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Considerations for applying the ERICA Integrated Approach

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ERICA (Environmental Risk from Ionising Contaminants: Assessment and Management) will provide an integrated approach to scientific, managerial and societal issues concerned with the environmental effects of contaminants emitting ionising radiation, with emphasis on biota and ecosystems. The project started in March 2004 and is to end by February 2007.

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Executive Summary

The ERICA Integrated Approach begins with problem formulation, see Figure A. All decisions taken during this first stage, with regard to protection of non-human biota, will guide the assessment to be carried out and impact on the options available once results are obtained.

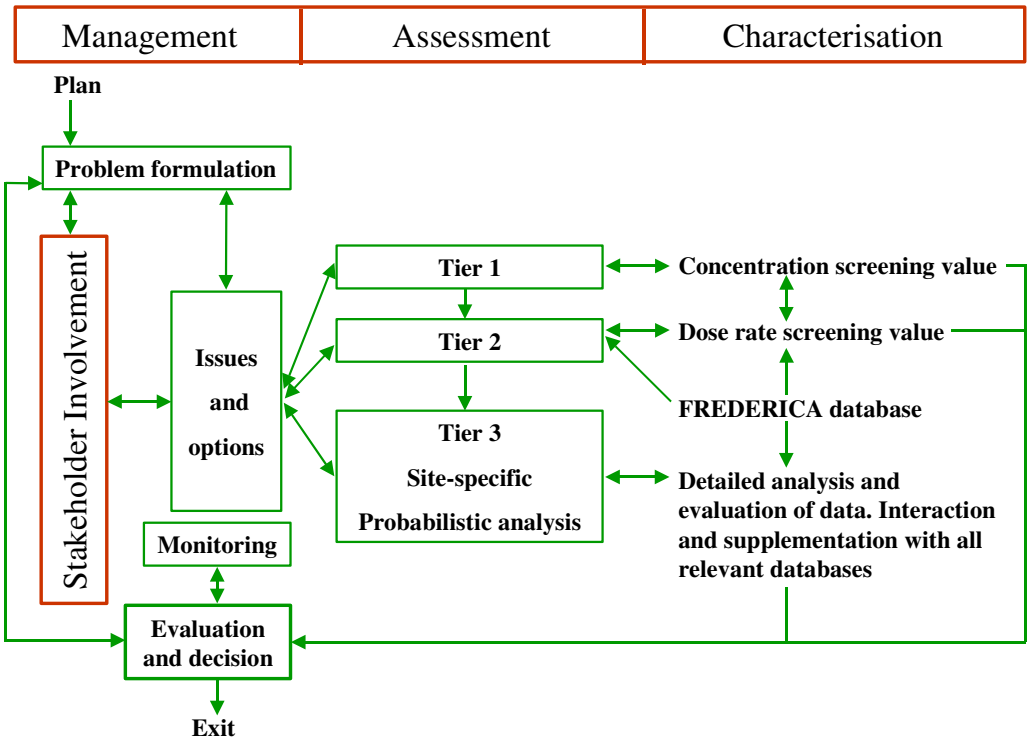

Figure A: Illustration of the ERICA Integrated Approach.

Decisions need to be taken prior, during and after the assessment. **To aid assessors, this report collates information to be considered at the formulation stage, which will impact on the scope of the assessment**. For each of the following topic, strengths and weaknesses of the options available are also included:

i) societal factors affecting decision-making;

ii) stakeholder Involvement;

iii) uncertainty types and approaches, as uncertainty relates to at all stages of the risk assessment process;

iv) a selection of issues and options: risk assessment criteria and standards; risk quotient; natural radiation;

v) accidental scenarios;

vi) monitoring for compliance and verification; and

vii) concluding an assessment.

Some considerations within this report extend outside the ERICA Integrated Approach, but these help the assessor to decide whether ERICA is suitable for his purpose.

Whilst the overall outcome of the exercise may need to take into account other issues outside the remit of the ERICA Integrated Approach, see Figure B, an assessor must be able to provide a concluding statement on the protection of non-human biota.

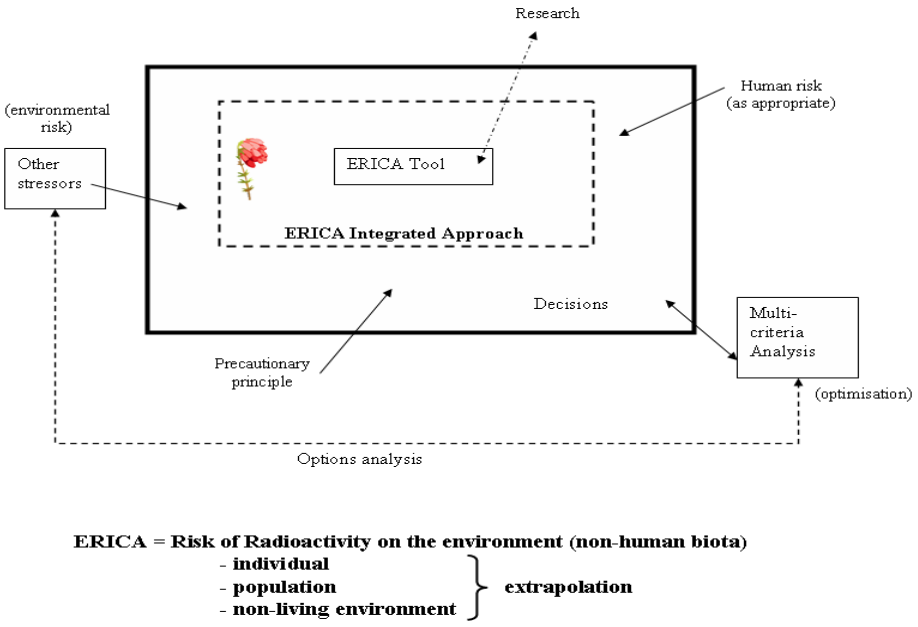

Figure B: Illustration of factors affecting decisions – not exhaustive.

<u>Published separately:</u> D8 Annex A: Review of international legal instruments that may influence decision-making.

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Also published separately:

D8 Annex A: Review of international legal instruments that may influence decision-making.

1 Problem Formulation

The FASSET framework, seen in Figure 1.1, as well as the ERICA Integrated Approach, Figure 1.2, begins with problem formulation. All decisions taken during this first stage, with regard to protection of non-human biota, will guide the assessment to be carried out and impact on the options available once results are obtained.

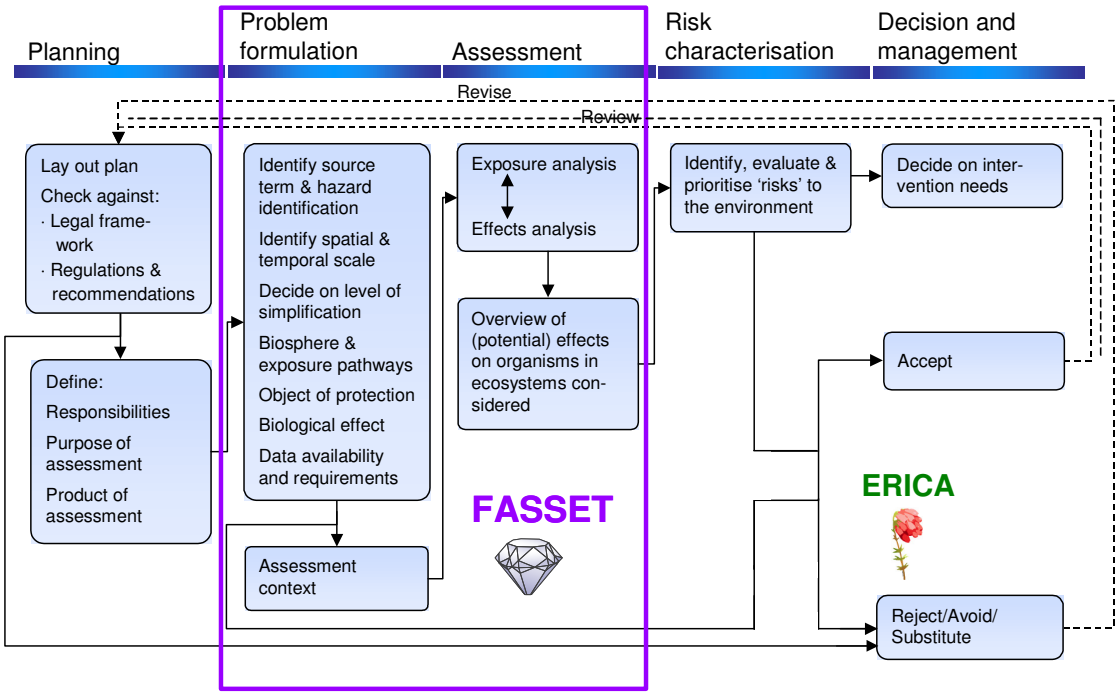

Figure 1.1 FASSET Framework and interaction with ERICA.

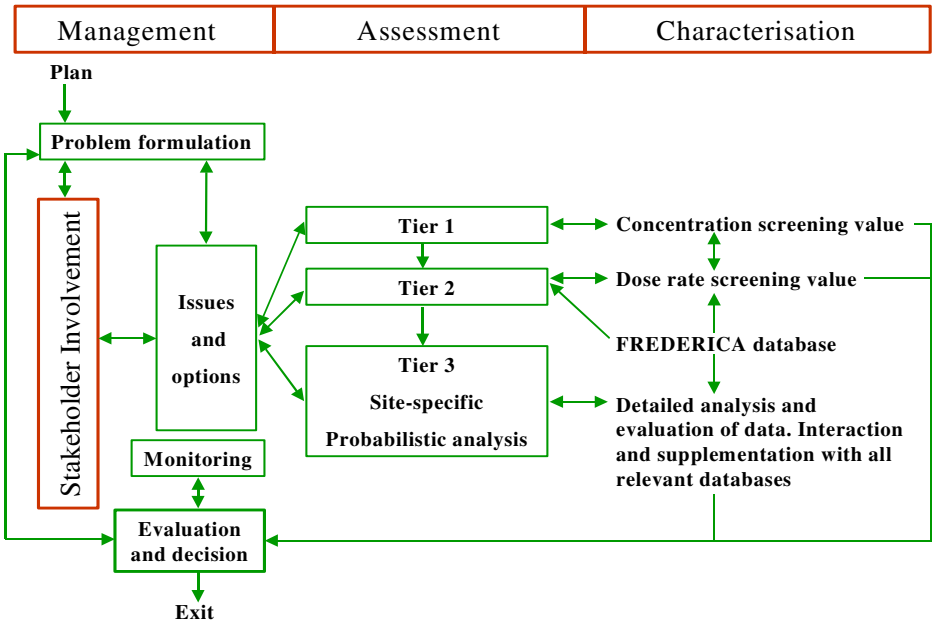

Figure 1.2: Illustration of the ERICA Integrated Approach.

