Policy, risk and science: Securing and using scientific advice

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The primary aim of this study is to offer recommendations for improving the quality of scientific advice received by government and used in policy development. Scientific methods are well established, and many scientific theories are highly successful, and can therefore inform analysis leading to policy decisions. The area of most interest in this study, however, lies outside the secure region in which scientific understanding is complete and undisputed. It is concerned with weak evidence, novel and incompletely known risks, hypotheses and gaps in data.

Information was gathered by means of a literature review, case studies, and informal interviews with a wide range of interested parties (including non-governmental organisations (NGOs), scientists, policy-makers and ministers).

The conclusions of this study are a set of recommendations expressed in the form of: principles, which are fundamental and comprehensive; a model process, which is the clearest way to secure scientific advice that is fully compatible with the principles; and supplementary notes, which include detailed recommendations for some aspects of the process.

The suggestions made in this report are radical because they call for significant changes in the operation of existing mechanisms. If implemented, they should produce advice that is more robust because it will have more developed ways of embracing uncertainty, recording rational justification and managing bias. This should lead to policy decisions that are better informed and should help to provide a system of policy development that achieves a higher level of public confidence and the support of the scientific community.

This report and the work it describes were funded jointly by the Health and Safety Executive; the Cabinet Office (Regulatory Impact Unit); the Department of the Environment, Transport and the Regions; the Department of Health; the Environment Agency; the Food Standards Agency; the Office of Science and Technology; and the Scottish Executive. Its contents, including any opinions and/or conclusions expressed, are those of the authors alone and do not necessarily reflect the policies of the sponsors or the government.

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EXECUTIVE SUMMARY

Introduction

This report has been prepared primarily for the eight government bodies (the Health and Safety Executive; the Cabinet Office (Regulatory Impact Unit); the Department of the Environment, Transport and the Regions; the Department of Health; the Office of Science and Technology; the Environment Agency; the Ministry of Agriculture, Fisheries and Food and the Food Standards Agency; and the Scottish Executive) that co-sponsored this study. It may also be of interest to other government departments, executive agencies, and non-departmental public bodies that use scientific advice in developing policy, and to individuals and organisations that participate in giving scientific advice or are affected by related policy decisions.

This report is the culmination of work carried out by OXERA (Oxford Economic Research Associates Ltd) between April 1999 and August 2000. OXERA gratefully acknowledges the valuable contributions of the Steering Group, OXERA's internal Advisory Board, and others who participated in the study. OXERA takes sole responsibility for the content of this report, which presents the study's findings that have not been determined nor endorsed by the Steering Group or the sponsoring departments.

The study took part in three phases. Evidence was collected in the first phase; in the second phase it was analysed, and solutions were proposed and tested; and, in the final phase, a consultation was held on the findings, and the emerging recommendations were refined.

This evidence was collected in:

- eight case studies;
- a literature review; and
- more than 65 interviews with policy-makers, government Ministers, scientific advisers and others—some interviews covered particular case studies and others were of general relevance.

The primary aim of this study is to offer recommendations for improving the quality of scientific advice received by government and the way that it is used in policy development. The study is concerned with the way in which government takes decisions that rely in part on scientific advice to characterise the risks that might result. The government has sought external scientific advice on many of the recent policy issues that have attracted greatest public concern. In addition, it employs many scientists who provide internal scientific advice. The recommendations in this report could be applied to both external and internal advisers. This report recognises and draws upon the important work that has taken place within government to develop guidance on securing and using scientific advice for policy, including, for example, Guidelines 2000—Scientific Advice and Policy-Making. It is not the role of this report to offer formal guidance, but to recommend good practice and model processes for consideration in the further development of official guidelines in this area, such as the forthcoming Code of Practice for Scientific Advisory Committees.

The report addresses all stages in the resolution of policy questions in which science plays a part:

- identifying problems for which scientific advice is needed;
- seeking and obtaining scientific advice; and
- building that advice into policy.

The recommendations in this report have been designed to be widely applicable and to allow sufficient flexibility to accommodate a wide range of types of problem and solution. The report contains recommendations in the form of:

- **principles**, which are intended to be fundamental and comprehensive, and pervade these recommendations. These principles form an internally consistent set; it is suggested that any process for obtaining scientific advice should be consistent with all of the principles;
- a **model process**, which is a way to secure scientific advice that is fully compatible with the principles. It is not presented as the only acceptable process, but it is recommended that whatever process is used, it should be compatible with the principles.

- **supplementary notes**, which discuss in more detail some of the themes that emerged during the study, and include detailed recommendations for some aspects of the process, notably good practice in taking decisions under risk and uncertainty, in securing scientific advice in emergencies, and in selecting advisers.

These three components constitute a possible foundation for a system for securing and using scientific advice. Upon this foundation, more detailed structures and procedures could be built. In the course of the study, no reason was found to discard the existing advisory mechanisms, but many important themes emerged that would have a strong influence on their effectiveness. These themes are described below. In addition, within the main text, the subtleties and complexities of the practical implementation of the suggestions are discussed and as far as possible resolved. These subtleties are extremely important to the successful operation of the system. The foundations are broadly compatible with the wide range of advisory structures currently operating within government, but if implemented, they would require substantial changes to current practice.

Four functions of individuals can be distinguished in the scientific advisory process:

- **decision-taker**—a person with the authority to take a policy decision. This may be a government Minister, or a person or body with the delegated authority to take a decision in the name of a Minister;

- **policy-maker**—a person or organisation charged with assisting a decision-taker in reaching a decision by providing policy analysis, generating policy options, or by conducting risk assessment (policy has been interpreted to include regulation);

- **scientific adviser**—a person or organisation responsible for providing scientific input to policy-making or decision-taking. This includes both scientists expert in narrow disciplines relevant to the problem in question, and more broadly-based scientists able to integrate several disciplines, and those within and outside the civil service;

- **stakeholder representative**—a person or organisation representing the interests and opinions of a group with an interest in the outcome of a particular policy decision.

EMERGENT THEMES

Rights of those at risk

The study observes that some stakeholders have been well represented in the policy-making processes but that in some cases other stakeholders have not been so effectively represented. The recommendations in this report to improve access for all stakeholders to the policy-making process align with, and support, the current movement to broaden stakeholder inclusion. However, if stakeholders are asked to produce the scientific advice itself, then the advice could be biased—without this being apparent.

The report recommends the full inclusion of stakeholders in other parts of the process, notably: problem identification; defining policy issues and possible options; framing of scientific questions; selecting the advisory mechanism and adviser(s); and assessing the findings. It is vital that stakeholders are encouraged to participate in these stages of the process if the overall success of the process is to improve. In addition, all stages should be transparent, to avoid stakeholders being excluded through lack of information.

This transparency demands a presumption that the scientific advice will be published. However, it does not demand the publication of incomplete scientific analysis. It will usually be necessary to prepare a full draft of the scientific advice before it is published, because it could otherwise be misleading. The presumption should always be that the scientific advice will ultimately be published.

Needs of decision-takers

On most policy issues, scientific advice will be one of many other inputs to policy-making, such as, for example, advice on economic impacts, and equity considerations. The decision-taker will wish to take account of all of these factors. If the recommendations in this report are adopted, the decision-taker

will be obliged, and assisted, to consider the scientific and other uncertainties, and their potential implications.

The questions put to scientific advisers will often require them to consider the risks involved if different policy options were to be followed, and to communicate any additional options that they identify. Decision-takers should be presented with a choice of policy options, each of which is accompanied by an analysis of its risks, benefits, and uncertainties, and the scientific and other inputs which underlie this analysis. They should be able to rely on policy-makers to gather and synthesise these inputs to the analysis of policy options.

A rational explanation for the decision could be given, and this could include an explanation of why the options that were not chosen were rejected. This offers decision-takers a basis for responding to critics, and an easier way of revisiting decisions in the light of new scientific information.

Behaviour of the participants in the advisory process

It is concluded in the study that the functions of scientific adviser, policy-maker, stakeholder and decision-taker should be clearly distinguished, so that the conflicting interests of different stakeholders can be expressed and addressed in their proper place, and the biases of scientific advisers can be managed. If one individual (or group) is carrying out more than one of these functions, they should act in only one capacity at any given time. By introducing a clear structure into the relationship between these functions, a more transparent, reliable and trustworthy process should emerge.

There is a conflict between independence and expertise. It may not be possible to acquire expertise relevant to a policy issue without also acquiring interests in the issue. The independent scientist is an ideal: individuals tend to have biases and personal motives. In practice it is better to identify and manage the biases of expert advisers, than to require their total independence.

Competence as a scientific adviser means not only proficiency in the relevant scientific disciplines, but also familiarity with the range of views of others within the field.

The responsibility to be placed upon scientific advisers is clear. They should be asked to act purely in their capacity as professional scientists, excluding all partisan interests. When in doubt about where their primary duty lies, they should always remember that when giving advice to government, their duty is to the public interest—and that this duty over-rides any personal or professional interests. This provision would empower and require advisers to resist external pressures.

As well as duties, scientific advisers could also be given rights. Scientific advisers could be given rights to adequate support from a secretariat, independence from that secretariat, and some protection from civil liability, so long as they conduct themselves honestly and competently. This provision would also help then to resist external influences.

PRINCIPLES

These principles express an underlying philosophy which appears to be applicable to all scientific advisory mechanisms, whatever the policy issue may be. In them a collection of ideas is distilled from the evidence-gathering phase of this study. The need for a set of principles applicable to scientific advice emerged from the case studies and initial debates within the study team, when it became apparent that points of principle were emerging that called for resolution.

The dominant consideration in settling the final form of the principles was the need for a disciplined framework in which the participants in the scientific advisory processes can operate. Other schemes were considered, in which there would have been more reliance on subjective judgement, but these were judged to carry greater risks of abuse and error. Some of the principles may seem self-evident or trivial, but in practice all make an important contribution to the definition and implementation of a valid scientific advisory process. Each principle addresses (as far as possible) a distinct issue. The principles are mutually compatible and not overlapping. It is suggested that these principles could be used to guide working practices and could be made available as a reference if the conduct of the scientific advisory process were to be challenged.

The principles were conceived for application to the process of seeking and using advice from experts in the natural sciences; their relevance to the social sciences has not been explored and remains untested.

Scientific advice should be founded upon observation and theory, and should describe both the scientific conclusions and their uncertainty; these should be deduced from the evidence by reasoned argument.

Scientists use a core of firmly established information. Outside this core, there is a large body of valuable indicative information that is less firmly established, and, beyond it, on the boundaries of current research, there is significant uncertainty. In these less secure regions there is still much that can be said to characterise a range of possible outcomes, by stating the risks and uncertainties. It is suggested that a disciplined approach be taken to the handling of evidence, and that the presentation of this evidence be made by deductive reasoning from what is known and from the incomplete evidence that is available.

The functions of scientific adviser, policy-maker, decision-taker and stakeholder representative should be distinguished.

Scientific advice is but one contribution to a policy decision. In formulating policy, it should be taken into account, together with economic and social considerations, political constraints, values, and the views of stakeholders. Scientific advisers are not necessarily also qualified or authorised to make policy decisions, nor to provide advice involving judgements of social values; equally, decision-takers are usually not competent to assess scientific issues.

Policy-makers may wish to elicit the views of stakeholders during the policy-making process. However, the contribution that stakeholders can make to the scientific advice does not include *negotiating* on behalf of their constituencies as a representative.

Full information about the process of seeking and using scientific advice should be made public, and stakeholders should be encouraged to comment. Scientific advice itself should be published promptly in a transparent manner, once it is complete.

There are many individuals and groups with a stake in policy, including the public (as the main risk bearers and potential beneficiaries), industry (as providers of benefits and generators of risks), and pressure groups. These stakeholders demand access to the decision-taking process, including the scientific advisory process. Stakeholders have an important part to play in ensuring that the scientific questions being asked are pertinent to the policy issues that are of concern to them.

Decision-takers may find that it is useful to explain how scientific advice was taken into account in a policy decision. This would confirm that the scientific advice has been correctly understood, and that it provides assurance to stakeholders that the issues of concern to them have been addressed. It would provide valuable feedback to the scientific advisers, and, hence, contribute to the continual improvement of the scientific advisory system.

An audit trail of the scientific advisory process could be made available to policy-makers, decision-takers and, ultimately, to stakeholders. This audit trail might cover the generation of the scientific questions; the scientific arguments, calculations and analyses; alternative scientific opinions and uncertainties; and the scientific appraisal of policy options.

Care should be taken to avoid a form of ‘openness’ that actually obscures key messages through obscure terminology or dilution in a large volume of detail. Detail should be available for the expert reviewer, but the aim of this principle is effective communication with the public. This requires transparent communication of the key findings, including uncertainty.

Scientific advisers should be selected for their competence. It is not necessary for advisers to be independent of all interests in the policy question; however, the advisory process should ensure that interests are declared and any resulting biases are balanced or taken into account.

Scientific advisers should be selected for their competence, and their field of expertise should be appropriate to the scientific question. They must possess not only personal proficiency but also

awareness of the wider state of knowledge in the field, and an aptitude for communication. Scientific advisers should show willingness to consider scientific uncertainties and opinions that are at variance with their own, and to discuss these in their advice. They should be able to analyse the scientific consequences of a range of policy options, and assess the probability of various outcomes.

Some scientists who have the potential to contribute useful information to the advisory process—owing to their relevant knowledge and experience—may be employed by organisations, such as industries or pressure groups, that have an interest in the policy issues. Such scientists should not be excluded from the process, but they should advise as experts rather than negotiators. Scientific advisory committees may achieve overall freedom from bias by appointing a balanced group of members with different affiliations. This will help to define the range of scientific opinion on a particular issue and hence reveal the existence of uncertainties.

The declaration of interests by scientific advisers is necessary whether they are academics, employed by industry, or employed by pressure groups. Possession of interests should not be presumed to compromise an individual's integrity. It may not be possible to apply to scientific advisers the Nolan principle that appointees should not 'place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their public duties'; nevertheless its spirit can be recognised in other ways.

The scientific adviser's over-riding duty is to the public interest. Advisers should not seek to promote any special interests in preparing their advice.

Scientific advisers may face a conflict of interest because they have other occupations and interests outside their role as advisers. This professional experience of experts contributes to their ability to provide advice. Experts who are employed in industry or academia may possess expertise not available within government.

Some of these scientific advisers may feel under pressure to bias their advice, for example, to suit the constituency that nominated them as advisers, to be consistent with established scientific consensus, to lead to a particular policy outcome, or to suit their employers. Individual advisers should be empowered, and required, to resist such influences.

It is difficult to define the public interest, but it is suggested that it would be sufficient for scientific advisers to be required not to promote *any* special interest in preparing their advice. The aims of this requirement are to ensure that scientific advisers recognise that they are forbidden from placing a conscious bias on their advice, and to empower advisers to use this requirement to resist any pressure to do so. This requirement addresses only conscious bias, and does not guarantee that advisers will be free from unconscious bias, nor remove from policy-makers the duty to balance, or otherwise take into account, all sources of bias in the advice they receive.

Scientific advisers and policy-makers should be candid about the limitations of scientific knowledge and should always assess the uncertainty in scientific advice and the risks associated with each policy option; this information should be taken into account by decision-takers.

There are limits to the extent of scientific knowledge, particularly concerning new technologies and the assessment of risks. Scientific advice in some areas is therefore characterised by uncertainty and differences of scientific opinion. For good decision-taking, it is essential that these uncertainties be taken into account.

Scientific advisers should seek out the sources of uncertainty in their advice, and be candid about these uncertainties and any differences of opinion among their peers. They should be ready to explain how the uncertainties arise and what assumptions have been made, and to provide an estimate of the overall uncertainty. In particular, they should avoid the temptation to seek closure on scientific issues, where an error or misjudgement could have adverse consequences.

Scientific advisers are not duty-bound to provide a subjective judgement where the evidence cannot resolve a question, nor should they be (or feel they are) subject to any pressure to do so. Decision-takers need to accept and understand the uncertainty in the advice they receive, and to consider it in making their decision.

The effort expended on securing scientific advice should be proportionate to the importance of the policy issue and the difficulty of the scientific investigations required.

The choice of mechanism for generating scientific advice is likely to involve a trade-off, for example between the cost of generating the advice and the degree of certainty achievable. Advice can be most cost-effective when the effort expended reflects the potential magnitude of the policy consequences and the value of reducing uncertainty.

MODEL PROCESS

The model process gives effect to the themes and principles identified earlier. It helps to demonstrate that the principles could be applied in practice and shows how this might be done. It is a benchmark or ideal process, against which the practicalities of day to day pressures need to be set. The model is compliant with the principles set out earlier. There may be other models that have equal validity.

The model described in the report is divided into a set of discrete and bounded steps. In practice, these may overlap or even merge, and may not always be clearly distinguishable. It is presented as a sequence of steps with some explicit feedback loops. In practice, the steps may be iterated several times.

The model process proposed here is not prescriptive and could be adapted, in which case:

- it is suggested that the adapted process should remain consistent with the principles;
- the justification for omitting or adapting parts of the model process, and for the alternative adopted, could be recorded so that the operation of the process can still be audited; and
- it is recommended that efforts should be made to conform to the spirit of the model.

The model process allows functions to be clearly distinguished without compromising the quality of the scientific advice or the decisions based on it. It places demands on all the participants to recognise and fulfil their functions. It is suggested that stakeholders should be entitled and invited to contribute to most stages of the process. Stakeholders have a valuable role to play in challenging both the scientific advice and the actions of the policy-maker.

In distinguishing the functions, different people would normally perform each function. However, if there is a good reason for one individual (or group) to enact more than one function (perhaps because the problem is small, or specialised, or requires urgent action), the process requires the person to be sure which function they are fulfilling at each point in time, and to act accordingly.

In practice, a written record of the logical argument of the case would provide an audit trail and justification if subsequently challenged.

The steps in the model process

Detect the issue

The early detection of a policy issue is desirable because it maximises the range of policy options available and the time available to analyse them. Systematic procedures could be employed to maximise the chance of detecting an issue promptly. Such procedures are discussed in the report.

Establish the policy context and policy options

Before seeking scientific advice, policy-makers identify the policy issues on which the science bears, the policy options that are available, and the scope of advice that is needed. It is recommended that, as far as possible, policy options should be kept open until scientific advice has been taken.

Scientific considerations may help to identify policy options that were not apparent before. Policy-makers are therefore encouraged in this report to reconsider the range of policies that are available in the light of emerging scientific evidence.

Define what the policy-maker needs to know

The policy-maker needs to be competent to specify scientific questions. The questions can be refined through discussion between scientific advisers and policy-makers, and may be further refined by challenge from stakeholders. In this model, the questions put to scientific advisers must be restricted to scientific issues, and must admit a purely scientific answer, in order to maintain the distinction of functions.

In order to comply with the principle that the functions of scientific adviser and decision-taker be disinguished, the policy decision must not be delegated to scientific advisers by posing the question in such a way that the scientific advice determines the policy option to be adopted.

Choose the scientific advisory mechanism

The report discusses the relative merits of four common mechanisms. The discussion is intended to help policy-makers make a reasoned choice of advisory mechanism, which should be proportionate to the scale, complexity and importance of the policy issue and to the scientific challenge.

Choose the adviser(s)

The selection of scientific advisers is dominated by two drivers:

- the need to obtain a high level of expertise;
- the need to identify and manage bias and conflicts of interest.

Taking into account the effect of the principle of over-riding duty to the public interest, the balancing of committees and the valuable input that may not be available elsewhere, advisers affiliated to stakeholders are acceptable, and may be desirable, so that all schools of thought are included.

Where a single expert is used, vested interests or bias can be critically important. Also, the individual must possess a suitably broad range of knowledge and expertise. However, the members of a committee do not need to have all these qualities individually—collectively the committee should be balanced.

Stakeholders could be invited to make recommendations for, or comment on, the choice of advisers. This may help the policy-maker to identify candidate advisers and may help to assess potential bias in the advice that might be provided.

Agree and confirm the brief

The evidence collected in the study showed that it is essential that the scientific adviser and the policy-maker have the same understanding of the questions that are to be addressed. This can be tested if scientific advisers replay the questions in their own terms. In order to avoid misunderstanding, the questions should be stated explicitly and agreed with advisers. In order to further clarify the need for advice, the scientific adviser could be told the policy options and given an explanation of the policy background. The scientific adviser could be asked to evaluate the scientific consequences and likelihood of a range of outcomes of each policy option that fully represents the risks involved.

The distinction between analysing the scientific issues and making value judgements must be made clear to the scientific adviser, in order that the adviser can offer advice which is not based on value judgements, and does not usurp the legitimate function of the decision-taker. At the same time, the policy-maker could make clear to the adviser any constraints on the way in which they should work, for example:

- the procedures to be followed to maintain an audit trail of the advice;
- how uncertainty and risks should be presented;
- whether meetings are to be open or closed;
- when reports are to be prepared; and
- whether any draft scientific advice should be published, or if there is to be any communication with the press or general public while the work is in progress.

This report makes suggestions about how some of these constraints might be framed by the policy-maker and met by the scientific adviser.

Prepare the scientific advice

The report reaches a firm conclusion that the preparation of scientific advice is not the same as the conduct of scientific research. The former involves the synthesis of known science with estimates of what is unknown or uncertain, directed towards the resolution of a policy issue. The latter is not necessarily policy-focused and customarily applies very strong tests of evidence before a positive finding is accepted. Furthermore, scientific advisers are required to appreciate the information needs of policy makers, and to reflect candidly the full scope of scientific views, and not just their own scientific position. The advisers may recommend, or even conduct, further research in the course of preparing the advice, but the two activities are clearly different.

In order to communicate the range of possible scientific outcomes identified in their advice, scientific advisers will need a systematic procedure for identifying and handling uncertainty. They will need to consider all types of uncertainty (for example, inadequate data, incomplete theory, conflicting theory, limitations of theory) and will need to characterise their advice accordingly. Where evidence is inconclusive by the conventional standards of scientific research, they should evaluate what risks are implied by the evidence as it stands. Sensitivity analysis could be used to test how the advice might need to be changed if new evidence were to emerge, or if a theory that has been used were found to be incorrect. A statement could be made of what new evidence, if it were to emerge, would require the advice to be changed. The study concludes that it is not the function of scientific advisers to apply the precautionary principle or any hidden safety margin. The application of the precautionary principle is important but it should only be applied at the point where a final decision is taken, or there will be excessive caution.

If dissenting advisers are encouraged to present their views constructively then it will be easier to observe bias and to avoid overlooking less likely outcomes or outcomes based on unconventional theories. Committee chairpersons could be asked to ensure that those views are considered, accurately reported, and given appropriate weight so that the rights of advisers to submit their findings are protected.

Communicate the advice

The communication of the scientific advice is an important step, and it is important that the full content of the advice is preserved in the policy process. The report suggests ways in which scientific advisers can present their advice in such a way that it will be fully understood by the policy-maker and decision-taker. If asked to present and explain scientific advice to the general public, it has been observed that scientific advisers may have to exercise great care in order to restrict their comments to the science, without discussing the wider policy issues.

Prepare advice on policy options

The policy-maker is responsible for managing the process by which scientific advice informs policy. The policy-maker must therefore be able to make use of advice that carries explicit scientific uncertainty, because most scientific advice will carry some uncertainty.

When presenting policy options to the decision-taker, the policy-maker will need to make clear the implications and robustness of the scientific analysis if the decision-taker is to be able to take the decision based on all the evidence available. The report suggests how this might be achieved, by characterising the policy options according to:

- expected outcome and possible worst-case outcome;
- the degree of reversibility of the option;
- sustainability—whether the option can be sustained in the long term;
- any precautionary arguments that may be relevant;
- reliability of the key assumptions and evidence; and
- the source of the advice, and the weight that should be attributed to that source.

Take the decision

The report argues, from constitutional principles and existing guidance to Ministers, that it is the legitimate function of the decision-taker to take the decision, and not to allow it to be taken by the scientific advisers. The decision-taker has a duty to expressly consider the costs, risks and benefits of each policy option.

Since the decision-taker is accountable for the decision, they must be satisfied that the scientific advice is sound, must understand it, and must be able to explain, and defend, a reasonable decision. The decision-taker could consider stating the advice and explaining the reasoning that led to the decision: this would have the advantage that a decision can more easily be reversed in the light of new evidence; both accountability and general understanding of policy would be improved.

Audit and maintain the process

The study considered the maintenance of scientific advisory mechanisms and concluded that quality assurance and audit functions have a valuable role to play, in:

- auditing the operation of the scientific advisory systems to ensure that they are compliant with agreed guidelines;
- training those who provide and those who use scientific advice to ensure that they understand and fulfil their duties. All participants in the system, particularly advisory committee chairpersons and policy-makers, could be trained in techniques for posing questions and operating the various advisory mechanisms;
- reviewing, adapting and maintaining the advisory system to ensure that it remains fit for purpose.

There are four checks on the quality of scientific advice: quality assurance, peer review, audit, and Parliamentary scrutiny. Quality assurance could be provided by the policy-maker who would check that the scientific advisers are following good practice, consistent with the recommendations in this study. To ensure the system, including the communication of advice, remains fit for purpose, it is recommended that the departmental chief scientists should arrange for it to be periodically and independently audited and reviewed. The results of these audits and reviews, and any changes to the system, could be reported to the department's management board and to OST.

The study found strong support for the production by Ministers of a 'reasoned opinion' that explains the links between the policy options and evidence collected in the policy-making and advisory process, as described above.

RIGHTS AND DUTIES

The report argues that scientific advisers should be given clearly defined rights and duties that reflect the principles. The key rights are:

- a brief which sets a question that is amenable to a scientific answer and that does not demand broader policy questions to be addressed by the adviser;
- sufficient resources;
- protection as far as possible from any civil action arising from their work as advisers, whether brought by a third party or by the government department which appointed them; and
- to record a personal statement which sets in context their declarations of interest, and their understanding and acceptance of their duties.

Scientific advisers would have duties to:

- disclose any interest which might be seen to have the potential to distort their judgement; and
- keep confidential any aspects of the subject they are advising on, if so required by their brief, including the fact that they are advising.

Chairpersons of advisory committees could have further duties, to:

- ensure that every member of the committee is heard and that no view is ignored or overlooked;
- refrain from forcing closure where the evidence is compatible with a range of possibilities; and
- be responsible for ensuring that the committee acts in accordance with available guidelines.

CONCLUSIONS

The investigations described in this report covered a wide range of situations in which government might use scientific advice on issues involving risks to the public interest. In doing so, it identified a complex set of interrelated issues that bear on the effectiveness of the scientific advisory system, both as it exists today and as it might be developed.

The findings of the study include the observations that the existing structures within which scientific advice is provided to government appear well suited to their function, but that the shortcomings of the advisory system in the recent past appear to have been related to the way in which the processes have been conducted. For this reason, a set of universal principles was developed, to guide individuals and organisations in the course of scientific advisory work and related policy making.

To demonstrate the practicality of these principles, a model process was worked out in greater detail. This is suitable for implementation directly or may be adapted for specific cases.

Several pervasive themes emerged from this work, reflecting issues raised by politicians, stakeholders, civil servants and professional scientists during recent public debates on this subject. These themes address: the broadening of stakeholder inclusion; the proper structuring of policy decisions in the face of risks; and the behavioural code that should guide the actions of individuals engaged in the scientific advisory processes.

The study team is convinced that improvements to the scientific advisory system are achievable and that these would secure better scientific advice and more soundly-based policies to manage risks to the public. The outcome of the study is a coherent set of recommendations that give substance to this conviction.

CONTENTS

Abbreviations

ACMSF	Advisory Committee on Microbiological Safety of Foods
ACNFP	Advisory Committee on Non-food Products
ACP	Advisory Committee on Pesticides
ACRE	Advisory Committee on Releases to the Environment
ACTS	Advisory Committee on Toxic Substances
BSE	bovine spongiform encephalopathy
CBI	Confederation of British Industry
CEFAS	Centre for Environment, Fisheries and Aquaculture Science
CEP	Committee on Expert Panels
CHIP	Chemicals (Hazard Information and Packaging for Supply) Regulations 1994
CMO	Chief Medical Officer
COSHH	Control of Substances Hazardous to Health Regulations 1994
COT	Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment
CSA	Chief Scientific Adviser
CSTA	Council of Science and Technology Advisers
DEHP	di(2-ethylhexyl) phthalate
DETR	Department of the Environment, Transport and the Regions
DINP	di-isononyl phthalate
DTI	Department of Trade and Industry
EA	Environment Agency
EC	European Commission
EU	European Union
FAC	Food Advisory Committee
FACA	Federal Advisory Committees Act 1972
FAI	fatal accident inquiry
FEPA	Food and Environment Protection Act 1985
FSA	Food Standards Agency
GLC	Greater London Council
GM	genetically modified
HACCP	Hazard Analysis and Critical Control Point
HMIP	Her Majesty's Inspectorate of Pollution
HSC	Health and Safety Commission
HSE	Health & Safety Executive
ICES	International Council for the Exploration of the Seas
ILGRA	Inter-Departmental Liaison Group on Risk Assessment
LGC	Laboratory of the Government Chemist
MAFF	Ministry of Agriculture, Fisheries and Foods
MBAL	minimum biological limit
NEPI	National Environmental Policy Institute
NGO	non-governmental organisation
OCT	outbreak control team
OECD	Organisation for Economic Cooperation and Development
OES	occupational exposure standard
the OST	Office of Science and Technology
PDF	probability density function
PLA	Port of London Authority
PSD	Pesticides Safety Directorate
SCF	Scientific Committee on Food
SCHIP	Standing Committee on Hazard Information and Packaging
SCIMAC	Supply Chain Initiative on Modified Agricultural Crops
SCTEE	Scientific Committee on Toxicity, Ecotoxicity and Environment
SSB	spawning stock biomass
TAC	total allowable catch
TDI	tolerable daily intake
TUC	the Trades Union Congress
WATCH	Working Group for the Assessment of Toxic Chemicals

INTRODUCTION

Terms of reference

1 In late 1998, eight government bodies[1] co-sponsored this study, with the objective of collecting evidence, based on wide research and consultation, and identifying good practice in securing and using expert scientific advice. This report is addressed primarily to the eight co-sponsoring government bodies. It may also be of interest to other government departments, executive agencies, and non-departmental public bodies (referred to collectively in this report as government bodies) that use scientific advice in developing policy, and to individuals and organisations that participate in giving scientific advice or are affected by related policy decisions.

2 The primary aim of this study is to offer recommendations for improving the quality of scientific advice received by government and used in policy development. A consequence of improving scientific advice and subsequent policy decisions should be increased confidence of the public in the scientific advisory system. The recommendations in this report could be applied to external advisers and to internal advisers.

3 This report is the final result of work carried out by OXERA (Oxford Economic Research Associates Ltd) between April 1999 and August 2000. The work was coordinated by a Steering Group, comprising representatives of the funding departments, and chaired by the Chief Scientist of the HSE. In conducting this study, OXERA has been assisted by an Advisory Board, appointed to review the ideas developed during the project, and to advise on the conduct of the study and the presentation of its results. The Advisory Board members were: Sir Bernard Crossland, Dr George Greener, Dr Jerry Ravetz, Professor Gordon Stewart, Baroness Wilcox of Plymouth, and Dr Tom Wilkie, and the Board was chaired by Dr Dieter Helm, Director of OXERA.

4 The essential characteristic of the sciences is a rigorous procedure (the 'scientific method') for testing hypothetical explanations for the behaviour of natural or man-made systems, and predictive models. Scientific methods are well established, and many scientific theories are highly successful, and can therefore inform analysis leading to policy decisions.

5 The area of most interest in this study, however, lies outside the secure region in which scientific understanding is complete and undisputed. It is concerned with weak evidence, novel and incompletely known risks, hypotheses, and gaps in data. In this area, there is great scientific uncertainty. In many of these situations, scientists will only be able to provide incomplete information, perhaps a structured judgement or a subjective opinion without full supporting evidence.

6 The Interdepartmental Liaison Group on Risk Assessment (ILGRA, 1998*a*), quoted below, recommended that this study be undertaken. The full terms of reference of the study are listed at the end of the report.

> The time is therefore ripe to reassess the role of experts in the process of informing and adopting decisions with a view to:
>
> - opening up to public scrutiny and peer review the scientific advice elicited from experts, and being clear where scientific judgement or opinion has been applied to convert information and expertise into intelligence about risk problems;
> - exposing and explaining the assumptions made, and the uncertainties that pervade the assessment of risks and the effectiveness of possible risk management options;
> - adopting appropriate procedures to enable stakeholders and experts to contribute throughout the process of framing the issue, assessing the risks, identifying risk management options, adopting decisions, implementing the decisions and evaluating the effectiveness of the action taken;

[1] HSE; the Cabinet Office (Regulatory Impact Unit); DETR; the Department of Health; the OST; the EA; MAFF and the FSA; and the Scottish Executive.

- explaining how expert advice, together with relevant sociological, economic, ethical and political considerations, contributed to the decisions made.

To facilitate this work, HSE is currently setting up interdepartmental research to:

- identify and categorise current practices within Government for eliciting expert advice; and

- draw up principles of good practice for the engagement of experts, the elicitation of their advice, and for the incorporation of the advice in decision-making.

7 The Modernising Government White Paper (HMSO 1999) calls for the use of evidence-based policy-making. Other recent work that is relevant includes the House of Lords report on 'Science and Society', the House of Commons Science and Technology Select Committee investigation of the scientific advisory system, the work of ILGRA, the guidelines on scientific advice and policy-making produced by OST, and the recent draft code of conduct for advisory committees.

8 The full tender specification for this study is reproduced below (page 118).

9 OXERA is solely responsible for the content of this report.

Context

10 Government is responsible for developing and implementing policies for combating natural hazards and regulating activities and technologies that present a potential risk to the public or the environment. To do this it must have access to scientific advice and it must know how to use that advice effectively in taking policy decisions.

11 The scientific advisory system has been scrutinised in recent vigorous public debates, which have mainly focused on public health, the environment and engineering reliability standards.

12 The tenor of some of these recent public debates has been adversarial. A number of explanations can be proposed for the criticism that the scientific advisory system and associated policy decisions have received. These illustrate the scale and nature of the problem facing policy-makers in this area. These possible explanations are described below.

13 It could be that there have been a series of particularly difficult problems that have attracted public scrutiny, for which it has been difficult to formulate policy responses. The policy responses may have been difficult to make because the risks are not known precisely, and the consequences of an incorrect decision are high, either in costs for an industry, or in public health costs.

14 It could be that scientists have not paid sufficient attention to risk and uncertainty in preparing their advice, or that uncertainty has not been effectively communicated to policy-makers, or that policy-makers have ignored uncertainty in scientific advice. Alternatively, it could be that policy-makers have rejected uncertainties as rendering advice useless, and so demanded over-confidence from their advisers.

15 It could be that science has been treated as too difficult for stakeholders to comprehend. They may not have been consulted sufficiently or some stakeholders may have been given greater access to the scientific advisory systems than others.

16 It could be that policy decisions have been taken first, and scientific advice then obtained to justify them. It could also be that policy-makers have been able to manipulate scientific advice by choosing scientists who support the government view. They might also have been able to restrict the remit of advisers or to capture stakeholders onto committees, and subsume their views into a consensus.

17 These possible explanations represent characterisations of the origins of public mistrust, encountered during the study.

Scope

18 This report is intended to apply to decisions that:

- are the responsibility of government, and must therefore be taken by a Minister, or by a civil servant or appointed body with legitimate delegated authority to act in a Minister's name;
- are in part dependent on science, which is uncertain either because the relevant scientific theory is incomplete or controversial, or because the data are inadequate; and

- involve potential risks to the public or the environment, and therefore call for a balancing of costs, benefits and risks.

19 The report address all stages in the resolution of policy questions in which science plays a part:

- identifying problems for which scientific advice is needed;
- seeking and obtaining scientific advice; and
- building that advice into policy.

20 The UK government has moved towards a broader definition of scientific advice recently, illustrated in the May guidelines (Guidelines 2000—Scientific Advice and Policy Making (Office of Science and Technology, 2000)), which use the definition used by the Office for National Statistics for its Government R&D. This definition covers the following disciplines: medicine, dentistry, engineering, technology, agriculture, fisheries, forestry, veterinary science; biological, environmental, mathematical and physical sciences; psychology, geography, economics and social studies; and humanities. The recommendations of this study apply to the process of seeking and using advice from experts in the natural sciences. Their application to other disciplines (for example, the social sciences) has not been tested.

21 This report does not address the government's strategy for science and technology development or funding for research, except where it is influenced by the need to generate advice.

Methodology

22 The first phase of the study was dedicated to information gathering by means of a literature search, case studies, and informal interviews with a wide range of interested parties (including NGOs, scientists, policy-makers, and Ministers). The objective was to gather diverse examples and views prior to the process of synthesis that took place in the second phase. This is described in the 'Analysis' section below, and in the evidence sections towards the end of the report. The study team is grateful to all those individuals, who gave up their time to speak to the study team (see 'Acknowledgements').

23 The evidence gathering influenced the subsequent work in two ways:

- informally, by exposing the study team to a range of scientific advisory situations and viewpoints; and
- formally, by providing material from which general principles could be extracted, and which could be used to test emerging recommendations.

24 The ideas in this report were developed systematically, by extracting observations from the evidence, identifying general principles, developing detailed guidance and processes consistent with the principles, and, finally, by testing these ideas in progressively wider consultations.

25 The Steering Group provided valuable guidance as the study progressed, by drawing the project team's attention to significant issues that have arisen within government in the recent past; by facilitating the selection of case studies; and by arranging access to the individuals who were interviewed during the project.

26 The Advisory Board met three times during the project. It commented on the planned approach to the study at the start of the project, and reviewed the evidence gathered during Phase 1. It also commented on, and discussed in detail, an early draft of this report.

27 The recommendations that emerged were extensively tested by the study team to ensure that all were necessary, and that, collectively, they were sufficient to meet the challenges raised by the evidence collected. Further review ensured that they were internally consistent, and that each recommendation was addressed to the appropriate participant in the scientific advisory process, and at the appropriate stage in the process.

Conclusions

28 The conclusions of this study are a set of recommendations expressed in the form of:

- the **principles**, which are fundamental and comprehensive, and pervade these recommendations. These principles form a set; any process for obtaining scientific advice should be consistent with all of the principles.
- a **model process**, which is the most appropriate way to secure scientific advice that is fully compatible with the principles. However, this does not

exclude the use of other processes that are compatible with the principles.

- **supplementary notes**, which discuss in more detail some of the themes that have emerged during this study, and include detailed recommendations for some aspects of the process.

29 Although no new advisory mechanisms have been proposed (despite attempts to identify them), the suggestions made in this report are radical because they call for significant changes in the internal operation of existing mechanisms. If implemented, they should produce advice that is more robust because it will embrace uncertainty, will contain rational justification, and will manage bias. This should lead to policy decisions that are better informed and justifiable. These recommendations should help to provide a system of policy development deserving of public confidence and the support of the scientific community.

ANALYSIS OF THE EVIDENCE

30 This study took part in three phases. Evidence was collected in the first phase; in the second phase it was analysed, and solutions were proposed and tested; and, in the final phase, a consultation was held on the findings, and the emerging recommendations were refined.

31 The evidence sought included:

- the structure and functioning of the current UK advisory system;
- the structure and functioning of advisory systems in other countries;
- a sample of the personal experience and views of advisers, policy-makers, decision-takers, and representatives of public-interest groups and other stakeholders;
- published reviews;
- previous studies;
- existing guidance;
- the professional practices of civil servants;
- the practical feasibility of different options; and
- cases of the practical application of scientific advice to policy problems.

32 This evidence was collected in:

- eight case studies;
- a literature review; and
- more than 65 interviews with policy-makers, government Ministers, scientific advisers and others—some relevant to particular case studies and others of general relevance.

Observations from the case studies

33 The purpose of the case studies was to provide evidence against which hypotheses emerging from the rest of the study could be tested.

34 The case studies are only concerned with the way in which scientific advice was sought, provided and used—not with the scientific issues themselves.

35 Recent and ongoing cases that are currently subject to review were not considered because the participants would not have been able to discuss the scientific advisory process in full. Eight cases were studied in detail, using published reports, and interviews. Summaries of each case are presented towards the end of the report and are listed in the table overleaf.

36 The case studies provide examples covering each of the following attributes of situations in which scientific advice is sought:

- uncertainty;
- novelty;
- criticality;
- urgency;
- bias;
- problem detection;
- policy and strategy;
- tactical response and regulation;
- emergency response; and
- information and communication.

The table below illustrates these attributes of the eight case studies.

Case studies

	Uncertainty	Novelty	Criticality	Urgency	Bias	Problem detection	Policy / strategy	Tactical / regulation	Emergency response	Communication
1. *E. coli* O157 food poisoning in Scotland				x	x			x		
2. Margins around field trials of genetically modified crops	x	x						x		x
3. The structural integrity of the Forth Rail Bridge	x		x		x		x			
4. Phthalates in soft plastic toys	x	x			x		x	x		
5. Total allowable catches of sea fish				x	x	x		x	x	
6. The decision to construct the Thames Barrier	x				x			x		
7. Assessment of safety cases for radioactive waste disposal	x		x			x	x			
8. Advisory committees on toxic substances	x		x		x					

37 Each case study included the process by which the policy issue was broken down to yield specific scientific questions; the way in which those questions were handled; the selection of advisers; and the way in which the policy decision was built up from the scientific answers, identified uncertainties and other inputs (see the case study protocol, page 109). An attempt was made to probe the robustness of the process by examining what might have happened under different circumstances.

