THE ENVIRONMENT AGENCY'S RISK PORTFOLIO

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EXECUTIVE SUMMARY

This document describes the existing approaches to risk assessment in the Environment Agency across all of its Functions and summarises current experience and practice. It incorporates, as an Annex, a register of the more common risk tools and techniques in use.

An earlier version of the portfolio was drafted in 1995/96 by the Ad-hoc Working Group on Risk in the Environment Agency. It pulled together the wide ranging expertise from the Agency's predecessor bodies. Since then, the document has been restructured, consulted upon widely internally and used to formulate the Agency's thinking as to how our handling of risk might converge over the coming years.

The Portfolio is maintained by the National Centre for Risk Analysis and Options Appraisal This revised edition brings the document up to date and reflects recent changes in risk-related activities within the Agency across England and Wales only, unless otherwise specified. It does not cover health and safety management issues or the handling of corporate risk as these are dealt with in other documents. The National Centre hopes you will find this a useful valuable reference document and welcomes any comments you may have. We will aim to incorporate further improvements at the next revision.

The Agency operates with constant reference to environmental risk[1]. Many of the operational and strategic decisions made by the Agency involve some implicit consideration of risk principles, but increasingly, a more explicit treatment is being required. Pressure is coming from two directions:

- a renewed emphasis on quality regulation within Government[2], on the appropriate use of scientific advice in policy-making[3], within the context of sustainable development[4]; and
- an increasingly specific reference to risk assessment within the statute.

Recommendations for Departments and Agencies to publish their high level frameworks[5] within which they consider 'risk' have been endorsed by Government and the first of these have been consulted upon[6,7]. It is timely, therefore, that the Environment Agency reviews the handling of risk within its regulatory and supervisory remit and sets out the contexts within which it makes risk-based decisions. That is the principal aim of this document.

The portfolio has been produced with the following objectives in mind:

- to promote awareness and consistency among the different parts of the Agency involved in risk assessment;
- to act as an information source for interested external parties;
- to support the Environmental Protection Directorate's initiative on risk-based regulation;

[1] POST(1996) *Safety in Numbers?* Risk assessment in Environmental Protection. Parliamentary Office of Science and Technology

[2] Cabinet Office (1999) *Modernising Government*, Cm 4310, 66pp., The Stationery Office, London,

[3] DTI (1998) *The Use of Scientific Advice in Policy Making*, Department of Trade and Industry, London, 9pp

[4] DETR (1999) A Better Quality of Life: A Strategy for Sustainable Development for the United Kingdom, 96pp., The Stationery Office, London

[5] ILGRA: Interdepartmental Liaison Group on Risk Assessment (1998) *Risk Assessment and Risk Management: Improving Policy and Practice within Government* Departments, 37pp., HSE Books, Suffolk

[6] HSE (1999) *Discussion Document: Reducing Risks, Protecting People*, 82pp., HSE Books, Suffolk

[7] DETR and the Environment Agency (2000) *Guidelines for Environmental Risk Assessment and Management, Revised Guidance*, DETR, the Environment Agency and the Institute for Environment and Health, in preparation

- to provide a foundation for the further development and application of risk assessment in the Agency; and
- to support the development of the Agency's expertise and capabilities in integrated environmental assessment and protection across all functions.

This review has highlighted a number of key issues. An overview is provided in Section 5 in which the following recommendations are made:

- the revised Departmental Guidance on environmental risk assessment and risk management (due for publication in 2000)[7] should be reviewed and, as appropriate, cascaded through the Agency's Directorates and Functions;
- the Agency should review its training needs in risk assessment and establish a set of training courses appropriate to the various needs;
- the Agency should work in partnership with other Agencies, industry groups and professional bodies to raise skills and competencies in environmental risk assessment and management;
- through its R&D programme, the Agency should endeavour to establish how stakeholder involvement can be meaningfully incorporated into risk assessment;
- formalised procedures should be examined for combining: (i) experimental data with elicited expert judgement; (ii) predictive exposure scenarios with illustrative exposure scenarios; (iii) qualitative with quantitative expressions of risk and with the associated uncertainties; and (iv) methods of addressing problems where the science is not sufficiently advanced to allow formal modelling;
- the Agency should examine the need for a more informed interpretation of the characteristics of environmental harm or impact (magnitude, reversibility, latency, spatial and temporal extent, etc.) including social and economic aspects;
- there should be greater transparency on how different criteria (e.g. environmental standards or guidelines) are set to facilitate comparisons between these and encourage consistency; and
- the Agency should continue to promote a tiered approach to risk assessment with a view to reserving quantitative assessment techniques for complex and/or high-risk situations where good quality data are available to support this level of sophistication.

Keywords: risk assessment, tools, techniques, regulatory process, cross-functional.

Links to Agency duties and powers: risk assessment is both a formal and general requirement of environmental legislation. Where formalised within the statute, the requirements for risk assessment are made explicit. Otherwise the need for a risk assessment provides regulatory confidence in support of sound decision making.

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ACRONYMS

AA	Annual Average
ALARP	As Low As Reasonably Practicable
BAT	Best Available Techniques
BATNEEC	Best Available Techniques Not Entailing Excessive Cost
BNFL	British Nuclear Fuels
BPEO	Best Practicable Environmental Option
CAU	Chemicals Assessment Unit
CIMAH	Control of Industrial Major Accident Hazards
CLEA	Contaminated Land Exposure Assessment model
COMAH	Control of Major Accident Hazard
CSO	Combined Sewer Overflow
DETR	Department of the Environment, Transport and the Regions, formally the DoE
DoE	Department of the Environment
DTA	Direct Toxicity Assessment
DTI	Department of Trade and Industry
EAL	Environmental Assessment Level
EAP	Environmental Action Plan
EC	European Community
ECB	European Chemicals Bureau
EIA	Environmental Impact Assessment
ESR	Existing Substances Regulation
EU	European Union
EPA	Environmental Protection Act
EPNS	Environmental Protection National Service
EQ	Environmental Quotient
EQO	Environmental Quality Objective
EQS	Environmental Quality Standard
FDMM	Flood Defence Management Manual
GWP	Global Warming Potential
HLW	high level waste
HMIP	Her Majesty's Inspectorate of Pollution
HSE	Health and Safety Executive
ICRP	International Commission on Radiological Protection
IEI	Integrated Environmental Index
ILW	intermediate level waste
IPC	Integrated Pollution Control
IPPC	Integrated Pollution Prevention and Control
LEAP	Local Environment Action Plan
LLW	low level waste
LQ	Land Quality
MAC	Maximum Allowable Concentration
MAFF	Ministry of Agriculture, Fisheries and Food
MATTE	Major Accident To The Environment
MoD	Ministry of Defence
NCEHS	National Centre for Ecotoxicology and Hazardous Substances
NCRAOA	National Centre for Risk Analysis and Options Appraisal

Nirex	UK Nirex Ltd
NOAEL	No-Observed-Adverse-Effect-Level
NONS	Notification of New Substances Regulations 1993
NOEC	No Observed Effect Concentration
NRA	National Rivers Authority
NRPB	National Radiological Protection Board
NuSAC	The Nuclear Safety Advisory Committee
OECD	Organisation for Economic Co-operation and Development
OFWAT	Office of Water Services
OMA	Operator Monitoring Assessment
OPA	Operator Performance Appraisal
Operators	This term is used throughout the document to refer to the operators, dischargers, abstractors, developers or other persons
OPRA	Operator and Pollution Risk Appraisal
OSPAR	Convention for the Protection of the Marine Environment of the North East Atlantic (the OSPAR Convention)
PAGN	Project Appraisal Guidance Notes
PEC	Predicted Environmental Concentration
PHA	Pollution Hazard Appraisal
PIR	Process Industries Regulation
PNEC	Predicted No Effect Concentration
POCP	Photochemical Ozone Creation Potential
R&D	Research and Development
RSPB	Royal Society for the Protection of Birds
RWMAC	Radioactive Waste Management Advisory Committee
SEPA	the Scottish Environment Protection Agency
SNIFFER	Scotland & Northern Ireland Forum for Environmental Research
SoS	Secretary of State
TDI	tolerable daily intake
The Agency	The Environment Agency for England and Wales
UK	United Kingdom
UNCED	United Nations Conference on the Environment and Development
UPM	Urban Pollution Management planning methodology
USEPA	United States Environmental Protection Agency
WHO	Word Health Organization
WMP	Waste Management Paper
WMR	Waste Management Regulation
WPZ	Water Protection Zone
WR	Water Resources
WRA	Water Resources Act

CONTENTS

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VOLUME 2: REGISTER OF TOOLS

This volume is to be made available in the Environment Agency's Intranet in the near future. If you require a hardcopy in the meantime please contact Pam Grant at the NCRAOA.

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1 INTRODUCTION

1.1 Background

The principal aim of the Environment Agency[8] is to protect and enhance the environment as a whole and to contribute to the Government's goal of sustainable development. In doing so, the Environment Agency evaluates the severity of risks and the effects that these have on the environment. The basis for this activity and the broad approach to its delivery is set out in the Agency's Environmental Strategy (Environment Agency 1996a and in prep.) and summarised in Figure 1.1. The Agency operates at a series of levels, from the site-specific assessment of risks from individual facilities, through the evaluation of risks at a regional scale, to the determination of national priorities. Throughout, the Agency is required to take account of the costs and benefits of its actions (Environment Agency, 1994), these will include costs and benefits to the Agency, society at large and those directly affected by the actions. The Agency's framework for the consideration of 'risks' and 'values' at a strategic level is in preparation (Environment Agency, 2000a).

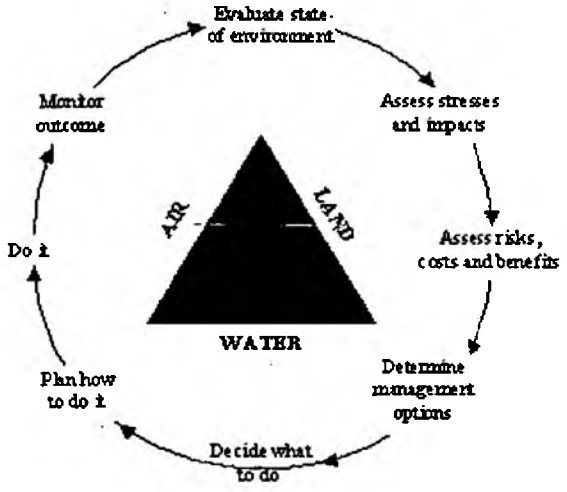

Figure 1.1: Environmental Management Cycle

Risks of harm to people and to the environment can be increased as a result of human activities. It is generally assumed that such risks are not created for their own sake. They often arise as a by-product of some function or process, and therefore there is a need to balance this against the benefits that arise. Equally, however, there are situations where risks already exist, either naturally - such as flooding, or because of the presence of high levels of natural or artificial radionuclides - or because of historic human activities – land contamination, for example. In recognition of the

[8] The Environment Agency of England and Wales was established by the Environment Act 1995 to combine the functions of Her Majesty's Inspectorate of Pollution (HMIP), the National Rivers Authority (NRA) and the Waste Regulation Authorities and to exercise and be subject to a number of additional powers and duties. It took over the functions of those former bodies on 1st April 1996 on which date HMIP, NRA and the Waste Regulation Authorities ceased to exist.

risks inherent in all of these activities, systems for their regulation and management have been developed. As well as its responsibilities for sustainable development and to balance costs and benefits, where risk assessment and risk management have been given a clear role, the Agency has responsibilities for regulating and managing a large number of environmental risks.

The Agency operates with constant reference to environmental risk (POST, 1996). Many of the operational and strategic decisions made by the Agency involve some implicit consideration of risk principles, but increasingly, a more explicit treatment is being required. Pressure is coming from two directions:

- there is a renewed emphasis on quality regulation within Government (Cabinet Office, 1999), on the appropriate use of scientific advice in policy-making (DTI, 1998), within the context of sustainable development (DETR, 1999a); and
- there is also an increasingly specific reference to risk assessment within statute

Recommendations for Departments and Agencies to publish their high level frameworks (ILGRA, 1998) within which they consider 'risk' have been endorsed by Government and the first of these have been consulted upon (HSE, 1999; DETR and Environment Agency, 2000). It is timely, therefore, that the Environment Agency reviews the handling of risk within its regulatory and supervisory remit and explains the contexts within which it makes risk-based decisions. That is the principal aim of this document.

The Agency's responsibilities are currently carried out, either explicitly or implicitly, using risk assessment as a regulatory or management tool. In some areas structured and explicit procedures have been established; in other areas, the approach is more intuitive and reliant on expert professional judgement. This is a reflection of developments in environmental legislation and the broad range of risk-related activities that fall under the Agency's remit, which include:

- directing pollution prevention activities;
- regulating radioactive waste disposal;
- managing flood defence;
- assessing dangerous substances;
- allocating resources to individual regulatory functions; and
- setting corporate business priorities.

1.2 Purpose

The National Centre for Risk Analysis and Options Appraisal (NCRAOA) was established in 1997 as a forward thinking centre to progress activities in the field of risk assessment and options appraisal and to provide a corporate lead in the development of risk-based tools and techniques. This document summarises the context within which the Agency makes risk-based decisions. It describes the principal risk-related activities in the Agency and presents current experience and practice. It also incorporates, as an Annex, a register of the most common risk tools and techniques used within the Agency.

This document builds from an earlier version drafted in 1995/96 by the Ad-hoc Working Group on Risk in the Environment Agency, chaired by the Director of Environmental Strategy (Environment Agency, 1996b). It pulled together the wide ranging expertise from the Agency's predecessor bodies. Since then, the document has been restructured, consulted upon widely and used to formulate the Agency's thinking as to how our handling of risk might converge over the coming years.

The portfolio has been produced with the following objectives in mind:

- to promote awareness and consistency among different parts of the Agency involved in risk assessment;
- to act as an information source for interested parties external to the Agency;
- to provide a foundation for the further development and application of risk assessment in the Agency;
- to support the Environmental Protection Directorate's initiative on risk-based regulation;
- to provide a foundation for the further development and application of risk assessment in the Agency; and
- to support the development of the Agency's expertise and capabilities in integrated environmental assessment and protection across all functions;

There are additional reasons for reviewing the risk-related activity of the Agency:

- providing a better appreciation of the range of risk-related activities undertaken by the Agency;
- to guide further formalisation of intuitive approaches;
- providing for defensible and consistent decision-making across the Agency taking into account cross-functional issues; and
- providing a mechanism for targeting resources more effectively

This document does not aim to cover Health and Safety issues. The Portfolio needs updating on a regular basis to reflect changes in the regulation and in the risk-based approaches used as well as to include new approaches, tools and techniques. It is envisage that this document will be revised in two years time. However, the Register of Tools should be continually updated as and when new tools, techniques and/or procedures emerge.

1.3 Structure of the report

Following this introduction, Section 2 of the portfolio provides an outline of the principles of risk in the context of the Environment Agency's responsibilities, including definitions of terms and the role of risk assessment in environmental regulation. Sections 3 and 4 then provide an overview of the Agency's risk assessment approaches and examples on how different functions address risk assessment. Section 3 summarises the key activities by function whilst Section 4 presents the non-statutory uses of risk assessment within the Agency. Information is presented on each of the function's regulatory powers and duties and the current risk-based approaches. In addition, a summary of the key tools, techniques, procedures and models used to support the risk assessment process are also provided. For consistency Sections 3 and 4 have been structured as follows:

Rationale	Summary of key legislative powers, duties and responsibilities by function (i.e. what is the basis for the function's role)
Organisational framework	List of key partners, collaborators and guidance documents necessary to ensure that risk-based regulatory activities are adequately conducted by Agency. For example, the Department of Trade and Industry (DTI), Department of the Environment, Transport and the Regions (DETR), Local Authorities or industry.
Approaches Used	Brief explanation on the role of risk assessment and how risk is assessed, to include a generic figure that provides an overview of the approach used – i.e. the basis for decisions within the guidance documents mentioned above. This section will also include information where available on: • how (and why) risk assessment is used to support decisions made by each function; • what is the risk assessment process used for (e.g. application for license, corporate planning?); and • what is the level of detail of the assessments (i.e. is the procedure followed in an ad-hoc manner, or does it follow a mre structured approach)?
Tools and Techniques Used	Register of the most important risk assessment tools, together with a description of those used within each function. Information is presented in Sections 3 and 4 as well as in the Annex.

Section 5 provides an overview of the risk-based activities across the Agency. This section compares and contrasts the different approaches used and highlights the reasons why different approaches have been development. Priorities for development and recommendations are also presented.

Finally the Annex provides a Register of Risk Assessment Tools (i.e. techniques, procedures and models) used to support the risk assessment processes. This Annex does not attempt to be fully comprehensive as tools are constantly being developed and updated. Nonetheless it contains most tools and therefore should provide a

does not attempt to be fully comprehensive as tools are constantly being developed and updated. Nonetheless it contains most tools and therefore should provide a valuable source of information. To facilitate keeping this Register of Tools up-to-date, please contact the NCRAOA with any additional information you may have on tools which have been omitted or are currently being developed by the Environment Agency. Because the Annex needs to be constantly updated, it is only going to be made available on the intranet[9].

[9] For further details contact the NCRAOA

2 PRINCIPLES OF RISK IN ENVIRONMENTAL REGULATION

2.1 The Risk Portfolio and Existing Guidance

The Department of the Environment first provided guiding principles for environmental risk assessment in 1995 (DoE, 1995a). This document, informally referred to as 'Green Leaves', provides general advice for public sector environmental risk assessments as well as a framework for the practice of risk assessment within environmental decision-making. DETR and the Agency are currently in the process of revising this document, which should be published in the near future (DETR & Environment Agency, 2000).

The Environment Agency is in the process of developing a strategic vision ('Risks and Values') that allows decision-makers to respond to environmental risks by taking into account society's values (Environment Agency, 2000a). This vision is in line with the Agency's commitments to sustainable development and should provide a policy basis for deciding what to do to deliver a better environment as highlighted by the Agency's environmental management cycle (Figure 1.1).

The 'Risk Portfolio' fits under this 'Risks and Values' framework. It provides information on the approaches currently used in the Agency to assess environmental risks in terms of the regulatory processes, operational decisions and the tools available to support these. This Portfolio is an extension of the guidelines provided by DETR (DoE, 1995; DETR and the Environment Agency, 2000), but is specific to the work conducted by the Agency. It reviews the role of risk assessment within the context of environmental regulation and summarises the use of tools and techniques used internally by the Agency to place its activities on a risk basis. It provides guidance on how the Agency uses risk assessment and points the reader to other documents in use for specific aspects of regulation.

An earlier version of the portfolio was drafted in 1995/96 by the Ad-hoc Working Group on Risk in the Environment Agency, chaired by the Director of Environmental Strategy (Environment Agency, 1996b. It pulled together the wide-ranging expertise from the Agency's predecessor bodies. This version incorporates new developments that have taken place since then. The document has been restructured, consulted upon widely and used to formulate the Agency's thinking as to how our handling of risk might converge over the coming years.

2.2 How Does the Agency Apply Risk Assessment?

The application of risk assessment by the Agency for the purpose of assisting regulatory decision-making can be grouped according to whether it is:

- **a regulatory risk assessment**, whereby the Agency undertakes the risk assessment *itself*; for example, in the Agency's work for the DETR and the European Community (EC) on the notification of new and existing substances; or

- **an applicant risk assessment**, whereby operators, dischargers, developers, abstractors or other persons[10], are required, either by specific legislation or at the general request of the Agency, to undertake risk assessments in support of their application to discharge, operate or develop facilities.

The majority of the Agency's activity in risk assessment is in guiding and reviewing the latter category of risk assessment. However, the Agency may also develop its own risk assessment procedures, in consultation with others, to assist in prioritising and resourcing its work. The development of 'operator and pollution risk appraisal' (OPRA) for process industry regulation and waste management inspection are two examples of this, but similar examples also exist from corporate planning, flood defence project management and from the prioritisation of the Agency's R&D programme.

Not all activities require risk assessment. Familiar activities where the risk is negligible do not require assessments. The Agency may apply general rules or default standards for the management of these risks. As the uncertainty increases and the likelihood of severe consequences becomes less clear, however, a formalised process of risk assessment assists in understanding more about the source and nature of the risk and how to avoid or manage it. Benefits of a formalised assessment include:

- being able to evaluate the underlying hazard and its likelihood of being realised;
- establishing a more logical basis for managing the risk; and
- recording decisions made for future use.

These are the principal reasons why the Agency requires risk assessments to support its regulatory and supervisory activities. A further benefit is gained by making the judgement process and its underlying logic transparent for others to appraise.

2.3 Definitions

Risks can not occur without *exposure* of a receptor (or target) to the source of the hazard. In terms of chemical exposure, this principle is encapsulated within the phrase 'the *dose* makes the poison', that is, it is the amount of a hazardous substance that reaches a receptor that is important in determining the risk. Risk assessment is a process for combining what is known and what can be reasonably inferred about an exposure situation for the purpose of managing the risk. 'Risk' can therefore be defined as the probability of suffering *harm* from a *hazard*; this term embodies both the likelihood and consequence. 'Hazard' refers to the potential adverse *effect* posed by the source of the hazard (e.g. a toxic substance or hazardous situation) and 'harm' relates to the observable *damage* that occurs (this term is often referred to as the detriment, impact or response). Hazard, risk and harm are discrete terms and should not be confused or used interchangeably.

There is often considerable uncertainty involved in assessing environmental risk, particularly in the assessment of environmental exposures and impacts. The greatest effort must be targeted to ensure that there is a balance between the amount of effort

[10] For simplicity, hereafter this term will be simplified to 'the operators'

put into conducting a risk assessment and the benefits that can be obtained. For example, greatest effort should be directed towards high risks, where uncertainties are high, or where the costs of the assessment are justified by the benefits to decision-making. A proportionate and iterative approach to risk assessment facilitates early risk prioritisation and avoids unnecessary detail. Such an approach also ensures that the level of detail required with respect to the methodology used to assess risks matches the needs of the problem under investigation (Figure 2.1). This is described in detail elsewhere (DETR and the Environment Agency, 2000).

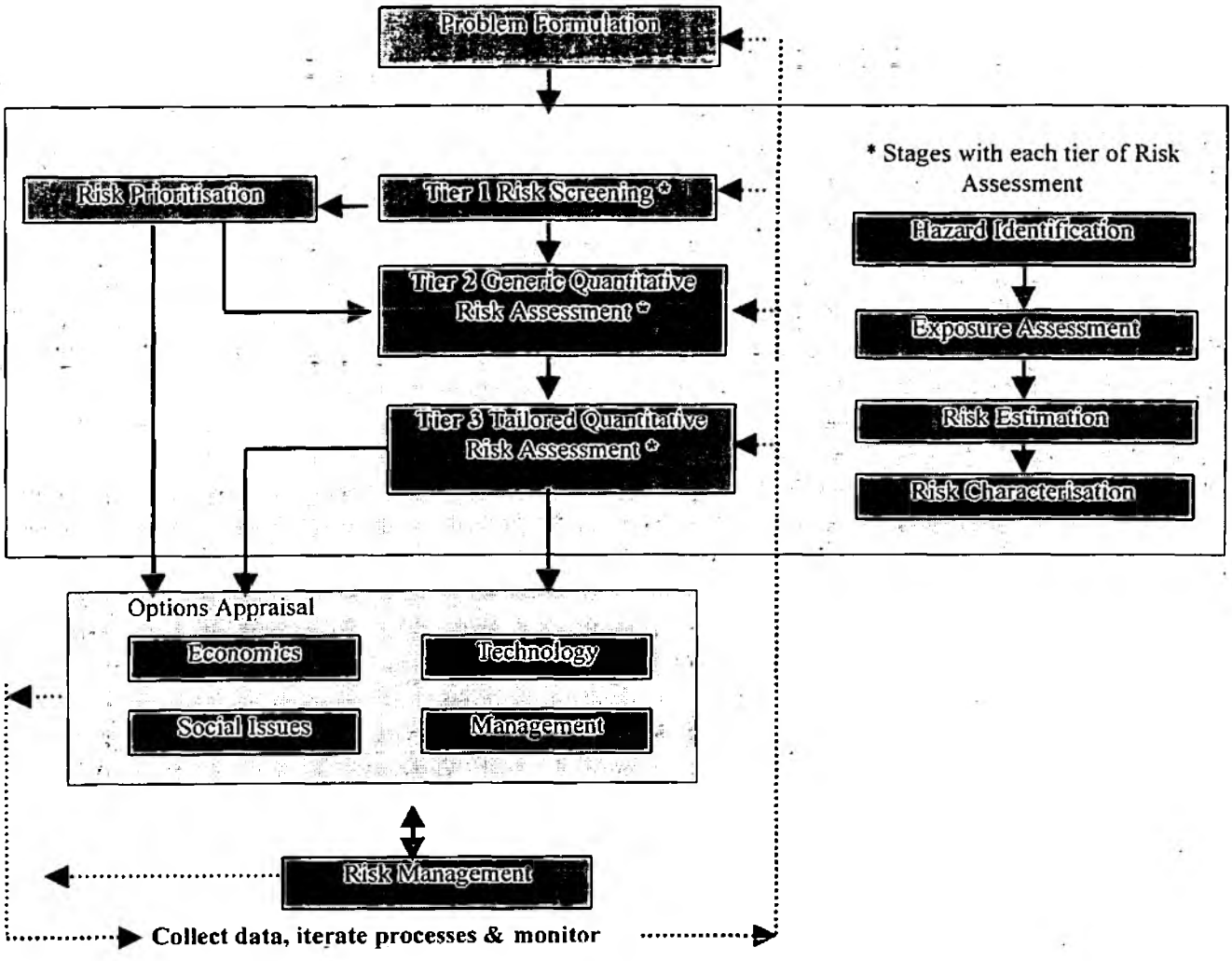

Figure 2.1 Framework for environmental risk assessment (NCRAOA, 2000)

2.4 The Risk Assessment Process

The process of risk assessment typically involves four stages each of which aims to answers various questions (Table 2.1).

