THE SETTING OF SAFETY STANDARDS

A REPORT BY AN INTERDEPARTMENTAL GROUP AND EXTERNAL ADVISERS

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FOREWORD

In January 1996 the Health and Safety Executive published a report on behalf of the Interdepartmental Liaison Group on Risk Assessment (ILGRA), on The Use of Risk Assessment in Government Departments. In parallel and in close consultation with work on that Report another interdepartmental group, supported by some external experts, considered the directions in which the general procedure and methodology of setting safety standards offered most scope for development. This further Report describes the outcome of that work.

CONTENTS

1 : INTRODUCTION

1.1 SCOPE

This report is about health and safety standards in general (including the health and safety dimensions of environmental standards). It does not comment on specific standards, except by way of illustration.

It is concerned with the balancing higher levels of safety against higher costs, and with the role of absolute limits for safety risks. It is concerned especially with bridging the gap between, on the one hand, information about risks and costs and public values and preferences and, on the other hand, the development and the presentation of public policy measures which are efficient, fair and publicly acceptable. It is therefore about the economic, psychological, ethical and administrative aspects of safety standards. It is not directly concerned with the scientific analysis of levels of risk, nor with the equally crucial issue of enforcement.

The geographical and political focus is the United Kingdom. UK safety (and environmental) regulation is increasingly determined by the European Union and, especially in sea and air transport, by other international organisations. However the authority and influence of UK regulators in setting domestic standards, in interpreting international standards, and in contributing to the development of international standards, remains very strong.

The variety of risks addressed is broad. The principles discussed apply directly to conventional "accidents" such as explosions in industrial plants, transport collisions, fire safety, or dangerous consumer products. They also apply to health threatening environmental hazards, some of which may have long delayed impacts, as from asbestos, or natural or generated radiation; and to the hazards of, for example, toxins in the air, or in food or water, or from medicines. The principles apply to a lesser extent to lifestyle choices, such as smoking, exercise and diet; and in more complex ways to risks such as those to the public from people with a dangerous history. The paper is not concerned with environmental impacts on, for example, wildlife, or scenery, or people's convenience as opposed to health and safety, although many of the principles apply also to these areas. It is not concerned with other risks such as financial risks, which present largely different technical, managerial and political challenges.

1.2 FROM SCIENCE TO SAFETY REGULATION

Why should there be safety regulation? In many areas of life people are free, and prefer to be free, to make their own decisions about their safety, but sometimes standards are needed. For *consumers*, standards may sometimes be the best way to provide them with the balance between cost and risk which reflects their preferences, because the information is otherwise very costly to obtain or too difficult to interpret. *Third parties*, for example living near a potentially dangerous industrial site, may have too little market power, or have too weak or too costly access to the law, to enable them to negotiate effectively with those who manage these health or safety risks. *Producers* can value standards which reduce uncertainty about exactly what balances of cost and safety will be acceptable in their labour and product markets. Some standards can be set and enforced satisfactorily by groups of producers or consumers, in response to market forces, but there is often also a role for government.

There will always be debate about what risks should be the concern of government, although pressure for more UK government safety regulation tends to come from public opinion rather than from the regulators. There is less public debate, and only limited consensus among regulators and their expert advisers, and in public opinion, about how standards should be set, and in particular about the scope for formal analysis.

The most important and substantial technical inputs to safety regulation are physical scientific data, about the potential harms and probabilities of their occurrence. The policy application of this data will always entail political judgement, about what ideally should be done, about what can be done and about presentation.

A fully "rule-based" approach to safety regulation, where all regulations were set according to universal formulae quantifying and valuing costs and benefits, would be unrealistic. It is however often presumed that there is little if any scope for analysis in between physical scientific data on the one hand and, on the other hand, political and administrative judgement about what regulation if any there should be. People's values and preferences are sometimes seen as issues for such judgement alone, or for the experienced judgement of the expert scientist or engineer, or, in some contexts, of the lawyer, with little systematic information to help these judgements. The costs of regulation are also sometimes given little or no weight.

The concern of this report is the scope for helping these difficult policy decisions by analysis of the preferences of those at risk and of the general public and of producers, and of the cost of tighter regulation, and analysis of the regulatory process itself.

It should be possible, over time, to establish common frameworks for the analysis of the costs and benefits of all safety regulations, which are flexible enough to handle the wide differences in availability of data and in attitudes towards different kinds of risk, and which provide a common basis for policy judgement and standard setting.

It should also be possible to achieve more understanding of the institutional processes by which the regulatory game is played, and of how they might be developed.

The development of technical and institutional frameworks in this way will help to promote more systematic and consistent regulation. It will also help towards public acceptance of a balanced approach to safety risks.

2: CURRENT PRACTICE

2.1 SUMMARY OF CURRENT PRACTICE

The complex distribution of responsibilities for safety regulation between government departments is summarised in Annex A. They are discussed more fully in the parallel report by the Interdepartmental Liaison Group on Risk Assessment (ILGRA) (Health and Safety Executive, 1996).

Practice varies widely across departments, because of different traditions, different degrees of statutory responsibility, different reasons for government regulation and, importantly, the widely differing characteristics of the risks with which departments are concerned.

Among UK safety regulators, and indeed world-wide, the *Health and Safety Executive* (HSE) stands out as having an exceptionally wide range of responsibilities and experience. Its conventions have also been exposed to some unusually severe public scrutiny, notably in the Sizewell B and Hinkley Point Public Inquiries (Barnes, 1990). The HSE has therefore been in recent years the main source in the UK of safety regulation development, most notably of the "Tolerability of Risk" (TOR) framework which is described in the following section.

The *Department of Transport's* responsibilities include road safety. This is the principal area in which cost-benefit analysis (CBA), using explicit valuations of risks of injury, is used as a major determinant of spending priorities. The Department has long been the main government source of development of valuation techniques for fatal and non-fatal injury. Among other transport modes, CBA has in recent years come to be increasingly used in railway safety. It is also now becoming accepted, to a lesser but increasing extent, in aviation and marine safety.

Many of the*Department of the Environment's* regulatory responsibilities, including those of Environmental Agency (which includes the previous HMIP and NRA), and other responsibilities including Building Regulations, genetically modified organisms (GMOs) and natural radon, and now also HSE, extend well beyond safety. The Department is a source of development across this whole area. It published in 1995 a "Guide to Risk Assessment and Risk Management for Environmental Protection" (Department of the Environment, 1995).

The regulation of fire safety has developed and been applied over many years with a high degree of professionalism based on principles such as maximum escape times from buildings. The *Home Office* is looking into how this may be further developed, by taking closer account of, for example, comparative costs and numbers of people at risk.

The *Department of Health* and the *Ministry of Agriculture Fisheries and Food* (MAFF) have joint responsibilities for food safety. This is an area where very limited information about risks and the wide range of susceptibilities of different people are felt to restrict severely the scope for formal analysis. The usual procedure for chemicals in food is to establish a "No Observable Adverse Effect Level" (NOAEL) from animal studies, which is normally divided by a factor of 10 to account for extrapolation to man and a second factor of 10 for differences in susceptibility between people. This 100-fold factor is sometimes further increased where, for example, the implications of results from animal testing are not entirely clear, or where the effects are such that particular groups of individuals may be more at risk. For genotoxic chemicals the advice is generally to reduce

levels to the lowest which are technically achievable. Similar problems apply to many of the risks of medicines, although the standard criteria in this case include the balance between benefit from the treatment and the risk of adverse effects. In contrast, formal CBA is applied fairly widely by MAFF to the more readily estimated risks of floods. The Department of Health has for many years been in the lead in promoting the development of QALYs (Quality Adjusted Life Years), as a way of comparing health states to help prioritise health spending. Some work has also been done on the use of QALYs to measure losses due to injury or illness in other contexts, such as road accidents and food poisoning.

