Guidelines for Environmental Risk Assessment and Management

Green Leaves III

Revised Departmental Guidance

Prepared by Defra and the Collaborative Centre of Excellence in Understanding and Managing Natural and Environmental Risks, Cranfield University

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Authors
Áine Gormley, Simon Pollard, Sophie Rocks
Collaborative Centre of Excellence in Understanding and Managing Natural and Environmental Risks, Cranfield University, Bedfordshire, UK.

Edgar Black *Department for Environment, Food and Rural Affairs, UK*

Case study contributors
Daniel Galson *Galson Sciences Ltd., UK*

Andy Hart *Food and Environment Research Agency, UK*

Phil Longhurst, Joe Morris, Simon Pollard, Mick Whelan *School of Applied Sciences, Cranfield University, Bedfordshire, UK*

Joseph Lovell *Department for Environment, Food and Rural Affairs, UK*

Peter Bailey, Cath Brooks, Anna Lorentzon, Ian Meadowcroft *Environment Agency, UK*

Edmund Peeler *Centre for Environment, Fisheries and Aquaculture Science, UK*

Jonathan Smith *Shell Global Solutions, UK*

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Foreword

I am pleased to present "Green Leaves III", the latest edition of our *Guidelines for Environmental Risk Assessment and Management.*

When the Department of the Environment, Transport and the Regions and the Environment Agency published the previous edition in 2000, it provided guidance in risk assessment and risk management, along with risk communication, as essential elements of structured decision making processes across Government.

Over a decade later, publication of this revised, peer-reviewed guidance emphasises not only developments in scientific knowledge and information that supports risk assessment, but also improves the relevance of risk assessment through case studies that demonstrate good practice.

The assessment and management of environmental risk is central to the environmental vision and operational activity of the Department for Environment, Food and Rural Affairs (Defra). At a strategic level, Defra recognises the need to manage our activities in a way that minimises the risks of environmental damage, while at the same time ensuring economic growth and social progress. Across our regulatory remit, we are increasingly challenged to supply the scientific rationale for decision making in a timely manner. In response, we facilitated the establishment of the Collaborative Centre of Excellence in Understanding and Managing Natural and Environmental Risks (the Risk Centre) as part of a strategic partnership between Cranfield University and the Research Councils. We have collaborated with the Risk Centre in preparing these revised and improved guidelines.

Developments in the field of risk assessment and management are reflected in this revision. These include pre-assessment considerations that help formulate the risk management question, tools and techniques to deal with uncertainty, and the identification of a broader range of options to manage the risk as a continuing process. This work is part of a wider set of actions to build a network of risk practitioners and to encourage a more consistent approach to environmental risk assessment and management within Defra.

Whilst the specific requirements of individual legislation will take precedence over this guidance, I trust you will find it a valuable document and useful starting point for your work in this field.

Professor Robert Watson
Chief Scientific Adviser
Department for Environment, Food and Rural Affairs

Executive Summary

This document provides generic guidelines for the assessment and management of environmental risks. The guidelines supersede earlier versions published in 1995 by the Department of the Environment, and in 2000 by the Department of the Environment, Transport and the Regions and the Environment Agency. This revision brings the guidelines in England and Wales in line with current thinking in the field of environmental risk management. Methods are described for estimating the probability of harm to, or from, the environment, the severity of harm, and uncertainty are described. The guidelines focus on generic principles, rather than domain-specific risks, such as from river flooding, animal disease or hazardous wastes.

A cyclical framework for environmental risk management is provided to offer structure in what would otherwise be a complex array of considerations for the decision-maker. The framework also offers a mechanism through which the process of environmental risk assessment and management can be explained to stakeholders, and acts as a valuable aide-mémoire to multidisciplinary teams conducting risk assessment. This framework identifies four main components of risk assessment: (1) formulating the problem; (2) carrying out an assessment of the risk; (3) identifying and appraising the management options available; and (4) addressing the risk with the chosen risk management strategy. Each component has a dedicated chapter in the document that provides guidance for completing that stage. The importance of iteration, communication and learning is woven throughout the guidelines and reinforced in the closing chapter.

Essential components of environmental risk assessment and management that are conveyed in the document can be summarised as follows. Risk questions are best informed by a range of stakeholders. When a risk problem is highlighted, the source, pathways and receptors under potential threat should be recognised. An assessment plan is then needed to outline the data requirements for assessment and the methods needed for data collection and synthesis. Resources for the assessment can be allocated following initial risk screening and prioritisation. Identifying the hazard at the beginning of the assessment should clearly define the harm to the environment that is of concern. An estimation of the potential consequences of the hazard being realised and an evaluation of the probability of impact can then be carried out. This evidence collected is used to provide judgement as to the significance of the risk.

It is advisable to employ suitable techniques to analyse and understand uncertainties within the risk assessment when possible. The risk management options should then be considered in terms of their positive and negative effects according to technical and economic factors, environmental security, social issues and organisational capabilities. The chosen strategy will usually involve terminating, mitigating, transferring, exploiting or tolerating the risk. The implemented strategy should be monitored to ensure the risk is controlled to an acceptable level. If this is not the case, iterations of the risk assessment and management processes should proceed as necessary. In all the above, a clear organisational and people framework is required to ensure accountabilities are understood. Each component should include openness and transparency, and involve stakeholders when feasible. When communicating the risk management strategy to the public, it is essential to highlight that the public have a responsibility to take reasonable care.

Case studies are provided throughout and used to illustrate key concepts. A comprehensive bibliography is provided, followed by appendices on definitions, legislation, risk management at the institutional level, and the types of uncertainty in risk assessment.

As with previous versions, we expect these guidelines to be consulted widely by environmental risk practitioners across the UK Government and their agencies, by practitioners providing risk advice to Government, and by other stakeholders with an interest in how environmental risks are assessed and managed.

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CHAPTER 1
Introduction to the Guidelines

1.1 Background

This document contains generic guidelines for the assessment and management of environmental risks. An original set of guidelines was published in 1995 by the Department of the Environment (DoE). In 2000 the Department of the Environment Transport and the Regions (DETR), the Environment Agency (EA), and the Institute of Environment and Health (IEH) published revised Guidelines for Environmental Risk Assessment and Management. This new document replaces the earlier versions and brings the guidelines in England and Wales in line with current thinking in the field of environmental risk management. It has been peer reviewed and revised in light of comments received.

As with previous versions, we expect these guidelines to be consulted widely by environmental risk practitioners across the UK Government and their agencies, by practitioners providing risk advice to Government, and by other stakeholders with an interest in how environmental risks are assessed and managed.

1.2 Purpose and scope

This document is intended to guide policy and regulatory staff in Government and its agencies, those assessing and managing environmental risks for Government, and other parties in the principles of managing environmental risks. The document assumes little prior knowledge and focuses on generic principles rather than domain-specific risks such as those from river flooding, animal disease or hazardous wastes. It is recognised that certain environmental risks (for example radioactive waste, flooding and animal disease) have their own technical language, conventions and individual approaches to risk analysis (Linkov *et. al.* 2006; Lundgren and McMakin, 2009). In these cases, additional guidance exists elsewhere in the literature. However, specific guidance is not available for many kinds of environmental risks, and it is intended that these guidelines may assist in setting out the general expectations and approach required.

The guidelines promote a structured approach to environmental risk management and provide advice and information that is consistent with good practice. Guidance on the scientific aspects of risk assessment is brought up-to-date where necessary. Methods for estimating the probability of harm to, or from, the environment, and the severity of harm, and for evaluating uncertainty are described. The guidelines promote the use of a generic framework to reach a decision on managing environmental risk. Recent developments in environmental risk management referred to in this document include:

a) the structuring of scientific evidence that informs decisions on environmental risk;

b) practical experiences of deliberative and participatory decision-making;

c) an increased focus on the governance of risk, including the organisational and human aspects, especially in light of the requirements for risk-informed regulation; and

d) developments in strategic and comparative environmental risk assessment.

This 2011 revision also provides an opportunity to furnish the guidelines with recent case studies and exemplars from within and outside Government that illustrate good practice.

1.3 Key definitions

Several key definitions pertaining to environmental risk assessment and management are detailed below. Appendix 1 provides a more exhaustive list.

- **Decision-making:** The process of identifying the likely consequences of decisions, establishing the importance of individual factors (Figure 1) and selecting the best course of action to take to manage an environmental risk.
- **Environmental security:** An environment protected from harm or adverse effects from natural or human processes so that resources are sustained for future generations.
- **Exploiting risk:** Adopting a strategy to increase the likelihood of exploiting unexpected positive effects (Hillson, 2001). Rather than hoping for an identified potentially positive effect to result from a chosen strategy, exploiting the risk can involve making an identified opportunity happen.
- **Governance:** On a national scale, governance refers to the structure and processes for decision making that involve non-governmental and governmental actors (Nye and Donahue, 2000). On a global scale, governance represents an organised structure of regulation encompassing state and non-state actors that bring combined decision making without the presence of one superior authority (IRGC, 2005).
- **Hazard:** A situation or biological, chemical or physical agent that may lead to harm or cause adverse affects.
- **Risk:** The potential consequence(s) of a hazard combined with their likelihoods/probabilities.
- **Risk assessment:** The formal process of evaluating the consequence(s) of a hazard and their likelihoods/probabilities.
- **Risk management:** The process of appraising options for responding to risk and deciding which to implement.
- **Stakeholders:** Individuals who are interested in, or affected by, an issue or situation.
- **Uncertainty:** Limitations in knowledge about environmental impacts and the factors that influence them. Uncertainty originates from randomness (aleatory uncertainty) and incomplete knowledge (epistemic uncertainty).

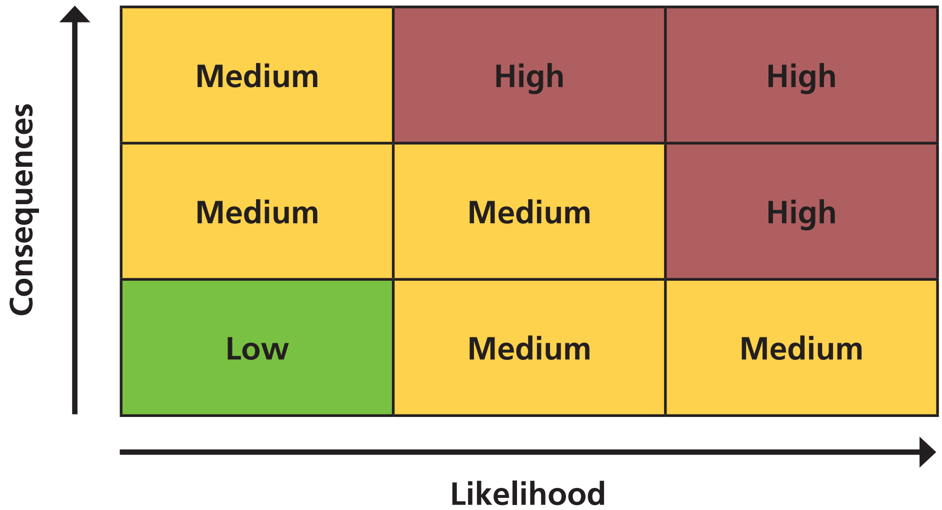


Figure 1: Assessing a risk involves an analysis of the consequences and likelihood of a hazard being realised. In decision-making, low-consequence / low-probability risks (green) are typically perceived as acceptable and therefore only require monitoring. In contrast, high-consequence / high-probability risks (red) are perceived as unacceptable and a strategy is required to manage the risk. Other risks (amber) may require structured risk assessment to better understand the features that contribute most to the risk. These features may be candidates for management (HM Treasury, 2004).

In the public domain, the language of risk is often less precise. It may be thought of in at least five ways:

- activities that can be a source of risk, such as oil exploration;
- specific hazards that pose a threat, such as an oil spill;
- exposure to hazards, such as oil adhering to wildlife after a spill;
- the harm that might result from exposure, such as bleeding in the stomach if oil is ingested; and
- a loss of value placed on these consequences by society, such as temporal bird population declines from exposure.

Also, emerging risks often generate public concern because they are usually assumed to be uncontrollable, not well understood or not competently managed. Therefore, it is important to strive for an environment of 'no surprises' and to consider social issues during all stages of risk assessment and management so that the process helps to secure beneficial outcomes. These issues are discussed within each chapter of the guidelines.

1.4 A structured approach to risk management

Risk management 'frameworks' have been developed in many countries and organisations, and are used to act as route maps for decision-makers. The purpose of any framework is to offer some structure to what would otherwise be a complex array of considerations for the decision-maker. Frameworks are a guide rather than a rigid set of instructions. They can be useful in explaining to stakeholders the process of environmental risk assessment and management and can be a valuable aide-mémoire to multidisciplinary teams progressing with a risk assessment.

One example of a structured approach to environmental risk management is provided in Figure 2. A cyclical approach suggests that environmental risk management is not a single, one-off exercise, but a dynamic process. This framework identifies four main components:

(1) formulating the problem;

(2) carrying out an assessment of the risk;

(3) identifying and appraising the management options available; and

(4) addressing the risk with the chosen risk management strategy.

Each of these four components is illustrated in Figure 2 with additional considerations shown as banners adjacent to each component. Some cross-cutting features are also shown in the middle of Figure 2. Decision-makers should expect to have to reconsider their analyses and decisions as new information comes to light (iteration), to communicate early and often, and to make arrangements for implementing the learning that comes from assessing risks, so as to ensure a preventative approach to risk management.

Not all risks require comprehensive and detailed assessment. Solid problem formulation should allow decision-makers to evaluate the extent of subsequent analysis required. The level of effort put into assessing each risk should be proportionate to its significance and priority in relation to other risks, as well as its complexity, by reference to the likely impacts. Consideration should be given to stakeholders' perceptions of the nature of the risk.

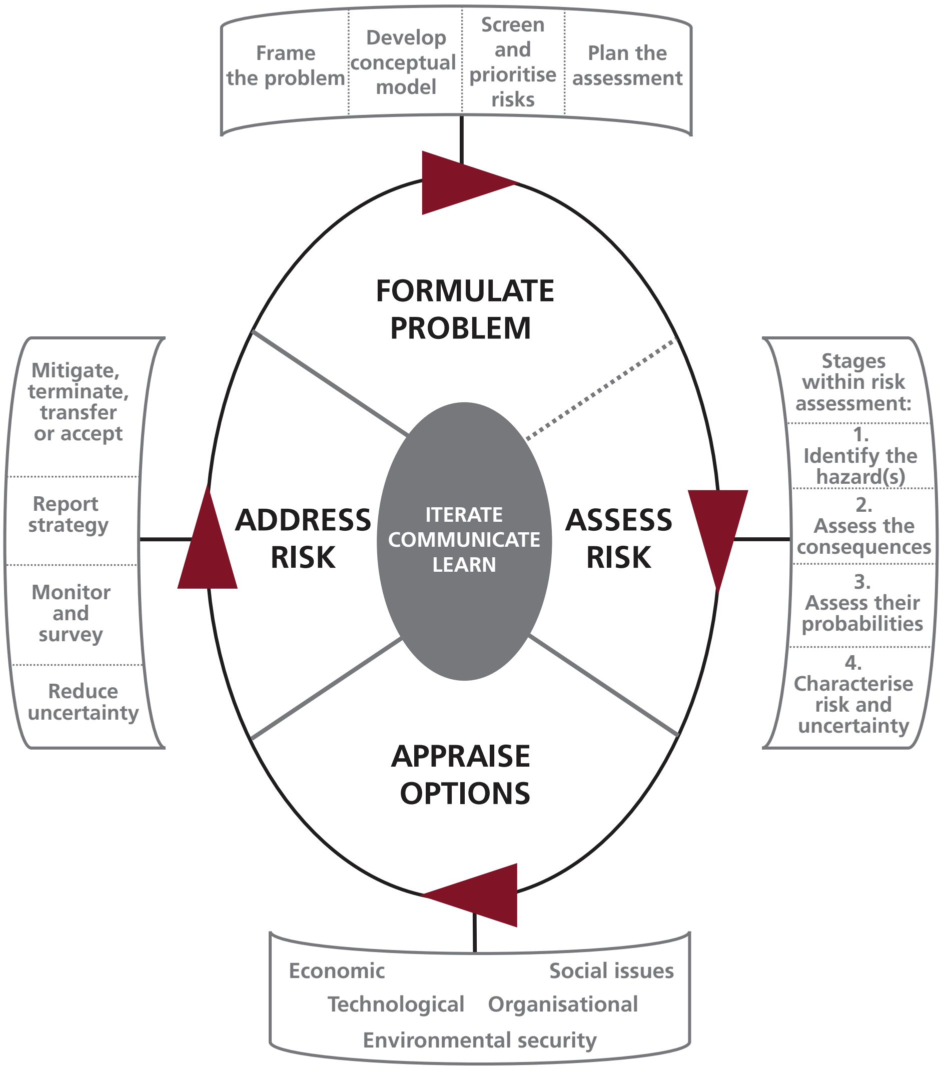


Figure 2: A framework for environmental risk assessment and management. The dashed line between the 'formulate problem' and 'assess risk' stages on the figure indicates the strong interdependencies between these two stages.

1.5 Outline of the guidelines

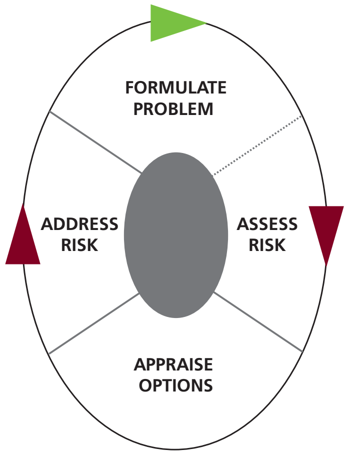
In the remainder of this document, each component in Figure 2 has a dedicated Chapter (2-5) that provides guidance for completing that stage. The importance of iteration, communication and learning (shown in Figure 2) is woven throughout the guidelines and reinforced in the closing Chapter (6).

The document is structured as follows: Formulating the Problem (Chapter 2); Assessing the Risk (Chapter 3); Appraising the Options (Chapter 4); Addressing the Risk (Chapter 5); and Iterating, Communicating and Learning (Chapter 6).

Relevant case studies are provided throughout and used to illustrate key concepts. A comprehensive bibliography is provided, followed by appendices on definitions, legislation, risk management at the institutional level, and the types of uncertainty in risk assessment.

CHAPTER 2
Formulating the Problem

2.1 The importance of good problem definition



Clearly setting out the problem at hand and the boundaries within which any decisions on environmental risk are made is important for effective risk management. It may be tempting to omit the formal definition of the problem, particularly where there is pressure to complete a risk assessment quickly or to apply numerical data readily at hand. However, failure to formulate the problem clearly could result in a loss of focus and, consequently, in an inappropriate output. Formulating the problem in clear and unambiguous terms will assist in selecting the level and types of assessment methodology used, and improve the risk management decision. It is also necessary to enable risk and uncertainty to be assessed because likelihoods should not be assigned to ambiguously defined outcomes. Therefore, if the risk decision is challenged or audited, a firm rationale for the process can be provided.

Stakeholders have an important role to play in formulating the problem and, when feasible, their early involvement will tend to make risk management decisions more effective and durable. Environmental risk assessments completed by reference to legislation (for example, environmental permits and environmental safety cases) may have quite specific requirements that should be discussed with regulators in advance. Most environmental risks relate to specific hazards and environmental components, are spatially and temporally determined and can often have wider consequences. Consider a theoretical chemical incident (accident) on the banks of the River Mersey, which results in large scale chemical releases into the river. This may have consequences for people living in the immediate locality, but also for the wider north west of England, depending on the type and nature of releases. There could also be national implications for the risk assessment of similar facilities across the UK. Additionally, if there was a risk of this chemical contamination reaching the Irish Sea this could have international implications for both the UK and the Republic of Ireland. If the evidence was that there was no significant risk to the Irish Sea, it would still be helpful to communicate this to relevant stakeholders in the Republic of Ireland. Horizon scanning techniques can also be used to complement risk assessment of potentially wider consequences by helping to identify low probability, high impact events, which are often termed 'unknown unknowns' or 'wild cards'(Petersen, 2008), or rare, extreme impact events with retrospective predictability, which are often termed 'black swans' (Taleb, 2007).

A critical early need is to establish basic information about the risk, including 'what', 'to whom' (or which part of the environment), 'where' (location) and 'when' (in time) (Figure 3). For example, framing a risk assessment for a discharge to a surface water body will require early agreement about which discharge point is to be considered, over what period in time, to which receiving water body, affecting which receptors or outcome measures.

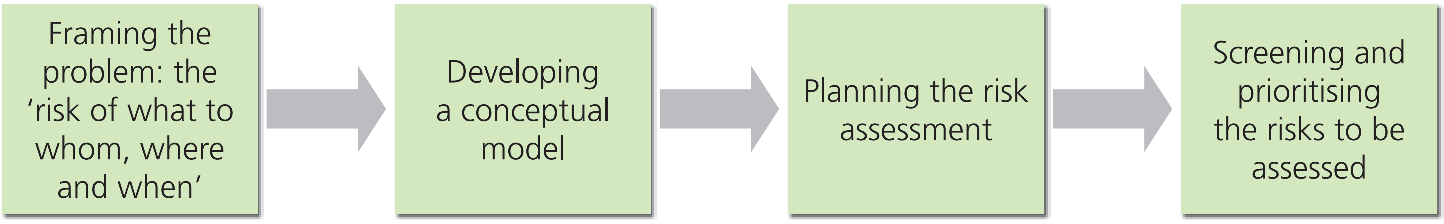


Figure 3: The components of the problem formulation stage, which require dialogue with stakeholders.

2.2 Framing the question

Risk assessments are generally employed where the outcome of a given activity is uncertain. The aim of the risk assessment is to evaluate the significance of the risk by reference to a societal norm, standard or view on its acceptability, and then make organisational and individual arrangements for its active management. Risk assessments frequently provide greater understanding of the features of an environmental issue and aim to identify those aspects that contribute most to the risk. In this sense they may be diagnostically useful, as well as estimating the significance of the risk. Examples of specific risk questions include:

- What is the risk of an environmental release from an engineered, contained process (e.g. from a system designed to treat waste contaminated with hazardous compounds)? What areas does this affect? For how long may they be at risk?
- What is the likelihood of environmental effects from the use of engineered nanomaterials in consumer products in the UK? What is the time frame for potential effects being realised?
- How likely is an incursion of an exotic fish disease in the UK, what are its potential consequences, and how long may they persist?
- What is the likelihood of a disruptive coastal flood event on the South Coast, and for how long may the disruption last?

Risk questions are best informed by a range of stakeholders. Increasing public awareness of risks and greater opportunities to access risk information result in both organised stakeholders and individual members of the public wanting to influence risk decisions more directly. For this to happen, they need to be able to participate in decision processes early so that they can understand and question the risk assessments being undertaken. The best decisions about environmental risks require both the best science and the best decision processes. The best decisions are those informed by people's knowledge and concerns (expert and lay), and are understood and supported by the people who may be directly affected by them.