Stage	*Definition*	*Questions that need answering*
Hazard identification	*Identification of the sources of the hazard and assessment of the consequences of the hazard if realised, including the identification of dose-response relationships, where appropriate*	*What hazards are present? and What are their properties?*
Exposure assessment	*Evaluating the plausibility of the hazard being realised at the target, and by which mechanisms, allowing an assessment of the probability, magnitude and duration of exposure*	*How might the receptors become exposed to the hazards? and What is the probability and scale of exposure?*
Risk estimation	*Consideration of the consequences of exposure with reference to effects and dose, expressed as a likelihood or probability of the hazardous effects of exposure being realised; and expressed over a range of spatial and temporal fields*	*Given exposure occurs at the above probability and magnitude: What is the probability and scale of harm?*
Risk characterisation	*Evaluating the acceptability and significance of risk with reference to standards, targets, background risks, cost-benefit criteria or risk 'acceptability' and 'tolerability' criteria and commenting on the uncertainties associated with the assessment*	*How significant is the risk? and What are the uncertainties?*

Table 2.1: Typical stages in the risk assessment process

A principal consideration for the application of risk assessment is the *type* of risk under consideration. With respect to environmental risks, the Agency is concerned with three main types of situation:

- **the risk of an initial event** occurring that may result in a release (e.g. the failure of a flood defence structure, a bund, a fuel tank or landfill gas extraction system);
- **the risk of exposure to the wider environment** following a release (e.g. the distribution of particulates from a cement kiln stack, the derogation of a drinking water supply from a leachate plume); and
- **the risk of harm resulting from exposure** (e.g. risks to individuals and properties from the surging flow of flood waters, risks to human or ecological health as a result of exposure to asphyxiant gases).

These different types of risk generally require quite distinct treatment and particular tools for their analysis.

Risk assessment is widely used across the Environment Agency as an aid to decision-making. The starting point is therefore a clear definition of the decision to be made which in turn will dictate the risk assessment approach adopted. For example, if the decision involves allocation of resources, the focus of the risk assessment can be on comparing relative risks rather than on assessing their 'absolute' value. However, all risk assessments whether they are qualitative, semi-quantitative, or quantitative

should follow the steps shown in Figure 2.1. The final step involves making the decision on the basis of the assessed risks and implementing the choice. The process of proceeding through each of these steps can be complex, not least because of the lack of relevant information, and a wide range of approaches is used in various applications of risk concepts. A number of factors can be identified which influence the approach used, including:

- the existence of historical frequency data and familiarity with failure probability concepts;
- the nature of the risk (many risks relate to pollution, but the risks of drought and flooding are different in nature);
- the complexity of the activity involved;
- the level of understanding of the exposure-effect relationships (for radiation, the dose-response relationships are relatively well understood and principles for protection have been established based on these; this is not the case for many other polluting substances); and
- the availability of hazard data (data are often only available for relatively high levels of exposure and for exposure of a few organisms; procedures then need to be developed for extrapolating the data to the situations of concern).

2.5 Additional References

Further general guidance is available on risk assessment principles and applications (see for example: EEA, 1998; Douben, 1998; Pollard *et al.*, 1995; and The Presidential/ Congressional Commission on Risk Assessment and Risk Management, 1997) and specific advice for individual functions is given in the following chapters. Risk policy is a subject of considerable debate and useful documents are available on this subject (for example: The Royal Society, 1983 and 1992; Adams, 1995; and Bate, 1997).

3 CURRENT REGULATORY FUNCTIONS

3.1 Context of Risk-based Decision-Making

Most of the day-to-day activities of the Environment Agency's operational staff involve some element of risk assessment and management. Decisions and judgements are made within the context of specific statutory duties and/or powers within the context of the principal legislation or regulations (Fry, 1997 and the Environment Agency, 1999a). In many cases, judgements are made implicitly on the basis of expert professional judgement and experience.

The Agency is working towards developing more structured and traceable procedures to provide a more consistent and transparent approach. This will lead to more formalised risk assessment activity and assist in ensuring the costs and benefits of the Agency's actions are more formally accounted for and allow appropriate allocation of resources across the Agency's wide range of supervisory and regulatory functions.

This section looks in more detail at risk-based activities within the Agency. Figure 3.1 provides an overview of the Agency structure and of where risk assessment is formally applied. Subsequent sections present pertinent information on individual risk-based approaches within each Directorate and function.

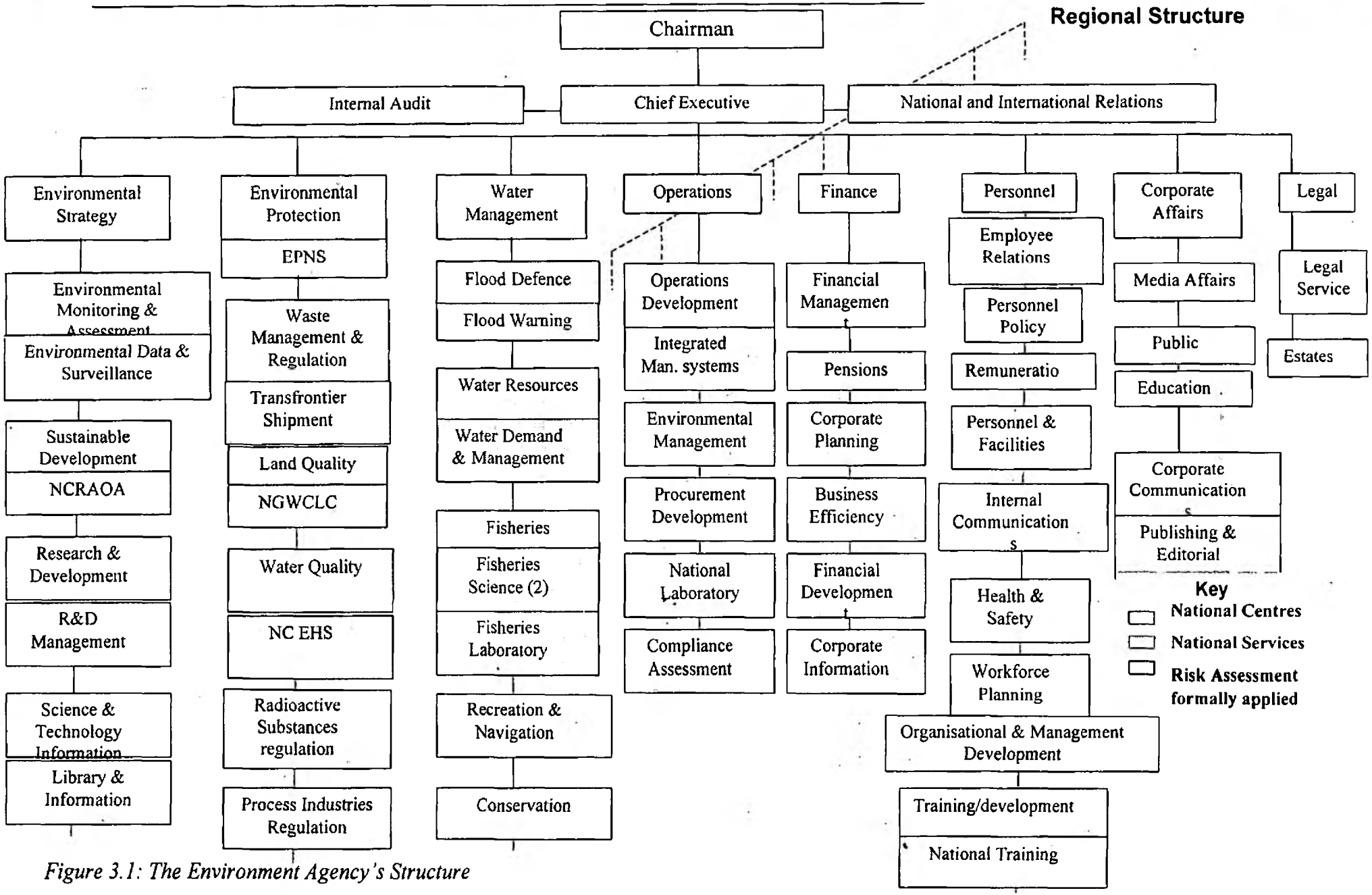

Figure 3.1: The Environment Agency's Structure

3.2 Environmental Protection Directorate

3.2.1 Process Industries Regulation

3.2.1.1 Rationale

The Process Industries Regulations' (PIR) role is to protect and enhance the environment as a whole by preventing and minimising pollution from the most technically complex and potentially most polluting industrial process in England and Wales. The principal duties and powers are governed by the Environment Act 1995 and the Environmental Protection Act (EPA) 1990 (The Environment Agency, 1999a)[11]. The Agency is responsible for the system of authorisation known as Integrated Pollution Control (IPC), currently being replaced by Integrated Pollution Prevention and Control (IPPC; see section 3.2.6 below for further details). In addition, the Agency has responsibilities for implementation of the Control of Major Accident Hazard (COMAH) Regulations. Both IPC and COMAH are briefly outlined below.

IPC governs releases into all environmental media (air, land and water) and applies to the most serious polluting processes that are defined by reference to lists of prescribed processes and releases of prescribed substances. Companies operating processes prescribed for IPC need to obtain prior authorisation from the Agency to operate the process. In determining an authorisation under IPC, the Agency is responsible in particular for ensuring that the Best Available Techniques Not Entailing Excessive Cost (BATNEEC) will be used to prevent, or where this is not practicable, to minimise and render harmless releases. Where releases to more than one medium are likely the Agency must have regard to the Best Practicable Environmental Option (BPEO) available. In addition, the Agency is required to place appropriate conditions within the authorisation. This is to ensure that releases do not cause, or contribute to, the breach of International or EC conditions and other requirements prescribed by the Secretary of State (SoS) or any statutory environmental quality standard or objectives (EQSs or EQOs).

The COMAH Regulations[12] were brought into force in the UK on 1 April 1999 to comply with the requirements of the Council Directive to control Major Accidents involving dangerous substances, including major accidents to the environment (the so-called Seveso II Directive)[13]. This requires operators of establishments where dangerous substances are present to take all measures necessary to prevent and mitigate the effects of major accidents to man and the environment. Demonstration of the presence of adequate safety measures is a key part of this process (Environment Agency, 1999b). Operators who were previously subject to the Control of Industrial Major Accident Hazards (CIMAH) Regulations will recognise similarities between these and the new COMAH Regulations. However, one of the key differences between the two is that under COMAH, safety and environmental risks are

[11] Other enactments to the legislation are the Environmental Protection (Prescribed Processes and Substances) Regulation 1991 (as amended); the Environment Protection (Applications, Appeals and Registers) Regulations 1991 (as amended); and the Environment Protection (Authorisation of Processes) (Determination Period) Order 1991

[12] SI 1999 743 The Control of Major Accident Hazards Regulations 1999 HMSO

[13] Council Directive 96/82/EC of the 9 December 1996 on the control of major accident hazards involving dangerous substances

given equal importance and should be treated, where practicable, in an integrated way. In this respect, the Agency is concerned with events that do not have a direct impact on people, such as the risks to flora and fauna and indirect risks to people, for example via contamination of drinking water or crops.

The general duty on every operator under COMAH is to 'take all measures necessary to prevent major accidents and limit their consequences to persons and the environment'[14]. All operators must demonstrate that:

- a Major Accident Prevention Policy and a safety management system are in place;
- top tier COMAH sites must also submit a Safety Report for consideration by the COMAH Competent Authority;
- all Major Accident Hazards have been identified and that the necessary measures have been taken to prevent such accidents and to limit their consequences;
- adequate safety measures have been incorporated into the design and construction and operation and maintenance of any installation or equipment;
- on-site emergency plans have been drawn up and sufficient information is supplied to enable the off-site plan to be drawn up by local authorities; and
- sufficient information is provided to the Competent Authority for land-use planning purposes.

3.2.1.2 Organisational Structure

For IPC the PIR function works with other Agency functions, process operators, other regulators, the public and other stakeholders to secure the optimum environmental solution.

The HSE and the Environment Agency act jointly as the Competent Authority for the enforcement of the COMAH Regulations. The Agency is principally concerned with the assessment of the environmental aspects of COMAH, whilst HSE is concerned with the safety aspects. Local authorities have the responsibility to carry out public consultation on emergency planning and to prepare, and test, these emergency plans.

3.2.1.3 Approaches Used

The 1990 Act requires BATNEEC to be used to prevent and minimise releases of prescribed substances and to render harmless any substances which are released and which might cause harm. Although the Act defines harm, it does not define the nature of the effects that may be considered harmful or the level in the environment at which they may occur. Nor does the Act provide guidance on what is required for demonstrating that the operator's choice of option represents the BPEO. In order to provide a transparent and consistent procedure to support the professional judgements of inspectors in addressing these issues, a technical guidance note has been produced as a practical approach to the assessment of harm and of BPEO (The Environment Agency, 1997a)

Environmental criteria (e.g. EQSs) provide a "benchmark" against which the relative harm of releases can be assessed. When specifying authorisation conditions, the Agency has to ensure that the process is appropriate for achieving compliance with the environmental criteria. Where this is likely to be breached, the Agency has to come to a view as to the most appropriate manner to reduce environmental concentrations to below the benchmark. Thus EQSs define the upper bound of the concentration of a substance in the environment which can be considered tolerable. At present, only a limited number of substances have statutory

[14] Regulation 5 and Schedule 2 of the Regulations

EQSs. An approach has been developed by which environmental harm can be judged by considering the concentration of a substance in comparison to a reference level, known as the Environmental Assessment Level (EAL), of that substance[15].

A judgement needs to be made about the relative importance of the releases in respect to the criteria used and involves balancing the effects of the releases on the environment against the costs to prevent, minimise and render harmless. In determining what is 'excessive' cost for BATNEEC, the following criteria are used: costs should not be disproportionate to the environmental benefits delivered, and costs should be affordable when considering the sector as a whole (sectoral affordability). In practice, BATNEEC is determined for each plant, using information provided in Technical Guidance Notes produced by the Environmental Protection National Service (EPNS) and taking into account site specific factors for existing plants. The Technical Guidance Notes contain some information on the costs of techniques available and on the economic situation of some sectors, which is used in determining BATNEEC. In addition, guidance is currently being prepared by the NCRAOA for PIR inspectors on the collection and use of cost information from operators, and a pilot database of abatement cost information to help inspectors verify and benchmark information from operators.

Once a process has been authorised, the Agency needs to be satisfied that the conditions in the authorisation are being complied with. This is achieved by carrying out periodic site inspections. The frequency and conduct of site inspections and follow up action are determined by a procedure based on risk to assess the performance of operators of prescribed processes, known as OPRA (Operator Pollution and Risk Appraisal; Environment Agency, 1997b). Further details of this risk-based approach are provided in Section 4.1.

BPEO assessment of IPC processes

The BPEO assessment procedure is concerned with identifying which combination of pollution control techniques represents the best option in terms of providing the most benefit or least damage to the environment as a whole, at acceptable cost, in the long term as well as the short term. Figure 3.2 illustrates the BPEO assessment methodology developed by the Agency for use by operators and inspectors of IPC processes. The first step in the procedure is to define the objective of the particular IPC process on which the assessment is to be performed. The operator then has to generate options for achieving the objective by looking at the available techniques, screening these and selecting a small number of options to achieve the objective, to include the preferred option[16].

An assessment of the environmental effects is then conducted on each of the options selected. Maximum concentrations of released substances in the environment should be compared with statutory EQSs or EALs. It also involves prioritising the substances released according to whether they can be considered insignificant, significant or a priority for control. For substances identified as being of priority for control, it is necessary to generate a number of options from a consideration of available pollution control techniques that will reduce releases to the environment. The potential environmental effects of all significant releases from each option then need to be estimated. For direct environmental effects this involves the calculation of the maximum long-term (and/or short-term) environmental concentration of each significant release and its comparison with the appropriate EAL. The ratio of the two

[15] Where there is a statutory EQS, then the EAL will be the EQS. Otherwise, these may be obtained from a variety of sources, such as World Health Organization (WHO) Guidelines, EC Directives, information developed by the US Environmental Protection Agency (USEPA), HSE occupational exposure standards and maximum exposure limits and expert judgement

[16] For a new process the preferred option is likely to be the latest, cleanest techniques. For existing processes, it is likely to be the current situation, unless there are plans to upgrade the plant

concentrations has been termed the Environmental Quotient (EQ) for the substance in the medium. The sum of the EQs for all substances and media (known as the Integrated Environmental Index, IEI) is used to provide a measure of the environmental risk presented by the option.

The operator also needs to determine whether there are any significant indirect environmental effects of concern, to include global warming, ozone creation and waste raisings. These are measured by using indicators such as the direct global warming potential (GWP), photochemical ozone creation potential (POCP) or waste hazard scores (The Environment Agency, 1997a).

The operator should then summarise the impacts arising from each option using the available indicators (IEI, GWP, POCP, etc) together with the cost of each option. The BPEO can then be selected as the option which gives the least impact (or greatest benefit) to the environment without entailing excessive cost. In identifying the BPEO it may be helpful to present the costs of the options against one or more of the indicators either graphically or in the form of a table.

COMAH

It is recognised that risks cannot be completely eliminated, but that measures are required for prevention and mitigation. Allied to this procedure is the comparison of the results of a risk assessment with risk acceptability criteria and the determination of the need for risk management action. This is based on the concept of risk tolerability which requires that measures are taken to reduce the likelihood of hazards and to limit their consequences until further reduction of risks cannot be justified, that is, that the risks are 'as low as reasonably practicable' (ALARP). The ALARP principle implies that ultimately there is a trade-off between the costs of risk reduction and the benefits obtained (and in doing so the BATNEEC is applied to environmental risks).

Under COMAH, there is a fundamental requirement for operators to approach the environmental risk assessment in a systematic way and to demonstrate clearly that all risks have been identified and that measures are in place to prevent major accidents and to limit their consequences if they occur. The use of risk assessment techniques in a systematic fashion allows for the identification of the most important high-risk accident scenarios and prioritisation of resources, resulting in a transparent, proportionate approach to the management of major hazards from dangerous substances.

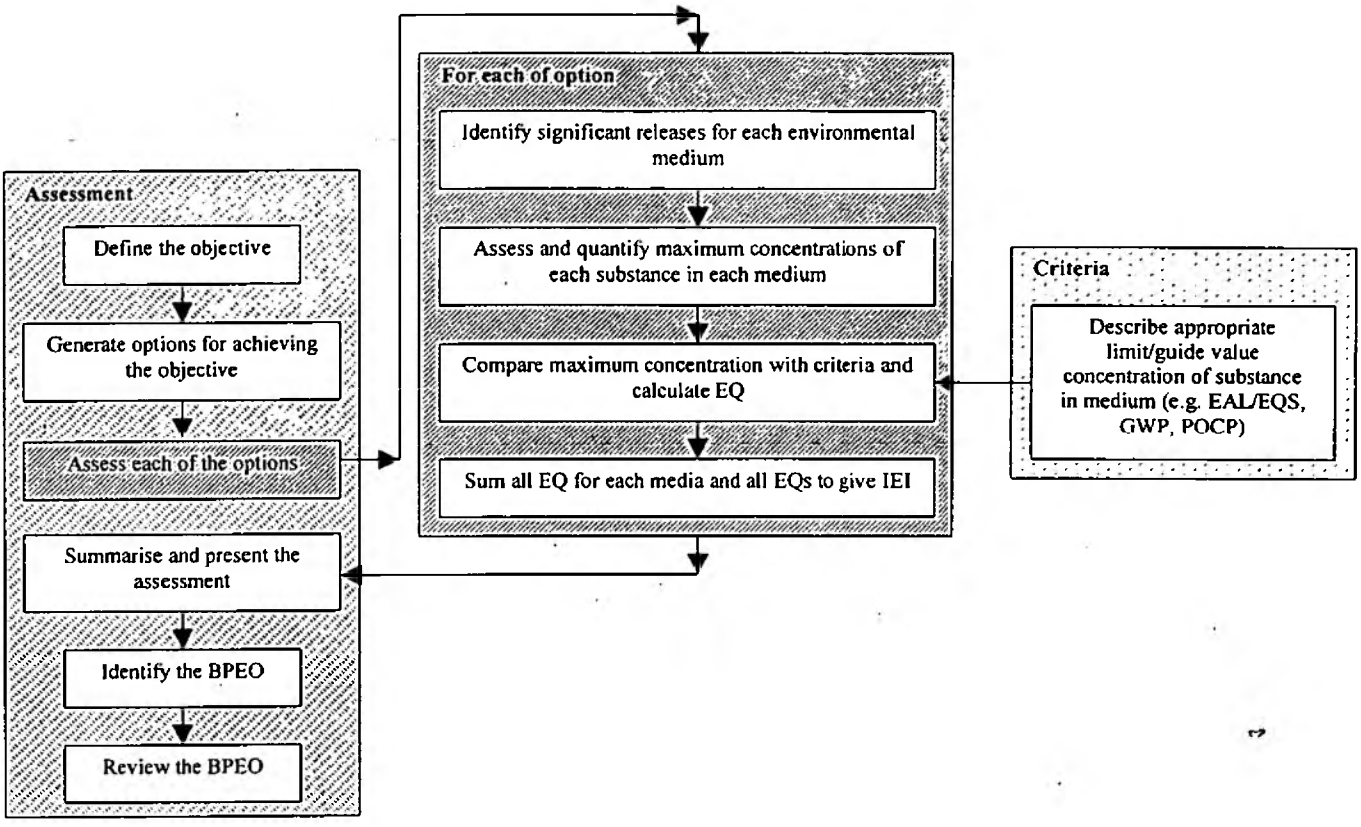

Figure 3.2: Assessment for BPEO

The first main stage in the risk assessment is to identify and understand the causes of the initiating events that may potentially result in a 'Major Accident To The Environment' (MATTE). This process should allow the operator to screen out lesser events that cannot cause a major accident, thereby concentrating their efforts towards those events and substances prioritised. The next step is to understand what the effect of the release will be. This requires both details of any changes in the substance following its accidental release and an appreciation of the effect of the resultant exposure to the environment. The predicted consequences of the various accidents considered may be compared with the guidance on situations which would be considered MATTEs under the COMAH Regulations.

For those events that may result in MATTEs, it is necessary to demonstrate that the risks are adequately managed. This requires a clear explanation of what measures are currently in place to prevent or reduce the possibility of a major accident occurring. Justification for not introducing additional control measures should also be provided; the extent of this justification should be proportionate to the magnitude of the risks.

When considering the efficacy of existing measures or the introduction of new measures it is essential that all reasonable options for eliminating the risk have been considered before identifying prevention or mitigation measures and control strategies. Risk management can be directed towards affecting any one of these, although the priority should be to reduce or eliminate the risk at the earliest practicable opportunity in the accident sequence.

3.2.1.4 Tools and Techniques Used to Support the Assessment

Numerous guidance documents have been produced for IPC (e.g. Environment Agency, 1997a). In addition a number of models are available to estimate and/or forecast pollutant concentrations, dispersion and deposition, following environmental releases to air. Examples

of these include HARM, NAMEII, UKADMS and DISTAR (see PIR001-006 in the Annex for further details).

With respect to COMAH, over 50 joint HSE/Environment Agency guidance documents have been prepared. One of these, publicly available on the Agency's web site, deals with Environmental Risk Assessment for COMAH (HSE and Environment Agency, 1999b) There are a number of models and software tools available, both in the public domain and on a commercial basis, which may be used to undertake these assessments. The Agency has no software tools to support the COMAH assessments and it is up to the operator to select the most appropriate techniques and tools that will suit the assessments of their establishments.

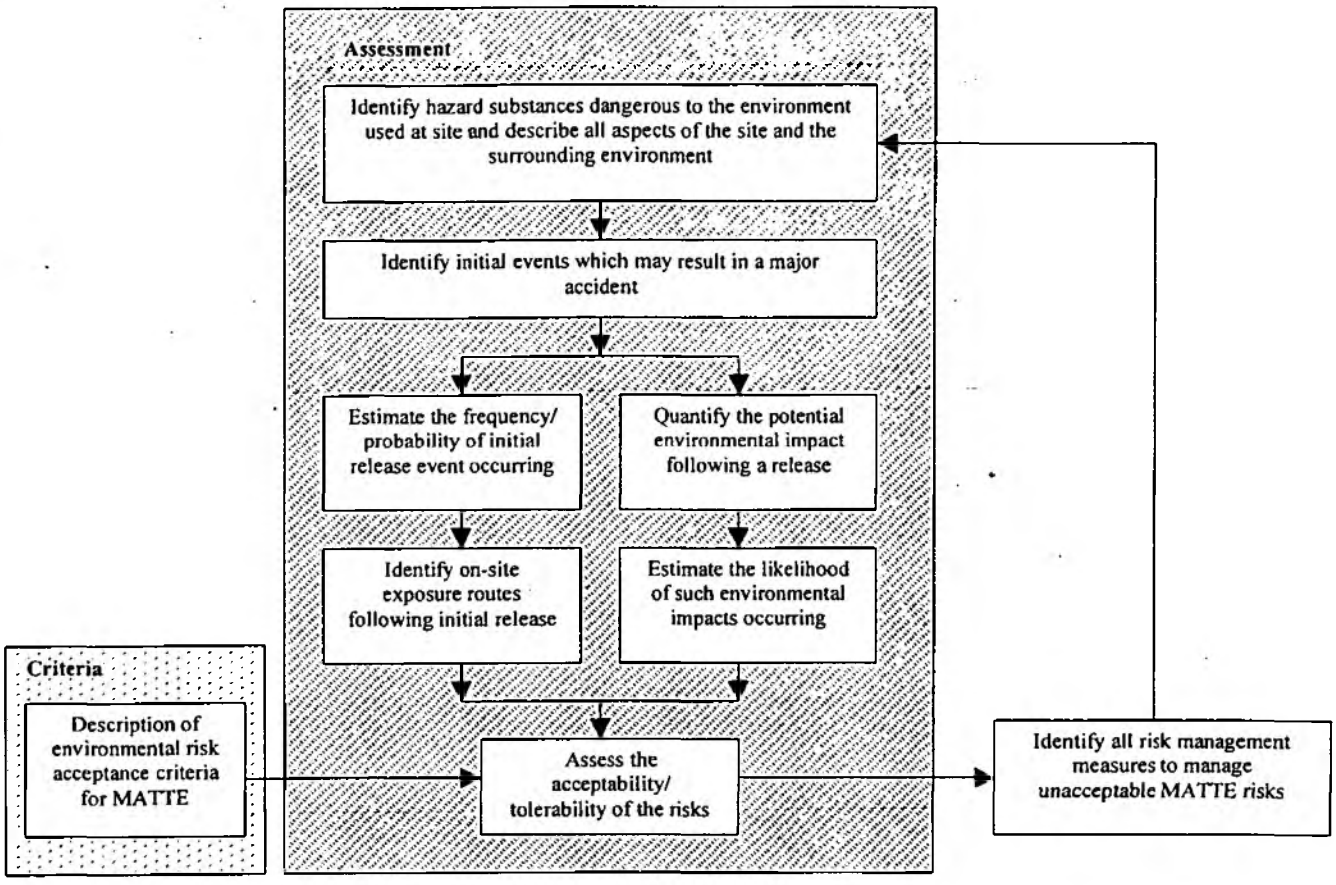

Figure 3.3: Typical risk assessment and management methodology for COMAH

3.2.2 Radioactive Substances Regulation

3.2.2.1 Rationale

The Agency regulates the use and the disposal of radioactive substances and radioactive waste under the Radioactive Substances Act 1993 as amended by the Environment Act 1995. The Agency's main statutory objective is to implement properly a policy and regulatory framework developed and maintained by the government, which ensures that radioactive wastes are not created unnecessarily and that any wastes that are created are safely and appropriately managed, treated and safely disposed of[17]. This must be done as to safeguard the interest of existing and future generations and the wider environment, and in a manner that commands public confidence and takes due account of costs.