The *Department of Trade and Industry* is responsible for consumer good safety - an area in which trade-offs between cost and risk are felt often to be fairly obvious, once the facts are established. The *Department of National Heritage* is responsible for, in particular, sports stadia, where safety standards are generally still set on the basis of professional judgement.

The *Deregulation Unit*, now in the Cabinet Office, has a specific remit to ensure that business interests are properly considered across the whole range of government regulation. The Unit issued "Regulation in the Balance. A Guide to Risk Assessment" in 1993 (Department of Trade and Industry) and a further edition this year (Cabinet Office, 1996), to follow up the Government's requirement that all regulatory proposals which impact on business should be subject to risk assessment.

The *Interdepartmental Liaison Group on Risk Assessment* (ILGRA), chaired by the HSE, brings together on a regular basis all the departmental health and safety regulators, together with the Deregulation Unit and the Treasury.

The *National Audit Office* sees the area as important. It has for example commissioned a report on "Transport Safety Performance Measurement", to promote discussion and debate.

Vital contributions to current practice are made by a large number of *expert technical advisory committees*. Almost all members of these bodies are from the relevant physical science disciplines - mainly from universities and from business. Sometimes these committees are required to advise solely on the risks, and sometimes also upon what action, or targets, might be appropriate. In some areas, including aviation, there are also *advisory committees of producers*. Nearly all of these advisory committees have an external chairman, with the regulator providing a secretariat.

Another, major external influence is that of *public inquiries*. Public inquiries into disasters are now required to publish cost-benefit analyses with their recommendations.

2.2 OBSERVATIONS

Several points stand out in current practice.

First is a sharply increased awareness among regulators in recent years that good regulatory frameworks cannot stand still. This has led several regulators to promote important and continuing developments, and to an increasing willingness to share experience, and to adapt to developments in the physical and social sciences and in public and political priorities.

Second is the range of technical conventions among regulators. Sometimes an explicit trade off is sought between the benefits of risk reduction and the costs of implementation (although often without the explicit valuation of risk). Sometimes levels of risk or levels of

emissions or engineering practice are specified on other criteria, such as the lowest levels considered to be ethically, or politically acceptable, or to be technically feasible. The example of food safety was described above. A similar example is the recommendation of the Expert Panel on Air Quality Standards of a 1ppb maximum concentration of benzene (Department of the Environment, 1994). Rules of thumb with rather little empirical basis are common. There is a place for a range of conventions, but at present they are not always applied consistently.

Third is the absence of consistent terminology. Even such basic terms as "risk assessment" are still used differently in different contexts. There is no established language to describe and maintain crucial distinctions, such as that between working limits set to reflect good practice and absolute, equity based tolerability limits[1].

Fourth is a related absence of any consistent set of ethical assumptions about the distribution of risks and benefits.

Fifth is a sparsity of reliable data, or theoretical analysis, on people's values and informed preferences and on how these preferences might best feed through to regulation. This applies especially to the handling of different qualities of risk. Some of the consequences are striking, such as the very different criteria applied to normal nuclear emissions (as opposed to accident risks) in comparison with the hazards of other energy sources (Ball, Roberts and Simpson, 1994) and the returns to extra expenditure on local road safety which, in terms of fewer injuries, appear to be extremely high[2] - much higher than the returns to extra expenditure on public transport safety.

A final observation on current practice is the range of responses to European Union regulation. Sometimes the transfer of responsibility to the EU has led to a focus almost wholly on the implementation of European Directives. In other fields UK regulators see a substantial, permanent role in participating in and influencing European debate on regulation.

[1] Although the HSE has recently produced a glossary (HSE, 1995) to help progress on this front.

[2] Returns *in the first year alone* to local authority safety schemes appear to be typically around 150 to 250 per cent (Toothill and Mackie, 1995). The returns to extra spending at the margin would be expected to be rather lower, but appear to be still clearly very high.

3: THE BASIS OF SAFETY STANDARDS

3.1 STANDARD SETTING IN PRACTICE

Safety standards are a product of history, public and political and sometimes commercial pressures, and of analysis. Practical standards emerge from one or more of three broad approaches.

3.1.1 TRADITIONAL APPROACHES

A popular, and sometimes professional approach to safety regulation is that potentially dangerous activities should be made either wholly safe, or **as safe as possible**. This approach has historically dominated inquiries following accidents, which have often been driven by a demand that "it must never happen again". These approaches serve well in many contexts. Many of the recommendations of the Fennell and Hidden Inquiries, for example, after the Clapham Junction and King's Cross tragedies of the 1980s (Department of Transport, 1988 and 1989), have been accepted as timely or overdue. Such recommendations often cover management practice - such as training, inspection and safety culture (Pidgeon, 1991) - as well as operating practice and design.

Rules of thumb are also a common traditional approach. For example it is often accepted as policy (and often fixed in law) that risks cannot be allowed to increase even if the balance of costs and benefits changes. An example is that of the difficulty of relaxing the limit on sulphur 35 emissions from AGRs. The limit had been reduced by a factor 10 in 1990, with the industry's willing agreement, but it was later found possible to uprate the reactors considerably and maintaining the low limit has imposed high costs. Another example, popular in the aviation industry, is that the annual number of fatal commercial air crashes, world-wide, should not be allowed to increase above its current level (on the grounds that this would be commercially damaging to the industry). It is also common for maximum acceptable levels of risk to be tightened by arbitrary factors of 10, for hazards which are considered to be specially undesirable or politically sensitive.

3.1.2 TOLERABILITY LIMITS, WORKING LIMITS AND TARGETS

A well known feature of safety regulation is **maximum tolerable risks**. The most often quoted examples are HSE's tolerability limits, set on ethical (equity) grounds, of 1 in 10^3 per year as the maximum tolerable risk of death to an employee from workplace hazards, for any significant group of employees; and a limit of 1 in 10^4 per year for risks imposed by producers on any hypothetical member of the general public; although in practice these limits very rarely bite. Absolute limits are also sometimes set on other criteria which do more often bite, such as historical precedent.

Maximum levels of risk, of emissions or of harm, are also sometimes set more flexibly as **working limits** to define good practice, decided upon in terms of value for money. Sometimes they are used to ratchet down levels of risk or harm, as technology develops. This last practice, while useful and effective, has dangers if the limits are not based on an underlying balance of costs and benefits.

Also fairly common are aspirational **targets** to give a policy, whatever its basis, more presentational focus. Thus it might be decided that more effort to promote road safety would be worthwhile, and a published target might be set as a goal for which to aim.

3.1.3 COST-BENEFIT TRADE OFFS

In a few cases safety risks are **explicitly valued** (usually in terms of people's estimated willingness to pay to reduce them) and compared in a cost-benefit analysis with the costs of reducing the risk, to obtain a quantitative cost-benefit trade off. Much more often a similar process is applied less formally. All of these processes are covered by acronyms such as **ALARP, ALARA, SFAIR** and **BATNEEC**[3]. Although testing in the Courts and differing traditions among regulators can lead to small differences, there are in practice no consistent differences between the meanings of these expressions. Traditionally BATNEEC tends to be used in environmental contexts, including non-safety, whereas the others are generally confined to safety.

A prominent example in 1995 of the application of ALARP was the case of Automatic Train Protection. This had been recommended by the Hidden Inquiry into the Clapham Junction disaster and was initially accepted by British Rail. However from subsequent analysis they concluded that the cost of its full implementation would far exceed the benefits. Ministers duly approved a much scaled down proposal (House of Commons, 1995; Evans, 1996).

