



Reducing Risks, Protecting People

The Health and Safety Executive hopes that publication of this paper will stimulate consideration and discussion of the issues raised.

Any responses to the document would be welcome and should be sent to:

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to reach him not later than 15 December 1999

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DISCUSSION
DOCUMENT

TABLE OF CONTENTS

	Page
Table of contents	i-ii
Preface	iii-vi
Foreword	vii-viii
Glossary of acronyms	ix
EXECUTIVE SUMMARY	1
PART 1 : OVERVIEW OF RISK AND RISK MANAGEMENT ISSUES	5
Why the need to explain decisions on the management of risk?	5
PART 2 : REVIEW OF DEVELOPMENTS THAT HAVE INFLUENCED OUR DECISION-MAKING APPROACH	9
Developments and influences	9
Advances in knowledge on how people view risks	9
Changes in the regulatory environment	12
The internationalisation of regulation	13
Increasing complexity in the regulation of risk	13
Clarification by the Courts on the meaning of hazard	15
Changes on the industrial scene	17
Changes in patterns of employment	17
Polarisation of approaches between large and small firms	17
Changes in the preferences, values and expectations of society	18
A growing perception that risks imposed on people should be justified	19
Increasing reliance by the public on regulators that they trust	19
Calls for greater openness and involvement in the decision-making process	20
PART 3 - APPROACH TO REACHING DECISIONS ON RISK	22
System for informing and reaching decisions	22
Stage 1 - Deciding whether the issue is one for HSC/E	23
Stage 2 - Defining and characterising the issue	25
Defining the issue	25
Characterising the issue in terms of risk	26
Handling Uncertainty	28
Stage 3 - Examining the options available and their merits	32
Identifying options	32
Assessment of Risk Reduction Action	35
Stage 4 - Adopting decisions	37
Stage 5 - Implementing the decisions	39
Stage 6 - Evaluating the effectiveness of action taken	40

Criteria for reaching decisions	41
Tolerability Limits	46
Boundary between the 'broadly acceptable' and 'tolerable' regions for risks entailing fatalities	46
Boundary between the 'tolerable' and 'unacceptable' regions for risk entailing fatalities	48
Risks giving rise to societal concerns	48
Applying the (generalised) TOR framework	52
ANNEX 1 : Some of the conventions adopted for undertaking risk assessments	56
Actual and hypothetical persons	56
Standards	57
Procedures for handling uncertainty	57
ANNEX 2 : Identifying and considering options for new regulations, Approved Codes of Practice and guidance	61
Architecture of health and safety law	61
Constraints	63
Hierarchy of options	63
ANNEX 3 : Some issues relevant to assessing risk reduction options	67
Implications of case law on 'reasonable practicability'	67
Risks to be taken into account	68
Ensuring consistency when comparing costs against benefits	69
Valuation of benefits	70
Costs to be taken into account	70
Discounting of costs and benefits	72
Comparison of risk against costs	73
ANNEX 4 : Some statistics for comparing risks from different hazards	76
Examples of large numbers taken from everyday life:	77
Examples of low probability taken from everyday life:	77
Average annual risk of death from various causes:	78

PREFACE

The need for public explanation of the basis for decisions about the regulation of risks now arises in wide areas of public policy-making. In former times, the issue hardly ever featured, at least outside the circle of technical specialists. Activities were, by implication or assertion, either safe or they were not. Indeed, that belief still features largely in the public imagination. Yet the conduct of human affairs does not divide into such black and white terms. The very word 'risk' itself denies it, implying that there are degrees of safety. And we all realise intuitively that the safety we seek must in some way be balanced against the benefits we forgo. We have our own individual needs as we perceive them for peace of mind and body. Society may wish in addition to ensure the regulation of risks that offend against society's collective sense of equity and fairness. Such offence is manifested for example in the public reaction to multiple fatality accidents or wide-ranging impacts on health.

For long, the priority of society was for the basic wants of life. Government legislated to avoid the excesses of harm from industrial activity, making its own judgements about which risks prevailing social attitudes would not tolerate. Greater prosperity and improved standards of living are now accompanied, perhaps not surprisingly, by greater public demand for healthier workplaces, a cleaner environment, better housing, safer food and commercial products. The end result is an apparent aspiration for a society free of involuntary risks, underpinned by a belief that the state has a duty to insulate people from harm. There is in consequence an increasing demand for explanation of how it is intended to protect against harm, both in general and in particular circumstances. Furthermore, there is an expectation that this explanation should be transparent and comprehensible so that the public can play its part, if it chooses to do so, in influencing the decisions.

This social pressure for explanation of and involvement in the basis of decisions about health and safety was a central influence on the Robens Committee of 1972. Their recommendations responded to that pressure, particularly those relating to representation of the different interests at the highest level of decision-making, to consultation with stakeholders and to the engagement of safety representatives and safety committees at the level of the workplace. But a very direct impetus for explanation was provided by the 1986 report of the Public Inquiry into the

Sizewell B Nuclear Power Station. The Inquiry Inspector, Sir Frank Layfield, asked that HSE should 'formulate and publish guidelines on the tolerable levels of individual and societal risk to workers and the public from nuclear stations.' As a result, HSE published in 1988 the document 'The Tolerability of Risk from Nuclear Power Stations.' The document set out a framework, which has since become known as the Tolerability of Risk or TOR framework, which describes HSE's philosophy of risk control for nuclear power stations. The philosophy specifically addressed in that context the need to advance from the division that things were either safe or not safe. The document was reissued in 1992 following public consultation, and the underlying philosophy has since gained considerable acceptance by other regulators and industry as having wider applicability beyond nuclear power. In particular, the argument is now widely accepted that a properly informed balancing act between risks and benefits is of central importance to decisions on the levels of risk that are tolerable. The word 'tolerable' acquired a particular meaning, in effect opening up a gap between absolutely safe and unsafe, with tolerable risks ('safe enough') occupying the range in between.

The balancing act has long been recognised in the law relating to health and safety at work. Indeed, the balancing act is applied at a fundamental level in that the law imposes a general duty that health and safety should be secured at all times, subject only to the qualification that measures should be adopted 'so far as is reasonably practicable.' Hence the general duties focus on health and safety, with no discrimination by level of hazard or risk. There is thus a requirement on the regulator to ensure that the health and safety of an activity is considered in a wide context. In many instances, the risks from an activity can be controlled by suitable measures to reduce the chance of harm to sufficiently low levels or, in other words, to reduce the risks 'as low as reasonably practicable' so that desirable activity can be undertaken in the absence of absolute assurance of safety which would be incompatible with continuation of the activity. In other instances, the activity may be so inherently and transparently unsafe that it cannot be allowed irrespective of whatever risk might be estimated. And yet other activities may not be admissible because, though sharing of the exposure to harm between many different individual may result in a low chance of harm to any one individual, other factors such as societal concerns are present which result in society regarding the activities as unacceptable and so not to be entertained. What the TOR document did was to expose to scrutiny the way that

the balancing act is applied by the regulator in the particular area of nuclear power generation. It relied on quantitative methods and this fitted naturally into a scheme pertaining to risks from nuclear power generation and similar activities where there is considerable available data on the nature of the hazards present and the risks that they entail. For some other areas, the approach adopted for nuclear power is directly applicable. But there is a wide range of harms where there is not enough data to use the quantitative methods used in TOR but where further explanation, adaptation and extension of the same basic philosophy is needed. This document seeks to fulfil that purpose by explaining tolerability in terms appropriate to the particular characteristics of the harm from which it is intended to protect people.

The description that follows is holistic and embraces the full spectrum of harms controlled by health and safety regulation. As with the earlier TOR document, the present one is being issued as a discussion document. It is aimed primarily at interested participants in the occupational health and safety arena. It focuses on the approach of the regulator (HSE) to the structuring of advice on policy to the Health and Safety Commission (HSC) and to the subsequent implementation of policy when decided by HSC following public consultation and Parliamentary/Ministerial approval. The document sets out the basis and criteria for decisions on control measures, 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 against its disadvantages. The HSC fully supports the publication of this document for discussion.

Advice to the Commission and the regulatory approach operate against the background that the Act is intended to maintain or improve standards of health and safety. Progress in good practice and technology means that we are able to use the SFAIRP principle to improve progressively health and safety standards - to 'go the extra mile for safety' as Stan Robertson, Chief Inspector of Railways, said in his 1997 Annual Report. In view of its broad applicability, the exposition will also appeal to anyone interested in the regulation of risk in general. So far as possible the text is kept clear of technical detail; such detail as is necessary is given in annexes or obtainable in cited references.

Throughout our history of consulting and negotiating with stakeholders we have been very conscious that we do not have a monopoly of wisdom on health and safety matters. We rely heavily on comments received to get things right and we look forward to receiving your views.

Jenny Bacon
Director General
Health and Safety Executive.