The Agency's duties relate to securing (i) proper control of radioactive materials on premises and (ii) proper disposal of radioactive wastes from premises. In discharging its duties the Agency:

- sets and monitors compliance with conditions in registrations and authorisations;
- examines justifications for any practice which uses radioactive material and/or which gives rise to radioactive waste;
- assesses the waste implications of existing, new or modified plant and operators' practices and procedures to ensure the use of best practicable means to minimise both discharges and the creation of waste; and

[17] An Action Plan for Radioactive Substances Regulation, the Environment Agency, Bristol

- ensures that all environmental impact considerations are properly assessed by the operator.

The principles of radiological protection, by which exposures to radioactive substances are regulated, are based on risk. The principles are expressed in terms of effective dose, a concept that was developed as a measure of the risk of harm to human health from low level exposure to radiation. Clearly specified recommendations by the International Commission on Radiological Protection (ICRP) on the numerical relationship between effective dose and risk invite the use of a risk-based methodology in radiological assessments. In the case of radioactive substances, the assumption is currently made that protection of man from the hazard will also provide adequate protection to the wider environment. As a consequence, risk assessments only consider the effects on human health of exposure to the radioactive substances. This assumption, however, is currently being re-examined and the Agency is contributing to international research on the potentially harmful effects of radiation on organisms other than humans (Environment Agency, 1998).

3.2.2.2 Organisational Structure

Radioactive waste management policy is currently developed by Government departments, led by DETR[18], who receive advice from independent bodies such as the Radioactive Waste Management Advisory Committee (RWMAC), the Nuclear Safety Advisory Committee (NuSAC) and specialist radiological protection advice from National Radiological Protection Board (NRPB). The main regulators in England and Wales are the Environment Agency and the HSE. The two principal disposal organisations are British Nuclear Fuels (BNFL), and UK Nirex Ltd (Nirex). BNFL owns and operates a disposal facility for 'low level waste' (LLW) at Drigg in Cumbria. Nirex retains responsibility for disposal of 'intermediate level waste' (ILW), and some LLW, but their repository development programme has been suspended since the decision, in March 1997, to refuse planning permission for an underground laboratory at a site near Sellafield. Currently the policy is to store 'high level waste' (HLW) for a period of at least 50 years and consequently there are no plans for disposal of HLW. BNFL is the principal organisation with responsibility for storage of HLW. BNFL's radioactive waste management operations are regulated by the HSE and by the Environment Agency.

3.2.2.3 Approaches Used

Assessment of the risks from radioactive waste disposal facilities

In the context of radioactive waste disposal, risk assessment is one aspect of the overall safety case for proposed or existing disposal facilities. For the authorisation of the disposal of solid low and intermediate level radioactive wastes to land, a risk-based methodology is usually adopted which considers the ways in which radionuclides could escape the containment of the disposal system and result in exposure of human beings. The methodology generally includes a comprehensive and explicit approach to treatment of uncertainties. Guidance has been published on the principles and requirements that would need to be addressed in a safety case for radioactive waste disposal (Environment Agency *et al.*, 1997). This guidance states that after control is withdrawn, the assessed radiological risk from a radioactive waste disposal facility to a representative member of the potentially exposed group at greatest risk should be consistent with a risk target of 10^{-6} per year (i.e. 1 in a million, per year). Radiological risk is defined as the probability that an individual will suffer a serious radiation induced health

[18] DETR is responsible for policy, together with the Ministry of Defence (MoD) and DTI

effect as a result of the presence of a disposal facility. In this context, a serious radiation-induced health effect is a fatal cancer or a severe hereditary defect.

The operator[19] is responsible for producing the safety case for an existing or proposed radioactive waste disposal facility including any risk assessment studies and the approach used tends to be based on the typical methodology illustrated in Figure 3.4. The Agency undertakes a review of any case presented in support of an application for authorisation of radioactive waste disposal. The review will assess the safety case against any statutory requirements and against the guidance published under the Radioactive Substances Act 1993 (Environment Agency *et al.*, 1997) In its examination of the safety case, the Agency may undertake independent risk assessment studies to examine key arguments presented by an operator or to explore key assumptions or areas of uncertainty. The scope of any independent calculations is likely to be limited to examination of a number of key issues and may not extend to a full risk assessment study. Where the Agency is satisfied that good engineering and science have been adopted and that the estimated risk to the public is below this target, no further reductions in risk will be sought. However, if the estimated risk is above the 'risk-target', the Agency will need to be satisfied not only that an appropriate level of safety is assured, but also that any further improvements in safety could be achieved only at disproportionate cost.

The operator must conduct the risk assessment to examine compliance with the published regulatory risk criterion (Figure 3.4). This assessment will include a comprehensive treatment of the processes that might, over long time periods, influence the release of radioactive substances from the waste and their migration to the biosphere, through engineered and/or geological barriers surrounding the waste. Releases to the biosphere are considered in terms of dose, and risk, to potentially exposed groups. Risk assessments of radioactive waste disposal involve estimations over very long time-scales (up to 1 million years). In doing so a wide range of features, events and processes, and their interactions need to be taken into account together with any associated uncertainties. Consequently, uncertainties need to be addressed in a thorough, systematic and explicit manner. The risk assessment procedure provides an estimation of radiological risk to a representative member of a potentially exposed group. One of the factors that contribute towards increasing uncertainty is the ability to choose a suitably representative range of situations for use in an assessment of radiological risk.

[19] In this section the operator is used interchangeably to refer to both the operator or the developer

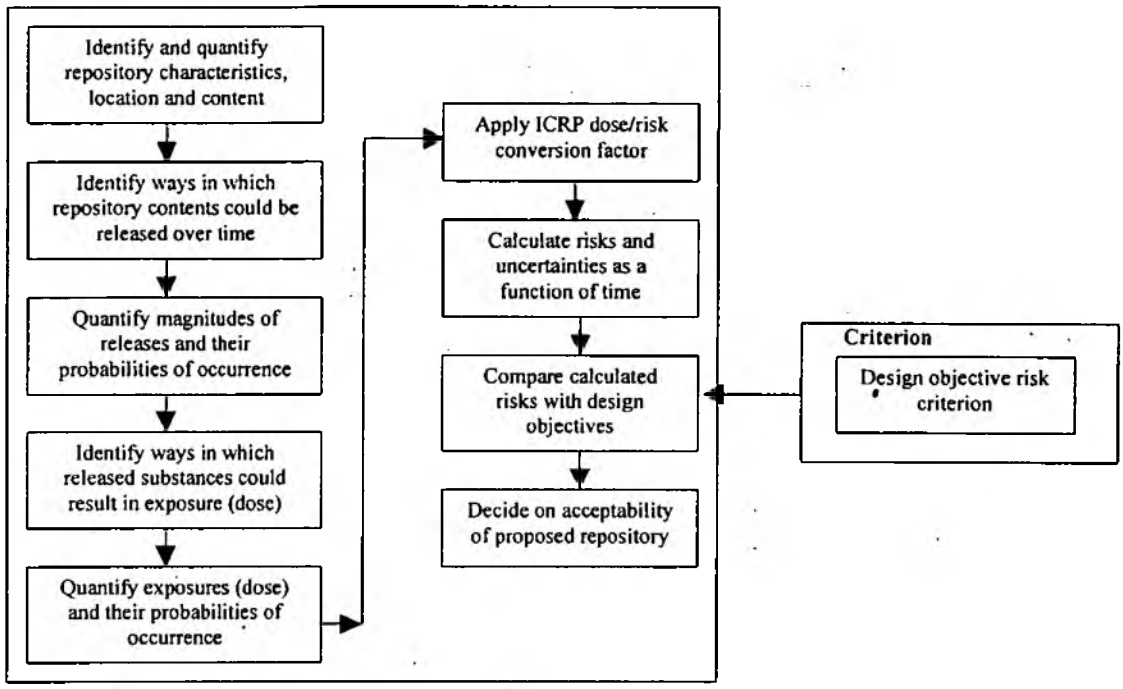

Figure 3.4: Typical risk assessment methodology for radioactive waste

3.2.2.4 Tools and Techniques Used to Support the Assessment

The radioactive waste disposal assessment "toolkit" provides the Agency with a quantitative capability to examine key arguments or areas of uncertainty within a safety case (see the Annex for further details). The "toolkit" was not designed or intended for undertaking a complete risk assessment as such an assessment is the responsibility of the operator of the facility. It might be used to look at specific issues within a safety case submitted by the operator or to undertake broader studies to examine possible alternative approaches to, say, treatment of the groundwater flow or climate change. It may also be used to undertake either deterministic calculations or for probabilistic risk assessment studies. The outputs would be data sets with appropriate graphic interpretations that might be used for comparison with similar information presented within a safety case. Alternatively, the outputs might also be used to provide further information to aid questioning of a particular line of argument within a safety case or to form a basis for any decisions taken by the Agency.

3.2.3 Land Quality

3.2.3.1 Rationale

The Agency's vision is to contribute to sustainable development by reducing the legacy of contaminated land and bringing it back into beneficial use, following an integrated approach to prevention of new land contamination. Land contamination may be present in many sites in the UK as a result of waste disposal or industrial use. However, not all these sites are cause for concern. New legislation allows for a greater focus on sites which cause problems in their current use and should ensure that other sites do not become 'problem sites' when they are redeveloped. Dealing with the legacy of land contamination is a considerable economic burden and it is currently not possible to bring all such land to a standard where it is fit for any purpose (i.e. multi-functionality). Instead, the aim is to ensure that sites posing the greatest risks are dealt with first and that risks are assessed in relation to the use of the land

concerned. The identification and promotion of suitable solutions must be based on sound science, an assessment of the risks and analysis of costs and benefits.

The Land Quality function deals with those issues that affect the quality of the land and soil. Agency powers and responsibilities under environmental protection legislation, including waste management, protection of controlled waters and regulation of major industries, are used to control existing activities and prevent new land contamination, including diffuse pollution of soils. New duties and powers have been introduced[20] to enable the Agency, in conjunction with local authorities, to tackle the legacy of contaminated land where it is causing a problem to health, the water environment or certain other receptors. The Agency also contributes to identifying and remedying land contamination through the planning and development control regime, as a statutory consultee on planning applications.

The Land Quality function:

- provides advice to the Government in its development of policy and legislation relating to land and soil quality, including contaminated land;
- develops Agency policy to deliver Government policy and legislative requirements to prevent future pollution of land or soil and to ensure that risks from existing contaminated land are adequately assessed and managed, such that the land can be brought into beneficial use; and
- develops, manages and delivers a research programme in support of policy objectives.

The new contaminated land regime is primarily administered by local authorities. However, the Agency has important responsibilities under the regime, including acting as enforcing authority for those categories of contaminated land classed as "special sites" under the Regulations. The Agency's duties include:

- providing information and advice to local authorities on land which may be defined as contaminated under the regime and on identifying pollution of controlled waters;
- ensuring remediation[21] of special sites and maintaining a public register of remediated sites; and
- preparing a national report on the state of contaminated land.

Part IIA EPA 1990 does not apply in relation to harm or pollution of controlled waters in respect of land contaminated by radioactive substances. However, the Government plans a parallel regime for dealing with land contamination from radioactive substances and the Agency's Land Quality function will be working closely with the Radioactive Substances Regulation function and Government to develop the new regime.

3.2.3.2 Organisational Framework

Local authorities are responsible for determination that sites meet the statutory definition of contaminated land. Once a determination is made, it is the responsibility of the enforcing authority to identify the appropriate persons, (these may be the polluter or the landowner), and to enforce remediation notices specifying what is to be done and by when in terms of

[20] Part IIA of EPA 1990, introduced by the Environment Act 1995 and brought into force in April 2000 through Regulations and Statutory Guidance

[21] Remediation involves: (i) assessing the condition of the contaminated land, any controlled waters affected by that land and any land adjoining or adjacent to the contaminated site; (ii) preventing, minimising, remedying, or mitigating the effects of any significant harm or pollution of controlled waters, or restoring the land or waters to their former state; and (iii) making subsequent inspections from time to time for the purposes of keeping under review the recondition of the land or waters (Environment Agency, 1999a)

remediation. The Agency is the enforcing authority in respect of Special Sites. Where the appropriate person(s) elect to carry out the necessary remediation voluntarily, the enforcing authority will not serve a remediation notice, but a remediation statement will be prepared by the appropriate person(s) instead.

Local authorities have the following duties:draw up and publsih inspection strategies; to inspect their areas to identify contaminated land; consult the Agency on pollution of controlled waters; ensure remediation of land identified as contaminated; transfer regulatory responsibility of special sites to the Agency; and maintain public remediation registers.

The Agency is working, in partnership with other organisations and using its statutory duties and powers, to address land contamination in an integrated way. Identifying and dealing with potential problem sites is one of the key areas where partnership with a wide range of other stakeholders (e.g. other regulators, environmental interest groups, national trade and industry groups, professional bodies, research councils/organisations, landowners, industry, the general public) will encourage best practice, sustainability and consistency in assessment and remediation[22].

3.2.3.3 Approaches Used

Good practice approaches to identifying and managing land contamination have long been based on risk principles. The Part IIA regime is also underpinned by a risk-based approach. UK policy for dealing with existing contamination follows the 'suitable for use' approach whereby risks are assessed and managed according to the current or intended use for the land.

Technical guidance is usually concerned with setting out an approach to risk assessment aimed at identifying adverse effects for a variety of receptors (or targets). For risk management purposes, contaminated land is best thought of as an existing rather than as an additional risk. Remedial action may focus on the source (e.g. bioremediation), on the pathway (capping and barrier systems) or on the receptor (choice of after use or design of site redevelopment to keep targets away from contaminated areas). The risk management criterion used for most common contaminants is a maximum tolerable level, which varies as a function of existing or planned future uses, combined with the ALARP principle. Depending on the receptor of concern the following may be considered: acute, sub-acute, and chronic health risks for humans; long-term exposures for ecosystem or building materials; both short and long term risks for controlled waters; and instant catastrophic risks for explosive gases.

For assessing site-specific risks to human health and to ecosystems or building materials the use of generic assessment criteria are encouraged so long as they are used with appropriate professional judgement. For risks to controlled waters, risk assessment is strictly site-specific. In both cases, good practice guidance provides a procedural framework in which the risks from contamination can be estimated and evaluated. Model procedures for the management of contaminated land (see Annex for further details), including a model procedure on risk assessment, have been developed to provide integrated guidance on good practice approaches to assessing and managing risks from contaminated land to all receptors. These procedures are supported by more detailed technical guidance focussed on particular categories of receptor. The risk assessment approach described by the model procedures involves the four stages of hazard identification, hazard assessment, risk estimation and risk evaluation. The merits of a tiered approach to risk estimation and evaluation are recognised within the procedures.

[22] An Action Plan for Land Quality. The Environment Agency

A key component of guidance on risk assessment is the development of generic assessment criteria, or guideline values, for contaminants in soil to assist the assessment of risks to human health. In practice this is usually achieved by estimating the probability of exceeding maximum tolerable *exposure* levels which, for human health risks, are underpinned (explicitly or implicitly) by toxicological data on exposure-effect relationships. In the case of explosive gases, the risk assessment approach is concerned only with estimating the probability of exposure to an explosive concentration of gas.

Human health guideline values (for assessing chronic risks) are usually based on maximum tolerable daily intakes (TDIs) for a lifetime exposure. These in turn are usually derived from No-observed-adverse-effect-levels (NOAELs) divided by a safety factor. A modified approach may be taken for some contaminants (e.g. for lead). For genotoxic carcinogens the criteria is as follows. One option is to base guidelines on published cancer potency slopes (or, equivalently, unit risks) combined with decisions about theoretical acceptable and tolerable excess lifetime cancer risks. Another option is to base guidelines on occupational epidemiology (i.e. what appears to be a safe level for long-term occupational exposure) combined with a safety factor. Criteria for setting guidelines for exposure to mixtures of contaminants have not yet been agreed. It is emphasised that, although guideline values are a generic approach, in the context of site-specific risk assessment they should only be used by professionals.

A new assessment procedure, known as the Contaminated Land Exposure Assessment (CLEA) model, is currently under development for determining new guideline values for contaminants in soils. This is based on an assessment of the ways in which contaminants could be released, and in which humans could then be exposed to contaminants depending on the proposed use of a site. CLEA involves a consistent and overt procedure in which exposure and toxicological assumptions are made explicit, and in which uncertainty and parameter variability are handled stochastically (Monte Carlo method). For a given contamination level in soil, the magnitudes and likelihood of release and exposure and the associated uncertainties can then be calculated. The resulting probability distribution of exposures can be compared with a tolerable exposure level, determined from a consideration of the exposure-effect relationship and of tolerable levels of risk. The contaminant level corresponding to the tolerable exposure level can then be determined. The procedure is illustrated in Figure 3.5.

3.2.3.4 Tools and Techniques Used to Support the Assessment

The various tools and techniques used to support the risk assessment process for the Land Quality function are presented in the Annex. These represent a hierarchy of guidance, with the Model Procedures for the Management of Contaminated Land providing the over-arching framework of procedural guidance for risk assessment and risk management. More detailed guidance on risk assessment techniques and specific tools (e.g. CLEA, guideline values, ConSim, the Integrated Methodology) underpin this framework and have a specific role in the process. A 'route map' is being developed which shows the interfaces and links between all the relevant tools and techniques. Other commercially available tools and techniques are also used by operators (rather than Agency staff) to support risk assessment (e.g. Risk-Based Corrective Action, RBCA).

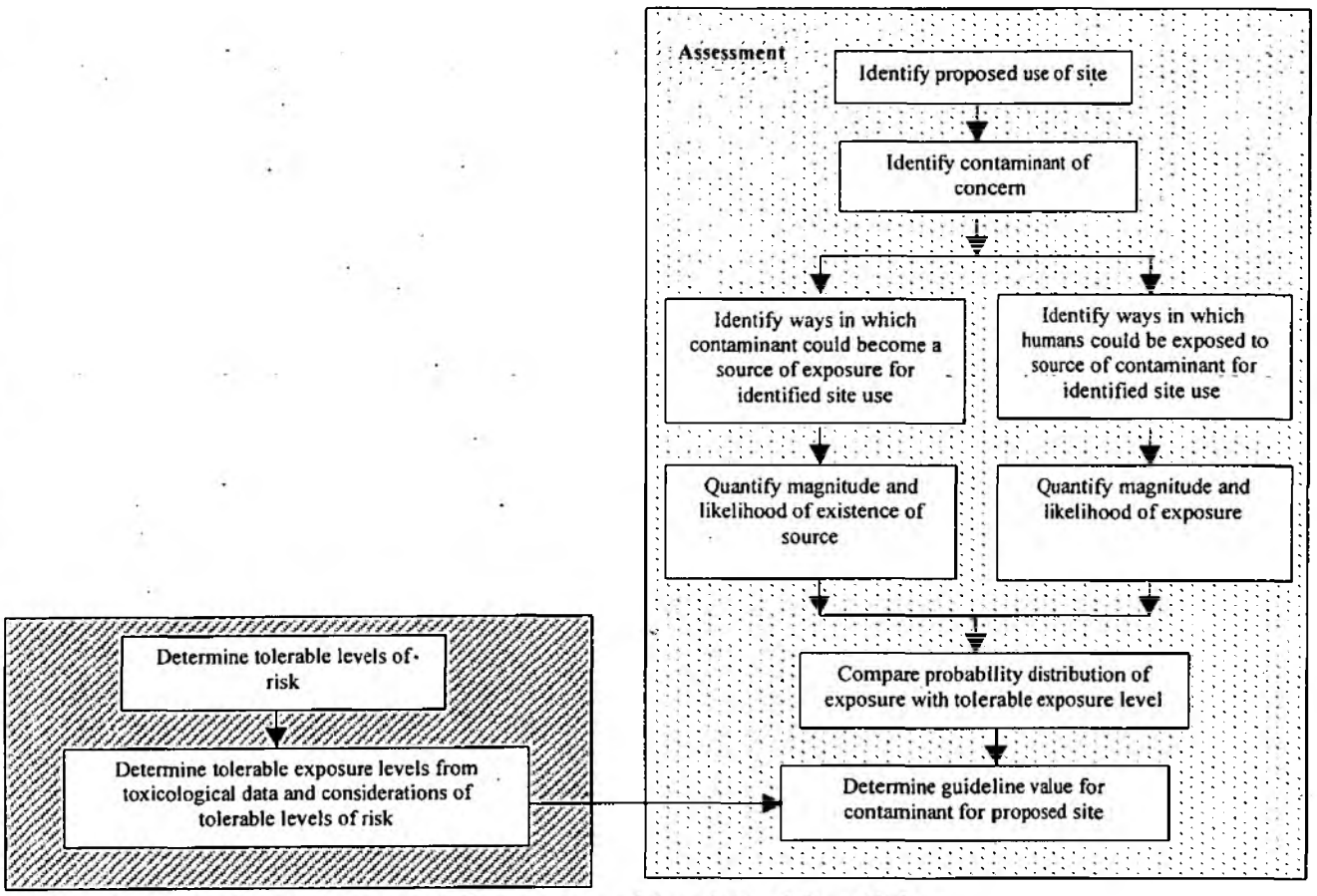

Figure 3.5: Assessment of Contaminated Land Guideline Values

Detailed guidance is currently being developed on assessing risks in connection with the protection of controlled waters, building materials and ecosystems. The Agency has also recently published a document that provides a tiered, risk-based approach for assessing the potential impact of contaminated soil on one or more identified water receptors, and hence making decisions about the level of remedial action required to prevent water pollution (Environment Agency, 1999c). Practical guidance on how to assess risks to building materials and ecosystems is under development through the Land Quality research and development (R&D) programme.

3.2.4 Water Quality

3.2.4.1 Rationale

Controlled waters include rivers, lakes and canals, groundwater, estuaries and coastal waters. Society makes varied, and often conflicting, uses of the water environment, which include water abstraction for drinking, agricultural and industrial use, disposal of treated effluent, development of fisheries and a wide range of recreational uses[23]. These uses must be reconciled with ensuring the suitability of waters as natural habitats for animals and plants. The role of the Water Quality function is to resolve these conflicting uses and ensure that water is of suitable quality to support them and to maintain diverse aquatic ecosystems.

[23] An Action Plan for Water Quality. The Environment Agency

The Agency is responsible for protecting and improving the quality of controlled waters and it does this by enforcing legislation and by influencing the actions of others. The responsibilities for protecting and improving water quality are set out in Water Resources Act (WRA) 1991, the EPA 1990 and the Environment Act 1995, which all serve to consolidate earlier statutes[24]. The privatised Water Companies are regulated through the Water Industry Act 1991 in respect of their trade effluent controls and broader environmental responsibilities. In addition to domestic legislation, EC Environmental Directives have been transposed into UK legislation and are playing an increasingly important role in the regulation of water quality.

The Agency's principal tasks with regard to protecting water quality[25] are to:

- monitor and classify water quality to ensure that relevant WQOs, including statutory objectives, are met;
- issue consents for discharges to controlled waters;
- enforce the authorised conditions by legal means;
- provide a public register with details of applications for consents to discharge, consents granted, sampling data and other related information;
- advise the SoS on the setting of appropriate WQOs;
- advise on the control of development as a statutory consultee in the planning process;
- issue and enforce notices where action is required to reduce the risk of pollution; and
- deal effectively with incidents of water pollution.

The River Dee Water Protection Zone (WPZ) was designated on the 21 June 1999. The legislation requires certain industries ('catchment control sites') storing or using chemicals ('controlled substances') above certain volumes (the 'relevant quantity') within the freshwater River Dee Catchment to apply to the Agency for consent to undertake a 'controlled activity'[26]. The application (including variations to existing consents) gives the Agency the opportunity to impose conditions on the consent for the prevention of pollution arising from the 'controlled activity'. Conditions can only be imposed where there is an identified risk to the drinking water supplies abstracted from the River Dee (these abstractions supply drinking water to in excess of 2 million people in North-east Wales, Cheshire and the North West).