3.2 ABSOLUTE STANDARDS VERSUS THE COST-BENEFIT APPROACH

Some safety regulations are based on predetermined levels of safety. These may be for example a maximum tolerable risk of fatal injury to a hypothetical member of the public, or predetermined physical requirements such as sprinklers in the Underground as a decision of principle, or maximum emission limits for a pollutant based on technical feasibility, or limits based on historical precedent. Other regulations are based instead on a trade off between the costs and benefits[4] of more or less control.

This distinction can polarise into irreconcilable extremes; one maintaining that safety is a moral, political, legal, and sometimes commercial issue, to be tackled by mature judgement, and unsuitable for numerical calculations of costs and benefits; the other maintaining that, on the contrary, it is only by dispassionate numerical analysis of costs and benefits that sensible decisions about safety regulation can be made. There is however a case for both absolute standards and cost-benefit based standards

In regulating safety the government is sometimes acting as an *agent of the consumer*, helping to feed consumer preferences into the costs and quality of goods and services, where normal market forces are too weak.[5] In other applications the government is acting as a*guardian of people's rights*, where the individual at risk enjoys little or no benefit from the risky activity and where the power of redress by individual legal action is in practice very weak. This often arises where, for example, a commercial or state activity imposes small but not necessarily negligible hazards on the general public.

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[3] These acronyms stand for As Low As Reasonably Practicable, As Low As Reasonably Achievable, So Far As Is Reasonable and Best Available Technology Not Entailing Excessive Cost. The political and practical interpretation of "reasonable" or "excessive" is the key policy issue in the setting of safety standards.

[4] This applies of course to all the costs and benefits. These may include important factors which cannot easily be valued and may sometimes extend far beyond just commercial costs and just safety benefits.

[5] Sometimes this is a direct service to the consumer - as for example in requiring road designs to reflect consumers' willingness to pay for higher levels of safety. Sometimes it is a service sought by producers - in defining common standards to which they can produce and market their products: but in this latter case standards should still reflect the preferences of consumers. The government may in this case act as a facilitator or arbitrator or negotiator of producer determined standards, to help prevent, for example, their being used as protectionist barriers to competition.

In regulating risks to employees governments will generally wish to legislate to protect those who may have very little power against a seriously irresponsible employer. Nonetheless in a developed economy the main role of employee protection, as with consumer protection, should be to reflect people's willingness to pay for lower risks (and to accept more pay for higher risks) - not least because the costs of tighter standards are often reflected in incomes and other costs and benefits to employees and the local economy.

Where the government is acting as an agent of the consumer, or of any other individuals who want a trade off, satisfactory to them, between higher risk and higher benefits, it is widely accepted, at least in the UK, that a cost-benefit approach to regulation is appropriate[6].

This acceptance is not universal. Other EU countries do not generally accept it on political grounds for employees. Some industries or enterprises seek more costly standards for consumer safety, which are felt to be commercially more attractive (and affordable, even if against consumers' interests, when the enterprise or industry as a whole has monopoly power). Within the UK the cost-benefit approach to consumer safety regulation is explicitly accepted and promoted by the HSE and DOT and, in principle, by HMIP (now part of the Environmental Agency), but less clearly by regulators with responsibilities for safety of food or medicines, or fire risks. This reflects, very largely, the exceptionally strong political pressures in these latter fields and, often, the exceptional uncertainties.

Where the government is protecting people's rights, ethics become more important. In principle people can adapt their places of work and leisure according to the hazards surrounding them, such as those of a chemical complex, a nuclear power station, factories emitting or potentially emitting health threatening substances, or airports. In practice people cannot generally obtain and understand the complex information needed to assess the risks and hazards from installations of this kind. Even where they can, they are not always well placed to have their preferences reflected in new developments. Governments in these cases usually take measures to ensure that the risks to third parties are not "unreasonably" high; and this seems to be readily accepted also by producers. There is a role here, in parallel with the cost-benefit approach, for upper "tolerability limits" for individual risk, set on a basis of fairness, which must not be exceeded whatever commercial or other non-safety benefits that might offer.

3.3 THE TOR FRAMEWORK

The problem of bringing these ethical and cost-benefit approaches together was addressed in the 1970s by the International Commission on Radiological Protection (ICRP, 1977). The Commission introduced a system which combined a cost benefit approach to most regulations with absolute upper limits for the risks to which individuals or groups of people may be exposed. These general principles were subsequently reflected in the Report of the Royal Society Study Group (Royal Society, 1983), which also included a lower limit of individual risk, below which risks may be regarded as trivial.

This general approach is the basis of what has come to be called the *Tolerability of Risk* (TOR) framework, developed by the HSE in the 1980s (HSE, 1992).

The TOR framework applies a cost-benefit approach to most applications but constrains it by also imposing absolute maximum levels of risk, set on the basis of equity. (It also

[6] A "cost-benefit approach" means looking for an explicit balance between the costs of more regulation and the benefits of the risk reduction which it would achieve. The benefit valuations may be imprecise, but any regulation implies some range of valuation of the benefits. The issue is not between valuation and no valuation. It is about explicitly considering the valuation in setting the safety standard.

applies a lower limit, generally of 10^{-6} per year for individual risk of death, as a broadly acceptable limit below which formal analysis of costs and benefits is not normally required.) The TOR framework has become fairly widely accepted among UK regulators and academic experts and among producers. It has also proved to be a constructive vehicle for discussion of safety regulation within Europe.

The framework is simple. In practical safety regulation absolute limits have and will probably always have a central place. It will probably always be widely held that, in the normal course of life, risks of serious harm, beyond some high level, should not be imposed on unwilling subjects, even in exchange for very high material gains for others. However the TOR framework confines these ethically determined limits to upper bounds, which should not generally change over time, leaving most regulation to be developed in terms of ALARP, which, in turn, it defines explicitly in terms of the cost-benefit approach[7]. The framework leaves the regulator with a great deal to do, not least the setting of tolerability limits and the appraisal of costs and benefits. However it is a powerful innovation.

3.4 THE QUALITY OF RISK

Hazards obviously vary in the probability of their causing harm and the prospective level of harm. However they vary also in other important ways. The radiation hazards of medical x-rays have historically caused those at risk much less concern than smaller radiation hazards from nuclear facilities (although there are signs that this is changing); higher standards of safety are expected by users of public transport than by users of private transport; and large accidents are often seen by regulators as more than proportionately worse than smaller accidents. Quality differences of this kind, which may be physical or institutional, weigh heavily with most regulators. They often lead to essentially arbitrary multipliers being applied to values of injury, or to tolerability limits, and sometimes to public information being constrained by concern to avoid excessive anxiety.

These differing qualities of risk have also led to the convention of *societal risk(s)*, which has been used sometimes to describe all risks beyond those to the individuals directly exposed, sometimes to describe incidents which, because of their scale or horror, provoke a large socio-political response, and sometimes as a general term to describe all hazards which have specially undesirable qualities, or these qualities themselves. The term helps to establish where different qualities of risk might play a role. On the other hand as an analytical tool it has now come to be criticised as an oversimplification, and as a concept which needs to be replaced, or perhaps redefined more clearly. The HSE now prefers the clearer term “societal concerns”.

[7] Although many who apply the ALARP cost-benefit **approach** confine it to professional judgement of a “reasonable” level of risk, when set subjectively against the costs imposed by regulation. The use of cost-benefit **analysis** to compare costs with quantitative valuations of risk is the exception.

4: REGULATORY BEST PRACTICE

4.1 GENERAL APPROACH

It was noted earlier that the setting of safety standards cannot be reduced to a set of rules based on universal formulae for quantifying and valuing costs and benefits. This is not just a question of political realism. Regulation in this field faces fundamental ethical questions which can only be resolved by political debate and judgement. On the other hand sound judgement can only be made on the basis of quantification and analysis, and within a framework which poses the right questions clearly, which provides good channels for them to be resolved.