FOREWORD

We are very conscious that our decisions can have widespread reverberations through society and that to gain the trust of the public and acceptance of our decisions, what we do must reflect society's values at large. We believe that this can only happen if we are open - as we try to be throughout this discussion document - about what HSE does (or should do) in undertaking its regulatory functions for ensuring consistency and coherence in its approach.

The compilation of this explanatory document has therefore necessarily been an internal matter. It was prepared under the auspices of an HSE internal working group representative of all the policy and operations functions of HSE. The drafting of the document has largely been undertaken by Dr Jean Le Guen, Head of HSE's Risk Assessment Policy Unit.

This document builds on a previously published document¹ (known as the TOR document) which set out HSE's philosophy for deciding the degree to which risks should be controlled in the nuclear power generation industry. The TOR document was first published in 1988 and revised in 1992. It provides a framework, now well established in the regulation of the nuclear industry, that helps to decide which risks are unacceptable, tolerable or broadly acceptable. But it is also being increasingly used in other sectors to decide on the degree to which risk should be controlled - a move prompted by a number of relatively recent legislative changes.

The quantitative methods described in the TOR document were particularly appropriate for the nuclear industry by providing a useful input to the informed dialogue between the regulator and the regulated that is central to the self-regulatory approach. However, it is often not appreciated that the TOR philosophy in its essentials - namely that risks can be classified as unacceptable, tolerable or broadly acceptable - is applicable across the full range of risks whether they are quantifiable or not. This discussion document is meant to fill this gap by setting out a generalised application of the philosophy.

We would welcome views on the principles, processes, protocols and criteria described in this discussion document, and would like to hear in particular:

- i) of examples which would seem to show that the framework for reaching decisions does not apply and, if so, what changes would be necessary for universal applicability;
- ii) of areas where the framework does apply but the criteria adopted on the tolerability of risk would cause difficulties and, if so, the nature of these difficulties and how they can be addressed;

¹ Health and Safety Executive, "The Tolerability of Risk from Nuclear Power Stations", 1988, (revised 1992), HMSO, London; ISBN 011 886368 1.

- iii) whether the use of good practice has been given the right emphasis in the decision making process;
- iv) whether the principles for assessing risk reduction options and conducting cost benefit analysis described at Annex 3 achieve the right balance between costs and risks. If not, how could the principles be amended?
- v) we would also like to have your views how (in the following order: very well, well, not well, poorly) you would rate this document in explaining the issues it addresses;
- vi) if you answered ‘not well’ or ‘poorly’ in (v) above, we would like to hear your suggestions how things might be improved for the future.

Please send your comments to Dr Jean Le Guen at the address on the front cover.

Dr J McQuaid
Chief Scientist, and
Director, Science and Technology Directorate,
Health and Safety Executive.

GLOSSARY OF ACRONYMS

ACoP	Approved Code of Practice
ACTS	Advisory Committee on Toxic Substances
ALARA	As Low as is Reasonably Achievable
ALARP	As Low as is 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
EC	European Commission
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HSW	Health and Safety at Work
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
SFAIRP	So Far as is Reasonably Practicable
TOR	Tolerability of Risk
WATCH	Working Group on the Assessment of Toxic Chemicals

EXECUTIVE SUMMARY

This document describes the decision-making process that we adopt and the factors that influence our decisions on what risks are unacceptable, tolerable or negligible and test the soundness of our approach.

It is in three parts and has four annexes as follows:

Part 1: i) Sets out the aims of the document, namely the need to:

- open to scrutiny HSE's approach to the management and regulation of risk and the philosophy underpinning it;
- make transparent the factors that inform our decisions on risks, 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 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 industry, in taking advantage of technological advances, will not be allowed to impose unnecessary risks on people;
- let other regulators, whose responsibilities may overlap with those of HSC/E, know the basis for the management of occupational health and safety risks and thereby help to promote consistency of decision-making amongst regulators.

ii) 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.

iii) Introduces the concept of tolerability which is central to the document. This concept refers to a willingness 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. As such, a 'tolerable' risk is not therefore necessarily one that will be judged to be 'acceptable' by those taking it.

iv) 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:** i) Reviews some of the developments that have influenced our approach to decision-making since the recommendations of Robens were incorporated in the HSW Act. 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.
- ii) 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 are accountable when things go wrong, but without resorting to unfair retribution.
- iii) Notes some of the above developments which have been particularly important, in particular:
- the need for the meaning of ‘risk’ to encompass more than physical harm by taking into account other factors such ethical and social considerations;
 - the ruling by the Courts on the meaning of ‘hazard’ which implies that approaches for managing risks must ensure that hazards present are properly addressed.

- Part 3:** i) Describes the six stage iterative system adopted for reaching decisions, 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, 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.
- ii) Sets out the framework, known as the Tolerability of Risk (TOR), for reaching decisions on whether risks from an activity or process are unacceptable, tolerable or broadly acceptable and their application in practice. In this context, tolerable does not mean acceptable. It refers instead to a willingness 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. 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**;
 - HSE starts with the expectation **that suitable controls must be in place to address all significant hazards** and that those controls, at a minimum, must implement authoritative good practice precautions **irrespective of situation-based risk estimates**;
 - where there is no reliable base of good practice for ensuring that risks are adequately controlled, it will be necessary to go through a risk assessment and evaluation process for deciding the degree to which the risks should be controlled;
 - that there are some risks from certain activities, processes or practice which are not tolerable whatever the benefits, ie 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 to such a degree 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;

- HSE has proposed numerical criteria for informing decisions on the tolerability of risks only for a very limited category of risk, namely those entailing fatalities either individually or in multiple fatality accidents.

Annex 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.

Annex 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 procedure adopted for identifying the hierarchy of options for new regulatory measures.

Annex 3: Examines some issues relevant to assessing risk reduction options, including:

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

Annex 4: Gives some statistics for comparing risks from different hazards.

PART 1 : OVERVIEW OF RISK AND RISK MANAGEMENT ISSUES

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

1 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 all too frequently, the trend averaged over the years has been markedly downwards.

2 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 who create risks should be made responsible for ensuring that adequate measures are in place to protect people and the things they value from harmful consequences that may arise from such risks;
- the State should be proactive in protecting people from risks as distinct from reacting to events.

3 Such expectations are counterbalanced in a free market economy by an underlying presumption that industry should be able to take advantage of new technologies, unfettered by State intervention as far as possible.

4 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 review², under the Chairmanship of Lord Robens, of the way occupational risks are regulated and managed. The result is that all 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 Health and Safety at Work Etc. Act 1974 (HSW Act) - and by a single set of institutions - the Health and Safety Commission (HSC) and the Health and Safety Executive (HSE)³.

² Safety and Health at Work : Report of the Committee, Cmnd 5034; HMSO, London, 1972.

³ The HSC is the statutory body responsible for the administration of the HSW Act. Its primary

5 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.

6 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.

7 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 but 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 dutyholders. Others, however, like the broad general duties are qualified by expressions such as "so far as is reasonably practicable" (SFAIRP)⁴ 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.

8 The general approach is to set out the objectives to be achieved and to give considerable freedom to dutyholders as to the regime they should put in place to meet these objectives. However, this is not universal. As explained later in this document, there are circumstances

function is to make 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, providing information and advice, and controlling the storage and use of explosives and other dangerous substances.

The HSE advises and assists the HSC in its functions. It has some specific statutory responsibilities of its own, notably for the enforcement of health and safety law; the licensing of nuclear power stations etc. Local authorities also have statutory responsibilities for enforcement of health and safety law. These apply mainly in the distribution, retail, office, leisure and catering sectors.

⁴ This is not the only qualification. There are other similar qualifications such as "as low as reasonably practicable" (ALARP); "as low as reasonably achievable" (ALARA).

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.

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

10 For a self-regulatory regime to work, dutyholders 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** to those affected by them. **In this context 'tolerable' does not mean 'acceptable'**. It refers instead to a willingness 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.

11 Providing such an exposition on 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 considerable discretion to the regulator and duty holders. At the same time, it must reflect the values of society at large on what risks are unacceptable, tolerable or negligible. Any genuine 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;
- the need to avoid the imposition of unnecessary restrictions on the freedom of the individual.

12 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 twenty-five 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. 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, and 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.

13 In short the aim of this discussion document is to:

- open to scrutiny HSE's approach to the regulation of risk and the philosophy underpinning it;
- make transparent the factors that inform our decisions on risks, 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 and the benefits they engender, and show how these shape the form and content of our regulations and guidance;
- help reassure the public that industry, in taking advantage of technological advances, will not be allowed to impose unnecessary risks on people;
- let other regulators, whose responsibilities may overlap with those of HSE, know the basis for the management of occupational health and safety risks and thereby help to promote consistency of decision-making amongst regulators.

PART 2 : REVIEW OF DEVELOPMENTS THAT HAVE INFLUENCED OUR DECISION-MAKING APPROACH

Developments and influences

14 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.