2.3 Developing a conceptual model

One way to formalise these aspects is by developing a conceptual model – that is, a representative schematic of the boundaries of the problem under consideration. Adverse consequences (harm, loss of function, detriment) cannot occur unless that environmental feature we wish to protect (for example, a top grade salmon river or a heathland) suffers exposure to a hazard. Hence there is merit is setting out the relationships between hazards, exposure and environmental features before we go on to analyse them in depth. Equally, if the risk management options are to be evaluated (e.g. the impact if there is a change in legislation) it is helpful for the options to be specified within the conceptual model. This ensures that the risk assessment is designed so that the options can be evaluated.

The level of detail required in the conceptual model will differ depending on the complexity of the risk assessment. A conceptual model can be highly specific and concentrate on just one facet of a large project, or it may be possible to embody the entire risk in one model. For example, for a single chemical affecting a single receptor, the conceptual model will probably be simple; in the case of multiple sources and multiple receptors (e.g. catchments) the model will be more complex. Conceptual models work particularly well for physical features present in environmental settings (Case Study Box 1).

It is desirable, wherever possible, that consensus is secured with both the decision-maker and stakeholders on what is included, and what is outside the scope of the assessment. Agreement on the scope of the assessment can be influenced by:

- the purpose of the assessment;
- legislative and regulatory requirements;
- boundaries of ownership;
- changes to the layout of a facility; and
- international, national, regional and local environmental aspects.

Examples of the European Directives and UK statutory instruments that require an environmental risk assessment to be carried out are provided in Appendix 2.

2.3.1 Source-pathway-receptor (S-P-R)

Conceptual models present the hypothesised relationships between the source (S) of a hazard, the pathways (P) by which exposure might occur, and the receptors (R) – those features of the environment that we value and that could be harmed (S-P-R). Existing or potential linkages between these components of a risk can be set out in tabular form with reference to a schematic or conceptual model, which summarises those relationships visually (Pollard, 2008). Table 1 provides an example of identifying and representing the S-P-R linkages regarding leakage from an underground gasoline storage tank containing benzene as a component of fuel. The intention is to represent the scope of the problem, clarify the environmental components at risk and set the boundaries of the risk assessment (Case Study Box 1).

Table 1: An example of identifying and representing the S-P-R linkages regarding leakage from an underground gasoline storage tank that contains benzene.

Hazard	Source	Pathway	Receptor	S-P-R linkage
Benzene	Underground gasoline storage tank	Leaching	Groundwater supply	Yes
		Groundwater supply	Public water supply	Yes

The S-P-R approach has proven flexible across a wide range of environmental risks. An alternative conceptual framework used in assessing and managing environmental risks especially at the policy level is the D-P-S-I-R model (Drivers-Pressures-State-Impacts-Responses). The drivers are the forces that increase or mitigate pressures on the environment (e.g. changes in land use). Pressures are the stresses that an activity, situation or agent places on the environment (e.g. waste disposal). State is the condition of the environment (e.g. land productivity decline). Impacts are the consequences or effects of environmental degradation (e.g. crop yield decline). Responses are those made by society to the environmental situation (e.g. conservation and rehabilitation). The D-P-S-I-R concept is similar to that of S-P-R, but it is important to specifically consider the likelihood of the impacts occurring when characterising the nature of hazards and evaluating the response options (The World Bank, 2006).

2.3.2 Factors controlling the hazard

When developing a conceptual model it is important to be aware of engineered, natural, and human events and processes that affect the risk. For example, factors such as soil moisture, chemical concentration and population growth can control the timing, intensity, spatial extent and duration of hazardous events. If influencing factors are not considered at an early stage, difficulties may arise in conducting meaningful assessments and selecting practical options. In relation to flooding, for example, factors such as the prevailing meteorological conditions, the condition of flood defence assets, the soil moisture deficit, and hydraulic capacity of the flood channel will all influence the magnitude of the hazard to some extent. Equally, plant operator performance, levels of investment, training and staff morale can be important factors in managing hazardous activities at process facilities.

Case Study Box 1

Response to an accidental release of fuel to groundwater
Shell Global Solutions, Chester, UK

A conceptual model was used to plan the risk assessment and associated collection of relevant data regarding an accident at a service station that resulted in the release of petrol to groundwater. The law and corporate procedures both require that a release is managed to ensure there is no unacceptable risk to human health or the environment. Risk management goals needed to be achieved in a safe and timely manner, using effective, practicable and sustainable techniques. Problem formulation required the assessor to determine the likelihood of damage from this spill, whether the damage would be unacceptable, and if so, what remedial actions were necessary. A risk assessment and management process was adopted. Initial steps were to:

- stop any continuing release; and
- identify and undertake any emergency response necessary to prevent unacceptable exposure of humans or environmental receptors.

Once imminent risks were controlled, the next stages were to further define the constraints within which risks should be assessed and managed. Typical steps in the process were:

- development of a Conceptual Site Model (CSM), including identification of plausible source-pathway-receptor (S-P-R) linkages and constituents of potential concern (COPCs) (Figure 4);
- assessment of the fate and transport of COPCs along each S-P-R linkage in order to predict the likely exposure of each receptor, and evaluate the associated risks;
- defining appropriate remediation objectives, e.g. reducing COPC concentrations at a certain receptor to defined values (such as environmental criteria), in order to reduce risk; and
- appraising alternative remediation options, considering factors such as technical feasibility and effectiveness, cost, constraints on time and physical space on site, and sustainability criteria.

Figure 4: Illustration of conceptual model of fuel release to groundwater (copyright SNIFFER, 2005).

2.3.3 Scenario building

The utility of futures research methods – most especially scenario building – as a complement to the development of a risk assessment conceptual model is now beginning to be assessed. Scenarios are plausible descriptions of how the future may develop and enable envisioning of alternative evolutions of whole systems rather than individual entities. Scenarios are based on a coherent and internally consistent set of assumptions about key relationships and driving forces concerning the issue(s) being researched. Scenario construction can be used to explore future risks, opportunities, strengths and weaknesses of current strategy and policy approaches, and to provide a long-term vision independent of political timetables. Done well, scenario building exercises can help to identify critical decision points and strategic options, but also develop a clear context for future strategies and polices (Finger *et. al.*, 2007).

2.4 Planning the assessment

The assessment plan outlines the data requirements for risk assessment and the methods needed for data collection and synthesis. Each assessment should start with research into existing legislation and guidance relevant to the assessment. Risks can be assessed quantitatively and/or qualitatively. Both qualitative and numerical data are appropriate and one should not necessarily be valued above the other.

The selection of assessment endpoints should also be considered, such as a quantitative measurement of the abundance of a species in relation to an environmental stress. The time period and spatial scale should be defined to make the assessment endpoint unambiguous.

A decision should also be made on which data are important for the analysis. For example, collecting data on a plant species that is known to be susceptible to a certain environmental stress is a higher priority than assessing the effects on species in distant taxonomic groups. In turn, planning facilitates the effective use of resources, which are best focused at collecting data essential to characterising the risk (Nickson, 2008). An assessment plan may also describe more sophisticated assessment techniques that could be conducted depending on the results of initial work.

Effective planning can help to answer hypotheses at an early stage in the assessment. If the information collected (or already present) is adequate and indicates that a stressor has no known toxicity or reasonable mechanism to be toxic to the plant species, further analysis may be unnecessary.

2.4.1 Stakeholder and public participation and engagement

As awareness of environmental problems has grown and people have become more concerned about risks to the quality of the environment and to their health, so demands have increased for more and better engagement in environmental decision-making.

Traditionally, environmental legislation requires increasingly that neighbours, local residents, national and local interest groups are consulted about the activities and developments that may impact on the environment. In practice, consultation has often been rather late in the decision process and some (e.g. Petts and Brooks, 2006) have argued that there has been little opportunity for people to actually influence the decision. The result has sometimes been public frustration and opposition, with demands for more information and consequential delays to decisions (Few *et. al.*, 2007). These difficulties have led to the adoption of analytical-deliberative decision processes in the UK and overseas (Stern *et. al.*, 1996), which allow for public discussion, debate and reflection about the risk assessment itself alongside the analysis of risk (often also known as participatory risk assessment).

Participatory risk assessment has been recognised as a valuable method to support public engagement. In planning a risk assessment, public engagement should be provided for if:

- stakeholder and the public's input and views can be taken into account in the decision;
- there is, is likely to be, or has been, concern about the risk issue; and
- support is needed for the decision from stakeholders and the public.

A participatory risk assessment process engages people through a bottom-up approach that aims to involve stakeholders and the public in problem formulation, appraising preferred management options and proposing solutions to particular risk problems. In planning a participatory risk assessment, key elements include:

- communicating information transparently and using a non-technical or domain – specific language;
- defining issues that need to be addressed and the questions that need answered – scoping the problem and framing the questions;
- identifying the data and information needed to deal with the questions;
- identifying the sources of data; and
- deciding how to deal with uncertainty.

The most effective participatory risk assessments use small discussion groups (10-20 people) and allow time (usually more than one meeting) for people to become familiar with technical issues, to read background material and to build confidence to take part in discussion and to ask questions (Petts *et. al.*, 2010). Formal methods involving small groups include citizens' juries, community advisory committees or consensus panels. The general literature on participation provides more information on these (e.g. Petts and Leach, 2000). They are particularly appropriate for policy and plan-making (e.g. flood risk management) processes where more time is available, and where people from a broad range of interests and perhaps different areas of the country or region may need to be involved. However, these methods can be expensive (often in excess of £20k and can be over £100k). For a site-specific decision – such as relating to the design of a flood risk management scheme, or a decision on remediation of a contaminated site – it may be appropriate to form a discussion group(s) or workshop(s). These might meet on two or three evenings (at least 2-3 hours each time) or at weekends, in order to learn about the risk decision that has to be made, to scope the problem and to discuss information needs for the risk assessment.

There is an extensive literature on stakeholder and public participation and engagement (including Renn, 2006; Petts *et. al.*, 2010). While this document focuses on presenting a generic approach to assessing and managing risk, further details on the subject of stakeholder and public participation and engagement are provided in Case Study Box 4, Chapter 4 and Chapter 6.

2.5 Screening the risks

In practice, some initial screening of risks will usually accompany development of the conceptual model. Screening can be used to determine which risks should be investigated in greater detail using techniques suitable to the nature of the risk and quality of the evidence base. If effective, screening should also identify those features that will not receive further analysis. Prioritisation allows for the efficient allocation of resources. Justifying and recording the accompanying rationale for screening risks is valuable.

At this stage, risk assessors may develop an early view as to whether they have sufficient data to support a quantitative assessment of the risk if this is deemed necessary, or whether additional data and evidence to support such an assessment might be required. Quantitative risk analysis (QRA) is an expert discipline, expensive to undertake, and requires substantive data and analysis. This may include formal mathematical modelling. Not all risks will require QRA however, either because they are deemed to be insignificant on the basis of the evidence already assembled, or because the risk manager is already confident about their significance and can progress to deciding how to manage the risk.

Risk screening is useful, therefore, for highlighting those risks where uncertainty could affect the management decision and their success in managing outcomes. Such risks may need to be analysed in greater detail with more sophisticated methods. Risk screening can also:

- rationalise why some risks may not be investigated further; and
- identify risks for immediate action, without need for further investigation.

Case Study Box 2 illustrates a process for screening a series of risks that have the potential to cause harm to animals, humans or the environment. Here, three 'filters' were used to prioritise significant hazards for further investigating.

A wide range of risk screening tools exist. Most are qualitative or semi-quantitative. Usually the focus is on screening out those risks deemed insignificant, so those of higher priority or with significant uncertainty can be examined in more detail. Risk screening may rely on the following (Bradford-Hill, 1965):

- the plausibility of linkages between the source of a hazard and a receptor;
- the relative potency of a hazard, availability of a pathway, or vulnerability of a receptor;
- the likelihood of an event, on the basis of historic occurrence or of changed circumstances; or
- a view on the performance of current risk management measures that, if they were to fail, may increase the potential for future harm.

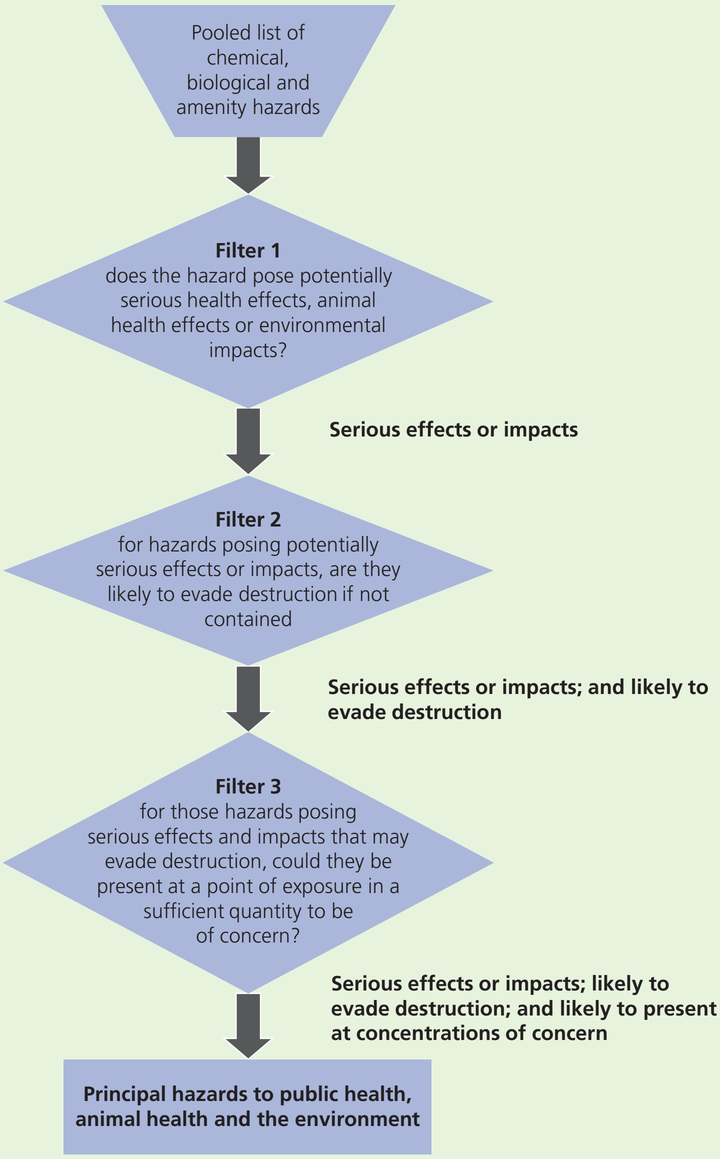
Risk screening tools may also adopt qualitative reasoning, belief nets (Ray, 2010), or qualitative systems tools to explore the interaction between hazards and receptors. Some risk ranking tools, used with or without weightings (Marcomini *et. al.*, 2010), are used to generate classes of risks of different significance and priority. Usually, screening assessments are designed to be precautionary in that, where uncertainty remains about the probability and consequences of harm, risks are escalated to the next tier of analysis as a precaution.

Case Study Box 2

Screening exposures during carcass disposal

Collaborative Centre of Excellence in Understanding and Managing Natural and Environmental Risks, Cranfield University, Bedfordshire, UK

The screening of hazardous agents (biological, chemical and nuisance) that were released during the disposal of animal carcases that have the potential to cause harm to animals, humans, or the environment was carried out to identify a subset of risks for prioritising further efforts. By reference to the conceptual model (source-pathway-receptor) developed during problem formulation (risk of what to whom, where and when?), the intent was to decide which risks should be within the risk assessment and which could be excluded.



This process often necessitates multi-stakeholder discussion because the constraints of the risk assessment may not be widely appreciated. For example, certain statutory risk assessment requirements are narrow in scope, whereas the requirements used to support an environmental management system may be open-ended and broad in scope. The context of application and views of the end user of the risk assessment are therefore often critical to risk screening.

In this case, given the large number of possible combinations of hazardous agents, exposure pathways and receptors that could be affected, the study (Pollard *et. al.*, 2008) considered those risks that could result in hazardous agents evading destruction in the environment and presenting concentrations of concern to receptors. A structured series of filters was adopted to screen potential exposures accordingly (Figure 5). The outcome of the screening exercise was to reduce the scope of the prioritisation that followed, dramatically reducing the onward processing effort during prioritisation. Setting rules for risk screening has important implications because risks screened out are unlikely to be revisited until a revised conceptual model is considered or the basis for the risk assessment revised.

Figure 5: Screening potential exposures prior to the risk assessment of significant hazards during carcass disposal (Pollard *et. al.,* 2008).

2.6 Prioritising the risks

Beyond establishing the plausibility of a risk, the risk analyst may seek to prioritise some risks above others, where there is supporting evidence.

Prioritising the risks needs to be transparent because of the challenge of comparing different risks and the weightings analysts may apply. Given the wide variety of uses, there is no single prioritisation system appropriate to all applications. Some ranking systems focus on: the relative condition of assets that might fail (condition assessments, e.g. National Audit Office, 2007); the relative potencies of different chemical hazards (e.g. Whaley *et. al.*, 1999); the relative availability of exposure pathways to receptors (e.g. Delgado *et. al.*, 2010); or the likelihood of harm should exposure occur (e.g. Richards, 2008). Many approaches used within environmental risk assessment seek to rank the relative feasibility of exposure by considering the viability of exposure pathways from source to receptor. These qualitative approaches evaluate source-pathway-receptor relationships by working through a conceptual model, exploring whether exposures may be direct or indirect, and determining the integrity of the barriers in place to minimise environmental exposure. Usually, high priority risks are considered for further analysis or direct or immediate risk management.

Some scientific communities have developed highly structured approaches to screening and prioritising risks. These are of particular value where there are a large numbers of S-P-R relationships as, for example, exist for combined surface and sub-surface environments. Case Study Box 3 illustrates how an analysis of the potential consequences of radiological impacts allowed the analyst to prioritise risks for more detailed analysis. Here the environmental features, events and processes (FEPs) inherent to a radioactive waste disposal facility are evaluated using a structured technique to explore which combinations would merit further in-depth analysis.

It is important that risks identified as being of low priority are not discarded entirely from the remainder of the process. Risks screened out may need to be revisited because of the inter-relationships that exist between risks. For example, inter-relationships exist between the impact of climate change on other risks, such as water availability, exotic animal disease, air quality and human health. A future risk management option targeted at high-priority risks may also reduce lower-priority risks through their interdependency. Equally, some risk management options may increase lower-priority risks.

2.7 Summary

Most environmental risks are spatially and temporally determined, so a critical early need is to establish the risk of what (is happening) to whom (or which part of the environment), where (location) and when (in time). Formulating the problem in clear and unambiguous terms will assist in selecting the level and types of assessment methodology used and improve the risk management decision. Stakeholders have an important role to play in formulating the problem and, when feasible, their early involvement tends to make decisions more effective and durable. It is important to recognise, early on, whether there is a need for public engagement and whether it is feasible. Development of a conceptual model can help to present in visual or written form the hypothesised relationships between the source (S) of a hazard, the pathways (P) by which exposure might occur and the receptors (R). The S-P-R relationship conceptualises the receptors at risk of exposure to the hazard. Risk screening can be used to identify what should or should not be investigated in more detail, while risk prioritisation typically provides a list of main concerns for further action. Both screening and prioritisation facilitate the effective allocation of resources. This process, whereby the problem is formulated and scoped, may need to be revisited as the assessment proceeds (see Chapter 6).

Case Study Box 3

Radioactive Waste Disposal Case Study

Galson Sciences Ltd. Oakham, Rutland, UK

Radioactive waste disposal facilities in the UK require an Environmental Safety Case (ESC), supported by environmental safety assessments. All such disposal programmes face the problem of determining which phenomena and components of the disposal system can and should be represented in the quantitative safety assessment. This problem is referred to as "scenario development," and the phenomena and components of the system are referred to as environmental FEPs, i.e. features, events or processes.

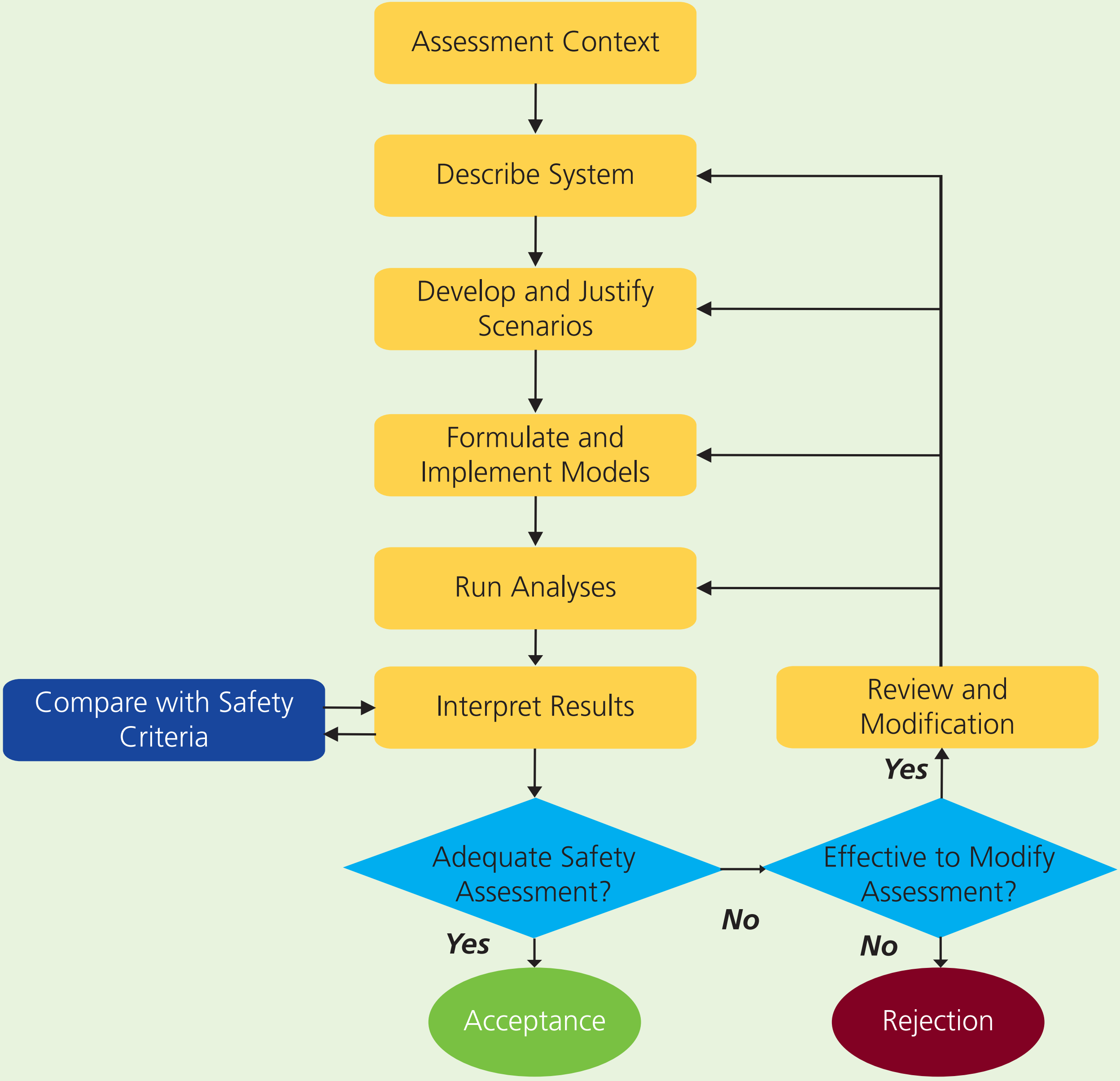


Figure 6: The ISAM assessment

The proposed new Low-Level Waste (LLW) Facilities at Dounreay used an environmental safety assessment methodology developed in the Improving long-term Safety Assessment Methodologies (ISAM) coordinated research project of the International Atomic Energy Agency (IAEA) (Figure 6).
The approach to scenario development followed four structured steps:

1. identification and classification of FEPs potentially relevant to the disposal system's performance;
2. elimination of FEPs from the performance assessment (PA) modelling according to well-defined screening criteria;
3. identification or formation of scenarios relevant to the performance of the disposal system; and
4. specification of scenarios for consequence analysis.