Regulatory best practice is considered here in terms first of institutional development, including the ethical framework, and then of technical development.

4.2 INSTITUTIONAL DEVELOPMENT

There is a developing literature on the institutional handling of safety regulation (Breyer, 1993; Majone, 1989; Royal Society, 1992(1); Saran, 1993). This is mostly in the USA, but includes a lively debate in Europe on liability.

An "institutional approach" to understanding decision-making:

- focuses on the processes by which decisions are made, rather than specifying optimal outcomes alone;
- concentrates on participants, incentives and information as the key elements of the
- aims to influence those elements by resetting the rules of the decision process.

In the context of safety regulation this traditionally covers issues of *standing* (both in a narrow legal sense and in a broader policy sense) of the regulator and other parties; of *liability* (including criminal versus civil law approaches to the management of risk); *rules prescribing the existence and duties* of particular positions, such as safety officers or committees; *disclosure rules*; and *default* or benefit-of-the-doubt rules.

Both policy and academic development could gain from a carefully structured inventory and, especially, evaluation of current and potential institutional approaches to UK safety regulation.

One set of issues follows from the long established argument for **building rivalry and social diversity into policymaking institutions**, to reduce the likelihood of "regulator" capture by producers at the expense of consumers, and to maintain among regulators a breadth of vision of all the potential impacts of their decisions (Schwarz and Thompson, 1990; Dunsire, 1992; Hood, 1996).

This leads to questions about the design of fora for productive adversarial exchanges in the process of regulatory decision-making - a question which (in an environmental rather than safety context) gained a flurry of publicity in 1995 with the Brent Spar controversy. Dialogue can be unhelpful if the different parties have inflexible, conflicting and hence quite irreconcilable sets of values. However the development of dialogue with those actively concerned about the risk more often eases problems of lack of trust or lack of

control, and can reduce the need for complex technical conventions to handle these features.

Another area of literature considers the implications for policy consistency and for professionalism of the **structures and staffing of regulatory bodies**.

There are arguments for and against having many independent regulators covering small areas, single regulators covering large areas, and the grouping of regulators together. These extend to the relationships between policymaking, monitoring and enforcement. There are further arguments about the degree to which regulatory staff should be specialists in safety regulation and the extent to which, in any case, they should move between regulators.

There may or may not be a case for developing safety (and may be environmental) regulation as an explicit specialism, with a corps of regulation experts who would move between the several regulatory bodies. This has attractions, but it could also discourage breadth of vision and innovation. While there is much to be gained from some people adopting career anchors in regulation, and from officials moving between regulators, the further, much stronger concept of a separate regulation specialism is less clearly attractive.

Under present arrangements, following the transfer to it in 1995 of HSE, there is a strong concentration of responsibility for safety regulation within Department of the Environment. That Department also has an established central role in environmental regulation. On the other hand many major areas of safety regulation remain elsewhere - notably with respect to road, aviation and marine safety; fire safety; food, medicines and medical products; and consumer capital goods; as well as some smaller areas, such as sports stadia and animal diseases.

There may be scope in due course for planning further restructuring of the regulators, to strengthen co-ordination and perhaps to reflect more understanding of the institutional approach as described earlier. However it would be best for any such proposals to follow more research into these issues.

There is no consensus among UK regulators on the **ethical assumptions** underlying safety risk policy. The ethical basis is important. It can imply widely varying standards, and is important in steering public debate. There is some literature - for example Rayner and Cantor (1987). However it is rarely debated. Regulation is sometimes dominated by administrative objectives, such as avoiding political embarrassment; and is sometimes dominated by a concern to establish and achieve "the-lower-the-better" targets for risks or for harms. Within private sector bodies, the protection of profits will always be a major objective.

The potential range of ethical assumptions is wide. It includes *expected utility maximisation*, which is the usual basis of CBA, but which seems not always consistent with public preferences for the regulation of risk of serious injuries. Often quoted is the "Rawlsian" approach of maximising the well-being of the worst-off, and the subtler version that *policymakers should decide as if they have no knowledge of where they or their interests would be* among those affected, in terms of, for example, income, status, location and time and perhaps nationality or cultural group. The Rawlsian approach, in most of its dimensions, does not evidently represent either general public or political preferences; but it has an altruistic appeal, and it contributes to the ethical basis of some tolerability limits. There are "Paretian" approaches, which in a weak version are similar to utility maximisation, but in a stronger libertarian version would constrain utility maximisation to solutions which *make no one worse off*. This is not realistic as a general

rule, but it is nevertheless a strong influence, for example on the presumption that safety should always increase. There is "Nietzschean" elitism, which aims to *seek benefits for those who can attain the greatest benefit*. While undemocratic, this is not wholly absent from safety regulation, sometimes notably in the past.

It is sometimes suggested that regulatory policy proposals should be analysed in terms of a range of ethical criteria (Shrader-Frechette, 1991). This has obvious practical limitations, but might sometimes be a stimulus to constructive public debate.

The absence of a clear ethical foundation can encourage the smuggling into policy of public (or other) prejudices through apparently technical decision formulae. Examples are essentially arbitrary factors applied without an empirical basis to valuations of safety benefits or to absolute limits for emissions or levels of risk. Adjustments of this kind are applied with good intentions, but they cannot be satisfactory.

In practice, current research and development on the institutional or economic aspects of safety regulation tends to presume that the ethical basis for advice by regulators to Ministers should be, in the first place, the values revealed by the *informed and considered preferences of public opinion*. Ministers will in addition have their own personal views, and will also expect advice on the handling of public pressures which may be based on views which are ill informed or ill considered, or are based on different sets of values.

4.3 TECHNICAL DEVELOPMENT

The technical analysis of safety regulation has over the years seen great advances. Examples are the development of concepts such as ALARP; the wide, even though not yet universal acceptance of valuation of risks of injury, and the techniques for deriving these values; and the TOR framework. There has been over many years an increasing understanding, by safety regulators world-wide, that public perceptions and attitudes are not simply a constraint on policy but, in many areas, an important input to policy analysis. However there remains a catalogue of unresolved problems, some of which are major obstacles to better regulation.

4.3.1 QUALITY OF RISK

One of the most serious obstacles to sharper and clearer debate about the technical analysis of safety regulation is the wide differences in the (physical and institutional) "quality" of risks which people face. Much research has been carried out which confirms that attitudes vary. This work is well summarised and fully discussed in the 1992 Royal Society Report (Royal Society, 1992(2)). A key paper is Fischoff et al (1984).

Better information is needed about this to help the development of both government and public understanding of why some risks evoke so much stronger concern than others, and hence of how these risks and concerns might best be handled. It is also needed to help the valuation of people's willingness to pay for reductions in risks of death and injury in different circumstances.

Sometimes public attitudes and perceptions are seriously misinformed. In this case it is reasonable for governments to act on the basis of good data, accepting popular opinion as a constraint rather than a guide. But this is a side issue. The central issue about quality of risk is that, even when fully informed and after careful consideration, people do have fairly systematically different attitudes to different kinds of hazard. As a pragmatic necessity, and some would argue as a principle of good regulation, this has to be reflected in public policy.

The discussion below examines the dimensions of quality of risk and their relevance to practical regulatory policy.

The best known psychometric work[8] in this field, versions of which are reproduced in the Royal Society report and in the recent ILGRA report, compresses the results of research into people's views of many hazards into the two dimensions. The experimental work took a large number of factors, such as those considered below, but the concepts of "dread" and "knowledge" seemed to the authors the best way of summarising the data (Slovic, 1987). Examples of hazards which appear in each of the four quadrants are shown in Table l. Hazards which are high on the "dread" and "unknown" scales, as in Box **BB** ("Bad/Bad"), generate especially high public demands for regulation. However other strongly regulated hazards appear in all four boxes.