38 The case studies showed that, even where there was a successful outcome, problems had sometimes emerged because of the way in which the scientific advice was sought, used or presented. In each case, aspects of good practice and shortcomings were apparent.

39 The most striking feature in several of the cases was the requirement for the individual expert or group of experts to take a policy decision or to propose policy actions, rather than to present scientific facts and scientific opinions. This happened in the investigation into the *E. coli* O157 food-poisoning outbreak in Scotland, where the terms of reference included 'to advise the Secretary of State for Scotland on the implications for food safety and the general lessons to be learned' [547–548].

40 The study of the setting of margins around GM crop trials illustrated many of the difficulties. The margins adopted were determined by a group from the agriculture industry [589–596]. That group used commercial arguments about crop purity, rather than any wider considerations of potential environmental damage.

41 The definition of the margins was widely misunderstood, with many people apparently believing that the experts had concluded that there would be no contamination outside the margin. That was obviously absurd—wind and bees can carry pollen many kilometres—and so the process received little public endorsement.

42 The margins set by the industry were implicit in the considerations by the Advisory

Committee on Releases to the Environment (ACRE) of the acceptability of individual trials. ACRE was aware that there was no explicit balancing of the potential harm that a GM release might cause with the potential benefits that might result. In the absence of such an explicit consideration, the members of ACRE perceived that they were responsible for the risk assessment and, hence, for making value judgements about balancing risks and benefits [587–590, 605].

43 This case study supports the provision of a model process, the principles and proper operation of which can be checked and audited. The case study showed several pitfalls of a weak process—a poor public perception of the result, and uncertainty in how policy should be developed when a review is needed.

44 In many cases the terms of reference given to scientific advisers have demanded that value judgements be made by the scientific advisers (for example, about the social acceptability of risks). It is common in questions of toxicology to ask for a committee to deliberate on guideline levels that are safe, in the manner that advisers were asked 'what level of exposure to phthalates is safe?' [640, 642]. This shows that asking scientific advisers (partly) non-scientific questions is common. At least in some cases, this has caused problems for advisers, decision-takers and the public: advisers are unsure of their remit; decision-takers are unsure what weight to place on advice they receive; and the public cannot see the criteria by which policy options have been chosen.

45 Another example is the recent Stewart report on mobile phones and health (Independent Expert Group on Mobile Phones, 2000). In response to its terms of reference, it offered value judgements about the acceptable balance between risk and benefit, and made recommendations for new policies that went beyond scientific advice.

46 Across the case studies, the terms of reference were clearly important both for the advisers' understanding of their task, and the usefulness of the advice. When setting fisheries quotas, the advisers were asked simply to provide figures for the total allowable catch for the following year. Because of the restricted nature of the advice, policy-makers did not receive scientific analysis of the trade-off between the consequences for the fish stock and other criteria, such as the variability of quotas from year to year. In this case, the scientific question did not reflect the policy considerations important to the decision-taker.

47 The policy constraints imposed on advisers or policy-makers by pre-existing decisions can limit the terms of reference. In the model process presented below [142–213], the terms of reference are iterated between the policy-maker and adviser to safeguard against misunderstanding and over-restrictive questions [190–196]. It is the prerogative of the policy-maker to define the terms of reference, and to constrain them within the bounds of available policy options, with the proviso that the scientific adviser may ask for them to be extended. The terms of reference could be published so that stakeholders have an opportunity to comment on whether they are appropriate [167].

48 It is quite common for stakeholder representatives or other non-scientists to be included on expert committees to help in the analysis of these policy questions, as is the case with the Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment (COT) [777–778, 856]. They sit on these committees as representatives of the public interest, or to ensure that advice produced by the committee is intelligible to a lay person. A minority representation on a committee does not guarantee that the views of the representative will be given proportionate weight in the advice, and it means that the scientific advice will be mixed with representative views [511]. This study concludes that stakeholder interaction is more effective if the avenues for interaction with the policy-maker are built into the advisory process outside the scientific advisory committee itself [151, 157–159].

49 In other situations, committee members act in a scientific capacity, but have an interest in the issue at hand. For example, the members of the Pennington Group were not all independent of the bodies with ongoing responsibility for managing the outbreak of food poisoning, yet the Group was asked to advise on the lessons that could be learnt from the outbreak [549].

50 The principles and process suggested in this study do not exclude individuals with interests related to the case from acting as advisers. Instead, they apply the common practice, followed by many advisory bodies, including COT, that advisers declare their interests [782–784]. Since the existing codes on declaration of interests are limited to very brief rules for public appointments, and do not state what type of interests should be declared, this study presents some suggestions for the interests that should be declared [242].

51 Advisers have not always been chosen for their expertise in the subject; Sir Hermann Bondi did not have particular expertise in the scientific disciplines bearing on the design of a Thames Barrier [706]. There is a role for general scientists to act as advisers when problems are unusual, innovative and inter-disciplinary [306–307]. However, in the Thames Barrier case, the adviser's role was not purely scientific, but included the evaluation of the costs and benefits of different options. Sir Hermann Bondi was not expert in these non-scientific issues. While his report came to a firm conclusion on a course of action that should be taken, it did not provide transparent analysis of the costs and benefits of all the other possible options.

52 The Thames Barrier issue had a long history of debate, during which time some policy options had been closed off by other decisions that were taken without regard to their impact on this issue [713]. If a record of the early advice on this issue had been made more widely available, the decision to foreclose options for the Thames Barrier might have been more informed. This case supports the publication of scientific advice.

53 Any process for obtaining scientific advice must be able to respond rapidly in emergency situations. In two cases, ongoing funding was being made available to external bodies to maintain expertise so that advice could be provided on demand. These bodies were the Laboratory of the Government Chemist (LGC), in the case of phthalates in toys [645], and the Centre for Environment, Fisheries and Aquaculture Science, in the case of fisheries quotas [670]. A brief supplementary note of guidance on emergency advice is included below [331–350].

54 The form of presentation of the advice was a determinant of its usefulness. Scientists advising on fisheries quotas presented the uncertainty in their advice as probabilities and scenarios, which a parliamentary committee found difficult to comprehend [680]. The experts in the nuclear waste disposal case presented their estimates as a probability distribution function for the parameter they were estimating [749–751]. The scientific advice must be intelligible to the policy-maker in order to fulfil its primary purpose in supporting policy decisions [208]. However, the advice may be technical in nature, and its complexity may make the details difficult to relate to a lay audience. Thus it is not always appropriate to expect that advisers should present their advice with a lay audience in mind. Rather, the advice should be communicated with its primary audience in mind—the policy-maker who commissioned the advice [208]. Policy-makers could receive training, to enable them to analyse scientific information and advice; advisers could receive training in communication.

55 Finally, it was apparent that different advisers faced with the same problem could come to different conclusions. This was noted in the phthalates case [649], and in a comparison of the findings of the Pennington Group and the Advisory Committee on Microbiological Safety of Foods (ACMSF) [560]. It shows that scientific advice is not just an objective exercise in gathering evidence, but that advisers will make judgements as part of their advice. In order to make clear to the policy-maker where the advice depends on the judgement of the advisers, the study recommends that advisers distinguish the components of their advice that rest on evidence, analysis, judgements and opinion [200].

Lessons from existing guidance

56 In the UK, the Office of Science and Technology (OST) has published a set of guidelines for 'The Use of Scientific Advice in Policy Making'—the 'May guidelines' (OST, 1997; the guidelines have recently been updates as OST, 2000*b*). These guidelines cover the selection of advisers, identification of issues, the publication of advice and the explanation of decisions. The guidelines are not prescriptive, and leave considerable discretion to departments. This study recommends much more detailed guidance, and introduces issues not covered in the above, much shorter, guidelines. The conclusions of this study are largely consistent with the May guidelines, except on one very important point. Scientific advisory committees have often been asked to take account of considerations wider than the purely scientific. The May guidelines address this by recommending that non-scientists serve on those committees. This report, in contrast, recommends that the advisory system should be restructured to reflect distinct contributions from scientific and other advisers. The report concludes that quality, transparency and accountability are otherwise compromised [104–109].

57 The May guidelines are complemented by the Nolan [444–445] and Peach [446] guidelines on standards in public life and appointments to public bodies. There is continued debate on the issue of appointments. The current guidelines permit wide discretion, which lies with civil servants in

the preparation of job descriptions and shortlists of candidates, and with Ministers for the final appointment. The Nolan and Peach guidelines have a focus on executive functions, which is not appropriate for scientific advisers who do not carry any authority to take decisions.

58 The Nolan and Peach guidelines were drawn up to make it clear that public service would place demands on the conduct of individuals of a quasi-contractual status. These concepts apply equally to scientific advisers. Scientific advisers already have some duties, arising from legislation, such as the disclosure of commercially sensitive information, but the principle that public appointment carries general public responsibility has been established by Nolan and Peach. The responsibilities that are carried across from the Nolan guidelines into the conclusions of this study on scientific advice are that advisers should:

- submit to appropriate scrutiny;
- be prepared to place the public interest above any other interest;
- declare private interests.

59 The Peach guidelines do not contain a definition of conflict of interests, but leave this to individual departments to determine. In this study, a list of potential areas of interest is offered, but, again, no formula prescribing the limit for a conflict of interest has been produced [242]. The range of interests and possible advisory scenarios made a definition impractical. Instead it is recommended that, where a substantial conflict of interest is apparent, a decision whether or not to appoint that adviser should be documented and should include reference to the potential conflict of interest.

60 In the USA, the operation of the Federal Advisory Committees Act 1972 (FACA) provides some guidance, especially on accountability to federal agencies and to Congress. This study considers the locus of accountability. In recognition of the role of Ministers [249–250, 490–495], accountability for policy decisions rests with Ministers. Currently, accountability for the scientific advisory systems has been placed with departmental chief scientists, while the policy-maker is responsible for the quality of the scientific advice in an individual case. In order to fulfil their Ministerial responsibilities effectively, it is recommended that policy decisions be supported by a 'reasoned opinion', containing all the evidence and analysis that led to the decision (and explaining why other options were rejected).

61 There is a substantial amount of guidance on the disclosure of information, on risk communication with the public, and the conduct of civil servants and Ministers [477–496]. It has been used to set this study into the context of the existing civil service framework and to determine the appropriate delegation of authority. The only part that has not been used greatly is the communication of risk to the public. This is because the study has focused on the communication of uncertainty between the scientific adviser and policy-maker and upwards to the decision-taker, and not the policy-maker's communication of risks to the public, which is covered by an extensive and separate literature.

Lessons from the literature review

62 The literature provided material from authors and institutions with a wide range of standpoints; some with a detailed understanding of particular disciplines, such as risk management; others with experience of the UK advisory system or the advisory systems of other countries. The review probed the relationship between advice (and advisory processes) and the success of policy outcomes, through papers on the role of science, the management of risk, guidelines for advisers and their clients, and the social science of advisory systems. There is little published work that directly addresses the interface between science and policy, although there are some papers that compare advisory systems in different countries, which were particularly useful.

63 History shows that the concerns driving the present study are not new. In 1961, ten years after the first US science advisory committee had been set up, President Eisenhower warned that public policy might become captured by the technological elite—that policy-makers would become reliant on the advice of experts and that democracy would be eroded [359].

64 Governments have responded to the increasing need for scientific advice by setting up scientific advisory systems within their civil administrations, either in central science and technology ministries, or as a network across departments. The scientific advisers assess the risks arising from new and existing technologies, provide the scientific analysis of policy options for government decisions, and support the regulation of industry and research.

65 The USA is noted for the extent of public access to its advisory system [371–374]. Meetings of advisory committees are usually

held in public, and both the minutes and papers are published. Part of the reason for this approach is the US culture of access to information, and part is the federal structure. A high level of consultation is needed to allow all the US states to participate in the policy process, but the US system goes beyond this in the level of public access it provides. As a result, there is a powerful audit trail, and clear accountability to federal agencies [371, 373].

66 It has been suggested that public access has constrained the proceedings in a number of cases in the USA, and there are several reasons to expect that a high level of public access might have some disadvantages. First, public access to meetings may cause advisers to moderate their deliberations and to tone down the content of their discussions, perhaps placing less emphasis on extreme scenarios. Second, it may expose advisers to pressure to change their advice. Third, it may make it difficult for advisers to reject views that are commonly held, or are held by vocal pressure groups, even if they are not well supported by scientific evidence. The US advisory system is well trusted by the US public, perhaps partly because of its openness, but it has been using a greater proportion of closed hearings recently [372]. In contrast, the UK has operated a closed advisory system, but is becoming more open.

67 Renn (1995) argued that, owing to the different styles of the advisory systems, the US system needs to work harder to avoid capture by special interests, whereas the European systems need to engage in more stakeholder consultation.

68 The US government supplements the advice it receives by a statutory arrangement for the provision of advice from learned societies. In some countries, expert panels are convened by learned societies; for example, the Royal Society of Canada has its own codified procedure for the conduct of expert panels [467]. Britain has no equivalent arrangement. Learned societies in Britain do not routinely have a formal role in the scientific advisory process. Although they have an independent status, learned societies have strong established interests through their traditions, the often close affiliation of their senior members with the administration of government and research funds, and their selective membership arrangements.

69 Scientific advice may not always be free from value judgements, and scientists themselves ascribe to political views and moral values (Weingart, 1999) [384]. Furthermore, scientific advisers are sometimes requested to make a value judgement. For example, advisers may be asked to make assumptions about the tolerability of risks when defining regulations. However, the tolerability of risks cannot be determined objectively [470]. Thus, the linear model of problem definition, advice and decision-making might be developed into a recursive model, allowing several rounds of negotiation. In this model, Edwards (1999) notes, the role of advisers is not merely to advise decision-takers, but to inform, educate and empower the public for their own interactions with decision-takers [386–388].

70 There is an advantage in distinguishing between information gathering and making value judgements about welfare distribution. There is a natural break in the policy process, where evidence may be circulated for consultation before policy advice is prepared. Experts may be needed to gather and analyse information, but only a Minister or those acting with delegated authority can legitimately make value judgements.

71 To address these issues, this study suggests a principle [104–109] that the legitimate Ministerial function for taking decisions should be distinguished from the policy-maker's function to formulate policy options, and the scientific adviser's function to provide scientific advice.

72 Weingart (1999) suggests that policy-makers become ever more reliant on expert scientific advice, and that scientists compete strategically to supply advice [388]. He suggests that a solution to this is a more formalised and prescriptive process of advising policy-makers. Scientific advice has become more important in policy as the pace of technological development has increased. The UK government receives a large volume of scientific advice, and has relied on this in many high-profile areas. The government routinely seeks advice from many hundreds of scientific advisory committees and individual advisers.

73 The advantage of a more formal process is that it is possible to audit and revise its operation, and its effectiveness may be measured and reported [144, 411–413]. The present advisory processes vary greatly in form, often for good reasons, but there is currently no guidance available on common elements that would constitute best practice [498–500]. It has been apparent from discussions with policy-makers and others that the advisory system needs to be flexible in order to address many different policy situations. A detailed and formal prescriptive

process would be cumbersome to operate and might restrict the policy process unnecessarily [144, 498]. The model process described in this study is designed to provide a safeguard level of good practice under a wide range of advisory situations, while retaining sufficient flexibility to be practical and convenient.

74 ILGRA has called for a framework for risk assessment to be applied consistently across departments [457, 470]. The group recommended that the framework should subject scientific advice to peer review and public scrutiny, that its assumptions and uncertainties should be explained, and its procedures developed to allow stakeholder input.

75 Public scrutiny of advice and policy decisions is a recurrent theme of all the evidence collected. One of ILGRA's proposals is that assumptions and uncertainties should be presented for stakeholder scrutiny. This study suggests that Ministers publish a 'reasoned opinion' explaining policy decisions in detail [0].

76 In seeking to open up the system to public scrutiny, this study is supporting current government policy on openness, but challenging the confusion that arises when examining the detail of the Freedom of Information Bill in the context of scientific advice [477–485]. The study concludes that scientific advice should not be regarded as advice to Ministers (and hence confidential), and that there should be a presumption of publication under the freedom of information rules.

77 From the sets of guidance and studies of advisory systems examined, it was clear that there are several models for securing scientific advice. The common features were as follows:

- all rely heavily on the established scientific community;
- they use a range of advisers, from single experts to committees;
- balance in the composition of advisory committees is important;
- transparency of advice, the explanation of uncertainties, and public access to information are important; and
- involving stakeholders in the process is also important.

78 The differences were in:

- the detailed management of the process by officials or sometimes by a non-governmental external body, such as a learned society;
- the person to whom the adviser is accountable, either officials, Ministers, or external bodies;
- the publication of evidence, the extent to which meetings are open or closed, and the method of communicating the advice;
- the rights of the advisers to have access to Ministers and independence from officials;
- the rights of the advisers to agree the terms of reference;
- the extent to which the procedures of the advisory system are codified;
- the degree of distinction between policy and scientific advice; although, in general, there is agreement that the distinction should be made;
- the degree of involvement of Ministers in the advisory process;
- the models for generating advice, ranging from adversarial to consensual;
- the remuneration of advisers;
- the way in which stakeholders and the public are engaged in the advisory process; and
- views about the value of peer review.

79 The UK system does not offer a clear distinction between the functions of scientific experts and stakeholders. In response, this study presents recommendations that provide a much sharper distinction between these functions.

80 In recommending a new balance in the government's approach to securing advice, the value of the existing flexible and fairly closed process has been compared with the greater public confidence and opportunity for quality control promised by a more clearly defined and open process.

Lessons from interviews

81 The interviews conducted during this study revealed strong feelings about the scientific advisory process, from advisers, policy-makers, decision-takers and other observers. The strongest comments concerned the motivation of individuals, and the incentives or interests that might influence them. In response, the declaration of interests and management of bias is an important part of the recommendations in this study [182–189, 242].

82 One of the main concerns of the interviewees was the reason why particular advisers are selected, and how government

might manipulate the output of the advisory process through the selection of advisers. A clear distinction of functions in the advisory process has been made in this study. The legitimate function of a Minister as the decision-taker is supported [104–109, 145], and the rights of the adviser and the need for a clear remit for the adviser and the policy-maker are reinforced [240–245, 145]. The danger of bias is reduced through stakeholder input, peer review, and publication.

83 The absence of guidance on the operation of advisory committees is recognised (the DTI has recently published a consultation paper on a code of conduct for members of advisory committees (OST, 2000*a*)). Several models have been suggested, such as courts of law and parliamentary select committees. Suggestions for guidance to assist committee members and chairpersons are made in this report [239–245], clarifying their rights and duties.

84 Interviewees expressed concern about the capacity of government departments to interpret scientific advice, and of Ministers to comprehend it. The recommendations in this report support the training of policy-makers and decision-takers in seeking and using scientific advice (and especially in handling uncertainty), and offer suggestions on how advisers can provide their advice in a useful format [272–304].

85 Finally, the interviewees emphasised—more than any other topic—the virtue of openness and transparency of advice and policy decisions [110–122]. While the existing rules for publication were noted, there was general support for more openness and transparency. This has been included in recommendations that stakeholders should be included at more stages [see Figure 2, page 22]; that aspects of the advisory process should be open to consultation and published; and that Ministers should provide information allowing more effective parliamentary scrutiny of decisions [226–227, 0].

Conclusions

86 The evidence showed that, within the UK and further afield, many different advisory processes exist. Some of them are codified and follow rigid rules, while others are completely ad hoc. Nevertheless, the variation did not disguise several common themes. First, the processes followed similar sequential steps; framing the question, seeking evidence, considering the views of interested parties, and reporting conclusions. Second, there was a common emphasis on the independence of advisers, the rights of advisers, and the importance of communicating uncertainty.

87 There were widely held concerns that, if the advisory process is too loosely defined, the functioning of the advisory system becomes unreliable, and that some form of codification is therefore desirable. Even where similar approaches are taken, the conclusions of different advisers may be different, and so codification would not prevent variation in the advice that is received. An explanation of the scientific reasoning, distinguishing between facts and opinions, could therefore be helpful in resolving disputes about the correctness of advice.

88 The evidence also identified many perceived problems with existing systems, which have been considered in the suggestions proposed in this report. Notwithstanding these points for which there was general support, many conflicting opinions about the best way for the advisory system to function were also apparent. This reflected the absence of a common agreed basis for the operation of an advisory system.

89 A strong theme that emerges is that an advisory system needs some clear basic principles according to which it can operate, and against which its operation can be judged.

90 A second clear theme is that some codification of the advisory process would be preferable, to provide consistency of operation, efficient functioning, robust quality of outcome, and to permit the application of the principles to be audited.

91 This study also recommends an audit trail from the advice through to the decision [120–121, 143, 201]; increased access for stakeholders, in general via the policy-maker [151, 157–159]; and the benefits of balanced committees.

PRINCIPLES

92 These principles express an underlying philosophy applicable to all scientific advisory mechanisms, whatever the policy issue may be. In them is distilled a collection of ideas derived from the evidence-gathering phase of this study.

93 The need for a set of principles applicable to scientific advice emerged from the case studies and initial debates within the study team. It became apparent at an early stage that some issues were being raised frequently, where points of principle were being advocated.

94 The initial step was to collect a long list of 'candidate principles' from all the material collated in the first phase of the study, and then to organise these under thematic headings. A draft was revised several times in consultation with the Advisory Board, the Steering Group, and, finally, after presentation at a seminar.

95 Some of the principles may seem self-evident or trivial, but in practice all make an important contribution to the definition and implementation of a valid scientific advisory process. Each principle addresses (as far as possible) a distinct issue. The principles are consistent and do not overlap.

96 The dominant consideration in settling the final form of the principles was the need for a disciplined framework in which the participants in the scientific advisory processes can operate. Other schemes were considered, in which there would have been more reliance on subjective judgement, but these were judged to carry greater risks of abuse and error.

97 The principles guide working practices and are available as a reference, should the conduct of the scientific advisory process be challenged.

98 The principles were conceived for application to the process of seeking and using advice from experts in the natural sciences; their relevance to the social sciences has not been explored and remains untested.

99 The following sub-sections set out the seven principles, which cover, in summary:

- reliance on logic and reasoned argument (rationality);
- distinguishing the functions of the expert scientific adviser, policy-maker, decision-taker, and stakeholder representative (legitimacy);
- ensuring that the process is transparent, auditable, and accessible to all stakeholders (inclusivity and transparency);
- criteria for selecting advisers and managing bias (competence);
- imposing on scientific advisers an over-riding duty to the public interest (over-riding duty);
- acknowledging the limits of scientific knowledge, expressing uncertainty and recognising this in policy-making (candour);and
- matching the advisory effort to the importance of the policy issue and the difficulty of the scientific questions (proportionality).

100 The following sections contain the principles, each preceded by the reasoning that led to it.

Rationality

101 Scientists use logic, evidence and reasoned argument in their work, an approach that is common to science, policy-making, legal decisions, and parliamentary and general public debate.

102 The scientific method has been shown to be extremely effective at producing theories with explanatory and predictive power. Science can make predictions about the consequences of actions, and changes in the physical environment through time. It can also link causes to effects.

103 Scientific advice can, therefore, inform decision-takers about the potential consequences of the options open to them. Scientists use a core of firmly established information. Outside this core, there is a large body of valuable indicative information that is less firmly established, and, beyond it, on the boundaries of current research, there is very significant uncertainty. In these less-secure regions, there is still much that can be said to characterise a range of possible outcomes, by stating the risks and uncertainties. It is recommended that a disciplined approach be taken to the handling of evidence and that the presentation of this evidence be made by deductive reasoning from what is known and from the partial evidence that is available.

Scientific advice should be founded upon observation and theory, and should describe both the scientific conclusions and their uncertainty; these should be deduced from the evidence by reasoned argument.

Legitimacy

104 Scientific advice is one component of a policy decision. In formulating policy, it should be taken into account, together with economic and social considerations, political constraints, values, and the views of stakeholders.

105 Scientific advisers should be competent to provide advice on particular problems within their field of expertise, to analyse the consequences of a range of policy options, and to assess the probability of various outcomes.

106 Scientific advisers are not necessarily also qualified or authorised to make policy decisions, or to provide advice that contains judgements about social values; equally, decision-takers are usually not competent to assess scientific issues.

107 The process of translating a policy question into a scientific question, and bringing scientific answers into a policy-making forum, requires particular skills—a combination of scientific literacy and policy awareness. The synthesis and analysis of scientific and other advice is the professional occupation of policy-makers.

108 Stakeholders, by definition, have an interest in the outcome of a policy question. One attribute by which the success of a policy option could be judged is its acceptability to stakeholders. Thus policy-makers may wish to elicit the views of stakeholders during the policy-making process. This could include asking stakeholders to comment on, or challenge, scientific advice. Stakeholders may also possess information that could contribute to the scientific analysis of policy options. However, the contribution that stakeholders can make to the scientific advisory process should not include *negotiating* on behalf of their constituencies as a representative. Further, all of these stakeholder functions are different to the function of a scientific adviser.

109 Each function is different, their objectives are different, and the output from each must be treated appropriately in the decision-taking process.

The functions of scientific adviser, policy-maker, decision-taker and stakeholder representative should be distinguished.

Inclusivity and transparency

110 There are usually many individuals and groups with a stake in policy decisions, including the public (as the main risk bearers and potential beneficiaries), industry (as providers of benefits and generators of risks), and pressure groups. These stakeholders demand access to the decision-taking process, and this includes the scientific advisory process.

111 Stakeholders have an important part to play in ensuring that the scientific questions being asked are pertinent to the policy issues that are of concern to them. However, active and direct participation by stakeholders in the generation of scientific advice itself could lead to generating scientific advice based on value judgements and stakeholder views, rather than on expert analysis of scientific evidence.

112 As risk issues have become more widely discussed, public debate has become more sophisticated and the fact that some situations offer no risk-free options has become more widely recognised. The late announcement of unwelcome news can undermine public confidence, so openness about potential risks is both a beneficial and a practical policy.

113 Care should be taken to avoid a form of 'openness' that actually obscures key messages through obscure terminology or dilution in a large volume of detail. Detail should be available for the expert reviewer, but the aim of this principle is effective communication with the public. This requires transparent communication of the key findings, including uncertainty.

114 The convention in the scientific profession is that new scientific results should be published freely so that they can be exposed to challenge and developed by others. If this convention were applied to scientific advice, it would impose the normal professional discipline upon individual scientists. It might also moderate the way in which special interests present their cases, and might stimulate debate and the expression of alternative viewpoints.

115 In the process of scientific investigation there may be an initial period when information is incomplete, there are competing views, and analysis is inconclusive. The balance of evidence and argument may shift while scientific work is in progress. Thus, partly finished work may be unbalanced and, hence, misleading. For these reasons, scientific advice should not be published until it is complete, at least in draft form—when balanced evidence has been collected, opposing views have been addressed, and residual uncertainties explored.

116 A judgement may need to be made by the policy-maker as to when scientific advice is sufficiently complete that it should be published. In addition, some policy problems may require advice on more than one scientific question. These pieces of advice may not all be completed at the same time. In some situations, therefore, a balanced picture may only be obtained once all the relevant scientific inputs into the policy-making process have been received. The presumption should be for early publication wherever possible, whether in part or in whole.

117 Where the developer of a potentially hazardous product is obliged under regulatory legislation to provide information about the product and its hazards (for example, in a marketing licence application), the law usually affords some protection of the applicant's commercial secrets through a limited confidentiality restriction. Such restrictions do not extend to essential safety information, such as the precautions to be taken during transport and use of the product, but could cover information such as original laboratory and trial results on efficacy, because these are costly to obtain and their publication might assist the applicant's competitors. There is a potential conflict between the rights of the applicant and the rights of the public to access such information. It is therefore recommended that the presumption in favour of publication continue to be applied with the absolute minimum of restriction, and that consideration be given to creating alternative mechanisms for protecting commercial interests while allowing full disclosure of the information on which product approval is based.

118 In no case should the existence of residual uncertainty be considered reason for withholding results.

119 However, the process by which the scientific advice is being generated should always be open to scrutiny. This would help to ensure freedom from bias and allow stakeholders to contribute to the advisory process.

120 An audit trail of the scientific advisory process could be made available to policy-makers, decision-takers and, ultimately, to stakeholders. This audit trail might cover the

generation of the scientific questions; the scientific arguments, calculations and analyses; alternative scientific opinions and uncertainties; and the scientific appraisal of policy options.

121 Decision-takers may find that it is useful to explain how scientific advice was taken into account in a policy decision. This would confirm that the scientific advice has been correctly understood, and that it provides assurance to stakeholders that the issues of concern to them have been addressed. It would provide valuable feedback to the scientific advisers, and, hence, contribute to the continual improvement of the scientific advisory system.

122 Despite the above, it is ultimately the responsibility of government to decide how, when or whether scientific advice to government should be made public.

Full information about the process of seeking and using scientific advice should be made public, and stakeholders should be encouraged to comment. Scientific advice itself should be published promptly in a transparent manner, once it is complete.

Competence

123 Scientific advisers should be selected for their competence, which should be appropriate to the scientific question, and should include not only personal proficiency but also awareness of the wider state of knowledge in the field, and an aptitude for communication. Scientific advisers should show willingness to consider scientific opinions that are at variance with their own, and to discuss these in their advice. The most distinguished research scientists may not always make the best advisers.

124 Some scientists who have the potential to contribute useful information to the advisory process, owing to their relevant knowledge and experience, may be employed by organisations such as industries or pressure groups, that have an interest in the policy issues. Such scientists should not necessarily be excluded from the process, but they should advise as experts rather than negotiators. Their contribution must be managed by the policy-makers and balanced by other sources of expertise. Their experience, and biases, can be a useful contribution to the evaluation of scientific uncertainty.

125 Scientific advisory committees may be balanced by appointing a group of members with different affiliations. This will help to define the range of scientific opinion on a particular issue, and may help to prevent undue bias from the influence of any one individual.

126 The Nolan principle that appointees should not 'place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their public duties' should not be applied rigidly in the case of individual scientific advisers. The aim of the Nolan principle should be met in other ways; namely, the declaration of interests, the balancing of sources of advice, the over-riding duty to the public interest, and the explicit communication of uncertainty.

127 The declaration of interests by scientific advisers is necessary whether they are academics, employed by industry, or employed by pressure groups. Possession of interests should not be presumed to compromise an individual's integrity.

128 In assessing the likely bias of a scientific expert, policy-makers should consider the whole of their professional profile (employment, affiliations, consultancy, employment history and experience), and not just their financial interest in the subject. Scientific preconceptions and adherence to particular schools of thought may also distort scientific judgement or introduce bias.

Scientific advisers should be selected for their competence. It is not necessary for advisers to be independent of all interests in the policy question; however, the advisory process should ensure that interests are declared and any resulting biases are balanced or taken into account.

Over-riding duty

129 Scientific advisers may face a conflict of interest because they have other occupations and interests outside their role as advisers. This professional experience of experts contributes to their ability to provide advice. Experts who are employed in industry or academia may possess expertise not available within government.

130 Scientific advisers may feel under pressure to bias their advice, for example, to suit the constituency that nominated them as advisers (which might or might not be the government), to be consistent with established scientific consensus, to lead to a particular policy outcome, or to suit the adviser's employers. Individual advisers should be empowered, and required, to resist such pressures.

131 The general public is often the bearer of risk associated with policy options. The aim of government in forming policy relating to risks is the protection of the public or the environment.

132 It is difficult to provide a universal definition of the public interest. Furthermore, scientific advisers are neither qualified nor authorised to make value judgements, and it cannot be possible to define the public interest without making value judgements. Thus, scientific advisers should simply be required not to promote *any* special interest in preparing their advice. The aims of this requirement are to ensure that scientific advisers recognise that they are forbidden from placing a conscious bias on their advice, and to empower advisers to use this requirement to resist any pressure to do so. This requirement addresses only conscious bias, and does not guarantee that advisers will be free from unconscious bias, or remove from policy-makers the duty to balance, or otherwise take into account, all sources of bias in the advice they receive.

The scientific adviser's over-riding duty is to the public interest. Advisers should not seek to promote any special interests in preparing their advice.

Candour

133 There are limits to the extent of scientific knowledge, particularly concerning new technologies and the assessment of risks. Scientific advice in some areas is therefore characterised by uncertainty and differences of scientific opinion. For good decision-taking, it is essential that these uncertainties are taken into account.

134 Scientific advisers could be asked to seek out the sources of uncertainty in their advice, and be candid about these uncertainties, and any differences of opinion among their peers. They ought to be ready to explain how the uncertainties arise, what assumptions have been made, and to provide an estimate of the overall uncertainty. In particular, they should avoid the temptation to close out scientific issues prematurely, where an error could have adverse consequences.

135 The merits of each policy option depend crucially on the consequences (costs and benefits) that could flow from it, and on the likelihood of those consequences. Scientific advice should therefore address not only the generally expected (most likely) outcome of each policy option, but also the risks of extreme and, especially, adverse outcomes that are still within the bounds of possibility. The supplementary note on 'Decision-taking under Risk and Uncertainty' contains a fuller discussion of this issue [272–304].

136 Scientific advisers are not, and neither should they, feel duty-bound to provide a subjective judgement where the evidence cannot resolve a question, nor should they be subject to any pressure to do so.

137 Scientific advisers themselves may not be the best judges of the uncertainty in their own advice, although they can make a major contribution to this assessment. It is a necessary skill of policy-makers to assess scientific uncertainty by careful drafting of questions to scientists.

138 Decision-takers need to accept and understand the uncertainty in the advice they receive, and to consider it in taking their decision.

Scientific advisers and policy-makers should be candid about the limitations of scientific knowledge and should always assess the uncertainty in scientific advice and the risks associated with each policy option; this information should be taken into account by decision-takers.

Proportionality

139 There is a range of problems for which scientific advice is necessary. Problems can be categorised by:

- urgency—a decision may be required very quickly;
- the magnitude of the risks;
- the frequency with which problems of the same type arise;
- the public perception of its importance;
- uncertainty in the existing science base;
- tractability of the problem.

140 Likewise, different ways of generating scientific advice can be characterised by:

- the time required and cost likely to be incurred;
- the available expertise and capabilities; and
- the degree of certainty achievable.

141 The choice of mechanism for generating scientific advice is likely to involve a trade-off, for example between the cost of generating the advice and the degree of certainty achievable.

The effort expended on securing scientific advice should be proportionate to the importance of the policy issue and the difficulty of the scientific investigations required.

MODEL PROCESS

Rationale for a defined process

142 The process described here is a model of best practice, designed to be compatible with the principles described in the preceding chapter. This process is not intended to be seen as mandatory, nor as inhibiting the freedom of departments to act efficiently. It need not be expensive to implement. The process is offered as a model that could be considered by departments when deciding how to address an issue on which scientific advice is needed.

143 A model process brings a number of advantages.

- Once a process has been defined it will be quicker and easier to follow it, when advice is required, than to define an ad hoc process each time.
- A codified process can be audited. Once audited, public confidence in the process can confer confidence in the advice.
- The definition of the process, and its audit and review, can be published to provide public accountability.
- A process reduces dependence on the judgement of individuals. Stakeholders may have confidence in a process, rather than have to place their trust in individuals.
- A defined process may help to ensure that advice is 'fit for purpose', since it helps to avoid ambiguity and uncertainty about the functions and contributions expected from the participants in the advisory process.
- If the same process is used across government, the outcomes are more likely to be consistent.

144 The disadvantage of a defined process is that it may not be sufficiently flexible to cover every circumstance in which scientific advice is sought. The model can be adapted as necessary, but:

- the adapted process should remain consistent with the principles;
- the justification for omitting or adapting parts of the process, and for the alternative adopted, should be recorded so that the operation of the process can still be audited; and
- even where the pressures of urgency or other constraints, or the close working relationship between the scientific advisers and those whom they advise, preclude the use of a distinct structured process, efforts should be made to conform to the spirit of the model.

Functions

145 Four functions can be identified in the policy process: decision-taker, policy-maker, scientific adviser and stakeholder representative. The first three are needed to take policy decisions. Stakeholders have views and interests that must be taken into account in reaching a decision. The functions can be defined as follows:

- **Decision-taker**: a person with the authority to take a policy decision. This may be a government Minister, or a person or body with the delegated authority to take a decision in the name of a Minister.

- **Policy-maker**: a person or organisation charged with assisting a decision-taker in reaching a decision by providing policy analysis, generating policy options, or by conducting risk assessment. Policy has been interpreted to include regulation.

- **Scientific adviser**: a person or organisation responsible for providing scientific input to policy-making or decision-making. This includes both scientists expert in narrow disciplines relevant to the problem in question, and broader-based scientists able to integrate several disciplines.

- **Stakeholder representative**: a person or organisation representing the interests and opinions of a group with an interest in the outcome of a particular policy decision.

146 There is a question over whether it is possible to separate the functions of policy-maker and scientific adviser. It is argued by some that the scientific and political elements of decisions are inextricably linked.

147 If scientific advice and policy-making are allowed to become inextricably mixed together, the resulting input to the decision-taking process is muddled and confusing, because it

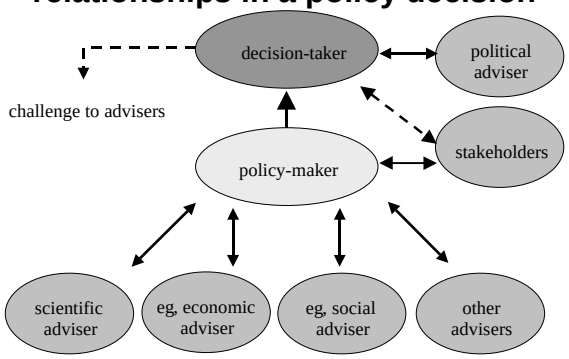
is unclear to what extent the advice depends on the analysis of qualified experts, and to what extent it depends on value judgements. This is likely to result in poor decisions, and a lack of confidence. Should such advice be published, it would be liable to be attacked by scientists as poor science, and also by stakeholders as not representing or taking fair account of their views. Such confused advice would also be incompatible with the government's stated aim of developing evidence-based policy.

148 The model process described here allows these functions to be clearly distinguished without compromising the quality of the scientific advice or the decisions that are taken based on it. It places demands on all the participants to recognise and fulfil their roles.

149 In distinguishing these four functions, different people would normally perform each function. However, if there is a good reason for one individual (or group) to enact more than one function (perhaps because the problem is small, or specialised, or requires urgent action), that person should be sure which function they are fulfilling at each point in time. The same person may then have to consider the output of one function as the input to another. In legal language, an individual with more than one function should 'direct themselves' to address each function appropriately. Failure to engage in this disciplined process might lead to poor advice and a poor decision, for the reasons given above. In any case, if the same person (or group) performs more than one function, transparency may be compromised.

150 This overlap of functions may be particularly challenging if a government-employed scientist with delegated responsibility for the decision has to exercise all three functions. In practice, a written record of the logical argument of the case would provide an audit trail and justification for the decision, if subsequently challenged.

Figure 1: Functions and relationships in a policy decision



151 The functions and relationships of the participants in the policy process are drawn in Figure 1. The key points are:

- the figure reflects the need for the policy-maker to obtain advice other than scientific advice, and for that advice to be reflected in the options and recommendations presented to the decision-taker;
- stakeholder representatives bring their concerns to the policy-maker, not to the advisers (scientific or otherwise). It is for the policy-maker to extract from the stakeholder representatives the elements that need to be considered by the expert advisers (including the scientific adviser);
- the scientific adviser has a close working relationship with the policy-maker but does not interact directly with the other advisers, other than through the policy-maker, who may wish to refer issues between advisers or bring them together to explore issues which overlap their competencies;
- all of the advisers, including the scientific adviser, may be challenged by the decision-taker. This is essential if the decision-taker is to be able to take responsibility for the decision. The decision-taker must be able to question the scientific adviser directly, in order to be satisfied that the scientific advice is robust (similar lines of communication may be necessary for the other expert advisers); and
- the decision is expressly recognised as a political decision, for which political advice may be needed, and it is the duty of the decision-taker to reach a balanced decision in which scientific advice plays its due part, but is not necessarily the determining consideration.

Types of advice

152 The use of scientific advice in three situations was considered in the course of defining this process. They are different in kind and in the way that the participants behave. Each of the participants in the advisory process should maintain a clear understanding of their responsibilities in these situations. The three situations are described below.

153 **General advice**: the policy-maker asks the scientific advisers for general advice on the science of an issue so that this may be taken into account when defining policy options. This may be a preliminary process, to be followed by

the preparation of a set of policy options that may then be reconsidered by the scientific adviser.

154 **Policy advice**: the policy options are known and require a balanced decision to be made, weighing up the benefits, risks and costs of each option. Scientific advice is a vital component of the decision but has to be built into a legitimate decision-making procedure that takes account of all other aspects as well as science.

155 **Technical decision**: the policy-maker may pose a set of policy options that are contingent upon scientific inputs, and the decision-taker may select and endorse these options. Once this has been done, the scientific advice may legitimately determine the policy option selected, since a due constitutional process has been adopted. For example, routine decisions on appropriate safety standards may depend only on technical analysis if the political decision about the tolerability of risk has already been made.

156 It is possible that an issue will be discussed in each of these situations in sequence. Initially, general advice is needed to identify and understand the issue. There may then be a need to implement policies to respond to it, for which policy advice is needed. Once the issue is well understood, its management might be purely technical and, with the appropriate policy guidelines in place, might be handed over to technical specialists to administer. The model process described below is designed to address all three of these situations.