The FEPs were then evaluated and prioritised according to the likelihood and potential consequence of radiological impacts, ensuring that the assessment was proportional to the hazard of the waste that is, the assessment needed to be sufficiently comprehensive to support decision making, while not unduly burdensome to conduct or overly detailed. The prioritisation was then used to develop a subset of potential exposure scenarios, from which screening decisions can be made. As illustrated in Figure 7, each FEP can be either excluded from the assessment because they are outside the scope, screened out on the basis of a low probability and/or consequence, accounted for in the undisturbed performance scenario, or included in the calculations of disturbed performance.

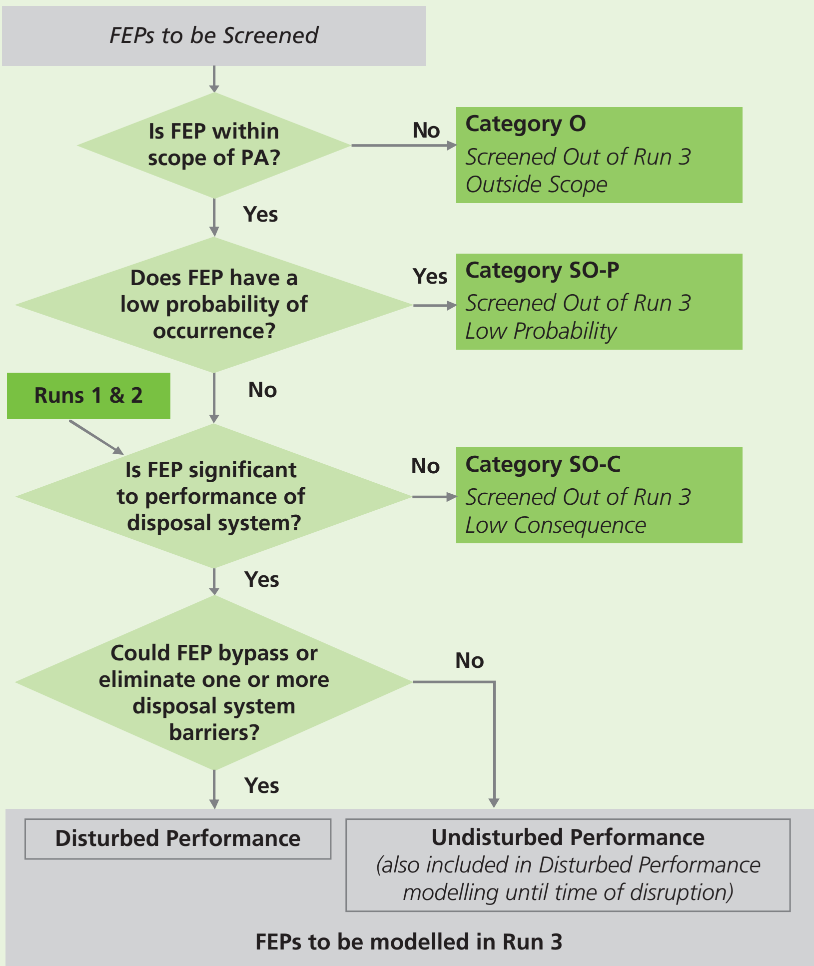
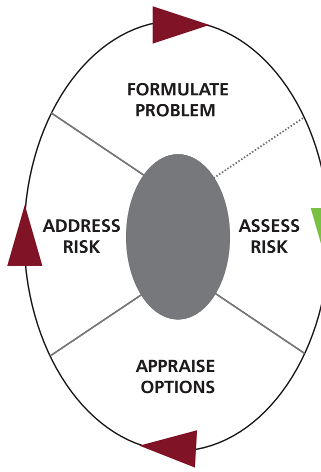


Figure 7: FEP screening and scenario development process for the Run 3 environmental safety assessment used to support the ESC for the proposed New LLW Facilities at Dounreay. Note that FEPs screened into the Undisturbed Performance scenario are generally also considered in the modelling of the Disturbed Performance scenarios.

CHAPTER 3
Assessing the Risk

3.1 Features of the risk assessment

Risk assessment is the formal process of evaluating the consequences of a hazard and their probabilities. The assessment itself typically involves four stages: (1) identifying the hazard(s); (2) assessing the potential consequences; (3) assessing the probability of the consequences; and (4) characterising the risk and uncertainty (Figure 8). In this sense, the risk assessment addresses the so-called 'risk triplet'; i.e. (a) what can go wrong; (b) what the consequences are; and (c) how likely the consequences are. The risk triplet is a favoured approach to assessing the risks from engineered systems (Pham, 2003). A similar approach (Figure 8) is commonly applied to situations in which a hazard exists in the environment and the risk it poses needs to be evaluated. Both approaches have elements in common, particularly with respect to environmental exposure. However, it is important to note that in cases of animal health risk assessment, hazard identification is part of risk analysis and not the official assessment process (OIE, 2010).



Social questions such as the significance of the risk are usually addressed separately to the assessment required, to estimate the magnitude of the risk. However, in some cases, it may be inappropriate to separate the magnitude of the risk from the significance of the risk, especially where the outcomes have a significant social component (e.g. equity issues). This issue should be recognised in the problem formulation stage (Chapter 2).

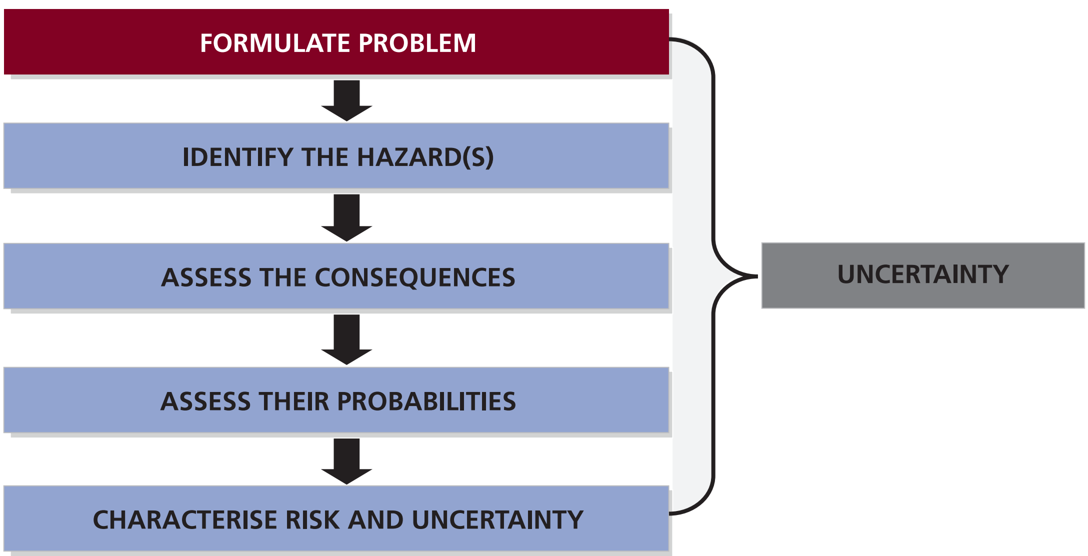


Figure 8: The primary stages of environmental risk assessment that sit within the overarching framework for environmental risk assessment and management (Figure 2). The assessment stages that precede characterising the risk and uncertainty address the 'risk triplet'; i.e. (a) what can go wrong; (b) what the consequences are; and (c) how likely the consequences are. Uncertainty should be considered at every step of the process.

Risk assessment approaches can be broadly categorised as qualitative, quantitative, and semi-quantitative. A vast array of tools and techniques exist. Qualitative methods include S-P-R analysis, ranking methods and qualitative event trees. These methods can be simple and cost-effective to execute, but are inevitably more subjective than quantitative methods.

The operation and outputs of qualitative methods may also be subject to ambiguity, because there is no way to know how similar one person's interpretation of qualitative inputs or outputs is to another's. This makes qualitative measures less useful for characterising the magnitude of the risk. Qualitative methods have value in establishing a sound logic for subsequent analysis, which may be a full quantitative risk assessment, if this is required.

Quantitative methods include quantitative exposure assessments, quantitative fault-tree analysis, simple deterministic risk estimation and Monte Carlo simulation techniques. These can be based on inputs derived by data or by expert judgement. Even when based on large datasets, they need not be resource intensive for the end-user, if the model is made available as software and requires simple inputs for each new assessment. However, quantitative methods are reliant on the selection or manipulation of the data.

Semi-quantitative methods include ranking, scoring, indexing, causal criteria and logic-based systems. These methods often offer a consistent and systematic approach when risk prioritisation is required. However, these methods are also subjective, akin to fully qualitative methods. As with all tools and techniques, the assumptions used and a justification of the data applied, and its reliability, needs to be communicated with the assessment. Often the design and operation of the approach influences the outcome of the analysis and so there is a continued need to ensure judgements about risk have a basis in scientific evidence.

3.2 A staged approach to risk assessment

Irrespective of whether the risk assessor applies qualitative or quantitative methods, there are similarites in the stages followed to estimate the magnitiude of the risk before evaluating its significance. Considering the 'risk triplet' and Figure 8 above, the risk assessment must understand the environmental consequences posed by a specific hazard, evaluate the consequences that may arise if the hazard is realised, and then evaluate the likelihoods of these consequences.

Stage I: Identify the hazard(s)

These guidelines define a hazard as a situation or biological, chemical or physical agent that may, under specific conditions, lead to harm or cause adverse affects (Chapter 1). This could include the bioaccumulation of endocrine-disrupting chemicals (EDCs) in fish (Appendix 3), a tidal surge along a stretch of the coast, the introduction of an invasive species, a dry summer leading to low river flows, or the planting of a genetically modified crop. Where a risk assessment is to be applied at the policy level, the hazard may be as broad as the adverse impacts of road transport on the environment or of induced climate change from the contribution of fossil fuel-derived carbon dioxide emissions.

The identification of the hazard will have an important bearing on the scope of the overall assessment. One common pitfall is to overlook secondary hazards that may also arise. For example, during a river flood, sediments may be deposited on agricultural land in the flood plain. If these sediments were to be contaminated, they may pose an additional hazard. Secondary hazards need consideration during problem formulation when the scope of the risk assessment is being agreed.

Stage II: Assess the consequences

The potential consequences that may arise from any given hazard are inherent to that hazard. The full range of potential consequences must be considered at this stage. For example, while the potential consequences of a discharge of high levels of nitrates and phosphates from a point source to surface waters may be self-evident, a flood may have additional, non-obvious consequences, such as pollution arising from an over-stretched sewerage system, or loss of habitats due to river scouring.

The consequences of a particular hazard may be actual or potential harm to human health, property, the natural environment or dependent valued services (the issue of probability of occurrence is covered below). The magnitude of such consequences can be determined in a number of ways, depending on whether they are being considered as part of a risk screening process or as part of a more detailed quantification of risk. At all stages of risk assessment the spatial and temporal scale of the consequences and the time to onset of the consequences need to be considered. In some cases the focus will be on estimating the social and economic impact of an environmental risk (Williams *et. al.*, 2008). For example, Case Study Box 4 illustrates how the Environment Agency (EA) used the Building Trust with Communities approach in order to assess the consequences that odours from a factory would have on a local community. The Building Trust with Communities approach involves working with communities early on, to understand their concerns, interests and priorities so that the solution will have considered all potential consequences (EA, 2007).

Case Study Box 4

Tackling odours with a partnership approach – Crown Pet Foods
Environment Agency, UK

The Building Trust with Communities approach was used to assess the social consequences of odours from Crown Pet Foods factory in Castle Cary, Somerset. The Building Trust approach is used by Environment Agency staff to work with communities early on to understand their concerns, interests and priorities (Figure 9).

Crown Pet Foods produce dry pet food kibbles from proteins, fats, vitamins and minerals. It has an Environmental Permit, granted in September 2006. In eight months over 2007-08 more than 1600 complaints were made about odours from the factory. Over 300 households were affected and the public demanded the problem be immediately resolved. Local residents were concerned about the consequences the odours would have on their quality of life, the environment, house prices, and the image of Castle Cary.

Using the Building Trust with Communities approach (Figure 9), the Environment Agency local area team produced regular newsletters, used websites, got involved in the site liaison group and visited the homes of local people who were concerned about the consequences of the odour problem. Staff explained the Environment Agency's role in regulating the site, the action taken and the role the community could play.

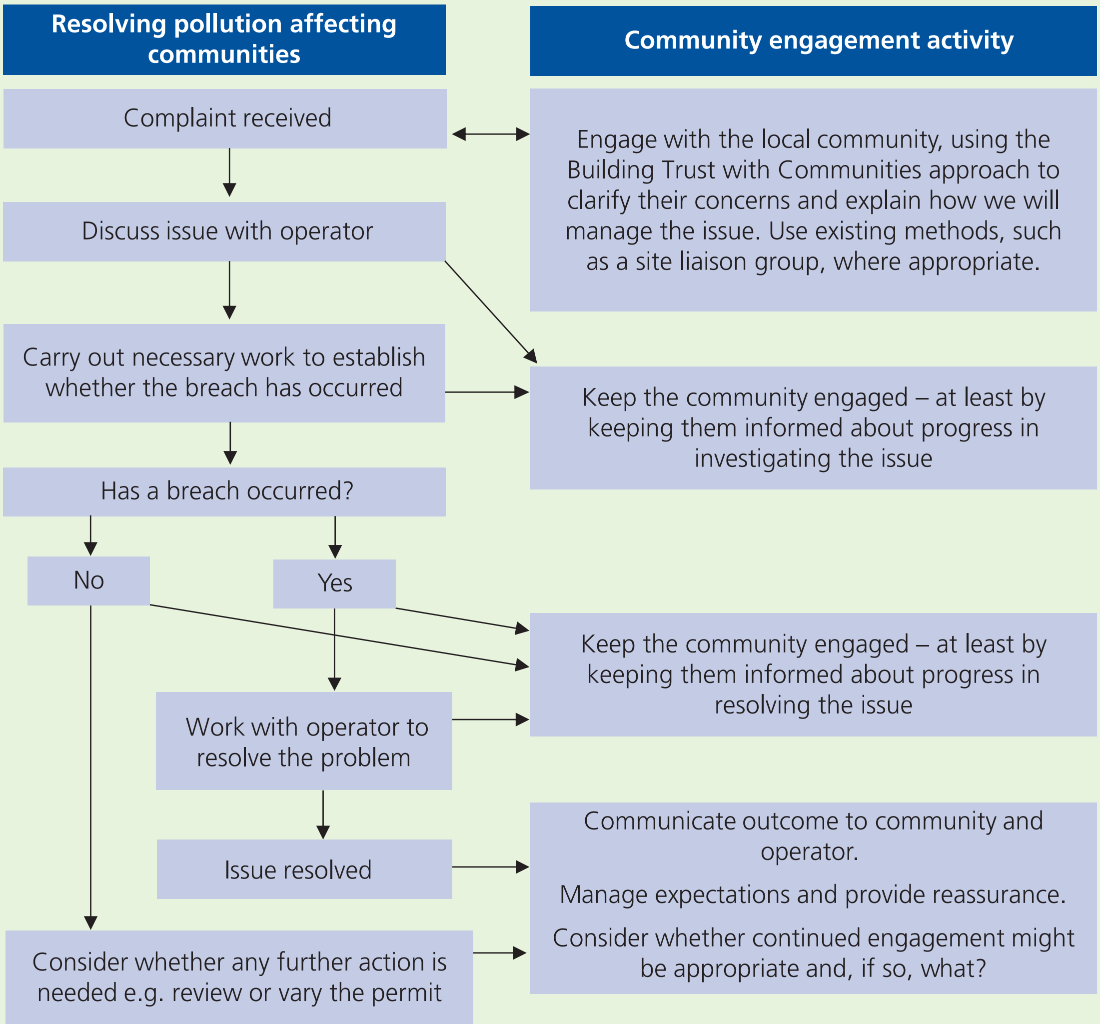


Figure 9: The Building Trust with Communities approach to dealing with a site with ongoing complaints and concerns.

In parallel, a strong open relationship was built with the operator, using a transparent approach to gain trust. Although the company was working within the conditions of the permit, the insights and evidence gained from working with local residents, as well as from monitoring, combined to form a case for action beyond the requirements of the permit to ensure quality of life for local people. The managing director of the site was able to use this evidence to persuade the board to invest £1million in odour abatement technologies, improving quality of life for 350 homes. The odour issues have been resolved, complaints reduced from 50 a day to 2 in the last 10 months and the Area team now enjoy a positive relationship with the local community.

Case Study Box 5 illustrates an approach to consequence assessment using a toxicity exposure ratio (TER) in the assessment of pesticide risks to birds. The information in Case Study Box 5 is developed further in Case Study Box 11 where probability density functions are used to evaluate uncertainties in elements of the TER calculations.

Case Study Box 5

Consequence assessment of pesticide risks to birds
Food and Environment Research Agency, UK

The flow chart below shows a model for the consequence assessment of acute risks of pesticides to birds. The box at the far right shows the assessment endpoint: this is a ratio of toxicity (measured by the LD_{50}) to exposure (TER), as specified under current EU regulations for this type of risk assessment. The rest of the chart shows factors that may influence this risk, and how they combine to determine the TER.

Factors that are considered when calculating the TER fall into four main groups: (1) factors used to estimate the daily food requirement of birds; (2) aspects of bird behaviour and diet; (3) factors influencing the concentration of pesticide on foods eaten by birds; and (4) the toxicity of the pesticide.

Some factors (indicated by dashed lines) are acknowledged as influencing risk but, for various reasons, are not included when calculating the TER (Figure 10). Therefore the potential influence of these factors should be considered when evaluating uncertainties affecting the assessment outcome.

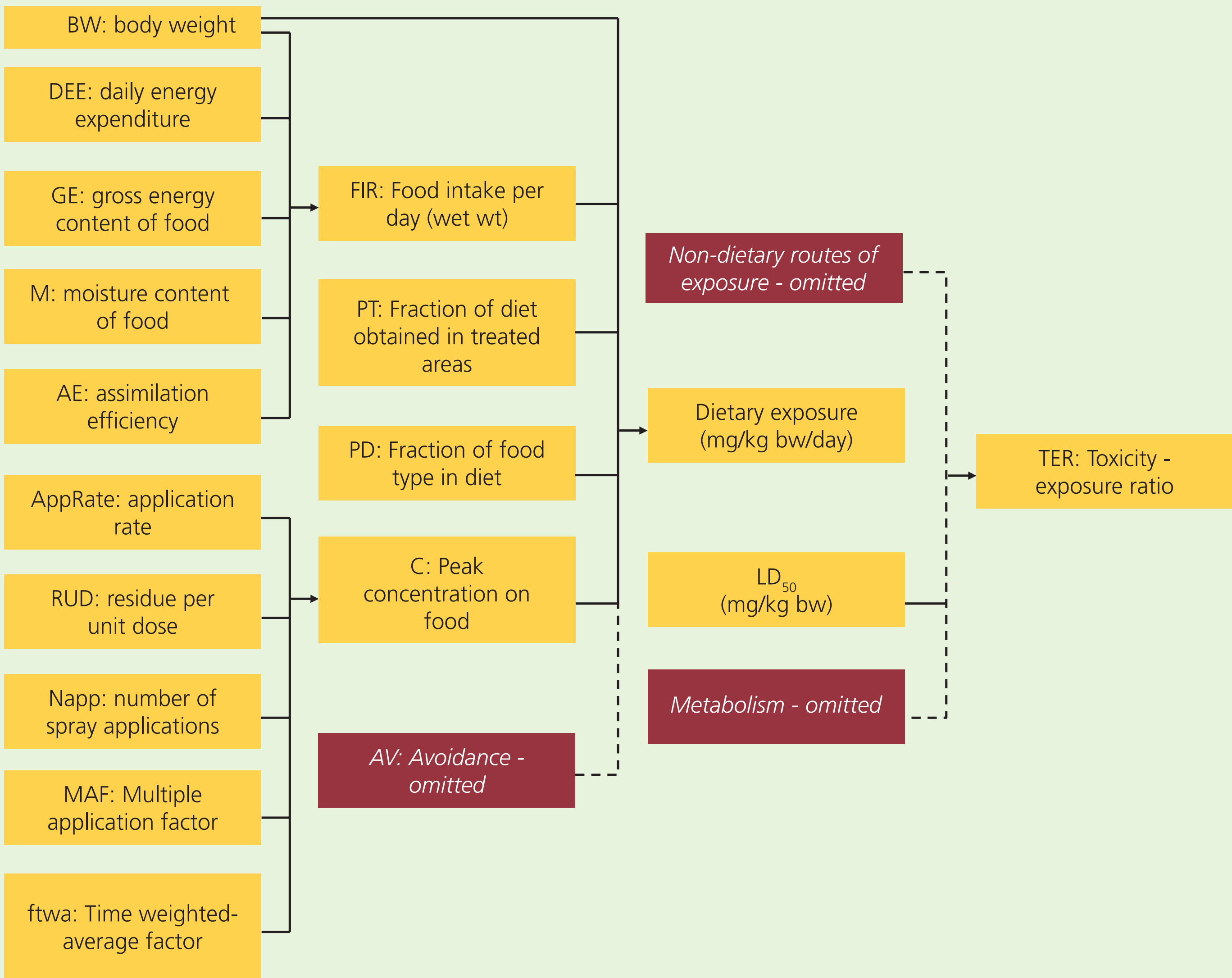


Figure 10: Model for the consequence assessment of acute risks of pesticides to birds (adapted from Hart *et. al.,* 2006).

Stage III: Assess their probabilities

With the range of potential impacts (which could be qualitatively or quantitatively described), the likelihood that they will occur may be expressed as a probability or frequency. It is important to assess probability with some degree of confidence as the credibility of the risk assessment is undermined if the probability presented appears to be wholly subjective or, conversely, indefensibly precise. Indeed, using data to define probabilities for discrete and rare events is more difficult than for those that can be readily observed. It is therefore best to consider how relevant the data is to the problem. These issues are also discussed in Chapter 2.1 and Chapter 5.6. Generally, risk assessors consider three aspects of the likelihood of consequences being realised.

a) The probability of the initiating event occurring

The probability of the occurrence of an event can be expressed as a fraction from 0 to 1. Events that are unlikely will have a probability near 0, and events that are likely to happen have probabilities near 1. Many environmental risks are manifest because engineered systems fail. Process engineers have therefore used fault trees, sometimes supported by quantification of contributing failure modes, to estimate the probability of a so-called 'top event' occurring. This might be an accidental release. More broadly, process risk analysis tools that estimate the probability of an initiating event may be used for the breakthrough of filters or landfill liners, for example, in the analysis of barrier failure, where multiple barriers protect the environment from a hazardous release; and where a sequence of events may occur to result in exposure (e.g. the progressive deterioration of flood defence assets). Sophisticated quantitative fault tree software and tools are in wide application within engineering systems. Case Study Box 6 provides an example of a logic sequence for an initiating event. The impact of uncertainty can also be investigated by carrying out further analysis or 'what if' scenarios within quantitative models (Regan *et. al.*, 2003).