Beyond the legislative duties and powers, the Government has provided the Agency with formal statutory guidance to, amongst other things:

- encourage voluntary action to improve environmental performance;
- encourage knowledge and understanding of environmental issues and techniques; and
- provide clear and accessible advice and information on the Agency's work and on best environmental practice[27].

[24] Key legislation: Water Resources Act Part III 19991; The Control of Pollution (Silage, Slurry and Agricultural Fuel Oil) Regulations 1991 and 1997; The Trade Effluent (Prescribed Processes and Substances) Regulation 1989 and 1992; Urban Waste Water Treatments Regulations 1994; The Sludge (Use in Agriculture) Regulations 1989: The Groundwater Regulations 1998; Control of Pollution (Applications, Appeals and Registers) Regulations 1996; and Anti-pollution Works Notice 19991, SI No. 1006

[25] The following regulations classify waters: Surface Water (Classification) Regulations 1989; Surface Water (Dangerous Substances) (Classification) Regulations 1989 and 1992, 1997 and 1998; Bathing Water (Classification) Regulations 1991; and Surface Water (River Ecosystem) (Classification) Regulations 1994

[26] The Water Protection Zone (Procedural and Other Provisions) Regulations 1999

[27] An Action Plan for Water Quality. The Environment Agency

memo

ENVIRONMENT AGENCY

To	**DISTRIBUTION LIST**	From	Dr Raquel Duarte-Davidson
Our ref.	Risk Portfolio	Date	26 June 2000
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NATIONAL CENTRE FOR RISK ANALYSIS AND OPTIONS APPRAISAL
Report Number 29: The Environment Agency's Risk Portfolio

1. Please find attached the Executive Summary of the NCRAOA Report Number 29. This document describes the principal risk-related activities in the Environment Agency and summarises current practice. It incorporates, as an Annex, a register of the more commonly used risk tools and techniques. It makes recommendations for the future application of risk assessment in the Agency.

2. The document is intended as a 'living' reference document for Agency staff, but will also be of use to operators, discharges and abstractors and their consultants. The main document is to be updated every two or three years and the Annex will be updated regularly as and when new tools and techniques become available.

3. The Portfolio is an important contribution to the 'Risk-Based Regulation' project in Environmental Protection, but its coverage extends beyond EP and it will be of value across the Agency. The document will be made available in the intranet in the near future. However if you would like to a hard copy, please contact Pam Grant (NCRAOA, Steel House, London) who will be happy to send you one.

4. To support your ongoing work in risk assessment, the National Centre will be forwarding to you in the near future two additional documents:

    - "Introducing Environmental Risk Assessment" – an introductory leaflet for Agency officers and external staff new to the field of risk assessment, explaining some of the basic principles; and

    - the revised DETR/Environment Agency "Guidelines for Environmental Risk Assessment and Management" - a "how to" document for experienced practitioners providing generic principles for all public domain environmental risk assessments.

Regards,

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EXECUTIVE SUMMARY

This document describes the existing approaches to risk assessment in the Environment Agency across all of its Functions and summarises current experience and practice. It incorporates, as an Annex, a register of the more common risk tools and techniques in use.

An earlier version of the portfolio was drafted in 1995/96 by the Ad-hoc Working Group on Risk in the Environment Agency. It pulled together the wide ranging expertise from the Agency's predecessor bodies. Since then, the document has been restructured, consulted upon widely internally and used to formulate the Agency's thinking as to how our handling of risk might converge over the coming years.

The Portfolio is maintained by the National Centre for Risk Analysis and Options Appraisal This revised edition brings the document up to date and reflects recent changes in risk-related activities within the Agency across England and Wales only, unless otherwise specified. It does not cover health and safety management issues or the handling of corporate risk as these are dealt with in other documents. The National Centre hopes you will find this a useful valuable reference document and welcomes any comments you may have. We will aim to incorporate further improvements at the next revision.

The Agency operates with constant reference to environmental risk[1]. Many of the operational and strategic decisions made by the Agency involve some implicit consideration of risk principles, but increasingly, a more explicit treatment is being required. Pressure is coming from two directions:

- a renewed emphasis on quality regulation within Government[2], on the appropriate use of scientific advice in policy-making[3], within the context of sustainable development[4]; and
- an increasingly specific reference to risk assessment within the statute.

Recommendations for Departments and Agencies to publish their high level frameworks[5] within which they consider 'risk' have been endorsed by Government and the first of these have been consulted upon[6,7]. It is timely, therefore, that the Environment Agency reviews the handling of risk within its regulatory and supervisory remit and sets out the contexts within which it makes risk-based decisions. That is the principal aim of this document.

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[1] POST(1996) *Safety in Numbers?* Risk assessment in Environmental Protection. Parliamentary Office of Science and Technology

[2] Cabinet Office (1999) *Modernising Government*, Cm 4310, 66pp., The Stationery Office, London,

[3] DTI (1998) *The Use of Scientific Advice in Policy Making*, Department of Trade and Industry, London, 9pp

[4] DETR (1999) A Better Quality of Life: A Strategy for Sustainable Development for the United Kingdom, 96pp., The Stationery Office, London

[5] ILGRA: Interdepartmental Liaison Group on Risk Assessment (1998) *Risk Assessment and Risk Management: Improving Policy and Practice within Government* Departments, 37pp., HSE Books, Suffolk

[6] HSE (1999) *Discussion Document: Reducing Risks, Protecting People*, 82pp., HSE Books, Suffolk

[7] DETR and the Environment Agency (2000) *Guidelines for Environmental Risk Assessment and Management, Revised Guidance*, DETR, the Environment Agency and the Institute for Environment and Health, in preparation

Full Reference for this document: Environment Agency (2000) The Environment Agency's Risk Portfolio. National Centre for risk Analysis and Options Appraisal, Report Number 29, the Environment Agency, London.

Acknowledgements

The NCRAOA gratefully acknowledges the following individuals for their valuable comments and/or contributions to this guidance note: Brian Arkell, Dave Bird, Martin Brocklehurst, Andrew Brookes, Chris Chubb, John Dalton, Jonn Davys, Martin Dawson, Alastair Driver, Susan Duerden, John Dalton, Steve Dungey, Bob Edwards, Brian Empson, David Forrow, Rod Gall, Dave Griffiths, Simon Halfacree, Mike Harget, Bob Harris, Sue Herbert, Ashley Holt, Jimi Irwin, Steve Killeen, Ian Meadowcroft, Peter Newman, David Parr, Ronan Palmer, Linda Pope, Colin Powlesland, Dave Purchase, Gerard Steward, Stuart Stearn, Roger Timmis, John Topping, Chris Tuckett, Jackie Vale, Helen Wilkinson and Roger Yearsley

3.2.4.2 Organisational Framework

In managing the water environment the Agency recognises the needs of those who make use of the water. This includes developing a close and responsive relationship with its customers and other interested organisations and individuals (e.g. Royal Society for the Protection of Birds, RSPB, Friends of the Earth, the Environmental Industries Commission and Surfers Against Sewage). The Agency regulates direct discharges to inland watercourses and groundwater, and from land based sources to estuaries and coastal controlled waters) and works with other regulators, trade associations, industry and farming representatives and the public to reduce the effects on non-point source or diffuse pollution.

The Agency is the "competent authority" for the enforcement of certain EC environmental directives. It monitors and reports compliance with Directive standards to the DETR, and plans improvements where necessary. The Directives include amongst others those covering Dangerous Substances, Bathing Waters, Surface Water Abstractions, Groundwater, Urban Wastewater Treatment, Freshwater Fisheries and Shellfish Waters. In addition to the implementation and ongoing monitoring of existing Directives the Agency is actively involved in advising the DETR and the European Union (EU) on technical aspects of proposed new Directives. The Agency also contributes monitoring data and reports as part of other international agreements such as the Oslo/Paris Convention (OSPAR)[28].

In recognising the needs of others the Agency also works with water industry and its representative body (Water UK), local authorities, Sea Fisheries Committees, and Port and Harbour Authorities, the Office of Water Services (OFWAT), partner organisations with statutory powers, such as English Nature.

3.2.4.3 Approaches Used

The need to develop clearer risk-based approaches to decision making in preventing pollution, regulation, and consenting and to introduce, where appropriate, a common risk assessment and management framework for the Water Quality function in the Agency has been recognised. The following subsections describe the approaches used for (i) setting discharge consents for releases to control waters; (ii) water quality monitoring; (iii) preventing and dealing with water pollution incidents and reducing diffuse pollution; and (iv) granting consents within water protection zones (WPZs).

SETTING DISCHARGE CONSENTS FOR RELEASES TO CONTROLLED WATERS

The regulation and control of continuous and intermittent point sources is achieved by the issue of discharge consents and by the monitoring of discharges and their impact on receiving waters. The Agency has national policies for consenting discharges housed in a manual that provides further guidance for its operational staff. The consenting policies and guidance in the Consents Manual (see the Annex for further details) are structured to make this process as objective as possible, within the regulatory constraint of remaining "reasonable". The manual details the methods for consent setting which are used to assess the risks of low river flow (or dilution) and variations in effluent quality. It also includes guidance for the consents relating to, for example, the quality of water required under the various EC Directives

[28] Convention for the Protection of the Marine Environment of the North East Atlantic (the OSPAR Convention)

mentioned above (section 3.2.4.2). Risk assessment is largely implicit in determining the frequency of monitoring, for which basic rules are included in the Consents Manual.

The approach used to consider discharge consents and determine consent conditions for fresh waters is based on an assessment of the probability distributions of the concentrations of the polluting substances in receiving waters and in the discharge. The characteristics of the proposed discharge and of the receiving waters are taken into account and variabilities and uncertainties are treated stochastically. The resulting probability distribution of concentration for each substance is then compared with a maximum acceptable concentration of that substance in the receiving water and the consent conditions are determined to ensure compliance with the EQS. EQSs derived within the UK are generally expressed as both a Maximum Allowable Concentration (MAC) and an Annual Average (AA). Although MACs are available for many compounds, the AA is mainly used in terms of the control of discharges to water because they have statutory status.

Discharge consents are issued to ensure compliance with the EQS. For discharge consents, the 'return period' is of importance, for example a consent will be an 'annual mean' with a clear definition of the start and end of that year. An example of this approach is illustrated in Figure 3.6 which shows how consents are set for continuous discharges to freshwaters. The approach used for discharges to tidal waters is different in that many more combinations of environmental and discharge parameters may be necessary to define the full range of discharge outcomes. In many cases extensive and complex modelling is undertaken but is also refined with subjective judgement of the most vulnerable conditions for which environmental protection is necessary. The limits in consents may represent a sub-set of parameters of concern and the control of risk may be exerted by regulatory controls of process or maintenance rather than substance.

Intermittent discharges, for example, for combined sewer overflows (CSOs), are consented using the Urban Pollution Management planning methodology (see the Annex for further details). This operates at varying levels of complexity, depending on the complexity of the sewerage system and its interaction with receiving waters. In the simplest case, where risk to the environment from operation of the CSO is low, a simple sewerage based algorithm may be all that is required. At the other end of the spectrum, detailed sewerage and catchment modelling may be required taking into account the concentration, duration and return periods of discharge events.

Environmental Quality Standards are derived from consideration of the available data on the effect of the substance on aquatic life. Data on fate and routes of entry are collated and considered but these are primarily used in relation to how the EQS is expressed (e.g. MAC and AA for short-term and long-term exposures, respectively) rather that to quantify exposure levels. Information on bioaccumulation affects the size of the safety factor applied. Underlying the determination of the standard for the concentration of a substance in water, therefore, is a consideration of the acceptable levels of risk of effects on receptors, which for the water environment is determined by the No Observed Effect Concentration (NOEC). Most EQSs and other water quality standards are generally set at EC levels through various Directives, although a number have also been set at Member State level as part of the requirements of the Dangerous Substances Directive. EQSs are only available for a limited number of substances. Where EQSs are not available, consents are set using the best available information on the impact of the chemical on the environment. The data are used to determine a Predicted No Effect Concentration (PNEC) which is used in the absence of an EQS.

The regulation and control of activities that could lead to groundwater pollution, including disposals, is achieved through the issue of authorisations or licences recognised as relevant authorisations for the purposes of the Groundwater Directive[29]. The Agency is developing integrated policies and guidance for the determination and enforcement of these authorisations following risk-based principles.

[29] These include authorisations through the Groundwater Regulations 1998, Part I EPA 1990, Water Resources Act 1991 and Regulation 15 of the Waste Management Licensing Regulations 1994

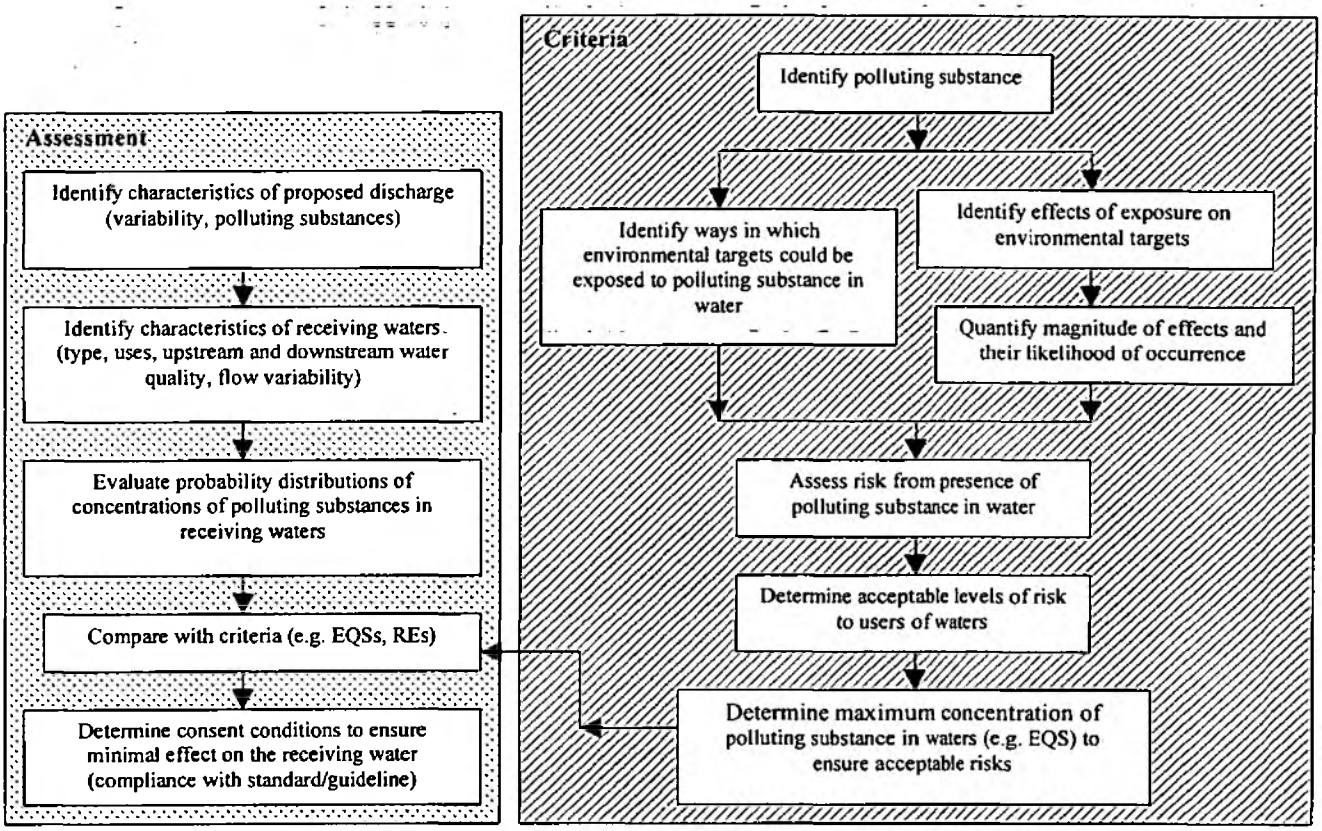

Figure 3.6: Setting discharge consents for continuous discharges in freshwaters

MONITORING

Water quality monitoring needs are assessed, not on a formal risk assessment basis but with reference to the following:

- the River Ecosystem Classification scheme for setting river quality objectives, which is the basis for long term planning and the framework through which consents to discharge are set;
- the General Quality Assessment scheme, which is the framework through which the overall quality of rivers is reported using chemical and biological gradings. There is a plan to incorporate nutrients and aesthetics into this assessment scheme;
- methods for the assessment of consent compliance, for example the look-up tables for WRA consent compliance assessment of sewage treatment works; and
- direction of the investment required of Water Companies to achieve improvements in Water Quality via the Asset Management Plans.

PREVENTING AND DEALING WITH WATER POLLUTION INCIDENTS AND REDUCING DIFFUSE POLLUTION

There are large numbers of varied activities that are not directly regulated by the Agency but which may have a significant impact on the quality of controlled waters. For example run-off from agriculture, poor oil or chemical storage and urban run-off can all contribute to poor transient water quality resulting from diffuse pollution and intermittent pollution. Preventing and dealing with these forms of pollution is often difficult for the Agency but nonetheless it views the prevention of water pollution as being fundamental to its objectives.

Traditionally, the Agency has become involved with diffuse and intermittent pollution by making an informal risk assessment of the situation and persuading those undertaking the activity to change the way of undertaking these so that the risk to the water environment is minimised. This usually involves site inspections and negotiation, but the provision of good quality guidance, education, training and raising awareness are also important in reducing the numbers of pollution incidents and the level of diffuse water pollution. Until recently this type of preventative work had little or no legislative basis and the Agency could only rely on negotiation to bring about the changes it required. This situation however changed in April 1999 when Works Notices, a widely applicable, risk-based legislative power was introduced by the Environment Act 1995.

Works Notices enable the Agency to prevent pollution by serving a legally binding notice on any person who, in the opinion of the Agency, is responsible for a facility or operation that poses an unacceptable risk to the water environment. This allows the Agency to act before pollution has occurred and the potential polluter bears the cost of any preventative work. The serving of a Works Notice dictates that a more formal, yet proportionate, risk assessment methodology is adopted. A risk assessment form has been developed in line with those set out within the Pollution Prevention Manual and training has been given on assessing risk within this context.

At about the same time that Works Notices were introduced the Groundwater Regulations were fully transposed into UK law. These also allow the Agency to serve notices prohibiting certain activities, or placing conditions on certain activities, where the risk to groundwater quality from pollution by List 1 and List 2 substances is unacceptable.

There are other situations where notices may be served to reduce the risk to the water environment. Within Nitrate Vulnerable Zones[30], designated under the Nitrate Directive, the Agency can serve a notice requesting that the farmer complies with certain requirements of the Directive, usually linked to the disposal of manure or the application of fertiliser.

Notices to reduce the risk of water pollution may also be served under the Control of Pollution (Slurry, Silage and Agricultural Fuel Oil Regulations 1991). These can only be served on specific structures that represent an unacceptable risk to the quality of controlled waters. The Agency has some experience of serving these notices as the powers have been available since 1991, but the threat of being able to serve a notice is often sufficient to bring about change.

[30] Nitrate Vulnerable Zones are designated areas which have been identified as having waters that are or could be affected by nitrogen pollution from agricultural sources

RISK ASSESSMENT AND THE RIVER DEE WATER PROTECTION ZONE

The Regulations require the Agency prior to granting consent within a WPZ to consider:

- the nature, quantity and location of controlled substances;
- the likelihood, accidentally or otherwise of their entry to controlled waters and the resulting concentration therein;
- the likely consequences of a release particularly with regard to the expected impact on the quality of water supplies intended for human consumption; and
- the frequency of those consequences.

When the former NRA applied for the freshwater Dee to be designated a WPZ they developed a scheme for assessing the risks posed to the abstractions from 'controlled activities'. This scheme was scrutinised by a Public Inquiry into the application that took place in March 1995.

The risk assessment protocol was adopted by the Agency and will be used to assess the risks posed by sites requiring WPZ consent (Environment Agency, 2000b). It follows a tiered approach with the Agency undertaking the initial stage on behalf of industry. This initial screening assessment estimates the worst case scenario of release and utilises the software package PRAIRIE (further details in the Annex) to estimate the consequences of release so that sites posing no significant risk to potable abstractions are eliminated from further consideration at an early stage.

For sites that could potentially pose a significant risk, the Agency has a scheme that can be undertaken by the applicant in order that the risks posed by their site can be further assessed by either a generic or site-specific risk assessment. These assessments aim to quantify the risks to the Dee abstractions and will serve to identify whether facilities are acceptable or not and identify any required pollution prevention measures. The results of these assessments will be reviewed by the Agency and compared with published risk criteria for the Dee. These criteria focus on the frequencies of undesirable events against relevant toxicological data and are based on the philosophy of acceptable societal risk of harm occurring. Acceptable/ unacceptable frequencies are identified along with an area between the two curves that identify an ALARP region. The risks posed by facilities within this region, although above the acceptable curve, may be tolerated by the Agency due to the perceived benefits that the activity brings subject to a detailed cost benefit analysis (in line with BATNEEC guidance) of the pollution prevention measures at the facility.

The driving philosophy behind the implementation of the regulations is that only matters of significance with respect to mitigating risks to the Dee potable abstractions are addressed by the Agency and that industry is given freedom for self determination in reducing their risks.

3.2.4.4 Tools and Techniques Used to Support the Assessment

A large number of guidance notes have been produced to support recent regulations. Examples of these include:

- the Agency's process handbooks and associated guidance notes on the Groundwater Regulations 1998 and on the Anti-pollution Works Regulations 1999;
- integrated methodology for the derivation of remedial targets for soil and groundwater to protect water resources and guidance on their interpretation (Environment Agency, 1999c); and
- application of Regulation 15 of the Waste Management Licensing Regulations 1994 (the protection of groundwater) with respect to landfill.

In addition a number of models have been developed to support the risk assessment process. Many of the procedures and models are applicable to other functions, specially land quality (LQ), waste management and regulation (WMR) and water resources (WR). For further details on models and procedures available, refer to the Annex (Proformas coded WR, WMR and LQ). Examples of cross-functional models include those that assess the likely impacts of waste disposal sites (e.g. LandSim) and of contaminated soils (e.g. ConSim) on defined water receptors.

3.2.5 Waste Management and Regulation

3.2.5.1 Rationale

The Government's policies for waste management are underpinned by a legislative framework (Environment Agency, 1999a). Under this framework the responsibility and ultimate fate of the waste is placed on all parties involved. The Agency is the responsible authority for the operation of the waste management licensing system, the regulation of special waste and the regulation of waste carriers[31]. It also has functions in relation to the National Waste Strategy and producer responsibility[32].

The Agency's duties, powers and responsibilities include:

- ensuring that controlled waste is treated, kept or disposed of in a manner that will not cause pollution to the environment or harm to human health;
- licensing facilities where waste is kept, treated or disposed and keeping a register of particular prescribed activities exempt from licensing;
- regulating special waste, waste handling and transportation and imports and exports of waste;
- enforcement against illegal waste management activities;
- response to incidents and emergencies;
- environmental monitoring and compliance assessment of licenses and of certain exemptions;
- conducting strategic waste management assessments;
- give advice on planning consultations and to DETR and other Government departments, local authorities and industry; and
- encouraging best practice and waste minimisation

3.2.5.2 Organisational Structure

The Agency is the regulatory body with respect to the management of waste. In carrying out its duties the Agency must have regard to the statutory guidance issued by DETR (formally DoE)[33]. The waste policy function works in partnership with central government, local authorities, other government agencies, waste management industry (e.g. Environmental Services Association, Institute of Waste Management, Metal Recycling Group) and industry and commerce (e.g. Confederation of British Industry, Packaging industry).

[31] EPA 1990 Part II (sections 29-78); Waste Management Licensing Regulations 1994 (as amended); and Controlled Waste Regulations 1992 (as amended); The Special Waste Regulation 1996 (as amended); Control of Pollution (Amended) Act 1989; and Controlled Waste (Regulation of Carriers and Seizure of Vehicles) Regulation 1991

[32] Producer Responsibility (Packaging Waste Regulations 1997)

[33] This includes a series of Waste Management Papers (WMPs) produced by Government

3.2.5.3 Approaches Used

The Agency is responsible for preparing waste disposal plans and has a duty to decide what arrangements are needed to prevent or minimise pollution of the environment or harm to human health. This is achieved through licensing of the recovery and disposal of waste or licensing of new landfill sites.

Regulating the recovery and disposal of waste
The principal control regime for regulating the recovery and disposal of waste is the waste management licensing system. Licensing authorities will seek to ensure that containment design for a landfill is adequate to prevent *release* of leachate so that "the risks of pollution to ground and surface waters" are minimised. Great emphasis is given to good engineering design and the adequacy of construction to prevent a failure of containment. As for leachates, the control of landfill gas is substantially through containment. Here it is also recognised that some release may be tolerated so long as adverse effects are minimised. Hence a licensee is required to monitor the environmental *effects* of the pollution from the landfill on the surrounding area (Waste Management Paper 4, WMP 4; HMIP, 1988).

Surrender of a waste management license is also based on *effects*, i.e. it is based on the likelihood of the land causing pollution of the environment or harm to human health[34]. Detailed technical guidance on assessing the completion of licensing landfill sites is given through statutory guidance (WMP26A; DoE, 1994). In assessing pollution, the Agency should have regard to the wider environment and should, for example, consider the impacts of emissions on global climate change as well as on local air, water, soil, flora and fauna (DoE, 1994).

Waste management facilities should be managed subject to BPEO and the regulation should be proportionate to the risks involved and the benefits to be obtained. The Agency may suspend a license when it appears that serious pollution of the environment or serious harm to human health has resulted from, or is about to be caused by, the activities to which the licence relates. Detailed technical guidance on landfilling of wastes is provided in a series of part papers produced under WMP 26 (DoE, 1995b and Environment Agency, 1996).