Engagement with stakeholders

157 Stakeholders should be entitled to contribute to most stages of the process. However, they do not have a *duty* to contribute and cannot therefore be held responsible for any part of the process.

158 Stakeholders have a valuable role in challenging both the scientific advice and the actions of the policy-maker. Methods to elicit stakeholder contributions have been reviewed recently within the ESRC Global Environment Change Programme (ESRC, 1999), including:

- focus group: typically 6–10 people, supported by a trained facilitator who guides the group through a set of questions in order to identify the main concerns;
- citizens' juries: usually 12–25 people who are presented with evidence for different policy options. Witnesses may be challenged and the jury votes to reach a majority decision;
- in-depth groups: longer-term focus groups;
- consensus conferences: larger citizens' juries;
- stakeholder decision analysis: combining quantitative multi-criteria techniques and qualitative evaluation; and
- deliberative polling: members of the public are polled after receiving a briefing.

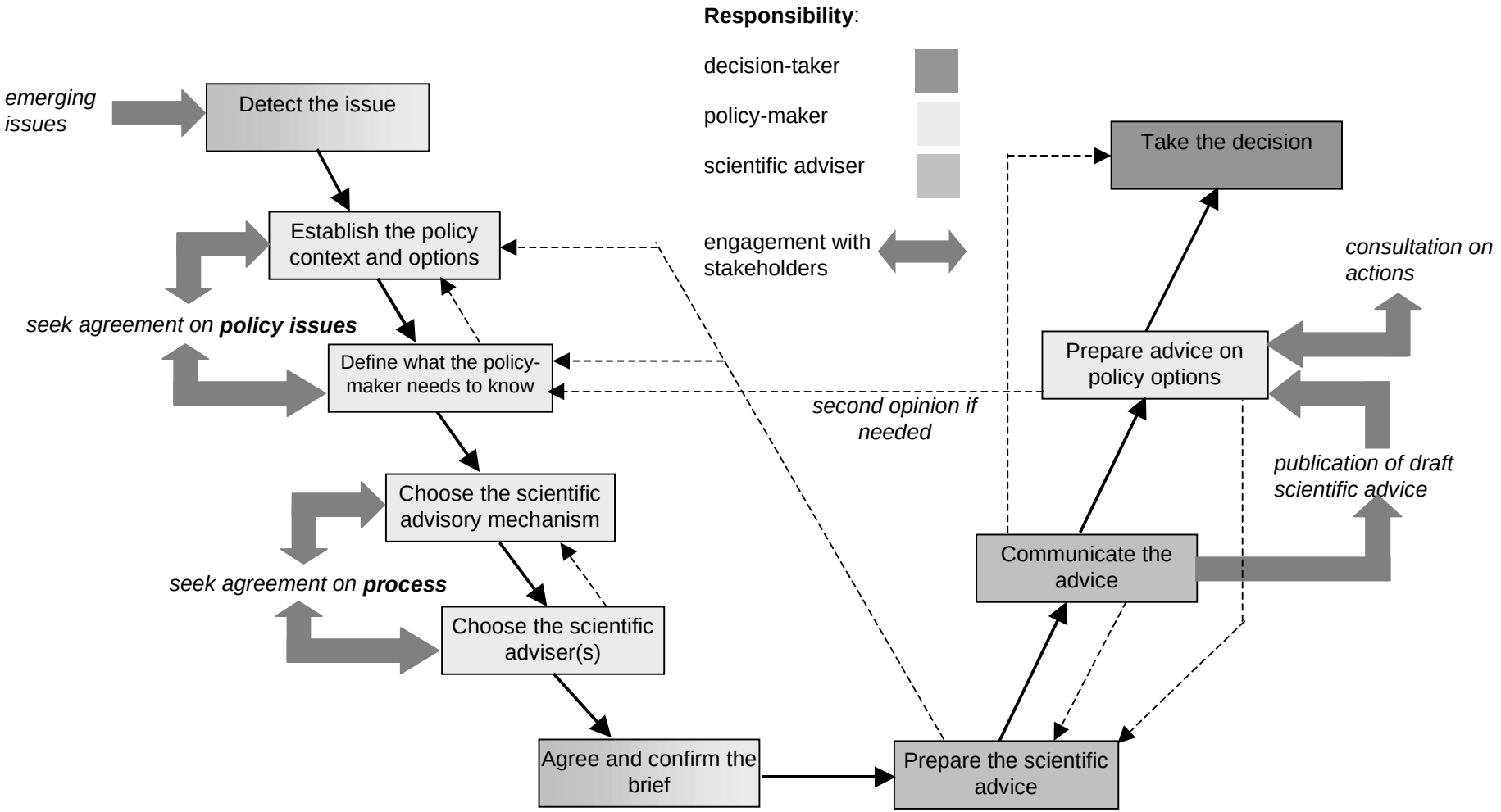
159 These techniques appear to be particularly useful for allowing decision-takers to gauge the views of the general public. As such, they are part of the wider decision-making process. These techniques might be useful in engaging stakeholders with an interest in a policy decision for which scientific advice is being sought. This is the subject of ongoing research in the social science community and elsewhere, and has not been examined during this study.

Nature of the model process

160 This is a benchmark or model process, against which the practicalities of day-to-day pressures need to be set. The process is compliant with the principles set out earlier (and the constitutional and other arguments that underpin them). There may be other processes that have equal validity.

161 The process is divided into a set of discrete and bounded steps (see Figure 2 overleaf). In practice these may be overlapped or even merged, and may not be clearly distinguishable. The model is presented as a sequence of steps with some explicit feedback loops. In practice, the stages may undergo many iterations.

Figure 2: Model process for securing and using scientific advice



Detect the issue

162 Policy issues may emerge from many sources, including parliamentary questions, departmental science staff, the media (including academic journals), and the general public. They may also be triggered by accidents, legal proceedings, patent applications, or technological innovations.

163 The early detection of a policy issue is desirable, because it maximises the number of policy options available and the time available to analyse them. Systematic procedures should be employed to maximise the chance of detecting an issue promptly. This might be achieved by:

- a duty on all standing advisory committees to produce regular (perhaps quarterly) briefings on key issues, which survey recent developments within their competence. The briefings should be concise and easily understood by policy-makers;
- a similar duty on all research councils;
- a 'policy-foresight' exercise, which seeks to detect issues that might arise before their effects can be felt. This might include systematic modelling of scenarios and monitoring of scientific developments and their possible effects; or
- an invitation to stakeholders, including NGOs and other expert interested parties, to take part in regular reviews of emerging science and its implications. This might be a role for standing committees, provided that their terms of reference are clearly stated to be to identify issues, not to offer scientific advice on policy options.

164 These procedures might be tested by conducting trials.

Recommendation: Procedures should be established and maintained to ensure that issues demanding scientific advice are detected as early as possible.

Establish the policy context and policy options

165 The policy context of the problem includes:

- what policy issue has arisen?
- what policy options are available and should be considered? and
- who has responsibility for dealing with the problem (including identifying and defining the scientific issues, selecting and briefing the adviser, receiving the scientific advice and building it into policy options)?

166 Systematic procedures, such as scenario modelling, might be used to ensure that a wide range of options is explored. Scenario modelling allows the policy-maker to ask 'what if' questions and is particularly valuable for detecting extreme possibilities and worst cases. Some scenarios might be contingent on a particular set of scientific circumstances, and the recognition of the existence of the scenario allows the correct scientific question to be posed.

167 Stakeholders may make an important contribution to this step by ensuring that the range of policy options considered is appropriate.

168 It is legitimate and desirable to frame the issue in terms of a choice of policies, where the choice is to be influenced by the scientific advice. This provides a mechanism for scientific advisers to set their work in context without delegation of the policy decision. Scientific advisers should assist in defining the policy options in consultation with policy-makers. This helps to ensure that scientific advice is relevant to the policy problem by ensuring that the right scientific questions are asked.

169 Scientific considerations may help to identify policy options that were not apparent before. It is therefore preferable that policy options should not be circumscribed before the scientific advice is available—it is much easier to reject a policy option after the science has been considered than to add one that has not

been taken into account earlier. Policy-makers should be prepared to reconsider the range of policies that are available in the light of emerging scientific evidence.

170 If some policy options have been ruled out by the decision-taker, then this should be made clear in the adviser's terms of reference.

Recommendation: Before seeking scientific advice, policy-makers should identify the policy issues on which the science bears, the policy options that are available, and the scope of advice that is needed. Policy options should be kept open as far as possible until scientific advice has been taken. Policy options should be reviewed in the light of scientific advice to ensure that a complete spectrum of options has been considered.

Define what the policy-maker needs to know

171 The policy-maker needs to be competent to specify scientific questions. The questions should be refined through discussion between scientific advisers and policy-makers, and may be further refined through challenge by stakeholders. The questions put to scientific advisers must be restricted to scientific issues, and must admit a purely scientific answer, in order to maintain the distinction of functions.

172 It may be necessary to pose several questions that require a range of scientific disciplines, and hence a number of scientific advisers.

173 The policy decision must not be delegated to scientific advisers by posing the question in such a way that the scientific advice determines the policy option to be adopted. The only exception to this is where policy guidelines establish that a decision depends only on scientific advice, and a proper decision-taking process has already been followed (the technical decision situation described above).

Recommendation: Policy-makers must define the scientific questions that bear on the policy decision. The definition must separate the scientific and policy issues, and pose questions that are amenable to purely scientific answers.

Choose the scientific advisory mechanism

174 Four mechanisms for the provision of scientific advice can be identified.

- **Scientific generalist**: this is an individual who can assimilate an interdisciplinary problem and apply systematic analysis to the interpretation of information. The scientific generalist is usually a highly respected scientist, but not necessarily an expert in the disciplines relevant to the issue.
- **Single expert**: this is an individual who is appointed as an acknowledged, pre-eminent expert in the field.
- **Consultancy contract**: this may be awarded to a private company, public laboratory, or academic research group. It is frequently used where there is much detailed work to be done (such as field trials or laboratory research), or when the intensity of effort required is beyond the capacity of the other mechanisms.
- **Scientific advisory committee**: committees are used to bring together a wide range of expertise, usually under an experienced chairperson.

In each case, some or all of the advisers could be government-employed scientists.

175 Three other mechanisms were considered.

- **Task force**: which is often used to respond to emergencies. The authority for making policy and taking decisions is delegated to the task force, which considers scientific matters when exercising that authority. A task force can—and, where possible, should—follow the process described in this report. However, because its brief encompasses all of the stages of taking a decision, it cannot be regarded as generating scientific advice. Scientific advice is a subset of the work of a task force, and should be obtained by one of the mechanisms described above.

- **Stakeholder committee or commission**: whose members *represent* the interests of stakeholders. The stakeholder committee or commission is not able to act according to the principles described in the preceding chapter because, by definition, its members are appointed to serve the interests that they represent. The committee exists to influence the policy-maker and decision-taker. As such, it can be profoundly undemocratic, representing only the views of those who are present and not any underlying public interest. A stakeholder committee may seek scientific advice and use scientific argument, but it does not offer scientific advice to government—it offers policy advice. Sometimes, where it has the authority, it may even be the decision-taker.

- **Public inquiry**: a scientific advisory committee may choose to employ the methods of a public inquiry (open evidence, cross-examination, formal proceedings). A more general public inquiry usually has a much wider scope than the preparation of scientific advice, and takes into account non-scientific issues. Like a task force, it may call on scientific advice.

176 Although these mechanisms may address scientific issues and produce advice, they will not produce scientific advice in a way that is compliant with the principles. They blur the distinction between the evidence on which policy is based and the policy itself.

177 Policy-makers should make a reasoned choice of advisory mechanism (that is, they should be able to give reasons for their choice, and that choice should be logical, justifiable and traceable). When making the choice, the policy-maker should take into account the need to ensure the appropriate balance of pure and applied science.

178 The mechanism chosen should be proportionate to the scale, complexity and importance of the policy issue and to the scientific challenge. When making the choice, policy-makers may wish to characterise the issue according to indicators, such as:

- urgency—how much time is available for taking advice before a decision is required;
- the magnitude of the risks that need to be managed by a policy decision;
- the frequency with which problems of the same type arise;
- the public perception of its importance;
- the uncertainty in the science relevant to the problem.

179 The cost of obtaining advice should be a consideration when choosing the mechanism. When the problem has been characterised, it will be possible to set a budget for scientific advice. This should reflect the number of advisers that are needed, the experience (and hence authority) that they bring, and the duration of their deliberations. It may need to be reviewed during the course of the investigation.

180 Some of the qualities of each advisory mechanism are summarised in Table 2 overleaf and are explored further in the supplementary notes below.

181 It may also be appropriate to use a combination of mechanisms—for example, a scientific advisory committee may let a consultancy contract to explore a specific issue in more detail.

Recommendation: Policy-makers should make a reasoned choice of advisory mechanism, taking account of the characteristics of the issue.

Table 2: Characteristics of advisory mechanisms

Process	Strengths	Weaknesses
Scientific generalist	Can synthesise many scientific factors	Vulnerable to choice of individual
	Authoritative	Lack of depth of expertise
	Able to communicate with experts from other disciplines	
	Decisive, swift, inexpensive	
Single expert	Decisive, swift, inexpensive	Vulnerable to choice of individual
	Can be radical	Can be radical, hence high risk
	Access to top expert	Quality of advice depends on quality of expert
		No due process
		Credibility
		Can be too specialised
Consultancy contract	Capacity—quantity of work, intensity of effort, support services	Potentially high direct costs
		May not be leading-edge science
	Incentive to do high-quality work and build reputation	May wish to please client
		Experts may not cooperate
	Knowledge of applied science	Profit incentive may cause skimping
	Can form teams with other consultants	
Scientific advisory committee	Allows many experts to contribute and achieve a balanced view	Not independent from its secretariat
		Can be dominated by a strong personality (especially if chairperson)
	Internal debate	
	Good links to research community	May lack time and resources, so vulnerable to manipulation by support services
	Can carry perceived weight, especially if statutory	Needs tight brief to keep to task
	Can have due process	Incentives for individuals to do high quality work are unclear

Choose the scientific adviser(s)

182 The selection of scientific advisers is dominated by two drivers:

- the need to obtain a high level of expertise; and
- the need to identify and manage bias and conflicts of interest.

183 The basic competencies that are desirable in scientific advisers include: knowledge of the relevant scientific field, experience, ability to structure problems and analysis, and time availability. Key individuals, such as committee chairpersons, will also need managerial ability, and skill in the facilitation of debates and communication.

184 In addition, it is desirable that advisers should receive training and detailed guidance. The training should enable the adviser to understand the place of scientific advice within the legitimate decision-taking system, and should help the adviser to present advice so that it can be assimilated and understood. The guidance should include a clear review of the terms of reference and duties of the adviser.

185 The criteria for selection of scientific advisers depend on the advisory mechanism that has been chosen. For example, where a single expert is used, they must be free from vested interests or bias, and must possess a suitably broad range of knowledge and expertise. However, the members of a committee do not need to have all these qualities individually; collectively, the committee should be balanced.

186 It is important to maintain the distinction between the functions of stakeholder representatives and scientific advisers established by the legitimacy principle [104–109]. This does not exclude the possibility that a person may act as scientific adviser while having some affiliation to a stakeholder. Indeed, this may be desirable because they could have relevant knowledge and their views may be used to balance other biases on a committee.

187 Committees should have a balanced membership reflecting all relevant schools of thought, and each individual member must not act except in the role of adviser, and certainly must not seek to promote any special interests.

188 Stakeholders should be invited to make recommendations for, or comment on, the choice of advisers. They might also nominate advisers (but not representatives) if that is needed to achieve the correct balance.

189 The selection of advisers for each of the advisory mechanisms is explored in more detail in the supplementary note, 'The Selection of Scientific Advisers' [305–330].

Recommendation: Advisers should be selected for competence, and bias and conflicts of interest should be managed. Advisers affiliated to stakeholders are acceptable, and may be desirable so that all schools of thought can be included. Advisers should receive training and detailed guidance.

Agree and confirm the brief

190 It is essential that the scientific adviser and the policy-maker have the same understanding of the questions that are to be addressed. This can be tested by the scientific adviser replaying the question in their own terms. The questions must be stated explicitly and agreed with the adviser.

191 The scientific adviser should be told the policy options and given an explanation of the policy background. The scientific adviser may be asked to evaluate the consequences and likelihood of all foreseeable outcomes of each policy option. Even if it is not possible to present the full range of policy options at a preliminary stage, it should be possible at a later iteration.

192 The distinction between analysing scientific issues and making value judgements must be made clear to the scientific adviser.

193 It may not be possible to finalise the brief at the start of the process, for example when general advice is being sought or where data must be considered before the scientific

question can be completely defined. The brief may have to be developed iteratively.

194 The policy-maker should require the scientific adviser to consider and express uncertainty. This should include:

- a realistic assessment of the robustness of all conclusions;
- an candid description of conflicting theories or evidence; and
- a description of new evidence, which, if it were to emerge, would cause the adviser to change their advice.

195 If any of the outcomes of a policy decision might have serious consequences, the scientific adviser should be reminded not to exclude unlikely outcomes.

196 When briefing the scientific adviser, the policy-maker should make clear any constraints on the way in which they should work—for example:

- the procedures to be followed to maintain an audit trail of the advice;
- how uncertainty and risks should be presented;
- whether meetings are to be open or closed;
- when draft reports are to be prepared; and
- whether any draft scientific advice should be published, or if there is to be any communication with the press or general public while the work is in progress.

Recommendation: The brief for the adviser must state the scientific questions and should list the policy options that are available. The terms of reference should make clear the scope of the advice that is sought, including the need to present uncertainty and the consequences of possible outcomes.

Prepare the scientific advice

197 Preparing scientific advice is not the same as conducting scientific research. The latter is an iterative process of generating hypotheses and testing them against evidence. It depends on the intellectual curiosity and creativity of the researchers, moderated by publication and peer review.

198 The preparation of scientific advice involves the synthesis of known science with estimates of what is unknown or uncertain, directed towards the resolution of a policy issue. It depends on the ability of the advisers to appreciate the policy needs, and to reflect candidly the full scope of scientific views, and not just their own scientific position. The advisers may recommend, or even conduct, further research in the course of preparing the advice, but the two activities should be clearly distinguished.

199 Scientific advisers should maintain the highest professional standards of scientific practice when preparing their advice, but they also need to be aware that the preparation of scientific advice is different from the process by which science itself is pursued. They should, for example, follow good practice in assessing evidence. They should give appropriate weight to partial (either incomplete or biased) evidence, and be aware of the dangers of errors of omission, bias, and preconception. Scientific advisers should comment directly to the policy-maker, separately from their advice, on any scientific aspects of an issue that lie outside the terms of reference. This could be part of the iteration of the terms of reference.

200 At all times the scientific adviser should remain aware of the basis of the advice. Four such bases can be recognised, all of which are within the scope of scientific advice but which merit different levels of certainty.

- **Observation**: empirical evidence that is unambiguous and uncontentious, although it may still be open to different interpretations.

- **Formal analysis**: which should lead to a consistent result, regardless of who conducts the formal analysis.

- **Reasoned judgement**: the outcome of a disciplined approach to a problem, whereby deductions are made by extrapolation or extension from formal analysis.

- **Opinion**: simply an assertion (ie, a belief), the value of which depends entirely on the integrity, competence and credibility of the party expressing the opinion.

201 An audit trail should be maintained, which makes clear how each element of the advice was derived and on which of the four bases it depends.

202 Scientific advisers should have a systematic procedure for identifying and handling uncertainty. They should consider all types of uncertainty (inadequate data, incomplete theory, conflicting theory, limitations of theory) and should characterise their results accordingly. Sensitivity analysis should be used to test how the advice might change if new evidence emerges, or if a theory that has been used is incorrect. This should result in a statement of what new evidence, if it were to emerge, would require the advice to be changed. Advisers should assess the consequences of uncertainty for each possible scenario, or each policy option.

203 Where more than one hypothesis is credible, the scientific adviser must not decide which is the more probable and offer that as the sole advice. The alternative hypotheses must be presented, together with the evidence and analysis, and the weight to be attached to each. In addition, where there are gaps in scientific evidence, it should be indicated how new evidence might support or contradict the hypotheses.

204 Dissenting advisers should be encouraged to present their views constructively. Committee chairpersons should ensure that those views are considered, accurately reported and given appropriate weight. Minority reports should be accepted if the dissenting views cannot be accommodated. It is not the place of scientific advisers to achieve consensus where differing views exist.

205 Where scientific advisers receive administrative support from the government department that appointed them, they should not be reluctant to call on assistance from the secretariat.

206 Scientific advisers should ensure that they contribute the scientific elements of risk analysis (such as quantification of the hazards). Scientific advisers should not apply the precautionary principle or any hidden safety margin. They may wish to draw the attention of the policy-maker to precautionary options, but the application of any value judgement by the scientific adviser, such as to the degree of precaution that is appropriate, usurps the role of the decision-taker.

207 Even if the policy-maker indicates that the advice will not be published, the scientific adviser should:

- prepare the advice to a standard that would be acceptable for publication;
- work constructively to consider the comments of stakeholders and others whom the policy-maker uses to challenge and review the advice; and
- present their advice in a report or other official communication to the policy-maker, and not in informal briefings; however, it may be necessary and desirable for the adviser to explain their reasoning in person to the policy-maker or decision-taker.

Recommendation: The scientific adviser should follow the good scientific practice of testing hypotheses, and should apply this to the full range of possible outcomes, explaining the basis of advice offered. The adviser should maintain an audit trail of advice and should present advice, of publishable quality, undistorted by value judgements.

Communicate the advice

208 The primary audience is the policy-maker, and subsequently the decision-taker. It is the responsibility of the scientific adviser to ensure the clarity and comprehensibility of the advice so that it may be fully understood by the recipient of the advice. The scientific adviser must be prepared to explain the advice in person to the decision-taker.

209 This duty may be particularly demanding if the advice involves a large amount data or difficult scientific principles. There may be merit in non-scientists or non-specialist scientists working with the scientific specialists to test the accessibility of the advice and to help with its presentation.

210 It is important that the scientific advice is reviewed, to challenge any assumptions, identify omissions or errors, and to engage with the wider community. The policy-maker might publish a draft of the advice in sufficient time to allow it to be modified before being finalised. If the model process described here has been followed, that advice should not fall within the definition of 'advice to Ministers', and therefore there is a presumption of publication. For important issues, a press announcement that the draft is available might be made, including highlights of the advice.

211 There is a difference between publishing a considered draft and exposing all of the work in progress to public scrutiny. The latter may be acceptable, but there are many cases where public concerns would be unnecessarily fuelled by early hypotheses that are later rejected. Too much public exposure at an early stage may cause scientific advisers to be excessively cautious, and thus compromise the quality of the advice.

212 Where scientific advisers are called on to present and explain their advice to the general public, they must restrict their comments strictly to science and the scientific advice. They should not 'second-guess' the decision-taker, nor should they seek to close off policy options. However, if the scientific adviser communicates the advice properly to the policy-maker, the policy-maker should be perfectly able to communicate it subsequently to the decision-taker and thence to the public.

213 However, scientific advisers should not moderate their advice in anticipation of public reaction. Uncertainties and conflicting opinions should be identified explicitly and not hidden under false certainty.

214 All participants in the advisory system, particularly advisory committee chairpersons and policy-makers, should be trained in techniques for posing questions and operating the various advisory mechanisms. The Civil Service College should be encouraged to take a lead in developing training material and ensuring that its courses for senior civil servants and Ministers include the handling of scientific advice—and especially uncertainty.

Recommendation: The scientific adviser should present the advice in full, in such a way that it will be fully understood by the policy-maker and decision-taker. If asked to present and explain the scientific advice to the general public, the scientific adviser should restrict their comments to science and the scientific advice.

Prepare advice on policy options

215 The policy-maker is responsible for managing the process by which scientific advice informs policy. Many other sources of information and advice may have to be taken into account, and the policy-maker is required to synthesise all of these into a set of policy options and supporting analysis to be presented to the decision-taker. In particular, the policy-maker must expressly consider the values and demands of the public and the political objectives of the government, as well as expert advice from scientists and other specialists.

216 This process of synthesis is a key skill of policy-makers and it would be inappropriate in this report to produce general guidance on policy-making. Scientific advice is not different in principle from any other input to the task of policy-making. However, it may be that many of the problems that have arisen with policies for which science is important have resulted from the attribution of undue weight to the

scientific advice, relative to the other inputs to policy-making.

217 Many of the policies for which science is important involve risk, where policy-makers are responsible for risk assessment, building on the risk analysis provided by the advisers. One of the causes of risk is uncertainty, and the level and cause of uncertainty should be made clear.

218 The policy-maker must be able to make use of advice that carries explicit scientific uncertainty. In addition, there may be several possible outcomes of a given policy. It is therefore necessary to include in the scope of the synthesis process the identification and characterisation, for each policy option, of the range of possible outcomes. This will require the policy-maker to consider the other policy inputs as well as scientific advice.

219 Policy-makers are sensitive to the danger that the way in which they conduct synthesis and present the results can have a profound effect on the range of options that is offered and the choice that the decision-taker will make. They can help to guard against bias by consulting stakeholders and presenting to them the range of options that are being considered, the advice that has been received and its significance. This should help to assess the likely outcomes of the options and ensure that the full range of options has been included.

220 If consultation or advice from other advisers identifies options that had not been considered by the scientific adviser, it may be necessary to put them to the scientific adviser and seek further advice. Policy-makers or decision-takers may also call for a more formal 'second opinion'.

221 When presenting policy options to the decision-taker, the policy-maker should make clear the implications and robustness of the scientific analysis. This might be achieved by characterising the policy options according to:

- expected and possible worst-case outcome;
- the degree of reversibility of the option;
- sustainability—whether the option can be sustained in the long term;
- any precautionary arguments that may be relevant;
- the reliability of the key assumptions and evidence; and
- the source of the advice, and the weight that should be attributed to that source.

Recommendation: The policy-maker is responsible for synthesising the advice from scientific advisers, other advisers and more general inputs, such as the values and demands of the public and the political objectives of the government. The synthesis should result in a set of options for the decision-taker, together with an assessment of the possible consequences of option, and their likelihood.

Take the decision

222 The decision-taker has a duty to consider the scientific basis and all other aspects of the policy options presented by the policy-maker. The decision-taker should not allow (or encourage) the scientific adviser to prescribe the range of policy options considered.

223 It is suggested that the decision-taker should:

- always consider the consequences of a 'do-nothing', or 'business-as-usual' policy option;
- consider all the policy options in terms of their costs and benefits, and risks and likelihood of success;
- avoid the use of absolute statements (or questions), such as 'safe', when it is more appropriate to balance costs, risks and benefits;
- consider the reversibility of the options, and the evidence that might require a decision to be changed; and
- check for the consequences of false-positive and false-negative errors.

224 The decision-taker must understand the advice and its uncertainties. The decision-taker must be satisfied that the scientific adviser understands the issues and that the policy-maker has correctly interpreted the scientific advice. If any doubts arise, the scientific adviser may be required to give a

briefing in person so that the decision-taker can gauge the credibility of the adviser and of the advice.

225 The decision-taker must at all times ensure that the decision is justifiable. There is likely to be strong public feeling that there should be no secrecy surrounding scientific advice relating to risks to which the public may be exposed. The decision-taker may wish to make public the reasoning that led to the decision.

226 It has been suggested by many people consulted in the course of this study that there would be great merit in encouraging decision-takers to make public the reasons for the decision. The decision-taker has no legal duty to give reasons for the decision, except through their accountability to Parliament, and may, if reasons are given, be vulnerable to legal challenge if those reasons are considered irrational. However, the advantages of giving reasons are:

- scientific advisers, and their contribution, can be acknowledged when a decision is announced;
- the way that scientific advice relates to policy can be revealed, placing the decision-taker in a stronger position to defend the decision;
- the decision is more likely to be acceptable to the public, especially when it is contentious;
- the uncertainties can be made explicit—this helps to protect the decision-taker if the policy has to be changed subsequently, perhaps because new evidence is presented; and
- in the event that the decision is found with hindsight to be sub-optimal, it is politically much easier to reverse the decision if the reasoning and advice on which it was based were known and have since changed.

227 Presented below is a suggestion which might provide a helpful structure for the full explanation of a decision:

- the decision was about X;
- this is important because of Y;
- the options were a, b, c …;
- advice was received from p, q, r …; they were chosen because …;
- their advice was …, and hence the consequences and risks of each option were…;
- in reaching the decision, account was taken of … (eg, international treaty obligations, long-term policies, implications for other areas of policy);
- the criteria adopted when considering the advice were …;
- where there was conflicting advice, p and q were accepted (and r rejected) because...; and
- hence the decision is … because … (summary of earlier points, values that were applied and weighting that was given to conflicting arguments).

Recommendation: The decision-taker must take the decision, not allow it to be taken by the scientific advisers. The costs, risks and benefits of each option should be expressly considered. The decision-taker must be satisfied that the scientific advice is sound, must understand it, and must be able to explain, and defend, a reasonable decision. The decision-taker should consider stating advice and explaining the reasoning that led to the decision.

Audit and maintain the process

228 The decisions that this process is intended to inform are taken by, or in the name of, Ministers. Therefore Ministers must be accountable to Parliament for the decisions and the scientific advisory system that supported them.

229 Three activities could contribute to the maintenance of the scientific advisory process:

- auditing the operation of the scientific advisory system to ensure that it is compliant with agreed guidelines;
- training those who provide, and those who use, scientific advice to ensure that they understand and fulfil their duties; and
- reviewing, adapting and maintaining the advisory system to ensure that it remains fit for purpose.

230 There are four checks on the quality of scientific advice: quality assurance, peer review, audit, and parliamentary scrutiny.

Quality assurance

231 During the preparation of advice by the scientific advisers, the policy-maker could review progress, to ensure that advisers are keeping to the timetable and to their remit. The policy-maker could also check more generally that the scientific advisers are following good practice, consistent with the recommendations in this study. This is a quality-assurance exercise for the policy-maker. It assures the policy-maker that the final advice will meet their quality requirements, and that the process by which it has been delivered is robust.

Peer review

232 In many cases, the policy-maker may wish to consult to check that the advice they have received from the advisers is complete, and to provide a formal opportunity for the scientific community to comment. One way of doing this is to circulate the advice to other experts for peer review. The selection of experts might be drawn from the same list of experts from which the scientific advisers were drawn. Peer review is used by most editors of professional journals, especially research journals, to certify the quality of the scientific papers. It is not a completely reliable method. Peer review cannot prevent falsification of evidence, errors in analysing unpublished data, or poor experimental technique. Where peer review fails, according to the opinions expressed to this study, it is commonly because the reviewer has not understood the paper, or the author of the paper has been misleading in their claims. There are numerous examples where peer-reviewed published research was later discredited.

233 In considering the value of peer review for checking the quality of scientific advice, the difference between scientific research and scientific advice is important. Scientific advice analyses policy options, and does not always involve original research, and may include expert judgements and opinions. It is more applied, and may be more subjective than scientific research submitted for publication. It may also be more forthright in its consideration of uncertainty and less stylised in its use of language. As a result, scientists acting as peer reviewers may not be effective in their review unless directed to particular aspects of the advice. For example, they might be asked to examine the adviser's survey of evidence and comment on whether any evidence has been omitted. They might also be asked to consider the set of hypotheses considered by the adviser and comment on whether it is complete. The reviewer should be given the terms of reference of the scientific adviser so that they can place their comments in context.

234 In interpreting the reviewer's report, the policy-maker should bear in mind that the purpose of the peer review is to widen the range of possible advice to be considered, rather than constrain it. This applies particularly where an adviser has adopted more unconventional thinking, which is out of line with the scientific consensus. There have been many cases where new scientific thinking has emerged slowly, partly because it is incompatible with the previous scientific consensus. The policy-maker should therefore reflect on the fact that the peer-review process has a tendency to reinforce the current scientific consensus.

235 Peer review is only a weak assurance of the quality of advice. This is because, although the reviewers may be accomplished, the time devoted to peer review is short, and peer review in scientific journals does not have a reliable record of screening out poor-quality work. Furthermore, peer review is appropriate for science research but less useful for scientific advice. Peer review of advice does not appear to be common practice in the UK.

Audit

236 To ensure that the scientific advisory system, including the communication of advice, remains fit for purpose, it is recommended that departmental chief scientists should arrange for it to be periodically and independently audited and reviewed. The results of these audits and reviews, and any changes to the system, should be reported to the department's management board and to the OST.

Parliamentary scrutiny

237 Ministers may be called to account for their decisions before Parliament. Parliament often exercises this right, but interviewees in this study commented that decisions are not always explained well. Parliamentary scrutiny does not provide a routine challenge to decisions because it is usually only used where a decision is disputed or an adverse event triggers the review of previous decisions. Ministers are under an obligation to explain to Parliament how they reach decisions based on the information presented to them, but in practice, where a statement is made at all, it is to show that there was

evidence to support the chosen policy. This is usually done by explaining the links between that policy and some evidence collected in the policy-making and advisory process. It does not always include: discussion of alternative policy options that were rejected; the level of uncertainty in the advice; or the balancing of interests and values which support the selection of the chosen option rather than any of the rejected options. There is strong support for the production of a 'reasoned opinion' that does all of these things. It could become the main output of the scientific advisory and policy process, [226–227]. The reasoned opinion need not be a chronological account of the scientific advice and policy process, but would, instead, explain the policy options and how they related to the evidence available to the Minister.

Recommendation: Government should establish and operate a system for auditing and maintaining the scientific advisory system, and for training those who work within it.

SUPPLEMENTARY NOTES

238 The following sections contain supplementary notes that discuss in more detail some of the themes that have emerged during this study, and include detailed recommendations for some aspects of the model process.

Rights and Duties of Scientific Advisers

239 The rights and duties proposed in this section could be incorporated into the terms of reference of advisers, or into a code of conduct.

Rights

240 Scientific advisers should have a right to:

- be given terms of reference which set a question that is amenable to a scientific answer and that does not demand broader policy questions to be addressed by the adviser;
- be heard by other members of the advisory team or committee;
- submit a minority or dissenting report if, as a member of a committee, they are unable to reach a common position with the other members of the committee;
- be allocated sufficient resources (both time to prepare their advice and adequate support from a secretariat) to ensure that they can answer the question satisfactorily and fulfil their duties. This does not allow advisers to call for indefinite time or other resources, but does allow them to decline to offer advice when, in their opinion, insufficient resources have been made available to allow adequate advice to be prepared and delivered; and
- be allowed to record a personal statement which sets in context their declarations of interest and their understanding and acceptance of their duties.

Duties

241 Scientific advisers should a duty to:

- act with integrity;
- put the interests of the public above any other, including personal interests, the interests of their employer, or the interests of the person whom they are advising;
- disclose, to the person proposing to appoint them, any interest which might be seen to have the potential to distort their judgement [242];
- disclose, to the person proposing to appoint them, any prior scientific position which could be seen as potentially causing the adviser to prejudge the issue;
- conduct their advisory work in the expectation that the findings might be placed in the public domain, and in such a way that they would be understood by policy-makers and the advisers' peers;
- present and explain the advice to policy-makers and decision-takers if asked;
- identify any sources of uncertainty in the advice being given and assess their significance;
- state what new evidence, if it were to be found, might require the advice to be changed;
- avoid any methodology which introduces bias to the scientific advice. For example, a clear statement of uncertainties is more transparent than appeal to the precautionary principle, which should only be applied by policy-makers during policy synthesis;
- act in an efficient manner, within the timescale agreed with the policy-maker;
- keep confidential any aspects of the issue, if so required by their brief, including the fact that they are advising, although the principles demand of the policy-maker the presumption that the advisory process will be conducted openly;
- recognise that the questions for which scientific advice is sought are different in kind from the type of questions that they face as practising scientists. Scientific advice may have to address questions

which are not amenable to certain answer;

- use good scientific techniques of observation and logical deduction, but not exclude inconclusive evidence or unproven hypotheses, which might be relevant; and

- express their advice in line with the terms of reference.

242 The interests to be disclosed by advisers might include:

- membership of professional bodies and institutions;
- membership of political or charitable organisations;
- directorships;
- material shareholdings;
- their employers and those of their close relatives;
- previous employers;
- sources of funding for research activities;
- advisory and other appointments;
- journal editorships; and
- a full list of publications.

243 The adviser should then be asked whether they expect that any of these interests might be compromised or enhanced by the findings of their advice. They should also be asked whether any of their interests would influence the way in which they produce their advice and the judgements that they may have to make about the scientific issues.

244 The policy-maker should then make a judgement as to whether the advice might be, or might be seen to be, compromised by the adviser's interests. In making this judgement, the policy-maker might consider the interests declared in the light of any statement that the adviser has made setting their interests in context of their experience.

Additional duties of chairpersons

245 Chairpersons of advisory committees have further duties. They should:

- ensure that every member of the committee is heard and that no view is ignored or overlooked, using, if appropriate, a structured process which ensures that all views are captured and explored;

- ensure that advisers consider not only the most likely outcome but also less likely possible outcomes, if these might have severe consequences;

- refrain from forcing closure, preferring to keep open all possible hypotheses to ensure that any diversity of opinion among the members of the committee is accurately reflected in the advice; and

- be responsible for ensuring that the committee acts in accordance with available guidelines.

Legal Issues

Constitutional background

246 The recommendations in this report are intended to apply to decisions that are taken by government. The constitutional basis of government must therefore form their starting point and they must be consistent with the constitution. In particular, the central principle of these recommendations, which is the distinction between the functions of decision-taker, policy-maker and scientific adviser, derives directly from constitutional principles.

247 Although there is no single document that contains the British constitution, statutes, court precedents, conventions and other texts set out rules which govern the behaviour of UK governments. It is inevitable that these leave areas that are unclear. This is both an asset, because it allows the constitution to respond and evolve, and a threat, because it leaves room for abuse. Accordingly, it is most important that all those engaged in government respect and consider the constitutional basis of their actions carefully, since there are no rigid and prescriptive rules to guide them.

248 The first principle is the supremacy of Parliament. In practice, this may be circumscribed by practical realities (for example, an Act which rejected EU legislation would be legal in the UK but might have such grave economic consequences that Parliament would not pass it). However, all other forms of authority derive from, and are subject to, the Acts of Parliament. This includes actions by, or in the name of, the Crown, where royal prerogative has been permitted by Parliament to remain.

249 Ministers act in the name of the Crown but, given the supremacy of Parliament, are constrained to act within the law. This requires them to take decisions which are within their lawful powers. They are also required to act rationally. A further requirement is that they must not fetter their powers by taking a decision which prejudges a subsequent decision or pre-empts legitimate options. It is not legitimate to take a decision using one power that pre-empts a decision that is yet to be taken under another power (*William Cory v City of London Corporation*, 1951). Similarly Ministers may not delegate their decisions without legitimate authority.

250 Ministers are accountable to Parliament for their actions. Ministerial practice has been codified as the Ministerial Code, the relevant parts of which are quoted below.

251 Ministers are served by civil servants. The concept of the professional service was first developed in 1854 in the Northcote and Trevelyan Report, and put into practice by Gladstone in 1870. Its principles were restated (and its text reproduced) in the Fulton Report of 1968 (Fulton, 1968). Civil servants are defined (Tomlin, 1931) as:

> servants of the Crown, other than holders of political or judicial office, who are employed in a civil capacity and whose remuneration is paid wholly and directly out of moneys voted by Parliament

252 Ministers may legitimately delegate administrative decisions to civil servants (*Carltona Ltd v Commissioner of Works*, 1943). Constitutional law recognises that it is not feasible for the Minister to take every decision personally and that civil servants may take decisions in the Minister's name. When they do so, they are constrained by law as if the decision had been taken by the Minister, and are subject to the same constitutional constraints.

253 The distinction of functions emerges naturally from these principles. The practical implications of this constitutional argument are set out below in terms of the duties imposed on decision-takers and policy-makers.

Duties of decision-takers

254 The decision-taker (whether a Minister or a legitimately delegated civil servant) has a duty to take decisions that satisfy the law. This is not as self-evident or trivial as it might seem. With regard to the *substance* of the decision, the decision-taker is only answerable to Parliament. However, the *process* by which the decision is taken is subject to challenge in the courts, by way of judicial review. The recommendations in this report have been designed to define a process that, if followed rigorously, would be robust against challenge.

255 The circumstances under which the decision-taking process can be challenged by seeking judicial review were summarised by Lord Diplock in 1985 (*Council of Civil Service Unions v Minister for the Civil Service*, 1985):

> Judicial review has I think developed to a state today when … one can conveniently classify under three heads the grounds on which administrative action is subject to control by judicial review. The first ground I would call 'illegality', the second 'irrationality' and the third 'procedural impropriety'. …
>
> By illegality as a ground for judicial review I mean that the decision taker must understand correctly the law that regulates his decision taking power and must give effect to it. …
>
> By irrationality I mean what can now be succinctly referred to as 'Wednesbury unreasonableness'. It applies to a decision which is so outrageous that no sensible person who had applied his mind to the question to be decided could have arrived at it. …
>
> I have described the third head as 'procedural impropriety' rather than failure to observe the rules of natural justice or failure to act with procedural fairness towards the person who will be affected by the decision. This is because susceptibility to judicial review under this head covers also failure by an administrative tribunal to observe procedural rules that are expressly laid down in the legislative instruments by which its jurisdiction is conferred, even where such a failure does not involve any denial of natural justice.