Whilst the overall outcome of the exercise may need to take into account other issues outside the remit of the ERICA Integrated Approach, an assessor must be able to provide a concluding statement on the protection of non-human biota.

Within the ERICA Integrated Approach, decisions are taken prior, during and after the assessment is carried out. **To aid assessors, this report collates information to be considered at the formulation stage, which will impact on the scope of the assessment**. For each given topic, strengths and weaknesses of the options available are also included.

- Chapter 1 – Societal factors affecting decision-making.
- Chapter 2 - Stakeholder Involvement.
- Chapter 3 - Uncertainty types and approaches, as uncertainty relates to at all stages of the risk assessment process.
- Chapter 4 - A selection of issues and options: risk assessment criteria and standards; risk quotient; natural radiation.
- Chapter 5 – Accident scenarios.
- Chapter 6 – Monitoring for compliance and verification.
- Chapter 7 – Concluding an assessment.

1.1 Introduction

Problem formulation is defined as the first step of any risk assessment and is intended to *identify the context and purpose of the assessment framework*. This should include relevant ecological, political and societal issues, and should integrate the process of choosing appropriate assessment endpoints, identifying sources and describing the environment [Suter, 1993; Moore and Biddinger, 1995].

The International Commission on Radiological Protection (ICRP) intends its forthcoming recommendations, due 2007, to be applied to all sources in the following three types of exposure situations:

- *Planned exposure situations* - situations involving planned operations, including decommissioning, disposal of radioactive waste and rehabilitation of previously occupied land. Practices in operation are planned exposure situations.
- *Existing exposure situations* are exposure situations that already exist when a decision on control has to be taken, including natural background radiation and residues from past practices that were operated outside the Commission's recommendations.
- *Emergency exposure situations* are unexpected situations that occur during the operation of a practice, requiring urgent action. Emergency situations may arise from practices.

The ERICA Integrated Approach covers most of the assessment purposes likely to be encountered under these exposure situations, as shown in Table 1.2.1 However, the ERICA Integrated Approach has not specifically considered the dynamic modelling necessary for full characterisation of non-steady state and transient scenarios associated with early emergency situations; the methodology is nevertheless applicable to provide 'snapshots' of the situation. Furthermore, an emergency situation eventually, without a sharp boundary, transforms into an existing situation, where the ERICA Integrated Approach may be applied in full.

Table 1.2.1: Examples of assessment purposes under each ICRP exposure situation applicable to both nuclear and non-nuclear sectors.

Planned	Existing	Post-Emergency
a) siting a new facility, b) re-assessment of the authorisation of an existing facility, c) decommissioning a nuclear facility, disposal of radioactive waste, d) remediation of sites, e) controlled practices involving NORM/TENORM, f) clearance	a) long-term exposure after an accident, b) exposure from residues from past or existing practices (not carried out within the current radiation protection standards) non-intervention / passive remediation	a) accidents in nuclear facilities b) accidents in transportation of radioactive materials c) deliberate / malevolent uses, including terrorism

The process of problem formulation in any of the above exposure scenarios is crucial to the interpretation of the results of an assessment. Its purpose is to encourage the assessor to think carefully about the assessment to be conducted and to document decisions and assumptions in a clear and transparent manner. For example, it is important at this stage to establish whether a full environmental risk assessment (i.e. selection of Tier 3) is indeed appropriate.

The problem formulation also represents the first stage at which an assessor might leave the process. A decision **not** to proceed might be made on either technical grounds (*e.g.* no direct exposure route) or social grounds (*e.g.* a veto on discharge of radionuclides regardless of risk to biota).

A number of elements can be considered when defining the problem, the purpose and extend of the assessment. This will also help justifying the tier selected to begin the assessment. Such factors include:

- identification and characterisation of the source – some notes in Section 4.4;
- identification of the receiving media – some notes in Section 4.3;
- legislative/regulatory requirements – see Section 1.1;
- assessment criteria, see Section 4.1;
- stakeholder involvement – see Chapter 2;
- conceptual model description; and
- risk characterisation, see Section 4.2.

Table 1.2.2 gives further information on each element.

Table 1.2.2: Elements of problem formulation for consideration.

Element	Definition	Examples of questions to answer as well as actions/decisions
Identification and characterisation of source	Identify anything that may cause radiation exposure, *e.g.* emitting ionising radiation or release of radioactive substances or materials. Identify the type of radiation and/or radioactive substances.	Which: (i) radionuclide(s) and (ii) ecosystem should be considered?
Identification of the receiving media	Identify recipient(s) and identify size and duration of exposure(s) and ecosystem(s) affected.	Exit assessment (i.e. no route between source and potential recipient). If recipient is identified, consider other elements as discussed in this table.
Legislative / regulatory requirements	Legal framework governing the acceptability of the source in question. Legal framework that requires an assessment to be carried out and how to do it.	Exit process (*e.g.* source not acceptable or exposure, of *e.g.* a protected habitat, not acceptable). Level of Stakeholder involvement (see below). Definition of protection endpoints, which may be referred to in legislation *e.g.* EU Habitats Directive.
Assessment criteria (choose and justify)	Preparation of a procedure for summarising the results of the evaluation, incorporating management criteria specific to a particular assessment that may influence the relative importance of different items considered.	Which: (i) endpoint(s), (ii) dose (rate)s or environmental concentration(s), and (iii) screening value(s) should be considered?
Stakeholder involvement	Take into account views of stakeholders. A stakeholder is defined as anyone who has an interest in or considers themselves to have an interest in the issue and therefore it goes beyond "representatives" of groups to include "interested members of the public".	Which stakeholders should be involved? How to create awareness among stakeholders? What: (i) stage of engagement, and (ii) method of engagement should be used? What results and actions from the consultation to be implemented?
Conceptual model description (source, pathway and receptor)	Representation of the environmental system and of the physico-chemical and biological processes that determine the transport/transfer of contaminants from sources through environmental media to ecological receptors within the system. The conceptual model is useful to help a) explain and support the decisions made by the assessor; and b) explain to any potential stakeholders how the problem under assessment has been defined.	What are the data requirements? What site-specific information is needed?

Element	Definition	Examples of questions to answer as well as actions/decisions
Risk characterisation	The synthesis of information obtained during risk assessment for use in management decisions. This should include an estimation of the probability (or incidence) and magnitude (or severity) of the adverse effects likely to occur in a population or environmental compartment, together with identification of uncertainties.	Record uncertainties Levels of environmental detriment and risk Should other contaminants be considered in the assessment? Should Sensitivity Analysis be carried out?

1.1.1 Other considerations

There are further elements that may influence the way in which the assessment will be carried out as well as how the outcome is interpreted. Two major examples are:

- **What about uncertainties?** The assessor should be able to identify and record uncertainties related to the processes under study at least in a qualitative sense in Tiers 1 and 2. At Tier 3, the problem formulation stage may help describe how the uncertainties can be included in the assessment using probabilistic approaches. Uncertainty is discussed in Chapter 3.
- **What are the results of the assessment?** In the case of an ERICA Tier 3 assessment, the assessor must be aware that the ERICA tool Tier 3 results consist of the following set of information:

  1. dose rates;
  2. effects data for those dose rates are mainly for individuals not populations;
  3. probability distributions of dose rates; and
  4. guidance for deriving benchmarks, for a given endpoint or organism.

  The assessor must consider this when setting the assessment criteria to protect the environment. The outcome will be either that risk is below concern, that there is insufficient confidence that the risk is below concern, or that the risk is of concern.
- **What about spatial or temporal averaging?** At its simplest level an assessor may wish to input the maximum measured or modelled activity concentration in the media of interest (soil, water etc) in Tier 1 to be conservative. However, in some cases, an assessment may be required for a contaminated area with clearly defined spatial boundaries or with a well-defined mixing zone for aquatic discharges. In these cases, spatial averaging may be desirable if not a prerequisite for calculations at Tiers 1 and 2. In other cases, selection of sampling sites beyond a mixing zone to mitigate, for example, the influence of short time-scale spatial and temporal fluctuations in contaminant levels may be required. The key point here is that the assessor needs to explain the reasoning behind their decisions on which activity concentration values should be entered into the assessment tool and which form the basis for subsequent calculations of dose rates to different species.

Other elements of concern may be identified by any party involved in the assessment, including reviewers and stakeholders. Any such elements need to be recorded and their relevance and weight assessed to secure the transparency of the decision-making.

1.2 Societal factors affecting decision-making

The objective of the ERICA project is to provide an integrated approach to scientific, managerial and societal issues concerned with the assessment and management of environmental effects of contaminants emitting ionising radiation, with an emphasis on biota and ecosystems. The objective of this chapter is to provide an overview of the main factors that influence decision-making within that context prior to starting an assessment. These include the following:

- international radiation protection guidance
- international law and binding agreements;
- socio-economics; and
- stakeholder involvement.

Each of these aspects of decision-making are considered below.

1.2.1 International radiation protection guidance

At present, there are no internationally agreed criteria that explicitly address protection of the environment from ionising radiation. Traditionally, the system of radiological protection has been focused on the protection of man. National and international policies and legislation related to radiological protection are generally based on the recommendations of an international advisory body, the International Commission on Radiological Protection (ICRP) which, until recently did not deal explicitly with environmental protection. In its 1990 recommendations, ICRP stated that '*The Commission believes that the standards of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk*' [ICRP, 1991].

In 2000, the ICRP set up a Task Group to consider the issue of environmental protection and the role of ICRP in this regard. This group proposed an approach to 'fill the conceptual gap' in radiological protection in its report in 2003 [ICRP, 2003]. This approach is based on the development and use of a small set of reference animals and plants, with their associated dose models and data sets. This approach is designed to be harmonised with that for the protection of humans. It is also closely associated with the approaches adopted in the FASSET [Larsson, 2004], EPIC and ERICA programmes, and related to those underlying the US and Canadian approaches.

The following reference animals and plants were identified: deer, rat, duck, frog, trout, flat fish, bee, crab, earthworm, pine tree, grass and seaweed. The criteria governing the choice of these animals and plants include the level of radiobiological information available; the extent to which they are amenable to future research; the degree to which they are representative of particular ecosystems; whether they are likely to be exposed to radionuclides as a result of bioaccumulation and their lifecycle; the ease with which their exposure can be modelled and their resonance to members of the public.