Assessment of licence applications and modifications
The Agency has developed and is using a Library of Licence Conditions and Working Plan Specifications, for the risk-based assessment of applications and preparation of licence conditions (Environment Agency, 1999d). This provides a framework for the risk assessments supporting licence applications and modifications, and for identifying the risk management systems that will be required on a site-specific basis. Supporting guidance is being developed to assist Agency officers, applicants and operators on the application of environmental risk assessment and management for waste management licensing of sites undergoing licence application or modification (Environment Agency, 1999e). It provides a framework for progressing through risk screening assessments, as necessary and as provided under other guidance (see below), to detailed qualitative, semi-quantitative and/or quantitative assessments, as considered appropriate. The framework has been developed to be consistent with the risk-based approach used for site inspections described below.

Assessment of new landfill license applications
A risk-based tool is used to assist waste regulators to make rational and defensible decisions about the suitability of site engineering proposals for landfills. It has been designed to provide a formal, assessment methodology that couples a realistic appraisal of liner and

[34] EPA 1990, s.39(5).

leachate drainage designs with the vulnerability of the location. The procedure addresses the five elements determining the risks from landfills, namely the source term, the engineered barriers, the geosphere, the biosphere and the receptors. The biosphere is represented by contaminant concentration at a point within groundwater at a chosen distance from the site. This is the point at which the health risk could be calculated for the target population groups (i.e. receptors). Uncertainty analysis using Monte Carlo simulation is an integral part of the assessment. Figure 3.7 illustrates the procedure.

INSPECTIONS OF WASTE FACILITIES

Anyone carrying out a waste disposal or recovery operation under a waste management license is subject to appropriate periodic inspections by the Agency[35]. This involves supervising licensed sites and ensuring that license conditions are complied with. The Agency has proposed to replace the existing site inspection system with a system similar to the OPRA approach developed for IPC. The frequency of site inspections will be determined by a procedure based on risk to assess the performance of operational management (DETR, 1999b). For further details of this risk-based approach see Section 4.2.

3.2.5.4 Tools and Techniques Used to Support the Assessment

In order to promote a more uniform approach to site licensing across the country and to help provide a common base for decisions on landfill licensing, a computer-based risk methodology for assessing the suitability of proposals for new landfills is used (see the Annex for further details). The computer package is not a substitute for the risk assessment expertise within the Agency. Rather, it is a decision support system designed to assist in the initial assessment of the risks to groundwater from landfill sites.

As mentioned earlier, the Agency has developed and is using a Library of Licence Conditions and Working Plan Specifications for the risk-based assessment of applications and preparation of licence conditions (Environment Agency, 1999d). Supporting simple, user-friendly guidance on risk assessment tools is also being developed on the application of environmental risk assessment for waste management licensing (Environment Agency, 1999e) to assist Agency officers, applicants and operators.

[35] Waste Management License Regulation 1994

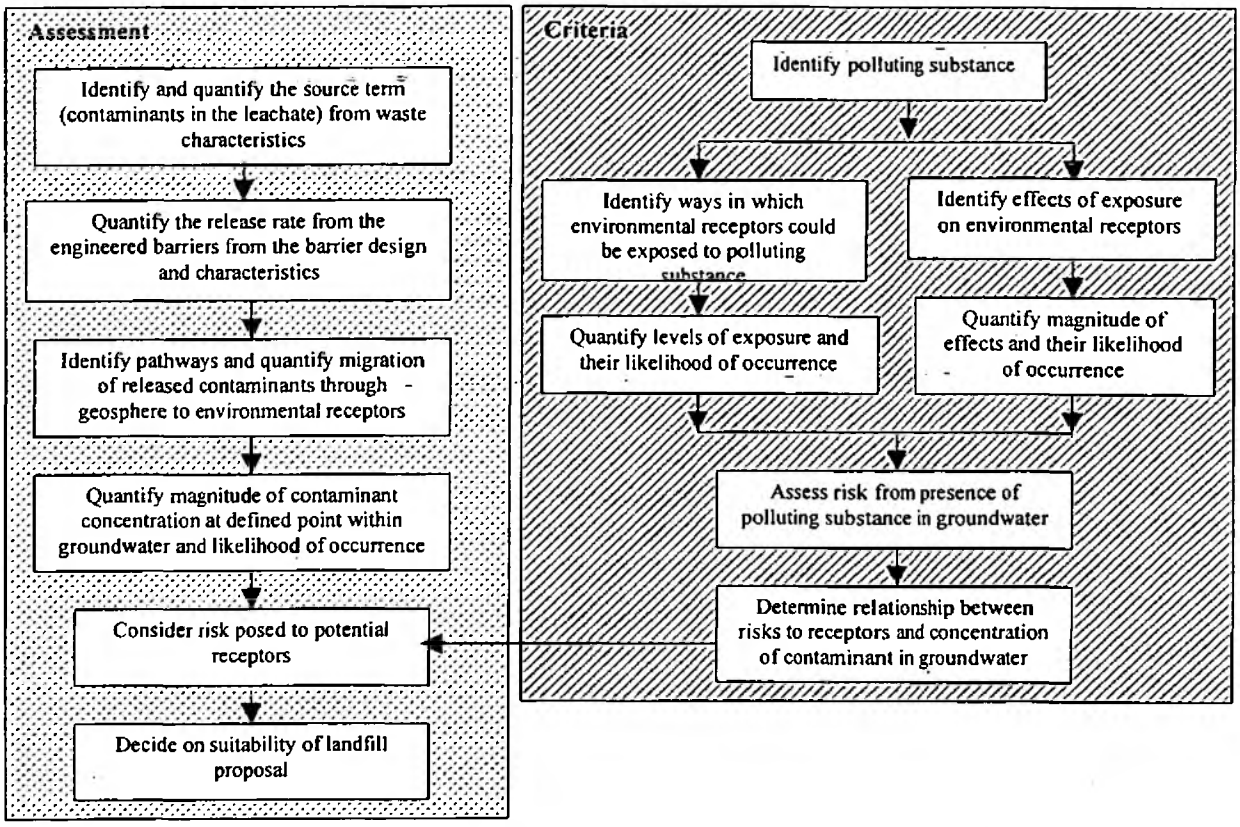

Figure 3.7: Assessment of new landfill license applications

3.2.6 Integrated Pollution Prevention and Control

3.2.6.1 Rationale

The 1996 European Council Directive 96/61 on "Integrated Pollution Prevention and Control (IPPC)", was to be transposed into national legislation by each Member State by 30 October 1999. The Government enacted the IPPC Act 1999 and the Agency expects that regulations will shortly be made under this Act to complete implementation later this year. The Directive lays down measures designed to prevent, or where it is not practicable, to reduce emissions to air, water and land from these activities in order to achieve a high level of protection of the environment. It requires Member States to make the necessary measures to provide the Competent Authority with the means to ensure that operators each have the basic obligations which the Directive sets down. Although IPPC shares much with IPC (see section 3.2.2 for further details), there are some important differences:

- IPPC is to cover a wider range of activities to include, not only those under PIR, but also Land Quality, Water Quality and Waste Management;
- the responsibility for compliance with IPPC will lie firmly with the operator;
- the new Directive covers installations rather than processes;
- a wider range of environmental impacts will have to be considered by the permitting authority to include emissions of pollutants to air, water and land, energy efficiency, consumption of raw materials, noise and site restoration; and
- IPPC makes no special provisions for 'triviality'.

The Directive is, however, also based on the concept of balancing the costs of measures to provide environmental protection with the benefits to be obtained.

3.2.6.2 Organisational Structure

The Environment Agency and local authorities will both be involved in enforcing the Directive in England and Wales, working together to achieve an effective outcome. All statutory consultees and the public will have to be consulted on all IPPC applications and the regulator will have to consider all responses made prior to issuing a permit.

The Agency is considering how best to organise its work across all its functions to achieve integrated implementation in the most effective way.

3.2.6.3 Approaches used

A guidance document is currently being prepared by the Agency for IPPC and from the information available to date IPPC is likely to follow a similar risk based approach as that highlighted above for IPC (see section 3.2.1 and Figure 3.2).

3.2.6.4 Tools and techniques used to support assessment

The Agency is in the process of preparing an IPPC Process Handbook which will provide a high level overview and main steps of the IPPC process. The Agency is also preparing (and is currently consulting the public on) a draft regulatory package a draft regulatory package, an integrated set of documents involving application forms, guidance notes and permit templates. These should provide for the efficient production of permits that are cost-effective and transparent.

3.2.7 Risk Assessment and Risk Management of New and Existing Chemical Substances

3.2.7.1 Rationale

The assessment and control of environmental risks arising from the supply of industrial chemicals in the UK is driven largely by European legislation[36], which in turn is influenced by global priorities[37]. The Existing Substances Regulation (ESR) seeks to establish priority lists of existing industrial chemicals and subsequently obliges industry to provide all the necessary data for a comprehensive risk assessment to be conducted. The assessment of real or potential risk for people and the environment from existing substances requires a full evaluation of the risks that could arise from all uses, at all points in the lifecycle, and to all environmental compartments[38]. The risk assessments are carried out by competent authorities designated by the responsible Member States to act as rapporteurs.

The Notification of New Substances Regulations 1993 (referred to as "NONS")[39] requires the supplier of a new substance to notify the competent authority of the relevant Member State

[36] Within Europe, the chemical assessment effort has largely been focussed through Council Regulation (EEC) No. 793/93, generally known as the Existing Substances Regulation

[37] The United Nations Conference on the Environment and Development (UNCED) in Rio de Janeiro (1992) adopted 'Agenda 21' which was intended to provide a framework for achieving sustainable development into the 21st century. Chapter 19 addressed the issue of the 'sound management of toxic chemicals' and laid down a programme for a concerted international effort to assess the risks arising from toxic chemicals. All participating countries, including the UK, pledged to contribute to this process.

[38] As laid down in Commission Regulation (EC) No. 1488/94

[39] These implement Council Directive 67/548/EEC (as amended for the seventh time by Directive 92/32/EEC) on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

before placing the substance on the European market for the first time[40]. Having accepted the notification (a dossier of identity, use and hazard information) the competent authority is required to carry out an assessment of the risks of the substance to people and the environment in accordance with the principles set out in Commission Directive 93/67/EEC. The evaluation of substances new to the market is a vital stage in protecting the environment from these potential risks and promotes the development of less hazardous new chemicals.

For existing substances, the risk assessment determines whether there is a need to consider further risk reduction measures beyond those already in place. This can have far reaching consequences for the chemical industry involved, since the ultimate course of control action is a ban. For new substances, risk assessment can have the same consequences, but in addition it guides testing strategies as increasing amounts of a substance are placed on the market.

3.2.7.2 Organisational Structure

In the UK, the DETR leads the risk management process and the strategic direction of ESR and NONS. The Agency, through the Chemicals Assessment Unit (CAU), within the National Centre for Ecotoxicology and Hazardous Substances (NCEHS) and HSE have joint responsibilities for delivering environmental and human risk assessments for both programmes as the UK Competent Authorities.

Due to the international nature of the work, there is also a strong link with the EC through the European Chemicals Bureau (ECB) and DG XI, and the Organisation for Economic Co-operation and Development (OECD). Through these bodies there are close links with member states, via participation in technical meetings where risk assessments and methodologies are discussed and developed.

3.2.7.3 Approaches used

The assessment of risk is based on a comparison of the potential adverse effects of a substance (i.e. the intrinsic dangerous properties, or "hazards") with the reasonably foreseeable exposure of people and the environment. Risk is therefore an indication of the likelihood of the hazard being expressed during the life cycle of a substance.

The assessment is intended to cover all aspects of the life cycle of a substance, from manufacture through formulation and use to ultimate disposal. For the environment there are five main areas for which risks are routinely assessed, the aquatic and terrestrial environments, the atmosphere, waste water treatment plants and predators. The assessment process is briefly outlined in Figure 3.8.

Industry must submit a minimum data set for priority existing substances to ensure a minimum set of results[41]. Toxicity data submitted for existing substances often varies in terms of quantity and quality[42]. In such cases expert judgement is used to evaluate their

[40] The relevant competent authority of the country in which the substance is to be manufactured or into which it will be imported

[41] There is a base-set testing package required for notified new substances as defined in Annex VIIA of Directive 67/548/EEC (new substances follow a tiered approach for information provision, dependent on the quantity supplied). At least studies on short-term toxicity for fish, daphnids and algae must be made available (representing a simple aquatic food chain)

[42] For example, there may be several reports for a single endpoint, giving dissimilar results, or there may be studies which have not been conducted according to current test guidelines and quality standards, or for which details are lacking

adequacy. On the basis of these data, an estimate is made of the concentration in the medium of interest (e.g. water) below which an unacceptable effect is not likely to occur (i.e. the PNEC). The data set is examined to determine the most sensitive relevant test species, by comparing like effect concentrations from adequate studies. Assessment (or uncertainty) factors are then applied to allow extrapolation to the ecosystem of interest (e.g. to take account of interactions between species, variability and sub-lethal effects). The size of the assessment factor depends on considerations such as the number of species tested and how much of the life cycle of a sensitive species has been studied with the chemical.

An estimate of environmental concentrations (Predicted Environmental Concentration or PEC) is made for each relevant release point, at local, regional and continental scales. Information is also required on degradation, bioaccumulation and partitioning behaviour to indicate how persistent a substance is, together with its likely environmental sinks. Data are often lacking and so physicochemical data are commonly used to derive relevant parameters[43].

This information is combined with release estimates (based on tonnage on the European market and use scenarios) to derive PECs for each relevant media. Initially, the estimate is a worst case scenario based on default parameters for a "generic environment" with predefined agreed environmental characteristics. If the subsequent risk characterisation indicates a concern, the exposure estimate is refined with more realistic data for the specific use and locality.

New substance exposure assessment is generally straightforward because of restricted use patterns and niche markets. Existing substances generally have wider uses, and a problem is that users are either difficult to identify or reluctant to provide information (there is no legal requirement for them to do so, unlike manufacturers or importers). In addition, the default values used have not been validated and so often lead to significant overestimation of exposure.

The risk characterisation is carried out by calculating a PEC/PNEC ratio for each derived PEC. A ratio greater than 1 indicates a concern for that compartment/release. In such cases the next step is usually to refine either the PEC or PNEC (or both) with more appropriate data (e.g. specific use information or more relevant tests or tests of longer duration to assess more of a species' life cycle) and repeat the risk characterisation.

The decision to request the generation of additional data is based on the principles of lowest cost and effort, highest gain of information and the avoidance of unnecessary testing on animals. This iterative approach has precautionary aspects as data gaps are filled by worst-case assumptions or high assessment factors. If refinement does not remove the concern the conclusion is that risk reduction measures must be considered. Since new substances are used in relatively small quantities when the risk assessment is first performed, the requirement for additional information can sometimes be postponed until the next tonnage trigger has been reached.

If it is not possible to conduct a quantitative risk assessment, because the PEC and/or the PNEC cannot be derived, a qualitative evaluation is carried out of the likelihood that an adverse effect may occur. In addition, the size of the PEC/PNEC ratio alone is not always the only factor determining the risk. Other factors to be considered include indications of

[43] The most important of these is the octanol-water partition coefficient (Kow), which is used to model soil/sediment adsorption and bioaccumulation (and even toxicity).

bioaccumulation potential and hazardous properties which may not have thresholds (e.g. carcinogens).

Hence, there can be many conclusions from a risk assessment. For example, one part of the substance's life cycle may lead to a concern in a specific compartment but not others; whilst other uses may raise concern in different compartments and yet other parts of the life cycle give rise to no concerns at all.

3.2.7.4 Tools and techniques used to support assessment

The principal tool for risk assessment of new and existing chemicals is the Technical Guidance Document (TGD, 1994), which is followed by all European Member States. This has been incorporated into a computer program, called the "European Union System for the Evaluation of Substances" (EUSES) version 1.0. The program contains all the equations necessary to perform PEC/PNEC calculations for the scenarios described in the original document. The models are generic, but specific models have also been used where there has been justification to do so, mainly for existing-substance exposure assessment (e.g. to estimate dilution in estuaries).

Risk assessment methodology is still being developed in some areas, e.g. for metals and metal compounds, petroleum substances and the marine environment.

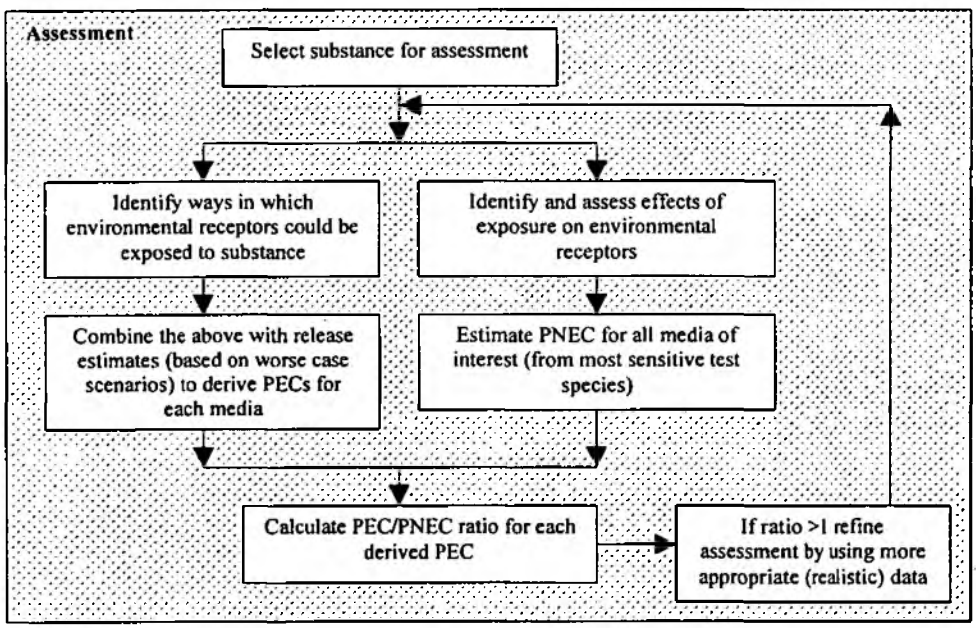

Figure 3.8: Risk assessment for new and existing substances

3.3 Water Management Directorate

3.3.1 Flood Defence

3.3.1.1 Rationale

The Environment Agency has powers to provide and maintain flood defences of urban and rural areas, and to provide adequate arrangements for flood forecasting and warning. Most flood defence schemes involve some degree of protection of land from flooding by use of embankments to retain the flood water level within the river, flood plain, coastal sea or flood storage structure, and to protect the adjacent land from inundation. The flood defence function within the Agency is concerned with the natural catchment area of watercourses and rivers and their channels, flood plains and washlands, including land at risk of flooding from tidal lengths of river, fluvial, tidal and sea defences[44].

The main flood defence powers, duties and responsibilities of the Agency are set out in the WRA 1991 and Land Drainage Act 1991, as amended by the Land Drainage Act 1994 and the Environment Act 1995 (Environment Agency, 1999a and ICE, 1996)[45]. The Agency has powers, which include:

- to maintain, improve or construct drainage works for defence against flooding from watercourses or sea or tidal inundation;
- to construct works to secure adequate outfall of main rivers to the sea;
- make arrangements with Internal Drainage Boards to carry out works on main rivers;
- apply to the Ministry of Agriculture, Fisheries and Food (MAFF) or the Welsh Assembly to modify navigation rights in certain circumstances in order to improve drainage and to transfer drainage functions for a main river to the Agency from a drainage board; and
- to provide and operate flood warning systems.

In addition it also has powers of regulation to enforce repair of watercourse, bridges etc; and grant or refuse consent for (i) works which obstruct the flow on ordinary watercourse and (ii) works on a main river.

The Agency's powers are, on the whole, permissive, but it also has a duty (under Section 105 of the WRA) to provide surveys of areas (primarily main rivers and sea defence works) covered under its flood defence functions[46].

While flood risks can never be eliminated, they can be reduced. Risks can be reduced by: constructing new capital works, maintaining and improving existing defences, providing flood warnings and discouraging development in flood-prone areas.

MAFF and the Welsh Assembly aim to reduce the risks to people and the developed and natural environment from flooding and erosion. The policy essentially aims to reduce flood risks in the most appropriate way by reducing the consequences and the probability of flooding through flood warning systems and by providing physical defences and by encouraging technically, environmentally and economically sound measures. In addition

[44] An Action Plan for Flood Defence. The Environment Agency

[45] In addition, there are a large number of local Acts, statutes, and statutory instruments. The legislative provisions are administered, in England by the MAFF and in Wales by the Welsh Assembly

[46] Development and Flood Risk. Circular 30/92 (DoE), FD 1/92 (MAFF), 68/92 (Welsh Office).

they aim to discourage inappropriate development in areas at risk from flooding or coastal erosion (MAFF, 1993a).

Investment of public finance in defences is only made where projects are economically viable, i.e. where the benefits outweigh the costs over the period of the appraisal (normally 50 years). These policy aims are supported in practice by a tiered system of large scale shoreline and catchment plans, strategic plans and scheme development and appraisal. MAFF has produced Guidance for each of these stages (MAFF, 1993b, 1995 and 1997a). MAFF are currently in the process of revising their Project Appraisal Guidance Notes (PAGN) and the new appraisal guidance will include advice on risk assessment and management.

3.3.1.2 Organisational Structure

MAFF and the Welsh Assembly are the Government department with overall responsibility for flood defence and coastal protection. The Agency's flood defence function is funded by a combination of government grant for capital works and levies raised on local authorities and local drainage boards.

MAFF encourages appropriate flood defences through its administration of grant aid for flood defence studies and schemes, and through Supplementary Credit Approvals dispensed to local authorities for flood defence works. At present, the Agency and MAFF are working to introduce a system of block grant for the Agency, whereby schemes below a particular threshold would not require individual approval by MAFF. It is understood that the new system will continue to reflect MAFF's priority scoring and other criteria[47]. Other partners include the DETR, Internal Drainage Boards, local authorities and Riparian owners.

3.3.1.3 Approaches Used

Planning and Development Control

The Agency is, together with partners, currently in the process of adopting long-term (50 years or more) strategic plans for flood and coastal defence for river and/or coastal management. These plans follow MAFF guidance for the strategic planning and appraisal of flood and coastal defence schemes, to include developing a strategy and programme of work to meet defined flood or coastal defence objectives for a planning unit. The planning unit may be an individual coastal management unit, a set of related coastal management units, an estuary, a river catchment, a coherent sub-catchment or an integrated river reach.

The strategic approach is designed to provide the high level basis for decision making and action related to the provision and management of flood or coastal defences. Figure 3.9 illustrates the relationship between the different planning levels (i.e. schemes, strategies and large-scale plans). This is a 'top down' process, whereby each strategy conforms to the overall management plan for the region. Similarly, individual schemes are developed and appraised within a strategy plan rather than individually or on a piecemeal basis.

This tiered approach is itself a form of risk management strategy. The chance of unwanted interaction between schemes is reduced if they are planned as a coherent programme, and it is possible to optimise the phasing of schemes in a programme to maximise benefits in terms of reduced flood risk.

[47] Environment Agency, Corporate Plan, 1999-2000

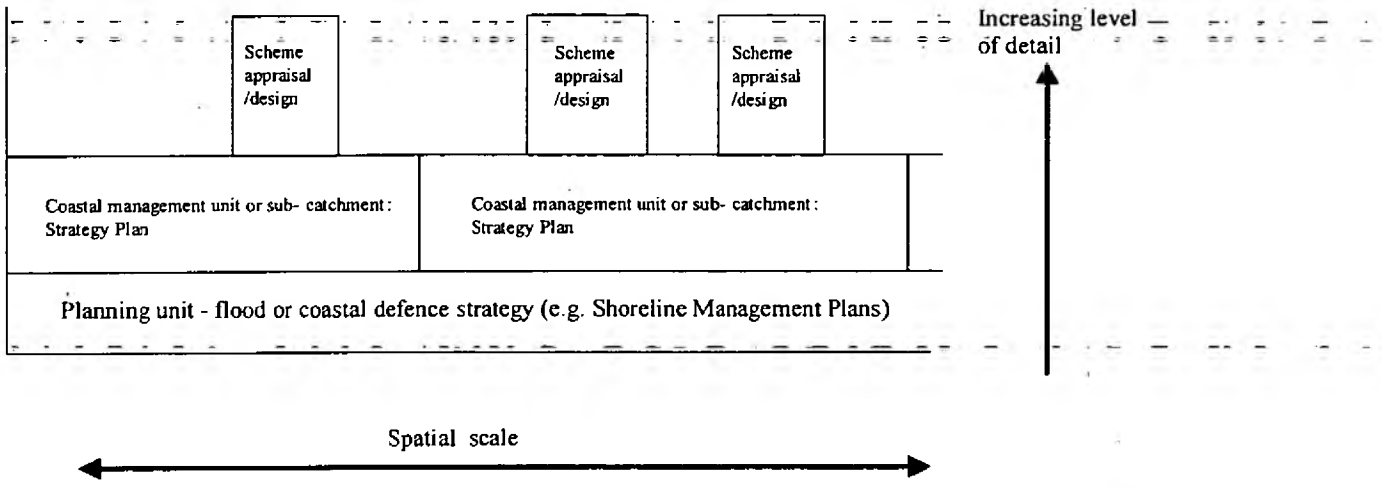

Figure 3.9: Scheme processing within wider scale planning and strategic framework (adapted from MAFF, 1997a)

Appraisal

Grant aided projects (and non-grant aided projects greater than £500k) are justified in accordance with the PAGN being developed by MAFF. In line with treasury guidance for appraisal and evaluation in central government, expenditure must be justified on the basis of benefits and costs (Figure 3.10). The benefits of a proposed scheme generally include reducing the frequency of flooding, its impact, or both. The appraisal process consists of identifying the problem and issues, defining a range of options and determining benefits and costs for each option. The options may be different types of scheme and cover a range of design standards.

The 'design standard' is usually expressed probabilistically, in terms of the 'return period' and associated severity of the flood or storm event that the defence is designed to withstand. The benefit-cost analysis is therefore risk-based, in that it includes consideration of probability and consequences. In addition, other elements of the flood defence system are represented by probabilities. For example, the appraisal process may take into account the changing probability of a breach through time, and incorporate this into the economic appraisal.