15 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

16 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 in-built mechanisms for dealing with risk - mechanisms that reflect our personal preferences and the values of the society in which we live.

17 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 facing traffic to cross the road.

18 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.

19 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 voluntarily⁵".

20 Other studies⁶ on perception of risk have led to a theory which considers that it may be simplistic to believe that there is a derivable 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

⁵ Fischhoff B., Slovic P., Lichtenstein S., Read S., and Combs B. (1978). "How safe is safe enough? A psychometric study of attitudes towards technological risks and benefits". *Policy Sciences*, **9**, 127-152.

⁶ M.S. Douglas and A. Wildavsky, "Risk and Culture", University of California Press, Berkeley, 1982.

S.O. Funtowicz and J.R. Ravetz, "Three Types of Risk Assessment and the Emergence of Post-normal Science" in "Social Theories of Risk", ed. S. Krimsky and D. Golding, Praeger, Westport, Connecticut, 1992, p. 251-274.

N.C. Pidgeon, C. Hood, D. Jones, B. Turner, and R. Gibson, "Risk: Analysis, Perception and Management", The Royal Society, London 1992, p. 89-134.

B. Wynne, "Risk and Social Learning: Reification to Engagement" in "Social Theories of Risk", ed. S. Krimsky and D. Golding, Praeger, Westport, Connecticut, 1992, p. 275-300.

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.

21 The theory has been used to explain why, for many new hazards, high quality risk assessment by leaders in the field often fails to re-assure 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 judgemental 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.

22 Social scientists have also proposed another theory⁷ for explaining why risks that are minor in quantitative terms at times produce massive reactions while major risks are often ignored. 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.

23 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.

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

- i) **Individual concerns** or how individuals see the risk from the 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

⁷ Kasperson R. E., Renn O., Slovic P. *et al.* (1988). "The social amplification of risk: A conceptual framework". *Risk Analysis*, **8(2)**, 177-187.

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.

- ii) **Societal concerns** or the risks or threats from the hazard which impact on society as a whole. This type of concern is often associated with hazards that give rise to risks which, were they to be realised, could provoke a socio-political response, eg risk of events causing widespread or large scale detriment. Typical examples relate to nuclear power generation, railway travel, or the genetic modification of organisms.

25 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 the risks and benefits tend to be unevenly distributed, not only between groups of people with the result that for example some people bear more of the risks and others less of them, but perhaps also 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 most 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.

26 In addition to the direct societal concerns about the impact of the hazards on those affected, there is also and importantly a concern that the stability of the political system would come under threat in the wake of a catastrophe, however remote the chance of its happening. The consequential fear is a loss of trust by the public in the regulator and Government. Consideration of how regulation should approach hazards of this kind is intensely political and usually described on a case-by-case basis. A prime consideration is the affordability of measures to eliminate the hazard relative to the total detriment suffered by society in the event of the hazard being realised. An eloquent account of Government decision-making under such circumstances, relating to the Thames barrier, has been given by Bondi⁸.

Changes in the regulatory environment

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

⁸ H. Bondi, " Risk in Perspective", in *Risk : Man-made Hazards to Man*; p8-17, Edited by M. G. Cooper, Clarendon Press, Oxford, 1992.

The internationalisation of regulation

28 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 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. Many countries are calling for such technologies to be regulated at international level as the only effective way to prescribe appropriate standards.

29 The pressure towards the internationalisation of regulation not only requires innovative forms of regulatory co-operation but 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 - particularly since the legal instruments used for that purpose (eg directives) take precedence over national legislation.

Increased complexity in the regulation of risk

30 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.

31 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.

32 Moreover, whereas in the past agreement, on 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 risks should take account of the quality (or attributes) of the hazard as distinct from objective assessment of the quantity of risk.

33 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 considerations⁹ 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 ecosystems¹⁰. In short, the concept of risk has evolved to include values that cannot readily be verified by traditional scientific methods.

34 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 large scale risks. 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:

- 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 para 20 above);

⁹ L.R. Beach, "Image Theory: Decision Making in Personal and Organizational Contexts", Wiley, New York, 1992.

P.M. Sandman, N.D. Weinstein and M.L. Klotz, "Public Response to the Risk from Geological Radon", *Journal of Communication*, 1987, **37**, 93.

E. Vaughan and M. Seifert, "Variability in the Framing of Risk Issues", *Journal of Social Issues*, 1992, **48(4)**, 119.

¹⁰ E. Ashby, "Towards an Environmental Ethic", *Nature*, 1976, Vol **262**, July 8, p84-85.

- 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.

35 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 risk. The proper use of a risk assessment would require *inter alia* that:

- more often than not, the results of a risk assessment should be expressed as a value judgement rather than a number;
- the risk problem should be properly framed;
- the nature and limitations of the risk assessment are understood; and
- the results of the risk assessment are used to inform rather 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 hazard

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

37 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 likely to pay more attention to consequences than to likelihoods.

38 Nevertheless, it has proved useful to make a conceptual distinction between a hazard and a risk by describing a hazard as an intrinsic property or disposition of anything to cause harm and risk as the chance that someone or something that is valued will be adversely affected in a stipulated way by the hazard. HSE 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.

39 But, there will also often be cases where the distinction between hazard and risk is blurred in actual practice. HSE, for example, might attach a different weighting to the likelihood that harm will occur from the weighting attached to the consequences. The more weighting we attach to the consequences, the more we blur the distinction between hazard and risk. And should we choose to concentrate solely on the consequences, the distinction disappears, the possibility of the consequences taking complete priority over the chance.

40 However, the use of the latter approach by HSE has been challenged by some - perhaps because the HSW Act makes reference to 'risk' but not 'hazard'. In that respect, a ruling by the Courts on the meaning of 'hazard' for the purpose of the HSW Act is very relevant. The Court of Appeal in *Regina vs Board of Trustees of the Science Museum, 1993*, noted that 'hazard' and 'risk' are often used interchangeably. They understood the arguments why conceptually it was useful to make a distinction between these two terms. However, the Court ruled (see below) that, as far as the use of 'risk' in the HSW Act was concerned, this word should be interpreted as conveying the idea of a possibility of danger, or what conceptually is regarded as 'hazard'.

"The starting point must be the ordinary meaning of the language of section 3(1). In our judgement 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 judgement 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." [1993] 1 WLR 1171 at page 1177.

41 The implication of this interpretation is that, to be successful, approaches for managing risks in the workplace must ensure that hazards present are properly addressed. As we shall see later, the processes and criteria described in Part 3 meet this important condition. For example, they ensure that for hazards surmised to have consequences that may be irreversible and deleterious, ie entailing a high possibility of danger, there is an overriding need to introduce control measures for addressing the hazards even when there is considerable uncertainty about the nature of the hazards.

Changes on the industrial scene

Changes in patterns of employment

42 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 symbiotic organisations. 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; and a monolithic railway organisation has become a series of separate companies with different responsibilities for operating the track, the rolling stock and the networks.

Polarisation of approaches between large and small firms

43 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, which not facing the same problems, are very much at ease 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 (see Annex 2) of regulation.

Changes in the preferences, values and expectations of society

44 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, 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.

45 These shifts in preferences and values result in:

A growing perception that risks imposed on people should be justified

46 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 radioactive waste.

47 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

48 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 motor car or by plane may find their employment or promotion opportunities severely restricted. A person wanting to avoid processed food because of their fear of additives would only be able to do so 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.

49 The net result is that, increasingly, people are having to rely on authoritative bodies such as HSC/E as a source of reassurance. 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.

50 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

51 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 Force¹¹. These require:

- 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 were arrived at and what are their implications; and
- accountability: making clear, for all to see, who are accountable when things go wrong but without resorting to unfair retribution.

52 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.

¹¹ 'Principles of good regulation'. Available from Better Regulation Task Force, Room 72q/2, Horse Guards Road, London SW1P 3AL.

53 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 ethical and social considerations (paras 20-26);
- clarifications by the Courts on the meaning of hazard which implies that approaches for managing risks must ensure that hazards present are properly addressed (paras 36-41); and
- how we apply the principles at para 51 above.

54 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

55 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 risk issues. 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 negligible.

56 Many systems have been developed for informing and reaching decisions, and some particularly pertinent to health and safety have been described¹². The following stages characterise the system, governed by the principles set out in para 51, that has evolved in HSE in the course of undertaking its own statutory responsibilities and in advising and assisting the HSC, for example in implementing policies on modernising health and safety legislation.

- i) Deciding whether the issue is primarily one for HSC/E.
- ii) Defining and characterising the issue.
- iii) Examining the options available for addressing the issue, and their merits.
- iv) Adopting a particular course of action for addressing the issue, informed by the findings of (ii) and (iii) above and in the expectation that as far as possible it will be supported by stakeholders.
- v) Implementing the decisions.
- vi) Evaluating the effectiveness of actions taken and revisiting the decisions and their implementation if necessary.