The International Atomic Energy Agency (IAEA) also addressed the issue of the protection of other species [IAEA, 1976, 1979]. More recently, the IAEA continued by considering the effects of current radiological protection standards on animals and plants in terrestrial and freshwater environments [IAEA, 1992], and then by identifying issues that would need to be resolved in establishing a framework for environmental protection [IAEA, 1999]. In 2002, IAEA published a report on the ethical considerations underlying environmental protection, which identified the following key principles: sustainability; maintenance of biodiversity; conservation and preservation; environmental justice and human dignity IAEA [2002]. In 2003, IAEA organised an international conference on protection of the environment from the effects of ionising radiation [IAEA, 2003], which strongly supported the development of a framework for environmental radiation protection and clarified the roles of the various international organisations involved.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) also considered the full range of information available on the effects of ionising radiation on non-human biota, and related dosimetric issues, in its report of 1996 [UNSCEAR, 1996]. UNSCEAR concluded that '*chronic dose rates less than 400 µGy/h (10 mGy/d) would have effects though slight in sensitive plants but would be unlikely to have significant deleterious effects in the wider range of plants present in natural plant communities*' and that there is little indication that dose rates up to an order of magnitude less than 40-100 µGy/h (for the most sensitive animals, mammals) would affect either mortality or reproductive endpoints. For aquatic organisms, a maximum dose rate of 400 µGy/h '*would not have detrimental effects at the population level*' [UNSCEAR, 1996]. In the absence of other information, these values have been widely used as benchmarks for the comparison of the results of biota dose assessments; see for example Copplestone *et al.* [2001].

The International Union of Radioecology (IUR) has also demonstrated its continuing interest in this issue, and its support for the reference organism approach [Pihet 1998; Strand *et al.,* 2000].

The Nuclear Energy Agency of the OECD (NEA) has supported a series of meetings to facilitate stakeholder involvement in the development of a system for environmental radiation protection in Taormina in 2002 and Lanzarote in 2004.

National policies for environmental radiation protection, and associated standards and/or methodologies, are also under development in a number of countries, for example: Canada [Environment Canada, 2001 and Thompson and Chamney, 2001], UK [Copplestone *et al.*, 2001] and the USA [United States Department of Energy, 2002].

In summary, currently there is an absence of guidance on how to deal in practice with the protection of the environment from ionising radiation. Recently, significant national and international work has been undertaken by a range of organisations to address environmental radiation protection. However, this work is continuing and there is a need to consolidate a consensus on frameworks and assessment methodologies, and on the development and application of criteria.

National and local politics

While a consideration of national or local politics is beyond the scope of this report, it is clear that local politics and policies will influence the way in which decisions are made. There will be differences in the decision-making structures existing in different countries, for example the extent to which decisions and resource allocation is made by central government or by regional or decentralised bodies. The type of decision under consideration will also influence which bodies are involved. Furthermore, the state of existing institutional arrangements, and the nature of relations, and the competence and confidence existing between the different institutes involved, will have an influence on the success of the decision-making process. More particularly, the level of public trust in politicians and decision-makers will influence the perception of the decision-making process and the acceptability of the final decision.

A detailed consideration of different forms of decision-making in different countries is beyond the scope of this report. However, the international instruments discussed in this report provide the general context for many decisions, particularly since they inform national legislation and local and regional policies.

1.2.2 International law and binding agreements

There are a number of types of legislative instruments, which contain factors relevant to the management of risks associated with environmental effects of contaminants emitting ionising radiation.

There are, at present, no specific international standards or criteria that specifically address the protection of the environment from the effects of ionising radiation. Although one purpose of the Euratom Treaty is to guarantee high safety standards [European Commission, 2005], the Treaty and its subsidiary legislation are focused on protecting the health of workers and the general public, rather than non-human species.

But there is now a range of other international legislation and binding agreements that include requirements to protect the environment more broadly – including protection against the harmful effects of radioactive contaminants. It may therefore be concluded that there is a gap that needs to be filled, such that radiological protection approaches will be brought up to date with, and incorporate, current environmental protection requirements.

The range of legislative instruments includes:

- conventions (of varying regional relevance);
- protocols;
- EC Council Directives;
- EC Council Regulations.

These are, in some cases, underpinned by:

- agreements;
- EC Council decisions;
- EC Council recommendations;
- EC Council opinions.

In terms of making decisions about how to manage risks, it is useful to consider the factors that need to be taken into account to comply with legislative instruments. Such factors may be grouped into:

- actions which affect the amount of radioactivity entering the environment by controlling the source and are aimed at **general environmental protection;**
- actions which are aimed at **protection of specific ecosystems;**
- actions which are aimed at **the protection of specific environmental media;**
- **prospective and retrospective assessment of the impact** of the radioactive contamination;
- **monitoring or measurement of the impact;**
- gathering or dissemination of **information;**
- **decision-making;**
- specific factors which relate to **unusual events** i.e. radiological accidents or emergencies.

Table 1.3.1 summarises key provisions and factors affecting decision-making, derived from a review of existing legislative instruments. The main objectives, scope of international legal instruments of relevance in the European context, and the derived requirements, i.e. Table 1.1, are published as part of D8 Annex A. Many conventions contain a range of requirements that relate to different aspects of environmental protection and, for the purposes of this report, the key requirements are discussed under the functional headings above, to ensure that the full range of requirements are captured.

Table 1.3.1: Summary of key provisions and factors affecting decision-making derived from international legal instruments.

International law and binding agreements	Key provisions	Factors affecting decision-making
General environmental protection	• The requirement for prior authorisation of certain practices • The requirement for prospective impact assessment of certain practices • The prevention, reduction and control of impacts and of pollution at source	• The need to prevent, reduce and control potential sources of environmental contamination • The need to ensure nuclear safety to prevent environmental impact • The need to control shipments of radioactive substances
Protection of specific ecosystems and species	• Designation and control measures placed on areas or species of particular importance to conservation and the maintenance of biodiversity; • Effectiveness measured in terms of the ability of population dynamics and the ability of a population to maintain itself or for the habitat to support it. • The placing of controls on emissions into designated ecosystems	• The need to identify and designate species and areas of significance (*e.g.* for conservation or biodiversity) and to protect them accordingly • The need to establish a baseline status and surveillance measures • The need to establish suitable protective measures to species or areas defined
Protection of specific environmental media	• The placing of controls on emissions into particular environmental media. • Co-operation between contracting parties to achieve environmental objectives	• The need to control emissions into trans-boundary media, including air, watercourses and lakes
Prospective and retrospective assessment of the impact	• Environment Impact Assessments are required for all plans or projects likely to result in significant environmental effects. All direct and indirect effects of the project or plan should be taken into account (including impacts on fauna and flora). • Although nuclear safety provisions are generally based on the protection of human beings, the Convention on Nuclear Safety requires that assessments of the safety of existing nuclear installations be undertaken which take account of environmental impacts.	• The need to undertake EIAs for any plan or project likely to result in significant environmental impacts (in advance of decisions being made). • The need to ensure that assessments take account of direct and indirect impacts of all stages
Monitoring or measurement of the impact	• Monitoring of emissions and media is required to determine compliance with source-specific permit requirements and media-related environmental objectives. • Surveillance related to the status of the environment is required where there are protected species or habitats present, or	• The need to monitor compliance with emission limits and environmental objectives

International law and binding agreements	Key provisions	Factors affecting decision-making
	where there is a potential for significant environmental effects (for which SEAs are required)	
Provision of Information	• The provision of periodic reports on the status of various environments to other contracting parties. • The exchange of experience on, for example BAT and other scientific or technical advancements. • The notification of the nature of environmental effect, measures to prevent or reduce environmental impacts, alternatives and the nature the decision. • The provision of information to members of the public within a state in which environmental effects may occur on the nature of environmental effects, measures to reduce effects and alternatives.	• The need to exchange information with States potentially subject to transboundary impacts and to report on progress against specific environmental objectives included in various conventions • The need to make information available to the public in an accessible form particularly to provide for participation in decision-making
Decision- making	• That the results of environmental assessments, and the results of any consultations with other States or with the public, be taken into account in decision-making. • Public participation in the planning of projects that may have a significant impact on the environment. • Public participation in the establishment of regulations that relate to environmental protection.	• The need to take due account of the EIA and comments made in the decision-making process • The need to include all interested parties (including the public) in the decision-making process • The need to involve representatives from other Member States that may be affected by impacts
Unusual events	• The assessment and mitigation of potential impacts of accidents • The preparation of emergency plans • The provision of information to other States about the results of monitoring undertaken in response an emergency. • The establishment of agreements on liability and compensation	• The need to reduce and mitigate the impacts of any unusual event • The need to inform other States of monitoring results in the event of an accident • The need to agree arrangements for liability and compensation in the event of environmental damage

1.2.3 Socio-economic factors

As indicated above, international legal instruments, relating to environmental protection, include provisions that require environmental management decisions to take account of a wide range of factors. For example, there are requirements to protect areas of cultural as well as natural importance,

and to involve the public in decision-making and in the development of regulatory requirements. Moreover, the issue of sustainable development forms the background to many environmental management decisions: this by definition requires environmental, social and economic development objectives to be balanced. The application of the precautionary principle, and requirements to apply 'best available techniques' also require the balancing of risk, cost and benefits. **In practice, decisions regarding the acceptability of a plan or project will necessarily involve the consideration of a range of consequences, including potential impacts on human health, and environmental, economic, ethical and societal factors.** This may include, for example, considerations of social capital and issues linked to cultural heritage (such as community and local identity). Hence, the evaluation of risk needs to consider a number of criteria, in addition to health or environmental detriment. Such factors may be considered as part of a site-specific assessment, or in the specification of risk-based criteria that will inform site-specific assessments.

The following section considers the role of socio-economic analysis in environmental management decision-making in terms of the nature of risk criteria. The succeeding sections discuss the nature of socio-economic analysis and the approaches available for such analysis. **However it is understood that the ERICA Integrated Approach would only fit in the broader decision-making** and that this area falls outside the remit of the ERICA project. Figure 1.3 illustrates discussions held during one of the ERICA End-Users Group meeting [ERICA D7g, 2007].