There is no automatic right to any particular level or standard of flood defence. MAFF publish 'indicative standards of protection' to help establish the range of options likely to be appropriate at a site. For example, a standard of 100 years return period is indicated for protection of high-density urban areas against tidal flooding. There is the provision within PAGN to override the maximum benefit-cost ratio criteria in certain circumstances, to provide schemes to standards appropriate to the land use.

In order to qualify for Ministry grant aid, a scheme must meet each of three separate requirements (MAFF, 1997b)

- it must satisfy certain thresholds and conditions (e.g. conforming to a Shoreline Management Plan);
- it must achieve an appropriate 'priority score' based on purpose and type of scheme, and its urgency; and
- it must satisfy MAFF's project appraisal requirements set out in PAGN, and meet conditions set out in MAFF's Grant Memoranda.

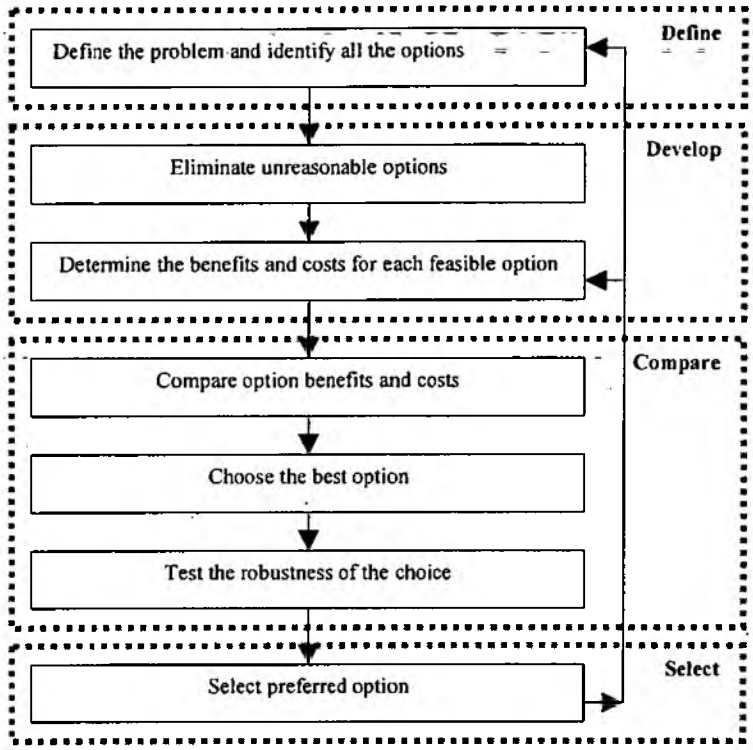

Figure 3.10: Stages in benefit-cost analysis (adapted from MAFF, in prep.)

The benefit cost criteria together with the application of 'priority score' system ensures that at present, the economic benefits of flood defence capital expenditure far outweigh the costs. In 1996/7, for example, the aggregate benefit/cost ratio of schemes approved was 6:1 (Agriculture Committee, 1998).

The Agency operates a system for justifying and prioritising non grant-aided expenditure, such as maintenance and revenue works. This is based on the same principles as MAFF appraisal guidance, but differs in some details. The Agency makes assessments on the basis of the annual expected number of houses flooded, and the average cost of flood damage per house. Damage to other assets is also expressed in terms of the House Equivalent damage. Resources are allocated on the basis of a priority scoring system, accounting for social factors, urgency of the works, their purpose and the strength of the economic case.

Project risk management

The Agency recognises the importance of assessing and controlling risks in the projects which it manages, and has implemented a procedure for project risk assessment and management (Environment Agency, 1997c). This is used to identify hazards and risks, rank these by importance and develop and document risk control measures. The system is also used to identify any residual risks and assess appropriate contingencies.

3.3.1.4 Tools and Techniques Used to Support the Assessment

There is a wide range of risk assessment and risk management tools in use and particular tools or techniques will often combine more than one of these. For further details on specific tools, refer to the Annex. These can be categorised into three main groups.

Flood risk assessment tools are used to characterise flood risk in terms of likelihood and severity, and the impacts of flooding. These range from:

- screening assessments (hazard assessment) such as identification of areas that may be at risk, from knowledge of topography, historical flooding and, possibly, flood modelling studies;
- scoring and weighting systems used to prioritise flood defence activities, including flood warning needs (Environment Agency 1999f and 2000c) and defence maintenance priorities (e.g. Flood Defence Management Manual; FDMM; Environment Agency, 1997d); and
- quantitative assessment including use of hydrological and hydraulic models, and various methods for valuing flood damage and impacts. Appraisal of costs and benefits of flood defence investment is based on quantitative assessment (e.g. PAGN, FDMM).

Tools have also been developed for business process risk assessment and risk management. These are used within the project management process to identify what can go wrong with a project or process. The main impacts are in terms of cost, delay and reputation. Key concerns often relate to issues such as communication, clarity of roles and procurement (external requirements/authorisations). Tools are mainly qualitative, often focussing on risk areas, and mitigation measures may be in terms of specific actions or more general attitude or organisational changes.

Finally, various generic methods are used for modelling uncertainty. These include sensitivity and interval analysis, simple probability modelling or more sophisticated Monte Carlo modelling. Statistical methods for estimating 'design' conditions such as water levels or rainfall to low probability levels are also widely used. Specific tools include the Flood Estimation Handbook for estimating extreme rainfall and river flows and the joint probability methods such as JOIN-SEA[48] for assessing extreme design conditions of waves and water levels at the coast. These can be combined to study how uncertainty in different parts of an analysis impacts on the assessment and on any decisions.

3.3.2 Water Resources

3.3.2.1 Rationale

The water resource function is concerned with ensuring that existing management and future development of our resources is carried out in an environmentally sustainable manner through balancing the needs of abstractors and other users with those of the environment. In doing so, it is important to achieve an appropriate balance between the need to maximise economic efficiency and taking a precautionary approach[49] both to protect the environment and in planning for risks and uncertainties in water resources and supplies.

The foundations for the management of water resources were laid down under the WRA 1963 and these have since been incorporated, with minor changes, into the WRA 1991 and the Environment Act 1995. The Government's Review of Abstraction Licensing Legislation is expected to lead to new legislation in the near future.

The Water Resources function of the Agency discharges its statutory duties, in particular by:

- monitoring the state of water resources;

[48] JOIN-SEA is a suite of software tools development by HR Wallingford and the University of Lancaster, under a MAFF R&D contract. It is used for assessing extreme design conditions at the coast, specifically combinations of waves and water levels. It is currently being piloted by selected consultants and has therefore not been widely released

[49] An Action Plan for Water Resources. The Environment Agency

- water resources planning in relation to prospective demand for abstraction and available water resources and appraisal of potential water resource schemes and strategies;
- issuing and enforcement of abstraction licenses for both river and groundwater abstractions;
- entering into and maintaining agreements for water resources schemes;
- operating river flow support schemes;
- alleviating low flows due to over-abstraction, particularly of groundwater; and
- drought contingency planning, granting drought permits and making applications for certain drought orders.

The aquatic environment has many potentially legitimate, but often conflicting, uses. The ability of the water environment to satisfy any use depends on the needs of the environment, water quality, water quantity (including existing uses) and physical features, such as fish passes or flood defence structures. In using the water environment to satisfy a particular need, any one of these parameters may be affected to the detriment of its further use for the same or another requirement, including that of sustaining aquatic flora and fauna. It is the duty of the Agency to balance these uses, so that sufficient water of appropriate quality is available to satisfy the needs of water users and to sustain a healthy aquatic environment.

Whilst in general, there are sufficient water resources across England and Wales to satisfy present requirements, regional and localised (in both spatial and temporal terms) deficits as well as surpluses may exist. Current forecasts of demand for water resources indicate that deficits may be exacerbated under certain economic, demographic and climatic conditions. The Agency has a duty to take such actions as it considers desirable to conserve, re-distribute or otherwise augment water resources and secure their proper use. In planning for the sustainable development of water resources, the Agency has co-ordinated the development of water resource plans by water companies to include setting out the longer-term framework for water resources to 2025. These plans along with assessments of other uses will form an integral part of the Agency's water resources strategies both at the regional and national scale.

3.3.2.2 Organisational Structure

The Water Resources function works closely with all other functions in the Agency, but particularly Water Quality, Flood Defence, Fisheries, Conservation, Recreation and Navigation. The Agency also works closely with external stakeholders, including Government Departments (DETR, MAFF, Welsh Office), OFWAT, the water companies (and umbrella organisations), agricultural (e.g. the National Farmers Union), industrial, conservation (e.g. English Nature; RSPB; Wildlife trust) and fisheries interests as well as the general public.

3.3.2.3 Approaches Used

Sustainable development underpins the Agency's activities at the strategic scale through its central role in regional and national planning of water resources and, at the local scale, through its licensing of abstraction. The Agency's integrated plan for the sustainable development of Water Resources follows a number of key initiatives:

The National Environmental Programme	Abstraction licence review
Water Companies' Water Resources Plans	Abstraction Management Strategies
Water Resources Strategies	EU Water Framework Directive

The main mechanism for achieving sustainable management and development of water resources is through the Agency's regulation of water abstraction. A license from the Agency is required to take water from rivers and underground water. The Agency is also charged with enforcing abstraction license provisions and protection of the quality of groundwater and surface water resources.

Amongst the many potential issues taken into consideration in determining new abstraction licences, in this context the Agency has to consider:

- risks to the water environment due to resulting changes to flow regimes; and
- risks of failure in supplies and, particularly, risks to supplies and the environment in planning to meet demands during droughts..

Whilst other uncertainties and risks are involved, the risks associated with the reduced yield to a resource zone due to lack of rainfall and low river flows or below average recharge of an aquifer can be typically measured in terms of the frequency of risk of drought. Typically, this will be based on droughts of specific severity or frequency such as a 1 in 50 or 1 in 100 year occurrence. The existence of long term, reliable rainfall data, borehole and river flow records greatly assist these approaches. The same thinking underpins the Agency's non-regulatory/advisory activities in the water resources area. Through its licensing of water abstraction the Water Resources function recognises the need to reconcile the competing requirements of the environment and abstraction, the public and others who utilise or value the benefits of the aquatic environment.

Risk based activities undertaken by the Water Resources function include the recently implemented risk-based system to target inspection frequency of abstractions. Water resources planning guidelines require water companies to undertake some risk assessment in the form of basic sensitivity analysis of a number of climate change scenarios.

LOCAL ENVIRONMENT ACTION PLAN (LEAP)

The sustainable management of water resources within local communities is promoted through the Agency's LEAP process. LEAPs are used by the Agency to provide a framework for consultation with other organisations and the public on catchment state and pressures, specific issues, establishing a long-term vision to balance conflicting uses and to identifying and prioritising actions and investments to improve the water environment. A more detailed catchment-based approach to the sustainable management of water resources is currently being developed by the Agency. Abstraction Management Strategies will be used by the Agency to set out and consult on local water resources management strategies and will address the identification of environmental needs, programmes for imposing time limits or reducing quantities in licences and future abstraction.

3.3.2.4 Tools and Techniques Used to Support the Assessment

Conceptual and numerical models play a key role in the development of groundwater resources in identifying the sustainable yield of groundwater units and in regulating abstractions to ensure that the impacts of abstractions on springs, rivers and wetlands are limited to the point which is acceptable. As the demand on groundwater resources increases, it is increasingly important for the Agency to improve its knowledge and understanding of aquifer systems if robust and defensible decisions are to be made regarding the management of the resources. Provided that there is sufficient data, groundwater models allow the resources available for exploitation to be quantified more accurately that other methods. For further details on tools and techniques used, refer to the Annex.

3.3.3 Fisheries

3.3.3.1 Rationale

Under the Environment Act 1995, the Agency has a general duty to maintain, improve and develop salmon, trout, freshwater fish and eel fisheries under its jurisdiction. It also has wide regulatory responsibilities and powers in relation to fishing, the protection of fisheries and the control of fish disease (Environment Agency, 1999a). Some of the key areas of responsibility include:

- the regulation of fisheries through the enforcement of licenses, orders, bylaws and consents;
- monitoring the performance of fisheries in rivers and inland waters, estuaries and, where appropriate, coastal waters, including fish stocks, their habitat, fishing efforts and catches; and
- producing clear strategies for the long-term management of each of the main types of fishery.

Other powers and duties relate to conservation, pollution, water abstraction and land drainage.

3.3.3.2 Organisational Structure

The Fisheries function is unusual in that it has a very large number of people who pay directly towards annual licensing fees[50]. Thus 60% of its revenue comes from fishermen, mainly anglers. Key stakeholders are the government, the general public, netsmen, anglers and fishery owners. The Agency also works closely with a range of governmental organisations and a large number of non-governmental organisations to fulfil its responsibilities. These include MAFF, Country Landowners; Association, Countryside Council for Wales, Salmon and Trout Association and the National Federation of Angles, just to mention a few.

3.3.3.3 Approaches Used

Key to the success of the fisheries service is to ensure a truly integrated approach to environmental protection and management. To achieve this it is important to have a sound knowledge about the state of the water environment in terms of the fish stocks and the impacts acting upon them, success generally being measured in terms of overall improvement of the nation's fisheries and improved opportunities for fishing. In addition, success will be measured in terms of customer satisfaction (i.e. of those paying licenses). The most effective way to contribute to optimise the social and economic benefits of this resource whilst conserving and improving its environment is to concentrate the available resources towards activities which will have the greatest impact. Thus, although no formalised risk-based approaches are used, a balance has to be struck between the financial resources available and minimising the environmental impact to the fish population.

[50] An Action Plan for Fisheries. The Environment Agency

Much of the work conducted by staff within the Fisheries function involves enforcement of fisheries legislation (e.g. investigation of fisheries offences, patrol checking of rod licenses) and monitoring (e.g. boat work, fish netting operations). In order to ensure staff safety, the fisheries function is in the process of developing a health and safety risk management manual. This aims to assess the risks from the various activities undertaken by the staff and to consider the best control measures to minimise these risks. The approach has not been presented here as it is outside the remit of this guidance document.

3.3.3.4 Tools and Techniques Used to Support the Assessment

No tools or techniques are formally used to support the risk assessment process.

3.3.4 Conservation

3.3.4.1 Rationale

The Agency has a general duty to consider and promote (Environment Agency, 1999a)

- the conservation and enhancement of the natural beauty and amenity of inland and coastal waters and of land associated with such waters;
- the conservation of flora and fauna which are dependent of the aquatic environment; and
- the use of such waters and land for recreational purposes.

Conservation means taking action to sustain or improve the intrinsic value of natural or historical assets. Therefore its remit covers wildlife, landscape and physiographical features, plus sites, objects and buildings of archaeological, architectural, engineering and historic interest that are directly or indirectly affected by our regulatory and operational remit (Environment Agency 1999g). In doing so the Agency has to take into account likely costs, including costs (and benefits) to relevant sectors of society (including regulated organisations) and to the environment. The Agency can only achieve its conservation objectives through the exercise of statutory powers and duties of the Agency's functions as a whole[51].

The role of conservation staff is to advice all the other functions as well as external third parties. This involves exploiting available opportunities for furthering and promoting conservation. Staff in the Conservation function also act as an internal technical audit to ensure that criteria and procedures are applied in line with the Agency's statutory conservation duties.

The Agency is not directly responsible for site or species protection, although it can have a major influence when using its regulatory duties and powers to prevent and control pollution to protect the environment across air, land and water; and manage the water environment and its resources.

The Agency has a major influence when using its regulatory duties and powers to:

- actively encourage or progress conservation, wherever possible, when carrying out water management functions; and
- have regard to conservation when carrying out pollution prevention and control functions.

[51] An Action Plan for Conservation. The Environment Agency

The Conservation function also has a free-standing duty to promote the conservation of natural beauty and amenity, and the wildlife dependent on the aquatic environment. In addition, there is a specific duty to consult with the statutory conservation agencies before authorising others or carrying out work that may damage the special conservation interest of designated sites.

3.3.4.2 Organisational structure

The conservation function works internally with all the other functions and provides a link with statutory and non-governmental bodies. Some of the closest contacts are English Nature, Countryside Council for Wales, Broads Authority, National Parks Authorities, Countryside Agency, English Heritage, Cadw, The Wildlife Trusts, County sites and monuments records offices, National Trust, Council for the Protection of Rural England and the RSPB.

Statutory agencies, notably English Nature, the Countryside Council for Wales and, in the case of archaeological sites, English Heritage and Cadw have responsibility for site and species protection.

The Conservation function also have a statutory objective to develop close and responsive relationships with the public, local authorities and other representatives of local communities and regulated organisations.

3.3.4.3 Approaches used

The service provided by Conservation in the Agency is based upon detailed, accurate and up-to-date information relating to the wildlife, landscape heritage and archaeology of river catchments. This information is gained through receipt of information from other environmental organisations, commissioning of surveys using external consultants and surveys of sites and river corridors by conservation staff. This information is input to computer and hardcopy databases and is used by conservation staff as a reference when screening internal and external proposals and when determining future conservation projects. There are relatively few risk assessment-based systems in conservation due to the huge diversity of work carried out by the function, the highly specialised nature of the work and the need to treat each site and project proposal on its own merits. In seeking to implement the habitats Directive, the Conservation function has developed a structured approach to assessing existing authorisations such that the greatest effort is focussed on those posing most risk to the integrity of the designated area.

3.3.4.4 Tools and techniques used to support assessment

Survey tools and techniques include River Habitat Survey, River Corridor Survey and Landscape Assessment. For further details on specific tools see the Annex. The list presented in the Annex is not comprehensive, but rather aims to present key tools used in Thames Region. Although most regions are likely to use similar techniques, there may be area/regional variations. "Filter" systems are used to help select the type of schemes and proposals which are sent to conservation for comment; there include a formal matrix system for screening planning applications. Health and Safety procedures are also being drawn up.

3.3.5 Navigation

3.3.5.1 Rationale

The Agency's navigation responsibilities are diverse, ranging from its role as a harbour and conservation authority and a deep water navigation authority to operational duties for navigation using land drainage byelaws[52]. Navigation is a valuable resource in environmental, recreational, commercial, heritage and social terms. They also form an important part of the entire inland waterways network and coastal chain of harbour and estuaries.

Although the Agency has no overall responsibility for navigation, by virtue of its general conservation and recreation duties, it is required to promote both the conservation of inland and coastal waters and the use of such waters for recreational purposes. In addition, the Agency has specific operational navigation responsibilities in four of its regions[53] and has responsibility for locks[54] as well as managing navigation through various rivers[55] to control speed limits on tidal stretches to reduce bank erosion.

On river navigation where the Agency is not the navigation authority, it still maintains the responsibility towards water quality, water resources, food defence, fisheries, recreation and conservation.

The Agency's statutory responsibilities for inland navigation in England and Wales are covered through separate pieces of legislation[56]. Where the Agency is the navigation authority, the day-to-day operational and management responsibilities are to a large extent governed by local and special Acts and Orders[57]. In addition the Agency has byelaw-making powers for inland waters where there is a public right of navigation and while no other authority legitimately exercises navigation powers.

3.3.5.2 Organisational Structure

The Agency encourages communication with all those who use the navigational system under the Agency's control. This included boat owners, the Association of Inland Navigation Authorities, specially British Waterways and the Broads Authorities, industry (e.g. trade, marine, tourism and hire boat industries), the British Tourist Authority, Countryside Commission, Countryside Council for Wales and English Nature. Local authorities have a key role to play through the planning system; in addition they often own riverside land that provides facilities for boats, locations for land-based access, viewpoints and visitor areas. The Agency relies on the actions of others to help maintain and develop the navigational system under its control.

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[52] An Action Plan for Navigation, The Environment Agency, Bristol

[53] This includes lengths of the rivers Thames, Medway and several East Anglian rivers, the Dee Estuary and the Harbour of Rye

[54] On the Yorkshire Derwent and Market Weighton Canal

[55] Rivers Adur, Arun, Sussex Ouse and the Dorset Frome

[56] Land Drainage Act 1976, Sea Fish Industry Act 1951, Pilotage Act 1987, Harbour Docks and Piers Clauses Act 1877 and Regulations made under shipping and waterways legislation

[57] The Anglian Water Act 1977, the Upper Medway Navigation and Conservancy Acts 1911 and 1914, The Southern Water Authority (Transfer of Lower Medway Navigation Function Order) 1979, The Southern Water Authority Act 1982, The Harbour of Rye Revision Order 1976, and the Thames Conservancy Acts 1932, 1950, 1959, 1966 and 1972

Other tasks include the management of navigational structures to include river navigation, locks and associated weirs and sluices, registering and licensing boats and providing services such as mooring and pump-out facilities and recreational facilities.

3.3.5.3 Approaches used

The Navigation function manages its responsibilities as an integral part of the river management process. This is an efficient and effective means of balancing demands with the capacity of the environment. At an operational level multi-functional staff maintain the navigation system and ensure that water supply, water quality and flood defence requirements are met. For example, lock keepers are responsible for operating sluices to maintain water levels for abstraction purposes and ensuring that at times of high flow, these are lowered to avoid flooding.

No formalised risk-based approaches are used within the Navigation function. However, in conducting its activities, it aims to maximise the potential of the navigation systems in a sustainable manner. This involves striking a balance in terms of the resources available to maintain and manage navigational structures and encourage the conservation of natural resources, flora, fauna and man-made heritage, whilst making best recreational use of land or water under Agency's control.

Much of the work conducted by staff within Navigation involves patrolling the rivers to ensure enforcement of local legislation and byelaws (e.g. behaviour, boat safety, boat speed, boat registration and licensing). Health and safety risk management procedures need to be in place to ensure the safety of staff whilst carrying out such activities. Navigation is in the process of preparing a manual to assess the risks from the various activities undertaken by staff and to consider the best control measures to minimise these risks. The approach has not been presented here as it is outside the remit of this guidance document.

3.3.5.4 Tools and techniques used to support assessment

No tools or techniques are formally used to support the risk assessment process.

3.3.6 Recreation

3.3.6.1 Rationale

The Agency's recreational responsibilities extend to all inland and coastal waters and associated land. The term recreation coves all aspects of water-related leisure activities, to include navigation. The Agency has a number of statutory duties in respect of recreation, access and amenity[58]. These include:

- promoting the enhancement of the natural beauty and amenity of inland and coastal waters and the use of water and associated land for recreational purposes;
- having regard to the protection and conservation of man-made heritage and the effects on the economic and social well being of local communities in rural areas;
- having regard to preserving access to recreational sites when considering proposals relating to non-pollution control functions;
- making best recreational use of land or water in the Agency's control;
- following the code of Practice on Conservation, Access and Recreation issued by the Government which gives practical guidance and promotes best practice; and

[58] An Action Plan for Recreation, the Environment Agency, Bristol

- having regard to National Park statutory purposes when undertaking activities that affect the parks.

3.3.6.2 Organisational Structure

The Agency liases and communicates with recreation groups and other organisations with a responsibility or interest in recreation (e.g. Countryside Commission, Countryside Council for Wales, Central Council for Physical Recreation, Country Landowners Association and National farmers Union, land and riparian owners and local authorities. The Agency is also a member and funding partner for the Countryside Recreation Network, which provides an effective way of exchanging information and research and discussing policy with other organisations and government agencies with an interest in countryside and water recreation.

3.3.6.3 Approaches Used

The Agency delivers its greatest contribution to its recreation duties through the work of its other functions. Recreational staff ensures that other functions consider and take on board recreational opportunities by:

- screening the work of other functions and providing expert advice to ensure that recreation is considered and taken on board (e.g. screening applications for Agency consents and licences for recreation implications);
- developing and applying tools which allow recreational parameters to influence the Asset Management Planning process, application of water resources legislation and the development of environmental standards;
- commenting on planning and influencing the statutory planning system; and
- influencing local Agency planning through LEAPs.

Whilst there is a recognition that rural tourism and recreational activities make an important contribution to the rural economy, it is also recognised that there is a balance between the needs of the visitor, the character of the local environment and the quality of life of local communities. Key to the Agency's success is to ensure a fuller understanding of the demands and impacts which recreation makes upon the environment. However, the Recreation function does not use risk assessment in carrying out its daily activities.

3.3.6.4 Tools and Techniques Used to Support the Assessment

No tools and techniques are formally used to support the risk assessment process.

3.3.7 Environmental Impact Assessment

3.3.7.1 Rational

Environmental Impact Assessment (EIA) is a process designed to ensure that all potential environmental effects are satisfactorily assessed and taken into account in the planning, options selection, design, authorisation, construction, operation, maintenance, and were appropriate, decommissioning stages of a project. The need for EIA to be an integral part of the Agency's work has been recognised at a national level by the Policy Group.

All Agency works and activities should be subject to some form of environmental appraisal before they go ahead, whether this involves a formalised EIA or not. This is necessary to fulfil the Agency's duties under the Environment Act 1995. Two sets of EIA Regulations

may be applicable to Agency activities; these relate to land drainage improvement works[59] and new works where planning permission is required[60]. Where such projects are likely to have significant effects upon the environment, an Environmental Statement has to be produced.

3.3.7.2 Organisational Structure

Environmental Impact Assessment is a multi-functional activity. Early involvement of relevant internal specialists is crucial both to identify appropriate options at the outset and to programme EIA into project timescales. It also provides the mechanism to involve and consult external organisations and individuals on the agency's proposals.

EIA requires close work with external organisations. Some of the closest links are with MAFF, English Nature, Countryside Council for Wales, Broads Authority, National Parks Authorities, Countryside Agency, English Heritage, Cadw, Local Authorities, the Wildlife Trusts, county sites and monuments records offices, National Trust, Council for the Protection of Rural England and the RSPB.

All Regions should ideally have dedicated EIA staff with full responsibility for the co-ordination, quality assurance and auditing of the whole process to ensure that high standards are maintained and developed. In addition, to ensure independence, they should have a separate reporting line to those promoting the activities that are being assessed[61].