TABLE 1: EXAMPLES OF HAZARDS GROUPED BY PUBLIC PERCEPTIONS OF "DREAD" AND "KNOWLEDGE"

	LOW "DREAD" ('Acceptable')	**HIGH "DREAD"** ('Bad')
"UNKNOWN" RISKS ('Bad')	**AB** Cosmetics Aspirin Food colouring	**BB** Nuclear power Herbicides Liquid natural gas
"KNOWN" RISKS ('Acceptable')	**AA** Alcohol Boxing Motor vehicles Rail travel Surgery	**BA** Warfare Crime Dynamite

One problem with data of this kind is that it is only qualitative. A more fundamental problem is that the dimensions chosen are so diverse, and yet may also omit some important factors. "Dread" includes, among other factors, accident size, involuntariness, unfairness, fatality, and unaccountability. "Knowledge" includes scientific knowledge, familiarity, immediacy of impact and observability. Neither discriminates between the views of different cultural groups. It seems unlikely that data of this kind on public perceptions can be of much practical value unless the most important dimensions can be much more firmly tied down .

One dimension of quality which was not explored in these earlier studies, but which is now being given some prominence, is *trust* - that is public trust in government's or industry's willingness and ability to control risks, and in their willingness and ability to communicate open mindedly and impartially with those who are or might be at risk (Slovic, 1993). This relates to a still wider complex of partly institutional issues, relating to trust, responsibility, blame and the mechanisms by which people's views are expressed and absorbed. It also relates closely to the degree of choice and control enjoyed by those at risk.

[8] The other main strand of research in this field, which is empirically weaker but theoretically stronger than the psychometric work, is the development of cultural theories, as in for example Kasperson et al (1988).

There is wide (although even here not universal) agreement that these latter qualities of *voluntariness* and *controllability*, within the "dread" scale, not only are but should be important determinants of the scope of regulation, and of both tolerability limits and of the appropriate balance between costs and risk. Table 2 illustrates these two dimensions, which in practice fit much more closely the attitudes of governments and public opinion to regulation. Box **aa** generally attracts no safety regulation of participants (although for a hazard such as smoking, where the risks are not self evident, there is a government role in providing information, and for regulation of sales to children, and a case for measures such as high taxation and advertising restrictions to help counter the effects of addiction). Box **ab**, which contains rather few hazards, entails little regulation, although there is more often a government role in providing information. Serious hazards in Boxes **ba** and **bb** are almost always regulated, although some equipment, machinery, or vehicles may be regulated by confederations of producers or users rather than by governments. Surgery and rail travel in Box **AA** in Table 1 are in Box **ba** in Table 2. As the latter implies, they are heavily regulated. Serious hazards in Box **bb** are usually accepted as demanding substantial government regulation.

TABLE 2: EXAMPLES OF HAZARDS GROUPED BY CONTROLLABILITY AND VOLUNTARINESS

	CONTROLLABLE BY THOSE AT RISK ('acceptable')	**NOT CONTROLLABLE BY THOSE AT RISK** ('bad')
INVOLUNTARY EXPOSURE TO THE HAZARD ('bad')	**AB** Natural radon in existing buildings Sunlight *Some of Box **AA** from Table 1*	**BB** Sea or river flooding Dangerous buildings *Most of Boxes **BA** and **BB** from Table 1*
VOLUNTARY EXPOSURE TO THE HAZARD ('acceptable')	**AA** Smoking DIY Rock climbing *Much of Box **AA** from Table 1*	**BA** Rail, air, or coach travel Equipment for DIY or rock climbing Surgery *Most of Box **AB** and some of Box **AA** from Table 1*

There is less agreement about the importance of other factors.

One surprisingly contentious factor is that of *incident size*. The issue is not whether incident size matters. It is obvious that large incidents attract more media attention, and commercial bodies will be more than proportionately concerned to prevent them because of their bad impact on marketing. Governments too may wish to weight regulation in this direction, to avoid adverse publicity. The issue is how this media (or societal) response should be handled in the setting of safety standards. It is widely held among regulators, but much less often among academic or other commentators, that people should as a general rule be less well protected from the risk of incidents that affect only one or a very few people at once than from the risks of incidents which affect many people - such as a major rail or air crash -, although there is no consistent evidence that this reflects the preferences of those at risk (Slovic et al, 1984).

There are some good reasons for expecting large incidents to impose more than proportionately higher costs. They can lead to irresistible public pressure for new, excessive controls, to prevent any possibility of anything like it happening again. They may cause excessive anxiety - as for example with the fall in Underground travel after the Kings Cross tragedy. Accident size also tends to be a proxy for lack of control by those at risk. However it is not clear that government regulators, in advising Ministers, should bury a weighting for accident size in the technical analysis (in terms of, for example, defining tolerability limits or valuing risks of injury).

Less discussed is the *pain and suffering* preceding particular fatal injuries or illnesses. Is being drowned or suffocated in the Underground worse than being crushed or burnt on a motorway? There is very little data on how this varies, or is perceived to vary across hazards, or on its importance in public perceptions or preferences in terms of willingness to pay.

Another obvious factor in public perceptions is *familiarity*. Most people accept hazards such as those of smoking and alcohol, car driving, and long established foodstuffs, which, if they were new, might be seen as intolerable risks. Familiarity certainly eases the political constraints within which regulators work; and novelty increases them. It is not clear however that familiarity should have much if any direct bearing on tolerability limits or the valuation of injury.

Another quality is *observability*. It is often suggested that the invisibility of nuclear radiation contributes to its emotive impact. Many other hazards are similarly unobservable to those at risk, such as lead in tap water, and, before they were identified, the delayed consequences of tobacco smoke or asbestos fibres. And so too for potential explosive or chemical hazards, which will often be quite unknown to many of those at risk. Observability is perhaps best seen as an aspect of controllability. For unobservable hazards those at risk are dependent upon others to inform them, raising questions of trust and responsibility.

Delay in impact on the affected individual is itself a quality. It is understandable, yet paradoxical, that the prospect of a delayed impact, which may often extend over 20 years or more, should be seen as a "bad" feature of such hazards, even though most people, given the choice between the risk of immediate death and an equal risk of long delayed death, or even for serious illness, would prefer the delay. Perhaps it should be seen simply as an extension of observability and hence of control. There is little if any useful data on which to base judgement about how delay should influence tolerability limits, if at all, or how it affects people's valuations of risk.

Another quality is the *baseline level of risk*, which is being regulated. It is widely held by regulators, and by the Courts, that higher costs are justified, per increment of risk reduction, if the initial level of risk is high than if it is low[9]. Sometimes this is explained in terms of people having an increasing aversion to extra risk as the level of risk increases. They almost certainly do. But in practice virtually all regulation, at least for very serious harms such as death or serious injury, applies to very low levels of risk - usually much less than 1 in 10^4 per year of death - and over this very low range people's aversion to a small extra risk might be expected to be for practical purposes constant. There is no clear evidence to suggest otherwise.

[9] A related but distinct question is whether, even for low levels of risk, people's willingness to pay to prevent a step change of risk is more than proportional to the size of the change. It would be curious if people were willing to pay more to avoid a step change in risk than to avoid lots of small changes which added up to the same total, but not impossible.

It is certainly true that, for high risks, people's willingness to accept compensation for risk increases much more than proportionately with risk. Thus most people would not accept any financial compensation in exchange for a risk of immediate death of, say, 50 percent. However this largely reflects the declining value of extra money with increasing wealth, rather than any measure of the changing welfare cost of increasing risk.