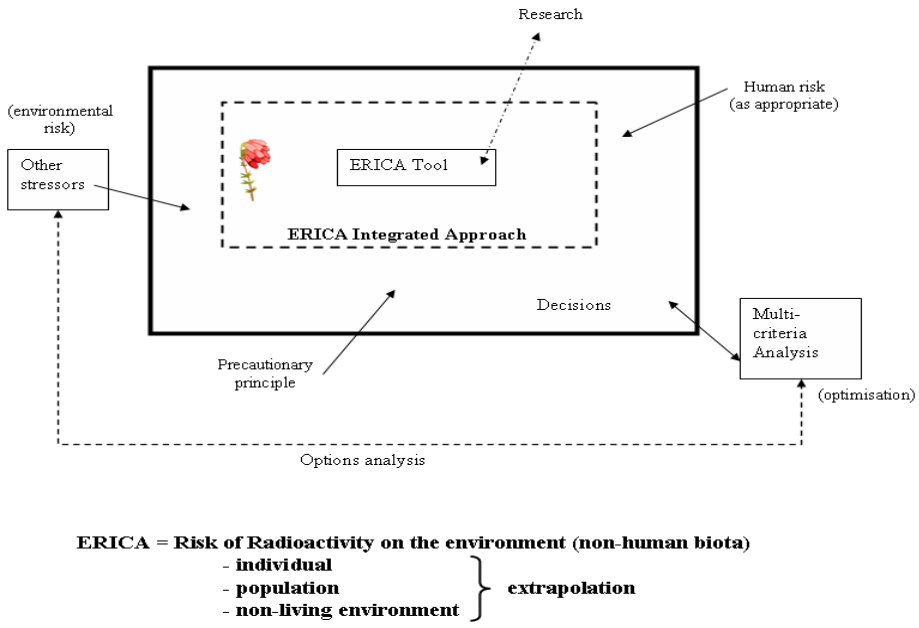

Figure 1.3: Illustration of factors affecting decisions – not exhaustive.

Risk-based criteria and decision-making

As indicated in more detail below, human health considerations have until recently been the primary driver for radiological protection, including for decisions relating to the input of radionuclides to the environment, or the management of radioactive material already present in the environment. For most routine situations, dose criteria exist that relate to 'unacceptable' risks to human health. Other criteria have been defined to denote levels that imply risks that may be considered to be 'trivial' or 'below

regulatory concern'. In many cases, these criteria have been derived by international and national bodies, on the basis of a socio-economic analysis of risk acceptance implied by practices in various types of industries, and in other forms of risk-related decision-making. When applied as strict dose limits, these criteria have the effect of taking some aspects of socio-economic analysis out of the scope of site-specific assessments. In effect, this approach rules out certain options on the basis of human health criteria. At levels between these criteria, or in situations such as accidents where the applicability of the criteria is debateable, there is scope for a more specific analysis of the socio-economic implications of decisions.

Environmental assessments, for other forms of pollution, have tended to focus on more site-specific analysis of potential environmental effects, rather than on the comparison with an externally defined generic risk criterion, (although environmental quality criteria exist for example related to concentrations in air, soil and water). Such analyses entail consideration of (amongst other things) the nature of the risk, the feasibility and cost of alternative courses of action that may lead to a lower risk, and the distribution of that risk over time, space and population group (or stakeholders).

The difference in the form of socio-economic analyses underlying human health and environmental impact assessments is partly due to the wider range of endpoints that need to be considered in environmental assessments (*e.g.* the range of species and forms of impact and the potential for ecological interactions).

Undertaking socio-economic analysis

Socio-economic analysis is a process that allows for the explicit, systematic and consistent consideration of social and economic factors, which have an impact on decision-making. It involves the clear definition of objectives together with the identification and appraisal of options for meeting those objectives.

One of the keys to undertaking socio-economic analysis, and in ensuring successful stakeholder involvement, will be the specification of its objectives. It is important the intentions of the commissioning body (and decision-makers) are clearly and accurately stated and that the concerns of the stakeholders are fully addressed. The UK Health and Safety Executive and the UK Treasury have suggested that objectives of a socio-economic analysis should be SMART (specific, measurable, agreed, reasonable and time-dependent) [HSE, 1995].

The key aspects of such an analysis are as follows:

- establishment of the baseline (the health, social, environmental and economic conditions in the absence of the risk or environmental management measure under consideration);
- identification and assessment of the risks and benefits associated with the risk or environmental management measure and alternatives (*e.g.* from application of ERICA);
- management of uncertainties and communication issues;
- consideration of the distribution of risks and benefits and the implications of this distribution;
- consideration of the time periods considered and the assessment implications of this and other assumptions.

The type of objectives that underlie the decision-making process may be illustrated by the social criteria recently identified by the UK Environment Agency to inform its decision-making [Environment Agency, 2005]. They set out to:

- promote health, safety and well being (including consideration of health, liveability and crime);
- help meet social needs (improvement in goods and services, contribution to urban and rural regeneration);
- promote fairness and social cohesion (promote equal opportunities and social justice, support the development of *social capital* or robust communities);
- demonstrate corporate social responsibility (external and internal responsibilities);
- increase stakeholder, citizen and community participation (by increasing effective engagement, develop appropriate partnerships, support appropriate external activities);
- help develop a learning culture (*capacity building*) (increase staff skills and knowledge of social issues and develop new areas of knowledge and practice).

These criteria are considered in conjunction with economic and environmental criteria.

Environment Canada [Environment Canada, 1997] has also identified a range of considerations used in chemical risk management that include:

- the implications for competitiveness of the industry concerned (and minimisation of financial burden);
- the provision of incentives for creativity and innovation in development and implementation of cleaner technologies;
- the ease of enforceability and compliance;
- the need to allow for economic growth within the framework of environmental requirements;
- the speed with which environmental objectives may be reached;
- fairness and the degree to which the measure will impose an unfair burden of certain sectors or stakeholders;
- intrusiveness and flexibility and the interaction between regulatory and industry responsibilities;
- the intensiveness and availability of necessary data;
- the compatibility with existing or other initiatives
- public acceptability.

Tools for socio-economic analysis

Given the diverse range of considerations that need to be included in the decision-making process, and the need for transparency implied by stakeholder involvement, a range of tools has been developed to facilitate a systematic approach to the inclusion of socio-economic factors in decision-making. The approaches most commonly encountered are: cost-effectiveness analysis (CEA); cost-benefit analysis (CBA) and multi-criteria analysis (MCA). The key features of these methods are as follows.

- CEA is based on the principles of economic appraisal. It may be used to identify the most cost-effective way of achieving a pre-defined target at the least cost (but it will not provide information about, for example, whether the benefits gained by an action outweigh the costs).

- CBA is based on the principles of welfare economics, and is based on the assumption that values (for example for risk avoidance) can be determined from individuals' willingness to pay to achieve them. This provides the potential for direct comparison of the implications of regulatory decisions, for example, but concerns are often expressed about the validity of converting some aspects of decision-making into monetary terms, particularly those connected to non-tradable goods such as health and environmental integrity. As a consequence, semi-quantitative approaches to its application have evolved.
- MCA is based on utility theory (and the identification of means that achieve the most overall utility or benefit). It specifically allows for the multi-faceted nature of decision-making by explicitly allowing qualitative and quantitative factors to be included in the analysis. It potentially allows the impact and the importance assigned to it to be distinguished from one another. The sensitivity of the decision to variations in the importance assigned to different factors can therefore be determined, thereby potentially facilitating transparent decision-making. However, there are often difficulties in defining scoring and weighting schemes and ensuring that factors are not double-counted. The techniques applied range from simple checklists to trend analysis and intricate mathematical procedures.

The context for, and the way in which, socio-economic analysis is undertaken varies amongst States and according to the type of decision being made. For example, the OECD undertook an analysis of regulatory appraisal practices in its Member States in 1997 [OECD, 1997] and identified that countries make use of a wide range of approaches, including: compliance cost assessments, CEA and CBA, checklists, simple scoring and weighting techniques, MCA and other qualitative/semi-quantitative approaches. Within the EC, a range of attitudes regarding the use of socio-economic analysis has been identified. Some Member States favour a precautionary approach, in situations where the existence of risks is highly disputed, while others place a greater emphasis on the fact that actions should not be undertaken that entail large costs in the absence of a significant benefit [European Commission, 1998]. As a result, there are also different views on the use of analytical tools; some Member States prefer simple checklist techniques, while others consider fully quantitative socio-economic techniques to be appropriate. In all cases, there is the question not only of what tool to use but also of who applies the tool and who decides the magnitude of the costs and benefits. As these include social values (noted in Section 2.3.2), the involvement of stakeholders and the public represents an additional consideration.

The selection of an appropriate analytical approach will depend upon the specifics of the situation. The decision-making context will determine the extent to which quantitative or qualitative analysis is appropriate. For example, the magnitude and complexity of the situation under consideration will influence the resources available for the analysis, the number of costs and benefits that need to be considered and the nature of information available. The EC has suggested that the form of analysis, appropriate for developing risk reduction strategies, will depend upon the following factors [European Commission, 1998]:

- the severity and extent of the risk;
- the scale of the drawbacks;
- the balance between the likely advantages and drawbacks;
- the information available within reasonable cost and a reasonable time frame; and
- the level of uncertainty surrounding the likely advantages and disadvantages.

A qualitative analysis will tend to be cheaper and may be appropriate in situations where there is general agreement over the measures to be taken. In other cases, there may be dispute over whether

projected benefits outweigh the costs and a more quantitative analysis may be required. In general, quantitative analyses will be more resource-intensive, although there is clearly a range in their complexity and corresponding resource requirements. It is necessary to balance the thoroughness of the analysis with the practicalities of its application.

A stepped approach to socio-economic analysis has been recommended by the Nordic Council of Ministers, with the magnitude of analysis being determined by the magnitude of the predicted trade-offs [Hokkanen and Pellinen, 1997]. Thus, the nature of the assessment should be based on the nature of the problem; if the impacts of the decision are limited to minor and localised increases in cost with limited impact on human health or the environment, then a relatively simple analysis may suffice. However, there may be need for more comprehensive analysis in cases where there is likely to be a significant trade-off between cost and benefit, with significant cost implications for a range of industries and other stakeholders, and possibly of controversial trade-offs between environmental impacts and human health. This approach is consistent with the ERICA Tiered Approach recommendations.

1.2.4 Stakeholder Involvement

The general premise of stakeholder involvement in risk assessment and environmental policy decision making is to involve stakeholders as early as possible in the assessment and management process, and that this engagement should be continuous and ongoing throughout the process. While the ERICA Tiered Approach supports stakeholder engagement, it is important to recognise that the type and level of involvement can be expected to vary with the progression of the assessment. The amount of resources directed towards stakeholder involvement needs to be kept in proportion to the assessment (i.e., how much might one justify in spending on public consultation to decide that there is no problem?). However, since many of the initial issues in the problem formulation stage of the risk assessment include social and political issues that extend beyond a technical evaluation, some form of stakeholder engagement is likely to be necessary even at this early stage.

Issues for consideration are discussed in Chapter 2.

1.2.5 How ERICA may interact with decision-making

The ERICA Integrated Approach is designed to aid environmental assessment, risk characterisation and management decisions related to ionising radiation. As indicated above, there are at present no specific international standards or criteria that specifically address the protection of the environment from the effects of ionising radiation. Relevant approaches are under development by a number of international organisations, notably the ICRP, and it would be advisable for any user of the ERICA Integrated Approach to keep informed of this work and to consider the possible practical implications of the emerging recommendations for the way in which ERICA is applied.