57 We examine, in further detail below, what is involved at each stage. However, it is worth emphasising three 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.

¹² The Presidential/Congressional Commission on Risk Assessment and Risk Management, 'Framework for Environmental Health Risk Management', Final Report Volume 1 (1997). The Commission on Risk Assessment and Risk Management, 529 14th Street, Washington DC.

58 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/E must take final decisions where consensus is not possible, for example, because different stakeholders hold opposite views based on deep-rooted beliefs.

59 Thirdly, as a corollary to the first point, how we proceed through the above stages is not encapsulated in a single document but is reflected, for example, in the way we assist HSC and its Advisory Committees to go about their business, the consultative documents that we publish, the responses to such consultation, and discussions that take place with our stakeholders, both formal and informal.

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

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

- pressure of events and experience in terms of statistics of accidents and ill-health and reports of investigations into particular accidents;
- 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;
- 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.

61 However, it is not often appreciated that the objectives of the HSW Act include not only the securing of the health and 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, in the interest of the workability and effectiveness of the arrangements that can be put in place under health and safety legislation and/or its enforcement - aside from the practical consideration that other institutions with relevant powers may not exist within the Government machine.

62 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.

63 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. To avoid duplication of work 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. As a rule, if a risk is subject to specific legislation, HSE will not attempt to enforce the general duties of the HSW Act in situations where public safety will be adequately guaranteed by the enforcement of the specific legislation.

64 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 an uneven distribution 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 the HSC:

- i) 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
- ii) to deliberately limit its consideration of the issue by looking only at 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 (i) above. For example, HSE has made it clear¹³ that in its consideration of the tolerability of risks from nuclear power stations, it has limited its

¹³ Michael Barnes, Hinkley Point C Inquiry report, Transcript of Proceedings, 1989. J L Harpham Ltd, 55 Queen Street, Sheffield, S1 2DX.

Reference 12, para 190.

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.

65 A quite different issue arises when a European directive is enacted under Article 118A, the health and safety article of the Treaty of Rome. It is not always the case that matters covered by a 118A directive are interpreted as health and safety matters in Great Britain. Such a question arose when we had to advise the 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 the HSC) were not convinced that all elements of the directive (eg paid annual leave) were primarily an 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.

66 In short, if an issue ends up being regulated under health and safety legislation, it is invariably 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

67 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.

68 For example, the retention of older rolling stock on the railways is an issue with two quite different dimensions:

- i) of transport policy, in discouraging the wider use of public transport; and
- ii) of public safety policy, in denying the public the safety benefits of modern rolling stock.

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

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

- the action to be taken can be efficiently delivered by HSE acting within their powers and arrangements as discussed in paras 60-66 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.

70 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 (paras 60 *et seq.*). We sometimes use discussion documents as a means of seeking convergence towards a workable option.

Characterising the issue in terms of risk

71 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.

72 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.

73 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 resources devoted to establishing sound information and intelligence on risk account for around 25% of HSE's total resources. 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.

74 Because we are interested in identifying both the individual risk and the societal concerns engendered by the hazards, and other issues such as whether the risks should be entertained at all or should be regulated in a particular way, the risk assessment we carry out at this stage is much broader than the one that we would generally expect a duty holder to undertake in complying with the duty to assess risks under the Management of Health and Safety at Work Regulations. The risk assessment under those regulations would usually concentrate on looking at the prospect of harm to individuals (and in some cases to society as a whole) to identify in the light of good practice what needs to be done to comply with the law. On the other hand, the assessments we carry out under this 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 comes to reflect the risk assessment by HSE and compliance with good practice implicitly conforms to a risk-based approach to control.

75 Thus, we use a risk assessment essentially as a tool for extrapolating, from available data, on our experience of harm or for compressing a large amount of scientific information and judgement into 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) embrace such considerations as the relative weightings to be attached to the likelihood and consequences as discussed in paras 37-39 and the way that public perceptions of the risk should be taken into account.

76 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 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 toll of the risks on society.

77 The proper characterisation of the risk is important to the effective application of the preferred risk control hierarchy originally advocated by the Robens Committee and since promoted by HSE 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. 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 risk it entails. This would be particularly true for activities where there are considerable uncertainties in the estimates of the risks attached to them.

Inherently safer design

Adoption of the principles of inherently safer design is particularly important where the consequences of plant or system failure are high. In certain circumstances HSE may require plant to incorporate inherently safer design features rather than rely on 'bolt-on' safety systems or mitigation procedures to control the risk.

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 requirements¹ because, under certain conditions, a rapid increase in temperature of the reactor core can lead to an increase in the rate of the nuclear fission process, further increasing the temperature. Such a large 'positive temperature co-efficient' can result in rapid runaway of the nuclear reaction. This inherently unsafe aspect of the reactor design, coupled with experimentation by the operators under conditions where other safety systems had been overridden (which would also not be allowed in this country), led to the infamous incident at Chernobyl in 1986.

¹ Health and Safety Executive "Safety Assessment Principles for Nuclear Plants", ISBN 0-11-882043-5.

78 Indeed, in line with our earlier discussion on the meaning of hazard at paras 36-41, the regulation of health and safety is replete with examples of where the hazard rather than the risk 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.

Handling Uncertainty

79 Uncertainty permeates the whole process of assessing risks. For example the science underpinning the assessment may be complex, ambiguous or incomplete and/or the necessary data may not be available.

80 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. Para 73 described the very broad base of expertise called into play in HSE's consideration of the science of risk. A further measure is to practice

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 1997 policy statement of the Chief Scientific Adviser¹⁴.

An Example of a Qualitative Assessment of Risks Crowd Safety at the 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. 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 risks and substantially reduce 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:

Health and Safety Executive guidance HSG 175 "Fairgrounds and amusement parks: guidance on safe practice", ISBN 0-7176-1174-4, HSE Books.

81 Uncertainty itself is a state of knowledge in that, although the factors influencing the issue are identified, their effects 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

¹⁴ 'The Use of Scientific Advice in Policy Making' (1997). Issued by the Office of Science and Technology and available from the Department of Trade and Industry, 1997.

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.

Quantitative Risk Assessment

As indicated in a previous example, estimates of risk are often qualitative rather than quantitative.

A few sectors of industry, however, have focused on the tool of quantitative risk assessment (QRA). Whilst QRA is a useful tool, care needs to be taken to avoid numerous pitfalls which can trap the unwary. For example, in estimating the likelihood or frequency 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 can lead to bias; too large a sample may result in the inclusion of events that developed differently from those in question;
- ▼ the time period - too short a period may lead to the omission of representative indicators; too long a period may again result in the inclusion of events that developed differently from those 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 increased public expectations;
- ▼ the statistical method - historical accident/incident data may not include the cause, and selective choice of the data and/or the model used can result in figures that do not properly reflect actual history.

Whilst the process of undertaking a QRA can be instructive in identifying the main factors that contribute to a risk, the past is seldom a good predictor of the future! The numerical estimates that emerge from QRA are only indicative and should never dictate the action needed to address both individual risk and societal concerns.

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. 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 elimination 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 chaotic and unpredictable.

82 However, our risk assessment and risk management procedures have a number of safeguards to ensure that our approach is in line with the Precautionary Principle, ie to rule out the lack of certainty as a reason for not taking preventive action. The Precautionary Principle describes the philosophy that should be adopted for addressing risks subject to high uncertainty, particularly in the environmental field. It is incorporated in EEC Treaty under Article 130r, and other international treaties and conventions concerned with 'global' environmental issues (eg climate change, ozone depletion). Though not defined in the EEC Treaty, the Precautionary Principle has been defined 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.'

83 Thus, as a rule, our risk assessment procedures:

- require that assumptions to fill gaps in knowledge be tested through recognised methods, eg sensitivity analysis;
- attach more weight to consequences for hazards giving rise to irreversible and potentially severe detriment, eg cancer;
- give more weight to the consequences of a risk being realised than to its likelihood, the greater the uncertainty about the latter. For example, by assuming that working with genetically modified organisms entails a very high degree of risk and must therefore be subject to a very stringent control regime;
- build safety factors in 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;

- consider worst case scenarios, the greater the uncertainty about consequences. These can span from a 'most likely' worst case to a 'worst case possible' depending on the degree of uncertainty, societal concerns and, again, attributes such as irreversibility of realised consequences or potential for affecting future generations;
- 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.

84 All the above show that assessing risks is far from being a straightforward exercise. At times the risk assessment will be a straightforward 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 Annex 1.

Stage 3 - Examining the options available and their merits

Identifying options

85 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, in the knowledge that further measures will continue to be sought to reduce the risks as low as reasonably practicable.

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

- improving the available knowledge base through research;
- providing more information and guidance to duty holders to enable them to fulfil their responsibilities;
- publicity campaigns to create awareness so that those exposed to risks can exert their influence, 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;
- 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 able to control the risks as distinct from imposing lowest common denominator provisions on all and sundry; and
- in the final analysis, proposing new measures that are commensurate with the risks to be addressed, eg new law.