A better explanation for giving more than proportional weight to higher risks is that, because of considerations of *fairness*, risk at its upper tolerability limit is in effect given an infinite value, so that, as risks approach these levels, especially if there is uncertainty about the risk, it is reasonable to cost them more highly. This is explicitly used by the HSE as an explanation of "gross disproportionality", long established as a legal defence against providing extreme safety measures to protect employees, and well embedded in safety regulation culture. (The HSE logic is that at levels of risk not far above the broadly acceptable lower limit costs of safety measures should not be "disproportionate", while at levels of risk approaching the higher limit costs should not be "grossly disproportionate", relative to the same valuations of risk.)

This appears also to be the basis of the "multiplying factors" applied by the National Radiological Protection Board to their "base-line" value per unit of radiation damage (NRPB, 1993). For increasing levels of individual risk, beginning rather below the conventional TOR lower limit of a 10^{-6} risk of death, the curve defines an increasing multiplying factor, rising from 1 to around 5 or 10 for levels of risk around the upper TOR limit and continuing to rise smoothly thereafter. (The graph of the multiplying factor against radiation dose is called a "fuzzy curve" because it is presented as band of about ±20% for any given dose, rather than a single value.) This offers an alternative to the TOR convention which has stood some test of time. The numbers are intended to reflect people's supposed more than proportionate aversion to increasing levels of individual risk, but they are acknowledged to be judgemental, rather than having an empirical basis.

A related quality is the *concentration* of the risk. People seem generally to feel that, if there were a given chance of someone being killed or seriously injured, it would be better for this chance to be spread not only widely, which as an ethical judgement is unsurprising, but very widely indeed. These issues of fairness are discussed by Broome (1991).

Yet another quality is *uncertainty* about impacts and about the effects of safety measures. Some recent research suggests that the public may prefer proportionately more resources to go into safe bets of risk reduction than into uncertain ones (Savage, 1993 and Jones-Lee and Loomes, 1995). At the same time, institutions who carry responsibility will tend to play safe. For hazards which are not only uncertain but also potentially catastrophic the *precautionary principle* (which still entails a balance of costs and benefits, but weighted towards caution) is established policy, and generally uncontroversial within government (Department of the Environment, 1994)

Another characteristic which is surprisingly treated sometimes as a quality of risk is *physical damage*, with the valuation of injuries being increased to reflect these costs. This practice seems to be declining, in favour of the better practice of estimating physical damage costs as a separate item.

4.3.2 DISTRIBUTIONAL EFFECTS

Many issues arise in discussion of the distributional effects of safety regulations. This applies especially to the relative weights which should be given to the interests of different generations, and different income or cultural groups.

Investment in safety presents the usual problems in public policy of comparing costs and benefits at different times, but some of the problems can become unusually acute. These include the ultimately political problem of whether or to what extent the *marginal welfare of more distant generations* should be given less weight than that of today's or closer generations. Current Treasury guidance gives some decreasing weight to more distant generations. This almost certainly reflects most people's considered preferences, and is consistent with the obviously greater weight which is given by all countries to the interests of their own contemporary citizens than to those of other countries. However some commentators, appealing to Rawlsian ethical principles, are uneasy about this.

An extension from this is the question of how absolute tolerability limits should be adjusted for future risks, including the very distant future. This again is ultimately political, although it would be sensible for such judgements to be based on systematic evidence of people's preferences - of which there is at present little if any. The HSE convention is that tolerability limits, which are set as ethical limits to the hazards which society may impose on individuals, should be maintained unchanged for at least several generations, but not into the indefinite future beyond, say, one or two centuries. (This is of course distinct from the wide acceptance, noted above, that if action is needed now to prevent a catastrophic harm in even the very distant future, it should be taken.) On the other hand in environmental contexts radiological exposure limits tend to be seen as timeless, so that forecast radiation from waste storage, for example, should be no more than would be allowed today even in a million years time. This can lead to very high costs in trying to prove that this very low limit will be achieved.

A more conventional problem is that of *valuing future injuries*, in a way which reflects the higher real monetary values which future populations, with higher incomes, would be likely to place on them. A common practice is to assume that such values will increase in proportion to people's incomes. A technically more defensible procedure could be to regard risks of injury as measures of absolute welfare, and discount them at whatever rate, perhaps 1 or 2 per cent, is considered appropriate for future welfare (as opposed to real income). This would be equivalent to applying the currently standard discount rate, of 6 per cent for future real income, to real monetary values of future injury risks uprated (to reflect increasing willingness to pay for marginal welfare as income increases) by say 4 or 5 per cent per year. This would imply a fairly substantial increase in willingness to pay to reduce safety risks as income increased over time. On the other hand some cross-sectional study of "values of life" used by developed countries implies that this increases less than proportionately with income (Alfaro, Chapuis and Fabre, 1994).

Safety regulation has sometimes to face the question of what comparative weights should be put on risks to different contemporary groups of people, such as those of different *age* or of different *income.*

Monetary valuations of risk applied by different countries should be expected to vary, especially with their incomes. It would be both unfair and inefficient to impose on other countries a higher or lower value of risk than their own willingness to pay, although political and sometimes commercial pressures, in the EU and elsewhere, can lean towards "level playing fields" whatever people's willingness to pay. Within any one country there may be situations where those concerned would prefer, and would be willing to pay for, say, higher or lower safety standards in exchange for, for example, higher or lower prices, or lower or higher wages, or less or more of a particular kind of employment. Such preferences should be respected. However for many activities there are ethical concerns which lean towards common standards of safety for all of those at risk from a particular hazard, regardless of for example age, income, or nationality. It seems for example to reflect public preferences, and to be ethically acceptable, that for road safety analysis all

people are usually given equal weighting. On the other hand this may largely reflect the lack of knowledge about who will be at risk. Thus it is widely accepted that priorities for limited resources for life saving surgery, where individuals are known, should give more weight to the young than to the old.

4.3.3 TOLERABILITY LIMITS

Two upper tolerability limits are used by the HSE. The limit of 1 in 10^3 per person for risk of death for groups of employees is usually explained as being the maximum average risk faced by any significant group of employees (such as deep sea fishermen). It is also the broad order of magnitude of the risk faced on average by employees as a whole of death, from all causes, natural or otherwise (a lower risk for younger adults and higher for older ones). The upper limit of 1 in 10^4 for a hypothetical member of the public is a fairly arbitrary factor of ten smaller. It is also the average probability which people face of being killed in a road accident, which, while being a level of risk which does and should cause concern, is not a source of continuing anxiety for most people. There is little reason to challenge these limits (which rarely "bite"), although such limits would be more robust if they could be based, at least in part, on well researched evidence of public attitudes.

There is no corresponding rationale for the much tighter limits applied to certain kinds of risk, often because they are politically sensitive. It is possible that considered public preferences, as distinct from instant gut responses, would favour tighter limits to risks of this kind, although there is no evidence of this. There is also very little information available on the costs imposed by these tighter limits. The case for specially tight enforcement of these limits may be stronger than the case for specially tight limits.

Absolute tolerability limits in practice affect only a small proportion of safety regulation. It is a paradox that they attract much more attention in industrial and scientific circles than cost-benefit trade offs for risks which fall below these levels.

4.3.4 VALUATION OF INJURY

There is a wide and expanding literature on the valuation of injuries. In the UK this has been promoted mainly by the Department of Transport for use in the appraisal of road projects. In the 1970s the main focus was on fatal injury and on the value of the gross output which a person would produce, were he or she to continue living, as a measure of the loss of welfare if he or she were to die. This came to be seen as an inappropriate measure and has been superseded mainly by studies of people's "willingness to pay", in money or in kind, to reduce small risks of death. The Departmental review on which the present value is based is summarised by Dalvi (1988). The willingness-to-pay methodology is described by Jones-Lee, Loomes, O'Reilly and Phillips (1993). Hopkin and O'Reilly (1992) complete the technical picture with figures for fatal and non-fatal injuries including appropriate costs of lost output and medical costs. Hopkin and Simpson (1996) record the latest revisions and summarise the methodology. Jones-Lee (1989) includes a comprehensive review of major willingness-to-pay studies.