There is a wide range of international instruments that relate to environmental protection that will have an impact on the way in which the ERICA Integrated Approach is to be applied. While these pertain across varying geographical extents – from specific regions (*e.g.* the Alps) to pan-European Union (for EC Decisions and Directives) to the global extent of some United Nations Conventions, it is, nevertheless possible to identify some fundamental requirements that relate to environmental assessment, risk assessment and management that will need to be borne in mind in most cases.

The fundamental objectives of environmental protection are expressed in the Rio Declaration and the Convention on Biological Diversity. These place the environment at the centre of developmental decision-making (in the form of sustainable development) and place objectives on the maintenance and enhancement of biological diversity and on the conservation and preservation of particular species and habitats. These requirements imply the need for tools that can evaluate endpoints that relate to sustainable development, biodiversity and conservation conditions.

The central focus of sustainable development and the corresponding need to consider social, economic and environmental issues, in an integrated manner, highlights the fact that any environmental management decision will necessarily involve the consideration of a complex range of factors. The involvement of stakeholders (including the public) in decision-making is also one of the fundamental features of legal instruments related to environmental protection. This inevitably influences the degree of transparency required in the decision-making process and on the design of the decision-aiding tool. This consideration has informed the development of the ERICA Integrated Approach but it will also need to be a feature of the way in which it is applied. Technical information will need to be provided in an accessible form and the implications of both technical and socio-economic factors in the decision will need to be presented in a clear and consistent manner.

The details of the decision-making context and the country in which the decision is being made will influence the way in which ERICA is applied. The magnitude of the potential impacts and the legislative and regulatory procedures in place, and the role of stakeholders within these procedures, will have a profound influence on the scope of the ERICA application. For example, it has been recommended (by the Nordic Council of Ministers) that the level of detail of socio-economic analysis used to support the decision-making process be determined by the magnitude of predicted trade-offs. Thus, a simple checklist approach may be sufficient for decisions that are likely to result in minor localised impacts, while a more comprehensive (quantitative) analysis that involves stakeholders, will be required where there may be significant impacts on more than one group of stakeholders, particularly where decisions may involve potentially controversial tradeoffs. This recommendation is consistent with the application of the ERICA Tiered Approach.

The first stage of setting up an ERICA Integrated Approach comprises a detailed consideration of the decision-making context, i.e. the Problem Formulation – refer to Section 1.2. This will include consideration of the legislative framework, the scope of the application, an identification of potential impacts to be considered and the decision criteria against which they will be assessed. In undertaking such analysis, it is essential that its scope and objectives, and the extent and role of stakeholder involvement, be clearly identified. Thus, this stage may include, for example, consideration of which tier of ERICA need to be applied, in view of the legislative requirements relevant to the situation.

A range of legal instruments relate to the designation of areas, habitats or species that require special protection for various reasons, including ecological importance. The designation process is outside the remit of the ERICA programme but, once designated, ERICA would be used to establish a baseline assessment of, for example, conservation status, and to design and evaluate results from appropriate surveillance programmes to ensure that such areas are not placed under undue risk.

An Environmental Impact Assessment is required for any plan or programme that may significantly affect the environment. Undertaking such assessments and evaluating their impact on decision-making is likely to be one of the primary roles of ERICA. In defining the scope of an environmental assessment, it is important to take account of a range of factors, including the presence of designated habitats or species. The magnitude of potential impacts and the characteristics of the environment will have an influence on the applicability of generic assumptions and criteria, and thus on which tier of ERICA it is appropriate to use.

The ERICA Tier 3 implies a site-specific effects analysis; this would be particularly relevant to the consideration of impacts on designated species or habitats. This also allows a greater potential for considering multi-stressor impacts. ERICA Tiers 1 and 2 employ numerical criteria that are expressed in terms of concentrations or dose rates. ERICA would have a role to play in the specification of such criteria, by providing the technical data needed to relate dose rates and concentrations to particular effects that may have an impact on biodiversity or conservation, and by supporting the socio-economic analysis that underlines decisions regarding the acceptability or otherwise of a given level of risk. This is likely to be undertaken primarily by regulatory bodies, but in conjunction with the public (in

accordance with the Århus Convention [1998]). ERICA Tiers 1 and 2 applications may be more relevant when the likely impacts are low and an assessment of radiation impacts alone is sufficient.

The concept of pollution prevention (and the associated implications of controls placed at source) is another key feature of environmental protection included, for example, in a number of conventions related to protection of particular media. Permit and emission requirements are included in such instruments as the IPPC Directive [1996]and in the Basic Safety Standards [1996]. There are requirements that emission limits are based on considerations of best available techniques (BAT) and an assessment of best environmental practice (BEP), which implies the need for consideration of environmental impact, in which ERICA would clearly have a potential role. The BSS also requires assessments of risk – but to members of the public. In many cases in which ERICA is applied, it is likely to be necessary to consider the impacts on man and on the environment, in addition to the range of other socio-economic impacts identified above, such that consistency and transparency of approaches is desirable.

For the purposes of planning for unexpected events, ERICA may be applied to help define the environmental conditions that would constitute environmental damage, as the basis for international agreements on circumstances under which compensation will be required. There may also be a requirement to acquire monitoring information following an incident to determine the potential impact on the environment, and to determine the side effects of measures taken to protect humans in the event of an accident.

2 Stakeholder Involvement

2.1 Background

In recent years steps have been taken in the Commission and EU Member States to enhance the process of decision/policy making. A particular focus has been to improve the use of scientific evidence in decision-making. These developments have been driven by cases where there have been perceived failings in the use of science to inform decision-making – *e.g.* BSE – and by concerns about falling public confidence in decision-making processes. This section tracks recent developments in the Commission and, to illustrate parallel developments in Member States, in the UK.

2.1.1 European Commission

The publication by the European Commission in 2001 of a White Paper on European Governance [European Commission, 2001] led to an Action Plan on Science and Society [European Commission, 2002b] and the publication of guidelines on the collection and use of expertise by the Commission [European Commission, 2002a].

The White Paper recognised the need to open up the EU policy making process to get more people and organisations involved in shaping and delivering policy, and to boost confidence in the way expert advice influences policy decisions.

The Science and Society Action Plan had, as one of several aims, to "put responsible science at the heart of policy making". Specific actions proposed to meet this aim included:

- promote dialogue between the scientific community and other stakeholders on ethical and sustainability issues arising from scientific and technological developments
- initiate exchange of experience across Europe on risk assessment, management and communication of scientific uncertainty
- enhance mechanisms to provide scientific support to policy makers (leading to the SINAPSE (Scientific INformAtion for Policy Support in Europe) initiative – a web-based communication platform enabling the exchange of information between the scientific community and policy makers - http://europa.eu.int/sinapse/sinapse/index.cfm.

The guidelines on expertise apply to the collection and use of expertise by Commission departments and set out three core principles of quality, openness and effectiveness. The motivation for the guidelines included the issues of how to deal with conflicting expert opinion and to ensure that the processes for the collection and use of expertise are credible. With regard to the three principles set out in the guidelines:

- **Quality**: three determinants are identified:
- **Excellence**: advisors should be recognised as expert in their fields by their peers, but experts should include those with practical experience
- **Independence**: experts should act in an independent manner and practices should be established which promote integrity
- **Pluralism**: wherever possible, a diversity of viewpoints should be assembled, which should include minority and non-conformist views
- **Openness**: transparency is recognised as a key precondition for more accountability for all involved. The issues and the advice received should be made understandable to non-

specialists. The Commission must be capable of justifying and explaining the way expertise has been involved, and the choices it has made based on advice.

- **Effectiveness**: arrangements for collecting and using expertise should be designed in proportion to the task in hand

The guidelines apply whenever Commission departments collect and use advice of experts coming from outside the responsible department. However, they are not legally binding and do not apply to the formal stages of decision-making as prescribed in the Treaty and in other Community legislation. The guidelines have recently been criticised in this respect in a report by the European Policy Centre [European Policy Centre, 2005]

UK

Initiatives to improve the use of scientific evidence have been taken in several member states of the EU [see, for example, European Policy Centre 2005]. This section summarises developments in the UK as an example of those national initiatives.

The Modernising Government White Paper published in March 1999 [Cabinet Office, 1999a] sets out a significant agenda for reform of how government in the UK works. Enhancing policy making was identified as one of five key commitments. The white paper indicated that policy making should be a continuous learning process, should make better use of evidence and research, and should be "forward looking and shaped by evidence".

The "Professional Policy Making for the Twenty First Century" report [Cabinet Office, 1999b] followed in September 1999 setting out a descriptive model of a modern policy making process including nine core competencies (forward looking, outward looking, innovative and creative, using evidence, inclusive, joined up, evaluates, reviews, learns lessons). An audit of practice identified some examples of good practice but concluded that in some areas the policy making process was not as strong as it should be and that "little of the research commissioned by departments or other academic research was used by policy makers".

Guidelines on the use of science in policy making were issued by the Office of Science in Technology in 1997, and updated in 2000 [OST, 2000]. They set out the now well-rehearsed principles of looking ahead, seeking a wide range of advice from the best sources and publishing the advice and supporting papers. The current draft for consultation puts increased emphasis on the use of all forms of evidence and on public engagement, and poses questions about peer review and evaluation of departments' performance on the use of science in policy.

An OST report on the implementation of the guidelines [OST, 2001] identified a number of issues on the basis of feedback from departments including:

- difficulties in defining the key questions due to the lack of in-house expertise, particularly with respect to social dimensions
- the traditional approach of some policy officials
- lack of resources as an impediment to the full implementation of the guidelines, particularly with regard to stakeholder engagement.

The review by the European Policy Centre [European Policy Centre 2005] identified substantial common ground between national initiatives in defining good practice for the use of science in policy making. Nonetheless, experience in the UK suggests that the practical application of guidelines present ongoing challenges.

2.1.2 How Stakeholder Engagement may influence Problem Formulation

An allowance for public concerns and public participation is an essential part of environmental management and associated decision-making processes, as illustrated by the prominence given to public participation in the environmental international legal instruments, refer to Section 2.1.1.

It is useful to identify some of the characteristics of stakeholder involvement (including public participation) that need to be considered in making decisions. Different States place emphases on stakeholder involvement in decision-making, at all stages of the decision-making processes and employ a number of processes to achieve it. However, in general, it may be argued that involving stakeholders in the decision-making process should result in a process and decision that is more transparent and defensible.