Case Study Box 6

The introduction of an exotic fish virus to the UK through imports of live fish vector
Centre for Environment, Fisheries and Aquaculture Science, Weymouth, UK.

The UK enjoys freedom from a number of notifiable fish diseases including epizootic haematopoietic necrosis virus (EHNV). EHNV affects perch and rainbow trout in Australia, thus no live imports of these species from Australia to the UK is permissible. However, other species can be traded, and large specimen carp for recreational angling have been imported. The import of species not recognised as susceptible, may introduce the virus (i.e. in the gut, on the skin or in mucous) and this was qualitatively assessed for a consignment of 30 carp (Peeler *et. al.*, 2009). A scenario tree of events necessary for the introduction was developed (Figure 11). A wide range of data (e.g. epidemiology and biophysical properties of EHNV, fish population distribution in Australia) was used to qualitatively assess
(from negligible to high) the likelihood and uncertainty of each step; the qualitative assessments were combined using a matrix to produce a conditional likelihood. The likelihood that a consignment of carp would introduce the virus was judged to be low. There was a high level of uncertainty around the likelihood that contact between the carp and an infected fish would result in contamination of the carp with the virus. The virus is only likely to establish when water temperatures are above 12°C. Assessment of the water temperatures in rivers in southern England indicated that on average the water temperatures were permissive for 14 weeks during the summer.

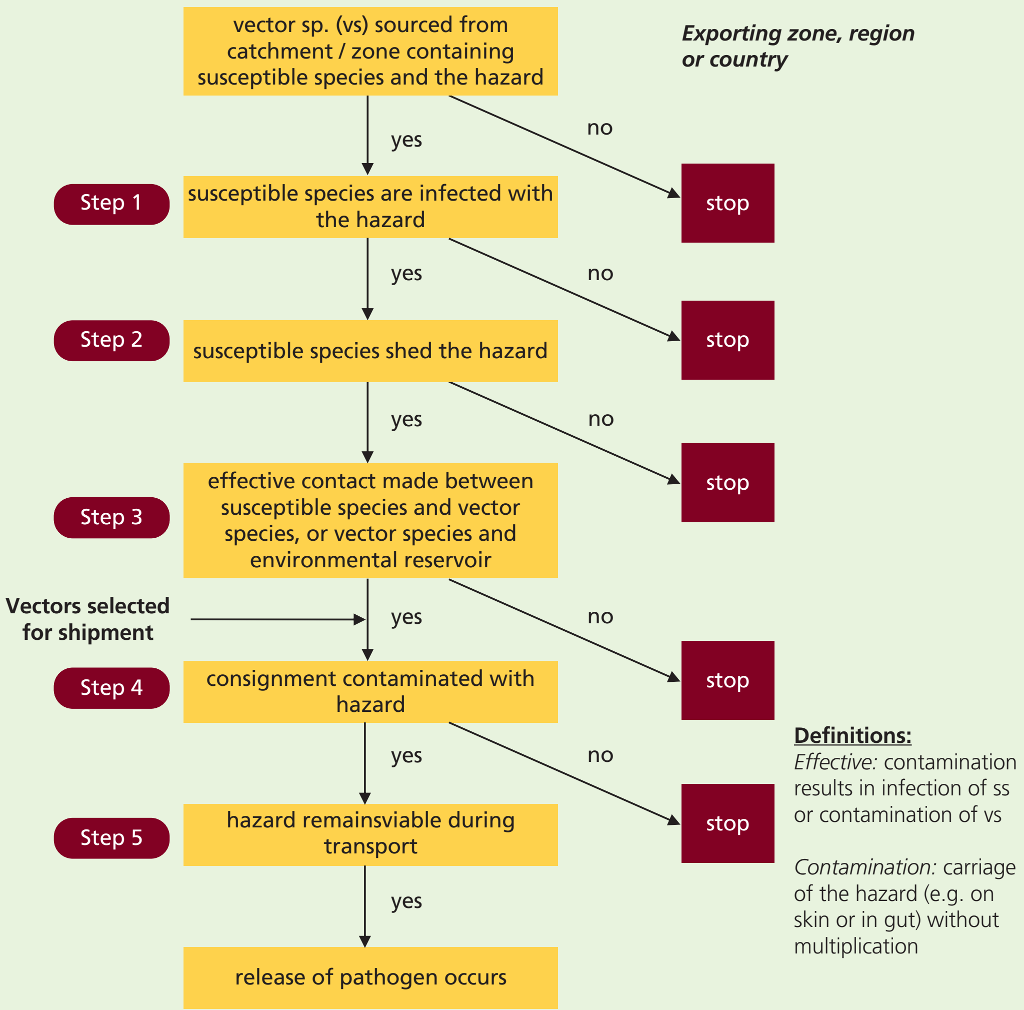


Figure 11: Release pathway for the introduction of an exotic pathogen via imports of a vectors species (vs).

b) The probability of exposure to the hazard

Risk assessors also have an interest in what happens should a release occur. Usually, hazardous agents are released to the wider environment and may travel some distance to receptors. Consider the releases of bioaerosols from large composting facilities, for example, or the transboundary distributions of persistent organic pollutants at a global level, or the hydrogeological transport of contaminants in an aquifer. Here, the assessor must characterise the temporal and spatial distribution of hazardous agents from the point of release to the so-called 'exposure point'. A wide variety of environmental dispersion tools exist to characterise contaminant transport, for example. These are sometimes coupled to exposure assessment tools that estimate the likely 'dose' at the exposure point.

c) The probability of the receptors being affected by the hazard

Should exposure to a hazard occur, the risk analyst is then interested in the likelihood of harm that may result from the exposure. The likelihood of harm depends on the susceptibility and vulnerability of a receptor to the hazard, on the potency of the hazard itself, and on the amount or extent of exposure. For chemicals and pathogens, this is often simplified in terms of a dose–response relationship, which relates exposure to the expected magnitude of harm for certain receptor types. In flood damage assessment, for example, standard depth–damage curves can be used to relate the depth of flood waters to the damage sustained by a building or its contents, again according to the extent of exposure to the flood waters and property type.

Often the risk analyst is interested in all three probabilities above – from the likelihood of the initiating event through to the likelihood of harm. The three probabilities can be assessed together (e.g. as part of a single model), or the later steps can be assessed conditional on the outcome of earlier steps (e.g. if a landfill liner leaks, what will be the down gradient consequences for an abstraction borehole?). That is, various risk scenarios may need to be set up and then explored in detail (Finger *et. al.*, 2007). In pathogen hazards, for example, the approach is typically to describe a range of outbreak scenarios with different likelihoods.

Stage IV: Characterise risk and uncertainty

Risk characterisation pulls together the information from the previous three stages. It is concerned with determining the qualitative and, if possible, quantitative likelihood of occurrence of the known and potentially adverse effects that an activity or agent presents to a given receptor under defined exposure conditions, along with acknowledging the assumptions and uncertainties (OECD, 2011). Here we are concerned with the significance of the risk. Risk characterisation can be achieved through reference to some pre-existing measure, such as an environmental quality standard or a flood defence standard, or by reference to pre-established social, ethical, regulatory or political standards.

A variety of methods can be used to characterise the risk. A basic approach might involve comparing contaminant concentrations in lake water with guideline values and deciding what this means in terms of how likely it will be that adverse consequences will be realised. Considerations may also include how valid the guideline values are for the site of concern and whether further investigations were necessary in order to justifiably characterise the risk (Davis, 2002).

In many ecotoxicological risk assessments, for example, the ratio of the measured or estimated environmental exposure concentrations to the predicted no-effect concentration (PNEC) can be used to evaluate the significance of the risk for target ecosystems. The dose level at which no critical effect is found and the lowest dose at which the effect is found may be identified from studies in human populations or data from studies in experimental animals and other test systems, where a benchmark dose (Setzer and Kimmel, 2003) may be used as an alternative. This information is then used to derive a standard considered to represent a level of exposure or intake at which it is believed there is little, if any, likelihood of developing ill-health effects. This standard is then compared directly with the measure or estimate of exposure. This approach also requires a consideration of the uncertainties in exposure estimates when interpreting the ratio (Case Study Box 7).

Different approaches are adopted by different regulators but often a safety factor or safety margin is included in the risk characterisation process to allow for uncertainty. For example, using the no observable adverse effects level (NOAEL) approach to pesticide risk assessment normally includes a safety factor of 100 times to ensure that the maximum possible exposure will be less than the NOAEL, by at least 100 times (Cao *et. al.,* 2011). The uncertainty within the exposure estimates can result from inappropriate species/strain, gender differences, the safety factors assumed and used to predict the end result, and/or possible combinations with other chemical compounds.

Further guidance on characterisation of the risk based on the strength and weight of evidence, expert elicitation and dealing with uncertainties is provided in the following sections.

Case Study Box 7

Assessing ecotoxicological risks for "down-the-drain" chemicals in surface waters

Cranfield University, Bedfordshire, UK

Environmental risk assessments for chemicals are generally based on comparing exposure with an effect threshold (Predicted No Effect Concentrations: *PNEC*). For so-called "down-the-drain" chemicals (such as pharmaceuticals and the ingredients used in household cleaning products), exposure assessments (i.e. calculations of Predicted Environmental Concentration: *PEC*) are usually based on a simple ratio of per capita consumption and per-capita domestic water use, which is then adjusted for removal during sewage treatment and for dilution in the receiving environment using a generic dilution factor (e.g. 10). One problem with this procedure is that it does not take into account spatial and temporal variability in dilution which changes with the relative magnitude of point-source loads and river discharge at the point of emission.

Higher tier exposure models such as GREAT-ER (Geography-referenced Regional Exposure Assessment Tool for European Rivers: Koormann *et. al.*, 2006) can be used to predict the statistical distribution of river-reach-specific concentrations (Figure 12), accounting for time varying emission and in-stream dilution and degradation. These predictions can be compared with effect thresholds or integrated with distributions of effect end-points in a range of organisms (species sensitivity distributions) to identify risk "hot spots" or predict overall risk. This approach has been employed to assess the aquatic risks associated with triclosan (an antimicrobial substance used in soap and toothpaste) for urbanised catchments (Capdevielle *et. al.*, 2008) and whole regions in the UK (Price *et. al.*, 2010). These assessments suggest that although local exposure can be high, particularly under low flow conditions, overall risks are generally acceptable, especially when toxicity adjustments are made for pH dependent speciation of triclosan.

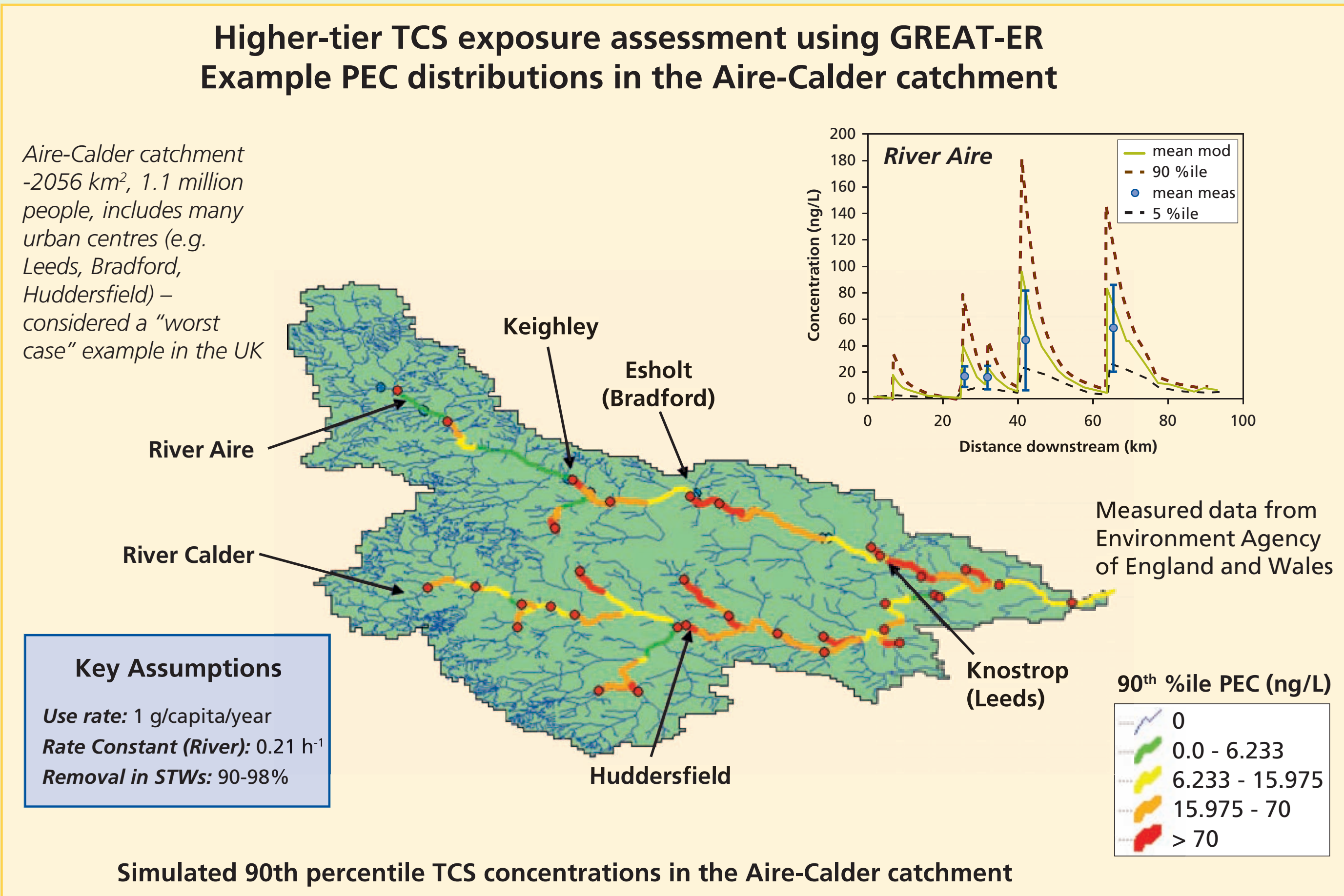


Figure 12: Higher-tier triclosan (TCS) exposure assessment using GREAT-ER example *PEC* distributions in the Aire-Calder catchment.

3.3 General issues in risk assessment

3.3.1 Direction, strength and weight of evidence

Rarely does all the evidence on an issue support the conceptual model on whether and how a hazard might be realised. Conclusions are formulated using different data and lines of evidence that vary in the degree to which they support or contradict the conceptual model. In deciding whether evidence supports the risk assessment, the risk assessor will need to consider the direction of evidence (does the evidence offer support for or against the plausibility of the relationship between cause and effect), its strength (how confident is the assessor that individual lines of evidence support the plausibility of the causal relationship) and the overall weight (given other possible competing theories, what is the overall balance of evidence?). For example, the conditions needed to establish a causal relationship between two items can be based on (Bradford-Hill, 1965):

- analogy – if a similar agent exerts similar effects, it is more likely for the association to be causal;
- consistency – the more studies finding similar results, the more likely it is to be causal;
- coherence – a coherence between empirical and laboratory evidence suggests more causality, however the absence of coherence cannot nullify the findings;
- experimental evidence – an association from experiments may be enough to show causation;
- strength – the stronger the association, the stronger the likelihood of causation;
- specificity – the more specific the association between a cause and effect is, the larger the probability of a causal relationship;
- plausibility – a plausible mechanism between cause and effect is helpful, but may be limited by current knowledge;
- temporality – the cause must precede the effect; and
- biological gradient – greater exposure should generally lead to greater incidence, frequency or magnitude of the effect, i.e. dose-response.

The use of different lines of evidence raises the issue of how best to assess their degree of independence and the quality of the underlying content. This is important because estimates of risk are fundamentally determined by the origin, quality and provenance of the evidence that supports them (Suter II and Cormier, 2011).

Table 2 shows one example of a set of quality indicators for scientific evidence. Additional measures are offered using the pedigree analysis approach, which is part of the NUSAP (numbers unit spread assessment pedigree) system for uncertainty assessment (van der Sluijs *et. al.*, 2005).

Table 2: Example of quality indicators for scientific evidence (after Bowden, 2004).

Quality rank		Indicators of evidence quality					
		Theoretical basis	**Scientific method**	**Auditability**	**Calibration**	**Calibration**	**Objectivity**
	Very high	Well established theory	Best available practice: large sample; direct measure	Well documented trace to data	An exact fit to data	Independent measurement of sample variable	No discernable bias
	High	Accepted theory; high degree of consensus	Accepted reliable method; small sample; direct measure	Poor documented but traceable to data	Good fit to data	Independent measurement of high correlation variable	Weak bias
	Moderate	Accepted theory; low consensus	Accepted method; derived or surrogate data; analogue; limited reliability	Traceable to data with difficulty	Moderately well correlated with data	Validation measure not truly independent	Moderate bias
	Low	Preliminary theory	Preliminary method of unknown reliability	Weak and obscure link to data	Weak correlation to data	Weak indirect validation	Strong bias
	Very low	Crude speculation	No discernable rigour	No link back to data	No apparent correlation	No validation presented	Obvious bias

In addition, there is an argument for explicitly addressing the question of data availability and quality (EFSA, 2009). Table 3 suggests a generic means of scoring the data available, which in turn can provide a measure of epistemic uncertainty, i.e. when uncertainty is brought about by a lack of knowledge (Section 3.3.3).

Table 3: Scoring system for addressing the question of data availability regarding epistemic uncertainty (taken from EFSA, 2009).

Score	Description
Low (1)	• Solid and complete data available; strong evidence in multiple references with most authors coming to the same conclusions; or • considerable and consistent experience from field observations.
Medium (2)	• Some or only incomplete data available; evidence provided in small number of references; authors' or experts' conclusions vary; or • limited evidence from field observations; or • solid and complete data available from other species which can be extrapolated to the species being considered.
High (3)	• Scarce or no data available; evidence provided in unpublished reports; or • few observations and personal communications; and/or • authors' or experts' conclusions vary considerably.

Assessing the quality, reliability and relevance of experimental or empirical evidence, and the underpinning conceptual model, is an important part of risk assessment and management. It is as necessary when considering a single line of evidence as it is when multiple sources are used. Case Study Box 7 provides an example of evaluating the direction and magnitude of the impact of different uncertainties. Likewise, the appropriateness of the techniques/methods used in the risk assessment should be reviewed by internal or external risk assessors, or other experts who can comment on the data used within the risk assessment and the validity of the results. A helpful review of the use of multiple conceptual models, assessment of their pedigree and reflection on their reasonability is provided in Refsgaard *et. al.* (2006).

Case Study Box 8

Qualitative evaluation of uncertainties in pesticide risks to birds

Food and Environment Research Agency, Defra, UK

The Webfram models of pesticide risks to birds (Case Study Box 10) quantify some uncertainties probabilistically. However, it is important to consider how other uncertainties, which remain unquantified, might change the assessment outcome. This was done using 'uncertainty tables', a qualitative method for evaluating uncertainties that has since been taken up in guidance for REACH (ECHA, 2008). To construct an uncertainty table, the user lists sources of uncertainty together with an evaluation of their impacts on the assessment outcome, represented by symbols indicating the direction and magnitude by which the 'true' risk might differ from the estimated value (Table 4).

For example, '+/- - -'indicates an uncertainty that could alter the true risk in either direction, from a little higher (+) to a lot lower (- - -). The user then evaluates the combined effect of all the uncertainties and expresses this using symbols and also in a narrative form to be included in the conclusion of the risk assessment. For more information on uncertainty tables, see Hart *et. al.* (2010).

Table 4: An 'uncertainty table' used to evaluate the impact of uncertainties in an assessment of pesticide risks to birds.

Source of uncertainty	Direction and magnitude
General uncertainties	
Distribution choice is always somewhat uncertain, and goodness of fit is questionable or not testable (due to insufficient sample sizes) for some parameters. Raw data were unavailable for some.	+/-
Measurement uncertainty applies to all variables but not quantified for any.	+/-
Exposure assessment	
Not all cereal fields will be treated with the pesticide under assessment.	- -
Those cereal fields that are treated, will not all be treated on the same day.	-/- -
Uncertainty about estimation of diet composition and seed preference is represented by running models with different combinations of assumptions. True values are likely to be intermediate.	+/-
Assimilation efficiency data for leaves and seeds represent variation between sites and may underestimate variation between individual animals.	+/-
Assimilation efficiency data for arthropods are for different species and there is uncertainty in extrapolating to the species of concern.	+/-
Variance of gross energy for dicot leaves may be over-estimated	-
Moisture content of dicot leaves estimated from crop plants, weed foliage may have lower moisture content.	-
Insect residues are estimated from data on forage and small seeds and the extrapolation is very uncertain. Recent research appear to show some possibility of higher values but more of lower values.	+/- -
Animals, radiotracked, may not represent a sample of population visiting cereal fields. Time spent active in field may not be a good surrogate for proportion of diet obtained in field, and may vary between months.	+/-
Non-dietary routes of exposure are omitted. Could increase total exposure by 2-5 fold.	++
Effects assessment	
Differences between pesticides in the degree of between-species variation, and uncertainty in its estimation.	+/-
Variation of standard deviation of dose response slope between pesticides, and uncertainty in its estimation.	+/-
Uncertainty extrapolating from toxicity in lab to field conditions (for same species)	++/- -
Avoidance response (if applicable to pesticide under assessment)	-/- - -
Metabolism and depuration of pesticide under assessment. If %mortality is low, exposure probably requires most of a daily intake of food, and provides a period for depuration and metabolism to reduce internal dose.	-/- - -
Overall: There are many factors which may decrease or increase the true risk. We consider that the balance of the identified factors is likely to decrease risk; i.e. the true risk is likely to be lower than estimated, especially for the pesticides with substantial avoidance responses and rapid metabolism. For pesticides with little or no avoidance and slow metabolism, the models are likely to underestimate risk.	+/- - -

3.3.2 Expert elicitation

Expert judgement is always required in risk assessment, whether concerned with how representative the conceptual model is, with the elicitation of specific data from a selection of possible choices, or with the plausibility of specific exposure scenarios. It can also be used to estimate quantities for which data is lacking, or to quantify uncertainties. Judgement can be used informally, such as a single expert working in an office estimating and documenting the data for a parameter value for use in a model. Or it can be elicited from one or more experts, using a formal, structured procedure such as an expert opinion workshop.

Often the complexity of the risk problem is such and the uncertainties are so large that a formalised approach is adopted using a range of experts from many disciplines. Good examples exist in the hydroelectric dam risk assessment and radiological waste literature (e.g. Rashad and Hammad, 2000). Here the consequences of poor decision-making are often substantial, so the operators of hydroelectric dams and radioactive waste facilities have developed and employ highly structured approaches for the selection and use of evidence. Formal expert elicitation is a structured practice to elicit beliefs on generated risk scenarios. At this level of sophistication, expert elicitation is a complex activity on which there is an extensive literature and multiple contrasting approaches and schools of thought. O'Hagan *et. al.* (2006) provide a comprehensive overview.