87 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 for preventing the substance being released into the workplace or the environment; introducing licensing regimes to limit the number of people using 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.

88 We can often build on our experience of using the framework for identifying options that are likely to work in certain circumstances. For example we identify at Annex 2 the options that should be considered when introducing new regulations or guidance and the order in which they should be examined.

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

- *what constitutes good practice* for addressing the hazards identified and evaluate its merits as an option. If good practice is not available we would also examine the merits of good practice that apply in comparable circumstances if we believe that this is directly transferable or can be modified for addressing 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 Annex 2, we would wish to adhere to the general principle 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. Annex 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 paras 82-83). As we shall see later, HSE adopts a framework (see para 110ff.) for reaching decisions which intrinsically ensures that while there is a bias 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 entity or the process 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 would not 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 HSW Act. Though there is a duty on the HSC to adopt this principle when modernising 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.

Assessment of Risk Reduction Action

90 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 quantitative or 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 makes more sense to compare the difference in costs from switching from one option to another against the gains so achieved in terms of avoidance of harm.

91 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.

92 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, when conducting CBAs, we currently take as a benchmark that the value of a statistical life¹⁵ (VOSL) is about £902,500 (1998 prices). This figure derives from the value used by the Department of the Environment, Transport and the Regions for the appraisal of new road schemes. However, we would regard higher values as being appropriate for risks for which there is high aversion, eg those which give rise to high levels of societal concern or individual risk.

93 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.

¹⁵ As is made clear in Annex 3, the value of a statistical life 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.

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 costs and effort of reducing exposure. Both groups comprise appropriate representatives of the stakeholders, e.g. employers and employees, together with independent 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, e.g. 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 information for each substance on the toxic effects, typical exposure levels, measurement methods 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 advise the Secretary of State that a new MEL should be added to Schedule 1 of the COSHH Regulations.

Further information:

Health and Safety Executive guidance booklets EH40, "Occupational Exposure Limits" and EH64, "Summary criteria for occupational exposure limits", both published annually.

Fairhurst S., "The uncertainty factor in the setting of occupational exposure standards", *Annals of Occ. Hygiene*, Vol 39, p375-385, 1995.

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.

94 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.

95 We give further information on our approach for appraising options at Annex 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.

96 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

97 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:

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

98 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
- by being open on the science, assumptions and other critical inputs that have contributed to the estimate or judgement used for obtaining the risk estimate.

The importance of societal concerns - adventure activities

The regulatory controls recently put in place on certain adventure activities (eg 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 licence certain providers of certain adventure activities. The proposed controls took the form of a statutory licensing system even though (as the CD noted):

- v the historic risk of fatalities was low;
- v 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); and
- v a cost benefit assessment showed that resources required for introducing the licensing system could be used more profitably elsewhere to achieve greater improvements in health and safety.

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 by 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.

Note: Although made under "The Activity Centres (Young Persons' Safety) Act 1995", 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, and the licensing authority has to report annually to the Health and Safety Commission.

99 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 paras 36-41).

100 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

101 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. As explained in paras 5-6, 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.

102 Whatever the regulatory tool we apply, our approach is to use it to encourage those who have to introduce measures to manage risks to:

- enlist the co-operation and involvement of those affected, by pointing out for example, that employers are unlikely to be able to control 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 Management of Health and Safety at Work Regulations 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, eg eliminating risks, combating the risk at source, applying collective protective measures rather than individual protective measures and generally applying sound engineering practice such as inherently safer design.

103 We give further details on these aspects of our approach in a number of our publications¹⁶.

Stage 6 - Evaluating the effectiveness of action taken

104 Finally, our process for ensuring that risks are properly managed would not be complete without *ex post* procedures 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 what was 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 and those affected by, or having an interest in, the risk problem.

105 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 (para 102 above). Since there might be some time before the full impact of risk reduction measures can be monitored, we might first focus on our success in getting risk managers to introduce appropriate measures before concentrating on the success of the decisions as a whole.

¹⁶ Health and Safety Executive, "Successful Health and Safety Management", HSG65, ISBN 0-7176-1276-7, HSE Books, PO Box 1999, Sudbury, Suffolk CO10 6FS, 1997.

Health and Safety Executive, "5 Steps to Risk Assessment", INDG 163, HSE books.

Health and Safety Executive, "Management of Health and Safety at Work. Management of Health and Safety at Work Regulations 1992. Approved Code of Practice, L21, ISBN 0-7176 0412-8, 1992.

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

Criteria for reaching decisions

107 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.

108 Research has shown that the criteria used by regulators in the health, safety and environmental field 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" technology is employed to control risks whatever the circumstances.

New technology

HSC/E seek to harness technological developments to improve standards of health and safety, particularly where the consequences of an accident are high.

For railway safety, for example, HSC recently published a consultative document inviting comments on proposed new regulations that, taking account of developments in technology and cost benefit considerations, and subject to transitional arrangements, would:

(a) reduce significantly the risks of an accident at key locations throughout the rail network by requiring the provision of suitable train protection systems that would automatically apply the brakes if a train passed a stop signal, or travelled at excessive speed approaching a stop signal or part of a railway where there was a speed restriction; and

(b) mitigate the consequences of an accident by prohibiting, after a set date, the use of Mark 1 rolling stock (which is known to have a relatively poor level of crashworthiness and door safety in comparison with later designs) unless rebodied to provide a similar standard of safety as new stock.

The consultative document noted, for example, that presently only a small proportion of Britain's railway system is covered by modern, technically advanced train protection systems, which are much more effective in preventing collisions than the basic automatic warning system first introduced 60 years ago. The document made clear that, in HSC/E's view, further safety improvements were now needed.

Following consultation, HSC proposed to Ministers that the measures summarised in (a) and (b) above should have the force of law. New Regulations, The Railway Safety Regulations, are due to enter the statute book in the Spring of 1999.

109 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 other ethical considerations than just achieving a balance between costs and benefits. For example, some people believe that certain hazards should not be entertained at all, no matter how low the risks, 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;
- technology-based criteria would, for example, require wood furniture manufacturers to adopt the state-of-the-art technology developed for keeping clinically clean, factories manufacturing electronic chips - hardly a realistic proposition.

110 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.

111 The framework is illustrated in Figure 1. The triangle represents increasing level of 'risk' (measured by the individual risk and societal concerns they engender) 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 benefits. Any activity or practice giving rise to risks falling in that region would 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.

N.B. The meaning of 'risk' in the above figure encompasses more than physical harm and also takes account of other factors such as ethical and social considerations (see paras 20-26).

112 The light zone at the bottom, on the other hand, represents a broadly acceptable region. Risks falling into this region are regarded as insignificant and adequately controlled. Further action to reduce risks will not usually be required unless evidently 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 are so well controlled that risk control measures are at the limit of practicability. Further resources involved for reducing risks will usually be grossly disproportionate to the risk reduction achieved. Nonetheless, if it is possible to reduce the risks at minimal costs, such action would be warranted.

113 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 made available. 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 risks are not unduly high and kept as low as reasonably practicable (the ALARP principle - see Annex 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.

114 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.

115 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.

116 It must be stressed that Figure 1 is a conceptual model. 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 remaining is driven down the tolerable range so that it falls either in the tolerable 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

117 When addressing any particular hazard, whether the option we have chosen to control the risk ALARP is good enough or not depends a lot on where the boundaries lie 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. 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. However, HSE on the basis of its wealth of experience accumulated over the years in dealing with 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 death either individually or in multiple. 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.

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

118 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 1-5 at Annex 4, we live in an environment of appreciable risks of various kinds which contribute to what we call the 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 entail or exceed such levels of residual risks, for example, using gas and electricity, or engaging in air travel.

119 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

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 mean 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 (see below). 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 Box on page 36) 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).

However, 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 paras 118-121 (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).

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 level 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

120 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 to 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 risks 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 tolerable¹⁷ 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 one in ten thousand per annum.

121 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

122 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

¹⁷ Provided of course that all steps have already been taken to reduce the risks as far as reasonably practicable as explained above.

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" (paras 118-120).

For example, for commercial diving, the annual fatality rate has been estimated at 1 in 2,700 based on the number of fatalities over the last 7 years. Similarly the rate in 1995/96 for mining and quarrying (including offshore oil and gas) was 1 in 4405. For agriculture, hunting, forestry and fishing (but not sea fishing) and for construction, the fatality rates in 1995/96 were 1 in 12,500 and 1 in 20,000 respectively. In traditionally less hazardous industries the annual risk of death for workers is lower still; for example in the service sector in 1995/96 it was 1 in 242,000.

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, in 1995/96 the risk of death to the public from the use of gas (fire, explosion or carbon monoxide poisoning), averaged over the entire population, was 1 in 1,350,000 - 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:

Annex 4 gives other examples of the magnitude of different risks.