The resulting "value of statistical life" (VOSL) is the aggregate of many people's willingness to pay for a reduction in an already very small risk of death. This concept is now well accepted in principle among UK regulators, and is fairly widely used. However the problems of measurement are severe. There are also problems of its acceptability.

It is for example very often known that despite some regulation some people are bound to be killed (for example in road accidents). As an issue of public policy this is no more than part of the tough reality of decision making. However it is widely held - and it would be troubling if it were not so - that if identified individuals are mortally threatened (for

example trapped in some hazardous situation) all the facilities available should be used to save them. It can be seen as morally wrong to plan in effect for people to be killed, even if they are not yet identified.

A related problem follows from the question of concentration. It could be argued, perhaps, that proportionately less weight should be placed on reducing risks which are widely dispersed than those which are more concentrated on limited groups of people, even when both are expected to produce the same total number of injuries.

There are no indisputable answers to these and other problems. However most experts in safety analysis seem content to accept that (so long as the future victims cannot be individually identified) values derived in this way do reflect people's preferences. People do for example, to save small amounts of time or money, voluntarily and frequently take risks - such as crossing the road away from the pedestrian crossing or before the lights have changed - which they know increase, however slightly, the risk of death or serious injury.

It could be helpful to clarify and broaden the definition of the "roads" value of statistical life. Much of the research on which it is based is specific to roads, but it is derived very largely as a value which people are willing to pay to reduce a quite abstract risk of death, with no extra element of dread or lack of knowledge or trust, or for involuntariness or lack of control. It is essentially a baseline VOSL, for a general, largely voluntary and controllable risk. The current value is based on research carried out in 1982-83. It was chosen, for reasons specific to that time, from the lower end of what was considered the then credible range, and has been uprated since then only in proportion to GDP, which as discussed above may be conservative. At some time this value will need to be re-examined.

A further problem with VOSL, and even more with the shorthand expression "value of life", is that the terms are emotive and tend to be understandably disliked by Ministers. Sometimes "value of life" is used misleadingly to mean "cost of a life saved" by some particular safety measure, and this misuse should be discouraged. (This cost of a life saved is the cost side of the cost-benefit comparison, for comparison with the benefits side, which includes valuations of risks of death.) The ideal phrase or acronym would describe the "Valuation of a statistical life for small ex ante risks". The "small" risk to individuals is important, even though, as noted above, the risk of one or more deaths occurring among the whole population at risk may be effectively 100 per cent. In the absence of this ideal the Department of Transport often use the terms "valuation of safety" and "valuation of reduction in risk" in place of "value of life". Such forms of words should be encouraged.

The valuation of risk of <u>non</u>-fatal injury is philosophically simpler than valuing the risk of fatal injuries. It has however the extra complication of the great variety of injuries whose effects may be short, or long lasting, or permanent; may entail pain, handicap and/or disfigurement; and may be physical or mental. The Department of Transport has promoted research in this area, the results of which are also used by other regulators. There may be scope for more use in this area of the Department of Health work on QALYs.

There is an overlap between the concept of *value of statistical life* and that of valuing "*life years*". It is sometimes suggested that if the "quality adjusted life year" (QALY) could be valued then the present value (PV) of a person's future expected QALYs should relate closely to the valuation of a risk to the person's life; or conversely that the VOSL may be used to value the QALY. However the welfare costs of death are not well measured by the welfare which the dead person would have enjoyed. Before the event this prospective welfare will usually be but one factor determining that person's willingness to pay to reduce the risk of death. After the event (for a fatal injury, as opposed to a non-fatal injury) the **only** welfare costs will be those falling on other people, which are often considerable,

but are a different concept. However this remains an unresolved area. A recent philosophical perspective is explained in Broome (1996). The use of the VOSL to derive a value of for a life year is illustrated in Soby, Ball and Ives (1993), in a paper which describes the Relative Utility Loss Approach (RULA) to comparing the valuations of different non-fatal (and fatal) injuries.

There remain serious empirical problems in measuring willingness to pay for reductions in risk even when there are no serious problems of quality. Any such work will always be imprecise - looking for values within say plus or minus 50 per cent. There is also very little information about how people's valuations vary with the quality of risk, partly, no doubt, because of the absence of a well established, workable framework for describing risk, to use as a basis for quantitative research. However, prompted by London Transport and more recently HSE, research is now progressing in this area in the UK.

Some of these problems are inherent in the ethics of safety regulation. However it is only by quantitative research that the true ethical questions, which have to be resolved by Ministers, can be disentangled from the technical analysis.

5 CONCLUSIONS AND RECOMMENDATIONS

5.1 GENERAL PRINCIPLES

Crucial to good safety regulation are physical scientific data about potential harms and probabilities of their occurrence. The use of this data for standard setting very often needs substantial political, administrative and scientific judgement.

Also important, but less widely recognised, is the scope for improving these judgements by formal analysis of institutional processes, of public values and preferences, and of costs.

A fully "rule-based" approach to safety regulation, where all regulations were set according to universal formulae quantifying and valuing costs and benefits, would be unrealistic. Nonetheless ***common frameworks could and should be developed for all safety regulations, despite the wide differences in available data and in attitudes towards different kinds of risks, so providing a common basis for policy judgement and standard setting.***

This common approach would not only help regulators directly. It would also contribute to wider public acceptance of a balanced approach to safety regulation.

To help make this possible ***further measures are needed to develop a common and consistent terminology for safety regulation.***

5.2 CURRENT UK PRACTICE

It is now widely accepted among UK regulators that good regulatory frameworks cannot stand still and many regulators are promoting important developments.

There is nonetheless scope for much more consistency, in terminology, in underlying assumptions and in regulatory concepts. Although regulation is widely based on the best available scientific data, there is much variation in the extent to which costs of risk reduction, and the examination of public values and preferences, are taken into account. Rules of thumb with little empirical basis are common. The differing natures of different hazards and their impacts account for some of this variation, but not for all of it.

The approach of UK regulators to the UK role in setting and implementing EU standards is more proactive in some areas than in others.

5.3 THE BASIS OF SAFETY STANDARDS

The objective of all regulation should be a considered balance of costs and benefits. In the case of safety regulation this has sometimes to include taking into account important ethical constraints on the distribution of costs and benefits.

It is useful to distinguish between regulation to protect third parties and regulation to reflect consumer interests. ***The protection of consumer interests should generally reflect consumer's informed and considered preferences, with no need for such separate, ethically based limits determined by government.***

However in regulating to protect third parties, and sometimes employees, ethical constraints on maximum levels of risk can be important. ***The Tolerability of Risk (TOR) framework should be used wherever practicable as the means of applying these ethical constraints***.

A clear distinction should be drawn between absolute tolerability limits, based on ethical judgement about upper limits to the risk which may be imposed on third parties, and working limits used as operational definitions of good practice.

Working limits should be based on a cost-benefit trade off and be correspondingly flexible. If regulated limits are used as a managerial device to ratchet down risks or harms, this should be within a cost-benefit framework.

The concept of "societal risk" is useful in highlighting where different qualities of risk might play a role, but as a analytical tool it is an oversimplification. The recent change of terminology to "societal concerns" is to be welcomed.