Expert judgement methods may be used to elicit: a) distributions; b) preferences, rankings or pair comparisons; c) qualitative information (links, interrelationships); d) point values (most likely, minimum, maximum, quantiles); or e) probabilities. For example, the following steps describe how probabilities (of defined events) can be elicited (after Vanrolleghem, 2010):

1) identify and select experts;
2) explain the nature of the problem and the elicitation procedure to the experts;
3) chose a scale and unit familiar to the experts for defining the quantity;
4) discuss and document the sources of current knowledge and evidence, its relevance to the problem, its strengths and weaknesses;
5) elicit and assess extremes of the distribution;
6) elicit and specify the distribution;
7) confirm that the distribution represents the experts' beliefs; and
8) decide if the distributions elicited from different experts should be aggregated and, if so, how (Bedford and Cooke, 2001).

Examples in which expert elicitation methods were used are provided in Case Study Box 9 and 10. Case Study Box 9 describes the study structure of an assessment that used expert elicitation related to qualitative categories, while Case Study Box 10 provides an example of a formal elicitation approach relating to quantitative information.

Case Study Box 9

Anaerobic digestion [AD] risk assessment and residue hazards
Centre for Energy and Resource Technology, Cranfield University, UK.

Market confidence is central to the use of organic waste materials in UK agriculture. A thorough and independently traceable process of risk assessment is needed for assurance that processed waste materials can be used safely. This process often requires the combination of both existing evidence and expert knowledge from the sector. Waste material processing brings together stakeholders from a wide range of expertise. These include farmers, process operators, waste management contractors, land management specialists and food supply-chain representatives, such as food standards and supermarket representatives. The project team was tasked with drawing together the available evidence on the hazards present for all wastes allowed into AD processes as a feedstock. In addition, expert knowledge from members of the steering groups was sought to ensure that operational and agricultural practices could be taken account of within the assessment. Figure 13 shows the sequence of evidence gathering and analysis which draws on key reference documents as well as expert stakeholder input.

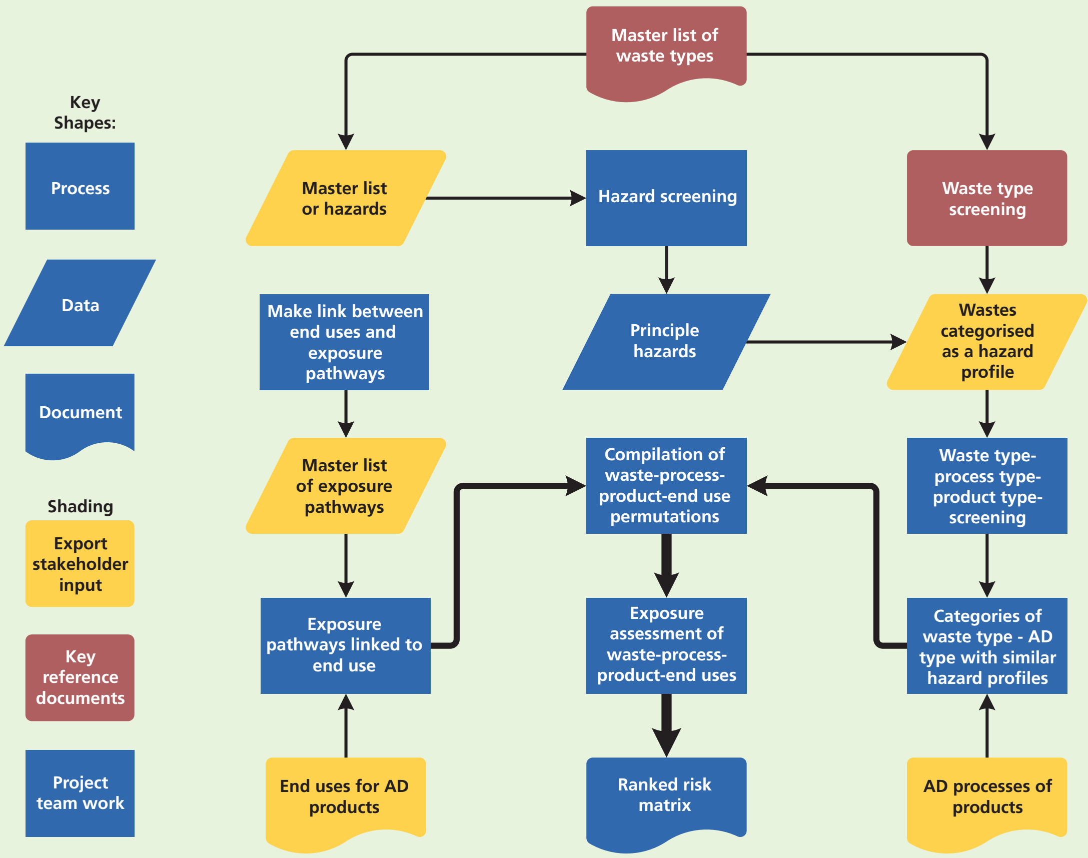


Figure 13: Overview of risk assessment method for the safe use of AD residue.

In excess of 38 million potential combinations of; waste types, hazards, process types, viable pathways, end user groups, and exposure risks made up the series of range scale combinations to be considered. Spreadsheet-based modelling techniques were used to collate key decisions from stakeholders and, in turn, to relate stakeholder decisions to each stage in the sequence (e.g. exposure pathways).

Release of hazardous agents including; human and animal pathogens, plant pathogens, potentially toxic elements [PTEs], persistent organic pollutants [POPs], physical hazards and odour, along the processing and end-use pathway to unacceptable concentrations would erode market confidence in AD biofertiliser use. Agricultural land-use for this residue would be closed-off and the resulting reduction in land bank available for disposal would raise the cost of AD processes and potentially return materials to landfill in order to assure the protection of animals, humans or the wider environment. Assuring a transparent, documented, evidence-based process was central to developing and maintaining market confidence.

Case Study Box 10

Eliciting expert judgments about the future cost of livestock diseases
Food and Environment Research Agency, Defra, UK.

As part of a public consultation on animal health in 2009, Defra published estimates of the average annual cost of future outbreaks of exotic animal diseases. The estimates were made by Defra vets and economists who were expert in the field, but it was recognised that the estimates were highly uncertain and thus 'illustrated very roughly the possible scale of outbreak costs'.

For a revised assessment in 2010, formal methods of expert elicitation were used to help the Defra vets and economists express their uncertainty about each element of the calculation underlying the estimated costs. They were asked in a structured group discussion to provide upper and lower estimates as well as central figures for each element, which were used to construct probability distributions representing their uncertainty. These distributions were then combined using Monte Carlo simulation to estimate a probability distribution for the total costs.

The results were presented in a table of estimated costs, similar to that in the 2009 assessment but, this time, adding ranges to show the uncertainty (Table 5). This provides a picture of the how different the true costs might be, which was previously lacking.

When the results are plotted as a cumulative distribution, it is possible to estimate the chance that the average annual cost will fall below any given value. For example, there is a 60% chance that the average annual cost excluding unknown diseases will be less than £20 million – and therefore a 40% risk it will exceed £20m (see Figure 14). This type of information could help decision makers consider what financial provisions to make for future costs.

Sensitivity analysis was used to identify which parts of the calculation contributed most uncertainty: these might be priorities for data collection or modelling to reduce the uncertainty of future estimates.

Table 5: Extract from results of expert elicitation, for the average annual cost to government for one disease. Similar results for multiple diseases were combined to estimate a total (Defra, 2010).

Disease	Main species affected	Average interval between outbreaks	% probability that outbreak is major	Incidence cost £m if outbreak is minor	Incidence cost £m if outbreak is major	Average cost per outbreak £m	Average annual cost £m
Foot-and-mouth disease	Cattle, sheep, pigs	25 (10,59)	5 (2.3,7.9)	50 (18,125)	400 (90,3200)	76 (30,227)	3.1 (0.86,12)

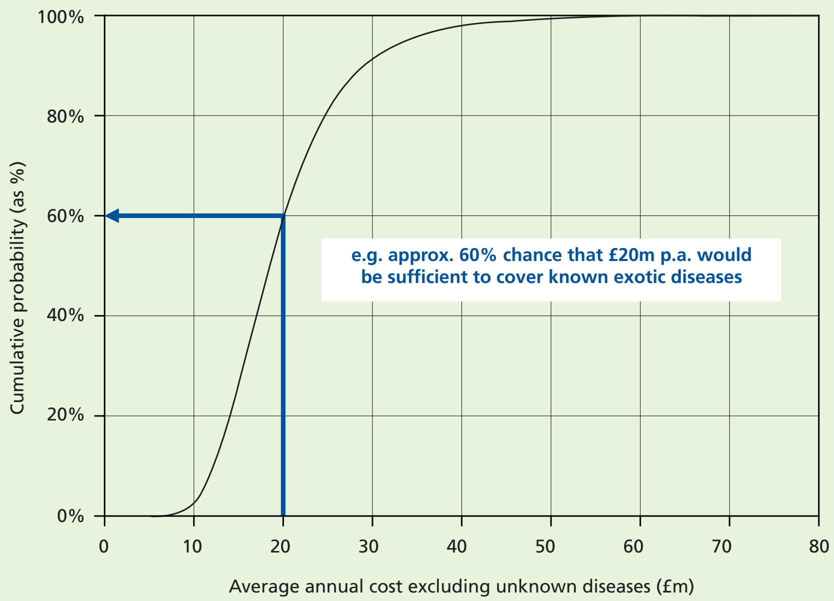


Figure 14: Graph showing the uncertainty expressed by experts in estimating the average annual cost of known exotic livestock diseases in England (government costs only).

3.3.3 Dealing with uncertainty

Uncertainty is associated with every component of risk assessment (Section 3.1). Rarely, in environmental science can uncertainties be quantified with precision. The uncertainties present can be defined as epistemic, where their existence is brought about by a lack of knowledge; or aleatory, which relates to the inherent variability of any natural system. Classifications within each of these types of uncertainty are detailed in Appendix 4.

Identifying uncertainties is the first step towards quantifying them. Whilst only epistemic uncertainties can be reduced, clear recognition of all uncertainties can help improve the quality at every stage.
For example, data may be incomplete (e.g. data may be lacking on the times series of emissions from a certain incinerator, the total emissions over a defined period, or the precise nature of the emissions). Also, data may be subject to rounding-off (e.g. 0.342 may have been recorded as 0.3); specified only as a maximum permitted level of emission; poorly specified (e.g. instead of the electricity use of a 80-l boiler in France in 2007, one may have data for a 75-l boiler in Germany in 2006); erroneous (e.g. measurement errors or mistakes in recorded units); subject to sampling variability (e.g. a small number of incinerators surveyed); sampling bias (e.g. in selection of incinerators surveyed); or extrapolation (e.g. from incinerators in a country where data are available to another country which lacks data).

Multiple techniques exist for dealing with uncertainty within environmental risk assessments. Selection of the most appropriate method depends largely on the type(s) of uncertainties identified. Below is an outline of the most commonly used techniques.

- *Further research*

The collection of information enhances knowledge and understanding and reduces uncertainty. Situations in which data are sparse, imprecise, or uncertain in some other way will benefit from further research and development (Aven and Steen, 2010). This should in turn reduce the uncertainties associated with subsequent processes such as modelling and decision making.

- *Uncertainty factors*

Uncertainty factors (also called safety factors) are often used to take account of uncertainty (OECD, 1995). They may be thought of as providing a margin of safety: they attach a factor-based correction to the data being used which is designed to reflect the level of uncertainty within it. Some uncertainty factors are used to take account of extrapolation uncertainties, for example, the standard uncertainty factors used to take account of species differences in toxicology and ecotoxicology.

- *Probability density functions*

Many methods have their focus on computational modelling processes. One such technique is the use of Probability Density Functions (PDFs), a technique based on Bayesian probability theory that is used to estimate unknown model parameters based on the degree of belief about these parameters (Bolstad, 2007). In practice, Bayesian probability theory is applied mainly to situations such as noise in data where no unique solution exists (Neil and Bretthorst, 1993). All the relevant information is summarised in a PDF, which may then be used in the modelling process to present a risk as a spectrum of possible outcomes with a distribution of frequencies or probabilities for each (also known as a risk curve). Modelling the risk in this way can be done with various tools including Monte-Carlo simulation or Latin Hypercube sampling. Case Study Box 11 describes the use of PDFs to quantify variability and uncertainty within the calculations carried out in the risk assessment of pesticide risks to birds that was illustrated in Case Study Box 4.

Case Study Box 11

Probabilistic modelling of pesticide risks to birds

Food and Environment Research Agency, Defra, UK

The 'Webfram' projects developed a suite of probabilistic models for assessing environmental risks of pesticides. The completed models were implemented as web-based software and are available for online use at www.webfram.com. The approach for acute risks to birds and mammals is based on the same conceptual models as are used for deterministic assessment (see Case Study Box 5) but using probability distributions to represent variability and uncertainty affecting different elements of the calculation, as illustrated in the diagram below (Figure 15). Probability distributions show the range and relative likelihood of possible values for each input and output, and thus provide a fuller picture of the possible outcomes.

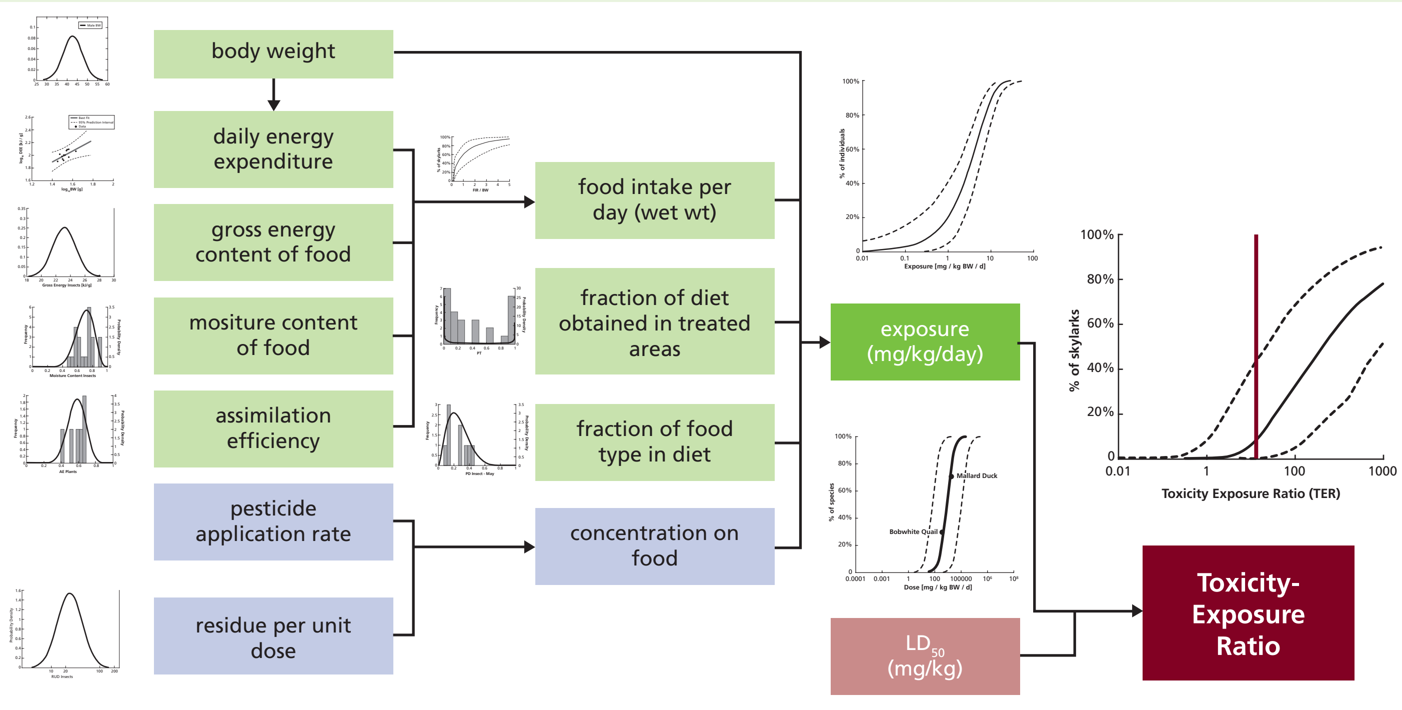


Figure 15: Illustration of a probabilistic model for assessing acute risk of pesticides to birds.

The user enters information on the application rate and toxicity of the pesticide. The models then estimate dietary exposure using the best available data on the diet and feeding behaviour of relevant species in UK conditions. The output is a distribution estimating the variability of the toxicity-exposure ratio (TER, as used in current deterministic assessments) in the population of animals that visit the treated crop on the day of pesticide application.

The models quantify some important types of uncertainty: 'sampling' uncertainty that is caused by having only limited amounts of data for each model input, and uncertainty about the extrapolating from toxicity for species tested in the laboratory to those exposed in the wild. The effect of these uncertainties is shown by distributions or confidence intervals for the model outputs, showing how different the "true" TERs could be. Other types of uncertainty, which were not quantified, were considered in a qualitative way (see Case Study Box 8). More details are available online at www.webfram.com and in Hart *et. al.* (2006).

- *Bayes linear methods*

Unlike PDFs, which describe uncertainty in terms of probability, Bayes linear methods describe uncertainty by expectation. By making expectation the fundamental quantity for the quantification of uncertainty, demands for probability specifications are lifted to allow for a partial analyses in terms of the limited beliefs that can be specified (Goldstein and Wooff, 2007). These methods are therefore useful if the problem formulated is too complex to allow a full prior specification, or if the analysis is too difficult because of the full prior specification (Coolen *et. al.*, 2001). It is for these reasons that the Bayes linear approach is sometimes viewed as a generalisation or simple approximation to the full Bayes approach (Randell *et. al.*, 2010). An overview of the Bayes linear approach is provided in Goldstein (1999).

- *Sensitivity analysis*

Sensitivity analysis is used to determine which uncertainties have the largest impact on assessment performance measures. It is good practice to conduct sensitivity analysis as an early step in model design, to identify which factors are important to include, as well as at the end of the assessment. Sensitivity analysis is of diagnostic value because it can usually highlight which aspects of the system being assessed contribute most to the risk (Saltelli *et. al.*, 2008). Depending on the degree of control one has over these higher contributors, these features may then become priorities for management control.

A sensitivity analysis also enables the uncertainty in the output of a mathematical model to be attributed to different sources of variation in the input of the model. This can provide an understanding of how robust a model is. Sensitivity analysis can help to identify the significance of uncertainties in the model in order to highlight areas that require further research or data collection. A useful overview and qualitative comparisons of available sensitivity analysis methods, including mathematical, statistical and graphical methods, is provided in Fray and Patil (2002).

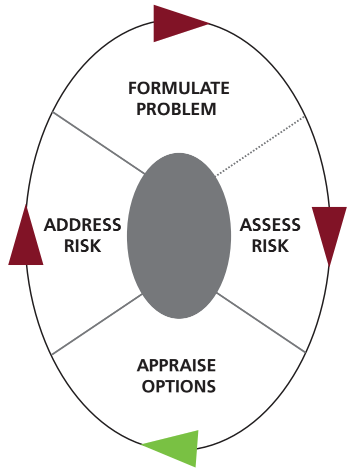
3.4 Summary

Risk assessment involves four stages: (1) identifying the hazard(s); (2) assessing the potential consequences; (3) assessing their probabilities; and (4) characterising the risk and uncertainty. The output of this structured process provides a judgement as to the presence likelihood of the risk and its significance, along with details on how the risk was assessed and where assumptions and uncertainties exist. The evidence required to provide judgements and subsequently characterise a risk in this way can be qualitative, quantitative, or semi-quantitative. Either way, for each problem, appropriate tools must be employed. Where data is lacking or inaccessible, elicitation provides a formal method for obtaining expert judgement. Uncertainty is always present when conducting each stage of an environmental risk assessment. The techniques available to analyse, understand and manage these uncertainties include the collection of more data, the use of trusted sources, probability density functions, Bayes linear methods, and/or sensitivity analysis.

CHAPTER 4
Appraising the Options

4.1 Introduction

Risks deemed unacceptable require management to lower them to a tolerable level of residual risk. Usually, the decision-maker has access to a range of risk management options to reduce, eliminate or exploit risk. Zero risk is usually unachievable.



Options appraisal is the process of identifying and selecting the most appropriate risk management strategy given the constraints of the decision-maker (HM Treasury, 2003). This may involve scoring, weighting and/or reporting different risk management options. Various criteria are used for identifying the 'best' option, according to context, but a common framework is to seek to maximise some long-term definition of human well-being such as environmental security, net social benefit or value for money (risk reduction per unit cost). Key inputs for this process are the controlling factors for each risk identified during the problem formulation stage (Chapter 2). For instance, if a controlling factor is the level of investment in monitoring and control equipment, then risk management options can be identified that focus on those issues immediately.

It is important to identify the risk management options as a distinct preliminary step because ill-considered risk management strategies may otherwise result in wasted effort and expenditure (HM Treasury, 2004). The risk management options available usually take one of the following forms (Figure 16):

- **terminate** the source of the risk where possible;
- **mitigate** the effects by improving environmental management techniques or engineered systems;
- **transfer** the risk through new technology, procedures or investment;
- **exploit** the potential benefits of the risk by embracing new opportunities; or
- **accept** the risk by not intervening with new or existing situations.

To select the preferred option, the potential positive and negative effects associated with each option may be considered under the following headings (Figure 16):

Technical factors: whether the options were likely to reduce the risk, by how much, and how difficult it would be to implement the option; for example, the extent of required research and development.

Economic factors: the cost of implementing the option (to the organisation, affected businesses, exposed groups or society as a whole).

Environmental security: the potential impacts of the options on the health and sustainability of environmental resources including the impact to existing habitats.

Social issues: the social impacts of the risk, such as the potential costs or other losses to the community, jobs or house prices, life expectancy and/or amenities.

Organisational capabilities: considering the risk management capability within the organisation or body, or the capability of society or exposed groups.