Further information is available in *Health and Safety Statistics 1996/97* published by the Health and Safety Commission.

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.

123 Nevertheless, HSE has adopted the criteria below (some of which are currently under review). These were 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 transport¹⁸. Such criteria were

¹⁸ HSC, Advisory Committee on Dangerous Substances, Major hazard aspects of the transport of dangerous substances, 1991, ISBN 0 11 885676 6.

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). These were found to provide 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 little else it has proved a helpful tool if used sensibly¹⁹. 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.

124 Thus, where societal concerns arise because of the risk of multiple fatalities occurring in one event from a single major industrial activity²⁰, 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 fifty people or more in a single event should be less than one in five thousand per annum.

125 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 Annex 1) receiving a dangerous dose, or worse, together with certain characteristics of the development.

126 Thus in the case of most housing developments, for example, HSE advises against granting planning permission for any significant development where individual risk for the hypothetical person is more than 10 in a million per year, and does not advise against granting planning

¹⁹ For a review of the merits and disadvantages of FN curves - see Ball D. J. and Floyd P J (1998), Societal risks. Report available from the Risk Assessment Policy Unit, HSE.

²⁰ 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.

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 1994 (COSHH). Control of exposure to substances hazardous to health, for example, must be achieved by

- ▼ prevention (e.g. by avoiding use altogether, or by substituting a less hazardous substance), or where this is not reasonably practicable by
- ▼ control measures (e.g. engineering controls such as containment or local exhaust ventilation), or where this is not reasonably practicable by
- ▼ 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 1992¹ require application of "the principles of good microbiological practice and the following principles of good occupational safety and hygiene" (six 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 microbiological safety, a legal requirement which demands application of accepted good practice in step with evolving scientific knowledge and technological developments.

¹ These Regulations implement Directive 90/219/EEC on the contained use of genetically modified micro-organisms, which includes the same wording.

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, eg 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).

127 Cases of proposed housing development where the individual risk 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 plants²¹.

²¹ Risk criteria for land use planning in the vicinity of major industrial hazards, HMSO, London ISBN 0 11 885491 7. (Under review).

Applying the (generalised) TOR framework

128 When we apply the framework to policy formulation, regulatory development and enforcement activities, we start with the expectation that duty holders have in place suitable controls to address all significant hazards arising from their undertakings, and that those controls implement authoritative good practice precautions, irrespective of site-based risk estimates. In this context we would:

- i) regard a hazard as significant unless:
 - informed common-sense, 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; or
 - the risks that the hazard gives rise to are outside the control of the duty holder (see Annex 3).
- ii) accept 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) provided the guidance had gained general acceptance in the safety movement that it does represent good practice.

129 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 Annex 3 and the criteria in paras 110-127 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. This is because authoritative good practice represents a consensus between regulators, technical experts, duty holders, safety representatives etc. as to the action necessary (taking account of what is technically feasible, the balance of costs and benefits and, if necessary, other relevant factors such as the need to alleviate societal concerns) and usually results in a tolerable level of residual risk.

130 One consequence of linking the control regime necessary to authoritative good practice is that the control measures so derived apply regardless of the length of exposure. 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.

131 There will be, however, cases where good practice:

- was not identified as an option in our identification of options 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.

132 In these circumstances we have to examine (again by adopting the procedure described at para 56 above) whether any of the other options identified at stages 2 and 3 would reduce the risks ALARP. If one is found we would advocate its adoption.

133 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 ALARP. This will be the case for risks from activities:

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

134 We would conclude in such circumstances that we are dealing with risks 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

Intolerable risks - I

There are relatively few examples in health and safety legislation of processes or activities that have been banned because the risk 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 (para 133(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.

1) The manufacture and use for any purpose of 2-naphthylamine and its salts were banned under the Carcinogenic Substances Regulations 1967 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 1994 (COSHH).

2) The Control of Lead at Work Regulations 1998 (CLAW) 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 (i.e. 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.

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 Annex 2).

135 Nevertheless, in situations where (i) or (ii) above 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 blue asbestos prior to demolition of buildings is a case in point.

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 (para 133(ii)). One concerns the employment of young people (under 18 years) in certain long-standing work activities where there is potential for exposure to high levels of lead.

The Control of Lead at Work Regulations 1998 (CLAW) 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.

136 We must stress that we use the above criteria and framework flexibly and with commonsense. As we have pointed out, because of the iterative nature of the decision-making process as we go through its stages, we often gather information from one stage which is relevant to other stages and that, for example, going through the decision-making stages may suggest new options that should then be considered.

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, as already mentioned in para 40, the courts have ruled that we cannot wait for people to be actually exposed to the risks before taking decisions about whether the risk 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 is an hypothetical type of 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 is often controlled by considering the exposure of an hypothetical person who is in good health and works exactly forty hours a week.

3. 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.

Standards

4. 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 could 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 however short the actual exposure.

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:

- a) direct radiation from normal operation of the plant itself;
- b) routine emissions to air, water, etc.;
- c) direct and indirect radiation 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 a) to c) above, respective examples might be: a child present continuously in the nearest dwelling to the site or at the point of greatest dose if further away; 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); and 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", ISBN 0-11-882043-5.

Note: In England discharges to the environment are regulated by the Environment Agency; food safety is currently the responsibility of the Ministry of Agriculture, Fisheries and Food. Broadly parallel arrangements for Scotland and Wales are expected to be little changed on implementation of the Government's devolution proposals.

Procedures for handling uncertainty

5. 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.

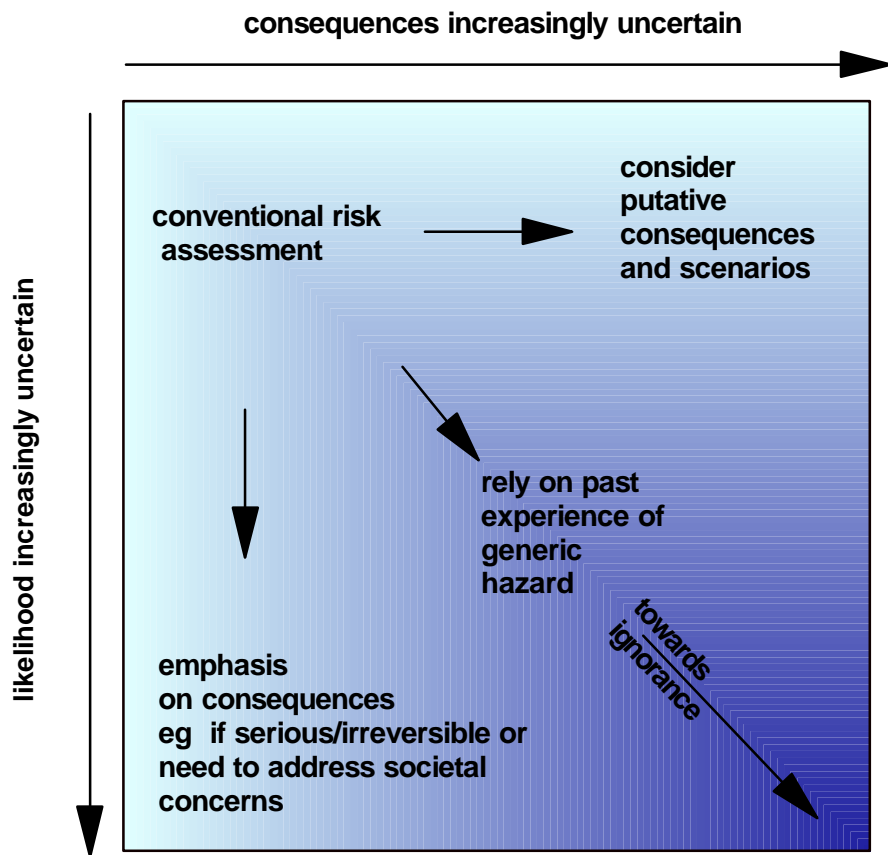


Figure 2

Procedures for tackling uncertainty when assessing risks

6. 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.
7. For example, at the bottom of the vertical axis where there is a high degree of uncertainty about likelihoods, 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.
8. It is also worth noting that though more information frequently leads to a decrease in uncertainty, it does not 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. This is illustrated by the puzzle²² in Figure 3.

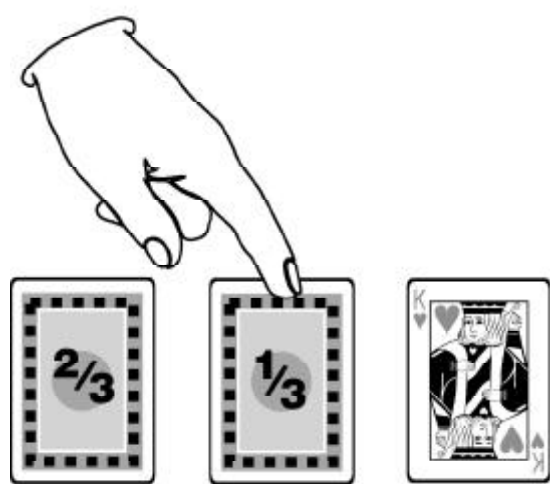
²² Puzzles from Martin Gardner, reproduced from Scientific American, August 1998, p49.