256 For a decision to be legal, amongst other requirements:

- a decision-taker must take into account all relevant considerations and disregard all irrelevant considerations. This requires the decision-taker to seek appropriate scientific advice and to consider it when reaching the decision;
- a decision-taker must not fetter their discretion, for example by making contractual commitments which predetermine subsequent decisions; and
- a decision-taker to whom the exercise of a discretion has been entrusted must not delegate the exercise of that discretion to another unless clearly authorised to do so. This delegation may be neither express nor implied, nor may it be to another part of government (*Lavender v Minister of Housing and Local Government*, 1970), but it may be to a civil servant (*Carltona v Commissioners of Works*, 1943).

257 All of these can be illustrated with examples of illegal behaviour in seeking scientific advice. If the decision-taker has demanded of scientific advisers a dichotomous choice (for example, by asking them a question such as 'is it safe?') where the science is uncertain, and therefore has ignored the uncertainty in the answer, they will have failed to take account of a relevant consideration. By making a pre-emptive decision before obtaining considered scientific advice, the decision-taker may have effectively fettered their discretion to take an informed decision in the future. By asking (or allowing) the scientific advisers to apply the precautionary principle, the decision-taker has delegated the decision. All of these give grounds for challenge.

258 The need to avoid the charge of irrationality is often interpreted as requiring a decision-taker to take a decision that lies within the spectrum of possible reasonable decisions. Provided that it lies within that spectrum, it cannot be challenged on the ground of irrationality. This ground, which overlaps with the first ground of illegality, is often cited where the decision-taker has introduced irrelevant considerations (such as wider political or moral objectives, as in the decision to grant aid to the Pergau dam project).

259 Procedural impropriety is particularly concerned with decisions that are unfair, for example because an affected party was not given an opportunity to set out a case, or where there is 'a real danger of bias' (*R v Gough*, 1993). It also applies where a decision-taker has failed to follow a statutory procedure, for example by not consulting appropriately. It is easy to imagine how, for example, the manipulation of the membership or terms of reference of an advisory committee to achieve a desired result could amount to procedural impropriety.

260 Ministers are also subject to the Ministerial Code:

> Ministers have a duty to give fair consideration and due weight to informed and impartial advice from civil servants, as well as to other considerations and advice, in reaching policy decisions; a duty to uphold the political impartiality of the Civil Service, and not to ask civil servants to act in any way which would conflict with the

> Civil Service Code; a duty to ensure that influence over appointments is not abused for partisan purposes; and a duty to observe the obligations of a good employer with regard to terms and conditions of those who serve them.

261 The first part of this gives effect to the requirements of a legal decision, which is immune from challenge by way of judicial review.

Duties of policy-makers

262 Policy-makers are usually civil servants or, if not, act subject to the Civil Service Code (Cabinet Office, 1999*a*) (which, for example, applies to special advisers). The code states:

> Civil servants should serve their Administration in accordance with the principles set out in this Code and recognising:
>
> - the accountability of civil servants to the Minister or, as the case may be, to the Assembly Secretaries and the National Assembly as a body or to the office holder in charge of their department;
> - the duty of all public officers to discharge public functions reasonably and according to the law;
> - the duty to comply with the law, including international law and treaty obligations, and to uphold the administration of justice; and
> - ethical standards governing particular professions.
>
> Civil servants should conduct themselves with integrity, impartiality and honesty. They should give honest and impartial advice to the Minister or, as the case may be, to the Assembly Secretaries and the National Assembly as a body or to the office holder in charge of their department, without fear or favour, and make all information relevant to a decision available to them. They should not deceive or knowingly mislead Ministers, Parliament, the National Assembly or the public.

263 Where civil servants are legitimately delegated to take a decision in the name of the Minister, that decision is immune to legal challenge other than by way of judicial review, and the heads listed above apply to the process.

Implications for scientific advisers

264 A list of rights and duties of scientific advisers is set out in the preceding section of this report [239–245]. The two key duties are based on the legal considerations above.

265 There are no established codes of conduct or rules of procedure for expert advisers to government. However, there are rules for expert witnesses in court proceedings, which could provide a guide. These were explained by Lord Justice Ottan (*The Ikarian Reefer*, 1993):

> Expert evidence presented to the court should be, and should be seen to be, the independent product of the expert uninfluenced by the exigencies of the litigation.
>
> An expert witness should provide independent assistance to the court by way of objective unbiased opinion in relation to matters within his expertise. An expert witness in the High Court should never assume the role of an advocate.
>
> An expert witness should state the facts or assumptions upon which his opinion is based. He should not omit to consider material facts, which could detract from his concluded opinion.
>
> An expert witness should make it clear when a particular question or issue falls outside his expertise.

266 The core principle is codified by the courts in the Civil Procedure Rule 35.3:

> (1) It is the duty of an expert to help the court on the matters within his expertise.
>
> (2) This duty overrides any obligation to the person from whom he has received instructions or by whom he is paid.

267 Expert witnesses are granted immunity from any civil action arising from anything that they say in court or write in their preparations for court. This is intended to give them the freedom to act fearlessly and honestly, without the fear of actions for, for example, negligence, if they feel obliged to make a statement which is not in their client's interest.

268 By analogy with the rights and duties of expert witnesses, it is recommended that:

- scientific advisers should have an over-riding duty to the public interest, which takes precedence over their duty to their client (who has sought their advice) and to any employer;

- scientific advisers to government should be protected as far as possible from any civil action arising from their work as advisers brought by a third party, or by the government department which appointed them.

269 During the research leading to this report, some scientific advisers stated that they had felt constrained by the risk of legal action in the event that their advice was subsequently found to be wrong (through no fault of the adviser), or were to be misused or misinterpreted. An incomplete solution to this problem would be for the government to indemnify advisers and underwrite legal costs. However, this would not protect advisers' reputations or personal costs when facing a prosecution. Even a small likelihood of incurring these large personal costs may deter some experts from advising.

270 An indemnity might not protect an adviser who wished to retreat (resile) from previous advice without being accused of negligence. This might discourage advisers from changing their advice when new and better information became available.

271 It could at least be made clear to advisers what their position is with respect to immunity. The Biocides Consultative Committee model might be adopted (Biocides Consultative Committee Information Pack):

> The government has indicated that an individual committee member who has acted honestly and in good faith will not have to meet out of his or her personal resources any personal civil liability which is incurred in the execution of their committee function, save where the member has acted recklessly.

Decision-taking under Risk and Uncertainty

272 This supplementary note presents a discussion of a number of related concepts and issues: policy options; scenarios, consequences and outcomes; uncertainty; risk; and the optimisation of decision-making under uncertainty. The concepts presented here originate from risk-management practice and are particularly relevant to the integration of scientific advice, with its uncertainties, into the decision-taking process.

273 All policy decisions involve consideration of multiple factors, such as price effects, environmental harm, ill-health or unemployment. Professional policy-makers in the civil service are expert in handling these multi-faceted problems and in presenting options to decision-takers. Ministers themselves are used to considering the balance that often has to be struck between various interests and concerns. If all the consequences of a decision were perfectly predictable, the decision would strike a balance between the interests of the affected stakeholders, and there would be no uncertainty—even though there might be winners and losers.

274 However, some of these policy-making problems involve an additional factor—risk. This term is used to refer to situations where, for example, the consequences of a policy decision are not certain. It expresses both the likelihood of a harm or loss, and the severity of such consequences. This supplementary note addresses the extensions to existing policy-making approaches that are necessary for the proper handling of risk.

275 Where there is risk, there is a need to consider the alternative scenarios that might flow from each policy option. Each scenario is a possible future—some being more likely than others—and a likelihood can be expressed for each scenario. In addition, each option has costs and benefits for stakeholders.

276 Awareness of a risk allows a risk-management response: for example, monitoring of events as the impact of the chosen policy starts to be felt, and corrective action if an unwanted scenario appears to be unfolding.

277 Uncertainty will also affect many of the non-scientific inputs to the policy decision. However, the scientific component may be a significant source of uncertainty in problems involving novel technologies, health and environmental risks.

278 Therefore, policy-makers need to possess, or acquire, expertise in assessing the uncertainty in each piece of scientific advice they use, and in assessing the corresponding risks to stakeholder interests.

279 Decision-takers are reputed to be reluctant to confront uncertainty, and unwilling to explain decisions that admit any risk. However, the case studies have shown that uncertainty is an irreducible feature of many policy problems. Moreover, the decision-takers who participated in this study asserted that they wished to be advised of any scientific uncertainties, and that they were willing to take these into account in their decisions.

Policy options

280 Policy options should span the range of freedom within which the decision-taker could reasonably exercise discretion, otherwise the decision could be open to challenge.

281 Because of scientific and other uncertainties, the ultimate consequences of choosing one policy option today will depend on which scenario actually unfolds subsequently. In general, each policy option will have several possible scenarios, and the merits of the options will depend on the spread and valuation of all possible future scenarios.

282 Where major risks are present, it is especially important to consider a wide range of options. This is because the multiplicity of scenarios stemming from each option makes it more difficult to determine, early in the assessment, whether one particular option should be eliminated from the frame. Therefore, options should be preserved and examined well into the assessment, and not discarded until the risks have been established.

283 Any list of policy options should always be kept open to additional entries and should not circumscribe the scientific advice.

284 Uncertainty may affect scientific advice in several ways, including:

- experimental observations, subject to instrument error;

- scientific models that work well under laboratory conditions, but do not explain natural phenomena, or require extrapolation beyond the region in which they have been tested;
- competing theories that yield different predictions;
- ignorance—of an important factor; and
- unproven assumptions in the analysis.

285 Although science is founded on a rigorous discipline of experiment and reasoning, scientists can only offer an approximate model of reality, whose predictive ability depends on the proximity between the policy problem under consideration and the applications in which the theories have been tested.

286 Uncertainties also arise from randomness or chaos in the real world.

287 Where a risk arises from scientific uncertainty, it may be reduced by pilot studies, monitoring programmes, or other further research.

Option evaluation: scenarios, consequences and outcomes

288 A proper evaluation of the merits of a single policy option requires consideration of the events that may occur subsequently, or phenomena that may come to light. A single scenario is defined as a sequence of such events. The events comprising each scenario may have probabilities attached to them, and the combination of these will be the probability of the entire scenario.

289 Each scenario will therefore be described by at least a probability and a consequence.

290 The challenge in addressing risk-bearing scenarios in this way is that the amount of information to be considered by the decision-taker is large.

291 To limit the volume of information generated, the dominant characteristics of each of the options should be identified and the appraisal effort concentrated on these features. For example, the expected (ie, most likely) outcome should be included, as should any outcome with severe consequences, so that the precautionary principle can be properly applied by the decision-taker. In some circumstances, it may only be possible to identify the dominant characteristics after fairly detailed investigation.

292 The brief to the scientific advisers should be expressed in terms such as the following.

- Consider the following three (for example) policy options.
- Identify and evaluate the consequences that might flow from each option.
- Consider the robustness of the scientific theories and data (including assumptions, external events, natural variations) on which the models chosen are based. Identify what variations of view exist among scientists expert in the field, and what the implications would be for the assessment if any of these variations turned out to be well founded.
- Against each combination, evaluate the consequences and likelihood of its occurrence, given that the policy option in question had been selected.

293 This form of brief embodies an important change of perspective: the scientific adviser is called upon not only to advise on how they believe the world to be, but also on the state of scientific knowledge.

294 The policy-maker would have to extract, from all the advice tendered, the principal differences between the options. Policy-makers should receive formal training in analysing uncertainty and risk.

295 It is inadvisable to reduce the consequences into single indices of merit for each option. Indexing will average the variation in outcomes and thus conceal low risks of severe consequences. For example, an average expressing the expected value of losses associated with the option does not convey any information about the maximum possible loss.

296 It is therefore not appropriate to use solely the customary measure of risk (the probability of occurrence of an adverse event multiplied by its cost) in the context of policy decisions.

297 The characteristics of options that relate to risk and uncertainty must be described. For example, suppose that a particular technology proposal carried some uncertainty concerning health risks. There might be three scenarios flowing from a decision to allow the proposal to proceed:

- no health effects will occur;
- health effects will occur, but will be detected by early monitoring and the programme is abandoned; or

- health effects will not be detected until they are widespread and irreversible.

If there is no great confidence that the third scenario can be eliminated then the policy-maker could advise that health effects of epidemic proportion are a worst-case consequence of any decision to proceed. Otherwise, the worst case could be the second scenario.

298 Decision-takers have a duty to consider the worst-case scenario.

299 If it is necessary for this complexity to be reduced then the policy-maker should judge when the probability of a scenario is so low in relation to the consequences that the scenario need not be considered. This judgement should be consistent across all policy areas, and is tantamount to a risk-acceptability criterion.

Taking decisions

300 Once the options have been assessed, the conclusions will be presented to the decision-taker.

301 Certain decision-taking criteria may be applied thereafter:

- optimisation—maximising the overall expected benefits;
- sustainability—keeping future options open, avoiding irreversible actions;
- equity—fair treatment of all stakeholders;
- the precautionary principle—ie, where there is uncertainty and there are major potential harms, decision-takers should act with caution.

302 These recommendations have been designed to ensure that decisions are rational and justifiable. Good decisions are those that:

- are well balanced between risks and rewards;
- are equitable;
- are sustainable over time;
- keep future options open;
- carry little or no chance of catastrophic outcomes.

303 It is important that the precautionary principle is only applied once—at the end of the entire process. If precaution is applied at intermediate stages in a chain of reasoning then the final conclusion may be far more cautious than the decision-taker intended.

304 The EC has recently issued a Communication on the precautionary principle (Commission of the European Union, 2000), and the practice recommended here is in line with this.

The Selection of Scientific Advisers

305 The criteria for the selection of scientific advisers depends on the advisory mechanism chosen, because each mechanism uses different methods for securing adequate management of bias and uncertainty. These are discussed separately under the sub-headings below.

Scientific generalist

306 This class of scientific adviser is typically used when the issue calls for a synthesis of various scientific aspects that interact strongly. The latter type of expert should possess:

- ability to comprehend the scientific knowledge in the relevant fields;
- knowledge of the spread of competent opinion in the fields, and willingness to address the associated uncertainty;
- intellectual rigour and analytical skills—particularly in the synthesis of interdisciplinary problems;
- personal credibility related to professional standing, open-mindedness and freedom from attachment to particular schools of thought; and
- communication skills.

307 The scientific generalist is a class of scientific adviser that has been little used in relation to scientific advice for policy on risk issues. Their value in this context arises from the fact that most issues of risk to public or environmental health are inter-disciplinary problems, and call for a degree of understanding not only of scientific mechanisms but also of more general matters. An important factor is the evaluation of the consequences of policy options, where the identification of potential risks calls for a thought process more common in the generalist than in the specialist.

Single expert

308 This class of scientific adviser is typically used when there is a need for expert understanding of a specialist subject, or where some element of a wider policy issue is reducible to a highly specific scientific question.

309 The particular qualities sought in such an expert are:

- leading expertise in the required specialism;
- familiarity with the state of scientific knowledge in the field, and with the range of opinion held by competent experts;
- personal credibility related to professional standing, open-mindedness and freedom from attachment to particular schools of thought; and
- willingness and ability to address the uncertainty.

310 The selection of the single expert must be closely allied to the definition of the scientific question, as the expert should not be placed under any temptation to stray beyond their field of competence, to apply value judgements, or to advise on policy aspects.

311 It is the duty of the policy-maker to provide the necessary scrutiny and challenge to single experts. They must be able to recognise when a single expert has not fully justified their opinion, or has wrongly assessed the uncertainty. If necessary, a second specialist expert may need to be selected.

Consultancy

312 In addressing consultancies, the authors of this report declare a conflict of interest, being themselves consultants. The following paragraphs are informed by their experience of acting as consultants to a wide range of clients under a variety of tendering and contractual frameworks, and from observation of their clients.

313 In this context, ‘consultancy’ may be any organisation, whether academic, commercial or publicly owned, that sells the time of its scientific staff. Consultancies include universities, research institutes, commercial consultancies, and government research laboratories. All of these types of organisation are similar, in that they depend on contracts to maintain their staffing levels, and this gives them a vested interest which must be taken into account in their selection and in evaluating their advice.

314 It makes little difference whether the organisation is in the public or private sector. However, some organisations may have charters that specifically enshrine professional principles, such as publication rights or requirements of non-interference of clients in scientific judgements. These policies should be examined before any consultancy is engaged to provide scientific advice to government.

315 Consultancies are suitable where there is a scientific problem that calls for a large amount of research or investigation, or particular facilities, beyond the resources of unpaid advisers or government scientists. Therefore the capacity to deliver these services is an important criterion for selection.

316 A second, equally important, criterion is quality. There is tension between cost and quality in this area. There are consultancies whose commercial strategy is to win contracts on price, but which only provide a basic level of service. Often, their clients want this level of service. Even a top-class team can produce poor work if they are under-funded. Neither case would meet the needs of government in procuring scientific advice on a matter of high public interest.

317 Therefore, the selection of a consultancy to provide scientific advice is closely allied to the question of funding. There are two approaches that can work well. The first is by pre-qualification of a shortlist of candidate organisations on capacity and quality of personnel but not on price, followed by a competitive tender process. The second is for the client government body to declare its budget for the work and seek the best technical proposal.

318 The latter option is especially appropriate when the scope and depth of the work is open to widely varying interpretations, and bidders would be guessing what level of effort is proportionate to the policy issue at stake. It also has the considerable advantage that bidders are not tempted to pare down their price to levels that would make it difficult for them to deliver a satisfactory piece of work. They are able to offer their best proposal for the fixed price, and hence this practice encourages selection of the most competent team. The expenditure by the client, moreover, will reflect their judgement of proportionality to the importance of the problem.

319 In evaluating offers, the client body should satisfy itself that the consultant will act in accordance with available guidelines for providing scientific advice to government.

Advisory committee

320 This section covers standing committees and ad hoc committees formed for a specific policy-making purpose.

321 There are two types of committee that currently handle scientific advice in the UK. First, the scientific advisory committee, which is comprised of experts (who may have stakeholder connections, usually in balance). Second, a policy advisory (or even decision-taking) committee, which is a pure stakeholder committee, and act as a negotiating forum.

322 The policy advisory committee should not be considered a source of scientific advice, but it often handles such advice and frequently has a policy-making or even a decision-taking function. It should not offer scientific advice. Instead, it should obtain such advice from another source, such as a scientific sub-committee—the Advisory Committee on Toxic Substances (ACTS) and its technical sub-committee, the Working Group for the Assessment of Toxic Chemicals (WATCH), is an example. The following paragraphs discuss the selection of members of scientific advisory committees.

323 The exclusion of applicants with affiliations or interests has sometimes served well when the issue has a high profile and is so contentious that an extremely high degree of independence is required. However, it carries the disadvantage of severely restricting the field of candidates, and possibly excluding those whose views would aid the evaluation of the science and its uncertainty. Often the declared interest that would cause a candidate to be rejected is trivial, and represents only a small proportion of the individual's overall work and sources of income. Accepted candidates may have other, more subtle, biases. Increasingly, practitioners in this area are coming to realise that there is no such thing as complete independence.

324 This leads to the concept of the balanced committee in which individuals with stakeholder affiliations are not excluded, but the overall balance of competing influences is carefully maintained. This format has the twin advantages of allowing the full diversity of scientific opinion to be expressed, which is generally welcomed by stakeholders (including industry and NGOs), and assisting the evaluation of uncertainty and the possible adverse consequences of policy decisions subject to risk.

325 The members of scientific committees, whether they have stakeholder affiliations or otherwise, would still owe their primary duty to the broad public interest, and the chairperson is responsible for ensuring that they conduct themselves accordingly. As individuals, they would be allowed to express their sincerely held views and their personal biases, but not to act consciously as negotiators on behalf of their stakeholder interests.

326 In the selection of individuals for such positions, it should be borne in mind that many experts are engaged by stakeholders on the basis of their reputation for probity and independence, or because the stakeholder wants an internal 'devil's advocate'. There is therefore a marked difference between, for example, a lifetime's employment by a company and being hired by that company as a consultant. The former could build in deep and unconscious prejudices, while the latter might generate conflicts of interests. The real nature of stakeholder affiliations is therefore a subtle matter, and the selection process should not only list all affiliations, but also examine the professional relationship between the expert and any affiliated organisation.

327 It is particularly important that the chairperson of a scientific advisory committee should be free from conflicts of interest.

Government scientists

328 There are many circumstances in which the best scientific adviser under any of these four mechanisms may be one employed within the civil service. One common situation is where a government body has to deal with a larger number of small cases every year, and has developed specific expertise for that purpose that cannot be obtained elsewhere.

329 Another example is where there is no other academic or commercial motive for creating a centre of expertise. Equally, the government may wish to create a centre of expertise that is free from commercial or stakeholder influence.

330 It may, however, be necessary to consider whether government itself (or a department of government) has a stakeholder interest in an issue through having responsibility for policy on the issue. Government scientists should be considered as candidate advisers on a par with external advisers, and subject to the same rights and duties (recognising that they are also subject to the Civil Service Code). It may be undesirable for the Chairperson of a scientific advisory committee to be a civil servant from the department responsible for policy in the area on which advice is being sought.

Scientific Advice in an Emergency

331 Disasters are unpredictable in their timing, and action must often be taken very quickly if loss of life, impairment of health or damage to the environment is to be minimised. It is important that the actions taken are effective and that they do not add to the danger in unexpected ways. For these reasons, reliable scientific advice may be needed.

332 The problem of providing appropriate scientific advice in an emergency differs from the standard case for several reasons:

- advice will be needed extremely rapidly;
- the greatest uncertainties may be due to lack of information from the field, rather than a gap in fundamental scientific knowledge; and
- the emergency-response measures must be practical and capable of rapid deployment.

333 This supplementary note explores the differences between emergency response and more general scientific advisory problems. Its recommendations are based on the evidence from the *E. coli* case study; on a short review of the UK response to the airborne radioactive cloud from the Chernobyl reactor disaster; and on good practice in emergency planning in other spheres.

Preparedness

334 Successful emergency response depends on prior preparation, characterisation of potential threats, definition of functions and responsibilities, and identification of the resources that might have to be mobilised. All government bodies should have emergency-response plans in place, which should be based on a risk assessment of the specific hazards within their domain. A good example is the Scottish Office (now Executive) Department of Health's plan for food-borne outbreaks of disease, which was activated in the *E. coli* case.

335 However, such risk assessments will only provide a broad description of the foreseeable cases. Many emergencies are novel, or at least present unique characteristics, so there may be a need for additional scientific advice during an emergency.

336 As far as possible, scientific resources that might be needed should be identified in advance and, if necessary, generic tools and methods developed. An example of the latter is the service in long-range airborne pollutant trajectory modelling that is now available from the Meteorological Office, but which was not in existence at the time of the Chernobyl disaster.

337 There may also be a need for identification of emergency-response functions for departmental scientific staff, and on-call access to advisory committee members (such as applies with COT, for example) or for external contractors.

Detection and issue identification

338 The identification of an emergency is not usually difficult. However, in unprecedented situations—well exemplified by the Chernobyl case—there may be a lack of appreciation of the scale of the event. Another problem may be the identification of the particular mechanisms by which the event might cause harm.

339 It is therefore good practice for government bodies to consult among a variety of scientific advisers at an early stage, in order to ensure that the full implications of emerging events are quickly identified and that information-gathering efforts are correctly targeted. Usually, these advisers would already be known to government bodies through their routine advisory work.

340 Some emergency situations present a problem of diagnosis. For example, in the *E. coli* outbreak in central Scotland, there was a need to identify the source of the contamination (which was achieved quite quickly) and to map out the distribution routes (which was a much slower process).

341 The main technical problems will be likely to take the form of quantitative application of predictive models based on well-understood principles.

Organisation

342 Disasters often involve more than one government department, so there is a need for coordination across departments and provision of consistent scientific advice to the relevant Ministers and to the public.

343 The UK response to the Chernobyl incident called for a combination of

meteorological, environmental, agricultural and radiological protection expertise that was provided by a single integrated team serving all departments. This team dealt with all scientific matters, and its existence ensured that a consistent and comprehensive technical brief was provided. The balancing of interests between departments was done in a different forum; namely the Civil Contingencies Unit, which is hosted and staffed by the Home Office and operates like a stakeholder body. These arrangements provide a good model for emergency situations, fully consistent with the principles of these recommendations.

344 Since the required actions will be tactical solutions that cannot be delayed for research, effective emergency response calls for an executive team of people with command and operational experience, and with personal contacts in relevant sectors. Improvisation and informal communication is often the most effective way of achieving quick results. This means that parties directly involved in the matter may be best placed to act as advisers.

345 This executive team may be separate from the providers of scientific advice, because there is no need for the scientific advisers to be permanently engaged in the emergency response itself. However, in smaller cases, the two functions could be combined.

346 The contribution of interested parties needs careful management and supervision, however, because these parties may be concerned about the legal liability of their organisation or staff for the consequences of the event. This may inhibit timely provision of information, and affect the completeness or accuracy of that information.

Information to the media and public

347 Provision of the necessary resources for briefing of the media and communicating with the public should be an integral part of the emergency-response plan.

348 Those at risk have a right to information about an incident. Communication is also a valuable instrument for reducing the consequences of an incident. Also, the pressure of public and media enquiries may become a major difficulty for the emergency-response team and for their scientific advisers. In the Chernobyl case, for example, the inter-departmental scientific team set up a team of six staff to deal with telephone enquiries that were beyond the capability of the departmental public relations offices. The scientific team prepared standard responses to the most common questions, which were issued to departments, while the more difficult questions from individual members of the public were handled directly by the scientific team. There was strong media interest, and the scientific team referred press enquiries to the departmental press offices for handling by public relations professionals.

Post-event review

349 It must be borne in mind that the adequacy of the emergency response will usually be revised as part of the subsequent investigation of any serious incident. The scientific advice provided will be part of this, and a record must therefore be kept of all communications and advice, including the information on which the advice was based and the reasoning.

350 Any difficulties encountered should be recorded at the time, with a view to future improvement of the emergency-response system.

LITERATURE REVIEW

351 This chapter describes the ideas and evidence gathered by a review of published literature, and is divided into two sections:

- theory and practice;
- concepts and ideas.

352 The review seeks to describe what is known about the relationship between how expert advice is generated and incorporated into policy, and the quality, or perceived quality, of the decisions made. This particular relationship has not previously been addressed directly in the literature. However, there is literature on historical or international comparisons of scientific advisory structures, on guidelines developed on the basis of case studies, and on social theoretical work on the relationships between science, policy-makers, and the public. This material has been reviewed with the aim of distilling current thinking on the link between process and policy outcome. In addition, ideas that might be useful for analysing the various processes for obtaining expert scientific advice, and existing or proposed guidelines, have been extracted from the available literature.

353 Relevant literature has been identified by searching bibliographic databases, by browsing journals with relevant coverage, and from suggestions made by researchers active in this field.

354 Existing literature that is relevant to this work falls into a number of categories, including:

- reflections on the role of science and scientists within society;
- analyses of the assessment, perception, communication, and management of risk;
- comparisons between the scientific advisory structures in different countries;
- guidelines and recommendations for advisers or receivers of advice; and
- social scientific analyses of the theory of advisory systems, and of the principles according to which they operate.

355 There is no significant body of literature directly addressing the link between the process of advising policy-makers and the success of the policy outcome. This review attempts to address that link by drawing together work from the fields described above.

356 Existing guidelines on scientific advice and policy-making are reviewed in the following chapter.

Theory and practice

357 The role of science and the expert scientific adviser in public life has been evolving continually. However, one aspect of the relationship between science and society has changed significantly in the twentieth century. A strong science base became essential for military success, and more generally, for strong economic growth. For example, after the Manhattan Project, and the development of the nuclear weapons programme, the relationship between scientists and policy-makers became more explicit in the USA. A Science Advisory Committee was established in 1951, initially within the Office of Defence Mobilisation, and soon reported directly to the President as the President's Science Advisory Committee (Weingart, 1999). In contrast to earlier times, when individual scientists or benefactors funded research, science was now funded with public money.

358 Formal systems for providing scientific advice were established in many countries, and scientists were perceived as independent from the political process (Johnston, 1993).

359 The newly raised profile of science gave some cause for concern. President Eisenhower warned in 1961 that public policy might be captured by the scientific-technological elite (Weingart, 1999). There were two concerns: first, that scientists would be able to exploit their public profile to obtain increased funding for research; and, second, that policy-makers would become reliant on the advice of individuals, and that accountability and democracy would be eroded.

360 The relationship between science and policy-making has two components. 'Policy for science' refers to government funding for research, and the contribution of scientific and technical progress to economic growth. 'Science in policy' refers to the use of science by policy-makers in developing policy generally (see, for example, Bondi, 1992). The focus of this study is 'science in policy'. However, there is some overlap when research is commissioned directly by policy-makers in order to address a policy question, and when individual advisers carry out government-sponsored research. Although

this division has been emphasised by some commentators, it is almost always blurred in practice.

361 Since the first formal scientific advice to policy-makers in the 1950s, a number of changes have taken place (Johnston, 1993).

362 Science itself has become the object of academic study. Discourses on the nature of scientific knowledge, the process by which it is acquired, and on the human nature of scientists themselves, have lessened the perceived objectivity and authority of expert scientific advisers. Scientists are no longer held in awe.

363 Various controversies and disasters (especially surrounding civilian and military nuclear programmes) have highlighted uncertainty and conflicting opinions within science, and the subject of scientific competence is now debated. Scientific arguments have served on occasion to support both sides of an argument, leading to polarisation rather than to a consensus (Nelkin, 1975). Scientists are no longer regarded as infallible.

364 At the same time, science and technology has become a much more important fundamental requirement for economic growth.

365 The frameworks within which science and policy interact have evolved diversely in different countries. There is considerable variation in the relative importance of individual advisers, who advise Ministers or Prime Ministers directly; expert bodies (such as learned societies), who provide advice from outside government; and scientifically qualified officials, who provide advice from within government. The representative features of these frameworks are briefly described in the following section.

Structures

366 The structures of the advisory systems in different countries have been reviewed (see, for example, Stein and Renn, 1998; Johnston, 1993; and Skoie, 1993). Broadly speaking, the organisation of the provision of expert scientific advice has either been centralised in one ministry for science and technology, or decentralised across all departments requiring advice and having the funding to commission research. A new structure is emerging in a number of countries, combining features of both centralised and cross-departmental organisation. In the UK and Australia, for example, departments are responsible for scientific issues affecting their work, but there is also central coordination on cross-departmental issues and a central mechanism for scientific advice at Cabinet level (Johnston, 1993; the OST, 1998*a*).

367 The underlying function of the structures is broadly similar in each country. The 1963 report of the OECD's Committee on Science Policy (Skoie, 1993) recommended that countries should:

- formulate a national policy for science;
- ensure coordination of scientific activities; and
- integrate science with general policy.

368 The diversity of structures in place shows either that no recognised optimum arrangement has yet been found, or that the arrangements for the provision of advice necessarily depend on the local style of policy-making.

369 Renn (1995) has described four cultural styles in the use of expertise in policy-making. These styles can be summarised as follows.

- **Adversarial**—the process is open to public scrutiny; the policy selection must be justified scientifically; there are precise rules of procedure; and evidence is required. The emphasis is on evidence and knowledge, not judgement. Due process is used to resolve conflicting positions. The process is contingent on claims of objectivity of method.

- **Fiduciary**—there is public input, but no public control; there are few rules of procedure; and the system depends on trust. The emphasis is on background knowledge, in-house expertise, and bureaucratic efficiency. The process uses personal contacts and networks.

- **Consensual**—the process is open to 'members only'; negotiations are closed; the procedure is flexible; and internal consensus is the goal. The emphasis is on scientific reputation, expert judgement, and personal status.

- **Corporatist**—the process is open to interest groups and experts; there is high public visibility, but little public control; procedural rules are strict; and the aim is to sustain the trust of the decision-making body. The emphasis is on judgement and political prudence,

impartiality of experts, and negotiation only within limits set by scientific experts.

370 Renn suggests that the advisory system in the USA is broadly adversarial, in Japan it is consensual, in northern Europe it is corporatist, and in southern Europe fiduciary. However, calls for increased openness and public participation in Europe and Japan, and for increased focus on communities in the USA and elsewhere, are leading to a more mediatory style. This may involve more stakeholder consultation than is currently common in Europe or Japan, while seeking to avoid the capture by special interests that often occurs in the USA.

371 The USA is unusual in that its expert advisory committees, reporting to federal agencies, are covered by blanket rules of procedure, and there is congressional oversight of their work. Scientific advisory committees advising policy-makers in the USA are subject to the FACA. This requires that committees have a charter specifying mission and objectives, are certified as balanced by the federal agency to which they report, and publish minutes of all meetings. Committee meetings are usually (but not always) open to the public. In addition, all committees are required to provide Congress with an annual report on their work. The FACA was recently extended to cover (in modified form) the work of the National Academy of Sciences.

372 It seems to be generally felt that the FACA has been successful in promoting public trust in the advisory process without unduly restricting the availability of good scientific advice (Stein and Renn, 1998). Although the principles behind the FACA are broadly accepted, some of the practical details, such as the increasing prevalence of closed meetings, are not.

373 Although the FACA provides for openness in the US system, this has not, in practice, led to greater public participation in the process. Stein and Renn (1998) suggest that participation in the advisory process is low because the public have sufficient trust in the operation of the FACA. Since the workings of advisory committees are placed on record, there is a powerful audit trail that can be used to review decisions (Shapiro, 1990).

374 The development of regulations, distinct from policy-making, is not covered by the FACA. Public consultation on new regulations is compulsory (Stein and Renn, 1998).

375 The National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine are obliged by statute to provide advice to Congress. Over 200 reports are issued each year, for which the academies are paid at cost.

376 The scientific advisory system in the UK is described in a memorandum from the OST to the House of Commons Select Committee on Science and Technology (the OST, 1998*a*). Departments typically obtain expert scientific advice through advisory committees, in addition to their in-house scientific resources. Also, the OST and the government's CSA have a centralised responsibility for cross-departmental issues, and for fostering cooperation between departments. The workings of the system are guided by the principles set out below [441–443]. The UK government has no statutory arrangement for the provision of expert scientific advice from independent learned societies, unlike the US government [375].

The uses of scientific advice

377 The needs that policy-makers have for scientific advice are well recognised. Smith and Halliwell (1999) identify:

- monitoring, measurement and assessment for regulatory purposes (for example, health and safety regulations, fishing quotas);
- supporting negotiation of international standards and trade agreements; and
- providing advice to Ministers on complex technological issues, such as nuclear power, BSE or xenotransplantation.

378 Beckler (1992) identifies a number of reasons why governments require external scientific advice, including the following:

- a policy problem raises questions exceeding the capacity of in-house advisers;
- a problem is of such importance that an independent assessment is required;
- advice is needed for the longer term, such as advice on global climate change (in such cases, expert advice may be required because the policy timescale is longer than the political cycle, or because projections far into the future require the very best experts in order to reduce the uncertainty); or
- a problem is of such an esoteric nature that only specialised academics can contribute.

379 Boehmer-Christiansen (1995) gives further reasons for policy-makers to take expert advice—it provides:

- a source of authority and legitimacy for officials;
- a mechanism for legitimising, delaying or avoiding action;
- an opportunity to label unpopular policies as unavoidable;
- a cover-up for policy change—since science underlying advice may evolve, dependent policy U-turns may be explained; and
- a mechanism for centralising decision-making—since advice may be too expensive for local or regional policy-makers.

380 These points are illustrated by Boehmer-Christiansen with reference to European policy on transboundary air pollution. The nature of the scientific advisory system in general within the EU is discussed by Stein and Renn (1998).

Theory

381 Two models that have been proposed to describe the relationship between scientists and decision-takers are the decisionist model and the technocratic model (Weingart 1999 and references therein).

382 The decisionist model considers the relationship as follows: a supposedly factual, objective domain of science is separated from the value-laden domain of politics. Thus, scientists pass objectively determined facts to the politician, who uses them to develop policy. Policy is outside the domain of the scientist because it depends on a set of values or social norms that cannot be determined scientifically. In the decisionist model, information flows only from the scientists to the politicians, and there is no loss of democratic control, since the advice of the scientists is objective and factual (legitimised by the status of the scientists within their peer group), and the decision-takers are elected politicians. However, this model ignores the fact that most advice is sought on problems that are not well understood and draw the scientists away from the certainty of objective facts. In these cases, expert advice must contain subjective judgement and opinion.

383 The technocratic model recognises the 'scientification' of politics. The objectivity of science guides the politician in making policy decisions. Scientific rationalism replaces the subjectivity of politics. However, the technocratic model fails to take account of uncertainty, ignorance and conflict between different scientific disciplines or schools of thought. The technocratic model also undermines representative democracy. If decisions taken by politicians are to a large extent dictated by scientific analysis of the various policy options, democratic control can no longer be exercised.

384 According to Weingart (1999), both these models fail, either as a description of reality, or as a guide to improving current practice, because the linear sequence of political problem, scientific advice, and political decision, as described in the models, is not a good description of the real world. Scientists themselves may be required to define or identify the problems given to them to solve, and scientific advice may not always be free of values (the degree to which scientific knowledge itself is value-laden may be debated, but scientists certainly ascribe to political views and hold moral values). As an example, safety regulation may require experts to define the scope of regulation, and then to assess risks in a way that must include assumptions about the tolerability of risks. The tolerability of risks cannot be determined objectively [459–461].

385 These linear models of problem definition, advice, and decision-taking can be developed into a more realistic 'recursive model'. This allows several rounds of negotiation between experts and decision-takers as the problem is defined and refined, and as possible solutions are tested for political and technical fitness (Weingart, 1999; Jasanoff, 1990). This description of the process avoids the problems of the decisionist and the technocratic models. However, Weingart identifies a second problem: that of ever-increasing demand for scientific expertise, which is discussed below [388].

386 This more realistic recursive model is also discussed by Edwards (1999), who addresses the role of the public in the decision-taking process. The decisionist and technocratic models referred to above restrict the role of the public to the election of representative politicians. Experts interact directly with decision-takers, but not the public, and decision-takers interact with the public at election time. Edwards, referring to the ideas of Habermas, describes the function of the 'public sphere'. The negotiation between experts and decision-takers may take place against the background of public agendas, and media discussions of the problems being addressed. Alternatively, this function for the public sphere can be extended further: the public sphere acts as an intermediary between

the experts and the decision-takers. This situation arises if experts and decision-takers appeal directly to the public, to further strategic aims. Decision-takers wish to further political agendas and respond to popular concerns; experts may have their own strategic agendas—attracting funds for research, and promoting themselves as advisers. Taken to an extreme, the public sphere is the arena in which experts and decision-takers interact with each other, in full view of the public. The function of experts is not merely to advise decision-takers, but to inform, educate and empower the public for their own interactions with decision-takers.

387 Edwards (1999) also suggests that this description of the function of the public sphere may explain the apparent paradox (Weingart, 1999) that policy-makers' demand for expert advice remains high, despite the public loss of faith in that advice.

388 Weingart (1999) suggests that policy-makers become ever more reliant on expert scientific advice (scientification of politics), and that scientists compete strategically to supply advice (politicisation of science). This is another example of the mixing of 'policy for science' and 'science in policy'. If both the demand for, and the supply of, scientific advice are subject to inflationary pressures, the casualty may be quality. Weingart suggests as a solution formalising the process of advising policy-makers. On the demand side, this could take the form of common procurement arrangements across different branches of government (or, internationally, across different governments). Alternatively, on the supply side, this could involve the monopolisation (and quality control) of the supply of advice, by some kind of NGO.

389 Several authors have recognised that, on contentious issues, scientific arguments and experts may support both sides of a policy dispute. This position is most likely when the policy debate is conducted in an adversarial manner, which tends to polarise the debate, and gives equal weight to the view of the majority and minorities within the debate. van Eeten (1999) describes such cases as a 'dialogue of the deaf', because the two sides talk past each other. Resolution through argument is impossible because the two sides are arguing from different premises, and the premises themselves are based on values.

390 It is instructive to consider the weaknesses in stylised resolutions to these policy problems (after van Eeten, 1999).

- **Choose the better argument**: this approach can only work if the two sides of the debate are arguing from the same (or compatible) premises. If they are not, it is impossible to choose one of the arguments without making a judgement about the validity of the premises. This is likely to be a value judgement, not a scientific judgement.

- **Get the big picture**: it is plausible that, in such disputes, the two arguments may both be partly right—if the two sides could step back a little, they would see the bigger picture, which includes both positions. This synthetic approach assumes that the two sides are different pieces of the same puzzle. Unfortunately, there is no guarantee that the two sides are not different pieces of different puzzles (Roe, 1994).

- **Let politics decide**: while politicians have a mandate from the public to take decisions, science may have a valuable contribution to make to the search for an optimum policy outcome. Thus, allowing politics to decide without recourse to scientific advice is a failure. This failure mirrors the failure of the technocratic model described above; just as it is unacceptable to treat political choices as amenable to scientific decision-making, so it is unacceptable to treat conflicts between different sources of scientific advice as subject to uninformed political choice.

- **Participatory processes and discourse**: there is much support for increased stakeholder participation in controversial policy decisions. Although this may clarify opposing positions, there is no guarantee that any resolution of the disagreement will result from opposing sides understanding each other's positions more clearly.

- Finally, it is suggested that, while scientific advice cannot necessarily provide answers in these difficult situations, it may be used to reassess assumptions, test arguments, and re-frame the policy question.

Concepts and ideas

391 From the literature discussed above, a number of concepts and ideas that are central

to the successful provision of expert scientific advice to government can be identified. These concepts and ideas are drawn out and briefly discussed further in the following sections.