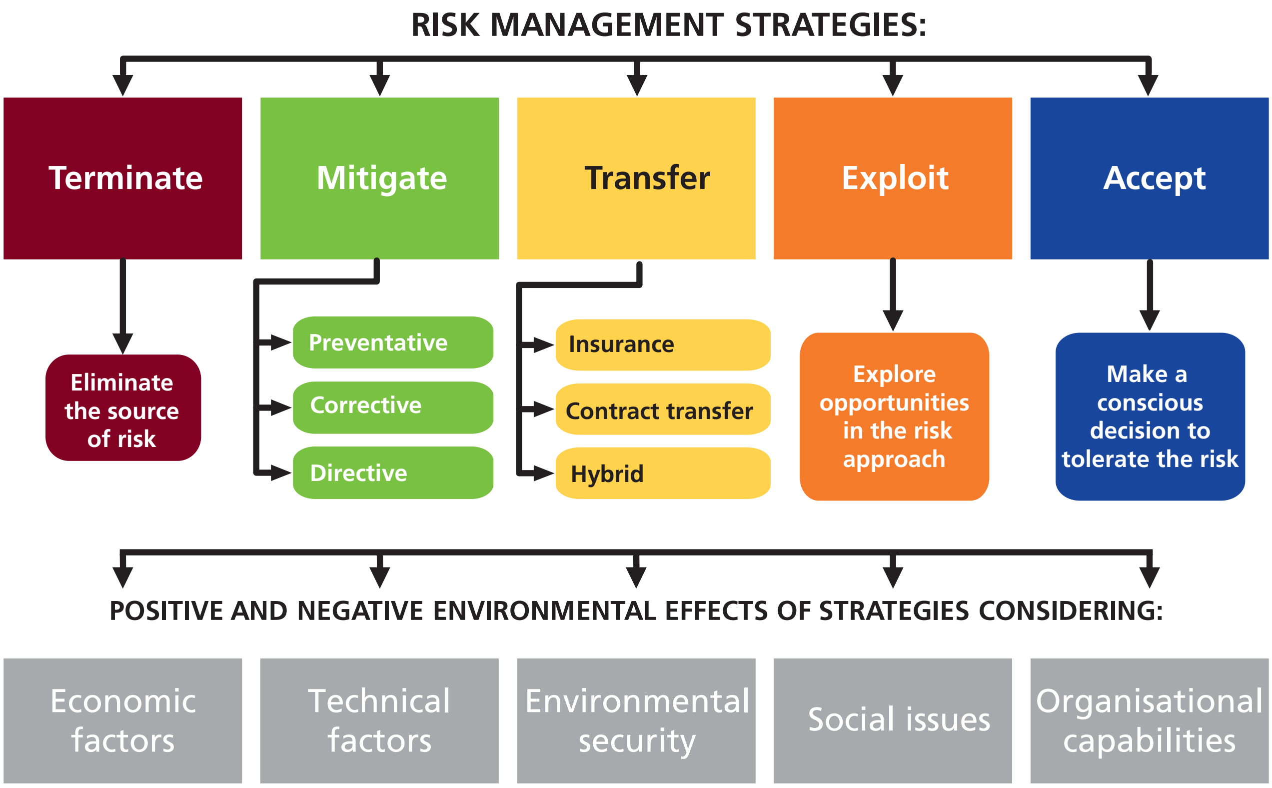


Figure 16: Identifying the optimal risk management technique involves consideration of the effects associated with economic and technical factors, environmental security, social issues and organisational capabilities (after Aon Corporation, 2011).

Combining these elements permits a systematic comparison of options for risk management. A recommended decision-making process is outlined in Section 4.2, and factors that should be considered when identifying the available options are detailed in Section 4.3.

4.2 Structured decision making

Regarding the systematic methods that can be used for comparing and evaluating risk management options; there is no universal method suitable for all circumstances. Rather, selection or adaptation of an existing methodology or development of a new methodology will often be necessary.

All good decisions rely on the effective analysis of alternative options. A systematic appraisal is important to ensure that the decision-maker is clear about the objectives and how to decide where the balance lies between the benefits from the reduction of the risk and the costs and implications for society of introducing potential control measures. A systematic appraisal of options will be the process of identifying, quantifying and weighting the costs and benefits of the measures which have been identified as means of implementation. This process must include all implications of the potential options, and not just those that can be quantified. A common framework can be envisaged consisting of the following steps:

1. Identification of the objective, ensuring a clear and common understanding of what is the desired outcome.
2. Identification of the options. In most cases there will be options that are obvious to the decision-maker. Some will be less applicable than others and it will be necessary to identify those that have the potential, either in whole or part, to meet the objective.
3. Clarify the decision criteria, the implications of change, and the social, economic and environmental benefits.
4. The options identified will need to be implemented using various tools, such as policy instruments, economic measures or regulations. Consideration should be given to the selection of those most appropriate while recognising that they will not be mutually exclusive and a combination of one or more may be appropriate for one or more options.
5. Identification of the impacts of the options. This will require collection of data from those stakeholders who will be affected by potential measures. Close consideration should be given to the implications of changes in working methods (good and bad) to meet the objective.
6. Compare the advantages and drawbacks for each option including the trade-off between quantified and qualitative data to draw conclusions.

When the required risk response becomes clear, the effectiveness of the chosen risk management action is then checked during the monitoring and review phases (Chapter 5).

4.3 Considerations in decision making

4.3.1 Reducing risks

Where the focus is on what the best strategy is to mitigate the assessed risks (Figure 16), consideration should be given to the risks that will remain after the chosen management option is implemented. This is commonly referred to as the 'residual risk'. As described in Section 1.3 and detailed in Appendix 2, there is a substantial amount of regulation that may constrain or enable an activity with uncertain consequences. In some cases it may be appropriate to strike a balance between risk reduction and cost, such as required under the regulatory principles of ALARP (As Low As Reasonably Practicable) and BAT (Best Available Technique) in England and Wales (Environment Agency, 2010).

The ALARP principle is from a specific regulatory framework that applies when risk needs to be reduced to as low as reasonably practicable. Adoption of the principle implies that any further reduction in the risk beyond ALARP can be achieved only at grossly disproportionate cost and that the benefits afforded by accepting the risk are judged to outweigh the costs.

The application of BAT means that the estimation of the risk associated with a particular activity can change over time as new techniques and technologies are developed, and the costs of existing techniques vary. Such changes may warrant another iteration of the risk assessment process. BAT relies not only on technological solutions, but includes other approaches such as environmental management systems and staff training.

4.3.2 The relevance and use of precautionary approaches

If a preliminary scientific evaluation shows that there are reasonable grounds for concern that a particular activity might lead to damaging effects on the environment, or on human, animal or plant health, which would be inconsistent with the protection normally afforded to these within the European Community, the precautionary principle may be invoked.

The precautionary principle states that 'In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation' (Principle 15 of Agenda 21).

If the precautionary principle is adopted, decision-makers determine what action is necessary, taking into account the potential consequences of taking no action, the uncertainties inherent in the scientific evaluation, and consulting interested parties on the possible ways of managing the risk. The adopted measures should be proportionate to the level of risk and to the desired level of protection. They should be provisional in nature, pending the availability of more reliable scientific data.

Research into the use of the precautionary principle (EEA, 2001) identified that the following issues should be considered: the acknowledgement of ignorance; the requirement for long-term monitoring; ensuring that real-world conditions are accounted for in regulatory appraisal; consideration of benefits as well as risks; ensuring the use of lay and local knowledge as well as specialist expertise; and avoiding 'paralysis by analysis' by acting to reduce potential harm when there are reasonable grounds for concern.

4.3.3 Environmental security

In appraising risk management options, the relationship between protecting and enhancing our environment and allowing economic sustained growth in the long term should be explored (Defra, 2010). Environmental security aims to achieve a better quality of life for everyone now, and for generations to come. The overall aim is to ensure that economic and environmental benefits are available to everybody.

Recently there has been much work developing sustainability appraisal methods to support contaminated land risk management decisions. In the UK this work has been led by the Sustainable Remediation Forum (SuRF-UK) and their framework guidance is now available (CLAIRE, 2010). Others in Europe (NICOLE, 2010) and the USA (SURF, 2010) have been doing similar work within their policy environments.

It has also been recognised that achieving environmental security requires collective partnership approaches to decision-making for environmental protection. Environmental management strategies must therefore consider economic demands and social needs, with the capacity of the environment to cope with discharges, pollution and other perturbations, and to support human and other life (Case Study Box 12).

Case Study Box 12

UK Climate change risk assessment – across a range of sectors

Climate Change Risk Assessment Project, Defra, UK

The Climate Change Act (2008) requires Government to implement policies to adapt to climate change – and to inform this, to lay before Parliament assessments of the risks posed to the UK by the impacts of climate to the year 2100. The risk assessment will be complemented with an Adaptation Economic Assessment (AEA) which will assess options for dealing with the largest risk, based on their costs and benefits.

The method for this first Climate Change Risk Assessment uses a tiered risk assessment to consider the risks posed to the UK by impacts cause by climate across a range of sectors (such as Health, Transport, Agriculture, etc). Analysis will be both quantitative and qualitative depending on the evidence and data available for each type of risk. To do this the following process has been used (Figure 17):

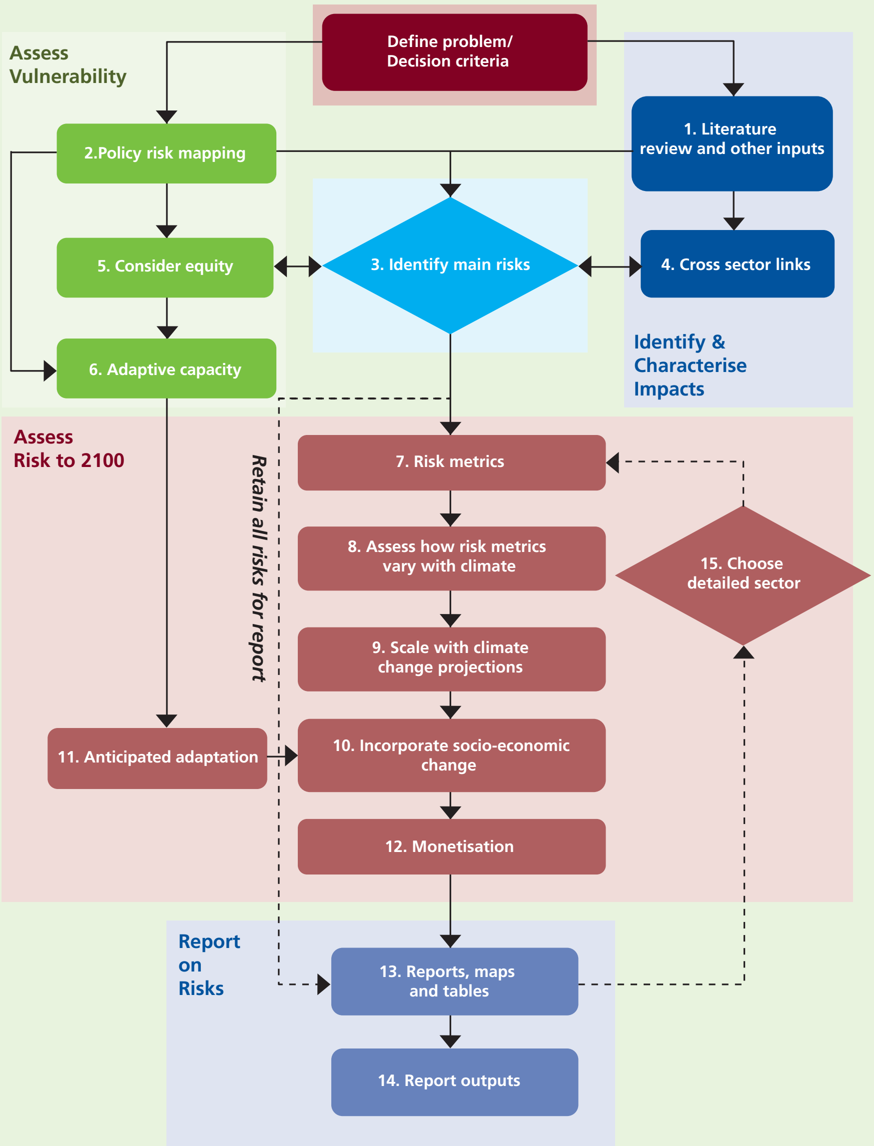


Figure 17: Framework for monitoring future climate change impacts.

Identify and characterise the impacts: through literature reviews, workshops and systematically mapping cross-sector impacts.

Assess vulnerability: As well as looking at possible future climate changes, this step of the method considers exposure to the risks through an assessment of the adaptive capacity of major sectors at the organisational level, an analysis of government policy, and uses a social vulnerability checklist to characterise impacts that have particular equity issues.

Identify main risks: A subset of risks with relatively higher magnitude and likelihood, and those where urgent decisions are needed will be selected for further analysis.

Assess risks to 2100: We will project future consequences using risk metrics to create qualitative, or sometimes quantitative, "response functions" that relate consequences to climate variables. Climate projections combined with socio-economic assumptions can assess the magnitude of possible future consequences. Accounting for the effects of autonomous adaptation and existing policies will provide an estimate of the 'residual' consequences.

Report on risks: using the assessment of impacts and vulnerability together, a report will be created to help Government identify priority areas for action, geographic variations and compare different risks where possible.

Inform the second CCRA (in 2017): by including a learning process within the project so that the expertise gained is retained in government and the wider research community.

4.3.4 Economic considerations

Economic factors can have a significant influence on the decision-making process and may affect the acceptability of a given option. In the case of flooding, for example, there are construction and maintenance costs associated with any flood risk management scheme; there may also be costs in terms of damage to the environment by habitat removal or alteration. An example of estimating flood damage cost to agriculture is provided in Case Study Box 13.

The best option is likely to be the one with the greatest excess of benefits over costs. The benefits are those accruing from protection (e.g. the damage or loss of property, materials, crops, human health and environmental assets that is avoided) taking account of the likelihood that these benefits will be realised. The costs are those social, regulatory and private costs of the control options, including construction, maintenance and environmental damage. This should include both those benefits and costs that can be monetised and those that cannot (or for which robust monetary valuations are not readily available) – the latter need to be assessed in physical and qualitative terms. As monetary values can more readily be assigned to some impacts than others, care is needed to ensure that adequate consideration is given in any decision-making to all non-monetised items that may be thought significant, relative to the monetised elements. Agreement should be sought at the problem formulation stage over what non-monetised metrics are acceptable to decision-makers. Where there are multiple endpoints, benefits and associated criteria, multi-criteria decision analysis may help discriminate the different benefits associated with different risk management options.

4.3.5 Multi-criteria decision analysis

Environmental decisions can be complex, largely due to the inherent trade-offs between social, environmental and economic factors. The selection of an appropriate risk management strategy often involves additional criteria, such as the distribution of environmental impacts or costs and benefits (Steele *et. al.*, 2009). Research in the area of multi-criteria decision analysis (MCDA) has enabled the development of practical ways to compare decision options when there are multiple criteria for assessing those options (Kiker *et. al.*, 2005). MCDA brings together criteria and performance scores, usually in matrix form, to provide a basis for integrating risk and uncertainty levels. In this way, it is possible to perform an evaluation (ranking) of the alternatives. The main advantage of MCDA is its capacity to draw attention to areas of conflict between stakeholders and decision-makers). However, the need to attempt to first reach a consensus on criteria and weightings in discussion with stakeholders can bring limitations to the use of MCDA methods (Section 4.3.6). Participants may initially be unready to relinquish their own subjective views, but through the use of MCDA, a deeper understanding of the values held by others is possible (Paruccini, 1993).

A basic example of a decision matrix is provided in Table 6 which can be used to describe a MCDA problem. The level of risk determined in the risk assessment process can be used to parameterise the decision matrix. Streamlining the factors against which the options are assessed can be a two-stage affair. First, how each option would affect the problem being considered is shown in terms of its positive and negative impacts on the three core elements: environment, society and the economy. Next, it can be helpful to consider if what appears to be the 'best' option is worth pursuing given the 'delivery' risks associated with this (e.g. organisational capability, complexity of implementation). This is where the "balancing of risk" comes to the fore. For example, the decision matrix in Table 4 shows that option 3 is most efficient from a risk reduction point of view but it is also expensive. Depending on the decision-maker's opinion of the budget, a decision-maker may select option 3 or a cheaper option 2, which may still result in an appropriate level of risk reduction (Kiker *et. al.,* 2005). Details on executing more technical and specific MCDA methods (e.g. aggregated indices randomisation method; analytic hierarchy process; the evidential reasoning approach; value analysis) are available in the literature (e.g. Higgins *et. al.,* 2008; Tam *et. al.*, 2006; Chan and Tong, 2007).

Table 6: Example of a decision matrix showing how each option under consideration will affect the economic, environmental and social risks identified.

	Option 1 *Do nothing*	**Option 2** *Mitigate*	**Option 3** *Terminate*
Economic	?	↑	↑
Environmental	↑	↓	↓
Social	↑	↔	↓

Key:
↓ Level of risk decreases
↔ No significant impact on the risk
↑ Level of risk increases
? Not enough information or too much uncertainty to judge the impact

4.3.6 Involving stakeholders and the public

As detailed in Chapter 2.4.1, in some cases it may have been necessary and feasible to involve stakeholders and the public in the risk assessment and management process. While it may not be necessary to involve the same people in all elements of the process (e.g. it might be appropriate to involve members of the local public in the scoping of the risk issues and framing of questions), certain groups may take on active roles within the decision-making process. It is also likely that those who were involved in the planning of the risk assessment will want to be involved in the post-assessment stages. This can be beneficial, as good decisions are often informed by the knowledge and concerns of stakeholders and the public, and are understood and supported by the people who may be directly affected by them (e.g. a new genetically-modified sugar beet trial; the assessment of coastal flooding; the design of a new flood control scheme; the licensing of an extension to a landfill; and the remediation of a contaminated site).

Involving stakeholders and the public in appraising options can result in positive outcomes, such as the resolution of conflict, social learning (e.g. Bull *et. al.*, 2008), integration of a broader knowledge base and community support (e.g. Weber *et. al.*, 2001). However, there may be multiple decision-makers (for example, planning authorities and environment agencies) that need to be involved in appraising the options. In this case, it is important to make clear to those involved the objectives and the limits of what can be achieved. For example, it may not be possible to change a land-use planning decision, but it may be possible to place conditions upon what is built and how it is operated. If people have expectations about what their engagement might achieve that are not fulfilled, the credibility of the process, the organisation and the decision can all be lost (Petts, 2008). These issues are discussed further in Chapter 6.

Case Study Box 13

Estimating flood damage cost to agriculture to inform risk assessment

School of Applied Sciences, Cranfield University, Bedfordshire, UK

Exceptional rainfall during the summer of 2007 caused widespread flooding and economic damage in England (Chatterton *et. al.*, 2009). Over 42,000 hectares of farmland were seriously affected, at the time of year when crops were approaching harvest and grasslands were being grazed or cut for winter feed (Figure 18). The 2007 floods provided a useful, albeit unfortunate, opportunity to assess the economic impact of large scale flooding on farming. This is required to inform the appraisal of flood risk management and investment options, whether to justify protection of high value agricultural land or to assess the cost of temporally storing flood waters on farm land to alleviate urban damage downstream.

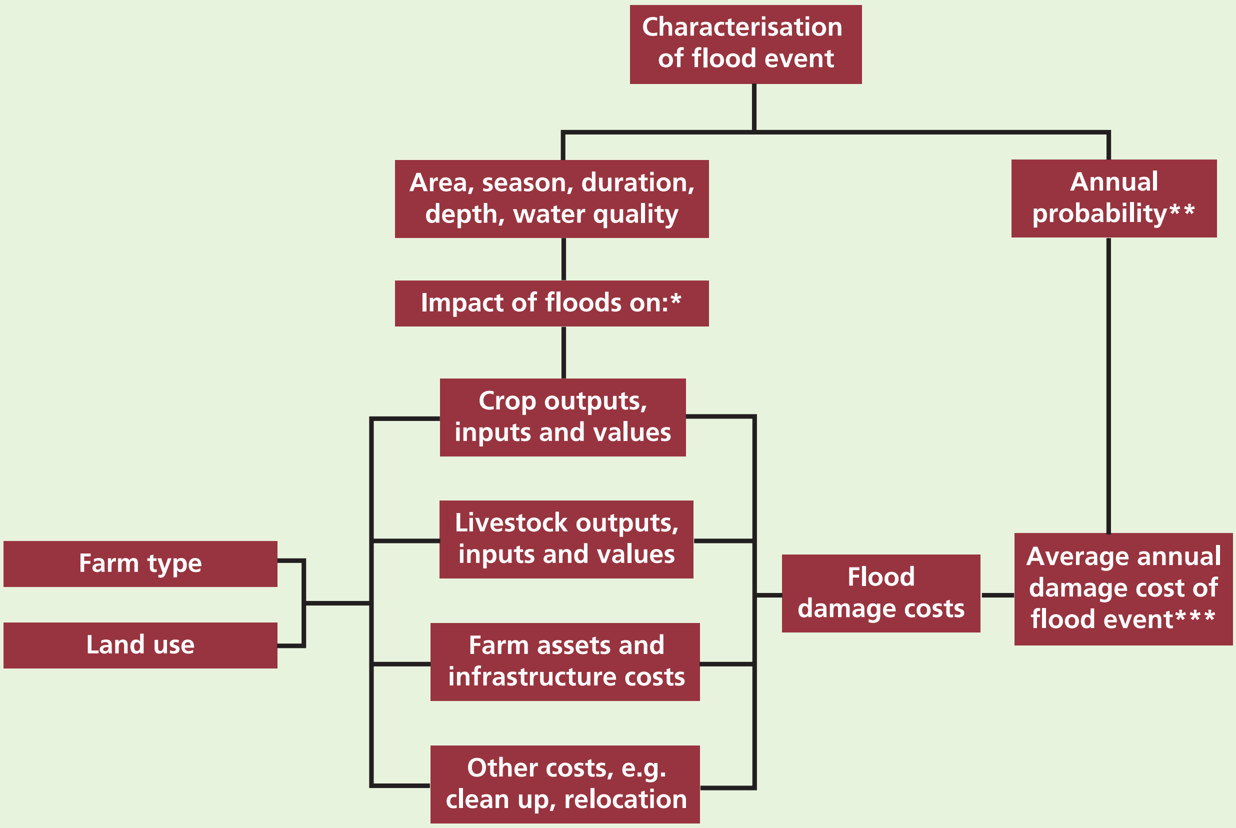
A personal visit survey of 78 farmers affected by flooding in the 2007 event was carried out in the West Midlands, Oxfordshire and Yorkshire, covering about 14% of the total agricultural area flooded (Posthumus *et. al.*, 2009). The method used is summarised in Figure 19.

Average flood damage costs were estimated at £1200 per hectare flooded, highest on horticultural and vegetable crops and lowest on grassland. Over 80% of flood damage costs were associated with losses of output and additional production costs, and the rest concerned damage to farm assets such as machinery, property and infrastructure.

At a total of £50 million, the costs to agriculture were only about 2% of the total estimated economic cost of the 2007 Summer Floods in England. At the farm level, flood damage costs (excluding household property) averaged about £80,000, with a median value of £43,000. Only about 5% of agricultural flood damage costs were insured compared with around 80% in the urban sector.

This case study serves three main purposes: (i) it provides evidence-based estimates of flood damage costs of summer flooding on farm land, (ii) it helps to refine the methods for estimating flood damage costs for benefit assessment of flood risk management options involving farmed areas (Penning-Rowsell *et. al.*, 2005) and (iii) it confirms the vulnerability of farming to extreme events and reveals how farmers might manage flood risks associated with future climate change, including the possible use of insurance.

Figure 18: Flooding on the River Avon, near Tewksbury, in July 2007 caused extensive damage to high value crops.



* Relative to situation 'without' this type of flood event.