Figure 3. Puzzle illustrating the relationship between probability, information and uncertainty.

You are at a game show. The quiz-master places three cards face down on a table. One of the cards is an ace, the other two are face cards. You are asked to place a finger on one of the cards, betting that the card is the ace. The probability that you have picked the ace is clearly $\frac{1}{3}$. The quiz-master secretly peeks at the cards. Since there is only one ace among the three cards, at least one of the cards you **didn't** chose must be a face card. The quiz-master turns over this card and shows it to you.

Question: What is the probability that your finger is now on the ace?

Answer: Most people believe that the probability has risen from a to $\frac{1}{2}$. After all only two cards are face down, and one must be the ace. Actually the probability remains a . The probability that you did not pick the ace remains b but the quiz-master has removed some of the uncertainty by showing that one of the two unpicked cards is not the ace. So there is a b probability that the other unpicked card is the ace. If the quiz-master gives you the option to change your bet, you should without hesitation shift your finger to that card.



When assessing risks the situation is of course even more complicated. Unlike the above example, we do not know all possible outcomes that may arise from a hazard nor their distributions.

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. In these circumstances, in our role in advising the 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 II 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 makes provision for modernising health and safety law according to a particular architecture. 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 interventions 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. All are qualified by "so far as is reasonably practicable" (SFAIRP);
- **regulations**, which clarify particular aspects of the general duties and are mandatory. 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 1992 (MHSWR). 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 are superimposed over 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 in that they reverse the burden of proof in legal proceedings. 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;
 - ♦ when 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 below);
 - ♦ when 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;
 - ♦ when 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. 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 say what are 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 occupational health and safety risks 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 Commission (EC) directives. 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 - irrespective of the results of the consultation exercise which the procedures laid down in the Act require the HSC to undertake when proposing new regulations;
- the need, when modernising legislation preceding the HSW Act, to maintain or improve the 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 *post* 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:

- i) *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 require more specific legislation to be introduced domestically;
 - societal concerns require that some explicit form of action is needed (politically or to allay public fears).
- ii) *use of guidance*. This may help to deal with some of the above, but could be insufficient if:
- EC Directives 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).
- iii) *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 and hence prevent over-response by industry, over-enthusiasm by enforcers and over-selling by intermediaries.

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 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.

iv) *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 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;
- fair competition 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 require more, such as the introduction of process regulations.

v) *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;

- 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 regulation will be used as last resort. Such regulations tend to be resource intensive and 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.

SOME ISSUES RELEVANT TO ASSESSING RISK REDUCTION OPTIONS**Implications of case law on 'reasonable practicability'**

1. As discussed in Part I of this document, health and safety legislation often imposes duties qualified by the concept of 'reasonable practicability'. 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 concept. 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.
2. Of particular importance in the interpretation of SFAIRP is *Edwards vs the National Coal Board* [1949] 1 A11 ER 743. 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.
3. When assessing 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), it is now taken for granted that such duties have not been complied with if the regime introduced to control risks fails the above 'gross disproportion' test. This is usually achieved by weighing each opportunity for an incremental reduction in risks against the presumed benefits in terms of the avoidance of injury.
4. As explained in paras 128-129, normally, risk reduction action can be taken using good practice as a baseline - the working assumptions 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, new regulations and, sometimes, in determining action following a formal risk assessment (see paras 97-100 & 132-135). Moreover, certain hazards regulated through a safety case regime require

an explicit demonstration in the safety case that control measures introduced conform with the ALARP principle. Though this requirement can often be met by showing that the control measures adopted represent good practice there will, nevertheless, be certain occasions where there will be a need to show (not necessarily by a full cost benefit analysis) the trade-offs between the costs of introducing particular options and the risk reduction thereby achieved.

Risks to be taken into account

5. 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 hazard on which to base 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.

6. HSE would not normally expect to consider risks other than those which:

- arise out of reasonably foreseeable events and behaviour. What is reasonably foreseeable will depend on the circumstances. For example, the risk of a well designed, properly built and well maintained building collapsing would not be considered 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 there was an external event such as a severe earthquake or explosion.

On the other hand, it would be proper to consider the effects of an earthquake or explosion in the case of major hazard industries because they could trigger an even greater catastrophic event; and the risk of a building collapsing during its demolition;

- are under the control of the duty-holder. This is in line with the regulatory framework 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, the risks which an employer needs to consider are limited to those 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 to consider such matters.

7. Within these constraints, it is important that the risk be assessed in an integrated manner. This will allow the 'full picture' of risk to be taken into account and avoid a distorted view from considering risks in isolation, or in a slice of time, or location by location rather than across the undertaking as a whole. There will therefore be a need to take into account that:

- a particular hazard might pose a risk of immediate traumatic injury and/or long-term health effect;
- 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).

Ensuring consistency when comparing costs against benefits

8. As discussed in paras 90-96 cost benefit analysis (CBA) offers a framework for balancing the benefits of reducing risks against the costs incurred for a particular option for 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 guidance²³ from HM Treasury.

²³ HM Treasury, Appraisal and Evaluation in Central Government, 'The Green Book' (1997); HMSO, London.

9. 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 balance between the cost and benefits of occupational health and safety measures.

Valuation of benefits

10. 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.

11. Where the benefit is the prevention of death, the current convention used by HSE is a benchmark value of about £902,500 (1998 prices) for the value of a statistical life (VOSL²⁴). This is the VOSL adopted by the Department of the Environment, Transport and the Regions for the appraisal of road safety measures. It may well be the case that individual's willingness to pay for risk reduction - measured in aggregate by the VOSL - will vary, depending on the particular hazardous situation. For example, there is evidence that individuals place greater weight on the reduction of rail risks, compared to roads. Thus, the particular hazard context will need to be borne in mind, whichever VOSL figure is adopted.

12. Moreover, it is also important to note that VOSL is not the only factor in balancing costs against risks. Measures to reduce risks to humans may also yield significant environmental benefits. And a judgement always remains as to whether costs are grossly disproportionate to benefits (see paras 17-23 below).

Costs to be taken into account

13. The Edwards case law, by referring to "sacrifice" as "money, time or trouble" suggests that a broad interpretation of 'cost' is appropriate. In the absence of interpretation by the Courts we believe that the following principles should apply:

²⁴ VOSL 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 VOSL of £902,500 corresponds to a reduction in risk of one in a hundred thousand being worth about £9.03 to an average individual. VOSL 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.

- 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 'Rolls-Royce' 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.

Temporary shutdown costs should be included since these clearly constitute part of the duty-holders' 'sacrifice' - though in cases where shutdown is necessary to avoid operating in the 'intolerable' region of the TOR diagram - as will often be the case in licensed industries - this clearly becomes irrelevant. The significance of these costs depends in practice on the particular industry concerned but since such costs include lost production, in some circumstances they may well swamp all other costs.

In these circumstances, full advantage must be taken of opportunities to reduce the effect of shutdown costs so that they do not exert unwarranted influence on the final result of the CBA. For example, shutdown costs can be reduced by the timing of the work required to put the health and safety measures in place, eg by carrying it out during planned maintenance, or when demand is known to be slack so that production can be made up elsewhere. It may often be appropriate to separate out temporary shutdown costs to see how they affect the overall costs and to see to what extent such costs can be reduced as suggested;

- 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 (e.g. 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 premiums²⁵ or civil damages.
- affordability is not a legitimate factor in the assessment of costs. This ensures that duty-holders are presented with a level playing field.

Discounting of costs and benefits

14. 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.

15. 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.

16. However, when costs and benefits accrue far into the future, the assumptions underlying these discounting conventions may need to be re-examined. The discounting of benefits that are spread over a long time-scale, say longer than 50 years, raises questions of equity between different generations. Special considerations may be needed for specific cases.

²⁵ 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

17. The test of "gross disproportion" when weighing risks against costs implies that, at least, there is a need to err on the side of safety in the computation of safety costs and benefits. In short, case law requires that there should be a transparent bias on the side of health and safety. The acceptance of this bias is fundamental to conformity with the law. 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 paras 82-83). Our general approach is that as a rule, whenever possible, standards, should be improved or at least maintained.

18. There will be circumstances where the introduction of new technology, or new systems of work, provide dutyholders with an opportunity to increase efficiency or quality at the expense of a small increase in risk. This issue is not new. For example, it arose in the middle ages when printing presses were introduced to replace quill pens. However, current regulations require duty holders to re-assess the risks introduced by the new technology, or new system of work, to ensure that the risks to health, safety and welfare are properly controlled.