Openness

392 Smith and Halliwell (1999) identify a drive for increased openness as one common feature of the way in which many advisory systems throughout the world are changing. The drive for openness in the provision of scientific advice is part of wider calls for more openness in government generally.

393 Openness has two components: allowing the public access to information used by policy-makers in arriving at their decisions; and allowing the public greater opportunity to contribute their views as inputs to the advisory system.

394 A debate is under way in the USA over a requirement for data produced by federally funded research programmes to be published. This requirement applies to all research that is federally funded, including research at universities or other independent institutions. Hahn (1999) argues that this requirement is important because it allows checking of the analysis on which new regulations are based. If data are not published, it is not possible for the analysis of the data to be properly audited, and inefficient and burdensome regulations based on flawed analysis may be enacted.

395 Openness in risk assessments may help to prevent barriers to trade, as it would then be harder to raise such barriers on spurious health and safety grounds (ILGRA, 1996). However, as may be seen elsewhere in this study, a risk assessment may depend on factors other than technical assessment of probabilities and consequences of hazards. Thus, openness per se may not prevent dispute.

396 On the other hand, publication of a scientific risk assessment might precipitate calls for regulation before other factors (such as the tolerability of the risk) can be taken into account (ILGRA, 1998*a*, *b*). In this situation, it is important that experts and decision-takers plan how they will communicate their assessment of risks.

397 The Freedom of Information Bill (House of Commons, 1999*a*) is likely to restrict any moves to publish advice given to Ministers. Clause 34 of the draft bill, presented to Parliament on November 18th 1999, states that information will not be disclosed if it would, or would be likely to, 'prejudice the maintenance of the convention of collective responsibility of ministers of the crown', or 'inhibit the free and frank provision of advice or exchange of views'. This is thought likely to rule out the publication of policy advice from officials. However, background papers and scientific analysis produced for government are likely to be in the public domain.

Transparency

398 An advisory system can be open without being transparent. The system is open if relevant documents are published (for example, minutes of committee meetings, and reports received by Ministers). However, the system is only transparent if it is a specific goal of the system to ensure that the public is able to understand the workings of the system. This is only likely to be achieved if communication with the public is part of the advisory system. Transparency is unlikely to be achieved if all of the relevant documents are simply placed on a web site.

399 Advice may not be transparent to the policy-makers to whom it is addressed, let alone to the general public. Transparency of advice could also involve distinguishing the components of the advice which depend on widely accepted fact, judgement, or opinion, and describing as fully as possible the assumptions or analytical methods on which any conclusions rest (National Environmental Policy Institute, NEPI, 1998). The identification and explanation of uncertainties are also a requirement for advice to be transparent. It may also be good practice to identify where new evidence might alter the conclusions of advisers, and where monitoring should be undertaken to ensure that the assumptions on which advice rests remain valid (Council of Science and Technology Advisers, CSTA, 1999).

Independence

400 The value of expert scientific advice may depend to an extent on the identity of the adviser as well as the content of the advice. However, independence is neither easy to define nor to achieve. Advisers may be independent from particular special interests, stakeholders, industries, political parties, or even scientific schools of thought. Absolute independence, however, may be neither achievable nor desirable. The selection of advisers is more commonly dealt with in terms of conflict of interest and balance, discussed below.

Balance

401 Various guidelines call for advice to be balanced (the OST, 1997), or for committees themselves to be balanced. Although the term 'balance' is not always explicitly defined, it is often taken to mean that experts should be chosen to represent a range of views, or even a range of constituencies. In some cases, this range may be an attempt to cover the different scientific viewpoints that might be held by the wider scientific community on a particular point. However, in other cases, it may be an attempt to cover the range of views of special-interest groups.

402 Thus, one balanced committee might have both toxicologists and epidemiologists as members; another might be balanced by having a government ecologist as well as an ecologist funded by an environmental pressure group.

403 The question of proper balance is therefore linked to the representation of stakeholders on expert advisory bodies, as well as to the question of whether stakeholder input into policy-making should be separate from the scientific input to policy-making.

404 The US experience of the requirement of balance under the FACA suggests that, in order for a requirement of balance to be sensibly interpreted, it must be tightly defined. A number of lawsuits have resulted from arguments over whether the requirement in specific cases could be satisfied without the inclusion of special-interest representatives (Shapiro, 1990).

405 The process of selecting balanced expert panels under the Committee on Expert Panels (CEP) in Canada might lead to the selection of a group of experts who admit to a range of views on controversial issues which touch on the proposed work of the expert panel.

Remuneration

406 The question of whether advisers should be paid for their advice is not discussed as often as other issues surrounding the provision of expert scientific advice. It is common internationally for advisers either to be unpaid or to receive token sums, although expenses are met and the government typically supplies administrative support. It appears that advisers are content with the reward of professional kudos, influence, and the sense of fulfilling a civic duty (Stein and Renn, 1998), although it may be that not all potential advisers can afford to advise for free. Smith (1997) recommends that experts be paid at commercial rates, once allowance has been made for contingent intangible benefits.

Liability

407 The question of liability of advisers for the advice that they give has only recently become an issue. The Committee on Standards in Public Life, under the chairmanship of Lord Neill, commissioned a study of personal liability in public-service organisations. The conclusions of this review were that the extent of liability is not always defined, and that the situation required clarification (Hambley, 1998). This issue may feature in the outcome of the ongoing Phillips inquiry into BSE.

Legitimacy

408 Two possible failings of the scientific advisory system are described above [381–384]—policy-makers may be tempted to use the apparent rationality of experts to advise on matters beyond science, or they may falsely assume that advice from experts is free from all value judgement.

409 These dangers may perhaps be avoided if the advisory process is opened to public scrutiny, and if the public are given more opportunity to provide input into the policy-making process.

410 The nature of consensus is discussed below [423–424]. It can be argued (in a somewhat circular fashion) that legitimacy can be achieved by reaching consensus among a sufficiently wide group. It may be difficult to decide when the usual processes of representative democracy are sufficient to empower decision-takers legitimately to balance the views of experts and others, and, when necessary, to use more direct forms of consultation.

Process

411 Smith and Halliwell (1999) argue that guidelines of process provide a counter to the lack of public confidence in the credibility of scientific advice; an assurance to decision-takers that the advisory system is robust and will be able to withstand future legal challenge; an effective means to ensure that the precautionary principle is incorporated into advice; and quality control over the advisory process, where implementation of guidelines can be followed. Being able to demonstrate that an acceptable process has been followed

could provide a defence against judicial review or liability claims.

412 Many of the sources discussed above assert the importance of procedure in seeking scientific advice and incorporating it into policy. It may be intuitively obvious to some that an auditable procedure will increase the acceptability of the policy outcome. However, others may not be so easily convinced, particularly if the 'straightjacket' of procedure may, in particular cases, compromise the ability of experts to advise in the way that seems to them most effective. One commentator, Perri 6 (1999), described the argument between those advocating the effectiveness of proceduralism and their doubters as follows: 'Since each side could offer only anecdote dignified by the title of case study, it is hard to assess the evidence for proceduralism.'

413 Shrader-Frechette (1990) provides an argument in support of proceduralism. Discussing risk-assessment methodologies, Shrader-Frechette argues that democratic, ethical and political factors need to be taken into account. Although the technical component of a risk assessment could be judged against an appeal to 'absolute' standards of scientific reasoning, the other components cannot be so judged. Philosophers hold that moral and ethical decisions cannot be judged against an appeal to explicit rules, but only by comparison with other decisions, generally held to have been compatible with accepted moral and ethical values. Thus, rules of procedure would allow examples of advice giving to be judged against the rules, or, equivalently, against a body of 'case law' of previous examples of expert advice, as in the legal system.

Terms of reference

414 Several of the guidelines reviewed above recommend that advisory bodies should be able to negotiate the terms of reference under which they work, and the wording of the questions that are put to them.

415 If a group of experts is to be asked to answer a very narrow technical question, it is unlikely that the question itself can be framed without input from the experts. On the other hand, if the question is framed more broadly, experts may need to negotiate with policy-makers in order to narrow the scope of the question such that it can be answered scientifically.

Uncertainty

416 Uncertainty arises from non-predictability inherent in the real world, and from gaps in scientific knowledge (or disagreement between experts). It is increasingly recognised that science, particularly at the frontiers of knowledge, is uncertain. This type of uncertain science may be the science that is of most relevance to policy-makers. Consensus may mask uncertainty (Beckler, 1992, and see 423). However, a best estimate, together with an indication of the range of possibilities, can be presented to policy-makers. On the other hand, communication of uncertainty to policy-makers may lead to the rejection of scientific advice, or to advisers being pressured to mask the extent of uncertainty (NEPI, 1998).

417 Irrespective of the degree of uncertainty estimated at the time advice was given, science does not stand still, and even scientific ideas with broad consensus support (almost having the status of facts) may be shown subsequently to be incomplete or even wrong. This has led some to suggest that policies which are heavily dependent on scientific advice should be reviewed within a period specified at the time of original implementation, in order to ensure that changes in scientific understanding can be taken into account (CSTA, 1999). For example, the Delaney Clause famously forbids the US Food and Drug Administration to approve any substance as an additive if it induces cancer in laboratory animals. This was based on the consensus at the time that there are relatively few carcinogens, all of which are dangerous at any dose. It is now thought that there are very many carcinogens, some of which present negligible hazards if exposure is very low. The result is that the US Food and Drug Administration has, on occasion, simply ignored the Delaney Clause (NEPI, 1998).

Scientific judgement

418 The distinction between scientific evidence, analysis, judgement and opinion is considered vital by the authors of several of the sets of guidelines described above (for example, the OST, 1997; Smith, 1997; Smith and Halliwell, 1999). Hahn (1999) distinguishes between data and analysis primarily on the grounds that analysis is prone to errors and must therefore be checked. In moving from scientific evidence, through formal analysis and reasoned judgement to opinion, uncertainty increases. However, at the same time as uncertainty increases, the extent to which non-scientific value judgements become incorporated may also increase.

419 Bacon (1998) recognises this in identifying scientific judgement as becoming 'a substitute or competitor for policy judgement'. Transparency in the advisory process, which should expose the relative contributions of evidence, analysis, judgement and opinion, may resolve this problem.

Formal methods

420 Experts on scientific advisory committees may be asked to resolve uncertainty, draw together results from different studies, or reconcile differences of judgement or opinion. A number of formal methods for achieving this have been developed, ranging from the Delphi technique to Bayesian statistics.

421 For example, Cooke (1991) describes a number of formal quantitative methods for dealing with uncertainty in expert advice. These methods focus on risk assessment. They are highly technical and therefore inaccessible to most policy-makers. As such, they may be relevant to the work of particular scientific advisory committees or groups of experts, but not to expert advice in general.

422 Bayesian analysis allows, for example, an existing estimate of a parameter to be updated by new experimental results. It also allows a weight to be assigned to the new results, which could be based on the degree of relevance that the particular experimental system has to the parameter of interest, or the degree of confidence that the expert conducting the analysis places on the new experimental results. The use of Bayesian methods has been illustrated by Lilford and Braunholtz (1996), using as an example the controversy over the health risks associated with some contraceptive pills.

Consensus

423 Policy-makers often ask groups of experts to reach consensus in answering questions put to them. For example, of the several hundred reports generated each year by the National Academies of Sciences in the USA, only half a dozen or so are not consensus reports. It may be easier to reach consensus when answers are expressed as a range. The wider the range, the greater is the likelihood of reaching consensus.

424 Where experts are asked to assess policy options, consensus may be harder to reach. Alternatively, experts may disagree about the application of particular methods or theories in analysing scientific evidence. The Radioactive Waste Management Advisory Committee (1999) gives as a definition of consensus 'the achievement of a sufficient concurrence of view at various stages to legitimise a decision to proceed with a particular course of action'. It also recommends that the process of achieving consensus must be open and transparent, and that, in the particular case of the disposal of radioactive waste, the consensus must be achieved across a wider group of people than just expert scientists.

Stakeholders

425 The need to consider ethical, moral or other value judgements along with expert scientific judgement has been discussed above in the context of risk assessment, and also features in several of the sets of guidelines covered in this review. The Royal Commission on Environmental Pollution (1998) discusses this question in its 21st report on setting environmental standards, and recommends that the public should be involved in the formulation of policies, rather than simply being presented with a choice of predetermined options.

426 Although there is broad agreement in the literature that the views of stakeholders need to be taken into account in the advisory process because, at least in some cases, the expert advice cannot be value-free, there is a variety of views on how this could be achieved. Some consider that stakeholders should be represented on expert scientific committees (Consumers' Association, 1999), perhaps as non-voting members (Shapiro, 1990).

Communication

427 Communication is often neglected as part of the risk-assessment and management process. ILGRA (1998*b*) recommended that more effort be put into appropriate communication of risks and risk-management strategies. Lack of communication during and after risk assessments carried out by expert committees may have contributed to the lack of public trust in the workings of such committees.

428 However, debate continues over whether expert scientific risk assessments can be improved by better *communication* of the results of the risk assessment, or whether involving the public in the process of risk assessment itself is also necessary if the quality of the assessment is to be improved (see, for example, Stirling, 1998). Risk communication may sometimes appear to be an attempt to educate the public away from

beliefs about risk and control of risks considered 'irrational' by experts. Although the views of the general public on risk may be unscientific, describing the general public as irrational may appear to an extent tautological (Shrader-Frechette, 1990). The reasons for divergence between expert and lay views of a given risk are usually clear—and far from irrational—but may have nothing to do with science.

Trust

429 It is widely perceived that a lack of public trust in government in general, and in government scientists in particular, is a significant hindrance to implementing effective public policy (for example, Worcester, 1999). In the particular field of managing technological risks, it is often accepted that the public perception of the risk depends, among other things, on the degree of trust in which the risk assessors and managers are held (Slovic, 1993). As discussed above, increased openness, public accountability, and adherence to rules of procedure have frequently been called for in order to increase public confidence and trust in the advisory process. However, calls for more openness seem to be made more on the basis of appeal to self-evident truths of human nature than on the evidence of actual experience.

430 Slovic (1993) compares the perception of risk from nuclear power in the USA and in France. While, in both countries, the risk is perceived to be high, the French public expresses a high level of trust in the authorities charged with managing the risk, but accept that they themselves have little control over the risk. On the other hand, the US public have very little trust in the nuclear industry or the regulatory authorities, yet feel that they (the public) are able to intervene to a certain extent in the risk-management process. Slovic notes that the anti-nuclear movement in France was slow to reach the political mainstream, and that the French government did not permit public intervention in the process of formulating or implementing policy. It may be that both the closed French system and the more open US system flow from the style of decision-making that operates in each country, but there is no support in this comparison for the thesis that increased openness builds trust.

Quality

431 Support for the peer-review process in assuring quality is not universal. Some suggest that peer review simply ensures that only results in accord with the prevailing consensus within a peer group are accepted (NEPI, 1998). Hahn (1999) articulates serious concerns about the peer-review process, and refers to studies where already published (and peer-reviewed) results were subjected to re-analysis which discovered errors, and where spoof results containing mistakes were sent to reviewers who did not find the mistakes. Hahn argues for publication of data to allow a much wider review of analysis and results dependent on the data.

432 As well as arguing for publication of the scientific data on which new regulations are based, Hahn (1999) also calls for all analysis that results in economically significant regulations to be repeated by an independent agency before the regulation can be enacted. He asserts that 'replication is a key to ensuring the quality of the results.' However, this does presuppose that the data itself is to be trusted, and he thereby makes a distinction between data and analysis, to a certain extent mirroring the distinction between fact, judgement, and opinion. These distinctions are not universally recognised, however [418–419].

Peer groups

433 Scientists tend to specialise, and fields of study to fragment. The peer group for a particular scientific problem may number around a dozen individuals (NEPI, 1998).

434 Scientific advice produced by individuals within a peer group is likely to conform to the consensus within the peer group. However, advice on the same problem from different peer groups may conflict.

Policy for science *or* science in policy

435 The importance of the distinction between policy for science (ie, the allocation of public money for research), and science in policy has been made many times since the Haldane Report of 1918 (the OST, 1998*a*; Wilkie, 1991). The OST, in its memorandum to the House of Commons Select Committee on Science and Technology, states that this principle of separation has been reinforced by the recent changes in the structure of the public-sector research establishments, and the increased emphasis on a 'customer–contractor' relationship.

436 Nevertheless, considerable overlap remains between the administration of policy for science and science in policy. This is illustrated, for example, in the role of the CSA and the Council for Science and Technology (the OST, 1998*a*).

EXISTING GUIDANCE

437 This chapter presents a summary of existing guidance on scientific advice and on general policy-making. Government departments have been active in reviewing this area over the last few years, particularly in relation to the Freedom of Information Bill, which the Home Office has led; reviews of policy-making, led by the Cabinet Office; guidelines for scientific advice, led by OST; and risk assessment, led by the HSE. Departments have prepared guidance for civil servants and Ministers, and, to a lesser extent for advisers, as well as commentaries on the shortcomings of certain policy issues, their potential remedies, and lessons to be learnt to improve the linked scientific advisory and policy processes.

438 This review begins with the current guidance on scientific advice in the UK, USA, Canada and New Zealand. It then draws out themes from a wider body of guidance on policy-making, risk communication, and scientific advice, reflecting the principles and process section of the report.

439 There are several sets of published guidelines that are a codification of current practice (or current best practice), or have been drawn up from case studies or in response to consultation on the general changes in the standards expected of public bodies and those in public life.

May guidelines

440 In 1997, the OST published a note by Sir Robert May, the UK CSA, entitled 'The Use of Scientific Advice in Policy Making' (OST 1997). The note contains guidelines addressed to departments and agencies of government that have responsibility for their detailed implementation. The Ministerial Science Group, which includes members from all government departments with an interest in science, has as one of its key priorities the implementation of the guidelines. The Group has asked departments to report annually to the CSA on their implementation of the guidelines. In addition, the CSA and departmental chief scientists meet regularly to review emerging issues (the OST, 1998*a*).

441 The guidelines are presented under three key principles, and are summarised below.

- **Identifying issues**—departments should use a wide variety of sources to aid early identification of issues, including external research and reports by special-interest groups. Capacity to recognise and respond to unforeseen issues that arise is also required, and exchange of information on cross-departmental or international issues will be handled by the OST.

- **Building science into policy**—the best available scientific advice should be sought. This should include independent advice (for example, from 'eminent individuals, learned societies, advisory committees, experts outside the UK, and consultants'). Experts from a range of disciplines, not necessarily scientific, should be asked to review evidence from a range of viewpoints. Data should be made available to the general research community as soon as possible. Scientific advisers should help to frame and assess policy options. Funding priorities should be kept under review in light of the need for advice, and a balanced view should be reached in a transparent way that is consistent across different policy areas.

- **There should be a presumption towards openness**—scientific evidence and analysis underlying policy decisions should be published. Scientists should be encouraged to publish associated research work. Uncertainties and policy options should be presented to the public in a manner that is consistent with the scientific advice. Departments should consider giving scientists a leading role in presenting their advice, with Ministers or officials describing how policy was derived from the advice. In addition, early communication with interest groups and other governments may be appropriate.

442 The guidelines were drawn up following wide consultation with government departments (seen as part of the process of opening up Whitehall that has taken place in recent years). Progress in implementing the guidelines has been reported on twice (OST, 1998*b*), and the CSA announced a review in December 1999 to determine whether any changes or additions might usefully be made to the key principles. This review involved consultation both within government and externally. The revised guidelines have been published as 'Guidelines 2000—Scientific Advice and Policy-making' (OST 2000*b*). The

guidelines have attracted praise from overseas observers (Smith and Halliwell, 1999; Stein and Renn, 1998; CSTA, 1999). It appears that the UK is unusual in having published such guidelines, although they are, for the most part, aspirational rather than prescriptive, and considerable discretion in interpretation is left to departments. Furthermore, it is not clear how implementation of the guidelines can be measured, although departments have reported specific case-study examples in their annual implementation reports.

443 The 'May guidelines' are currently under review. At the time of writing, consultation on an updated version of the guidelines is ongoing.

Nolan Principles and Peach Guidelines

444 The Committee on Standards in Public Life (the Nolan Committee) was set up in 1994 in response to general public concern. In particular, there was concern over allegations of payments to members of Parliament for tabling of questions in Parliament; that ex-Ministers had been employed by firms which they had regulated when in office; and over fraud or mis-spending in quangos (quasi-autonomous non-governmental organisations). The remit also included all holders of public office, non-departmental public bodies, and both civil servants and advisers to Ministers (Committee on Standards in Public Life, 1995).

445 The Nolan Committee devised 'Seven Principles of Public Life':

- selflessness—decisions should be taken solely in the public interest;
- integrity—individuals should not be under any obligation to outsiders that might confer influence;
- objectivity—appointments and contracts should be given on merit;
- accountability—holders of public office should be accountable for their decisions and must submit to appropriate scrutiny;
- openness—decisions should be taken openly, and access to information should only be restricted 'when the wider public interest clearly demands';
- honesty—private interests should be declared, and conflicts of interest should be resolved to protect the public interest; and
- leadership—the principles should be supported by leadership and example.

446 Following the recommendations of the Nolan Committee, Sir Leonard Peach was appointed Commissioner for Public Appointments, and guidelines were issued to departments on how appointments to public bodies should be made (Office of the Commissioner for Public Appointments, 1998). Appointments to bodies, such as the Advisory Committee on Novel Foods and Processes, are now made in line with the 'Nolan and Peach' guidelines (Rooker, 1999).

447 Departments are required to draw up job descriptions for each post, and candidates are shortlisted according to their merit against the job description. Equal-opportunity principles are applied. The guidelines require that the appointment process be scrutinised by an independent assessor, who will monitor the application of the guidelines.

448 The guidelines also address conflicts of interest. Such conflicts should be declared and documented, although the definition of a conflict of interest is left to individual departments, and it is acknowledged that some appointments will be more sensitive than others in this regard.

449 The selection of individuals from shortlists prepared by departments remains the responsibility of Ministers. In recent practice, appointees to advisory committees have been ruled out on grounds of being industry employees, although not if they are academics partly funded by industry. There is continued debate on this issue. Some argue that this interpretation of appropriate standards of independence unnecessarily rules out experts who have a contribution to make to the advisory process, and others argue that the interpretation does not go far enough in distancing advisory committees from the influence of industry (House of Commons, 1999*a*).

USA

450 Stein and Renn (1998) argue that scientific advice to government in the USA is more open than in any other country because of the operation of the FACA [371–374].

451 Beckler (1992) has written about the use of scientific expertise from outside government, based on the experience of supporting the provision of scientific advice at the highest level within the US government, at the OECD, the National Academy of Sciences, the Carnegie Commission on Science Technology, and government. The following recommendations are described.

- Decision-takers should recognise when advisers should be called in from outside

government, and should have procedures in place for their selection.
- Uncertainty and differences of view are common in science, and the decision-taker needs to ensure that different views are taken into account, both in decision-making and in deciding the composition of advisory groups.
- Recognising that, to a greater or lesser extent, values are inevitably embedded in expert advice, advisory panels addressing policy issues should be carefully balanced with respect to field of expertise, sector, and political inclination.
- Advisory bodies should have a well-defined remit, but should be free to reformulate questions or initiate study of emerging problems, with the consent of the policy-maker.
- Both advisers and policy-makers should be alert to the possibility of conflicting interests between an adviser's private and public work.
- Policy-makers need to be supported by policy analysis as well as expert scientific advice.
- The advisory process should be open and transparent, as far as is feasible.
- Decision-takers should provide feedback to advisory committees.

452 Beckler asserts that capacity for policy analysis is 'inversely proportional to the level of decision making', and that scientific advice and support for detailed policy analysis is lacking at the highest level of policy development, particularly on cross-departmental issues. It may be that the recent trend in the UK for the appointment of specialist advisers to Ministers (for example, economic advisers) is driven by this lack of established advisory capacity at the higher levels of government.

Canadian guidelines

453 The Canadian CSTA produced guidelines in 1999 for the use of scientific advice in a report entitled 'Science Advice for Government Effectiveness'. This report draws heavily on the work of May (the OST, 1997), Smith (Smith, 1997; Smith and Halliwell, 1999), and Beckler (1992). The guidelines include the following recommendations.

- Departments should maximise the use of expert advice to identify and address 'horizontal' issues across departments.
- 'Traditional knowledge' of local peoples should be given consideration, and decision-takers should balance the many views they receive (this point may illustrate the extent to which guidelines must recognise the political landscape).
- External advice should be sought when problems exceed the in-house expertise of departments, when there is a range of scientific opinion, or when there is a possibility of controversial policy outcomes that could benefit from independent advice to strengthen public confidence.
- Decision-takers should be open to both solicited and unsolicited advice.
- All advisory processes should be subject to due diligence, including rigorous internal and external peer review.
- Scientific advice must be supported by policy analysis; scientists should be able to analyse the consequences of their advice; and there should be a strong coupling between advisers and departmental policy analysis functions.
- Advisers and decision-takers must distinguish between scientific fact and judgement or opinion.
- Decision-takers should report back to advisers on how decisions were made, and involve advisers in the formulation of policy, in order to maintain the integrity of advice throughout the decision-making process.

454 In addition, the CSTA report proposes detailed guidelines on openness and review.

- Decision-takers should explain their decisions, and how advice was used in reaching the decision.
- Decisions could be explained at public meetings; scientific advisers could be asked to explain their advice; and officials could explain how the advice was secured, and how policies were framed in the light of the advice.
- In controversial cases, decision-takers should balance the need for timely decisions with the need for effective consultation.
- Departments should institutionalise a review process, so that once decisions are made, a follow-up exercise provides written responses to recommendations generated by advisers.
- Policy decisions should be reviewed to determine whether advances in scientific knowledge change the basis of science advice used in arriving at the decision. At the time decisions are taken, the latest intended date for a review should be announced.

455 Finally, the CSTA report recommends that the implementation of the guidelines be audited. This could be achieved by periodic review by an external body, or by the creation of a permanent 'oversight' function.

Risk perception, assessment, management and communication

456 It is widely recognised that risk is a component of many high-profile, contentious policy decisions where scientific advice is required. As such, risk issues are important to the work of all major government departments in the UK. ILGRA has responsibility for keeping under review developments in the fields of risk perception, assessment, management and communication, and identifying common approaches that can be developed by all departments.

457 ILGRA (1996) identified a need for the frameworks for risk assessment in different departments to be logically consistent with each other. Otherwise, for example, different departments may currently use different degrees of caution in risk assessment.

458 ILGRA (1998*b*) has also identified the importance of increasing public awareness of risk. The Internet and the general increase in communication worldwide have raised and broadened awareness of major accidents and the sensitivity of the public to risk issues, in that greater reporting means that issues attract more attention more quickly. Thus, governments or regulators may be called upon to act to control exposure to risks more often, earlier, and in a more controversial atmosphere.

459 Furthermore, there is growing acceptance among regulators that public perception of risk depends not only on the expected physical harm arising from hazards, but also on wider societal concerns attached to exposure. This adds a complication to risk assessment. A group of expert scientists may arrive at a consensus assessment of a particular risk which depends on their own value judgements about the wider social issues attached to the risk exposure. These value judgements may very likely differ between experts and the general public (as well as being different for different sections of the public).

460 Further concerns about the transparency of the risk-assessment process, particularly when it involves the use of experts on advisory committees, were identified by the ILGRA sub-group on the setting of safety standards. The sub-group recommended that the terms of reference for expert advisory committees be clarified, to affirm that it was the function of the committee to advise, rather than to set standards. Decisions would then be informed by the expert advice as well as by other inputs, such as societal concerns.

461 Finally, ILGRA (1998*a*) makes the following recommendations on the function of experts, in order to counter the problems described above:

- expert scientific advice should be open to public scrutiny and peer review, and it should be made clear where judgement or opinion is used;
- assumptions underlying advice, as well as uncertainties, should be exposed and explained;
- procedures should be adopted to allow stakeholder as well as expert input; and
- all considerations underlying decisions, including expert scientific advice, should be fully explained.

New Zealand expert panels

462 The New Zealand Ministry of Research, Science and Technology commissioned a review of 'Expert Panels for Provision of Scientific and Technological Advice for Development of Public Policy' (Smith, 1997). This followed the establishment by the New Zealand government of expert panels on BSE and the Tussock Moth. The review, carried out by Dr William Smith of the University of Auckland, recommends best-practice guidelines for the design and operation of panels of experts reporting to government departments.

463 The recommendations were prepared after interviews with members of the expert panels, officials, and Ministers. In addition, some interviews were conducted in the UK. The expert panels described by Smith are panels set up by a department of government. Expert panels operated by learned societies are discussed below [466–467].

464 The review concluded that for independent scientific advisory panels to provide useful and timely advice, it is necessary that:

- quality-control mechanisms should be built into the scientific advisory panel process, both in the selection of panel members and in its provision of information and advice;
- the composition of panels should reflect the nature of the issue to be addressed

and the breadth of judgement required. Panels should be carefully balanced in terms of disciplinary expertise, institutional allegiance and stakeholder interests;
- panels should be established with clear authority and accountability, and should be insulated from any attempt to manipulate or dictate working methods or the content of advice.

465 In support of these imperatives, a series of more detailed recommendations were made, the more innovative of which are summarised below.

- The terms of reference of expert panels should be a matter for debate and approval of the panel, in consultation with Ministers.
- Panels should have access to any analysis of their advice provided by officials to Ministers.
- All independent scientific advisory panels should report directly to Ministers.
- Panels should have the right to exclude officials from their deliberations.
- Panels should explicitly debate the function of officials in the drafting of advice to Ministers.
- The responsibilities accompanying membership of a panel should be clearly communicated to members on appointment.
- Panels should have a right to direct access to Ministers when required.
- Specific guidelines should be drafted for the conduct of the chairpersons of such panels.

Independent expert panels

466 Expert panels may be convened outside government ministries and departments. It has traditionally been a function of learned societies to advise governments in this way. For example, the Royal Society of London has an explicit objective to 'promote independent, authoritative advice, notably to UK government, on science and engineering-related matters, and to inform public debate' (Collins, 1998). Most learned societies provide advice to their national governments with or without a request for advice having been received, although arrangements for funding differ.

467 The Royal Society of Canada does not receive government funding. When reports are commissioned and funded by governments or other organisations, expert panels are run under the auspices of this Society. The Society is unusual in that it has a strictly codified procedure for the organisation and conduct of such panels. The following procedures and guidelines are summarised from its 'Expert Panels: Manual of Procedural Guidelines' (The Royal Society of Canada, 1998).

- The sponsoring organisation cannot dictate who does or does not sit on the panel.
- The scope of the task is agreed after negotiation between the CEP and the sponsor.
- In selecting members of the panel, composition and balance are optimised, and conflicts of interest are identified. The CEP aims from the outset to select a panel which will have the skills necessary to carry out the task assigned to it, and the balance of views required to ensure that the final report of the panel is widely accepted.
- In addressing balance, the CEP may ask prospective panel members to list their views on issues connected with the task of the panel. Balance may be achieved by having representatives of different views on the panel, or by appointing individuals without strong views on controversial questions.
- Issues of communication and dissemination of the report are considered explicitly by the CEP at an early stage in the process.

Europe

468 The work of the EC is supported by hundreds of scientific advisory committees. There are no universal guidelines covering the work of these committees at present, although the European Parliament has considered this issue (Stein and Renn, 1998).

Themes

469 The UK departmental literature began to emerge in the early 1990s, from roots 20 years earlier in Lord Rothschild's 1971 report, 'The Organisation and Management of Government R&D'. Sir John Fairclough, CSA, recognised that 'Science and technology is increasingly pervasive. There are very few policy areas upon which it does not impact.' (Fairclough, 1990). There was a strong recognition that scientific advice would play a central role in many areas of policy-making. There is no

reason to doubt that, at that point in time, he was referring to natural and physical sciences, and technology. This is the definition used in this study. The purpose of his advice to the Prime Minister of the day was 'to ensure that science and technology advice is fully integrated into the wider consideration of policy by Departments'. This review of subsequent reports and guidance shows how this objective has been translated into guidance over the last decade.

470 ILGRA, in its discussion of risk assessment and management, identifies areas where reform could be considered, and touches on the themes reviewed in this supplementary note.

> Traditionally Departments and Agencies have operated under the assumption that, with the assistance of experts as necessary, they would define the problem, assess the risks, identify risk management options, and adopt decisions. Typically ... the decision adopted was justified on the basis of reliance on the best independent scientific advice.
>
> Such an approach is becoming increasingly untenable for many reasons. First, as already mentioned, Departments and experts may not frame the problem in the same way as the stakeholders. Second, there is a tendency for experts throughout the decision-making process to substitute their own value judgements for those of the stakeholders. Third, stakeholders may feel disenfranchised if they have little or no opportunity to express their value judgements. And finally, assurances offered on the basis of objective science often implode into uncertainty because of unreliable or incomplete data, modelling uncertainties, debatable underpinning assumptions, or conflicts of scientific judgement in interpreting data (ILGRA, 1998*a*).

471 The general principles espoused by the Cabinet Office's Better Regulation Unit have been taken up by ILGRA in its guidance to government departments on risk assessment and risk management, 'namely transparency, accountability, targeting of action, consistency and proportionality' (ILGRA, 1998*a*). These principles form the foundation of the current civil service guidance on the handling of risks.

Legitimacy

472 This principle emerges as a constant theme in the history of guidance. Sir John Fairclough recalled the 'remarkably sound' principles set out in Lord Rothschild's report, which 'continue to underlie present arrangements, although his recommendations were not formally accepted' (Fairclough, 1990). Lord Rothschild recommended, above all, 'clear identification and rigorous separation of the roles of customers for scientific advice and the contractor who provided it, whether in-house or outside the department'. He also thought that 'advice should be given by or strongly informed by leading people from outside the civil service.' Sir John Fairclough concluded, 'The key remains a rigorous approach to the customer/contractor principle coupled with strong external input.'

473 This theme continues to receive support in more recent work, for example ILGRA's guide on risk communication, which warns that:

> The risk of inappropriate transfer of responsibility for decision making to experts needs to be guarded against carefully (ILGRA, 1998*b*).

474 ILGRA explained in more detail the reason for its conclusion:

> The role of scientific advisers is well established in the regulatory process, largely through their position on Government advisory committees. However, there is evidence of a lack of transparency in how experts reach decisions about the level of risk posed by particular hazards. The sub-group judged that thought could usefully be given to clarifying the terms of reference for such groups so as to make clear that their role is to assist decision makers and not to set standards as such. This would help to ensure and make apparent that other useful inputs, such as costs and benefits, are also taken into account in the formulation of policy. This was particularly important. Once an expert group's judgement on the balance of the scientific arguments is published, pressure may be created for Government to regulate, even if it is unjustified in cost–benefit terms.

475 It does not appear that this advice was followed in the Stewart report on mobile phones (Independent Expert Group on Mobile Phones, 2000).

476 The Select Committee on Science and Technology took up the theme by recommending that 'Ministers should obtain advice on these other, non-scientific, issues but should not seek such advice from the scientific advisory system.' The government did not address this recommendation in its response to the Committee's report (Science and Technology Committee, 1999).

Disclosure of information

477 The disclosure of information is subject to a large volume of guidance, not all of which is consistent. In support of the disclosure of information, several powerful statements have been made.

478 First, in laying down recommendations for risk communication, ILGRA noted:

> in certain fields, the provision of independent advice via expert committees is widely distrusted as part of the system. This may be because some of them have a history of taking their decisions behind closed doors. (ILGRA, 1998*b*)

479 Second, the government has supported a presumption of publication, which is summarised in the May guidelines; 'departments should publish the scientific advice and all relevant papers' (OST, 2000*b*). The Freedom of Information Bill requires authorities to adopt a scheme for publication, stipulating the information they will place proactively in the public domain, and agreeing the scheme in advance with the Information Commissioner. However, the Bill includes important exemptions to the presumption of publication or access.

> Information held by a government department is exempt information if it relates to—
>
> (a) the formulation or development of government policy....
>
> (b) would, or would be likely to inhibit—
>
> (i) the free and frank provision of advice, or
>
> (ii) the free and frank exchange of views for the purposes of deliberation
>
> (House of Commons, 1999*a*)

480 At present, access to Government information is described in the 'Code of Practice on Access to Government Information', and in the related 'Guidance on Implementation'.

> The code commits departments to give information on the factual and analytical background to new policies, but there is an important distinction between the process by which a decision or policy has been reached (which remains confidential) and explanation of the basis of the decision once reached (which should be as full and open as possible) (Cabinet Office, 1997, Home Office, 1998).

481 The Code also expresses an aim to 'improve policy-making and the democratic process by extending access to the facts and analyses which provide the basis for consideration of the proposed policy', and has a specific requirement to 'publish facts and the analysis of facts which the Government considers relevant and important in framing major policy proposals and decisions'.

482 This distinction may be difficult to apply, but does address ILGRA's concern, outlined above, provided that a clear distinction is made between external advice, and internal policy-making. Protection for the latter is explained as follows:

> The justification for confidentiality of internal opinion, advice, recommendation and deliberation is the need to ensure that matters can be discussed candidly and frankly within government, and a full record kept without taking account of the possibility of publication within any period of time during which the material might remain sensitive . . .
>
> Exposure of differences between Ministers, between Ministers and their civil servants or between civil servants, could prejudice working relationships and effective discussion of policy ... It is not the intention, however, to withhold this class of information *only* where internal differences and disagreements would be revealed . . . It is important that reasonable expectations of confidentiality are preserved.

483 It is not clear where the line between publication and confidentiality will be drawn, and there can only be consistency with the May guidelines, above, if there is a clear separation between advice that is purely scientific, and policy advice. Indeed, the special status of scientific advice is

recognised, but not to the extent of a presumption of publication.

> There is less need for confidentiality in respect of advice from expert advisory committees, ... where the availability of the assessment will enhance public debate and understanding ... or made available for peer group review.

484 In fact, the position of scientific advisory committees is vague:

> Advisory committees themselves are not usually within the jurisdiction of the Ombudsman, ... the Ombudsman may be asked to investigate complaints concerning refusal by departments to disclose expert advice on which they have relied.

485 The guidelines published to date have not given detailed guidance on the publication of information. There is an exception in the advice on the publication of information within the biotechnology regulatory framework, although its interpretation may be quite flexible.

> subject to confidentiality and commercial sensitivity, publish agendas in advance of meetings and minutes thereafter together with such explanations as will enable the reader to understand the issues, argument and basis of decisions taken . . . where information is confidential or commercially sensitive, write it in such a way as to make as much information public as possible without infringing legitimate concerns (Cabinet Office, 1999*f*).

486 This might be an indication of how scientific advisory committees in general will be treated in the future.

Over-riding duty

487 The principle of a duty to the public interest is applied within the draft Freedom of Information Bill to the disclosure of commercially confidential information, and might therefore be applied to scientific advice. The bill states that, with respect to publication of advice, where there is an exemption for commercially confidential information, the exemption from disclosure for commercial and confidential information may be set aside where there is a clear and outweighing public interest (HMG, 1997). There is clearly a fine dividing line between the operation of this clause, and the main exemption in the bill.

> The Government therefore considers that where information is supplied to a public authority in circumstances where a duty of confidence arises, it should not be required to disclose the information if to do so would constitute a breach of confidence actionable [under common law] by the supplier of the information.

488 Furthermore, the Public Disclosure Act 1998 also gives some protection to advisers through the 'whistle-blowing' conditions. It also applies to the public sector, supplementing the Civil Service Code. Under the Civil Service Code:

> it is preferable to raise the matter internally [with the appeals officer of the department] if appropriate and practical, or with Civil Service Commissioners ... Otherwise, the disclosure qualifies for protection under the Act, if in the reasonable belief of the worker making it, it tends to show that one or more of the following has occurred, is occurring, or is likely to occur:
>
> - the endangering of an individual's health and safety
> - damage to the environment
> - deliberate concealing of information tending to show any of the above.
>
> (Cabinet Office, 1999*a*).

489 Whether the term 'individual' also applies to unnamed members of the public in a general policy situation is not clear. However, similar protection could be offered explicitly to external advisers.

Accountability

490 Ministers are solely accountable to Parliament for the decisions they take:

> The constitutional position of civil servants in relation to Ministers is such that:
>
> > Ministers alone are accountable for the information given to Parliament;
> >
> > civil servants have no final authority to decide what information shall be made available to Parliament (Cabinet Office, 2000*a*).

491 The guidance on accountability of Ministers to Parliament is well established. It

complements the guidance on disclosure of information, but contains a crucial exemption: while Ministers and their officials are generally required to provide full information, the reasons for confidentiality include:

> internal discussion and advice: projections and assumptions relating to internal policy analysis; analysis of alternative policy options and information relating to rejected policy options (Home Office, 1998).

492 This could be interpreted to mean that only justification for chosen policies is required to be published, and not their alternatives (subject to the public-interest provisions above). This is an extremely important clause. It is clear that this is the intended interpretation, for:

> The aims of the Code are:
>
> > to improve policy-making and the democratic process by extending access to the facts and analyses which provide the basis for the consideration of proposed policy;
> >
> > to protect the interests of individuals and companies by ensuring that reasons are given for administrative decisions, except where there is statutory authority or established convention to the contrary (Home Office, 1998).

493 It can be argued that there is an established convention not to give justification for the selection of one policy option above another.