Ideally, a stakeholder process should involve representatives from all sectors of the society potentially affected by the decision, for example: the relevant industry, government departments, the general public, environmental organisations and other interested non-governmental groups. Timing, communication and approaches to ensure that those involved in the process are truly representative are important features of a successful process. Of course, securing the involvement of truly representative stakeholders is not an easy task and the resolution of conflicting views in reaching a final decision is often a complex process. Tables 2.1.1 and 2.2.2 identify:

(a) a list of possible stakeholders who might engage in discussing the key issues, and

(b) key issues that might be considered during problem formulation.

Tables 2.1.1: List of possible stakeholders who might engage in discussing the key issues.

Groups	Stakeholders
Core group	Industry Regulators Local authorities and/or government representatives Independent experts (research and academia) NGO's (particularly environmental and nature organisations) Worker representatives
Wider group for consultation and engagement	General public (public consultation required at all tiers) Other NGOs Other independent experts (scientists, legal experts, sociologists, philosophers, etc,) "Users" of the environment (recreation, food produce, etc) International representatives (for transboundary questions)

Table 2.2.2: Key issues that might be considered during problem formulation.

Areas for consideration	Types of questions
Overarching legal, political, social and ethical questions	The need for an assessment? Who decides and on what criteria? Is there a need for stakeholder involvement?
Linked to the facility/practice under assessment	What are the relevant options/alternatives? *e.g.* Is it a question of a facility or no facility? Or a question of finding the best site for a facility? Or a choice of the type of facility? What implications might the assessment have on future actions? *e.g.* future production of radioactive waste, increased economic cost of a product? What legislation is relevant and why? *e.g.*, Waste discharge, source limitations, environmental impact assessment (EIA), best available technology (BAT), precautionary principle Is the assessment to be carried out separate to or as a part on ongoing EIA/ecological risk assessment (ERA) of the facility? (*e.g.* from other environmental stressors)
Linked to the environment being assessed	Which legislation is relevant for the assessment? What is the status with respect to biodiversity and habitat protection? Are there transboundary issues that need to be addressed? Is the environment under threat from other stressors? Where to draw the physical boundaries for the environment to be assessed? Which species have particular natural value? Are there any sites of cultural heritage that should be included?
Linked to the local and national community	Who is bearing the cost of the assessment? Who will bear the cost of management or monitoring? Who will bear the liability in the event that the assessment is erroneous? What social risks and benefits are associated with the facility/practice (important for trade-offs between community, environment, development and workers)? What trade-offs exist between different actors and stakeholders? Who will be responsible for monitoring? Industry, external experts?
General – in the event that need for assessment is agreed upon	How are the benchmarks set at the different tiers? Are there other non-numerical criteria that should be addressed? What level of uncertainty is acceptable for the assessment? Who makes the decisions to exit or enter the various tiers? What are the options for review procedures? What type of public consultation and stakeholder engagement is necessary? What percentage of assessment and management costs should be used for stakeholder engagement? What percentage for monitoring and follow-up?

2.2 Potential methods

An expert group or committee should make a preliminary evaluation of assessment needs. The group should include a balanced cross section of experts to facilitate public trust. Results and conclusions should be open for public review and consultation. In addition to providing the results of the scoping assessment, the group should also address the questions highlighted above – even if the conclusion is that there is no requirement for risk assessment. The possibilities and procedures for "appeal" should be highlighted.

A round of public and stakeholder consultation (primarily for information gathering) would be advisable before decisions about the assessment are made. Any responses and input would be valuable for selecting a wider consultation group that could be involved for the rest of the assessment. Since the technical complexity also increases with the assessment tiers, this early and ongoing selection of stakeholders will help facilitate understanding and discussion. Although the level of stakeholder engagement is also likely to increase through the tiers (with more stakeholders involved in active consultation and engagement procedures in the higher tiers), the wider consultation group for review of the decisions may remain stable.

At each assessment tier:

- **Expert committee evaluation** focusing on the main assumptions and decisions. Whereas the initial assessment could be carried out by a group led by the industry or regulator, the need for a group chaired or led by an independent will increase as one goes through the tiers.
- **Technical assessment:** risk characterisation and knowledge gaps and uncertainties
- **Problem formulation**: consolidation of information on the economic and social impact of the outcome, revision and refinement of possible options and responses to the initial list of questions, identification of trade-offs between interests of different stakeholders
- **Public and stakeholder consultation** as a minimum: provision of information and options for review, release of the assessment outcome, the decision made and on what grounds. In the case of dissent, more contentious judgments and trade-offs between the interests of stakeholders, more extensive consultation and stakeholder engagement may be necessary (*e.g.*, from independent committees to citizens juries and consensus conferences).

2.3 When and how to involve Stakeholders

Recently, there has been greater openness and transparency) in a range of appraisal processes, which have been articulated as greater participation of stakeholders (both representatives of organised groups and members of the public. These processes are generally referred to as "environmental decision making processes", some of which have been named appraisal processes, in the sense that they are about choosing between options. In addition, integrated methods of appraisal are likely to be carried out for complex issues and will therefore involve a diverse range of information, together with trade-offs necessitate the involvement of stakeholders. Further details on the following sections can be found in Eales *et al*. [2003].

Involvement of stakeholders covers a wide range of approaches and degrees of involvement. Petts and Leach [2000][1] after Arnstein [1969] usefully describe four levels of stakeholder involvement:

1. education and information provision;

[1] See Petts and Leach (2000) for more detail on approaches.

2. information provision and feedback;
3. involvement and consultation; and
4. extended involvement.

Table 2.1 provides some examples of how each of the first three levels could be used in appraisal processes, with examples where possible. This is intended to be illustrative rather than exhaustive. Table 2.2 provides some examples of extended involvement.

Table 2.1: Examples of "opening up" the appraisal process [adapted from Petts and Leach, 2000]

Level	Technique	Potential use in appraisal process	Comments
1. Education and information provision	Leaflet with a description of the environmental decision making process which the appraisal is part of.	This could be sent out to a large number of stakeholders to raise awareness of the issue under appraisal and the process by which a decision is to be reached.	Unlikely to use this on its own as the raising awareness is likely to lead to requests for information, and questions about the process.
2. Information feedback	Staffed exhibits/ displays.	This could be used at the start of an appraisal process to convey information about the issue, collect views of stakeholders on what aspects they regard as important, and have "expert" staff on hand to answer questions. It could also be used at the end of an appraisal process as a method of communicating to a wider group of stakeholders.	Need to ensure that there is a mechanism for feedback to stakeholders and that it is clear what will happen to their comments and views. Again this is likely to be part of a wider stakeholder involvement process – either at the beginning or the end.
3. Involvement and consultative	Focus groups/ stakeholder forums	This could be used in a number of ways, to discuss with stakeholders their views of what is valued in an area but also to understand their perception of impacts and benefits of a particular issue or to provide weighting for different criteria in an appraisal.	Need to ensure that it is clear what the stakeholders' involvement will achieve, too easy to set up "talking shops" which do not have any influence over the appraisal process. Need to ensure that the tasks for these groups are clearly defined.

Table 2.2: Examples of more extended involvement methods [adapted from Petts and Leach, 2000]

Extended Involvement method	Description	Advantages	Disadvantages
Community Advisory Committees / Liaison Groups	Small groups of people representing particular interests or areas of expertise, *e.g.* community leaders, meet to discuss issues of concern and provide an informed input.	Can consider issues in detail and highlight the decision-making process and the complexities involved. Promotes a feeling of trust.	Not all interests may be represented. Requires commitment from participants. A longer-term process requiring more resources than some other methods.
Citizen's Juries	A group of citizens selected to be representative of the community brought together to consider a particular issue. Evidence is received from expert witnesses and cross-questioning can occur. At the end of the process a report is produced, setting out the views of the jury, including differences of opinion.	Can consider issues in detail and in a relatively short period of time.	Not all interests may be represented. Limited timescale may limit time available for participants to fully consider information received.
Consensus conferences	A forum at which a citizens' panel selected from the general public, questions 'experts' on a particular topic, assesses responses, discusses the issues raised and reports its conclusions.	Can provide a unique insight into the ways in which issues are perceived by members of the public. Suited to dealing with controversial issues of public concern.	Not all interests may be represented, limited timescale for consideration.
Stakeholder dialogue	A method pioneered by the Environment Council which focuses on active facilitation of groups with diverse knowledge and opinions, aims at win-win solutions. The design of each dialogue process is unique to the issue at hand.	Provides a focus on the process of engagement. Ensures that all views are heard and is flexible to the problem at hand. Suitable for dealing with controversial issues.	Not all interests may be represented. The flexibility of the method can also be a weakness in that key issues can be compromised.

2.3.1 Education and information provision

The first level would be that of purely providing information, for example, leaflets on a specific pollution issue.

2.3.2 Information provision and feedback

The second level is that where information is provided and views gathered on that information, but there is no intention of dialogue between the information providers and the stakeholders. This includes surveys and focus groups of stakeholders, where an organisation wants to gather views on an issue, for example local services. The intention is a one off information gathering exercise with little or no commitment to acting on the views or discussion with those stakeholders.

2.3.3 Involvement and consultation

The third level describes a situation where views are sought, there is an intention to act on and possibly discuss those views. The traditional consultation process, whereby information is sent out, usually in written form, and stakeholders are asked to provide feedback on the document possibly with direction to specific questions, should fit into this category although in the past it probably fitted better under the second category[2].

With respect to appraisal processes these three levels of involvement provide ways in which stakeholders could be involved in existing processes and can be thought of as "opening up" the appraisal process.

Whilst stakeholder involvement might be considered generally "a good thing", it is vital that clear objectives set for any stakeholder participation are established at the outset. The appraisal team must decide on clear objectives for that involvement, once that is done it then becomes possible to decide on what method might be most appropriate to use so that those objectives can be met [Delbridge *et al*, 2002]. A crucial question to ask is what influence the views of the stakeholders will have over the appraisal process. This can range from limited influence (*e.g.* providing information that otherwise would not be obtainable) or suggesting alternative options through to more extensive influence (*e.g.* influence over the objectives of appraisal and the choice of appraisal tools). The amount of influence given to stakeholder involvement will depend on how much control of the appraisal process is shared with stakeholders by the commissioning authority, and to what extent they are willing to stand by the results. If the appraisal process is very prescriptive (and in that way quite controlled) then extensive involvement of stakeholders is likely to be redundant as there will be no opportunity to influence the process. If, on the other hand, there is a genuine desire to work with both lay and expert views on issues then the process will be more amenable to extended stakeholder involvement, the final level of involvement.