** Probability of an event of this type occurring within the next 12 months.

*** Average annual damage costs associated with an event of this type and probability (i.e. flood risk).

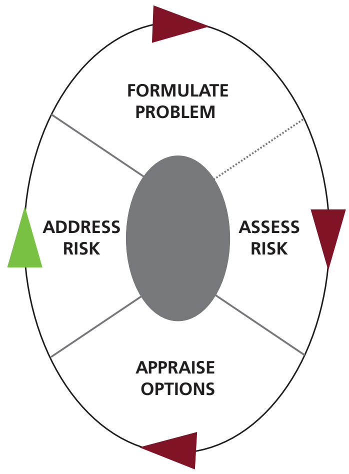
Figure 19: Procedure for assessing flooding risks

4.4 Summary

Evaluating risk management options involves identifying and considering a range of potential risk management techniques. The risk management options available are to terminate, mitigate, transfer, exploit or tolerate the risk. To select the preferred option, the potential positive and negative impacts associated with each option are considered according to technical factors, economic factors, environmental security, social issues and organisational capabilities. The decision-making process can be complex, owing to trade-offs between these factors, and because the consideration of one issue often has to take its place within a portfolio of concerns (i.e. the finite and limited money available often needs to be distributed across a portfolio of risks). Multi-criteria decision analysis (MCDA) provides a practical way to compare decision options when there are multiple criteria for assessing those options. Involving stakeholders and the public in appraising options can result in positive outcomes, but there may be multiple decision-makers that need to be involved and, therefore, it is important to be clear about the objectives and the limits of what can be achieved. If unsustainable environmental degradation is preventable, a lack of full scientific certainty should not be used as a reason for postponing cost-effective preventative measures. The best option is likely to be the one with the greatest excess of benefits over detriments, compared to the other possible options. The required response is about finding a balance within the boundaries of what is tolerable and justified by reference to the residual risk.

CHAPTER 5
Addressing the Risk

5.1 Implementing the risk management strategy



Addressing the risk involves undertaking any action, procedure or operation to fulfil the objectives of the risk management strategy identified at the options appraisal stage (Chapter 4). If a risk needs to be terminated, then all or part of an activity should cease. This may include the decision not to proceed with a new proposal or contracting out of an existing project. When a risk needs to be mitigated to an acceptable level, the treatment can often be built into operational activities. For example, Case Study Box 14 shows how the risk of flooding is managed in high-risk areas in England and Wales where flood defence schemes and improvements are being considered. If a decision was made to transfer a risk, risk managers could look to:

- use insurance;
- amalgamate the risk with another that is already managed to an acceptable level (hybrid risk transfer);
- arrange partnerships; or consider
- outsourcing. In practice however, risk can rarely be outsourced in its entirety. Even when liabilities are contractually transferred, reputational impacts may return to the origination of the risk.

Care should be taken that the risk is actually transferred and details of this are recorded. In addition, some risks (e.g. reputation) cannot be transferred. For example, whilst contract clauses might protect an institution against the less responsible operations and practices of outsourced parties, in practice these risks may still return to 'bite' the contracting organisation. Further details on operational risk management at the institutional level are provided in Appendix 4.

If the opportunity that a risk presents is to be exploited, the event should be made to happen in a measured, informed, calculated and monitored fashion. It may also be possible to increase the probability and therefore maximise the benefits.

To accept a risk generally means implementing a reactive approach without taking explicit actions. When implementing this strategy, it is important to clearly acknowledge acceptance of the risk(s) and monitor the effectiveness of the strategy (Section 5.8).

Case Study Box 14

National flood risk assessment (NaFRA)
Environment Agency, UK

The National Flood Risk Assessment (NaFRA) was developed to provide information on flood risk. This was a key part of the move to planning flood management on the basis of risk, rather than reacting to flood hazard. NaFRA is a generic quantitative risk assessment using a standard model designed for nationwide application. NaFRA results are available throughout the floodplain in England and Wales. Detailed quantitative flood risk assessments are used to appraise options at specific sites, particularly for high risk areas where flood defence schemes and improvements are being considered.

How the assessment works

The process used to create the national flood risk assessment is as follows:

1. The flood outline is split into impact zones that are 50m x 50m in size.
2. Information on flood defences; i.e. their location, standard of protection and condition are linked with the impact zones to identify which defences affect which impact zones. Information about the height of the natural banks affecting each impact zone is also added.
3. Predicted flood water levels are then compared to the height of the natural banks and the defences to calculate the likelihood of flooding by defences and natural banks overtopping for each impact zone.
4. The same predicted flood water levels are then compared to the condition of defences to calculate the likelihood of the defences failing and the effect that this would have on each impact zone.
5. The overall likelihood of flooding for each impact zone is calculated by combining the figures above.
6. The flood likelihood results are then put into three categories:

   Significant – where the likelihood of flooding is greater than 1.3% (1 in 75) in any one year

   Moderate – where the likelihood of flooding is between 1.3% (1 in 75) and 0.5% (1 in 200) in any one year

   Low – where the likelihood of flooding is less than 0.5% (1 in 200) in any one year.

How the risk is managed

Outcome measures have been set for the Environment Agency (EA) and other operating authorities managing flood risk. The five outcome measures appear in Table 7. The targets show what the capital programme, i.e. spending on flood defence upkeep and improvement projects – is expected to contribute to these measures until 2011.

Table 7: Outcome measures of NaFRA for the EA and other Operating Authorities (EA, 2009).

Outcome measures until 2011	Definition	Minimum target
Economic benefits	Average benefit cost ratio across the capital programme.	Five to one average with all projects having a benefit cost ratio greater than 1.
Households protected	Number of households with increased protection against flooding or coastal erosion risk.	145,000 households of which 45,000 are at significant or greater flood risk.
Deprived households at risk	Number of households in the 205 most deprived areas for which the likelihood of flooding reduces from significant or greater risk.	9,000 of the 45,000 households above.
Nationally important wildlife sites	Hectares of sites of special scientific interest (SSSI) land where there is a programme of measures.	24,000 hectares.
UK Biodiversity Action Plan habitats	Hectares of priority Biodiversity Action Plan habitat including intertidal, created by March 2011.	800 hectares of which at least 300 hectares should be intertidal.

5.2 Responsibility for residual risk

Whether the risk management strategy terminated, mitigated, transferred, exploited or accepted the inherent risk, residual risks may remain. The responsibility for addressing the residual risk is either shared by society (e.g. societal risk), remains with the individuals involved in developing or implementing the risk management strategy (e.g. private risk) or it is transferred further (e.g. to insurers).

5.3 Reporting the risk management strategy

Reporting risk management strategies is an important part of addressing the risk, particularly regarding decisions on addressing the most serious risks, and needs to be quickly and effectively communicated to the appropriate level and the appropriate individual within an organisation (Cooper *et. al.*, 2005). It is essential to be aware of accountability at both the organisational and individual levels (National Research Council, 2009).

At a time of crisis, the public generally expect the Government to provide a strong lead and to take charge of events and manage situations, thereby protecting the public. Where there is a need for leadership and reassurance, or a need for accountability and justification of decisions, the public will often look to governing authorities to deliver clear messages on how risks are being managed. When reporting a risk management strategy to the public, communicating the importance of self-responsibility to the public should not be forgotten. The actions of an individual may exacerbate an outcome (either for themselves or for others) and, if the public are not aware that they also have a responsibility to take reasonable care, the fault may be unduly proportioned to other organisations. A number of cross-cutting aspects relating to communicating the risk management process are detailed in Chapter 6. These should be referred to and considered prior to communication.

5.4 Surveillance and monitoring of residual risk

Surveillance implies an active evaluation of changing circumstances. Perhaps the residual risk is sensitive to some external influence that requires active monitoring. For example, a change in European environmental legislation may initially have no impact, but may have an impact over time as environmental attributes change and, therefore, the implemented risk management strategy requires monitoring (Case Study Box 13).

The emergence of new risks may be the result of a diverse set of risks such as climate change, increasing urbanisation, demographic changes, changes in social attitudes towards risk acceptability, and advances in technologies available to reduce risk. This can result in a new set of conditions against which existing risks should be compared and altered if necessary. The implication is that environmental risk assessments need to be living documents rather than static one-off reports. This issue of reviewing the entire risk management process is detailed further in Chapter 6.

5.5 Contingency planning

High-impact events with a low probability, such as certain animal disease outbreaks, severe flooding or natural disasters, are often addressed with the development of an emergency plan and a business continuity plan that ensure essential business activities can continue in the face of serious disruption as a result of these events (Defra, 2007). In general, regulatory bodies have strategies in place for contingency planning. For example the Environment Agency has in place a flood warning system to provide sufficient warning to those living in flood risk areas. The Health Protection Agency has a handbook for recovery options following a radiation incident (Nisbet *et. al.*, 2008). Water UK has a guide for effective control of water-based contamination incidents (Water UK, 2003). The Food and Environment Research Agency (Fera) produced guidance on the decontamination of buildings exposed to chemical, biological, radiological or nuclear materials (Fera, 2011). Also, some environmental risks (e.g. Case Study Box 14) are part of the National Risk Assessment and therefore the National Risk Register (Cabinet Office, 2010).

Likewise, the scale of risks and whether local, national or international intervention is required should be considered. It is important to look at the potentially wider consequences of a risk so that decisions based on a local situation are appropriate on a national and international scale, mitigating the potential for conflict and environmental damage or harm. If this happens in advance, then decision-making in a crisis of international proportions is likely to happen faster and with greater justification and public satisfaction. Effective public engagement is vital for the success of such strategies (Chapter 2 and 6).

5.6 Summary

Addressing the risk involves undertaking any action, procedure or operation in order to meet the objectives of the risk management strategy. The risk management strategy needs to have a documented rationale; it is important to be explicit and clear about the actions that you will undertake in support of the risk management strategy. Reporting risk management strategies is an important part of addressing the risk and can benefit one or a number of stakeholders.

Case Study Box 15

Did a change in legislation increase the likelihood of Gyrodacytlus salaris introduction to the UK?

Centre for Environment, Fisheries and Aquaculture Science), Weymouth, UK

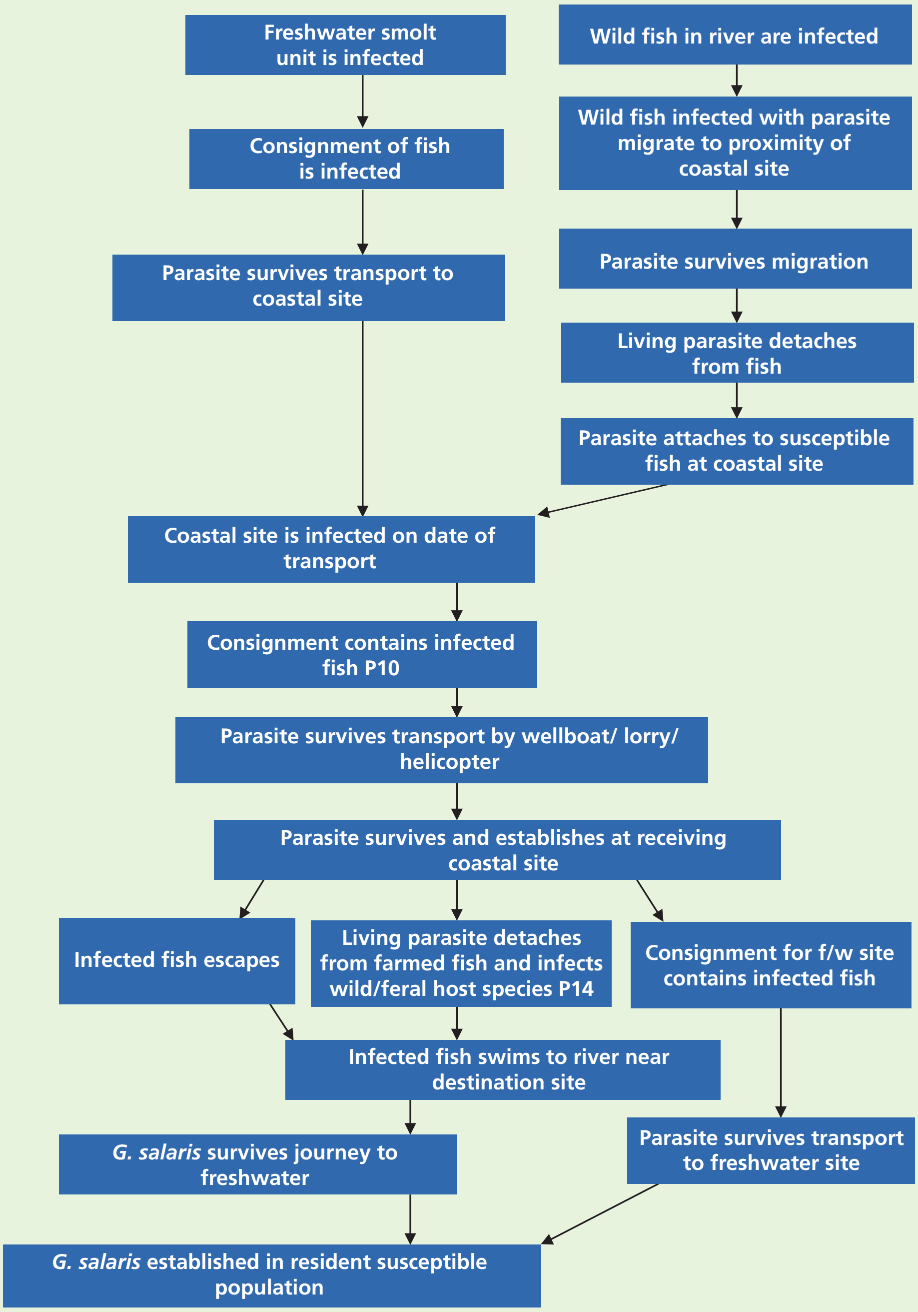
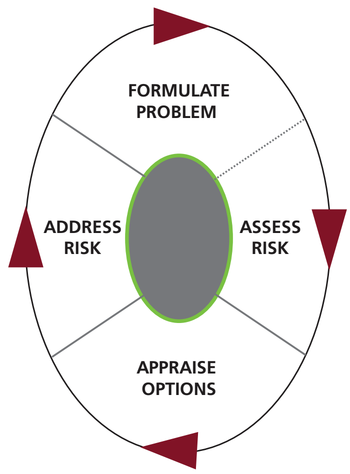


Figure 20: Scenario tree for the introduction of G. salaris from coastal sites to uninfected areas.

An assessment was carried out on the risk posed to UK salmon by allowing the movement of Atlantic salmon from coastal sites in countries where an Atlantic salmon parasite exists. Import risk assessments are generally undertaken in response to a proposed new trade. The rules governing trade in live fish within the EU is determined by European legislation. The European Commission proposed a change in legislation to allow movement of live Atlantic salmon from coastal sites in countries where the *Gyrodactylus salaris* (a monogenean ectoparasite of Atlantic salmon) was present but where the salinity does not drop below 25 % (parts per thousand) to territories which were officially free of the parasite. Potentially this increased the probability that *G. salaris* would be introduced to the UK and a risk assessment was undertaken (Peeler *et. al.*, 2006). A scenario tree of events, necessary for the introduction and establishment of the parasite was constructed (Figure 20); relevant information was identified, and the probability of each step qualitatively assessed. Salinity was shown to be the key environmental determinant of parasite survival; at 25 % the parasite survives for approximately 22 hours. The change in legislation did not create routes with a higher level of risk of *G. salaris* introduction per consignment of fish, compared with existing routes (i.e. from approved *G. salaris* free freshwater zones). Thus, based on the equivalence principle of the SPS agreement of the World Trade Organisation, there was no basis to challenge the change in legislation. However, as a result of allowing imports of salmon from coastal sites the total volume of live fish imports increases, and thus the absolute probability of *G. salaris* introduction, may too increase.

CHAPTER 6
Cross-Cutting Aspects of Risk Management

6.1 Introduction



As risks are dynamic in space and time, and the context in which they may be realised changes, managing a risk effectively can thus require regular ongoing monitoring, iteration of the previous analysis (Chapter 2 to 5), deliberation, and constructive communication and learning during the processes. Such activities strengthen the evidence base that supports the risk management strategy and ultimately help to reduce the uncertainties that surround the risk problem. This is particularly the case for those risks that might be deemed marginal in their magnitude or, because of their specific characteristics, are sensitive to change. Examples include where the progressive erosion of cliffs increases the risks to people and property over time, or where changes to international border controls influences the likelihood of exotic animal disease agents entering a country. Reporting risk management strategies is therefore an important part of addressing the risk and can benefit one or a number of stakeholders.

This Chapter serves to reinforce the general cross-cutting aspects to consider during the environmental risk assessment and management process.

6.2 Learning

Here learning refers to the gaining an awareness of knowledge, expertise, information, skills, values, expectations, failures and successes as a result of the risk assessment and management process. Learning as such is often inevitable, but should nonetheless be sought and acknowledged. Particularly as awareness of environmental problems has grown and people have become more concerned about risks to the quality of the environment and to their health; demands have increased for better engagement in environmental risk assessment and management. Sharing information and learning through communication and iteration are discussed in the following sections.

6.3 An iterative approach

Adaptive management aims to reduce uncertainty in the risk management process by taking an iterative approach. An iterative approach includes all stages as described below (Section 6.2.1 to 6.2.4). Put simply, iterations address whether the original concern (e.g. groundwater protection, the environmental release of chemicals, the effectiveness of flood gates) is still the main concern, and whether the environmental setting (source of hazard, exposure pathways, position and number of receptors) has altered since the original risk assessment. Frequently, new information comes to light during a risk assessment; either through research commissioned or by newly discovered or volunteered data. Risk analysts need to be open to revisiting earlier assumptions, redoing calculations on risk estimates, altering the conceptual model as new data comes to light, and exploring alternative scenarios. Often, local knowledge can be supplied by the public, stakeholders or other parties.

6.3.1 Problem formulation

It is important to review the process whereby the problem was formulated, specifically the conceptual model of exposure (Chapter 2), which is unlikely to be static. Also, the problem formulation stage may need to be completed more than once in order to complete planning for the risk assessment.
For example, a more sophisticated risk assessment may be necessary if preliminary screening indicates that an unacceptable risk could be associated with a particular action or event. The more sophisticated risk assessment would require either new data or more detailed models.

6.3.2 Risk assessment

The risk assessment process is by nature iterative (Chapter 3). An iterative risk assessment may be carried out even when a chosen risk management action is in place. If initial assessment indicates that the desired or necessary goals may not be reached, further iterations proceed until the goals are reached. Care should be taken that attempts to gather ever more information do not clash with the need to make a timely decision (so-called 'paralysis by analysis').

6.3.3 Options appraisal

Reappraisal of the options should not just be a review of what has already been considered. Each risk management option should be reassessed through the risk assessment process to determine whether it reduces the risks to an acceptable level.

6.3.4 The risk management strategy

A principal question for reviewing the risk management strategy is: are the measures in place (still) effective? Technological, organisational and economic solutions for risk reduction may also change with time. New institutional arrangements may be put in place that alters the accountabilities for risk management (e.g. legislation, contracting out operations). The technological performance of engineering systems (e.g. treatment plant) will deteriorate over time. Also, the financial support for continued risk management activity may dry up or become harder to justify in time, especially if it is perceived to be effective. In other words, an absence of failures may be used as a rationale for relaxing investment in risk management. It is possible that social attitudes to risk may also change and that demands for the level of risk reduction require tightening or relaxing. As the appropriateness and effectiveness of risk management actions are influenced by scientific and technical analysis as well as the opinions of stakeholders, iterations should include these opinions until competence, fairness and efficiency are ensured. Section 6.4 provides further guidance on the communication process.

6.4 Communication

Effective and well-planned risk communication can improve the reputation of the risk owner, and can help to implement the risk management strategy efficiently, control cost, and reduce stigma (Ash and Leone, 2006). The Cabinet Office (2003) state that understanding risk is important for: crises prevention; making better decisions on how to handle risk; smoother implementation of policies set out to manage risk; reassuring and empowering the public; and building trust in scientists, the Government and the media.

The following list gives examples of important elements to bear in mind when attempting to improve public involvement in risk-related decision-making:

- risk is complex and inherently uncertain;
- outrage shapes risk perceptions and behaviours;
- effective communication must be a two-way process;
- effective communication is necessary but not sufficient;
- trust and credibility are both essential;
- credibility is based on more than scientific and technical competence;
- expectations need to be managed;
- what works well in one context might fail in another; and
- differing viewpoints might be irreconcilable.

The success of any engagement effort and its impact on decision outcomes is not only dependent on the quality of the involvement opportunities offered to local communities, but is equally shaped by the motivations, ambitions and capacities of the individuals and groups engaged in the process.
When feasible, the benefits of public engagement include:

- ensuring that the decision reflects local circumstances and priorities;
- providing a form of 'quality control' by opening expert assessment to questioning and challenge;
- highlighting the uncertainty inherent in risk decisions;
- providing assurance that legitimate concerns have been addressed;
- promoting transparency in decision making;
- promoting consensus on the best option;
- resolving potential conflict early;
- enhancing public trust in decisions; and
- potentially ensuring that people are not exposed to actual or perceived risks.

In a democratic society, there will be diverging views about the merits and risks of many activities (Stern and Fineberg, 1996). Reasonable and effective public processes cannot expect unanimity, but it is equally certain that conflict will arise if decisions are made and imposed on parties who reasonably consider themselves to be directly affected and who have authentic concerns.

6.4.1 The frequency of reporting

The frequency of reporting on the risk assessment and management process should reflect how dynamic the changes in the underlying context are. For example, a national climate change risk assessment may be reviewed on a 5-yearly basis (Case Study Box 12) whereas changes to risk at a rapidly expanding integrated refinery may require annual review. When reporting on a risk management strategy, it is important to realise that the outcome of assessments on new or emerging risks are sometimes contradictory. For example, studies have highlighted how the use of a genetically-modified (GM) plant of cotton by Mexican and Indian farmers improved their living conditions. Yet, contrasting studies emphasise its potential negative impacts, such as the development of pests resistant to controls, reduced biodiversity, and the pollution of non-GM crops with GM material. This highlights the need for iteration in order to strengthen the evidence base for justifying and subsequently communicating a risk management strategy. In turn, this provides an effective learning base for future risk assessments and iterations.

6.5 Summary

Recognising the dynamic nature of environmental risk places a requirement on risk assessors and those that commission risk assessments to monitor the outcome of the risk management strategy and to iterate the process when necessary. A critical factor here is whether or not the risk management strategies in place continue to control the risk to the level of acceptable residual risk. Therefore, it is as important to review the problem formulation process, each stage of the risk assessment and the risk management options identified. Perhaps the original risk problem is no longer the main concern, or the environmental setting has changed since the initial risk assessment, or what constitutes the acceptable level of risk has shifted. As awareness of environmental problems grows and people have become more concerned about risks to the quality of the environment and to their health, demands have increased for more and better engagement in environmental risk assessment and management. However, consideration should be given to whether public involvement could violate the principle of fairness. Throughout the process, learning should be acknowledged and maintained as an exchange between those involved in or affected by the risk assessment and management process.