494 Otherwise, the rules for Ministerial accountability mirror the other rules on public disclosure. It is noted that they include explicit reference to the public interest. The guidance is contained in the Resolution on Ministerial Accountability (adopted by the House of Lords on March 20th 1997).

> That, in the opinion of this House, the following principles should govern the conduct of Ministers of the Crown in relation to Parliament:
>
> > (1) Ministers have a duty to Parliament to account, and be held to account, for the policies, decisions, and actions of their Departments and Next Steps Agencies;
> >
> > (2) Ministers should give accurate and truthful information to Parliament...
> >
> > (3) Ministers should be as open as possible with Parliament, refusing to provide information only when disclosure would not be in the public interest (Cabinet Office, 2000*a*).

495 It is also relevant to this report that the rules on disclosure, particularly in relation to scientific advice, are more flexible than in other areas. For example, the Cabinet Office's guidance to civil servants explains why Ministers may not normally have access to the papers of previous Administrations.

> If Ministers believe that there is sufficient evidence of an unsatisfactory state of affairs, it is open to them, after consultation with Ministers of the previous Administration, to appoint a suitable person to inquire into the events concerned, giving them necessary access to papers. The BSE Inquiry is a recent, large-scale example of such an inquiry.
>
> Thus scientific advice should be made available to succeeding Administrations, and to facilitate this—to make it possible without recall to special measures—scientific advice could not be given to Ministers, but to policy-makers instead, so that it does not attract privilege (Cabinet Office, 2000*a*).

496 The importance of the accountability of the process was implied in the conclusions of Sir John Fairclough. He recommended that departments should 'check periodically that the structures and mechanisms in place are matched to need', and that such checks need to be made 'against objective criteria'. No clear criteria exist in current guidance. He recommended that 'every four years thereafter, Permanent Secretaries should use these criteria to review the arrangements in place for obtaining science and technology advice within their Departments' (Fairclough, 1990).

Uncertainty

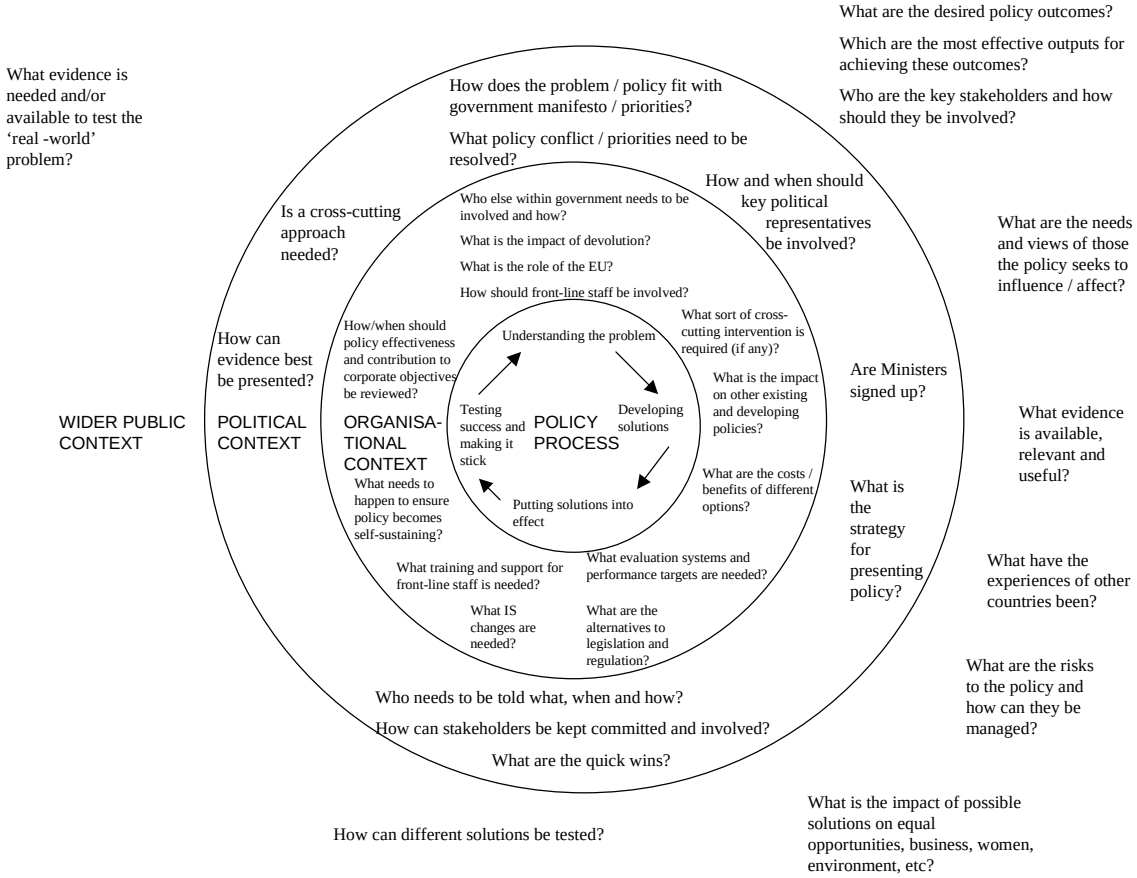
497 The expression of uncertainty in policy advice and decision-taking is only discussed in general terms in guidance. The focus of the guidance is on public perception and communication with the public, rather than internally within government. This is illustrated by the principles of risk communication published by ILGRA (1998*b*), 'listen to

stakeholders, tailor messages, and manage the process.' The same report concludes that 'Across Government, scientific input to the regulatory process is invariably strong.'

Process

498 There have been several attempts to describe the policy process as a process model. Most recently, the Cabinet Office review of professional policy-making found that a policy process model was not received warmly by experienced policy-makers because they felt that it did not accurately reflect the realities of policy-making (Cabinet Office, 1999*e*). The report presented a model of the policy process in context, which is reproduced below.

Figure 3: The policy process in context



Source: Cabinet Office, 1999*e*.

499 Earlier, in 1990, Sir John Fairclough had concluded that 'it is no longer [appropriate] to attempt to define a prescriptive model in the way that the Rothschild report did' because of the diversity of the advice required. He went on to note that a flexible process model is appropriate, but should remain within the firm control of the chief scientist. This leads naturally to ILGRA's conclusion that:

> Departments therefore need to develop ways of explaining the scientific and policy background to decisions to the public, and to establish how best to incorporate both expert judgements and society's preferences into the decision-making process (ILGRA, 1998*b*).

500 The order in which this occurs may be crucial. As an example of the confusion that can arise if the process is not clear, consider that the guidance in Sir John Fairclough's memorandum is 'to review and contribute to the presentation of Departmental policies having science and technology content, both nationally and internationally'. This could be interpreted to mean the review of policies that have already been set out. The decision and policy should flow from the advice, rather than in the other direction, although *ex-post* evaluation of policy effectiveness is a valuable function.

Framing the question and terms of reference

501 The definition of scientific questions relating to policy issues has not received wide treatment in existing guidance. The Treasury, in its guidance on policy appraisal (HM Treasury, 1997), notes that the first stage is to set clear policy objectives with departmental Ministers. ILGRA identifies the link between the framing of the question, the public perception of risk, and stakeholder concerns: 'the regulator must find out how much the risks matter, to whom and why, and agree an agenda with them'.

502 The Cabinet Office guidance (1999*e*) gives policy-makers detailed notes on the issues that they should consider, but does not offer similar guidance for scientific advisers. This guidance, issued to policy-makers by the Cabinet Office, is summarised below, and recommends that policy-makers refer to:

- a statement of intended outcomes at an early stage;
- contingency and scenario planning;
- evidence of taking into account government's long-term strategy;
- the work of international agencies, and policy in other countries;
- the origin of the issue;
- why previous policy options failed;
- the use of pilots (trials);
- new research that could be commissioned;
- feedback from implementers of current policy;
- cross-cutting objectives and inter-departmental issues;
- a programme of ongoing review;
- mechanisms to remove, reverse or modify policy.

503 ILGRA has provided a checklist for the consideration of policy and risk (ILGRA, 1998*a*). It is designed to help identify the risks to which a policy response may be needed, and to assess potential public reaction to these risks. ILGRA notes that 'risks are generally more worrying ... if perceived to be poorly understood by science, ... and subject to contradictory statements from responsible sources.' It is surprising that there is not more guidance on preparing terms of reference for scientific advisers.

504 The importance of setting the correct terms of reference is demonstrated by the advisory failures that can occur otherwise. For example, the government's response to the Science and Technology Committee discusses GM crops (House of Commons Science and Technology Committee, 1999). The initial scientific research did not take into account the concerns of a stakeholder, English Nature, so another research programme was later undertaken to address this. The report implies that the committee did not identify legitimate concerns and did not take into account the views of stakeholders.

Sources of advice and scientific data

505 The sources of scientific advice were given a taxonomy by Sir John Fairclough, who cited 'Home grown Chief Scientists, full or part-time CSAs drawn from industry or academe, independent advisory committees, consultants, scientists and engineers fully integrated into Departments at the working level'. This study did not find other classifications of sources of advice that expanded upon this list. There is sparse guidance for policy-makers on the selection of advisers.

506 There is little discussion of sources of data in the guidance literature. The Science and Technology Committee suggested that ACRE and Advisory Committee on Non-food

Products should not use anything other than an applicant's own data in their assessments, and supported evidence to the committee from Novartis that 'regulation by review of companies' risk assessments works well in pharmaceutical and pesticide regulation.' The government broadly endorsed this view in its response (House of Commons Science and Technology Committee, 1999). However, this approach does not acknowledge the value of evidence from other sources, the importance of a balance of access to the advisory process, and the ability of companies to edit evidence they present. Neither does it recognise the much more tightly defined rules and greater degree of rigour in analysis required for pharmaceuticals, and the clearer precedents explaining how the burden of proof operates in pharmaceuticals testing.

507 It has also been suggested that committee work and research should be coordinated with other similar work internationally.

Selection of advisers and conflicts of interest

508 The Science and Technology Committee recommended that no interests had a right to be represented on scientific committees, and the government endorsed this view (House of Commons Science and Technology Committee, 1999). They both rejected the suggestion that scientists' integrity is automatically compromised by association with industry. If advisers with associations were to be excluded, the government would deprive itself of access to many of the best advisers (House of Commons Science and Technology Committee, 1999). The committee asked for clear guidelines on the disclosure of interests, including annual disclosure, transparent procedures for review, and clear criteria for decisions on whether interests are material. The government responded that thorough safeguards are in place to ensure that interests are declared, but did not answer the other points. No guidance on assessing the materiality of interests was found.

509 There is some guidance in the Code of Practice for Public Appointments (Office of the Commissioner for Public Appointments, undated). This contains few details, and many of the recommendations within it are difficult to interpret. They are summarised below:

- the ultimate responsibility for appointments rests with Ministers;
- no appointment shall take place without first being scrutinised by a panel which must include an independent assessor;
- Board members must be committed to the principles and values of public service;
- the principles of open Government must be applied to the appointments process; and
- the appointments procedures need to be subject to the principle of proportionality.

510 The Code has several shortcomings. It does not explain what independent means, or whether, if the rest of the assessors are not independent, the independent assessor has the right of veto. There is no guidance on whether shortlists for appointments should be subject to public consultation before the appointments are made. The principles and values of public service are not articulated or referenced and principles of open Government are not elaborated.

511 The Science and Technology Committee recommended that scientific advisory committees should draw one-fifth of their membership from lay experts with a background in 'other, not necessarily scientific, disciplines, to ensure that the evidence is subjected to a sufficiently questioning review from a wide ranging set of viewpoints' (House of Commons Science and Technology Committee, 1999). The government felt, in response to this recommendation, that a requirement to have lay members was not appropriate, but that it should be at the Minister's discretion.

512 Sir John Fairclough (1990) laid an emphasis on external advice that is not apparent in more recent treatments of the subject. His criteria for selecting advisers included:

> the Departments should have independent advice of the highest calibre in order to complement internal advice, to act as a check and a balance to internal advice, and to introduce a wider perspective . . . Where the Chief Scientist is drawn from the career civil service, this is particularly important.

Rights of advisers

513 The Civil Service Code contains protection for civil servants, as listed below. This might be considered for application to scientific advisers. The civil servant has a right to appeal:

> where ... he or she is being required to act in a way which:
>
> - is illegal, improper, or unethical;
> - is in breach of constitutional convention or a professional code [which would need clarification in the case of scientific advisers];
> - may involve possible mal-administration;
> - is otherwise inconsistent with this Code. (Cabinet Office, 1999*a*)

Function of the secretariat

514 The secretariat is bound by the Civil Service Code. It has a duty to the government (Administration). Its duty to the advisory committee, if any, is not clear. The code is over-ridden by 'existing statutory or common law obligations to keep confidential, or to disclose, certain information'. According to the Code, 'Civil servants should not without authority disclose official information which has been communicated in confidence within the Administration, or received in confidence from others.' There is an important question as to whether they can pass on this information to advisers. Secretariats may also need guidance on the implementation of the Freedom of Information Bill with respect to scientific advice (Cabinet Office, 1990).

515 The Science and Technology Committee recommended that the secretariat should be of sufficient size to ensure the efficient working of the committee. In its reply, the government said that the secretariat's principal function was to ensure that decisions on whether to license releases are taken based on ACRE's advice (House of Commons Science and Technology Committee, 1999). This may be a subtle difference from a principal function in supporting the committee itself.

516 The government has stated that secretariats should have sufficient scientific competence to understand the issues they are handling (House of Commons Science and Technology Committee, 1999). In this case, training should be available. As Sir John Fairclough (1990) noted:

> There will be an increasing need not just for top level science and technology advice but for respected and competent scientific and technical advice at all levels within Government. And this will need to be fully integrated into the machinery that informs wider policy making and implementation.

Consultation and involvement of stakeholders

517 The Cabinet Office (2000*b*) has provided guidance on how to conduct consultations of different sorts. It recommends consultation from the start of the planning process for a new policy or service. With respect to the biotechnology regulatory framework, the government has asked the strategic advisory bodies to 'undertake consultations/issue consultation documents about specific issues and publish details, ensuring that respondents know that their views have been listened to and acted upon if appropriate, or if not, why not'. The Cabinet Office notes that 'It is desirable to keep as full an account as possible of responses, formal and informal, to consultations; both to ensure that everyone's view is fairly considered, but also to help address any allegation of privileged access.'

518 It is not apparent that this has been the common practice in the past. In laying down recommendations for risk communication, ILGRA (ILGRA, 1998*b*) noted 'it is the exception rather than the rule that communication is treated as an integral part of risk management policy.'

519 The consultation process is not just about framing the question, it is part of a two-way dialogue. The Home Office (1998) has recommended that 'Decisions ... should be published promptly ..., with a summary of views expressed ... and clear reasons for rejecting options that were not adopted.'

Conclusions

520 The review of guidance has revealed important areas where no guidance is available, particularly to scientific advisers, where guidance is ambiguous or contradictory, and instances where it is not followed, as well as cases of good practice and clear guidance. There is therefore a strong case for the study to examine the guidance and recommend improvements in both the guidance itself and its implementation.

CASE STUDIES

Introduction to Case Studies

521 The following sections of this report describe case studies investigated as examples of the working of the scientific advisory process.

522 Throughout the case studies, the focus of attention was on the process of securing expert scientific advice and on the use of the advice in decision-making, but not on whether the advice given by experts or the decisions taken were correct.

523 Within each case study, the origin of the policy question, the definition of the scientific question, the selection and briefing of advisers, the process of generating scientific advice, and the use of that advice in policy-making were all considered.

524 The case-study histories are based on documentary records, published by government or public inquiries, or published privately, and on a series of interviews with key individuals involved in the cases. The case studies are only concerned with the way in which the scientific advice was sought, provided, and used—not with the scientific issues themselves. The case studies necessarily contain a mixture of factual record and the personal perspectives of those involved. These are recorded without comment or attribution.

525 Some of the case studies examine issues that are ongoing, and on which new scientific advice is being sought, and new policy being developed. The focus of this study has been on the advisory processes, rather than the advice itself, so the case studies concentrate on the historical elements of these issues, rather than the more immediate and contentious aspects.

E. coli O157 Food Poisoning in Scotland

Origins of the Issue

526 Many strains of the bacterium *E. coli* can be present in the human gastro-intestinal tract without causing any illness. Certain strains, however, produce toxins that are extremely harmful, especially to young children and the elderly. One such strain is *E. coli* O157:H7, which was the agent responsible for an outbreak of food poisoning in central Scotland in late November 1996 that resulted in several hundred infections and 18 deaths.

527 This particular outbreak was traced to a butcher's shop, where poor hygiene and poor maintenance of separation between cooked and raw meat are thought to have led to the incident. Furthermore, unknown to environmental health officials, a substantial wholesale business was in operation at the same premises, and thus the potential scale of the outbreak was not immediately apparent.

528 *E. coli* O157 was first associated with a significant outbreak of infection in the USA in 1982, which was eventually traced to contaminated hamburger meat. There was a major incident in Washington State in 1993, in which 700 were infected and 4 died, while, in the UK, isolated cases were also observed as early as 1982. By 1995 it had been noticed that there was an unusually high incidence in Scotland. An outbreak in West Lothian in 1994 affected 100 people, and one child died; the outbreak was traced to contaminated milk.

529 *E. coli* O157 is found in the gut of cattle, sheep and pigs, in which animals it does not appear to be pathogenic. It is believed that the main reservoir is cattle, and that approximately 15% of these animals may harbour the organism.

530 The source of human infection is almost exclusively contaminated cattle faeces. There are also instances of human-to-human transmission, due to handling soiled clothing, for example. A common route is consumption of meat that has become contaminated with faeces during the slaughtering process, and has not been properly cooked. However, direct contact with farm animals may also sometimes be a route of infection.

531 At the time of the central Scotland outbreak, all of the above was known to public-health experts in Scotland, although few general practitioners or environmental health officers would have had professional experience of *E. coli* O157 food poisoning. The symptoms of infection by this organism are common to a number of other disease states, and confirmation of diagnosis is by microbiological testing.

532 This case study examines the role played by expert scientists in the discovery of the outbreak and the response to it—both in containment and in subsequent development of policy to prevent its repetition.

Framing of the Question

533 One of the special features of this case is that the scientific advisory process was triggered by the occurrence of an emergency—an outbreak of serious food poisoning. Thus, one of the key problems was detection. A subsequent problem was the correct identification of the cause and source of the outbreak, and the final problem was to develop policy for the prevention of future episodes.

534 Although each of these issues was examined in the course of this case study, it emerged that the first two problems were solved by procedures that already existed, without additional special recourse to expert scientific advice. These problems are only commented on briefly here. The third problem, however, did prompt expert scientific advice to be sought, and is developed in much more detail.

535 The Health Boards and the laboratory staff and general practitioners had policies and procedures in place for detecting outbreaks of food poisoning.

536 The requirement for fundamental scientific advice was minimal because the pathogenic organism had been identified at the detection stage, and its characteristics and typical modes of transmission were well known. However, experts from several disciplines were engaged to assist in determining the source of the outbreak so that it could be controlled.

537 The requirement for policy advice on the future safety regime was a problem that could be addressed more formally, but still with a degree of urgency. It was an issue that had already been considered by standing advisory committees [543, 552], but this outbreak stimulated new advice.

538 The questions posed by the Scottish Office, as will be seen below in the terms of reference of the Pennington Group [547–548], sought recommendations for action, and were thus not entirely limited to scientific issues.

539 Although there were many calls for a public inquiry, the accident was formally investigated through the mechanism of a fatal accident inquiry (FAI). Owing to the legal framework of such inquiries (the Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976), matters relating to the 255 non-fatal infections were not considered, and the Sheriff did not have authority to make recommendations. In addition, the concurrency of the Pennington Group's work with the criminal proceedings against the butcher at the centre of the case and his company may have restricted the freedom of the Group to comment on those aspects of the case that were sub judice.

540 It appears that, despite the conflicting pressures of this complex arrangement of inquiries, all the relevant facts did emerge.

Selection and Briefing of the Advisers

541 The detection of the outbreak may be viewed in two parts: first the detection of practices that were hazardous, before the event; and second, the detection of the event itself.

542 Local authority environmental health officers were responsible for carrying out a regime of inspection and monitoring of butchers' shops. Although the effectiveness of this regime was a subject of the Pennington Group's inquiries [548], the detection of hazardous practices itself did not require expert scientific advice.

543 An emergency-response plan was already in place that provided for the formation of an outbreak control team (OCT), responsible for responding to any sudden epidemic identified in the human population. This plan had been set out by the Scottish Office Department of Health Advisory Group on Infection in 1996 (Scottish Office, 1996).

544 This document set out the statutory requirements for Health Boards and local authorities to cooperate over outbreak control, and defined their shared and individual responsibilities. The Health Board informed the Environmental Services Department of North Lanarkshire Council about the occurrence on the first day of the emergency and an OCT was formed the following day.

545 The OCT for this incident comprised the following.

- A Consultant in Public Health Medicine (Communicable Diseases/Environmental Health) from Lanarkshire Health Board (Chairman).
- The head of Protective Services, North Lanarkshire Council.
- Representatives of:
  - the Lanarkshire Health Board;
  - local hospitals and National Health Service Trusts;
  - the Scottish Centre for Infection and Environmental Health;
  - the Wishaw Health Centre; and
  - the Scottish Office (as observers, from November 28th).

546 It was a tactical team of people with executive powers and good local knowledge. The team was effectively chosen in advance of the outbreak, following the procedures of the emergency-response plan. The team was therefore not necessarily independent of all the organisations responsible for the prevention of food poisoning.

547 In a separate development, the Pennington Group was appointed by the Scottish Office, only six days after the discovery of the outbreak, with the following terms of reference:

> to examine the circumstances which led to the outbreak in the central belt of Scotland and to advise the Secretary of State for Scotland on the implications for food safety and the general lessons to be learned.

548 The Pennington Report adds, in relation to the terms of reference:

> We were asked to examine the present knowledge of *E. coli* taking into account scientific research in this area, and the adequacy of present arrangements for, and guidance on, handling food poisoning outbreaks. The Secretary of State asked us to let him have any priority recommendations we wished to make by the end of 1996.

549 All the members of the Group were appointed by the Scottish Office. The Chairman, Professor Hugh Pennington, was, and remains, a prominent academic and a

leading expert on the organism involved in the outbreak. He did not play any part in the selection of the other members, who were:

- Dr John Cowden, Consultant Epidemiologist, Scottish Centre for Infection and Environmental Health;
- Dr Helen Zealley, Director of Public Health, Lothian Health Board, and Chair, Scottish Group of Directors of Public Health;
- Mr John Summers, Director of Technical and Leisure Services, Moray Council, and Immediate Past President of the Royal Environmental Health Institute of Scotland;
- Mrs Ann Foster, Director, Scottish Consumer Council;
- Dr Rosalind Skinner, Head of The Scottish Office Department of Health, Public Health Policy Medical Division;
- Mr Stephen Rooke, Chief Food and Dairy Officer, The Scottish Office Agriculture, Environment and Fisheries Department.

550 The establishment of the Group as a separate entity from the existing UK-wide body—the ACMSF—may have reflected the need for a focus of expertise in Scotland where *E. coli* O157 was unusually common. In scientific terms, there was no obstacle because the required expertise was readily available in Scotland.

551 There was one consumer representative, and all of the other members were either public servants or academics. There was no veterinary expert. Overall, therefore, the group was not constituted to be well balanced, although its members had first-hand knowledge of the issues.

552 The composition of this Group was different in character from that of the standing ACMSF, which had a broad mix of membership from local government, clinical medicine, medical science, the food industry, public health and consumer-interest backgrounds. Members of the ACMSF were, at the time, predominantly, but not exclusively, expert scientists. Central-government representation was relegated to a second tier of 'assessors' who attended meetings. However, the ACMSF working group on verocytotoxin-producing *E. coli* (of which the most important is O157:H7) had eight members broadly reflecting the composition of the parent committee, but with a greater emphasis on scientific expertise. There was a consumer-interest representative on this working group.

Preparation of the Advice

553 The Pennington Group took both written and oral evidence from all of the interested parties, visited the butcher's premises and interviewed members of the OCT. It interviewed senior officials from the various regulatory departments and agencies involved in both prevention and emergency response. It also studied the histories of previous outbreaks.

554 It considered papers submitted by its own members and, more generally, it relied upon their background in the field. There was a feeling within the Group that there was an opportunity to make a change—in particular, to reverse the deregulatory tendency that had characterised the control regime in the years before the outbreak. There was also a sense of mission—to improve food safety. The Group sat from early December 1996 and produced its final report on April 8th 1997.

555 An interim report was issued on January 15th 1997, addressing research into the incidence of *E. coli* O157 in animals, surveillance of pathogens in food, enforcement measures and outbreak management. On enforcement, the Group recommended:

- legislation on selective licensing of food premises;
- physical separation, within food premises, of raw and cooked meat;
- measures to promote awareness of the health risks;
- acceleration of the introduction of the Hazard Analysis and Critical Control Point (HACCP) system—the emerging global methodology for assessing and controlling food-related risks.

556 It was felt that the OCT had acted swiftly and with vigour, and was ultimately successful in containing the outbreak. The Pennington Report stated that:

> the guidelines, and the arrangements put in place locally for outbreak management and control, apparently worked reasonably well in practice—albeit that the nature and scale of the outbreak presented a stern test and challenges to the system.

557 Nevertheless, the OCT at the time identified gaps in scientific and technical understanding that hindered its work.

558 The final report of the Pennington Group produced further recommendations, including:

- increased awareness of *E. coli* O157 among farm workers, and precautions at farms to avoid transmission of infection to farm workers;
- improvements in cleanliness of animals presented for slaughter, and the adoption of HACCP and other measures at abattoirs to minimise the risk of contamination of carcasses;
- pending implementation of HACCP, arrangements for selective licensing of premises not already covered by the Meat Products (Hygiene) Regulations 1994;
- licensing to ensure: staff training, record-keeping to facilitate product recall, and physical separation of raw and cooked meat, and of equipment and staff involved in their preparation and sale;
- various measures relating to policy and resources for enforcement, research, surveillance and outbreak control.

559 The report stated that, while the Group had studied the central Scotland and other outbreaks exhaustively, it had also taken into account more general concerns about the incidence of food poisoning, and the wider socio-economic impacts of the preventative measures it was proposing.

560 The Pennington Group recommended, in its interim report, that the government request the ACMSF to review the Pennington Group's guidance on cross-contamination. This was done, and the report by the Working Group set up by ACMSF for this purpose was appended to the Pennington Group report. In summary, it concurred with the idea of expediting the implementation of HACCP, but it said that a prescriptive interim regime would send the wrong messages to duty-holders and would lull them into the false sense of security that code compliance offers. It did not accept that spatial separation of raw and cooked meats was necessary in all food businesses. This technical point reduced to a dispute as to whether separation in time (subject to suitable disinfection procedures) could be equally effective as separation in space. The ACMSF Working Group felt that the achievement of food safety had more to do with the level of awareness of personnel involved in the industry than with adherence to rules. It felt that hazard analysis would identify the key processes for which separation was necessary, and would therefore offer a greater assurance than any prescriptive scheme.

561 The Pennington Group, in its final report, commented on this as follows:

> We welcome the broad level of agreement that clearly exists between our Group and the ACMSF and the supportive nature of the Working Group's report. We have considered very carefully the points that have been made about the issue of separation. We cannot share the ACMSF's confidence in existing food safety legislation, however rigorously enforced, as an adequate means of protection for the public against *E. coli* O157. For that reason, and for the reasons set out earlier in this Chapter, we therefore remain persuaded of the need for the physical separation measures we have specified and of the need for licensing to bridge the gap until HACCP is universally implemented.

Use of the Advice in the Policy Decision

562 The interim report of the Pennington Group was received on January 15th 1997 and a statement was made in Parliament by the Secretary of State for Scotland the same day. The interim recommendations were accepted in full. Directions were given to the relevant Scottish Office departments, Health Boards and local authorities to review their procedures and to respond in time for their views to be taken into account during the remainder of the Group's investigations.

563 When the final report was published on April 8th 1997, a further statement was made by the Secretary of State for Scotland, in which it was again declared that all of the recommendations were accepted. On the issue of licensing, the statement confirmed that immediate action had been taken to ensure that the existing powers were fully utilised and that regulatory attention was focused on those premises presenting the greatest risk. A commitment to decide on the funding of local authorities' increased enforcement activities was promised as soon as possible after the general election on May 17th 1997 (by then imminent).

564 The statement went on to confirm the government's intention to implement, throughout the UK, selective licensing arrangements for certain premises not already covered by the Meat Products (Hygiene) Regulations 1994. In effect, this appeared to mean that the residual area of difference between the Pennington Group and the ACMSF had been decided in favour of the former.

565 The licensing measures have not yet been implemented, although they are due to come into force in October 2000.

Observations

566 Two members of the Group had direct and ongoing involvement in the control of the outbreak—their interest in that matter could have caused a conflict, but it does not seem to have done so. Another potential difficulty lay in the Chairman's involvement in research in the field, which could have been perceived as a conflict of interest affecting the recommendations of the Group that pertained to research.

567 There was considerable press interest in the progress of the outbreak, and the work of both the OCT and the Pennington Group.

568 The FAI report favoured a smaller team for the OCT, and suggested that, in view of the limited personnel resources available to some local authorities, it might be better to have a central team to cover the whole of Scotland. Such a team would be better qualified, would have authority to cross local-authority borders, and powers to close down business operations, etc. Such a group could also be independent of the local bodies (although still dependent upon them for information).

569 Much has been made of the differences of professional opinion between the Pennington Group and the ACMSF, and between the Scottish authorities and those in England and Wales. In this study, a high degree of agreement between these parties was observed, although there was a difference over the use of prescriptive standards as a short-term solution.

570 The Pennington Group strongly endorsed the HACCP approach as the long-term solution, thus aligning policy in Scotland with that in much of the rest of the world. This was also the solution favoured by ACMSF and MAFF. The proposal to introduce licensing of certain premises based on certain prescriptive standards was seen as 'a short-term measure while HACCP systems are being introduced' (Pennington Group report, Chapter 4).

571 Traditionally, safety regulation in many sectors has been prescriptive, setting out minimum standards of behaviour that can be readily verified by inspection. More recently, 'goal-setting' approaches have come into favour, in which the emphasis is on overall performance, and the methods are left more open. In the latter regime, as applied to food safety, responsibility is firmly pinned on the participants in the supply chain, and the focus of regulation by government is on the auditing of management systems, with reduced levels of policing performance in premises. The HACCP system is a management tool that duty-holders can use to discharge their obligations under such a regime, and the inspectors can audit it.

572 This case was characterised by ambiguity about the function of key advisory bodies, regulation and stakeholder interests. For example, both the ACMSF and the Pennington Group comprised a mix of experts and stakeholders. The two groups came to different conclusions on aspects of the regulatory mechanism, possibly because of the different mixture of stakeholder representatives on the two committees.

573 The Pennington Group came to its task with many years of experience and well-formed views. This was seen as a virtue in a situation where urgent action was required, although it inevitably brings a risk of bias, or of failure to assimilate evidence objectively.

574 The Scottish Office appointed the Group, and the procedure does not appear to have followed any particular guidelines, such as those of Nolan.

Robustness of the Process

575 The public interest was represented indirectly through the very few consumer representatives on the various committees. The FAI sat in public, but its powers were significantly restricted, especially in the area of recommendations. Thus, public participation was very limited, and, if the outcome had been less clear-cut in assigning blame for the outbreak, the public may have been less ready to accept subsequent policy changes. Therefore, this process may not suffice for some other outbreak where the blame for the incident could not be assigned.

576 The recommendation by the Pennington Group to pursue the licensing regime has not yet been implemented (although it is expected that it will be implemented in Scotland in October 2000). There was insufficient general support for licensing, especially as a temporary measure that did not fit well with the agreed long-term solution.

577 The Group recommended a specific course of action, instead of limiting itself to scientific issues. In part, this was because the Group had never seen itself as purely an

expert body, more as an ad hoc working party, with an objective to recommend new policy. This ambiguity risked the following possible outcomes:

- the Group is actually an expert scientific body, but nevertheless makes policy recommendations dependent on expertise it does not possess;
- the Group is actually a stakeholder group, and gives advice that appears to be scientific, but is in fact partially driven by policy aims. This distorts its interpretation of the science, and risks the development of policy that conflicts with scientific consensus and may be ineffective.

Margins Around Field Trials of Genetically Modified Crops

Origins of the Issue

578 A great deal of controversy surrounds the developing, testing, licensing, marketing, and growing of GM food plants, and the use of GM crops in food products. The policy questions facing decision-takers are complex. Scientific advice, along with many other considerations, has informed the development of policy in this area.

579 This case study on margins around field trials of GM crops has been carried out in order to illustrate the process by which government has taken scientific advice to answer a particular, well-defined question on the width of margins around fields where GM crops are being grown on a trial basis. This particular question has been chosen as an example of how government has taken scientific advice and used it to inform policy-making; it is not intended to cover all the issues raised by government's handling of the debate on GM food. The wider debate on GM food is beyond the scope and remit of this project, which examines particularly the process by which government obtains expert scientific advice, and incorporates it into policy decisions.

580 Margins, also called separation distances, define a minimum gap between GM crops and other crops. They are designed to maintain a low incidence of cross-fertilisation of non-GM crops outside the delimited trial areas, and to provide a physical separation from natural habitats. Volunteers (plants that grow from seeds that drift across field boundaries or are spilled, or plants that regrow from previous years' use of the land), are also controlled by management of the site both during and after the trial.

581 The licensing of GM crops, for trials or commercial production, is carried out in England by the DETR and MAFF acting jointly. Their concern is that the GM crop should cause no harm to the environment. Consents for experimental trials may include conditions that specify the width of the margins, and may also prescribe what may, or may not, be planted in neighbouring fields. Consents for commercial production are only awarded to the owner of the seed on an EU-wide basis by member states acting jointly, and are a general permit to allow the seed to be sold to farmers. However, consents do not govern the behaviour of the consent-holder's customers (farmers).

582 A critical issue for the agricultural industry is the purity of seed varieties. MAFF is concerned that there should be no commercial impact on other farms from trials or commercial production of GM crops. This is quite separate from any consideration of the health or environmental implications of trials of GM crops, which are governed by the licensing process. MAFF, however, has no authority to impose conditions on growers.

583 These functions of the DETR and MAFF are linked under legislation and by a Memorandum of Understanding, and in that both aims—protecting the environment from volunteer plants, and protecting neighbouring crops from contamination—depend (partly) on the width of margins around the field.

Framing of the Question

584 There are two separate questions.

- What margin is necessary to protect the environment during a trial?
- What margin is necessary to protect the commercial interests of neighbouring farms during production?

585 The first is posed by DETR/MAFF to ACRE; the second has been addressed by MAFF.

586 DETR/MAFF pose the first question to ACRE explicitly as part of the process of licensing a trial. The applicant proposes margins, and ACRE may either accept or increase them, or recommend that the application be rejected [594, 602].

587 DETR/MAFF have to ensure safety for human health and the environment. It invites ACRE to apply the precautionary principle, but expressly states that the committee is not mandated to weigh up the benefits. The European and UK legislation requires the decision on permitting a release to be taken solely on the basis of safety of human health and the environment. Any potential benefits cannot be taken into account. This is analogous to the Medicines Control Agency, which does not consider efficacy. There is thus no attempt at risk–benefit analysis. UK policy was explained in March 2000 by Mr Michael Meacher, Environment Minister, who said 'I want to make it perfectly clear that there will

be no commercial growing of GM crops in this country until we are satisfied that there will be no unacceptable effects on the environment. We can only find this out by testing under farm conditions'.[2]

588 However, ACRE's perception is that it ought to consider benefits. Concern has been expressed that ACRE is widely expected to decide whether the benefits of a proposed GM product outweigh the risks, which is outside its competence.

589 MAFF became aware of industrial concerns about cross-contamination, and consulted the industry in 1997, in order to answer the second question given above. The trade association, the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC), offered to investigate the issue, and prepared guidelines [596]. MAFF allowed the industry to frame the question of separation distances for itself, arguing that this would be more effective than waiting to create new regulations.

590 ACRE is aware of the second question on the commercial purity of seed, in that it assumes that applicants have prepared their applications in accordance with the SCIMAC guidelines. If different separation distances are required to protect the environment, ACRE can specify these.

Selection and Briefing of the Advisers

591 The DETR, MAFF and the devolved administrations appoint experts to sit on ACRE. A number of new members were appointed to ACRE in 1999 following the expiry of the previous Committee's term of office. New ACRE members were appointed by strict adherence to Nolan principles. The vacancies were advertised widely, and an independent sift panel was appointed to judge the applications against pre-agreed and published criteria, and to draw up a long list of potential candidates, solely on that basis. Interests (such as employment by the agri-biotech industry or pressure groups) were not considered. Ministers then selected experts from this list. The press reported a 'purge' of interests—the selection of only experts without any industrial affiliations from the long list.

592 ACRE members are paid the standard daily allowance (around £150 in 1999) for attendance at meetings, and they receive travel expenses. In practice, they do much unpaid work in preparation for meetings.

593 MAFF used its own staff, in the Chief Scientist's Unit, to comment on the draft Code of Practice on crop management, prepared by SCIMAC. MAFF also commissioned the John Innes Centre to research the specific issue of the relationship between GM crops and organic farming. MAFF also took advice from the DETR.

Preparation of the Advice

594 A critique of each application is prepared by DETR staff for ACRE. This is a scientific task, in which the staff pre-filter the applications before ACRE's assessment, to reject those which are bound to fail for reasons of incompleteness, or other errors in preparing the application. ACRE can recommend that Ministers accept or reject an application, and it can recommend amendments.

595 A crucial scientific judgement is whether the GM crop has a general survival advantage that would lead to amplification of genetic stock in subsequent generations. Such risks are always considered as a specific requirement of the legislation that has been in force since 1993. To date, it has always been concluded that the genetic modification only provides an advantage in the context of a managed environment (eg, herbicide tolerance is specific to a single herbicide, and other herbicides or natural hazards affect GM and non-GM crops equally). However, there may, in the future, be applications for crops modified to be resistant to fungus or invertebrate pests, which could contribute to the risk of amplification.

596 SCIMAC prepared a draft Code of Practice covering many aspects of the introduction of GM crops. It identified and mandated good practice in crop rotation and separation to avoid contamination (a non-pejorative term, meaning the unintended presence of a foreign plant or part of a plant). The industry has a long-established set of separation distances to allow different varieties of the same species to be sold as certified seed. The aim is typically 98% purity—that is, up to 2% of certified pure seed may be other than the intended variety. Similar arguments have been used for organic crops, where the separation distance between certified organic crops and non-organic crops is such that around 98% of the harvested crop will satisfy the organic growing rules.

[2] http://www.cabinet-office.gov.uk/gm-info/1999/gmcrops.htm

597 The SCIMAC draft Code of Practice recommended that the same separation distances should be used between GM and non-GM (including organic) crops as is already used between certified seed varieties. This is based on the assumptions that:

- the same level of purity is commercially acceptable;
- GM crops have no survival advantage that would lead to amplification of contamination in successive generations.

598 MAFF staff reviewed this and found that the assumptions were acceptable. MAFF asked SCIMAC to include in the final version of the Code of Practice an explicit statement of the separation distance required, rather than just stating that it was the same as that required for certified seed.

599 The SCIMAC Code of Practice requires different separation distances for different seeds, and for different levels of certification of the same type of seed. The required distances range from 6 to 600 metres. As the industry association, SCIMAC is able to force farmers to follow its guidelines by withdrawing access to GM crop varieties following infringements, through its control of the supply of seed.

600 A study undertaken by the John Innes Centre, commissioned by the Soil Association, concluded that a separation margin of six miles would be needed. This impractical figure was the result of setting effectively a 'zero-risk' standard. This may be contrasted with the organic agriculture industry's position with regard to cross-contamination of organic by non-organic crops, which is far less extreme. The zero-risk target, if accepted as necessary, would be a major challenge to the GM industry because it is impossible to eliminate all contamination—a single bee may fly many miles and deposit one grain of pollen from a GM crop onto an organic crop. The study by the John Innes Centre recognised this:

> No system for the field production of seed can guarantee absolute genetic purity of seed samples. Very rarely long distance pollination or seed transfer is possible, so any criteria for organic crop production will need to recognise this. There has always been the possibility of hybridisation and seed mixing between organic crops and non-organic crops. Organic farming systems acknowledge the possibility of spray or fertiliser drift from non-organic farming systems, and procedures are established to minimise this.

601 The study also drew attention to the practice of sourcing organic seed from other countries where the production criteria may be different. The overall conclusion is that some form of separation distance, together with other measures such as cleaning of implements, will have to be adopted by the organic agriculture industry.

Use of the Advice in the Policy Decision

602 ACRE's recommendation has always been accepted by the DETR and MAFF.

603 If ACRE recommends that a particular trial be permitted, it is on the basis that no significant harm to the environment will result from the trial.

604 MAFF's policy decision was to adopt the SCIMAC Code of Practice. When it was presented to the public, a widespread misunderstanding developed that the separation distances would ensure that no contamination would occur. The John Innes Centre study was then seen to undermine government policy because it stated expressly that there would be contamination.

Observations

DETR

605 The function of ACRE is crucial, although it is not clear that ACRE perceives its own function in the same way as the DETR. The absence of any formal risk–benefit assessment, together with Ministerial wishes not to allow any GM product to be grown unless it is safe, indicate that consent is only given if risks are negligible. This is also a requirement of the legislation. It could be argued that, if there are risks, benefits should be assessed, and only if the benefits outweigh the risks should consent be granted.