2.3.4 Extended involvement

The final level of involvement refers to more extended involvement and it is this area that there has seen most development over the past 5 – 10 years. Within this area new "methods" have been developed which aim at involving lay people, over a period of time in environmental decision making. There is a range of these processes some of which are more structured and designed with the specific intent of encouraging dialogue between experts and lay people. These processes have been termed analytic-deliberative approaches [Stern and Fineberg, 1996] with an emphasis on analysis *and* deliberation. This was summarised by Petts *et al* [2002] as "*both the analysis (the specific and more specialised process associated with risk assessment) and deliberation (a more interactive means by which ideas are deliberated upon by wider stakeholders) are not seen as mutually exclusive but instead inextricably linked and influential*" (page 21). Authors such as Irwin [1995] and Functowitz

[2] However, the process of consultation by government departments has been scrutinised under the Modernising Government programme and from that a Code of Practice on Consultation (Cabinet Office, 2000) has been developed which embodies good practice guidance on consultation and is encouraging standardisation within government consultations. This attention to the standard process of consultation is likely to lead to a general consideration of how government engages with its stakeholders, and in that sense may make it more of an active process than it has been in the past.

and Ravetz [1993] have discussed working towards a science that is improved by the *"creative conflict between popular and expert epidemiologies"* [Irwin, 1995, page 172] and it is these processes that should help facilitate this improvement.

This final level, due the nature of the involvement has the potential for transforming existing appraisal processes into new approaches. For this reason, appraisal processes that use deliberative approaches become hybrid tools. This involved a systematic evaluation and weighting of issues against a range of criteria (environmental, economic and social costs, risks and benefits). Petts *et al* [2002] provide an excellent review of examples of analytic-deliberative approaches to a range of environmental decisions, some of which are focussed on appraising a range of options. Box 2.1 outlines a three-stage process used in Germany, which gives some detail on how stakeholder groups might be involved in an options appraisal process.

In practice, given the increased complexity of the involvement processes, as one moves up the levels of involvement towards extended involvement, it is more likely that fewer stakeholders will be involved and that those stakeholders will tend to be representatives of organised groups rather than members of the public. The nature of the level of involvement does not dictate this by itself, but often given the time commitment asked for, together with the complex nature of the issues under examination, extra efforts will need to be made to ensure that members of the public are involved.

Box 2.1: Example of stakeholder involvement in an appraisal process [from Petts *et al*, 2002]

"Particularly the production of a co-operative discourse model, known as the 'three step process' offers a structured way of incorporating the views of a diverse group of stakeholders in environmental decision-making [Renn *et al*., 1993; Renn *et al.*, 1997; Renn, 1999]. The three steps are as follows:

Step 1 At this stage the various stakeholder groups identify their values and criteria for judging different options. These include economic, political, social, cultural and religious values. This concerns and criteria list is then appraised and added to by identification and measurement of impacts and consequences related to different policy options. The indicators are approved by the participants in the process and are used to evaluate each policy option. The group Delphi method involves experts from a range of disciplines who are asked to judge the performance of each policy option against each indicator, through group interaction and reconciliation of conflicts about the factual evidence.

Step 2 Identification and measurement of impacts and consequences related to different policy options. The indicators are approved by the participants in the process and are used to evaluate each policy option. The group Delphi method involves experts from a range of disciplines who are asked to judge the performance of each policy option against each indicator, through group interaction and reconciliation of conflicts about the factual evidence.

Step 3 The potential solutions are discussed by a group of randomly selected citizens who evaluate the policy options based on their own knowledge and values with regard to the decision. At this stage the various stakeholder groups, experts and sponsors act as witnesses to the panels. The process facilitator is responsible for the compilation of a citizen report. The final outcome at the end of this stage should be the priority of options and policy recommendations.

The potential of the three-step model lies in its structure and the clarity of the objectives and outcomes arising at each stage. It provides an holistic approach to environmental decision-making including a wide range of people and groups, by involving them in a proactive way [Renn, 1999]."

2.3.5 Communication to Stakeholders

Table 2.3 summarises a number of communication methods that can be used to inform stakeholders via information provision, consultation or consensus building.

Table 2.3: Some practical communication methods [adapted from EA, 1998].

Method	Advantages	Disadvantages	Effectiveness
Information provision			
Leaflets	• can target a specific audience, for example, local neighbours • relatively cheap to produce and disseminate	• may appear to be reaching a widespread audience but can be treated as junk mail • no direct response mechanism for questions or concerns	• generally effective in improving the public availability of information, but ineffective in arousing public involvement • difficult to evaluate • often most effective in provision of specific information about actions and operations at a site
Advertising	• relatively cheap	• limited scope to convey messages	• can be effective for introducing an issue, but indirect effects difficult to evaluate • primarily a public relations technique
Local newspapers	• readily available • relatively cheap • readers see editorial matter as an independent source of information	• limited audience • no direct response to questions • there may be problems with editorial control	• reasonably effective if a simple message needs communicating but limited for complex issues • ineffective in arousing public involvement
National press	• wider audience	• more expensive	• ineffective as a site-specific communication technique, but can be used for informing general public about company and authority performance
Television and radio	• can convey powerful images • high familiarity of the medium • potential to reach a very large audience	• expensive to organise, produce and transmit a programme • one-off coverage of issues • potential lack of control • requires careful planning	• messages conveyed this way can have a pronounced effect on public attitudes. However, the promoter will probably not have sufficient control to warrant the risk of appearing on documentary or news programmes

Method	Advantages	Disadvantages	Effectiveness
Video	• can convey powerful images (such as computer aided design views) to illustrate the nature and scale of a proposed facility • can be innovative and eye-catching • can be used at viewer's convenience • complete editorial control	• relatively expensive • access to a limited audience (those attending exhibitions) • unlikely to be regarded as independent: information may be dismissed as too biased to be of value	• very effective in site specific, local situations, particularly if used in conjunction with an exhibition (see below) • the producer of the video is important. Videos compiled by local authorities can be useful as a means of disseminating information about, for example, technologies
Exhibitions	• if staffed, provides one to one contact • flexible in content and design • can provide information at various levels to suit the audience • can provide useful feedback about concerns	• generally limited attendance so low coverage of potential audience • attracts only a small sub-set of a wider population	• good for a specific population such as residents around a proposed site • particularly effective if staffed
Telephone help lines	• relatively easy access for those interested or concerned • if staffed then feedback is possible	• if pre-recorded then limited flexibility or chance to obtain feedback	• little evidence exists about how effective these are in providing information. Pre-recorded lines are more useful to convey simple information such as the timing of events. Staffed lines can tackle more complex issues and respond to concerns. They are useful in promoting a feeling that a company is accessible
Newsletters	• allow on-going contact and may help promote trust • flexible, so can be designed to meet the changing needs of the audience • feedback possible	• may not be perceived as independent, therefore possible lack of information credibility	• as with leaflets, only a relatively small proportion of a population will bother to read a newsletter. However, those who do may respond and remain in touch • can be useful to support liaison groups
Consultation			
Surveys	• can obtain specific and detailed information	• can be expensive, especially if a representative sample is required	• surveys at a national/regional level can provide useful information about general attitudes towards waste (such as recycling) • at a local level surveys can identify the existing level of knowledge and concerns. Information can then be targeted more effectively

Method	Advantages	Disadvantages	Effectiveness
Public meetings	• attendance can generate respect • if run well (by an independent and respected person) public meetings can be a useful way of meeting more members of the community	• difficult to control • possible mob effect • poor as a method of information provision and developing dialogue	• public meetings show that officials are willing to be exposed to questioning (which can help to generate respect), but they do little else • public meetings rarely meet the objectives of any participant
Small group meetings	• good for listening and responding to concerns • can promote trust and respect between individuals and groups	• time consuming and expensive if representative sample is required	• can be very effective for covering difficult issues or the detailed, complex aspects of a problem • effective in promoting two way dialogue and trust
Consensus building			
Community advisory groups	• access to key stakeholders and community leaders • allow exploration of key issues and concerns • expose the real complexity of waste management issues • can promote trust • highlight the process of decision making as well as the outcome	• need careful planning and independent control • participants require a clear remit from the outset • time consuming • require significant commitment from participants • relatively expensive	• community advisory groups can be organised in different ways. However, if given sufficient time they can be good at emphasising the difficult decisions that must be made • most effective if adopted at the outset of a strategic waste management exercise rather than when many decisions have already been made
Workshops – full or half day	• relatively easy to organise • can be targeted at specific stakeholder groups • can examine specific issues in detail from a variety of alternative perspectives • allow some feedback	• one-off events are limited in subject coverage • unlikely to reach a wide audience	• a series of workshops is most effective: allows people to get to know each other and develop common understandings • nevertheless a one-off event can be effective if it focuses on a specific issue of concern, for example health effects
Visioning	• develops common view of future needs • promotes trust and sense of purpose	• lack of control over outcome • needs to be used in the very early stages of the decision-making process	• visioning can be used to establish a common perspective on the future which can serve as a goal for subsequent consultation. • most effective when it includes all stakeholders

Some of the advantages and challenges of employing more analytic-deliberative processes as part of appraisal are summarised in Table 2.4 below.

Table 2.4: Advantages and challenges of analytic-deliberative processes

Advantages	Challenges
• Most conceptions of sustainable development have involved a dialogical model, stressing the importance – indeed the centrality – of public engagement in determining what is sustainable [Owens and Cowell, 2002]. • Stakeholders may identify previously unforeseen impacts and bring new options to the table. • Stakeholders may feel ownership and responsibility for the outcome that can aid implementation. • Time will be saved at the end of the process as there will not be a need for rounds of consultation and approval by stakeholders. • Petts and Leach [2000] list three key advantages of participation in environmental decision-making which are relevant in the appraisal context: *"legitimation of decision-making, enhancement of democracy, and enlargement of citizenship"* (page 18). • It can open up the "black box" of appraisal to scrutiny, which can help build trust with a diverse range of stakeholders. • It can involve stakeholders who traditionally have not been involved in this type of decision-making (*e.g.* local residents). • In opening up the appraisal processes there a benefits in terms of *"social learning, responsibility and awareness"* [Petts and Leach, 2000].	• Designing an analytic-deliberative process needs considerable attention to the objectives of the process and a clear understanding of what aspect of the appraisal is open to influence, or change. • Analytic-deliberative processes may be relatively expensive, take considerable time to set up and involve a relatively small numbers of stakeholders. • These processes may not lead to clear cut outcomes and could increase conflict, rather than reduce it. • Although information must be supplied to facilitate the debate there is a difficult line to be drawn between providing information that expresses a range of viewpoints and steering the debate towards one particular outcome [Owens and Cowell, 2002]. • It is easy to allocate too little time to planning these processes and to providing enough time for participants to become familiar with the issues. • Experts in certain areas may feel their professional identities under threat from the involvement of members of the public. • There will be issues of language and terminology that have to be addressed so that all participants have a shared understanding of the task. • These processes typically require quite a commitment from stakeholders that may restrict the type of person who gets involved. • Their use raises the awkward question of what Foster [1997] referred to as 'discursive competence', an issue that tends to be evaded, perhaps because it provokes accusations of elitism, yet must nonetheless be confronted particularly when complex and demanding issues are at stake [Owens and Cowell, 2002].