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Appendix 1

Definitions

Accountability	Obligation to account for activities and disclose results in a transparent manner.
Aleatory uncertainty	Uncertainty that stems from the inherent variability of any natural system.
Assessment endpoints	An expression of the environmental value that is to be protected, operationally defined by an entity and its attributes. For example, a freshwater lake is a valued ecological entity; the flux of nutrients from its tributaries is an important attribute. Together, lake productivity and nutrient flux can form an assessment endpoint.
Assurance	An evaluated opinion, based on evidence gained from review, on the organisation's governance, risk management and internal control framework.
Benchmark dose	An alternative to the LOAEL (lowest observed adverse effect level) and NOAEL (no observed adverse effect level) for setting regulatory levels such as acceptable daily intakes. The approach provides a more quantitative way of obtaining regulatory levels for health effects assumed to have a nonlinear low dose–response relationship (Setzer and Kimmel, 2003).
Decision-making	The process of identifying the likely consequences of decisions, working out the importance of individual factors, and choosing the best course of action to take.
Delayed effect	A long time of latency between the initial event and the actual impact of damage.
Engagement	Where the public and/or stakeholders are asked to directly and actively take part in decision processes, but a public agency/authority is still responsible for the decision.
Environmental security	An environment protected from harm or adverse affects caused by natural or human processes so that resources are sustained for future generations.
Epistemic uncertainty	Uncertainty that originates from a lack of knowledge.
Expert	An individual widely recognised by their peers as a source of information/skills within a specific domain.
Exploiting risk	Adopting a strategy to increase the likelihood of exploiting unexpected positive effects (Hillson, 2001). Rather than hoping for an identified potentially positive effect to result from a chosen strategy, exploiting the risk can involve making an identified opportunity happen.

Exposure	The nature and level of a situation or biological, chemical or physical agent that an environmental component (landscape, water body, animal, etc.) may be subjected to intentionally or non-intentionally.
Extent of damage	Negative consequences of human activities or events.
Governance	On a national scale, governance refers to the structure and processes for decision making that involves non-governmental and governmental actors (Nye and Donahue, 2000). On a global scale, governance represents an organised structure of regulation encompassing state and non-state actors that bring combined decision without the presence of one superior authority (IRGC, 2005).
Hazard	A situation or biological, chemical or physical agent that may lead to harm or cause adverse affects.
Horizon scanning	Systematic activity designed to identify, as early as possible, indicators of changes in risk.
Impact	The effect that a risk would have if it happens.
Inherent risk	The risk arising from a specific hazard before any action has been taken to manage it.
Persistency	The temporal extension of potential damages.
Precautionary principle	Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.
Public	Lay members of the public, with or without a defined interest or expertise; can be individuals or groups.
Public risk	Those risks that affect any part of society and for which Government is expected to respond.
Qualitative risk assessment	Describes the probability of an outcome in terms that are by their very nature subjective as the assessment typically assigns relative values to assets, risks, controls and effects.
Quantitative risk assessment	A methodology used to organise and analyse scientific information to estimate the likelihood and severity of an outcome. In this approach, objective numeric values are calculated for each component gathered during a risk assessment.
Residual risk	The exposure arising from a specific risk after action has been taken to manage it and making the assumption that the action is effective.
Responsibility	The duty or obligation to satisfactorily perform or complete a task.
Reversibility	The possibility to restore the situation to the estate before the damage occurred.

Risk	The consequence(s) of a hazard(s) being realised, and their likelihoods/probabilities.
Risk analysis	The process of determining what decisions are appropriate to protect a system or environment from harm or adverse affects. This encompasses problem formulation, risk assessment, risk management and risk communication.
Risk appetite	The amount of risk that an organisation is prepared to accept, tolerate, or be exposed to at any point in time.
Risk assessment	The formal process of evaluating the consequence(s) of a hazard(s) being realised and their likelihoods/probabilities.
Risk characterisation	The process of providing an unbiased estimate of the level of risk being considered.
Risk management	The process of analysing exposure to risk before determining how best to handle the situation.
Risk owner	The person who has overall responsibility for ensuring that the strategy for addressing the risk is appropriate and who has the authority to ensure that the right actions are being taken.
Risk profile	The documented and prioritised assessment of the range of specific risks faced by the organisation.
Risk rating	A classification (e.g. high, medium, low or very low) given to a risk, based on its likelihood and potential impact.
Risk strategy	An organisational approach to risk management, which should be well-documented and accessible.
Semi-quantitative risk assessment	A numerical risk estimate based on a mixture of qualitative and quantitative data.
Scenario building	Scenario building provides a structured way to think about and plan for future uncertainties, and explores plausible pathways of how more than one possible future might develop.
Stakeholders	Individuals who are interested in or affected by an issue or situation.
Susceptibility	A condition that increases the likelihood that an environmental component will be exposed to a particular hazard.
Uncertainty	Limitations in knowledge about environmental impacts and the factors that influence them. It originates from randomness (aleatory uncertainty) and incomplete knowledge (epistemic uncertainty).
Vulnerable groups	Those who are prone to show more adverse responses than other groups, given the same exposure.

Appendix 2

Legislative requirements for risk assessment

The obligation to carry out environmental risk assessments arises from a range of European Directives and UK Statutory Instruments. For example, under the EU Directives on environmental impact assessment (97/11/EC) and strategic environmental assessment (2001/42/EC), practitioners are required to manage the aggregation of environmental effects past, present and in the reasonably foreseeable future by means of a cumulative effects assessment (CEA). Some pieces of legislation that specifically require a risk assessment include:

- Environmental Permitting Regulations (England and Wales) 2010;
- Directive 97/11/EC amending Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment;
- Directive 2001/42/EC on strategic environmental assessment;
- Directive 2000/60/EC on establishing a framework for community action in the field of water policy;
- Directive 79/409/EEC on the conservation of wild birds;
- Directive 99/92/EC on explosive atmospheres (ATEX 137);
- Nitrate Pollution Prevention Regulations 2008;
- Climate Change Act 2008;
- Control of Substances Hazardous to Health Regulations 2002 (COSHH);
- Control of Asbestos at Work Regulations 2002;
- Control of Lead at Work Regulations 2002;
- Dangerous Substances and Explosive Atmospheres Regulations 2002 (DSEAR);
- Water Resources Act 1991;
- Chemicals (Hazard Information and Packaging for Supply) Regulations 2009;
- Environmental Protection Act 1990 Part II – Waste Management;
- Waste Electrical And Electronic Equipment Regulations 2006 – Updated 2009;
- Hazardous Waste Regulations 2005;
- Town and Country Planning Act 1990; and
- EU REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) legislation (EC 1907/2006).

In addition, legislation exists to ensure public participation in the process of environmental risk assessment and management. Following the signature of the Aarhus Convention by the Community on 25 June 1998, the Community adopted in May 2003 Directive 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC.

Chemicals considered under REACH legislation

Chemicals with production or importation levels between 1 tonne/year and 10 tonnes/year must initially be considered within the EU REACH (Registration, Evaluation, Authorisation and restriction of CHemicals) legislation. For those species not covered by REACH (e.g. polymers, species under customs supervision or radioactive species) the risk assessment methodologies described above come into use. For non-isolated intermediates, for example, those species produced only within a chemical reaction and that are not released separately, no further hazard assessments are available.

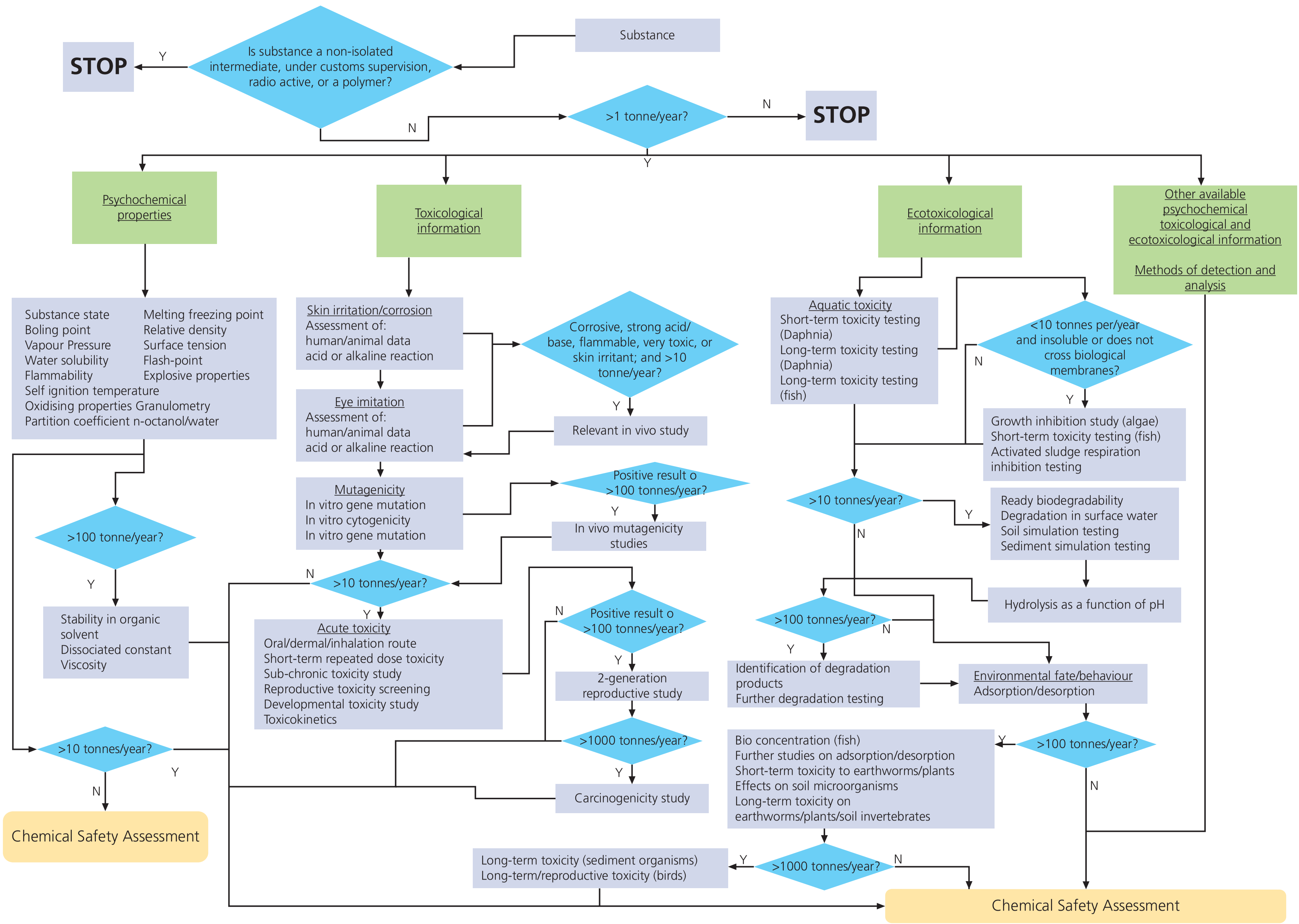

Figure 21: A flow chart demonstrating the systematic approach to assembling either a Chemical Safety Assessment or Chemical Safety Report for chemicals that come under the REACH legislation (i.e. those with production or importation levels between 1 tonne/year and 1000 tonnes/year). The diagram shows that the level of detail varies with particular weight and information triggers throughout the process (from Rocks *et. al.*, 2008).

Appendix 3

Endocrine-disrupting chemicals

Endocrine-disrupting chemicals (EDCs) are exogenous substances or mixtures that alter the function of the endocrine system and, consequently, cause adverse health effects in an intact organism, or its progeny or (sub) populations. The EDCs of greatest concern in the environment include various persistent organic pollutants (POPs), pesticides, phthalates, metals, and other compounds such as bisphenol A (Welshons *et. al.,* 2006). Due to the resistance of these chemicals to degradation, they have been distributed in small quantities throughout the world. Once they enter natural waters, they bioaccumulate in phytoplankton, zooplankton and fish (Figure 22), and may biomagnify up the food chain resulting in potential widespread human exposure to these chemicals.

Studies have associated exposure to EDCs with human and animal health impacts such as on brain structures involved in cognition and mental health (Lupien *et. al.*, 2009), adult ovarian dysfunction, the injury of salmonid olfactory tissue, and by extension, contribute to the threatened and endangered status of many salmonid stocks (Tierney *et. al.*, 2008). As a result, the Department for Environment, Food and Rural Affairs (Defra), the water industry, the Water Services Regulation Authority (Ofwat) and the Environment Agency (EA) have been working collaboratively to design an Endocrine-disrupters demonstration programme (EDDP) to help prevent these adverse effects of EDCs. In addition, concerns have been raised as to whether these chemicals should be considered as single compounds or whether they should be grouped together via endpoint or mechanism of action for a true representation of their effects, and consequently the assessment of the risk such chemicals have.

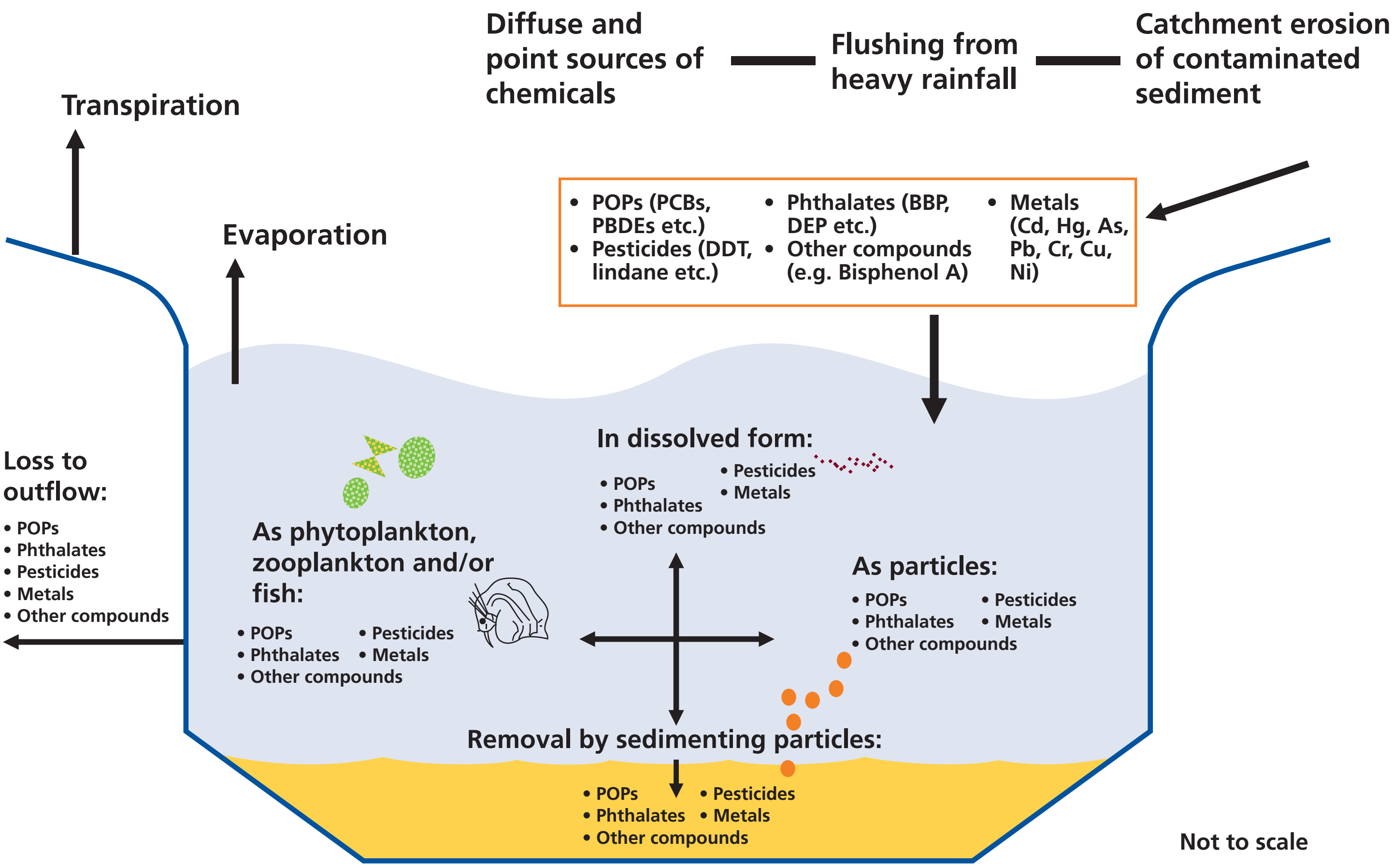

Figure 22: The biogeochemical cycle of EDCs at the cathment scale.

Appendix 4

Classifications of uncertainty

A number of classifications of uncertainty within environmental risk assessment and management processes are listed below.

- *Data* – pertaining to the level of confidence associated with its truth and correctness. Associated issues may relate to its availability, accuracy, or general trustworthiness.
- *Language* – its use is both unavoidable and necessary, and connected uncertainties primarily stem from a lack of clarity. For example, terms may be underspecific or ambiguous.
- *System* – relating to a lack of knowledge about the causes, processes, and effects within investigated systems.
- *Variability* – the inherent unpredictability of any human or natural system. It may be quantified and sources and factors contributing to the variability identified through statistical methods.
- *Analytical* – concerns the variability within processes employed, such as sampling or interpretive techniques, and therefore a change in procedure or sampling environment may alter the results of the analysis.
- *Model* – concerning the representation of real-world processes in model form.
- *Decision* – where doubt surrounds an optimal or preferred course of action, often in the face of differing objectives.

Identifying uncertainties is the first step towards quantifying them. Whilst only epistemic uncertainties can be reduced (i.e. data, language, system), clear recognition of all uncertainties can help improve the quality at every stage of the risk assessment process. The question "how safe is safe enough" must be answered even when considerable uncertainty exists in new technology in order to enable society to function. Where unknowns are significant, the precautionary principle can be used to enable decision-making.

Appendix 5

Risk management at the institutional level

Environmental risk management is an important function at the institutional or organisational level and it has grown in prominence over the last 15 years. The interface between corporate and environmental risk management is a particular area of debate. The Strategy Unit (2002) described a hierarchy of institutional risk (Figure 23). Strategic risks are associated with corporate priorities; programme or tactical risks are associated with institution-wide activity delivering to strategic priorities; and project or operational risks are localised and specific to individual projects. On occasion, risks to or from the environment may feature among the strategic risks of an organisation – for example, the possibility of floods overwhelming some critical infrastructure, resulting in the threat of a major outage of power or water supply with subsequent service loss to customers including vulnerable groups. In these cases, environmental risks must be considered alongside other strategic business risks within an integrated, enterprise-wide risk management framework.

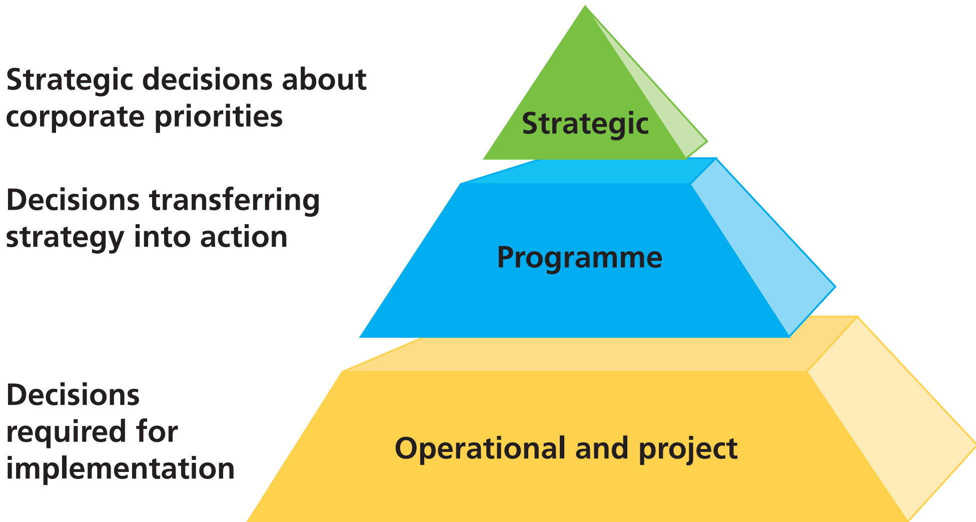

Figure 23: Strategic, programme and operational risks (after Strategy Unit, 2002).

Environmental risk versus business risk

Some of the key issues for consideration in comparing environmental risks with other business risks include the observations that:

- environmental impacts are not easily monetised and are often difficult to express in quantitative terms. This should not detract from their importance;
- environmental risks are frequently newsworthy events that pose considerable knock-on reputational impacts to organisations;
- environmental impacts may be felt over timescales well beyond conventional business planning cycles (decades, centuries);
- outsourced operations may incur environmental risks through the less responsible operations and practices of contracted parties. Whilst contract clauses might guard against these impacting on the institution, in practice these risks may still return to 'bite' the contracting organisation;

- being concerned with open, heterogeneous systems, environmental risks frequently harbour more uncertainty that those associated with closed, engineered systems;
- regulatory risk is often greater for environmental impacts because of the rapidly developing nature of environmental legislation; and
- regulators increasingly view corporate responsibilities to managing environmental risks as a surrogate for corporate social responsibility and good risk governance in general.

Internal auditing

Internal audit will verify compliance with the requirements of the risk management goals and explore the elements involved in identifying, assessing and addressing risks. Auditing should encompass the quality of available data, suitability of assigned responsibilities and the timescales for action. By assessing and auditing the internal risk management capabilities of the organisation, and comparing these with external organisations in similar sectors, institutions have sought to gauge where improvements can be made to their own processes. Some 10 years of benchmarking practice in risk management have revealed the importance of organisational culture, leadership on risk issues, the necessity of discussing an institution's appetite for risk and the management of risk knowledge as critical components of a well-developed risk management capability (Figure 24).

Leadership and Strategy **Integrity and Ethical Values** • Leader creates ethical workplace • Personal ethical practices **Communicate Mission and Objectives** • Policies and procedures • Top-down alignment of strategy	People and Communication **Commitment to Competence** • Employee competence • Training **Information and Communication** • Information quality • Top-down communication • Communication across processes
Accountability and Reinforcement **Assignment of Authority and Responsibility** • Assignment of ownership • Demonstrated accountability **Human Resource Policies and Practices and Performance Measurement** • Performance indicators • Incentives and discipline	Risk Management and Infrastructure **Identify and Assess Risk** • Risk assessment practices • Risk tools and processes **Establish Processes and Controls** • Process reliability and efficiency • Control effectiveness and efficiency • System access and security

Figure 24: Components of good risk governance (after PriceWaterhouseCoopers, 2005).

Climate change

One example where the requirements of environmental and business risk management are increasingly close is that of climate change. Through a range of statutory and other mechanisms, businesses are being expected to demonstrate to those who are affected by, or interested in, risk how they are considering the future impacts of climate change within their strategic business planning. For some sectors, especially those operating essential infrastructure (water companies, power utilities, waste companies, highways and rail network providers), future climate risks are likely to be a key consideration. Other examples of strategic environmental risks may include the continued use of production chemicals that are becoming increasingly obsolete under revised legislation and supply-chain risks associated with the extraction of minerals at source.

Ethical risks

In addition to these technical environmental risks, institutions may also face ethical risks posed by contentious developments, activities or future proposals. In countries where native indigenous populations have accepted rights over specific natural resources, organisations may be required to manage corporate risks initiated by perceived threats to cultural practices, spiritually significant land and ways of life. These issues have been historically underplayed whilst organisations focused on establishing corporate risk frameworks, risk committees and champions, and risk registers. We have learnt in practice that the cultural and business process elements of good risk management are critical. This infers the importance of the organisational and people framework alongside the competent application of technical tools and process.

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