606 Expert panels sometimes have lay or representative members; ACRE used to have one member from an environmental and public-interest group. The new ACRE members have no industry links, and were selected from a list of experts (leaving no room for a non-specialist). The Committee has no representatives or lay members.

607 The organic agriculture industry has not accepted the principle of an acceptable level of contamination, so their concerns have not been answered by the use of margins.

MAFF

608 MAFF has scientific expertise within its Chief Scientist's Group, which was able to comment on the draft SCIMAC Code of Practice. It was also able to commission the John Innes Centre to carry out an independent scientific analysis.

609 The agriculture industry recognises the need for sensible regulation to maintain purity of crops. It therefore funded and commissioned its own scientific advice, leading to a policy for government to endorse. Self-regulation is arguably quicker and cheaper than statutory control, and, in this case, has introduced commercial penalties for non-compliance that would be difficult to implement within the legal system. The industry welcomed Ministerial support and cooperated with MAFF to ensure that the decision was one that the Minister could endorse.

610 The problems resulting from the John Innes Centre report showed that a more open explanation of the risks, although difficult to present, would have pre-empted the subsequent embarrassment. The policy had been portrayed (and possibly presented) as setting separation distances which ensured that there would be no contamination, whereas the policy had always been that there would be an acceptably low level of contamination.

Robustness of the Process

611 The *findings* of this process (ie, consents containing separation distances) were, in the event, challenged by pressure groups opposed to genetic modification in principle, whose position was that the acceptable level of cross-contamination should be zero. That has left the issue unresolved because the wider issues surrounding the acceptability of GM food have not been addressed.

612 Surprisingly, the reliance on the SCIMAC guidelines has not attracted much challenge, but it remains a weak point in the process because of the lack of independence of SCIMAC in the matter.

613 The two government departments involved necessarily had different approaches to setting separation distances, which were difficult to explain to a wider audience.

The Structural Integrity of the Forth Rail Bridge

Origins of the Issue

614 The Forth Bridge was built over 100 years ago. Its maintenance has been part of folklore—as soon as the painters finish, they start again at the other end. In the 1990s there was public unease about the state of the bridge. The maintenance regime had changed, the bridge appeared to be rusty, and material had fallen from it.

615 The issue was of great political sensitivity because of the recent privatisation of the rail network, and because this Scottish landmark was under the stewardship of a company with headquarters in England. The routine assessment and approval of the structural integrity of a bridge became the subject of hostile local press attention.

616 Stephen Norris, then Minister with responsibility for transport and roads, took up the issue, in response to questions raised in Parliament. He requested advice from HM Railway Inspectorate, within the HSE.

Framing of the Question

617 The Minister informally posed the question of the safety of the bridge to the Director General of HSE. The latter, with HM Railway Inspectorate, identified the essential issues and framed two questions.

- Is the bridge safe to carry the weight of the trains that use it?
- Is the future of the bridge secure?

618 The first question required a condition survey (to establish the current state of the structure), and a structural analysis (to establish whether the existing structure met current design codes). The second required an analysis of the maintenance regime established and operated by Railtrack.

619 HSE conducted an initial inquiry using in-house expertise to establish whether there was a substantial case to consider. This convinced Railtrack (which is responsible for maintaining a safe bridge) that it should take action. This is standard practice where activities are regulated by a safety-case regime. The process is one of constructive challenge and dialogue in which either the duty-holder satisfies the regulator that the measures in place are suitable and sufficient, or the regulator acts to secure remedial action, either by persuasion or compulsion.

Selection and Briefing of the Advisers

620 HSE recognised that it was Railtrack's duty to provide a safe bridge and, therefore, that Railtrack should take the lead in checking and demonstrating that the bridge was indeed safe.

621 HSE and Railtrack agreed that:

- they would address the first question jointly and set up a joint steering group to oversee the project;
- Railtrack would appoint and pay a consultant (Pell Frischmann) to carry out the condition survey and structural analysis;
- Railtrack would remain responsible for decisions based on the consultant's results;
- HSE would place its own experts (from the Health and Safety Laboratory and elsewhere) on the technical sub-committee of the steering group.

622 The consultant appointed was a frequent contractor to Railtrack. The reputation of the consulting company, and the professional standing of the individual engineers, were not in doubt. It could be argued that it would have been difficult to find a consultant that had the necessary experience and was also completely independent of Railtrack.

Preparation of the Advice

623 It was quickly apparent to the joint steering group that a full structural assessment was not necessary to answer the questions concerning the safety of the bridge. The experts from all three parties (Railtrack, HSE, and the consultant) jointly agreed approximations and assumptions that were reasonable and necessary to answer the two questions without complex modelling. Conventional engineering practice is to make conservative approximations, although there appears to have been no formal attempt to estimate the reliability of those approximations in this case.

624 It was concluded that the answer to the first question was that the bridge was safe to carry the weight of the trains that use it, but

that the answer to the second question was that the maintenance regime was not adequate to ensure its future. Consensus on the definition of a new regime was reached, although there were some initial differences of technical outlook and methodology between Railtrack and HSE. Again, such differences are part of the challenge and dialogue that characterises the relationship between regulator and duty-holder in a safety-case regime.

Use of the Advice in the Policy Decision

625 HSE issued a formal Improvement Notice to enforce the immediate actions of the revised regime. Railtrack subsequently revised its procedures for approximately 30 major assets.

626 HSE prepared a short report that summarised the work carried out and the conclusions reached. It stated in absolute terms that 'the Bridge is safe, in its current condition, to carry Railtrack's present loading.' The report included an engineering annex that summarised the consultant's report and stated the approximations that had been made.

627 The Minister accepted these without qualification, and HSE held a press briefing and published the report. The report appears to have been accepted by the local public and no further action was required.

Observations

628 This case is instructive for several reasons.

- HSE acted both as the link between the policy-maker and the expert scientific adviser (in this case, the duty-holder under a safety-case regime) and as the regulator in producing evidence that required the duty-holder to take action.
- Railtrack had responsibility for maintaining the bridge in a safe state and this duty extended to the provision of such information as the regulator (HSE) needed. The potential conflict of interest, arising from the duty-holder providing advice on whether its duties were being adequately discharged, was resolved by the personal standing of the engineers (primarily those of HSE, but also those of Railtrack and its consultant), and the statutory authority of HSE.
- The methodology and the final report were based on the engineering judgement of all parties.
- HSE's technical expertise was crucial, in auditing the work carried out by Railtrack and its consultant, and in endorsing the conclusions.
- HSE performed twin functions of constructive cooperation with the duty-holder (and its consultant) and as formal enforcement authority. Both parties were aware that HSE held the power of veto.
- The outcome of the process was successful.

629 The advisory process was not a simple one-to-one relationship of adviser and decision-taker; a network of experts was involved. HSE helped the Minister to frame the question, audited work of the experts, and framed the conclusions for the Minister, acting as a policy-maker. The scientific information was generated by Railtrack and its consultant, in a process that was closely audited by HSE, represented by its own technical experts on the steering group that managed the process, and the sub-committee that dealt with technical issues.

630 This interaction between HSE and Railtrack was necessary because railways operate a safety-case regime, where the duty-holder must decide what it is going to do and submit its case for approval by the regulator.

631 The process was largely open, in that the published report to the Minister explained the methodology, assumptions and approximations, and named all of the parties. It was not open, in the sense that there were no stakeholders present when the work was being conducted. HSE, as policy-maker and regulator, had to judge whether the approximations and assumptions made in the analysis were acceptable, weighing the risk that the assumptions were invalid against the cost of a more exhaustive inquiry.

632 The Minister reached the conclusion that the report would be acceptable to the public. Subsequent public reaction bore this out, which suggests that the model of a trusted regulator, backed up by statutory regulatory powers, was able to produce an outcome acceptable to the general public and the press in this case.

Robustness of the Process

633 If the outcome of the approximate structural analysis had been less clear-cut or indicated that the safety margin was smaller, then there would have been a need for much more detailed surveys and stress calculations. It is not obvious that the same team would have been able to do this work, or how the financial resources would have been found. The extra costs could have been considerable, and this might have put pressure on the team to avoid this course of action. The studies would have taken longer, and the question of whether the bridge should be closed during the investigation would have to have been addressed. This would have been a decision to balance a short-term safety risk against considerations of commercial and public disruption.

634 HSE engineers and the Railtrack/Pell Frischmann engineers could have disagreed about methodology or results. It is not clear whether the process actually employed provided for this eventuality. If discussions on methodology or results were based on the professional standing of the individual engineers involved, it is not clear that the engineers acting on behalf of the regulator would have prevailed in any disagreement, or how the process could ensure that this would have happened.

635 The Minister or the general public might not have accepted an outcome based, even partly, on the work of a firm of engineers, however reputable, which worked frequently for Railtrack. Given the type of work involved, it is not clear that a frequent contractor to Railtrack would necessarily have been more suitable (on grounds of competence or cost, for example) than any of a number of civil or structural engineers with experience of bridge design and structural analysis, outside the pool frequently employed by Railtrack. Such experts could have been engaged on an 'arm's-length' basis, perhaps through HSE.

636 A key factor in this case was the confidence of policy-makers in the ability of HSE to engage in technical dialogue with the duty-holder. This was based on HSE's possession of sufficient in-house expertise to ensure that technical questions are properly addressed by duty-holders and any external consultants engaged by HSE itself. HSE had access to sufficient expertise, in this case, to audit the work carried out by Railtrack and Pell Frischmann.

Phthalates in Soft Plastic Toys

Origins of the Issue

637 The safety of phthalates used as plasticisers for PVC has been kept under review by the DTI and the LGC for many years. Historically, two phthalates have been used in children's toys: di(2-ethylhexyl) phthalate (DEHP) and di-isononyl phthalate (DINP). DEHP is no longer used in toys or childcare articles which are intended to be mouthed by children.

638 The present concerns arose in April 1997 when the Danish Environmental Protection Agency announced the results of tests that showed high levels of migration of phthalates from children's teethers. The Danes notified the EC, and the machinery of EC regulation began to react. This case study looks at how the UK government dealt with, and sought advice on the issue, in light of new information from the EC.

639 Responsibility for this issue rests with the Consumer Safety Unit of the DTI. Action on this issue at an EC level is ongoing.

Framing of the Question

640 Two questions were posed by the DTI to establish whether action was required.

- What level of exposure to phthalates is safe?
- What quantities of phthalates migrate from children's toys or other items that are intended to be, or might reasonably be expected to be, mouthed?

Selection and Briefing of the Advisers

641 The selection of advisers was automatic. The Department of Health Environmental Chemicals Unit, in the Environmental and Health Branch, advises the DTI's Consumer Safety Unit on the health effects of chemicals in consumer products. The Unit has access to scientific advice on issues relating to toxicity of chemicals from COT. In addition, expert advice on the specialist areas of carcinogenicity and mutagenicity can be provided by the sister committees covering these areas. These committees are established by the Chief Medical Officer (CMO) for England and provide advice to the Department of Health and to other government departments, on request, relating to the toxicity, carcinogenicity and mutagenicity of chemicals. Formal accountability lies with the CMO and advice is passed through him to the departments. In practice this is done by the secretariat, which is provided by the Department of Health.

642 COT was not asked to advise specifically on the question of phthalates in consumer products. However, it had already (in the late 1980s) advised on a range of phthalates in the context of their use as plasticisers in food-contact materials, and, more recently (in 1996), in the context of the presence of phthalates as contaminants in infant formulae.

643 The working of COT is examined in more detail in case study eight [769–860].

644 The second question was addressed to the LGC. Formerly part of the DTI, the LGC was privatised in 1996 and provides research, analytical and advisory services to both the public and private sectors. It has a contract with the DTI for services, including providing it with advice on a wide range of issues, and had been tracking the problem of phthalates in PVC for many years. It was contracted by the DTI to devise a method for the measurement of migration rates and to conduct migration tests. In parallel, the LGC has, with DTI approval and funding, participated in discussions and trials with other laboratories in Europe, looking at various test methods. The LGC has made presentations to the EC and others on the test methods it has developed.

645 The LGC–DTI brief falls within the formal contract for the LGC to support the DTI consumer-research programme on chemical matters. The relationship between the two has been in place for more than ten years, and this continuity has allowed the LGC to maintain expertise and awareness of the issue. The LGC also sometimes attends EU meetings, usually as advisers to the UK delegation.

646 The LGC has also had contact with the phthalates industry. One of its key staff chaired a panel of experts (the Weinberg Committee), convened on behalf of, and funded by, US companies engaged in making or using phthalates. Although this attracted some hostile comment, the LGC and the DTI were satisfied that it created no conflict of interest.

Preparation of the Advice

Toxicology

647 COT had previously advised on phthalates in the context of phthalates in food contact materials and as contaminants in infant formulae. In this case, its approach had been to support the use of tolerable daily intake (TDI) values that had been recommended by the EC's expert advisory committee, the Scientific Committee on Food (SCF)—although, in the case of two phthalates (butylbenzyl phthalate and dibutyl phthalate), further studies were recommended. The TDI is derived from doses that produce no effect in animal studies, divided by a 100-fold uncertainty (or safety) factor.

648 In the case of phthalates in soft toys, the Department of Health's advice to the DTI's Consumer Safety Unit was based on the previously expressed COT view that the TDIs recommended by the SCF were acceptable.

Migration

649 While it is difficult to reproduce the mouthing action on toys, the LGC has developed laboratory-based procedures that produce release rates that closely match those observed in human studies by the Dutch contract research organisation, TNO. These correspond to significantly lower levels of migration than those reported using a different technique in Denmark, which initiated the current concerns. The Danish results have not proved repeatable elsewhere.

Use of the Advice in the Policy Decision

650 The Department of Health's advice to the DTI (based on the opinions of the COT and SCF relating to phthalates in food) was that there were no health concerns if exposures were below the TDI. The LGC's advice on migration suggested that exposures were indeed below the TDI. The DTI concluded that phthalates as currently used in children's toys in the UK pose no risk to human health. However, this conflicted with an 'opinion' of the EC expert advisory committee, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE), which found that there was concern with DINP because the margin of safety was only 75. A subsequent opinion on September 28th 1999 found that the exposure measurements were insufficiently reproducible to form the basis of regulation.

651 The DTI concluded that no ban was necessary, but that migration limits should be introduced. Other European countries do not agree, and several have banned phthalates in children's toys. The EC is divided on the issue. The Directorate General for Consumer Safety and Public Health supports a ban on phthalates. The Directorate General for Industry does not agree that a ban is justified by the evidence.

652 It appears that the DTI has followed UK scientific advice on migration and acted in accordance with a reasonable view of the European advice on toxicology. The DTI has not been subject to the same pressure on this topic from activists, such as Greenpeace or Friends of the Earth, or from phthalates manufacturers, as its counterparts in other countries.

Observations

653 Several issues emerge from this case study:

- the status of a private contractor as scientific adviser;
- situations in which a private contractor represents a government department in international discussions and negotiations;
- the relationship between an adviser and a regulated industry;
- the composition and function of COT;
- the relatively small opposing voice in the UK.

The function of the LGC

654 The LGC continued to act as the DTI's adviser of choice after it was privatised. It has a constitution that prohibits capture by commercial interests. It does enter into contracts with industry, and, for example, provided the chairman of the Weinberg Committee. The LGC appears to have been successful in avoiding conflicts of interest.

655 The DTI chooses to continue to fund research and monitoring (referred to as 'intelligence-gathering') by the LGC which maintains the Laboratory's expertise and capability. If this research were to be dispersed across many contractors, it might be that no single laboratory would maintain the

critical mass needed to provide adequate advisory services. The corollary is that directing funding to only one contractor may restrict the choice of adviser in the future.

The function of COT

656 COT comprises a group of experts, mainly drawn from academia, which responds to questions raised by the Department of Health or other government bodies. The questions are framed by the secretariat. The members receive only nominal payment. A list of candidate committee members is drawn up by the secretariat after open advertisement and selection by an independent sift panel that makes recommendations to the CMO. Constitutionally, the Committee serves the CMO, who appoints its members from the candidate list and receives (and is responsible for) the advice. The working of COT is considered in more detail in case study eight [769–860].

Robustness of the Process

657 A striking feature of the phthalates case in the UK is that the government has not come under public pressure on the issue, in contrast to the situation elsewhere in Europe. Only very recently has the issue come to the attention of pressure groups, and the scientific advisory system in the UK has operated largely unchallenged either by pressure groups or by the phthalates industry.

658 The UK policy remains that phthalates (other than DEHP) in toys are safe, provided that TDIs are not exceeded. It has been difficult to obtain reproducible results from experiments designed to produce an estimate of exposure through mouthing toys.

659 It might be expected that any process leading to a ban would also have considered the alternatives to phthalates, and, hence, the wider consequences of a ban. The plastics industry has pointed out that some alternative plasticisers can make plastic toys easier to tear or bite through, with a consequently greater risk of small pieces breaking off and causing choking.

660 There could have been criticism that the advisory system of the DTI and the Department of Health had not compared the risks from phthalates with risks from alternatives. This would require the synthesis of a wider range of expertise than has been used to date. The question to put to expert scientific advisers would have to change from ‘are phthalates safe?’ to ‘what are the possible ways of making chewable toys that are acceptably safe?’. Although the UK has consistently called for any proposal for a ban to be accompanied by a consideration of the consequences of alternatives, this question has not been addressed by the advisory system.

Total Allowable Catches of Sea Fish

Origins of the Issue

661 For at least 100 years it has been recognised that it is possible to destroy fish stocks by over-fishing, and that it is therefore important to collect scientific data on fish stocks and catch sizes. Most parties involved in the fishing industry now accept that regulation to prevent over-fishing is essential. The Common Fisheries Policy is one of the core policies of the EU.

662 MAFF has lead responsibility for representing UK fishing interests in the EU. The Scottish Executive Rural Affairs Department also plays an important role.

663 There have been attempts to control the size of the catches using many different restrictions, including reducing net sizes, increasing mesh sizes, decommissioning boats, limiting engine size, limiting the days when boats may be at sea, restricting areas that are fished, and limiting annual landings of each species. The aim of regulation has been to maximise short-term production, as well as ensuring the long-term future of the fishery. More recently, advice has been applied in terms of a more precautionary approach.

Framing of the Question

664 The relationship between fisheries policy-makers and their scientific advisers has evolved over time. Historically, politicians simply sought the advice of eminent scientists to tell them what the policy should be. They now seek advice on the amount of fish that can safely be killed each year. This leads to the question: what is the safe total allowable catch (TAC) from each fishery for each commercial species?

665 ICES is asked to define reference or threshold levels for the number of fish that can be killed, and the minimum size of the stock, such that there is a high probability that the population will not crash.

666 Within Europe, this question is put to the International Council for the Exploration of the Seas (ICES). Fisheries scientists from individual countries meet under the ICES umbrella to consider the data each has available from national monitoring programmes. ICES reports form the basis for negotiation of TACs by EC Ministers.

667 A recent report of the House of Commons Select Committee on Agriculture stated:

> We believe that it is important that the advice from ICES is demonstrably scientific and that it is not the body best placed to offer objective economic analysis (eighth report, paragraph 20).

The paragraph continues:

> However, since it is accepted that economic factors should be taken into account in making decisions on allocations, it is clearly preferable that advice on this aspect is published before the recommendations are put to the Council of Ministers. The EC, in collaboration with member states, should continue to develop methodologies for the inclusion of economic criteria for evaluating biological recommendations for fish stocks.
>
> ICES does not (currently) consider economic criteria in recommending a TAC.

668 Although in the past, ICES has considered whether socio-economic issues could be incorporated into its advice on TACs, at present there is no *formal* mechanism for this to happen within ICES.

Selection and Briefing of the Advisers

669 The scientific adviser is ICES, which is made up of scientists from each of its 19 member countries. The scientists work at ICES through a structure of committees to generate a single consensus view. The governments of each of the member countries therefore have the same advice on which to base their negotiations.

670 The UK contributes to ICES via the Fisheries Research Service in Scotland, the Centre for Environment, Fisheries and Aquaculture Science (CEFAS)—a 'next steps' agency of MAFF—and the Fisheries Research Laboratory in Northern Ireland. Scientists from these agencies conduct research for their government departments, and other customers, including private industry. MAFF funds are administered by its Chief Scientist;

there is separate funding for research and for the monitoring work and preparation of advice, although, in practice, the two overlap. There is a strong customer–contractor relationship in force, and it is recognised that research is essential, both to improve the science (especially modelling), and because it is believed that it is not possible to retain good scientists without providing an opportunity to undertake basic scientific research.

Preparation of the Advice

671 The UK government scientists are active members of ICES, which generates an annual report on the state of each commercial species in each fishing area. The input data is sparse: there are a small number of research ships, but most data comes from declared landings, which can be inaccurate and incomplete, and may be biased.

672 The key concept is the safe minimum biological limit (MBAL). A simple interpretation is that a stock is secure if it is above the MBAL. ICES, in its latest annual report, adopted the precautionary principle for the first time.

673 In order to retain harvesting within safe biological limits, there must be a high probability that:

- the spawning stock biomass (SSB) is above the threshold where recruitment is impaired (recruitment takes into account all the factors that affect the rate of resupply of the stock, such as breeding rates and age distribution, and condition of the stock);
- the fishing mortality (which includes all fish deaths caused by fishing, not just landed catches) is below that which will drive the spawning stock under the safe biological limit.

674 Two thresholds are defined to represent these two constraints: B_{lim} (the SSB below which recruitment of new fish to the population is insufficient to maintain the population), and F_{lim} (the mortality above which the SSB will fall below B_{lim}). Two further thresholds are defined, B_{pa} and F_{pa}, which represent the safe thresholds after applying the precautionary approach. The difference between the limiting and precautionary thresholds reflects the uncertainty in the data and population models, and varies between species and fisheries.

675 ICES does not set TACs. It estimates the probability (which is low at F_{pa} and high at F_{lim}) that the stock will collapse at various mortality rates. It also does not attempt to estimate the value of F that would give the maximum sustainable yield (F_{msy}, which is adopted by the United Nations Food and Agriculture Organisation). It makes no commercial, political or economic statements in its advice.

676 The precautionary estimates, F_{pa} and B_{pa}, were first introduced in 1998.

677 An example is the advice given for cod in three sub-areas (North Sea, Eastern English Channel, and Skagerrak) for 1999 (ICES, 1999). The overall advice on management is as follows:

> ICES recommends that fishing mortality in 1999 should be reduced to F=0.60 (below the proposed F_{pa}), corresponding to expected landings of 147,000 t in 1999 in order to bring Spawning Stock Biomass above the proposed B_{pa} in the short term.

678 The table then presents a range of values of F from 0.4 to 0.8, with their implications for landings and the likely SSB that will result in the year 2000. The medium-term effects are expressed as a probability that SSB will be greater or less than B_{pa}. F_{lim} is 0.86.

679 This analysis includes a set of management options and estimates of the implications of selecting different levels of TAC.

680 This presentation has been criticised by the House of Commons Select Committee, which recommended that ICES be encouraged to 'present its advice on TACs in a more generally comprehensible form' (House of Commons, 1999*b*). It is hard to see how it could do so and still quantify the extent of uncertainty in the underlying science. By explicitly quoting the uncertainties and the difference between scientific best opinion and a precautionary position, it gives the policy-maker information on which to make a rational trade-off between commercial interests, conservation interests, and the future of the fishery.

681 Scientific advice is also taken when considering technical measures to be adopted in order to put TACs into effect. These include, for example, restricting access to spawning grounds or setting minimum mesh sizes for nets. Scientific advice is sought on how these restrictions might affect recruitment and mortality of the stock.

Use of the Advice in the Policy Decision

682 ICES estimates the likely consequences for the fish stock of different levels of mortality. The members of its committees, as scientists employed in member states, may also advise on the likely effect of proposed deviations from the TACs recommended by ICES. The policy-making process (at an EU level) translates this advice into controls on fishing.

683 Concern about this process has been expressed by the scientists involved and by the House of Commons Select Committee on Agriculture. Both have called for a more open and direct process. There is concern that the policy-making process in total does not make good use of data that include explicit estimates of uncertainty, and that it distances the science from the decision-making process. Some of the political compromises that have been adopted may conflict with the logic underpinning the scientific advice. For example, the eventual decision on TACs has sometimes reflected a political desire to smooth out large changes in TACs from year to year. However, given a highly non-linear system, such as a fish population, such smoothing may have profound consequences.

684 Fishermen, too, are concerned that there have been sudden and unexpected changes in policy, and would like to see scientific evidence at an (even) earlier stage of the annual policy cycle. There is also concern in the fishing industry that, because the policy is set annually, it lacks continuity.

Observations

685 At one level the setting of TACs could be a model of how to secure and make use of scientific advice. The government employs professional advisers, which it keeps informed by funding research. The advisers work in collaboration with many other scientists to generate a consensus scientific view. The international negotiations can then proceed on a common, agreed scientific basis. The scientific advisers expressly state the uncertainty, leaving to the politician the question as to how much risk should be accepted. The scientific advisers studiously avoid recommending a policy or taking into account any non-scientific issues (such as the economic consequences of the advice).

686 The level of detail in the current scientific advice is not sufficient to indicate the consequences of a wide range of policy options, yet even the level of detail that is provided is thought by some politicians to be hard to comprehend.

687 The introduction of express levels of uncertainty, and of the impact of applying the precautionary approach, provides new and more powerful data on which to base policy options. However, scientists believe that the consideration of other factors (economic, social and political) at a later stage in the (non-scientific) advisory process changes the scientific question that would have been asked.

688 Alternative models are used in other fisheries (for example, in some single-species fisheries in South Africa). Three policy aims can be defined: to conserve stocks, to maximise catches, and to stabilise TACs. The relative weight assigned to each objective is a political decision. Fisheries scientists are then able to model the effect of different levels of TAC, to score the outcomes against the three objectives, and, hence, to optimise the TAC against the stated political goals. On the basis of the outcome of this modelling process, politicians may reconsider the relative weights attached to each objective, and require scientists to recalculate options on the new basis. This model has not yet been used in the major European fisheries. It has the potential advantage that it allows the best use of all of the scientific resources. All interested parties can contribute to an explicit debate to draw up the weights assigned to the three policy objectives.

689 A number of stocks in the North Sea are at extremely low levels.

Robustness

690 The advisory process is robust, in the sense that it achieves scientific consensus on the probability distribution of outcomes, but it is vulnerable to challenge on other grounds. The science delivers a probability distribution of outcomes, but the policy-makers complain that they find these difficult to understand, and the policy-making process cannot currently make good use of them. There is therefore a need to develop ways of expressing uncertainty that decision-takers can accept and use with confidence.

691 The advice provided is for one year only, even though the underlying scientific models run over several years into the future; and the policy might be more effective if it were set for several years at a time.

692 There is a danger that an eventual decision might not reflect the scientific advice because of a false interpretation of the information about uncertainty. If the uncertainty is misunderstood as a 'safety margin' then politicians may wish to use part of that margin in pursuit of another policy objective.

693 A more complex process could be imagined, which would be more robust. It would require the policy-maker to agree with the decision-taker in advance a measure of the effectiveness of a policy, which would take into account not only the yield of the current year, but also future yields, the risk of population collapse and the commercial need for stability in TAC from year to year. Once this measure had been agreed, the scientists would have a more detailed brief against which to prepare their advice, and the advice would be more useful to policy-makers.

The Decision to Construct the Thames Barrier

Origins of the Issue

694 Control of the flooding of the River Thames began in Roman times, but the event that triggered the decision to construct the Thames Barrier was the 1953 disaster, in which 300 people were drowned in eastern England, and about 3,000 in the Netherlands.

695 Central London was not affected by the 1953 flood, but sea defences were overtopped along much of the eastern coast. In response, these defences were raised, and when, in 1965, a tide of similar height recurred, the waves lapped the tops of the parapets in central London, but there was no major overflow.

696 The historical record of extreme tides reveals a general upward trend in record tide heights. The underlying cause of this is now known to be the progressive lowering of the land in south-east England relative to sea level, and the raising of sea level caused by the melting of polar ice.

697 The policy set in the late nineteenth century had been to make the flood-defence level one foot above the highest recorded tide.

698 The capital expenditures for a barrier and associated bank raising were estimated in 1965 to be of the order of hundreds of millions of pounds at today's prices, and the costs of a serious flood, such as had occurred in Hamburg in 1962, were in the order of tens of billions.

Framing of the Question

699 There were two distinct questions.

- What is the appropriate defence level to use as the design basis for the sea defences of the Thames Estuary and the eastern coast?
- Is it right to construct a barrier across the River Thames, rather than the alternative of raising its banks?

700 There was a trade-off to be made between the incremental cost of raising existing defences and the one-off cost of constructing a barrier. If the barrier were to be built, the sea defences downstream of the barrier would have to be raised not only to match it, but also to deal with the additional surge levels that would be caused by the artificial damming of the river against the rising tide.

701 The design height of the defences was crucial because, if the required increase was small, bank raising would be preferred; a larger increase would favour the barrier (by obviating the need for unsightly and impractical bank raising in central London).

Selection and Briefing of the Advisers

702 Within three months of the 1953 flood disaster, the government set up a Departmental Committee of the Ministry of Housing and Local Government, chaired by Lord Waverley, who had been Home Secretary during the Second World War, and subsequently Chairman of the Port of London Authority (PLA). The Committee was given a free hand by the government to develop a policy that would solve the problem, and it enjoyed wide discretion to advise as it thought fit.

703 It reported after a year that further research was needed. In 1954, the Thames Technical Panel was established, comprising the following:

- the Chief Engineers of:
  - the Ministry of Housing and local government
  - the Ministry of Works
  - MAFF
  - London City Council
  - the City of London
  - three London Boroughs (West Ham, Woolwich and Barnes)
  - four river authorities (PLA, Lee, Essex and Kent);
- an Admiralty representative;
- a Trinity House representative;
- a Ministry of Transport representative;
- the Director of the Hydraulics Research Station.

704 This Panel was both a stakeholder body and an expert body. Unlike the Waverley Committee, its terms of reference were clearly specified:

- to make a survey of the existing flood defences;
- to estimate the cost of raising them;
- to advise whether, having regard to navigational and other requirements, the question of a structure across the river merited further consideration;
- to consider the appointment of a consulting engineer and the terms of reference.

705 The Thames Technical Panel and the two firms of consulting engineers appointed on its recommendation[3] (Rendel Palmer & Tritton, and Sir Bruce White, Wolfe Barry & Partners) spent the next seven years developing feasibility studies of the various options. By 1965, several schemes had been worked out in detail, and it was estimated that the costs would be between about £250m and £420m in today's prices. However, 12 years after the last flood, the project had lost momentum and new impetus was needed.

706 The government sought advice from the then CSA, Sir Solly Zuckerman. He recommended that a report be commissioned from a senior independent scientist, and, in due course, Professor Hermann Bondi (later Sir Hermann Bondi) was appointed to this task. Professor Bondi is an astronomer who at the time held the Chair of Mathematics at King's College, London. He is not an expert on flood defences, but he was considered expert in the comprehension of complex technical issues and in the application of scientific methods to such problems.

707 He carried out his investigation alone. It appears likely that he was appointed on the basis of the personal recommendation of Sir Solly Zuckerman. Professor Bondi has been influential in providing scientific advice to the UK government, and has written widely about the scientific advisory process [360].

708 By the time of Professor Bondi's appointment, the Panel and the consulting engineers had carried out a great deal of work, which had generated information about the flooding risk and the costs of flood-defence schemes. Professor Bondi's task was to determine whether a clear recommendation for action could be made on the basis of this information.

[3] The Thames Technical Panel recommended that three firms be appointed, but the government reduced this to two.

Preparation of the Advice

The Waverley Committee

709 Although the Waverley Committee was concerned mainly with policy and finance, it made two major decisions that defined the functional requirements of the flood-defence project.

- Any barrier across the river would have to be movable so that the interests of the PLA and ship operators would be preserved, and to avoid the risk of disturbing the natural flushing action of the tides and the stability of bottom silts.

- The Committee pronounced on the standard of protection that was required. The standard was to withstand a flood of the level of that in 1953 where areas or property of high value would be at risk, and, in lower-value areas, a standard that would reasonably have been considered adequate before 1953.

710 Both of these recommendations were non-scientific; they set out the aims but not the means, and they struck a balance between the conflicting interests of river users and coastal-land occupiers, but without carrying out a formal cost–benefit analysis.

The Thames Technical Panel

711 The 1954 Thames Technical Panel had a purely scientific and engineering remit. Acting on behalf of central and local government, the Panel, and its successor steering committees, sponsored studies of:

- underlying meteorological and oceano-graphic causes of surge tides;
- surge tide statistics and trends;
- siltation and estuarine hydraulics;
- existing defences;
- cost estimates for various elevations of defences;
- negative effects of raising river banks in central London (amenity and cost);
- engineering feasibility and costs of alternative barrier designs.

712 No single study made a holistic assessment; as gaps in knowledge became apparent, studies were undertaken to fill them.

713 The Panel favoured a barrier located in Long Reach (ten miles downstream of the eventual site in Woolwich Reach) until 1961, when the PLA declared that, consequent upon

its own decision to authorise new jetties to be built near to the site, Long Reach would have to remain unobstructed in order to allow vessels using the jetties to turn around. The PLA proposed an alternative location 2 miles upstream at Crayfordness. This radical and unexpected change in the PLA's demands not only rendered several years of work redundant, but also presented the engineers with unprecedented technical challenges, owing to the size of the movable barrier that would be required at this location.

The Bondi Report

714 Professor Bondi had a large quantity of information available from the preceding scientific and engineering studies, and advice from the people directly involved. He considered the calculations that had been made of the risk of flooding.

715 The actuarial calculations of the time indicated a low probability of flooding. However, because the cost of a major flood in central London had been estimated at £20 billion, the annual probability of flooding would need to be extremely low to make the investment of between £250m and £420m uneconomic (figures in 1999 prices).

716 There was also a commonly held view that the consequence of flooding was so large that the risk was unacceptable.

717 Professor Bondi, recognising the magnitude of the consequences of a flood, and the uncertainties extant in the statistics, decided upon a precautionary approach. His report concluded:

> The extremely severe effects on the life of the country of a tidal surge appreciably higher than that of 1953 (or 1965) makes it appropriate to take preventative measures, even though the probability of a high surge is not great.

718 The Bondi report went on to say that this precautionary standpoint might not apply in other cases where the available data were more robust and there was less uncertainty.

719 The report also observed that cost–benefit considerations had not been properly applied earlier in the project, especially in relation to the demands of the PLA regarding navigational requirements, which had been presented, and received, as non-negotiable. Ideally, these demands should have been subjected to a test of cost-effectiveness; a better overall decision might have been reached, in which the combined interests of the various stakeholders would have been maximised.

Use of the Advice in the Policy Decision

720 The Bondi report was accepted in full by the government and the necessary expenditure was authorised.

721 The newly formed Greater London Council (GLC) took over responsibility for the project and the Thames Barrier came into service in 1982. Its final cost was £530m in 1982 prices (£1.2 billion today). In the period up to 1998, it had been closed against surge tides on 33 occasions, which is in line with expectations. As envisaged in the earliest days of the project, further provision will have to be made to ensure adequate protection to central London in the year 2100 and beyond, and a working group commenced initial deliberations in 1999.

Observations

722 In the discussion of the first three papers during the 1977 Institution of Civil Engineers conference on Thames Barrier Design (various authors, 1978), Dr D. E. Wright of Sir William Halcrow & Partners questioned whether Professor Bondi's view that the consequences of a flood dictated the decision was a sufficient answer because it begged the question as to what standard of protection should be provided. Dr Wright said:

> Despite Sir Hermann's remark, the standard of protection that is to be provided by the barrier is still finite.
>
> He posed the issue of the degree of protection as a problem of costs versus benefits.

723 In their reply, the authors (Horner, Beckett and Draper, 1978) provided details of the cost–benefit calculations of 1970 (three years after the Bondi report). They stated that the annualised cost of flood damage was estimated at about £5m, which corresponded to a return period of about 400 years on a £2 billion loss. £5m per year discounted at 10% yields a net present value of about £55m, which was about the same as the contemporary estimate of the cost of the Barrier and associated bank raising (£61m). This is a crude method of discounting.

724 They went on to say:

> [discounting] tends to favour low cost protection against short return-period events. A high benefit–cost ratio means more frequent flooding. This of course is not what the public want. As a result of the flooding of the tributaries of the Thames in the summer of 1977, the cry has been heard again and again that action must be taken to prevent a recurrence of this kind of event. The additional cost on the whole project in the GLC area of less than 10% to raise the standard of protection from the 100 year return period to the 1000 year return period is therefore readily accepted.

725 Professor Bondi was not required to undertake any original scientific work, but made a decision based on the evidence presented to him.

726 The reliance on one individual to create an overarching assessment was evidence of a lack of direction among the rest of the participants, and a lack of a clear vision of the decision-making principles that the advisory process was supporting.

727 There was no ambiguity about functions of the Waverley Committee (policy) and the technical panel (science), but the case illustrates the need for a process of synthesis as an interface between the scientific and engineering investigation and the policy-making functions.

728 The case also illustrates the need to manage stakeholder interests openly and in balance. Although the PLA defended its stance vigorously at the 1977 Institution of Civil Engineers conference, other parties describe the PLA as unyielding and dogmatic. There was no direct representation of the public interest.

729 Uncertainty played a considerable role in this case—especially uncertainty in the frequency of extreme tides—and encouraged the precautionary approach of Professor Bondi. This sufficed for the main decision on whether or not to build the barrier, but it would not have sufficed for the other key decision that was needed—the setting of the new flood-defence level. The latter could only have been resolved by balancing cost and risk reduction.

Robustness of the Process

730 The trust that was accorded to Professor Bondi in 1965 might not be so readily given to a single scientist today, no matter how eminent or competent.

731 The advantage of using a single expert was that the advice could be very clear and persuasive. However, reliance on a single expert to recommend a solution ran the risk of reaching an idiosyncratic or impractical conclusion.

732 A modern cost–benefit analysis would have justified the Barrier, on the basis of the figures available at the time. However, if the balance between costs and benefits had proved marginal, the consequence-based argument that was used in 1965 might be an acceptable deciding factor in a modern assessment.

733 The advisory process made very slow progress, during which time flooding could have occurred. A simple calculation of extreme tide probability could have been used to set an optimum time horizon for decision-making and construction, but this was not done. It is possible that the slowness, and the recourse to a single expert for advice, may have been due to institutional factors: although many interests were involved in the decision, no single organisation had clear overall responsibility for defining and solving the problem.

734 The Waverley Committee set the standard of protection before full costings had been made, and pre-empted full cost–benefit analyses of all available solutions.

Assessment of Safety Cases for Radioactive Waste Disposal

Origins of the Issue

735 When nuclear power was first introduced, it was recognised that intermediate-level waste would require disposal. Two options for disposal existed at that time: disposal at sea (ie, 'dilute and disperse'), and deep geological disposal (ie, 'concentrate and contain'—which would evolve over geological time to 'dilute and disperse', but with much of the radioactivity having decayed). Although the risks associated with sea dispersal had been assessed as satisfactory on environmental and public safety grounds, this disposal option was soon found to be politically unacceptable, along with all forms of waste disposal at sea. Geological disposal became the preferred option, with the assumption that it posed no serious technical difficulties. By the late 1970s, however, it was apparent that deep disposal did present technical challenges. Two broad challenges arose.

736 First, over time, chemical action by groundwater leads to the deterioration of the containment system, ultimately allowing leaching of radioactive material into the surrounding rock. The key requirement was therefore to design a containment system sufficiently robust to ensure that the waste would be contained for longer than the period required for most of the radioactivity to decay naturally.

737 The second challenge was to prevent accidental or deliberate human access to the waste.

738 The containment period required for substantial decay of the radioactivity is greater than 100,000 years.

739 UK Nirex Limited was charged with devising a disposal solution and was required to prepare and submit a disposal safety case for approval by regulators. The regulators were:

- the Field Operations Directorate of HSE, responsible for the safety of the workers and others affected by the works during construction and pre-closure;
- the Nuclear Installations Inspectorate, part of HSE, responsible for the operation of the site after construction and pre-closure;
- Her Majesty's Inspectorate of Pollution (HMIP), from April 1996 part of the EA, responsible for authorisation of disposal of radioactive waste, including assessment of the post-closure safety case for the disposal facility.

740 This case study concerns specifically the actions of HMIP in preparing itself to review a post-closure safety case, up until the formation of the EA in April 1996. Subsequently, in 1997, the EA published guidance on the authorisation of radioactive waste disposal (Radioactive Substances Act 1993, Guidance on Requirements for Authorisation.)

Framing of the Question

741 HMIP intended to assess any safety case by means of a detailed scientific and technical examination of the case submitted by Nirex. Nirex was responsible for preparing the case and for devising the methodology by which it would be prepared, since no complete methodology then existed in the UK. HMIP had undertaken and published a number of partial hypothetical assessments, and there had been significant research in Canada and Sweden. However, there was no established approach to assessing the safety of a nuclear waste disposal facility, or producing a safety case. Furthermore, there was no experience of constructing such a facility in the UK and little experience in other countries. The regulators for underground disposal of nuclear waste had no experience of reviewing safety cases.

742 Thus, HMIP had to prepare methodologies for assessing the safety case. The question put to expert advisers was, therefore, framed in a general way—to conduct research into waste disposal safety, in order to provide the tools for assessing a case when it was eventually submitted.

