some statistics will be overstated, eg those that depend on engineering judgement because of the caution and pessimism that it is customary to build into such estimates. Others will be understated because, for many hazards, they compare only the chance of immediate death, ignoring that the hazards also carry with them a risk of injury or ill health or of delayed death.

4 Notwithstanding these important reservations, the tables below give some idea of how the different risks we run compare with each other in size and probability.

Examples of large numbers taken from everyday life

- 2 litre bottles of water in a 3 metre-deep, 50 by 20 metre swimming pool (1 500 000).
- Grains in a 500 gram bag of sugar (1 000 000).
- Teaspoons (5 millilitres) of water in a standard bath (0.5 cubic meters) (100 000).

Examples of low probability taken from everyday life

- The probability that the temperature below 500 metres in Great Britain will fall below a certain minimum value in a certain month, based on measurements from 1875 to 1990 (Tornado and Storm Research Organisation, 1996). For example:
  - On any day in September, a minimum temperature of -6 C or lower has occurred on a total of five occasions in five separate years (1942, 1948, 1974, 1975, and 1979), representing an annual probability of 1 in 23.

- The probability of a high-scoring draw at a football match. The statistics reported below are based on data from 10,148 matches from all English League Divisions, for the four seasons in the period 1990-95.
  - A 3-3 draw occurred 118 times, representing a probability of about 1 in 100.
  - A 4-4 draw occurred 11 times, representing a probability of about 1 in 1 000.
  - A 5-5 draw occurred only once, representing a probability of about 1 in 10 000.

- The probability of winning the National Lottery is reported by Camelot in terms of a single lottery ticket matching the main numbers and/or the bonus ball:
  - Match 6 of 6 main numbers (winning the jackpot): 1 in 14 000 000.
  - Match 5 of 6 main numbers and the bonus ball: 1 in 2 300 000.

Average annual risk of death/injury from various causes:

Table 1: Annual risk of death for various United Kingdom age groups based on deaths in 1999 (Annual Abstract of Statistics, 2001/Health Statistics Quarterly – Summer 2001).

Population group	Risk as annual experience	Risk as annual experience per million
Entire population	1 in 97	10 309
Men aged 65-74	1 in 36	27 777
Women aged 65-74	1 in 51	19 607
Men aged 35-44	1 in 637	1 569
Women aged 35-44	1 in 988	1 012
Boys aged 5-14	1 in 6 907	145
Girls aged 5-14	1 in 8 696	115

Table 2: Annual risk of death for various causes averaged over the entire population.

Cause of death	Annual risk	Basis of risk and source
Cancer	1 in 387	England and Wales 1999 (1)
Injury and poisoning	1 in 3 137	UK 1999 (1)
All types of accidents and all other external causes	1 in 4 064	UK 1999 (1)
All forms of road accident	1 in 16 800	UK 1999 (1)
Lung cancer caused by radon in dwellings	1 in 29 000	England 1996 (2)
Gas incident (fire, explosion or carbon monoxide poisoning)	1 in 1 510 000	GB 1994/95-1998/99 (3)
Lightning	1 in 18 700 000	England and Wales 1995-99(4)

(1) Annual Abstracts of Statistics (2001)
(2) National Radiological Protection Board (1996)
(3) Health and Safety Executive (2000)
(4) Office of National Statistics (2001)

Table 3: Annual risk of death from industrial accidents to employees for various industry sectors (Health and Safety Commission, 2001).

Industry sector	Annual risk	Annual risk per million	Basis of risk and source
Fatalities to employees	1 in 125 000	8	GB 1996/97 to 2000/01*
Fatalities to the self-employed	1 in 50 000	20	GB 1996/97 to 2000/01*
Mining and quarrying of energy producing materials	1 in 9 200	109	GB 1996/97 to 2000/01*
Construction	1 in 17 000	59	GB 1996/97 to 2000/01*
Extractive and utility supply industries	1 in 20 000	50	GB 1996/97 to 2000/01*
Agriculture, hunting, forestry and fishing (not sea fishing)	1 in 17 200	58	GB 1996/97 to 2000/01*
Manufacture of basic metals and fabricated metal products	1 in 34 000	29	GB 1996/97 to 2000/01*
Manufacturing industry	1 in 77 000	13	GB 1996/97 to 2000/01*
Manufacture of electrical and optical equipment	1 in 500 000	2	GB 1996/97 to 2000/01*
Service industry	1 in 333 000	3	GB 1996/97 to 2000/01*

**Health and Safety Commission, Health & Safety Statistics (1996/97, 1997/98, 1998/99 & 1999/2000) published by HSE Books. Figures used for 2000/2001 are provisional.*

Table 4: Average annual risk of injury as a consequence of an activity.