19. In such circumstances we need to distinguish between two situations:

- i) **the hazard and those exposed remain the same.** Typical examples are when an employer:
 - reduces maintenance intervals because new technology allows a more reliable method for detecting faults (eg replacing tapping and listening, by ultrasound as a method for detecting cracks in metal structures);
 - modifies a process or operating conditions etc. to increase output but with some reduction in safety margins thereby increasing risks (eg, raising the operating temperature of a process to speed up the reaction thereby reducing safety margin on the cooling system); and
- ii) **new hazards are created and/or risks are transferred to other parties.** For example, in the construction industry there is an increasing trend to replace manual labour on site with off-site fabrication of parts which are then assembled on site using cranes.

20. As far as the latter (19(ii) above) is concerned, depending on the merits of the case, we could consider this a new situation which must be examined on its own merits; ie requiring a

fresh judgement as to whether the new proposed control regime reduces risks ALARP, using the procedures described in Part 3. Moreover, because the situation has changed radically, there would be no need to make reference to the risks associated with the control regime it replaced. The possibility will also arise that some of the risks are transferred to a totally different employer. But here again under the framework of the HSW Act, it will be for each employer to ensure that they are complying with the relevant statutory provisions, including the need to ensure that risks are reduced ALARP.

21. However, in relation to 19(i) above, the circumstances in that situation remain fundamentally unchanged. The new control regime is essentially nothing more than an alternative control measure and it is entirely proper that a comparison be made between the risk associated with the new and old control measure.

22. Comparison might show either of the following for the new measure:

- i) there is a reduction in risk (or no change). In such circumstances, the comparison gives no grounds for objecting to the new technology/system of work. However, duty-holders would still need to consider whether there are any other 'reasonably practicable' measures they could take to reduce risk further; or
- ii) there is an increase in risk. *Prima facie*, the new technology/system of work is not acceptable since it has not reduced risks ALARP ie at least to the level achieved by the old technology etc.

23. However, such an increase in risk can conceivably arise in many different circumstances and though HSE will not condone increases in risks lightly there will be a need for HSE to retain some flexibility. The following examples are illustrative of the approach to be adopted to achieve this. Thus we could contemplate allowing an increase in risk provided that:

- i) we are confident that the residual level of risk after the new control regime has been introduced is within the 'broadly acceptable' region or near the boundary between the 'broadly acceptable' and 'tolerable' regions of the TOR geometry;
- ii) the change in risk, in absolute terms, is small; **and**
- iii) the new measure results in substantial benefits (including economic savings) but forms part of a package of change which overall maintains or improves the health, safety and welfare regime in the undertaking. The policy adopted here would be analogous to

the one adopted for section 1(2) of the HSW Act when considering the replacement of pre-1974 legislation with new regulations which must maintain or improve standards (for example though replacement of the absolute duty to guard moving parts of machinery by one qualified by 'practicability' in the Provision and Use of Work Equipment Regulations is a dilution of that particular requirement, overall the Regulations improve standards); **or**

- iv) the new measure replaces one previously adopted because the level of uncertainty surrounding the hazard was such that, in line with our precautionary approach, a demonstrably conservative measure was necessary, in terms of control needed to achieve a level of safety near to or within the 'broadly acceptable' region. New knowledge and reduction in uncertainty now show that the level of safety achieved by the old measure was in fact verging towards the negligible level and the newer and less costly measure achieves a level of risk no greater and possibly less than the risk previously assessed for the old method. However, here again duty-holders would still need to consider whether there are any other 'reasonably practicable' measures they could take to reduce risk further.

SOME STATISTICS FOR COMPARING RISKS FROM DIFFERENT HAZARDS

1. Comparing the size 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 below²⁶ give some idea of how the different risks we run compare with each other in size and probability.

²⁶ Extract from: Galson Sciences Ltd, Review of Risk Statistics for the HSE (1997).

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 meters 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:
 - v 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.
 - v A 3-3 draw occurred 118 times, representing a probability of about 1 in 100.
 - v A 4-4 draw occurred 11 times, representing a probability of about 1 in 1,000.
 - v 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:
 - v Match 6 of 6 main numbers (winning the jackpot):
1 in 14,000,000.
 - v Match 5 of 6 main numbers and the bonus ball:
1 in 2,300,000.

Average annual risk of death from various causes:

Table 1 : Annual risk of death for various United Kingdom age groups based on deaths in 1993 (Annual Abstract of Statistics, 1996).

Population group	Risk as annual experience	Risk as annual experience per million
Entire population	1 in 88	11,300
Men aged 55-64	1 in 74	13,600
Women aged 55-64	1 in 120	8,100
Men aged 35-44	1 in 590	1,700
Women aged 35-44	1 in 910	1,100
Boys 5-14	1 in 5,000	200
Girls 5-14	1 in 6,700	150

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 360	England and Wales 1993 (1)
All external causes (accidents, homicides, suicides, poisoning, others)	1 in 3,070	England and Wales 1992 (1)
All types of accidents	1 in 4,030	England and Wales 1992 (1)
All forms of road accident	1 in 15,700	GB 1995 (2)
Lung cancer caused by radon in dwellings	1 in 29,000	England 1996 (3)
Gas incident (fire, explosion or carbon monoxide poisoning)	1 in 1,350,000	GB 1986-95 (4)
Lightning	1 in 15,000,000	England and Wales 1982-95 (5)

(1) Annual Abstracts of Statistics (1996)

(2) Department of Transport (1995)

(3) National Radiological Protection Board (1996)

(4) Health and Safety Commission (1996)

(5) Office of Population, Census and Surveys and Office of National Statistics (1984-1995)

Table 3 : Annual risk of death from industrial accident to employees for various occupational groups (Health and Safety Commission, 1996).

Cause of death	Annual risk	Annual risk per million	Basis of risk and source
Work-related accidents (not including self employed)	1 in 100,000	10	GB 1995/96†
Work-related accident (self employed)	1 in 62,500	16	GB 1995/96†
All types of quarry accident (quarry workers)	1 in 5,500	182	GB 1983-92*
Construction	1 in 12,600	79	GB 1991/92 to 1995/96†
Energy and water supply industries	1 in 14,500	69	GB 1991/92 to 1995/96†
Agriculture, hunting, forestry and fishing (not sea fishing)	1 in 16,800	60	GB 1991/92 to 1995/96†
Metal manufacturing industry	1 in 55,000	18	GB 1995/96†
All manufacturing industry	1 in 72,500	14	GB 1991/92 to 1995/96†
Electrical and optical equipment manufacturing industry	1 in 150,000	7	GB 1995/96†
All service industries	1 in 242,000	4	GB 1995/96†

† Health and Safety Commission (1996)

* Health and Safety Executive (1993)

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

Activity associated with serious injury	Annual risk	Basis of risk and source
Irreversible paralysis within 30 days of polio vaccination	1 in 2,000,000 vaccinations	UK 1970-91 (1)
Fairground accidents	1 in 17,000,000 rides	UK 1981-88 (2)
Road accidents	1 in 17,000,000 kilometres driven	GB 1995 (3)
Rail travel accidents	1 in 7,630,000 passenger journeys	GB 1995/96 (4)

(1) Joice et al. (1992)

(2) Holloway and Williams (1990)

(3) Department of Transport (1995)

(4) Health and Safety Executive (1996)

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

Activity associated with death	Annual risk	Basis of risk and source
Pregnancy (direct or indirect causes)	1 in 10,200 maternities	UK 1991-93 (1)
Surgical anaesthesia	1 in 185,000 operations	GB 1987 (2)
Scuba diving	1 in 150,000 dives	UK 1987-94 (3)
Fairground rides	1 in 250,000,000 rides	UK 1981-88 (4)
Rock climbing	1 in 250,000 climbs	England and Wales 1987-92 (5)
Whitewater canoeing	1 in 2,000,000 outings	England and Wales 1985-95 (6)
Hang-gliding	1 in 80,000 flights	England and Wales 1987-96 (7)
Rail travel accidents	1 in 148,000,000 passenger journeys	GB 1995/96 (8)
Aircraft accidents	1 in 10,000,000 passenger journeys	UK 1986-95 (9)

(1) Department of Health (1996)

(2) Lunn and Devlin (1987)

(3) British Sub-Aqua Club (1996)

(4) Holloway and Williams (1990)

(5) Based on the assumption that there is a total of 45,000 climbers making an average of 20 climbs per year each. Office of National Statistics (1997) and British Mountaineering Council (1997)

(6) Based on the assumption that there are 100,000 whitewater canoeists making an average of 30 outings per year each. Canoe Focus (1996) and British Canoe Union (1997)

(7) Based on the assumption that there are 3,300 flyers making an average of 50 flights per year. British Hang-gliding and Paragliding Association (1997)

(8) Health and Safety Executive (1996)

(9) Civil Aviation Authority (1997)

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DISCUSSION DOCUMENT



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