[59] Statutory Instrument 99/1783
[60] Statutory Instrument 99/293
[61] This arrangement is currently only in place in some Regions. Where not in place, it is essential that procedures are implemented to ensure that independence is maintained throughout the EIA process and particularly to fulfil the quality assurance requirements described in the Handbook

3.3.7.3 Approaches Used

Any EIA involves three stages: (i) scoping (ii) evaluation and (iii) implementation, monitoring and auditing. The initial stage is to determine whether an assessment is required and if so to identify the appropriate procedures that should be followed (e.g. land drainage, planning routes). The next stage is the evaluation involves the collation of baseline data, consideration of alternatives, impact prediction and assessment and mitigation enhancements. Finally, implementation, monitoring and auditing involves (i) producing an Environmental Action Plan (EAP), which details the design, construction and monitoring requirements; (ii) ensuring that the EAP is finalised and the contract documents have been adequately reviewed; and (iii) conducting a Post Project Appraisal and Audit.

The assessment is an iterative process and the level of detail required in the assessment is determined based on the significance of the environmental effects. Four levels of EIA have been established and minimum and threshold levels have been set out for all Agency activities. The level of detail required will depend on the environmental effects so that if at the scoping stage the effects are considered negligible, then there is no need to proceed further. The assessment may therefore involve up to four levels:

- the scoping stage only (negligible environmental effects);
- completing and documenting all 3 stages mentioned above (level 3);
- an environmental appraisal (level 2); and
- a formal statutory EIA (level 1).

3.3.7.4 Tools and Techniques Used to Support the Assessment

Because of its multifunctional nature a wide range of tools and techniques are used in EIA (e.g. river corridor surveys, geomorphological surveys, consultation exercises, geotechnical surveys and archaeological watching briefs).

The National EIA Handbook provides national guidance on the environmental assessment of the Agency's internal works and activities which result in a physical change to the existing environment. The Handbook is relevant to all members of staff involved in such projects, as well as the consultants involved in the assessments.

Impact prediction and assessment and options appraisal are often undertaken, assisted by EIA tools such as matrices, where the magnitude and significance of impacts are summarised for comparison. EAPs are used to ensure that recommendations made from the EIA process are carried out from the reporting stage to the detailed design and construction project stages. These have been developed considerably in the Agency, particularly in the Midland and Anglian Regions. For further details on tools and techniques available refer to the Annex.

4 NON-STATUTORY USES FOR RISK ASSESSMENT

4.1 Operator and Pollution Risk Appraisal (OPRA)

4.1.1 Rationale

Once an IPC process has been authorised the Agency needs to be satisfied that the conditions in the authorisation are being complied with. In regulating prescribed process and enforcing the authorisation conditions, the Agency carries out periodic monitoring and site inspections to ensure compliance with the conditions of the authorisation and satisfaction with the overall performance of the process. The frequency and conduct of site inspections and follow up action are based on the professional judgement of inspectors about the risks posed by regulated operations.

In order to formalise this professional judgement and introduce greater transparency and consistency into the existing qualitative risk assessment and risk management process, the Agency has developed a procedure based on risk to assess the performance of operators of prescribed processes (Environment Agency, 1997b). This procedure, known as the Operator Pollution and Risk Appraisal or OPRA, should help the Agency target its resources better on the processes that pose the greatest risk. It should also be used to provide comparative information about changes over time or differences between similar processes.

4.1.2 Organisational Structure

This procedure has been developed for use by Agency PIR inspectors to assess the performance of operators of prescribed processes.

4.1.3 Approach Used

OPRA considers the two components of the risk from prescribed processes separately. Scores are assigned to seven attributes relating to the likelihood that an undesirable event could occur. These attributes provide a measure of the performance of the systems being used by the operator to manage the authorised process, and are site specific. Scores are also assigned to a further seven attributes, which relate to the scale of the consequences which could result if the undesirable event were to occur. These provide a measure of the intrinsically harmful nature of the process, and are process specific. A weighted sum of the first set of scores gives the Operator Performance Appraisal (OPA). This exercise should be carried out at the end of each inspection visit in discussion with the operator, to provide immediate feedback on the strengths and weaknesses of the operator's systems and to highlight areas where improvements are needed. A weighted sum of the second set of scores gives the Pollution Hazard Appraisal (PHA). This is completed when the process is first authorised and reviewed periodically thereafter. The overall risk is assessed from a combination of the OPA and the PHA. This procedure is illustrated in Figure 4.1. This indicates that, although the appraisal procedure itself is relatively simple, it relies on the development of generically applicable systems for the OPA and PHA.

4.1.4 Tools and techniques used to support the assessment

A document has been produced which provides detailed guidance on the OPRA system, to include details of the scoring criteria (see Annex for further details).

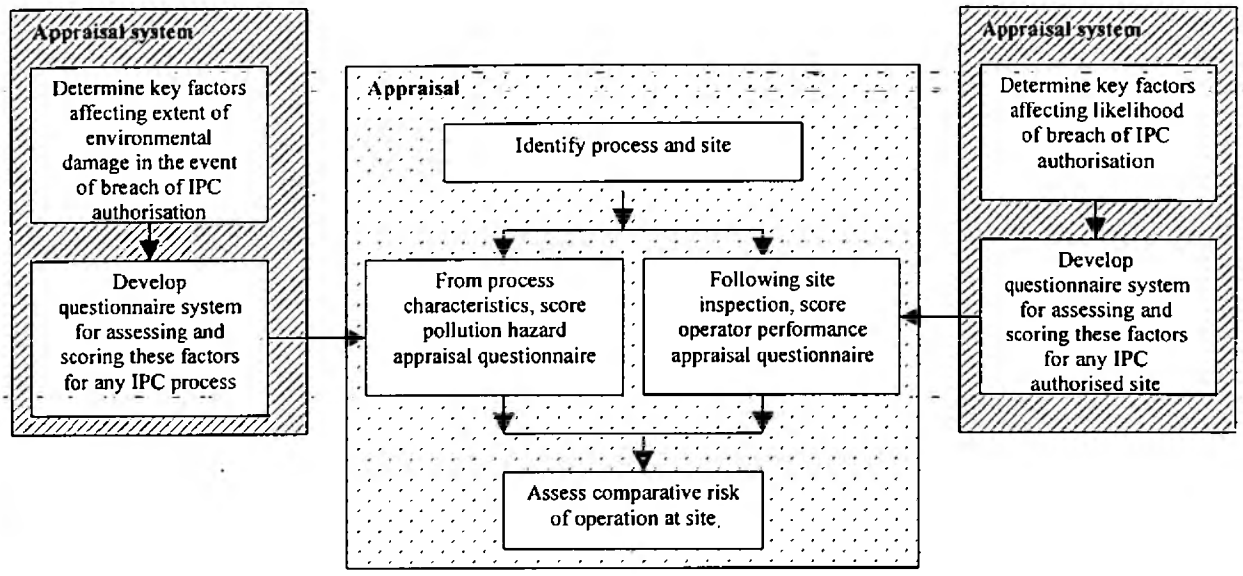

Figure 4.1: Operator and Pollution Risk Appraisal

4.2 Operator and Pollution Risk Appraisal (OPRA) for Waste

4.2.1 Rationale

The Government is required by the Framework Directive on waste to ensure that sites licensed to recover or dispose of waste are subject to appropriate periodic inspections[62]. This involves supervising licensed sites and ensuring that license conditions are complied with. The Agency has proposed a new site inspection system, similar to that developed for IPC (see section 4.1 above), known as the OPRA licensed waste management site inspection methodology. DETR and the Agency are currently carrying out a public consultation exercise to get some feedback on the proposed methodology before this is introduced (DETR, 1999b). OPRA for Waste should:

- make more effective use of Agency resources by targeting inspections on those sites where there are most needed;
- ensure site inspections are of adequate quality and consistency to allow for reliable risk performance appraisal;
- assist operators to improve their performance and to reduce risk; and
- contribute to the move towards more sustainable waste management.

[62] Waste Management License Regulation 1994

4.2.2 Organisational Structure

The Agency carries out site inspections on the basis of guidance issued by the Secretaries of State for the Environment and for Wales. Guidance is set out in WMP4 and 4A (HMIP, 1978 and Environment Agency, 1999d).

4.2.3 Approach Used

OPRA for Waste is a screening tool that provides a straight forward characterisation of the overall environmental risk from the waste disposal or recovery operation concerned. It considers both the probability of occurrence of an undesirable event and the consequences of such an event occurring.

Under the proposed scheme, the environmental aspects of the facility are assessed by evaluating both the infrastructure of the facility and the control measures in place. Scores are assigned to six criteria in terms of the source of pollution, inherent risks at the site and the potential long-term impacts. A weighted sum of this set of scores gives the Environmental Appraisal. In addition several aspects of the performance of the operator are also assessed (OPA). Scores are assigned to two criteria to measure the performance of the operator in terms of any breaches of the license conditions and the management control procedures in place to minimise damage. These take into account the type and severity of effect (following a breach) and the probability of environmental damage. This appraisal should be carried out at the end of each inspection visit[63] in discussion with the operator, to provide immediate feedback on the strengths and weaknesses of the operator's systems and to highlight areas where improvements are needed. These scores are then collected for a three month period which forms the basis of the re-assessment and thus the inspection frequency for the next period. The overall risk is assessed from a combination of the Environmental Appraisal and the OPA. This procedure is illustrated in Figure 4.2.

4.2.4 Tools and Techniques Used to Support the Assessment

A document has been produced which provides detailed guidance on the OPRA for Waste, to include details of the scoring criteria (see Annex).

[63] as outlined in the Licensed Waste Management Facility Site Inspection Methodology

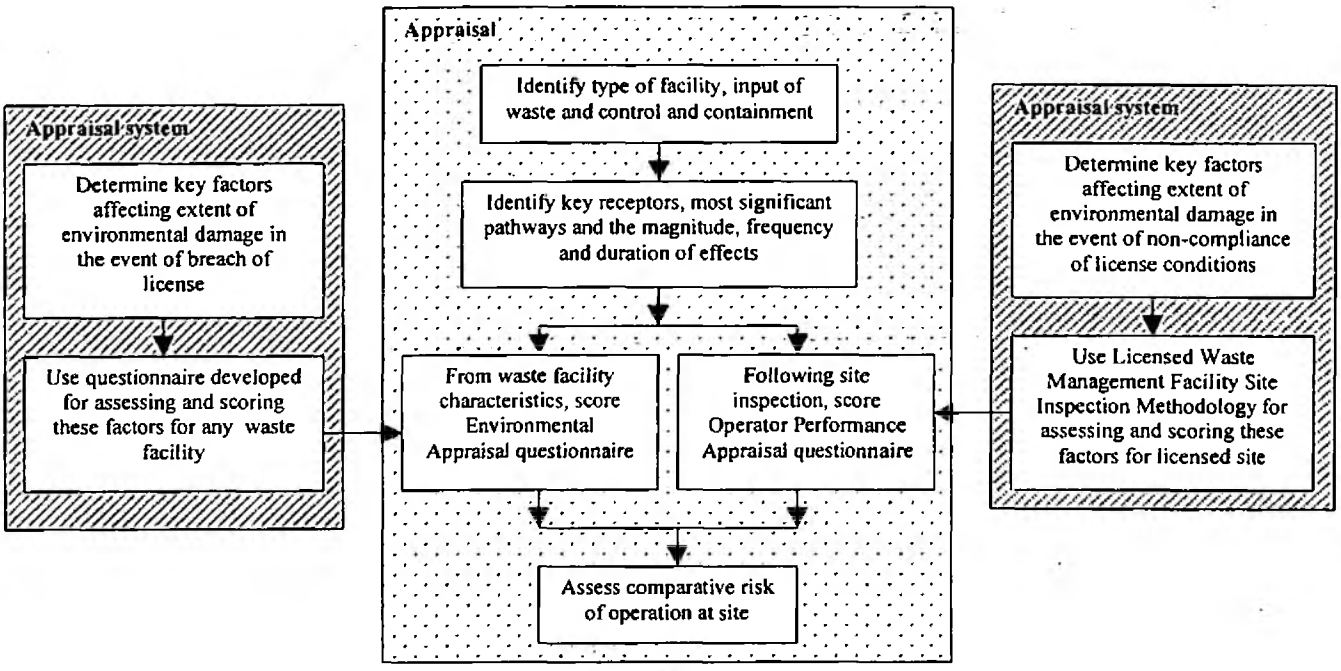

Figure 4.2: OPRA for Waste

4.3 Operator Monitoring Assessment

4.3.1 Rationale

Operators of IPC processes are required to carry out monitoring of releases from their processes and report the data to the Agency. This data is used to assess compliance with the authorised limits and is placed on the Agency's public registers. The Agency commissions a proportionate amount of independent monitoring (costs recovered by Agency from operators) to ensure this system of self-monitoring is working honestly and effectively. The extent and frequency of the Agency's monitoring is based on the professional judgement of PIR staff. In order to formalise this professional judgement and introduce greater transparency and consistency in setting the Agency's programmes, the Agency is developing a procedure to assess the quality of operators' monitoring arrangements, to be known as Operator Monitoring Assessment (OMA). This will help the Agency in targeting its monitoring programmes, concentrating on processes that pose the greatest risk. It will also provide a powerful incentive for operators to improve the quality of their monitoring to reduce the amount of Agency monitoring undertaken.

4.3.2 Organisational Structure

This procedure is being developed for use by PIR staff to assess the quality of operators monitoring arrangements.

4.3.3 Approach Used

OMA is in the early stages of development. It is envisaged that a set of monitoring specific attributes will be used to assess the quality of an operator's monitoring arrangements. This assessment will be combined with the PHA score from OPRA to provide an overall assessment of the requirements for Agency independent monitoring. The principle would be that processes with a low PHA would receive less Agency monitoring than processes with a high PHA for a given OMA score.

4.3.4 Tool and techniques Used to Support the Assessment

A document will be produced to provide the detailed guidance that is required to carry out an OMA. Operators will be assessed against a number of attributes, but in particular, whether they meet the performance standards specified in the Agency's Monitoring Certification Scheme MCERTS.

It is envisaged that OMA will be fully operational from April 2002.

4.4 Toxicity-based effluent control & assessment

4.4.1 Rationale

Where an effluent discharge is causing, or has the potential to cause, harm to the receiving water, the Agency has the power to reduce and control this harm by the use of a toxicity condition[64]. This method of control is acceptable in both the WRA and EPA licenses as this may introduce other conditions into an authorisation (as considered appropriate to the enforcing authority) for minimising the polluting effects of the discharges into controlled waters[65]. The acceptability of these powers has recently been reiterated at a Direct Toxicity Assessment (DTA)[66] legal workshop attended by regulators and representatives of the water companies and industry[67].

Toxicity based consents have existed in the UK for many years. However, there has been no national policy with regard to their application. As a result they have been applied inconsistently between sites, often using insensitive species and there has been little quality control on the testing performed. Because of these concerns no regulatory actions have been taken based on results obtained from effluent ecotoxicity testing. The Agency is looking into the wider and more consistent use of DTA for the more effective control of complex releases of toxic waste to waters. An R&D project is currently exploring the use of this type of approach[68]. As this has not been fully developed or agreed, this approach is not currently used in the Agency.

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[64] As part of the Agency's effluent control powers, duties and responsibilities are set out in the WRA 1991, the EPA 1990 and the Water Company's powers in the Water Industries Act 1991.

[65] See Part 1, Section 7 of EPA 1990 and Schedule 10, Section 5 of WRA 1991 for further details

[66] DTA is a bioassay technique that allows for the biological effect assessment of whole samples. This method provides a more holistic measure of the potential hazard of emissions to the receiving environment by measuring the effects of all substances present in a sample, rather than from single chemicals, i.e. it allows for the assessment of the integrated effect of mixtures

[67] Reported in Proceedings of the DTA Legal Workshop, North West Water Ltd. Offices, Warrington, 4th December, 1997

[68] R&D Project: Direct Toxicity Assessment (DTA) Demonstration Programme. Duration of contract 1997 to 2000

Although DTA can be used for the environmental management of the land, air and water environments, much of the current effort has focussed on procedures to control and monitor the release of complex point-source discharges to water. The role of risk assessment in the regulatory applications of DTA for effluent control is to determine the risk of an effluent causing environmental damage (potential or realised) in the receiving water. This will help inform the decision making process in applications for discharge licences, setting of discharge licences and the need for remedial action.

4.4.2 Organisational Structure

Initial work was undertaken by the Environment Agency and Scotland & Northern Ireland Forum for Environmental Research (SNIFFER). More recent development has been done in collaboration with bodies representing the manufacturing and water industries through R&D joint funded projects. However, following 'the polluter pays principle' much of the work required will be funded by the polluting industry. Discussions on the regulatory application of toxicity-based effluent control are currently occurring at a European level (e.g. OSPAR) which may affect how implementation takes place.

4.4.3 Approaches Used

The Agency is exploring the possibility of using DTA for assessing the risks from complex effluent discharges into the aquatic environment. A protocol has been developed and the initial effort has being directed at sites where there is evidence of biological impact in receiving waters likely to be due to a chemical contamination problem. In the longer term, however, this approach should be applicable to more comprehensive assessments of the hazard/risk of complex effluents. The approach is presented in Figure 4.3.

The risk of an effluent producing a toxic impact in the receiving water is established by using toxicological hazard data together with dilution/dispersion information for the effluent. If a discharge is considered to represent a reasonable risk after dilution in the receiving water then toxicity reduction of the effluent will be required. A target for reduction would be set at this stage. An agreement must be established between the regulator and the discharger to take action to identify where the toxicity originates, what chemicals are responsible for the toxicity and the most appropriate course of action to remove or reduce this toxicity. This may be in the form of an enforceable improvement plan, within a discharge licence, which establishes toxicity targets to be satisfied and timescales to identify remedial options.

Options for toxicity reduction and timescales for implementation are considered and the most appropriate option (considering costs and benefit) are implemented. Remedial activities may include improved operational control; chemical usage changes or substitution; plant replacement or upgrade or new/improved treatment capability. The success of the remedial action will be established by effluent monitoring.

Currently the protocol uses a simple PNEC/PEC comparison. For the purpose of DTA the PNEC is initially regarded as the lowest measured NOEC[69]. The PEC is the predicted concentration of an effluent at a point in the environment following release, taking into account the initial volume of the discharge and the available dilution/dispersion in the receiving water. This point may be at end-of-pipe or at a defined point in the receiving waters (point of protection) where a NOEC is desired depending on water use.

[69] Following characterisation of the effluent toxicity derived from initial testing with a trophic level (algal, invertebrate, fish) battery of toxicity tests followed by repeat testing with the most sensitive of these tests

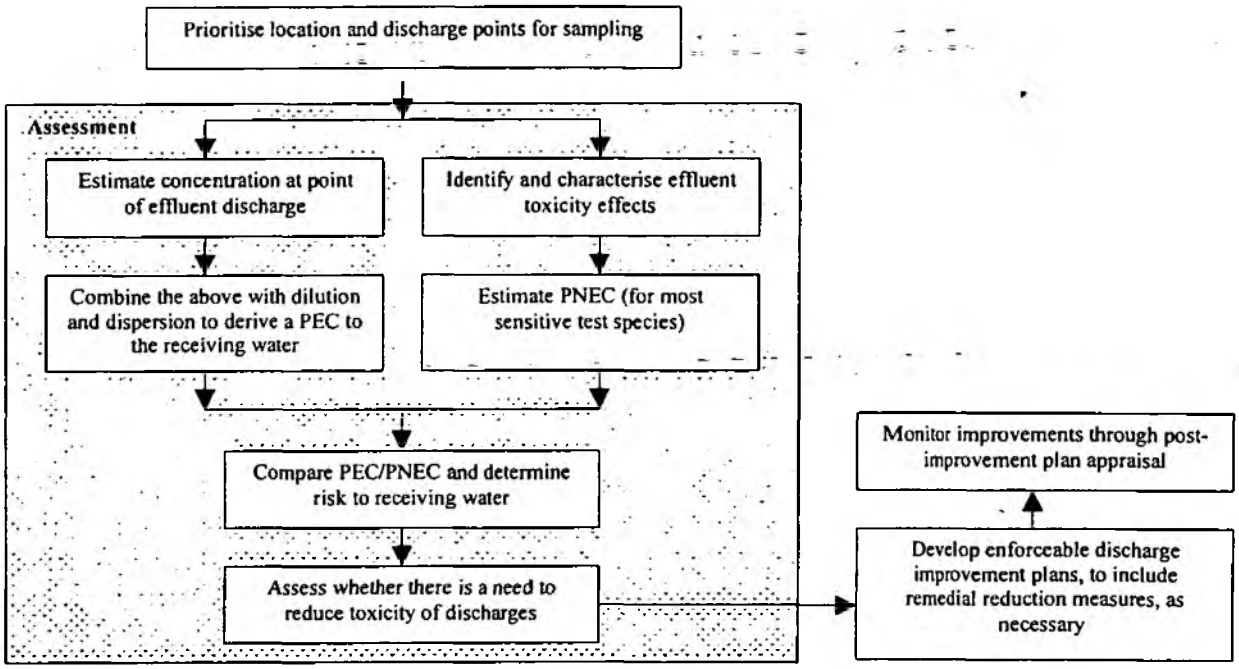

Figure 4.3: Setting effluent management requirements using toxicity based effluent control and assessment

In the future it is likely that a probabilistic risk assessment approach will be used. There are major benefits in moving to probabilistic risk assessments not least in that they encourage the generation of data by industry whereas simple PNEC:PEC comparisons do not (a lower toxicity value generated from testing would result in a lower regulatory limit whereas a higher one would not affect it).

4.4.4 Tools and Techniques Used to Support the Assessment

No specific risk assessment tools have been developed to date. However, the Agency, in partnership with the manufacturing and water industries, is in the process of developing generic technical guidance to satisfy the Agency's particular regulatory and effluent management requirements.

4.5 Research & Development Prioritisation

4.5.1 Rationale

New start proposals are prioritised by setting Business and Management questions which act as drivers for the Agency's R&D decision-making. They reflect issues of future concern, operational needs and the need for a business-like approach. These questions are clearly highly relevant in prioritisation but as they stand it is difficult to incorporate the answers into a ranking methodology that will allow for an easy and effective mean of prioritising R&D project proposals. As a consequence, the R&D Section has developed a scheme that allows for the prioritisation of R&D proposals in a cost-effective manner whilst ensuring that Agency business needs are met. The effective prioritisation of R&D has become increasingly important because there is:

- the need to demonstrate a business driven approach within R&D;

- a requirement to consider themes and issues as part of the planning and decision-making process while maintaining the Function driven management structure;
- a need to make the most effective use of the available budget; and
- the desire to provide a clear and transparent process of project selection.

4.5.2 Organisational structure

The R&D Section co-ordinates generic R&D activities across the Agency, while Programme Officers, Topic Leaders and Business groups[70] are involved in R&D activities within each Commissioning Function.

4.5.3 Approach used

The method, summarised below has been used to prioritise project proposals for the 2000/2001 R&D Programme and will be retained for future years if deemed to be successful. It is, however, recognised that this approach will be more appropriate and more likely to be used by the larger Agency Functions, such as Water Quality, which have to deal with a greater numbers of often complex and varied proposals for funding.

The prioritisation method involves the following two stages. An early high level screening of proposals by programme officers and topic leaders is initially conducted to ensure that appropriate research drivers are being addressed. This focuses on the Agency's business needs rather than on the technical quality of the proposals. At this stage all proposals not relevant to the Agency business needs are screened out.

Proposals passing through the initial screening are prioritised to provide a more refined evaluation of the business need and an indication of technical quality. These proposals are entered onto a standard spreadsheet and for each proposal a short "Business Impact Statement" is made justifying its inclusion within the programme against the four criteria shown below. A semi-quantitative ranking scheme is used, whereby each of above criteria a given a score. A checklist of factors likely to correspond to a low and high score is provided as guidance. These are largely based on the R&D business and management questions currently in use. Obviously, there is a degree of subjective judgement when ranking each proposal, but this scheme should encourage greater transparency on the reasons for selecting projects for funding.

[70] *Programme officers* are appointed by a Commissioning Function as the responsible budget holder for the R&D carried out by that function. They work closely with a specific R&D Management Support Officer to plan and monitor progress and delivery of R&D projects; Larger R&D Programmes (e.g. Water Quality, Flood Defence), are subdivided into topics for which individual *topic leaders* are made responsible. In the Water Quality Programme, for example, topics exist on Ecotoxicology, Groundwater Pollution etc. Finally, *business groups* provide the link between those planning R&D and those on the ground who provide feedback on new R&D needs and will largely be the users of the resulting projects

Criteria	*Factors used to assess criteria*
Seriousness	• *Potential risk to the environment* • *Degree of Agency's responsibility for issue* • *Ability to respond effectively to external influences and/or to forecast future needs* • *Ability to account for the consequences of the Agency's actions* • *Agency's ability to influence others*
Timeliness	• *Urgency of research issue* • *Impact on problem if R&D is delayed* • *Degree of political or public concern*
Delivery	• *Clarity in respect to how R&D is to be carried out and managed* • *Project is based on best available science* • *Review method is clear and of high quality* • *Benefits of implementing project are clearly defined* • *The outcome of the R&D project will result in either improved decision making or more effective actions*
Value for money	• *Economic return to Agency and others in terms of resources and efforts* • *Opportunities for collaborative work* • *Number of contractors able to bit for contract*

4.5.4 Tools and Techniques Used to Support the Assessment

The R&D Section has produced a customised spreadsheet with instructions to ensure that all Commissioning Functions draw up their prioritised lists in a consistent way (see Annex for further detail).

4.5.5 Corporate Governance and Business Risk Management

4.5.6 Rationale

The Agency first published a summary of key business risks in the 1999-2000 Corporate plan and has since issued preliminary guidance to managers on managing business risk (Environment Agency, 1999h). The final report (Turnbull, 1999) gives guidance to the effect that 'Directors should, at least annually, conduct a review of the effectiveness of the group's system of internal controls and should report to the shareholders that they have done so. The review should cover all control, including financial, operational and compliance controls and risk management'. For the previous and current financial years, the Agency's focus is on the system of internal financial control. The Turnbull requirements come into force for Annual Reports for 2000/01 onwards.