Type of accident	Risk	Basis of risk and source
Fairground accidents	1 in 2 326 000 rides	UK 1996/7-1999/00 (1)
Road accidents	1 in 1 432 000 kilometres travelled	GB 1995/99 (2)
Rail travel accidents	1 in 1 533 000 passenger journeys	GB 1996/97-1999/00 (3)
Burn or scald in the home	1 in 610	UK 1995-99 (4)

(1) Tilson and Butler (2001)
(2) Department of Environment, Transport and the Regions – Transport Statistics (2000)
(3) Health and Safety Executive (2001)
(4) Department of Trade and Industry and Office of National Statistics (2001)

Table 5: Average annual risk of death as a consequence of an activity.

Activity associated with death	Risk	Basis of risk and source
Maternal death in pregnancy (direct or indirect causes)	1 in 8 200 maternities	UK 1994-96 (1)
Surgical anaesthesia	1 in 185 000 operations	GB 1987 (2)
Scuba diving	1 in 200 000 dives	UK 2000/01 (3)
Fairground rides	1 in 834 000 000 rides	UK 1989/90-2000/01 (4)
Rock climbing	1 in 320 000 climbs	England and Wales 1995-2000 (5)
Canoeing	1 in 750 000 outings	UK 1996-99 (6)
Hang-gliding	1 in 116 000 flights	England and Wales 1997-2000 (7)
Rail travel accidents	1 in 43 000 000 passenger journeys	GB 1996/97-1999/00 (8)
Aircraft accidents	1 in 125 000 000 passenger journeys	UK 1991-2000 (9)

(1) NHS Executive (1998)
(2) Lunn and Devlin (1987)
(3) Based on assumption of 3 million dives per year. British Sub-Aqua Club (2001)
(4) Based on estimated 1 billion rides per year. Tilson and Butler (2001)
(5) Based on the assumption that there is a total of 45,000 climbers making an average of 20 climbs per year each. Mountain Rescue Council (2001)
(6) Based on the assumption that there are 100,000 whitewater canoeists making an average of 30 outings per year each. Drownings in the UK, RoSPA (1999)
(7) Based on the assumption that each member makes an average of 50 flights per year. British Hang-gliding and Paragliding Association (2001)
(8) Health and Safety Executive (2001)
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While every effort has been made to ensure the accuracy of the references listed in this publication, their future availability cannot be guaranteed

Glossary of acronyms

ACOP	Approved Code of Practice
ACTS	Advisory Committee on Toxic Substances
ALARA	As Low as Reasonably Achievable
ALARP	As Low as Reasonably Practicable
CBA	Cost Benefit Analysis
CD	Consultative Document
CEN	Comité Européen de Normalisation
CENELEC	Comité Européen de Normalisation Electrotechnique
CLAW	Control of Lead at Work Regulations
COSHH	Control of Substances Hazardous to Health Regulations
CPF	Cost of Preventing a Fatality
EC	European Communities
EU	European Union
HSC	Health and Safety Commission
HSE	Health and Safety Executive
the HSW Act	The Health and Safety at Work etc Act
ICRP	International Commission on Radiological Protection
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
MEL	Maximum Exposure Limit
MHSWR	Management of Health and Safety at Work Regulations
NOAEL	No Observed Adverse Effect Level
OEL	Occupational Exposure Limit
OES	Occupational Exposure Standard
QRA	Quantitative Risk Assessment
RBMK	Reactor Bolshoi Mozjnoct Kanali
SFAIRP	So Far as is Reasonably Practicable
TOR	Tolerability of Risk
VPF	Value for Preventing a Fatality
WATCH	Working Group on the Assessment of Toxic Chemicals

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(Figures in italics refer to boxed examples)

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