5.4 REGULATORY BEST PRACTICE

The present procedures for initiating and co-ordinating research in the social science aspects of safety regulation are in many respects satisfactory. In the technical field important results have been produced - notably on injury valuation, which put the UK among acknowledged world leaders. Dissemination across departments is also generally good. There is not sufficient evidence to suggest that, given other priorities, expenditure on research on safety regulation should be increased in total. Nonetheless many methodological and related institutional problems of safety risk merit further research.

An inventory and evaluation of current institutional procedures and conventions would be valuable. This might examine the range of institutional approaches to safety risks in the UK (and the EU), with a view to defining more clearly the ethical assumptions underlying safety regulation, and to identifying better procedures for bringing adversarial parties into constructive debate.

Another high priority should be the clarification of which qualities of risk, including issues of trust, are important in people's preferences, why, and to what extent, and how they might best be handled both in formal analysis (especially in setting tolerability limits and valuations of injury) and in institutional arrangements.

Other areas for potential technical research include the comparative safety impacts on groups of people of, for example, different income, or different generations and the comparative weights which should be given to these impacts.

The widely quoted dimensions for safety hazards of "dread" and "knowledge" are of little if any practical value. ***There is much more practical value in categorising hazards in terms of controllability and voluntariness on the part of those at risk, than in terms of the conventional dimensions of dread and knowledge.*** Activities which impose serious risks which people cannot control or avoid usually require regulation.

For small risks to the individual, there is little evidence to suggest that considered public preferences are that cost benefit trade offs or tolerability limits should vary much between those hazards which are regulated, despite the sometimes wide differences in media impact. ***Public attitudes to differing standards for different hazards should be further examined.***

In this and other fields i***t is unsatisfactory for public (or other) prejudices to be smuggled into policy through apparently technical decision formulae, by means of, for example, numerical factors imposed subjectively by technical experts to reflect supposed ethical or societal concerns.***

The concept of "value of statistical life" presents problems which remain not fully resolved, but as an operational concept it appears robust for the costing of most small risks to individuals, even when, among the whole population of those at risk, deaths are for practical purposes certain. A less emotive shorthand term for the concept would be helpful.

It would be helpful to develop the "roads value of life" as a more general baseline value of statistical life. The current value will in any case need to be reassessed in due course.

There may be scope for further consideration of the professionalism of safety regulation officials, but the present UK structures appear broadly satisfactory in this respect.

Social science research commissioned by government bodies in the field of safety regulation tends to concentrate on the economic aspects. It also tends to be commissioned by and for individual regulators. ***The case should be examined for buttressing present procedures for commissioning social science research with a more focused, government wide procedure, considering not only economic aspects, but also institutional frameworks, ethical assumptions, the quality of risk, issues of trust/ responsibility/blame, terminology, and European attitudes and developments; which all need to draw more heavily on other disciplines, such as psychology, law, public administration and political science.*** Although some useful steps are being taken, progress in these areas under present procedures is slow.

The promotion of change in safety regulation, in pressing regulators towards current best practice and in developing best practice itself, would be helped if some ***continuing external social science expertise could be drawn in to complement, and to work with, the essential and considerable expertise already so employed in the physical sciences.***

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Responsibilities For Uk Safety Regulation

ANNEX A: RESPONSIBILITIES FOR UK SAFETY REGULATION

Application	Main UK responsibility	Law	International body
Work related			
Nuclear	HSE(NII)	NIA/HSWA	EURATOM/ICRP
Mines	HSE(MI)	Misc./HSWA	EU
Offshore		HSE(OSD)	Misc./HSWA EU
Civilian explosives & toxic substances	HSE	HSWA	-
Other workplace	HSE	HSWA	EU
Quarries	HSE	HSWA/MQA	EU
Agriculture		HSE	
Transport			
Rail	HSE(RI)	Misc./HSWA	-
Roads	DoT	Misc.	UN
vehicles	DoT	Misc.	EU
drivers	DoT	Misc.	EU
Aviation	CAA		JAA/ICAO/ECAC
Maritime		DoT	IMO
Moving hazardous substances:			
by road	DoT/HSE	Misc./HSWA	EU/IMO
by pipeline	HSE		
Products			
Consumer goods	DTI	CPA	EU
Capital goods	DTI	ECA	EU
Food products	DH/MAFF	FSA	EU
Diet	DH/MAFF		-
Smoking		DH	-
Medical			
Devices & equipment	DH	CPA	EU
Medicines	MCA	MA	EU

Flood & coastal defence				
	MAFF	Misc.	-	
Environmental				
Drinking water	DoE(EA)	WIA	EU	
River & Coastal	DoE(EA)	WIA	EU	
Air	DoE(EA)	EPA	EU	
Solid wastes	DoE(EA)	EPA/COPA	-	
Toxic substances	DoE/HSE	HSWA		
Buildings				
Construction	HSE	HSWA		
Radon in the home	DoE	-		
Other	DoE	1984 Building Act	EU	
Fire				
Occupied premises	HO/HSE	FPA/HSWA	EU	
New premises	DoE	1984 Building Act	EU	
Dangerous animals				
Wild animals	DoE	DWAA	-	
Dogs	HO	DDA	-	
Rabies etc.		MAFF/DH	AHA	-
Recreation				
Stadia	DNH	Misc./HSWA	-	
Playgrounds	HSE/HO/DNH	HSWA	-	
Others	HSE	Misc./HSWA	EU	
Schools				
	HSE/HO/DFEE	Misc./HSWA	-	

ABBREVIATIONS

AHA	Animal Health Act (1981)
CAA	Civil Aviation Authority
COPA	Control of Pollution Act (1989)
CPA	Consumer Protection Act (1987)
DDA	Dangerous Dogs Act (1991)
DH	Department of Health
DFEE	Department for Education and Employment
DoE	Department of the Environment
DoE (EA)	Environmental Agency
DNH	Department of National Heritage
DoT	Department of Transport
DTI	Department of Trade and Industry
DWAA	Dangerous Wild Animals Act (1976)
ECA	European Communities Act (1972)
ECAC	European Civil Aviation Conference
EPA	Environmental Protection Act (1990)
EU	European Union
FPA	Fire Precautions Act (1971)
FSA	Food Safety Act (1990)
HO	Home Office
HSE	Health and Safety Executive
HSE (MI)	Mines Inspectorate
HSE (NII)	Nuclear Installations Inspectorate
HSE (OSD)	Offshore Safety Division
HSE (RI)	Railways Inspectorate
HSWA	Health and Safety at Work Act (1974)
ICAO	International Civil Aviation Organisation
ICRP	International Commission on Radiological Protection
IMO	International Maritime Organisation
JAA	Joint Aviation Authorities
MA	Medicines Act (1968)
MAFF	Ministry of Agriculture, Fisheries and Food
MCA	Medicines Control Agency
Misc.	Miscellaneous
MQA	Mines and Quarries Act (1954)
UN	United Nations
CIA	Water Industry Act (1991)

ANNEX B: COMPOSITION OF THE WORKING GROUP

The Working Group responsible for this Report was chaired by the Treasury and included representatives from the Health and Safety Executive and from the following Departments.

Ministry of Agriculture, Fisheries and Food

Ministry of Defence

Department for Education and Employment

Department of the Environment

Department of Health

Home Office

Department of Trade and Industry

Department of Transport

Northern Ireland Office

Scottish Office

Welsh Office

The Civil Aviation Authority was also represented.

The Working Group was supported by a technical group which included the following external advisers.

Dr David Ball (University of East Anglia)

Prof John Broome (University of Bristol)

Prof Andrew Evans (UCL/Imperial College)

Prof Christopher Hood (LSE)

Prof Michael Jones-Lee (University of Newcastle)

Prof Graham Loomes (University of York)

Dr Nick Pidgeon (University of Wales, Bangor)

Dr Tony Taig (AEA Technology)