Selection and Briefing of the Advisers

743 HMIP sought to develop a team of scientific experts who were independent of the nuclear industry. HMIP had no laboratory or source of expertise of its own, and therefore relied on contractors (consulting companies, academic departments and laboratories, which were either publicly owned or had been

privatised). HMIP recognised that it would not be possible to prevent individual staff moving between employers, but it sought to use contractors that had worked exclusively for the UK regulators or had experience from overseas disposal programmes.

744 HMIP developed its own expertise, and that of its contractors, largely by setting in place research programmes that addressed the uncertainties in the science and technology underpinning safe disposal. The research programmes were funded by HMIP and managed by its staff. The work in preparation for the assessment of Nirex's safety case was managed by HMIP staff, but was funded by Nirex under a voluntary, cost-recovery agreement with HMIP. Part of the funding provided by Nirex was used by HMIP to develop site-specific models for independent quantitative assessment of Nirex's safety case.

745 In practice, it was difficult to maintain the strict separation between contractors working for the industry and those that worked for the regulator within a finite pool of experts. Most of the available experts had worked for both the regulator and the industry. Rejection of the planning application for the rock characterisation facility in March 1997 resulted in reduced funding and shrinking capabilities in the UK in the field of deep geological disposal.

Preparation of the Advice

746 The advisers undertook research to define the parameters that would have to be taken into account in a safety case, the scenarios under which the parameters might vary, and hence to assess the consequences that might result. Once models had been built incorporating these features, it would then be possible to apply those models to proposed facilities.

747 Although the primary responsibility for building these models lay with Nirex, HMIP commissioned its researchers to carry out a parallel exercise in preparation for evaluating Nirex's eventual submission.

748 Much of the model building involved establishing the likely values (and associated uncertainties) of several key parameters (for example, the likely flow rate and chemical composition of groundwater). The researchers engaged in a systematic knowledge-elicitation exercise to determine likely values for these parameters.

749 This was designed to make the best use of the available expertise to estimate a probability density function (PDF) for the parameter. Uncertainty is made explicit by this process since the PDF reflects both the intrinsic variability between, for example, different rock types and formations, and the uncertainty in the state of scientific understanding (or disagreements between experts).

750 The process has been extensively documented, and derives from work originally conducted at the Stanford Research Institute in the 1950s and taken up in the UK, in particular by the London School of Economics. Key elements of the process are:

- a group of experts is convened, typically for one day, to address a specific problem;
- their aim is to produce a consensus estimate of the PDF of each variable under consideration (this means that uncertainty is explicit and expressed quantitatively);
- each expert makes an independent estimate without consulting the others;
- these estimates are then pooled and debated—outliers are not smoothed out by averaging, but retained and debated.

751 A trained facilitator manages the process, and some of the experts taking part may have expertise that is only peripheral to the problem. The overall aim of this process is to avoid capture by one powerful personality or by force of argument. By making each expert commit to a view, it requires a conscious decision by that expert to change the view in the light of pressure from the others. This ensures that 'heretical' views are not swept away and only disappear as a result of a reasoned argument. If no reasoned argument can be found, the non-conforming view broadens the PDF that results.

752 This process shares many properties with the Delphi approach to sampling expert opinion, but differs in that there is only one formal round and the process is much more intensive. It also draws on the approach of systematic innovation, in that it attempts to capture unconventional ideas and debate them, not reject them out of hand.

753 The scientific groups engaged in this process tested their draft methodology in an assessment of a hypothetical facility and site (Harwell, in an exercise called Dry Run 3).

754 While HMIP's research programme was underway, Nirex decided to postpone for several years any application to develop a waste disposal facility, until results from the planned Rock Characterisation Facility located at the preferred site could be evaluated. Funding for HMIP's research programme was withdrawn, and funding resources were then concentrated on data collection and on the development of Nirex's own assessment methodology, rather than on the development of parallel methodologies. The EA argues that it is the function of the regulator to be independent, and this may include repeating part of the work supporting a safety case. HMIP did not take some of Nirex's work into account because it was in draft form, and HMIP believed that its function was to respond to the Nirex safety case when finally submitted, not to become involved in its preparation. HMIP wished to work in parallel with Nirex in order to arrive at a position where it could assess a safety case independently of the process by which the case had been generated.

Use of the Advice in the Policy Decision

755 No policy decision on construction of a deep geological repository has yet been required because the planning application for the rock characterisation facility submitted by Nirex to the planning inquiry was rejected. This brought Nirex's preparations for a deep-disposal facility at Sellafield to an end. Nirex is currently engaged in researching those issues of concern in a generic safety assessment (ie, non-site-specific), and in the provision of advice to the nuclear industry on waste packaging and transport.

756 The problem of the management of intermediate-level waste was debated recently by a House of Lords Committee. The Committee recommended the setting up of a 'nuclear waste management commission' and a 'radioactive waste disposal company'. It is unlikely that any decision on setting up such organisations will be made before a new policy on radioactive waste management has been announced. The process for defining the policy will be initiated in late 2000 when the government plans to issue a Green Paper for wide consultation with stakeholders. In the shorter term, however, BNFL, operator of the low-level waste facility at Drigg, is currently preparing a post-closure safety case for the site for submission to the EA in late 2002. The EA plans to review the authorisation for Drigg and, as part of this process, will evaluate BNFL's post-closure safety case and decide whether the case meets the regulatory requirements, as set out in the published guidance.

Observations

757 This case raises several important issues:

- the concept of parallel and independent teams;
- methods for finding consensus among experts, including the use of PDF as an expert output;
- the need for a scientific capability within the regulatory authority;
- the funding of regulatory research by the regulated industry;
- the fundamental principle of evaluating the safety case for each site in isolation, without considering the wider implications of not approving *any* disposal route.

Parallel independent teams

758 The selection and maintenance of an expert team to evaluate the safety case that is independent of the team preparing that safety case is attractive, but proved difficult in practice because there was only a small pool of experts from which both teams had to be recruited. Further, there appears to have been insufficient funding to support a second expert team. Several individuals moved between organisations working on opposite sides of the regulatory divide.

759 Nirex felt that the regulators provided little feedback on the developing safety case. The process was informal, although well-documented, and there was no fixed review period. The approach taken contrasts strongly with the approach taken by the regulators in Sweden, who worked with the industry during the preparation of a disposal case. The USA adopts a similar (if somewhat more strict) confrontational approach to the UK, but it can be argued that this is more appropriate because there is sufficient funding available from industry in the USA to support several expert teams.

Expert consensus

760 The consensus-building process was formal and appears to have been effective. One test was conducted where two separate groups of experts addressed the same issue and reached similar conclusions. The process appears to have much to commend it when

compared to the working of a conventional advisory committee, where much of the control lies with the chairperson and secretariat, in the absence of guidance as to committee procedure in the committee's terms of reference.

Scientific capability of the regulator

761 The regulator relied upon contractors to provide the broad range of scientific expertise required to assess a safety case for disposal. To reduce the project-management load on its staff, HMIP selected two lead contractors to manage the review work and the independent quantitative assessment studies. HMIP staff had developed the required experience and expertise in directing assessment studies through the Dry Run exercises over a period of about 12 years. Some argue that the regulator relied upon contractors to provide too much of the scientific expertise, to the extent that it did not have sufficient expertise of its own to manage or direct its contractors effectively.

Funding of regulatory research

762 Part of the research conducted to prepare the evaluation team was funded by Nirex, under a voluntary levy. Nirex had no control over the conduct of the research, but it could determine the level of funding. Support was withdrawn before HMIP had been able fully to assess and endorse its consultants' reports, so these reports have never received official regulatory status or endorsement.

763 This funding arrangement contrasts with other regulated industries, where the applicant pays the cost of assessing the safety case, but the assessment procedure is already clearly defined (eg, the safety of medicines under the Medicines Control Agency). Each applicant pays the marginal cost of an assessment, not the cost of developing the assessment methodology in the first place. It has been argued that site-specific methodologies are required for the assessment of nuclear waste disposal.

Case-by-case evaluation

764 The scientific advisers were asked to generate a methodology to assess a safety case for disposal at a specific site. They were not asked to assess the best overall solution for waste disposal and were not asked to compare the safety of alternative sites.

765 It is necessary to break down a complex issue into separate manageable parts. However, in this case, it can be argued that the main choices were closed down too early in the process.

Robustness of the Process

766 The consensus-building techniques stand out as exceptionally well considered, but there was a shortage of expertise within HMIP. The process proved unsustainable in practice because it was too long drawn-out and there was not enough continuity of work to sustain critical mass in the team.

767 The process illustrates the difficulties of adopting a competitive approach as against a cooperative approach. Each method has advantages and disadvantages. The competitive approach used here avoids the risk of regulatory capture, but it needs financial commitment and, in this case, was always dependent on the goodwill of the industry. The disadvantage of such a lack of true financial independence is not so much that the finance may be withdrawn—that at least would be an open fact—but that the threat of withdrawal may subtly influence the research findings.

768 The main weakness in the HMIP position was that it had too few expert staff in-house to enable it to carry out the overall synthesis of the research programme that was a central requirement. This left HMIP dependent upon external contractors, with the inevitable problems of loss of continuity and knowledge-retention.

Advisory Committees on Toxic Chemicals

769 This case study examines one mechanism by which scientific advice is provided to government, rather than a specific issue. The advisory committee system is such an important mechanism for obtaining expert scientific advice from outside government that it merits individual treatment.

770 The scope of this case study is restricted to a particular group of committees that advise on matters relating to toxic chemicals. The committees provide advice on similar subjects, but have different advisory functions and report to different government departments. The committees studied are:

- COT, which reports to the Department of Health and the FSA;
- ACTS, which reports to the HSC; and
- the Advisory Committee on Pesticides (ACP), which reports to the Pesticides Safety Directorate (PSD), an agency of MAFF.

771 While dealing with related scientific issues, these committees have distinct functions and, therefore, different compositions and methods of working. This case study explores these differences and how they match the requirement for advice, and identifies common factors among all the committees.

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Terms of reference and referral of issues to the Committee

772 Prior to April 2000, COT was a Department of Health committee, reporting to the CMO. Following the establishment of the FSA, the COT secretariat became a joint activity of the Department of Health and the FSA. Other departments (MAFF, HSE and the DETR) continue to attend as 'assessors'—they make sure that broader implications are taken into account and that powers are not being exceeded.

773 COT's main function is to provide expert toxicological assessment of specific chemicals, which is done principally by evaluating reports in the scientific literature. It also declares allowable daily intake levels. COT does not consider itself to be a policy-maker and restricts itself to providing scientific advice.

774 COT normally examines issues referred to it by departments (the Department of Health and the DETR), or other interested bodies (HSE and the Food Advisory Committee, FAC). The FAC is primarily a stakeholder representative committee.

775 However, COT's terms of reference permit it to initiate its own investigations, which it has done on several occasions (for example, on peanut allergies). COT also has a duty to provide advice in an emergency. It is engaged following an initial approach to the chairperson, who mobilises a small working party of the members. There are mechanisms for postal exchanges of data and opinions so that meetings are bypassed for the sake of urgency. These tasks may be concluded in as little as three days.

Committee membership and selection procedures

776 The chairperson and members are appointed by the CMO following a selection process conducted by the Department of Health. There is a shortage of applicants—potential recruits have to be sought out—but the pool from which they are drawn is small because of the expert character of the Committee. Recruits mostly come from academia, and exceptionally from industry; however, in the latter case, they are appointed for their expertise rather than their stakeholder perspective.

777 There is one non-expert (lay) member. When this innovation was first proposed, there was a widespread view among the members of the committee that COT was such a highly technical committee that a lay member would be unable to contribute and would feel disadvantaged. However, in practice, the function of the lay member has emerged as highly valued because the lay member is able to challenge the arguments presented by the expert members of the Committee. The presence of the lay member causes the scientific members to express themselves more clearly, and this is a valuable discipline that assists the general functioning of the group. The consensus now is that the advent of the lay member has been entirely beneficial.

778 In one of the COT working groups there were two lay members, and this is considered

to have worked even better because of the support they are able to provide to each other.

779 Members are appointed for fixed terms, usually three years, and are eligible for reappointment. Thus, on average one-third of the membership comes up for renewal each year.

780 Members are paid a nominal honorarium for each meeting attended, plus reimbursement of expenses.

781 The secretariat is run by the FSA.

782 The COT procedural rules require members to declare their relevant interests, and these are then published in the COT Annual Report. When necessary, the chairperson will exclude a member from participating in the debate on a specific issue, on the grounds of conflict of interest.

783 Members' interests are classified as either 'personal' or 'non-personal', where the latter implies an interest only through the member's employer. Conflicts are classified as 'specific' or 'non-specific', according to whether the individual has an interest in the specific chemical that is the subject of a particular review.

784 The publication of members' interests has resulted in public accusations of bias within the part of the Committee, based on the fact that some 70% of members have at some time or other undertaken work on behalf of industry—either in previous employment or as consultants. The members strongly deny that these connections influence their professional judgement.

Method of working and form of scientific advice

785 The COT secretariat includes a scientific team of about four or five toxicologists, who carry out the major tasks of retrieving scientific literature, assessing its significance and drafting an overall assessment. The Committee itself meets about six or seven times a year to consider these issues and determine its programme.

786 There is a great deal of uncertainty in much of what COT has to do, which arises from the nature of the scientific data on which the Committee relies. COT expresses its view on the uncertainty in the science non-numerically; for example, in its report on CS sprays, it drew attention to the fact that 'the *available* data did not, in general, raise concerns regarding the health effects of CS spray itself.' COT also recommended follow-up studies.

787 COT has published a policy on openness on its web site. The policy has the following features:

- it refers to the 'common law of confidentiality' in justifying its policy of maintaining confidential any information provided to it that is of a confidential nature; in practice, this mostly covers results of toxicological trials submitted by industry;
- it commits to publishing agendas, finalised minutes, agreed conclusions and statements;
- it commits to the appointment of a lay member;
- it commits to the holding of some open meetings on specific topics;
- it stresses the need for all documents released to be finalised and agreed by the Committee.

788 Within the policy on openness there is a procedure for handling confidential information. Companies submitting data must identify information that they consider to be confidential, and state their reasons. There remains a problem that the results of toxicological trials are inherently commercially sensitive because they may lead to regulatory intervention. There will be inevitable pressure from companies to keep such results confidential until some time of their own choosing.

789 Companies are requested to release full copies of their submitted reports for deposit at the British Library, but there is no obligation on them to do so.

790 COT publishes, with its sister committees on carcinogenicity and mutagenicity, an Annual Report. The main content of this report is a set of summaries of its scientific findings and reasoning.

Use of the scientific advice in the policy decision

791 COT's advice is not the only scientific input to policy-makers. The other major scientific source is the lobbying by industry. COT values its independent status because it feels this gives its views more weight with policy-makers, in comparison with industry lobbying.

792 COT sometimes provides advice to other advisory committees with a more sectoral

mandate, for example the Veterinary Products Committee, the ACP, and the Committee on Safety of Medicines. These committees have mainly scientific membership, but are more concerned with application of products than with fundamental science.

793 In the main, COT does not receive much feedback on the way in which its advice has been used. The messages are indirect and often considerably delayed.

794 One particular case (vitamin B6) is of great relevance to the present study because of the issues it raises concerning the interplay between scientific assessment and consideration of wider political issues.

795 COT treated vitamin B6 like a food additive, and recommended restrictions. It recommended that the allowable daily intake of vitamin B6 from food supplements should be 10mg, reaching this conclusion on the basis of:

- quantitative results of one study, which it said had 'some methodological deficiencies', but which it felt it would be unwise to ignore in the light of other supporting human and animal data;
- qualitative support from studies at much high doses and quantitative scaling (by a safety factor of 300) from trials in dogs at high doses.

796 COT's advice was accepted by the FAC, and the government proposed to follow the policy advice of FAC to treat all food supplements with a daily dose in excess of 10mg of vitamin B6 as medicines. A consultation document to this effect stimulated a strong response because it would have had serious effects on the dietary supplement industry and, it was argued by some, on the freedom of the individual.

797 The House of Commons Agriculture Committee, in its fifth report (House of Commons, 1998), also took issue with the restrictions, on the basis that they were not scientifically justified. It criticised in detail the methodological deficiencies of the study that COT had used, and cited alternative contrary evidence—which was in turn rejected by COT.

798 Finally, the decision was made to take no action to change the status of vitamin B6 supplements.

Advisory Committee on Toxic Substances

799 ACTS advises the HSC, which is a statutory stakeholder body with representation from the Confederation of British Industry (CBI), the Trades Union Congress (TUC), local authorities and other interested parties—the so-called 'tripartite' constitution. HSE is the executive arm of HSC and provides policy advice to HSC; in its own right, it promotes compliance with health and safety legislation.

Terms of reference and referral of issues to the Committee

800 The terms of reference of ACTS are to advise HSC on:

> (a) matters relating to the prevention, control and management of hazards and risks to health and safety of persons arising from the supply or use of toxic substances at work, with due regard to any related risks to consumers, the public and the environment;
>
> (b) other associated matters referred to it by the Commission/Executive.

801 The general practice in HSC advisory committees is that their subject areas are aligned either with industry sectors (industry advisory committees), or with generic topical areas (subject advisory committees). ACTS is one of the latter. The scope of HSC committees also aligns broadly with segments of legislation for which HSC and HSE are responsible. In the case of ACTS, the major statutes are:

- the Control of Substances Hazardous to Health Regulations, 1994 (COSHH);
- the Chemicals (Hazard Information and Packaging for Supply) Regulations, 1994 (CHIP).

802 Other topics are dealt with on an ad hoc basis (examples are asbestos and lead, which have their own statutory provisions). The Committee also assists in developing the UK response to EU proposals on occupational exposure limits and other matters relating to chemicals. In general, HSC does not make specific referrals to ACTS—the Committee simply sets its own programme within its terms of reference, taking into account advice from HSE about legislative and hazard priorities. ACTS submits its work programme to HSC for approval.

Committee membership and selection procedures

803 The constitution of ACTS was determined by HSC and is an extension of the tripartite model. Its membership is as follows:

- a chairperson who is a senior HSE official;
- four nominees of the CBI;
- four nominees of the TUC;
- two local government representatives (nominated by the Local Government Association (LGA) and the Council of Scottish Local Authorities (COSLA));
- one environmental interests representative;
- one consumer interests representative;
- five independent experts.

804 HSE provides a secretariat, and much of the detailed work of the Committee is carried out by related units within HSE.

805 The nominees of the CBI, the TUC, the LGA and COSLA are proposed by those organisations and approved by HSC. The other members are more difficult to recruit and, in practice, the HSE secretariat searches for them using informal channels of communication, but with the overall intention of complying with Nolan principles. The secretariat seeks to balance the skills and experience of the independent members in particular.

806 Although many of its members are experts, ACTS remains primarily a stakeholder body. It is necessary for the stakeholder negotiations to be largely resolved at the ACTS (and other comparable HSC advisory committees) stage, otherwise HSC would be overwhelmed with work. Nevertheless, many of the stakeholder nominees are in fact experts as well—they are often professional occupational hygienists or health and safety specialists. Thus, the major stakeholder division within the Committee (between the CBI and TUC) is to some extent bridged by this shared background.

807 WATCH provides scientific advice, but ACTS nevertheless has five independent expert scientists as members. In practice, these independent expert scientists facilitate the debate between the stakeholders, help in resolving differences, and maintain a constant challenge to the process. They also provide a balance to the CBI representatives, who have more powerful technical support than the other stakeholders.

808 Process challenge is a valued function of the environmental and consumer representatives, and, in the longer term, their presence is expected to result in a stronger emphasis on the broader context of the work of ACTS, and improvements in its presentation.

809 Regarding declaration of interests, some members evidently represent the interests of their nominating constituencies. For the independent members, declarations of specific interest relating to a substance under the committee's scrutiny are made as appropriate (for example, a member whose research institute is undertaking a programme of work on that substance).

810 ACTS is reconstituted every three years. This process includes consideration by HSC of the need for the Committee, and of its membership, terms of reference and work programme.

811 The detailed work, of which there is a heavy load related to the setting of occupational exposure limits and labelling requirements related to COSHH and CHIP, is delegated to sub-committees, of which the two most important are:

- WATCH—the main scientific/technical sub-committee;
- and the Standing Committee on Hazard Information and Packaging (SCHIP)—a tripartite consultation forum.

812 This case study only examines WATCH. It is a technical expert committee that considers highly detailed risk assessments of individual chemicals carried out by cross-HSE teams drawn from a variety of disciplines. It also proposes to ACTS the level at which occupational exposure standards should be set.

813 WATCH meets three times per year and its functions are defined by ACTS. The terms of reference are:

> To consider in relation to chemicals and ill-health the technical aspects of hazard identification and character-isation, occupational exposure assessment, risk characterisation and the uncertainties involved in these issues; also to consider the technical aspects of associated occupational risk management measures; all of this in accordance with a programme of work

> agreed by ACTS; and to make recommendations to ACTS, HSE and, where appropriate, to SCHIP, based on such technical considerations. WATCH would also, where appropriate, consider broader risks to the public from occupational use of chemicals.

814 The reference to uncertainties is a recent amendment originated by ACTS.

815 The membership of WATCH is composed by discipline as follows:

- toxicology 7 members
- occupational hygiene 4 members
- occupational medicine 2 members
- epidemiology 1 member
- chemical pathology 1 member
- psychology 1 member

816 Members do have stakeholder affiliations, but the way these operate is the converse of the situation in ACTS itself. On WATCH, members contribute as experts first, and representatives second. The members are mostly individuals whose usual employment is within their scientific discipline, rather than in senior management. Personal or corporate interest in any item on the agenda is routinely declared.

817 In recruiting members to WATCH, HSE seeks a high level of scientific expertise and an overall balance of skills in the group.

Method of working and form of scientific advice

818 ACTS meets three times a year. It does not make any scientific judgements—these are delegated to WATCH. The aim, as in the HSC, is to reach a consensus.

819 ACTS considers a wide range of issues relating to the control of chemicals in the workplace. These include generic health effects, scientific methodology, classification and labelling, risk assessment and communication, as well as recommending levels for the setting of occupational exposure limits under the COSHH regulations.

820 In respect of occupational exposure standards (OESs), consideration of appropriate limits is undertaken against published 'indicative criteria'. These criteria require that scientific evidence is available to identify an exposure level that would not be harmful on the basis of continuous workplace exposure, with reasonable certainty; that short-term exposures above that level would not be likely to cause harm; and that compliance with the OES would be reasonably practicable. WATCH makes a recommendation as to whether an OES can be set for a particular chemical under these guidelines.

821 Chemicals are referred to WATCH by ACTS through an annual programming cycle. Newly introduced substances are identified to HSE by the suppliers, while the chemicals that are already in supply are selected by a process of prioritisation, as there is a large backlog. The priorities are proposed by the HSE officials on the basis of scale of use, initial judgements on the hazard, public concern (as expressed in enquiries from Parliament, NGOs, the media or private individuals), and EU or other legislative obligations.

822 The Notification of New Substances Regulations require suppliers of any chemical not already on the notified list to make a notification to HSE of its proposal to manufacture or import the substance, and various other information concerning its hazards, precautions, packaging and labelling.

823 HSE specialists present a detailed technical assessment, which includes a critical review of the literature, evaluation of implications of animal testing for human toxicity, uncertainty, methods of exposure measurement, and an assessment of the risk of using the substance in the workplace. WATCH reviews this work and determines what action to recommend to ACTS.

824 There is a need for judgement in deciding which papers from the scientific literature should be used, and how the extrapolations from animals to humans should be made. This is probably the main area where uncertainty enters the process.

825 The committees apply a safety factor when they recommend an exposure limit. This factor, which is judged for each case, reflects the nature of the extrapolation from animals to humans, and the quality of the available evidence. The way in which the factor is built up from the uncertainties in the assessment is explained in a published summary of criteria (EH64).

826 There are groups doing comparable work in Germany, the Netherlands, Luxembourg and Scandinavia, and these share data and the results of their assessments. Further relevant work is done in the USA and elsewhere.

Use of the scientific advice in the policy decision

827 Summaries of risk assessments are published in draft form for a three-month period of public consultation, after which they are revised to a final form and added to the published compendium EH40, which supports the COSHH regime. At this stage they are applied to practice and precautions in workplaces, and the inspection activities of HSE field operations inspectors. A summary of the scientific and technical justification for the limits is published in both the consultation document and in EH64.

828 Where WATCH finds that the indicative criteria for an OES are met, it recommends the level of an OES to ACTS. An analysis of comments received through the public consultation exercise is also included in the material put to HSC. Where the criteria are not met, the chemical must be considered again by ACTS. This is because the regulation of these more difficult cases involves striking a balance between risk and cost, which is seen as a matter for resolution by stakeholders rather than technical experts. These cases may be regulated by setting a 'maximum exposure limit'.

829 HSC usually accepts the recommendations of ACTS. Occasionally, owing to lobbying at the HSC level, there may be discussions about the more serious cases (the timing of introduction of the benzene maximum exposure limit was an example).

830 The advice of ACTS is presented to HSC alongside the advice of HSE officials, which may be different. Members of HSC may, in addition, be briefed by their own advisers.

831 A regulatory impact assessment is required for those chemicals that require a maximum exposure limit. The experience with these assessments, which are similar to cost–benefit assessments, is that compliance costs are easy to estimate, but the risk-reduction benefits are much more difficult.

Advisory Committee on Pesticides

832 ACP was originally set up in the early 1950s and was put on a statutory basis through Section 16(7) of the Food and Environment Protection Act 1985 (FEPA).

833 ACP advises on the use of pesticides and reports to Ministers (the Secretaries of State for Health and Environment, together with the Minister for Agriculture, Fisheries and Food, and the Ministers of the Scottish Executive and the Welsh Assembly). It deals with two main groups of products: pesticides for agricultural applications, and a varied group of products for non-agricultural purposes, such as timber preservatives and anti-fouling agents. It is supported by the PSD and HSE.

Terms of reference and referral of issues to the Committee

834 Section 16(7) of FEPA requires ACP to give advice to Ministers, either when requested or otherwise, on any matters relating to the control of pests in furthering the general purposes of Part III of the Act. These general purposes include protection of human health, animal and plant health; safeguarding of the environment; the securing of safe, efficient and humane methods of controlling pests; and making information about pesticides available to the public.

835 Under Section 16(9) of the Act, Ministers are required to consult the ACP regarding new or amended:

- regulations;
- approval, revocation or suspension of pesticide licences;
- conditions to licences.

836 ACP usually considers pesticides that are referred by other bodies, but it is also able to initiate its own investigations. These usually examine generic issues.

Committee membership and selection procedures

837 The membership of the ACP, as at 1999, comprised an independent chairperson plus 13 independent members (all senior scientists) and two lay members. There are six departmental 'assessors', representing the Department of Health, PSD, the Welsh Assembly, the Scottish Executive, HSE and the DETR, whose main function is to ensure that their departments reach a decision whether to accept or reject the advice from ACP. There are also 18 'advisers' whose function is technical, and a support staff of four scientific and four policy staff.

838 Members are required to declare their interests in any company or organisation with an interest in the subject area of the Committee, or such as would be likely to

prejudice their performance of their functions on ACP. Declarable interests include shareholding, current consultancy contracts, employment, and non-executive directorships.

839 The register of interests is published in the Annual Report. It is the recruitment policy that the overwhelming majority of members, including the chairperson and the deputy chairperson should have no such interests to declare. In 1997, only three members had such interests. The Committee has been largely free from criticism of bias.

840 Appointments are formally made by MAFF Ministers, with agreement from the other departments. In the past, recruits had to be actively sought out, and this was done by ACP and PSD, and the interested departments. From 1999, the Committee has used the full Nolan procedures (advertisement, applications, interviews, etc) for selection of new members. It has been found that advertisements generate plenty of applications.

841 Members are appointed for three-year terms with a maximum of two terms. They are paid an attendance fee of about £140 (in 1999) per meeting plus expenses, and this is deemed to cover any background reading time. The Committee meets seven or eight times per year.

Method of working and form of scientific advice

842 The main work of the ACP is to consider applications for approval of new pesticides under the Control of Pesticides Regulations 1986 (COPR), and retrospective reviews of approved pesticides. All approvals must be passed by ACP; however, in practice, there are many small technical re-applications that are processed by PSD or HSE following the framework and precedents established by ACP.

843 When offering a new pesticide for approval, or when responding to a request from PSD in relation to an approved pesticide, manufacturers must submit a detailed dossier for examination initially by the PSD/HSE scientific staff and then by ACP. For a new active substance (as opposed to a reformulation of an existing active substance), the evaluation might take 12 months. There are about 12–15 of these cases each year, and about 75% are eventually approved at some level.

844 Manufacturers have a legal obligation to reveal their health risk and efficacy data. The typical course of events is that a new pesticide first obtains a provisional approval, subject to a requirement to obtain more evidence; approval at first application is a relatively rare event—there was only one in 1997.

845 The selection of pesticides for retrospective review is made by PSD, which has a prioritisation scheme for this purpose. Also, the EU has a pesticides assessment programme in which PSD participates. In the first round, there were 90 cases, of which the UK handled 11.

846 The scientific staff (from PSD or HSE—as appropriate to the envisaged use of the pesticide) evaluate the dossier provided by the manufacturer and present a paper to ACP. The Committee plays a quality-assurance function with respect to the PSD scientific work. In addition, the ACP chairperson is a member of the PSD Ownership Board.

847 There may be a risk of bias in the original data submitted by manufacturers. For new chemicals, this is not considered to be a major problem because the demands of the evaluation procedure are so great that much of this work has to be contracted out to independent laboratories. Also, there is sufficient contact with other national regulators that data and findings can be checked—particularly for pesticides that have already been approved.

848 In seeking a balance of scientific data and interpretation, the principal counterweight to the industry view is provided by the PSD/HSE scientists.

849 ACP is a purely scientific committee, with a low public profile and a well-defined function. This format was deliberately chosen in preference to a stakeholder body. The lay members were appointed as a result of a broad initiative for all advisory committees in the Department of Health and MAFF. At the end of 1999, they had only recently started to make an impact on the scientific process itself. The content and style of the discussions had not changed much since they joined the Committee, and there was some disjunction between the lay contributions and those of the scientists.

Use of the scientific advice in the policy decision

850 Formally, regulatory decisions under FEPA and COPR are made by Ministers. In practice, the great majority of these decisions are made within PSD and HSE, on behalf of Ministers, following the advice of ACP.

851 However, PSD says that its Ministers wish to be advised of uncertainties. Ministers want to be able to challenge the advice, and one of the best ways of doing this is to press for openness about uncertainties.

852 ACP does consider a miscellany of special or generic issues, in addition to its main work on pesticide approvals. In 1997, there were 19 of these, including such topics as: poisoning incidents; practices in grain stores; feasibility of epidemiological research among pesticide users; use of buffer zones for risk management; and pesticides use minimisation. Some of these issues touch on policy matters. However, from the contents of the Annual Report it appears that the Committee usually restricts its advice to scientific and technical aspects. Its recommendations for action, however, occasionally go beyond purely scientific advice to include policy judgements.

Observations

853 The composition of COT and ACP membership is similar, and the main difference is the approach to members' interests. It appears that ACP's policy of excluding applicants with interests in the pesticide industry has served it well, although the problems that COT has had in this area may be undeserved.

854 ACTS, unlike COT and ACP, is openly a stakeholder body, reflecting the composition of its parent, the HSC. This Committee deals with the problem of identifying the scientific consensus by delegating its scientific function entirely to a technical sub-committee. Even this sub-committee has strong stakeholder affiliations, but its modus operandi is scientific debate.

855 ACTS and its sub-committee, WATCH, are an example of structural separation between the scientific contribution and the negotiation between stakeholders. This format allows the scientific constraints to be defined first, the stakeholders then challenge the science, and subsequently make recommendations.

856 The contribution of the lay members on COT has been very valuable, while on ACP they have been slow to find a role. It is not obvious why this is, because the two committees have very similar functions and constitutions. There are various public-interest members on ACTS, but it is debatable whether these can be considered lay members. Certainly, the arrangements on ACTS for ensuring a balance of stakeholder representation are quite elaborate and carefully engineered.

857 The terms in which all three committees express their sense of uncertainty appear opaque. There are several possible reasons for this:

- a desire not to confuse the decision-taker;
- a desire not to allow latitude for potential critics to exploit;
- a basic lack of expertise in handling probabilities;
- a desire not to appear vague or indecisive.

858 Some of the committees, ACTS and WATCH being an example, do consider uncertainty in a systematic way, and their methodology is published. However, the conversion of uncertainty into safety factors obscures the uncertainty itself, in the final determinations. This may have led to inconsistencies in regulation of different risks, to over-cautious positions in some cases, and to insufficiently secure positions in others.

859 All three committees depend heavily on their scientific and policy support units. These units actually wield significant power because of their agenda-setting function and their control over the detailed work of the scientific evaluations of chemicals.

860 Finally, some or all of the committees appear to be dependent on data supplied by the industries whose products they are regulating. The data supplied is often treated as confidential, having been so identified by the supplier. This may expose the process to bias if there is no effective check on the dependability of the data supplied.

Case Study Protocol

Case-study interview procedure

861 This note guided the study team members in the conduct of interviews for case studies.

862 It contains procedures and checklists. The former were intended to enforce a degree of consistency between the various case studies and to ensure that they could be assessed systematically during the second phase of the project. The latter were intended to be more flexible; they were an aid to the interview process itself and helped to ensure that all the key issues were raised during the interviews.

Definition of the cases

863 The scope of each case was defined by the decision-making issue that gave rise to it. This issue usually involved scientific and non-scientific elements. The study focused on the scientific elements, but with due regard to the wider context of the case.

864 The subject matter of each case included:

- the framing of the decision-making issue;
- the framing of the scientific questions on which advice was sought;
- the advice itself—its basis and the form in which it was expressed; and
- the utilisation of the advice.

Sources of data for the case studies

865 Interviewers prepared for interviews by reading suitable background material so that they had reasonable command of the subject matter.

Interviews

866 At least two interviewees were seen for each case. Typically, at least one was a provider of scientific advice and another was a user of that advice.

The interview procedure

867 The material exchanged during the interviews was, by default, not confidential and may appear in this report. However, if an interviewee wished to provide some information under a condition of confidentiality, that was accepted and the condition has been respected.

868 Both interviewers took notes. In general, it was not intended that interviewees would review the notes, because this might have introduced bias. None of the observations were attributed to individual interviewees.

869 The above ground rules were stated to the interviewee at the outset of the meeting.

870 It was not intended to discuss the science itself, only the process. However, where interviewees wished to illustrate their responses with scientific examples, these were recorded for illustration purposes.

871 Interviewees were in general seen individually, with the particular aim of capturing the different perspectives of providers and users of scientific advice. However, this was not an absolute rule.

872 At the outset, the background and status of the interviewee was ascertained and recorded, covering the following:

- position;
- role in the advisory or decision-making processes;
- organisation (government, advisory committee, government researcher, academia, consultant, etc);
- independence;
- applicability of a professional ethical code;
- remuneration in relation to the advice;
- stakeholder interest;
- scientific school of thinking—previous declared positions on the subject.

873 The interview then examined the issues listed in the checklists below, as appropriate to the type of interviewee. The checklists were used as an *aide-mémoire*, not as a rigid questionnaire. However, the meeting notes identified the topic under discussion, by its heading in the checklist.

874 An opportunity was provided for a free contribution from the interviewee, on the wider subject of the science advisory process, beyond the specific scope of the case study.

Checklists

The problem identification process

- How did the problem come to your attention?
- In hindsight, were there any prior warning signs or other indicators that could have picked up the problem earlier?

The selection of experts (questions mainly for decision-takers)

- How was the adviser selected?
- What were the criteria for selection?
- Was a search made for alternative sources of advice?
- How did the selection process handle bias and conflict of interest?
- Did the providing organisation or person change during the course of the advisory process? If so, why?

Other channels of advice (questions mainly for decision-takers)

- Was any advice provided on an unsolicited basis?
- Was any advice offered but declined or ignored?
- Was there active public or media interest at the time of the advice or the decision?
- Were there precedents from previous cases?
- What was the role of stakeholders, lobbies, etc?

Briefing of experts

- What was the brief given to the expert?
- How was this brief developed?
- What background information was given to indicate the context in which the advice was to be provided?
- Did the requirement change during the course of the work?
- Did the brief request scientific information, or recommendations?
- Did the brief address uncertainty?
- What resources were provided to the adviser?
- What timescale or deadlines were set?

The scientific analysis and preparation of advice (questions mainly for providers of advice)

- Problem definition—was the brief clear and complete, and did it provide sufficient context?
- In hindsight, was the brief properly interpreted?
- Was the problem affected by scientific uncertainty:
  - was it a novel issue?
  - was the basic science (theory) missing?
  - was data to populate the theory in short supply?
- Was the advice required urgently? What were the deadlines/time available for response?
- Was there any bias in the brief?
- Did the way the brief was presented influence the answer?
- Was enough information available and was any withheld?
- Did it unduly circumscribe the scope?
- Were sufficient resources used/provided for?
- What process was employed to generate the advice (eg, literature search, computer simulation, experiment, peer review, etc)?
- Who participated in the advisory process (eg, stakeholders, academics, consultants, committees, etc)?
- Would you characterise the process as any of the following: inclusive, consensual, partisan, or dominated by one individual?
- In the analysis, was the process risk-based, and, if so, did it address alternative outcomes or alternative theories/schools of thought?
- How would you characterise your advice, in terms of the following or any combination?
  - formal analysis
  - structured judgement
  - opinion
- In the advisory response, was uncertainty expressed, and, if so, how?
- Did the advice constitute a recommended decision, or confine itself to scientific matters?
- Were you satisfied with the way your advice was used?
- In hindsight, should anything have been done differently? (Another question is: Was the answer right? Although this is

not for reporting, it may illuminate this aspect.)

The decision-making process

- What was the decision required?
- What type of decision was required?
  - policy/strategy
  - tactical management/regulation
  - emergency response
  - public information

- What was at stake?
- Which of the following decision-making paradigms were invoked in what was actually decided?
  - precautionary principle
  - optimisation (eg, cost–benefit analysis, etc)
  - sustainability
  - risk management (probability, consequences, etc)
  - political judgement by elected representatives

- What other information and external factors, besides the scientific advice, were used in the decision?
- How were risk and uncertainty weighed?
- Was there any conscious aversion to large adverse consequences?
- What was the justification given for the decision?
- What feedback was given to the scientific advisers?

Evaluation of the outcome—was it a good process?

- Was the scientific advice suitable and helpful to the decision-making process?
- Which particular features worked well?
- What could have been improved?
- Overall, were you satisfied with the process?

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Tender Specification

Background

In assessing risks and adopting appropriate risk-management strategies, government regulators need, among other things, sound, authoritative expert scientific advice to inform decision-making.

While expert scientific input is essential, experience (perhaps most recently exemplified by food and medicinal safety concerns) indicates that there is often a lack of transparency as to whether the role of the scientific expert is to advise about facts (ie, what is known or not known about an issue, or to express a value judgement about the action that should be taken by government).

In addition, health or safety risks (particularly emergent risks) are often associated with significant uncertainty arising from, for example, unreliable or incomplete data, modelling uncertainties, debatable underpinning assumptions, or conflicts of expert judgement or opinion in interpreting the results.

The pervading uncertainty and the potential confusion surrounding the role of scientific experts may be compounded by the public perception that, to varying degrees:

- experts engaged to provide advice are not independent;
- the process by which expert advice is elicited is not transparent;
- the expert view of risk is out of tune with that of the public;
- resort to expert judgement or opinion does not provide reassurance, but
- leads to the spectacle of media confrontation between experts with very different views.

These considerations point to the need for government departments to be able to demonstrate that they follow good practice when assembling expert scientific advice that informs decisions.

Aims

To identify good practice for securing and using expert scientific advice.

To provide a sound framework, based on the dominant assumptions of openness and transparency, on which the UK government can assemble authoritative expert scientific advice that is robust when exposed to public scrutiny.

To enhance trust and confidence in the processes of risk assessment, management and communication by:

- opening up to public scrutiny the expert advice elicited;
- exposing and explaining the assumptions made, and the uncertainties that pervade both the assessment of risks and the effectiveness of possible risk-management options;
- making clear where expert judgement has been applied to convert information and expertise into intelligence about risk problems, or where the uncertainties are so large that the expert advice is essentially a matter of opinion;
- adopting suitable procedures to engage as appropriate both stakeholders and experts; and
- explaining how expert scientific advice, together with the relevant sociological, economic and political considerations, contributed to the final decision made.

Methodology and outputs

In Phase 1, to undertake a mapping study to:

- identify and categorise current practices within government for securing expert scientific advice, and incorporating it into policy; and,

- *review* what is known generally about the relationship between how expert scientific advice is incorporated into policy and the quality, or perceived quality, of the decisions made.

In Phase 2, to probe in greater depth and to draw out principles of good practice (including how to avoid pitfalls) for:

- the engagement of scientific experts (ie, selection, remit, independence, etc);

- the elicitation of their advice (ie, framing of issues, support provided, avoidance of bias, characterisation and reporting of

uncertainty, resolution of conflict, presentation of advice, etc); and,

- the incorporation of expert scientific advice in the wider decision-making process.

Prospective contractors are invited to devise the approach and methodology they consider appropriate. The sponsors will arrange opportunities for the successful contractor to interview selected:

- departmental scientists;
- external scientific experts who advise government, including chairpersons and members of advisory committees;
- departmental policy customers.

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