The main challenges are as follows:

- linking the identification and management of risk to the achievement of business objectives;
- internal controls should be risk-based and therefore should include an evaluation of the likelihood and impact of risks becoming a reality;
- all review procedures must cover business, operational and compliance risks as well as financial risk;
- risk assessment and internal controls should be embedded in ongoing operations;
- the Agency Board or relevant Board committee should receive regular reports during the year on internal controls and risks; and
- the principal results of the risk identification, evaluation and management review for the whole organisation should be reported up to, and reviewed at, Board level.

4.5.7 Organisational structure

Directors and senior managers identify key business risks and establish plans to manage them to an acceptable profile. Effective risk management is applied at every level in the Agency: (i) at the strategic and operational levels; (ii) in support functions such as finance, procurement, IT, etc; and (iii) in undertaking day-to-day activities and processes (e.g. communication or computer failures).

In addition, account should be taken of outside influences (e.g. failure of suppliers to deliver equipment, adverse public criticism or major catastrophes).

4.5.8 Approach used

The Agency's Directors have assessed the priority risks for 2000. These clearly link to the achievement of business objectives. Risk Champions (e.g. a Director) and Risk Managers have been assigned to each risk, and an action plan to reduce the risk prepared for each, incorporating target time-scales and accountabilities.

4.5.9 Tools and Techniques Used to Support the Assessment

The initial screening of business risks is achieved by reference to a simple "Boston Box" (see DETR, 1995a for an example of a Boston Box Matrix) approach. Here qualitative descriptors of probability (likelihood) and consequence (impact) are used to place individual business risks within a two-dimensional risk matrix.

4.7 Prioritisation of the Agency's Information Needs and Monitoring Programme

4.7.1 Rationale

The Agency is in the process of conducting a review to determine the current status of the Agency's monitoring programmes, identify areas for improvement, develop plans to implement the improvements and execute these plans. This review was initiated in relation to new statutory requirements, to the Agency's and in response to actions arising from the Government's Comprehensive Spending Review. The aim is to deliver a consistently managed, efficient and integrated environmental monitoring programme, which fully meets the Agency's information needs and monitoring programmes. Eight 'guiding principles' are being applied throughout this review process. These principles are that the monitoring programmes should:

- support the delivery of a better environment;
- give value for money, improve efficiency and effectiveness and apply the polluter pays principle;
- be balanced to meet our priority information needs; and based upon sound science and capitalise on innovative technology;
- make maximum use of information gathered by others;
- seek to minimise the environmental impacts of our own monitoring activities;
- seek to obtain better value from the data we already have and achieve a balance between the long-term view and short-term operational needs

A report has been produced on the current status of the Agency's monitoring programmes. Following consultation on the report, a set of five priority areas was identified for immediate implementation. The five priority areas are:

- streamline statutory monitoring programmes required by EC Directives and international commitments;
- develop a coherent approach to the monitoring of compliance with environmental licences across the Agency's regulatory functions;
- improve the integration of monitoring programmes across the Agency functions;
- develop and introduce national programmes for the water environment in preparation for the Water Framework Directive; and
- introduce operational systems to capitalise upon the benefits of monitoring instrumentation and remote sensing, and stimulate developments in new technologies

For each priority area there is a need to identify what needs to be done, by whom and by when. This scoping and implementation process forms the next phase of the Review.

4.7.2 Organisational structure

The review is being conducted by the by the Environmental Monitoring and Assessment section of Environmental Strategy Directorate. The final decisions on actions to be taken forward will be made by the programme board (the Collaborative Forum for Environmental Monitoring), the relevant Functions and Operations Directorate.

4.7.3 Approach used

The priority areas are being addressed through a series of projects run in a similar way to conventional R&D projects. The appraisal of options, the risks and the impacts on the Agency is included within the scope of each of the projects. Although no formal risk assessment methods have been employed, each of the projects will scope the range options for change to the monitoring programmes associated with each of the five key areas. These options will be appraised by determination of the risks and benefits associated with them. The balance of the risks and benefits of each option will be used by the project teams to select the preferred options for change.

4.7.4 Tools and techniques used to support the assessment

No tools or techniques have been developed.

5 OVERVIEW AND RECOMMENDATIONS

5.1.1 Summary

The Environment Agency has responsibilities in England and Wales for regulating and managing a wide breadth of environmental issues. In some areas of regulation, a structured and explicit treatment of risk is adopted; in other areas, the approach is implicit and reliant on professional judgement. The existing approaches to dealing with issues of risk have been summarised in the previous chapters of this document. A synopsis is given in Table 5.1, which illustrates the range of approaches of varying degrees of sophistication in use.

Application of environmental risk assessment in the Agency for assisting regulatory decisions falls broadly into two principal classes:

- *'regulatory' risk assessment,* whereby the Agency undertakes the risk assessment itself; for example, in work for the DETR and the European Community on the notification of existing substances, or for WPZs; and
- *'applicant' risk assessment*, whereby operators[71] are required, either by specific legislation or at the general request of the Agency, to undertake risk assessments in support of their applications for environmental permits.

The majority of the Agency's activity in risk assessment is in guiding, reviewing and utilising these assessments, largely as triggers for regulatory action or for setting conditions on authorisations.

Directorate *Agency Function*	***Context / Application***	***Approach / Decision Support Tool***
Environmental Protection		
Process industry regulation	*Authorisation of permits with reference to local and transboundary issues; Safety cases for COMAH sites with reference to EC Seveso II Directive; IPPC; inspection frequencies; notification of new and existing substances*	*Quantitative distribution modelling of predicted environmental concentrations in air at ground level; fault- and event-trees for safety cases, risk-ranking schemes for pollution hazard and operator performance (OPRA) and for Operator Monitoring Assessment (OMA; under development); generic, quantitative exposure assessment models for the notification of new substances (NONS).*
Radioactive substances regulation	*Safety cases for radioactive waste disposal; radioactively contaminated land (not yet implemented)*	*Quantitative risk assessment within performance assessment of disposal sites*
Land quality (not yet implemented)	*Designation of statutory contaminated land*	*Qualitative risk assessment and quantitative exposure assessment with reference to soil assessment criteria*

Table 5.1: Principal Applications of Risk Assessment for the Agency

[71] operators here refers to operators, dischargers, developers, abstractors, and/or other persons

Water quality	*Groundwater protection with reference to EC Groundwater Directive; discharge consent setting; prioritisation of pollution prevention visits; prioritisation of anti-pollution works*	*Qualitative and quantitative risk assessment with reference to groundwater protection policy, vulnerability maps and water quality criteria; quantitative distribution modelling of predicted environmental concentrations in surface waters; ranking tools for pollution prevention visits*
Waste management & regulation	*Protection of groundwater with reference to EC Groundwater Directive; licensing of installations; inspection frequencies*	*Qualitative and quantitative risk assessment of waste management installations; quantitative assessment of leachate leakage; risk-ranking schemes for pollution hazard and operator performance*
Water Management		
Flood defence	*Project risk appraisal for strategic plans and individual flood defence schemes; inspection of flood defence assets*	*Hazard identification brainstorm techniques for project life cycle risks; probabilistic modelling; fault- and event-trees for engineering risk; ranking schemes for asset management*
Water resources	*Assessments of critical flow levels for the granting of water abstraction licences; licence conditions may provide for river support to be provided by abstractor*	*Low flow hydroecological modelling, objective setting; tiered approach varying from look-up tables to detailed biological response modelling for river assessment*
Conservation	*Impact of regulated activities on designated habitats with reference to EC Habitats Directive*	*Sensitivity mapping and 'environmental footprints' of regulated sites;*
Fisheries	*Health and safety risk management of activities undertaken by staff*	*Qualitative assessments and checklists (under development)*
Navigation	*Pilotage of craft within ports and harbour areas operated by Agency*	*Comprehensive hazard identification and semi-quantitative risk ranking on basis of expert knowledge*
Recreation		
Environmental Strategy		
Environmental Strategy	*Strategic analysis of future issues and directions for Agency work*	*Analysis of uncertainty using scenarios (under development)*
Environmental monitoring and assessment	*Risk-based compliance and surveillance monitoring (ongoing)*	*(under development)*
Research and Development	*Prioritisation of R&D implementation*	*Qualitative / Semi-quantitative risk ranking based on delivery and business need*
Operations		
Areas and Regions	*Prioritisation of regional and local Agency plans; Y2K risks to Agency and externally; as support to environmental impact assessments for which the Agency is a statutory consultee; flood risk mapping and development control*	*Range of tools: most risk ranking approaches*

Table 5.1: Principal Applications of Risk Assessment (continued)

Finance *Corporate Planning / Internal Audit*	*Identification of business risks over 3 year horizon*	*Qualitative 'boston box' approach of importance and ability to influence*
Personnel *Health & Safety*	*Health and safety risk assessments at work*	*Qualitative assessments and checklists*

Table 5.1: Principal Applications of Risk Assessment (continued)

5.1.2 Risk Assessment for Environmental Protection

In terms of operational issues, the Agency is concerned broadly with three types of situation that cut across its remit:

Situation	***Examples***	***Analytical Tools***
The risk of an initiating event resulting in a release to the environment	*Failure of a flood defence structure, a bund, a fuel tank or landfill gas extraction system; a major chemical accident*	*Failure logic of 'closed' systems, through the use of fault- and event-tree models, focussing typically on the source term*
The risk of exposure to the wider environment following a release	*Distribution of pollutants from a cement kiln stack; deterioration of a potable water supply by contamination from a leachate plume*	*Distribution modelling within an 'open' system and the wider environment, focussing on the characterisation of environmental pathways*
The risk of harm resulting from exposure	*Risks to individuals and properties from flood waters; risks to human or ecological health as a result of exposure to chemical risks from historically contaminated land*	*Exposure, dose-response assessments and the varying sensitivities of different receptors*

Some assessments require a full analysis from initiating event to subsequent environmental harm over a range of spatial and temporal scales. In the application of risk assessment, the Agency places a strong emphasis on the application of a tiered approach, whereby the level of detail of a risk assessment is proportionate to the complexity of the issue and/or the level of risk involved (see section 5.2.7 below). Beyond the project and site-specific level, the Agency is developing procedures and tools for strategic risk assessment that have application for prioritising area and national environmental strategies.

5.1.3 Risk-based Resource Planning and Regulation

The Agency has also developed risk assessment procedures, in consultation with others, for prioritising and resourcing its own regulatory and supervisory work. The development of OPRA for IPC and the proposed arrangements of OPRA for waste management inspections are two examples. Other examples come from areas of corporate planning, construction project management, flood defence asset management and delivery of the Agency's R&D programme. Good practice guidance is being developed in each of these areas.

5.2 Conclusions and recommendations

5.2.1 Consistency

It is not appropriate nor practical within the constraints of differing regulatory regimes to standardise methods, but a set of common high level principles should exist, where commonality is evident, and consistency is promoted. These have been developed with the DETR (DETR and Environment Agency, 2000). For example, issues such as the treatment and presentation of probabilistic risk estimates and the treatment of uncertainty as a whole in risk assessment could be made consistent. It is recommended that on publication, the revised DETR Guidance on environmental risk assessment and risk management be reviewed and as appropriate cascaded through the Agency's Directorates and functions.

5.2.2 Skills and competencies

Risk assessment is a developing discipline in which training is required. Its recent application to areas where judgements have historically been made implicitly, and the involvement of lay audiences in risk assessment design, is placing demands on practitioners in terms of transparency of approach, and is also highlighting a substantial training need. There is a balance to be struck between the competing pressures on risk analysis. These include:

- calls to simplify assessments for presentation to and discussion with non-expert audiences;
- engaging lay and non-expert audiences in the development of risk analysis; and
- retaining the analytical power of risk analysis as a management tool, maintaining the underlying logic of approach and utilising 'best science' in the analysis

To many Agency staff, the area of risk assessment is new. It can be confusing because of the jargon that the discipline has inherited. It is therefore recommended that the Agency reviews its training needs in risk assessment and establishes a set of training courses appropriate to the various needs, from primer courses through to expert training in specialised packages. It is considered that there is a minimum level required for all regulatory and supervisory staff and that the Agency should seek mechanisms to meet this need.

The issue of training is not confined to the Agency, however, and it is clear that beyond the specialist few, much of industry and its professional advisors would benefit from formalised training. To facilitate this, it is recommended that the Agency work in partnership with industry groups and the professional bodies to raise skills and competencies in risk assessment and management in the environmental sector.

5.2.3 Problem definition and involving others

Individual stakeholders have different views with respect to the purpose, output and use of risk assessments, which often clouds and confuses the study boundaries. Achieving consensus on the scope of a study is a critical issue. Assessments conducted for other audiences, such as investors and insurers, for example, will rarely be appropriate for the regulator in support of setting environmental permits, usually because they attend to different aspects of the hazard. Early agreement on the scope between parties provides a clear steer for the study, can assist in responding to 'sideswipes' during the assessment and in communicating the output of the assessment.

Calls for increased stakeholder involvement from 'problem definition' through to the framing of risk estimates, and the transition to a 'right-to-know' society, are requiring greater access to all stages of the risk assessment process. Mechanisms for stakeholder involvement, however, are not well defined and, to date, procedures have not been clearly evaluated. It is recommended that, through its R&D programme, the Agency aims to establish at what stage and in what ways stakeholder involvement can be meaningfully incorporated into risk assessment. The current debate and the Agency's ongoing work on deliberative and inclusionary processes will inform this development.

5.2.4 Which tools to use – qualitative logic and quantification as appropriate

A tiered approach allows for risk screening, prioritisation and, in general, a qualitative treatment in advance of quantification. In practice, many risk problems are addressed using a qualitative analysis, providing the logic is sound and transparent. Complex environmental issues with significant consequences will invariably require a combination of qualitative and quantitative analysis, usually because certain aspects of the system are better described relative to others. For example, in radioactive waste disposal, whilst the engineering features of a disposal facility can be described in detail, future exposure scenarios in thousands of years time can only be represented by illustrative 'futures'. Mechanisms for combining qualitative and quantitative information need to be found and it is therefore recommended that the Agency examines formalised procedures for combining:

- experimental data with elicited expert judgement;
- predictive with illustrative exposure scenarios;
- qualitative with quantitative expressions of risk with the associated uncertainties; and
- methods of addressing problems where the science is not sufficiently advanced to allow for formal modelling.

5.2.5 Environmental harm – 'risks' and 'values'

Environmental regulations are increasingly concerned with assessing the risk of adverse effects *at the receptor level*; that is, in going beyond an expression of harm in terms of a surrogate quality standard. Regulation cannot be based on technical assessments of impacts alone. This is evident from the wider debate on environmental policy. It is underlined by specific new legislation, which requires regulators to go beyond such assessment. The EC Habitats Directive, the Seveso II (COMAH) Directive and proposed regulations in the UK on historically contaminated land under Part IIA of the Environmental Protection Act 1990, require assessments of harm; either to designated sites, the wider environment in general, human health, ecological receptors, or to buildings and property. This is a problematic area that often requires assessors to invoke societal values in deciding on the nature of an environmental impact. It is recommended that, at a generic level, the Agency examines the need for a more informed interpretation of the characteristics of environmental impact (e.g. magnitude, reversibility, latency, spatial and temporal extent etc.). This should including social and economic aspects, particularly for comparing consequences from a range of hazards in the context of sustainable development. Work on risks and values, strategic risk assessment and environmental harm will contribute to this (Environment Agency, 2000a; Environment Agency 1999i; Environment Agency 2000d, respectively).

There are differences in the criteria (e.g. environmental standards or guidelines) used in decision making across the Agency's remit. For example, in some cases where standards are risk-based, different levels of acceptable risk are applied in standard derivation. This reflects the time period and mechanisms by which standards have been derived and it would be unrealistic to assume that these discrepancies could be resolved in the short term. However,

greater transparency in the basis of the criteria used throughout the Agency would facilitate comparisons and help to encourage greater consistency.

5.2.6 Integrated risk assessment and options appraisal

Risk assessment should be an integral part of the assessment of options in the decision-making processes of the Agency and other bodies. The Agency is developing ways of doing this in its internal processes and engaging the wider debate in the subject.

5.2.7 Proportionality

Although there is a general trend towards more quantitative procedures, this does not imply that the ultimate goal should be to use full, probabilistic risk assessment (including probabilistic treatment of uncertainties) in all cases. There are many areas in which such a comprehensive approach is neither necessary nor appropriate. The degree of detail and depth required in the assessment should be fit for purpose, i.e. sufficient to enable a robust decision to be made about the intention. In many cases, where the requirement is to compare and rank risks, qualitative or semi-quantitative approaches can be appropriate. In others, a relatively simple, conservative assessment can help to screen out situations where the decision is clear-cut from those that need more detailed consideration and assessment. It is recommended that the Agency continues to promote a tiered approach to risk assessment among its Directorates and functions with a view to reserving quantitative assessment techniques for complex and/ or high risk situations where good quality data are available to support this level of sophistication. The aim should be to arrive at a point where the level of sophistication adopted to assess risk was commensurate with the degree and nature of the risk, and appropriate for the complexity of the processes involved.

6 REFERENCES AND BIBLIOGRAPHY

Adams J (1995) *Risk.* University of Central London Press, London, 228pp.

Agriculture Committee (1998) *Flood and Coastal Defence.* Agriculture Committee Sixth Report Volume II, 30 July 1998, The Stationery Office

Bate R (ed.) (1997) *What Risk?* Butterworth, Heinemann, Oxford, 328pp.

Cabinet Office (1999) *Modernising Government*, Cm 4310, 66pp, The Stationery Office, London

DETR (1999a) *A Better Quality of Life: A Strategy for Sustainable Development for the United Kingdom*, Cm4345, 96pp. The Stationery Office, London

DETR (1999b) *Waste Management Licensing. Risk Assessment Inspection Frequencies. Operator Pollution Risk Appraisal "OPRA for Waste".* A Consultation Paper

DETR and Environment Agency (2000) *Guidelines for Environmental Risk Assessment and Management, Revised Guidance.* Department of the Environment, Transport and the Regions, the Environment Agency and the Institute for Environment and Health, in preparation

DoE (1994) *Waste Management Paper 26A: Landfill Completion (A Technical Memorandum providing Guidance on Assessing the Completion of Licensed Landfill Sites.* Department of the Environment, HMSO, London, 47pp

DoE (1995a) *A Guide to Risk Assessment and Risk Management for Environmental Protection.* Department of the Environment, HMSO, London

DoE (1995b) *Waste Management Paper 26B: Landfill Design, Construction and Operational Practice.* Department of the Environment, HMSO, London, 289pp

Douben PET (ed.) (1998) *Pollution Risk Assessment and Management.* Ecological & Environmental Toxicology Series, John Wiley & Sons, Chichester

DTI (1998) *The Use of Scientific Advice in Policy Making*, Department of Trade and Industry, London 9pp

EEA (1998) *Environmental Risk Assessment: Approaches Experiences and Information sources,* European Environment Agency, Copenhagen

Environment Agency (1994) *Taking Account of Costs and Benefits.* Sustainable Development Publication Series, the Environment Agency, Bristol

Environment Agency (1996a) *An Environmental Strategy for the Millennium and Beyond*, the Environment Agency, Bristol

Environment Agency (1996b) *The Environment Agency's Risk Portfolio.* Internal Draft, National Centre for Risk Analysis and Options Appraisal, Environment Agency, London

Environment Agency (1996c) *Waste Management Paper 26E: Landfill Restoration and Post-Closure Management.* Second Consultation Draft, the Environment Agency, Bristol, 305pp

Environment Agency (1997a) *Guidance for Operators and Inspectors of IPC Processes. Best Practicable Environmental Option Assessment for Integrated Pollution Control.* Technical Guidance Note (Environmental) E1, the Stationary Office, London

Environment Agency (1997b) *Operator and Pollution Risk Appraisal. Objectives, Guidelines and Procedures*, the Environment Agency, Bristol

Environment Agency (1997c) *Risk Assessment and Management: Guidance for Assessment and Management of Risks in Project Management for Engineering Works*, the Environment Agency Report RISK2, Bristol, October 1997

Environment Agency (1997d) *Flood Defence Management Manual*, the Environment Agency, Bristol

Environment Agency (1998) *The Impact of Radioactive Discharges on Native British Wildlife and the Implications for Environmental Protection*. Environment Agency R&D Technical Report P135, Bristol

Environment Agency (1999a) *An Overview of the Responsibilities of the Environment Agency*, the Environment Agency, Bristol, January 1999

Environment Agency (1999b) *Guidance on the Environmental Risk Assessment Aspects of COMAH Safety Reports*, the Environment Agency, Bristol, April 1999, Available on the Environment Agency's web site

Environment Agency (1999c) *Integrated Methodology for the Derivation of Remedial Targets for Soil and Groundwater to protect Water Resources*, Environment Agency R&D Publication 20, Bristol

Environment Agency (1999d) *Library of Licence Conditions and Working Plan Specifications; Volume 1: Waste Management Licences; Volume 2: Waste Management Licences for Metal Recycling Sites* (Edition 2; August 1999), the Environment Agency, Bristol

Environment Agency (1999e) *Guidance on the Application of Environmental Risk Assessment for Waste Management Licensing* (Version 1.1 (Consultation draft for comment), March 1999), National Centre for Risk Analysis and Options Appraisal, Guidance Note Number 25, the Environment Agency, London

Environment Agency (1999f) *Flood Warning Service Strategy for England and Wales*, the Environment Agency, Bristol

Environment Agency (1999g) *Conservation Directory Conservation Directory 1999*, EAS/301/3/1/Version 1 July 1999, the Environment Agency, Bristol

Environment Agency (1999h) *Managing Business Risks in the Environment Agency. Guidance for Managers*, the Environment Agency, Bristol

Environment Agency (1999i) *Strategic Risk Assessment*, the Environment Agency R&D Publication 70, Bristol

Environment Agency (2000a) *Risks and Values Framework*, the Environment Agency, Bristol, April 2000

Environment Agency (2000b) *Risk Assessment and the Water Protection Zone (River Dee Catchment) (Procedural and Other Provisions) Regulations 1999*, in preparation

Environment Agency (2000c) *Review and Development of the Risk Decision Box for Flood Warning*, the Environment Agency, National Centre for Risk Analysis and Options Appraisal, Report No. 20, Final Draft

Environment Agency (2000d) *A Strategic Approach to the Consideration of "Environmental Harm"*. National Centre for Risk Analysis and Options Appraisal, Technical Report Number 36, the Environment Agency, London, in preparation

Environment Agency (in prep.) *From Viewpoints to Visions, Progressing the Agency's Strategy for a Better Environment in England and Wales*, the Environment Agency, Bristol, in preparation

Environment Agency, Scottish Environmental Protection Agency, and Department of the Environment for Northern Ireland (1997) *Radioactive Substances Act 1993 - Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation*, the Environment Agency, Bristol

Fry M (1997) *A manual of environmental protection law. The pollution control functions of the Environment Agency and the Scottish Environment Protection Agency*. Clarendon press, Oxford

HMIP (1988) *The Licensing of Waste Facilities: a Revision of Waste Management Paper No. 4 (1976) to Provide a Technical Memorandum of the Licensing of Waste Facilities including a Review of Relevant Legislation*. Her Majesty's Inspectorate of Pollution, London, 48pp

HSE (1999) *Discussion Document: Reducing Risks, Protecting People*, 82pp. Health and Safety Executive Books, Suffolk

HSE and Environment Agency (1999) *COMAH Guidance, Meeting Regulations for Environmental Risk Assessment*, available from www.environment-agency.gov.uk

ICE (1996) *Land drainage and flood defence responsibilities*. 3rd Edition. Institute of Chemical Engineers, Thomas, Telford

ILGRA: Interdepartmental Liaison Group on Risk Assessment (1998) *Risk Assessment and Risk Management: Improving Policy and Practice within Government Departments*, 37pp, Health and Safety Executive Books, Suffolk

MAFF (1993a) *Strategy for flood and coastal defence in England and Wales*. Ministry of Agriculture, Fisheries and Food, London

MAFF (1993b) *Project Appraisal Guidance Notes*. Ministry of Agriculture, Fisheries and Food, London

MAFF (1995) *Shoreline Management Plans - A Guide for Coastal Defence Authorities*, Ministry of Agriculture, Fisheries and Food, London

MAFF (1997a) *Interim guidance for the strategic planning and appraisal of flood and coastal defence schemes*. Ministry of Agriculture, Fisheries and Food, London. July 1997

MAFF (1997b) *Funding for Flood Defence and Coast Protection: Notes for Guidance*. Ministry of Agriculture, Fisheries and Food, London, LDW12 (7/97)

MAFF (in preparation) *Flood and Coastal Defence Project Appraisal Guidance: Economic Appraisal*. Ministry of Agriculture, Fisheries and Food, final Draft Report FCD PAG3

NCRAOA (2000) *A Guide to Risk Analysis at the National Centre for Risk Analysis and Options Appraisal*, National Centre for Risk Analysis and Options Appraisal, the Environment Agency, London

Pollard SJ, Harrop DO, Crowcroft P, Mallett SH, Jeffries SR and Young PJ (1995) Risk assessment and environmental management: approaches and applications. *The Chartered Institute of Water and Environmental Management*, 9, 621-628

POST (1996) *Safety in Numbers? Risk assessment in Environmental Protection*. Parliamentary Office of Science and Technology, London

TGD (1994) *Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances*, ISBN 92-827-8012-0

The Royal Society (1983) *Risk Assessment*, The Royal Society, London

The Royal Society (1992) *Risk analysis, Perception and Management*, The Royal Society, London

The Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) *Risk Assessment and Risk Management in Regulatory Decision-Making* (Final, Volume 2). Washington DC, USA

Turnbull (1999) *Internal Control and Risk Management.*, Report of the Turnbull Committee, Institute of Chartered Accountants in England and Wales, London

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