3 Uncertainty

An assessment of the risks of ionising radiation to non-human biota is complicated by a variety of sources of uncertainty, as with any other complex environmental issue. At all stages, the assessments require the use of models, scenarios, assumptions and extrapolations. Knowledge bases are characterised by partly irreducible, largely unquantifiable uncertainties on parameters (*e.g.* large data gaps on transfer coefficients for many radionuclides, and effect data for non-mammalian organisms and non-mortality endpoints), multi-causality (i.e. observed and predicted effects are not exclusive to radionuclides) and imperfect understanding (*e.g.*, complexity in extrapolation from individual to population and ecosystem effects). Unforeseen complexities often make it the case that more research will not result in less uncertainty [Funtowicz and Ravetz, 1993].

In addition, van der Sluijs [2003] has stressed the need to deal openly with the deeper dimensions of uncertainty, and to acknowledge that uncertainty is intrinsic to complex systems and that not all uncertainties can be quantified. These include uncertainties that arise from the societal context and subjective valuations that form part of the assessment process. Approaches for mapping and prioritising the assessment of both the broader and more readily quantifiable aspects of uncertainty have been developed, as discussed in more detail below.

To make sensible decisions about addressing uncertainties, it is important to understand the types of uncertainty, their significance under different situations and the options that exist for dealing with them – in general and within the specific context of the ERICA Tool. This information is provided in the following sections, the development of which was informed by an ERICA End-User Group (EUG) event specifically dealing with uncertainty issues [ERICA D7e, 2006].

3.1 Types of uncertainty

Uncertainties have been categorised in various ways – in terms of the sources of uncertainty or on the way in which uncertainties are expressed. There is a general tendency to focus on the quantifiable aspects of uncertainty. However, more recently, there has been a greater focus on broader (generally less quantifiable) aspects of uncertainty – particularly related to using uncertain information in decision-making and in communicating uncertainties.

3.1.1 Developments in uncertainty 'typology'

One of the clearest categorisations of uncertainty, that allows broader (more qualitative) elements to be incorporated, was provided by Walker *et al.* [2003], and subsequently extended by van der Sluijs *et al*. [2005]. This combined 'typology' was developed specifically for the treatment of uncertainties in model-based decision-analysis, and therefore particularly relevant to this report.

Walker *et al.* [2003] classified uncertainties in terms of their *location* (where they occur) and their characteristics – given dimensions of *level* (whether it can best be classified as statistical uncertainty, scenario uncertainty or recognised ignorance) and its *nature* (knowledge related uncertainty or inherent variability). van der Sluijs [2003] added dimensions on the *quantification of knowledge base* (identification of weak and strong parts in the assessment) and *value-ladenness of choices* (biases that may shape the assessment). This combined 'typology' and the subcategories of uncertainty that exist under each dimension are illustrated in Figure 3.1 below.

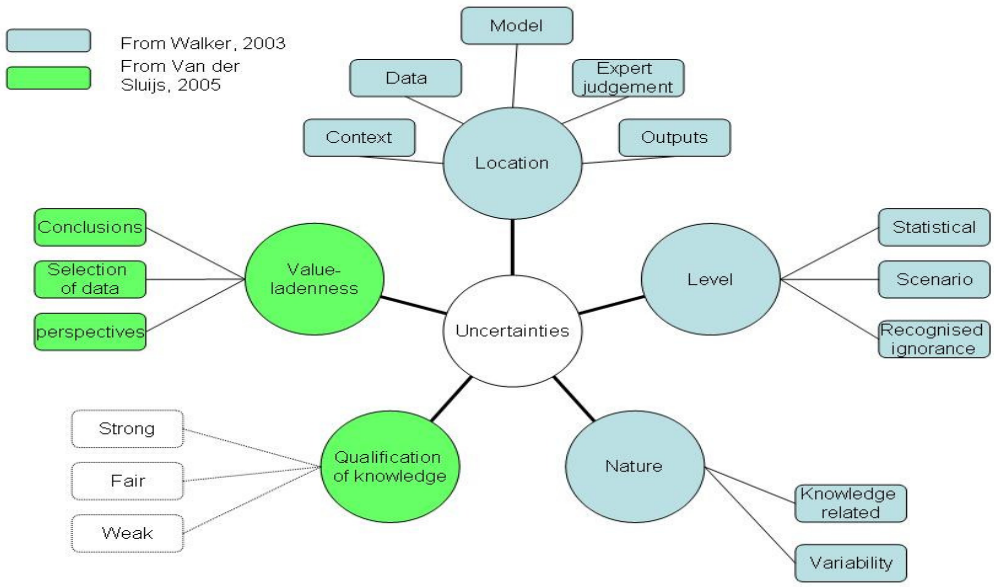

Figure 3.1: Illustration of the categorisation or 'dimensions' of uncertainty identified in van der Sluijs *et al.* [2003].

It is useful to bring out a few key points related to the dimensions of uncertainty – using Figure 3.1 for navigation purposes by beginning at the top of this figure (location) and moving in a clockwise fashion around each of the subsequent dimensions of uncertainty.

The dimension of *location* involve five subcategories[3] which relate to:

1. Context – uncertain elements involved in framing the problem (including the scenario) and its completeness;
2. Data – uncertainties associated with the collection and application of raw data (*e.g.* from measurements);
3. Model – relates to different aspects of modelling, *e.g.* model structure, model parameters and input values;
4. Expert judgement – uncertainties associated with qualitative, interpretive aspects of modelling and assessment;
5. Outputs – uncertainties in the application and presentation of outcomes, indicators and statements.

The second dimension is *level* and is, in effect, a scale of certainty (spanning from certain – not known), which may also be considered under four headings:

[3] Note that the categories within and between the dimensions are not exclusive, since uncertainties can impact on many levels. For example, uncertainties on measurements can be manifested in both model inputs and model outputs.

1. Statistical uncertainty – primarily numerically-based uncertainties that may be expressed statistically;
2. Scenario uncertainty – less numerically defined uncertainties related to the adequacy of the situation under consideration being described by measurements or model parameters;
3. Recognised ignorance – the recognition of a range of possible outcomes;
4. Unknown unknowns – that are not possible to allow for in any quantifiable sense.

The third dimension is the *nature* of uncertainty, which can be categorised in two headings, but it is recognised that uncertainties exist as a mix of forms difficult to delineate quite so clearly[4]:

1. Epistemic – or knowledge-related – which relates to incompleteness or fallibility of knowledge regarding a situation. It is possible to reduce this type of uncertainty by improving the knowledge base – *e.g.* by making more measurements;
2. Ontic – or intrinsically indeterminate or variable. This type of uncertainty is not reduced by improved knowledge.

The fourth dimension, added by van der Sluijs, is *qualification of knowledge base*, which allows the robustness or degree of reliability to be expressed – as a step towards pedigree analysis (NUSAP, [Funtowicz and Ravetz, 1990]), outlined in more detail below. In this context, the term 'weak' implies that there is significant knowledge-based uncertainty in the analysis.

The final (fifth) dimension, also added by van der Sluijs, is *value-ladenness,* which allows the degree to which an analysis is affected by possible bias. Three types of bias are identified [van der Sluijs et al, 2005]:

1. Perspectives – the way in which the analysis is framed in terms of various perspectives. There will always be an element of judgement;
2. Selection of data – relates to the way in which knowledge and information is selected;
3. Conclusions – the bias included in the way in which explanations and conclusions are expressed.

More practically, van der Sluijs has presented the typology of uncertainty as a matrix, Table 3.1, which provides a framework for considering the uncertainties that arise at each stage in an assessment to be identified and characterised, as illustrated in the following section. An illustration of how the uncertainty matrix could be used to map some of the main types of uncertainty in the ERICA Assessment tool is given in Appendix 2.

[4] Equivalent to the Type I and Type II uncertainties referred to below (Section 3.1.2) and with which modellers and assessors are familiar.

Table 3.1. Uncertainty matrix [van der Sluijs, 2005].

UNCERTAINTY MATRIX		Level of uncertainty *(from determinism, through probability and possibility, to ignorance)*			Nature of uncertainty		Qualification of knowledge base (backing)			Value-ladenness of choices		
Location ↓		Statistical uncertainty (range+ chance)	Scenario uncertainty (range as 'what-if' option)	Recognized ignorance	Knowledge-related uncertainty	Variability-related uncertainty	Weak –	Fair 0	Strong +	Small –	Medium 0	Large +
Context	Ecological, technological, economic, social and political representation											
Expert judgement	Narratives; storylines; advices											
Model: Model structure	Relations											
Model: Technical model	Software & hardware implementation											
Model: Model parameters												
Model: Model inputs	Input data; driving forces; input scenarios											
Data (in general sense)	Measurements; monitoring data; survey data											
Outputs	Indicators; statements											

3.1.2 Traditional categorisation of uncertainties

With regard to the quantifiable aspects of uncertainty, two overall categories of uncertainty (related to its *nature* – see below) may be defined as follows:

- *Knowledge uncertainty (Type I uncertainty)* – arising from lack of scientific knowledge about specific factors, parameters or models (that can partly be reduced through further study). This includes parameter, model and scenario uncertainties. It can be expressed by the uncertain belief about the likelihood of the variable (random variable) having different values represented by probability distribution.
- *Variability (Type II uncertainty)* – arising from natural variability due to true heterogeneity that is not usually reduced through further study. Variability is characterised by frequency distribution (discrete random variable) or through a probability density function. This includes actual differences that occur between different environments or individuals.

While this distinction is a useful theoretical construct, it can often be difficult to make and it is often the case that some parameters demonstrate extrinsic uncertainty – due to limitations of measurements and models – and intrinsic variability. The difference between uncertainty and variability are thus not always straightforward and it should be appreciated that variability in input parameters can be a legitimate component in the uncertainty in outputs,

Historically, the focus of uncertainty analysis has often been on the quantifiable aspects. For example, the uncertainties in each step of the calculation of effective dose (to humans) have been considered to determine the combined uncertainty in the overall estimate of dose coefficients by the UK Committee

Examining Radiation Risks of Internal Emitters (CERRIE)[5], as illustrated in Figure 3.2. In many cases in radiation protection, this type assessment represents the implicit assumption that uncertainty can be quantified and expressed as an error, and that the quantity has a central value within a definable range. As discussed in detail in the CERRIE report, it is only one of the dimensions of uncertainties in estimation of radiation risk.

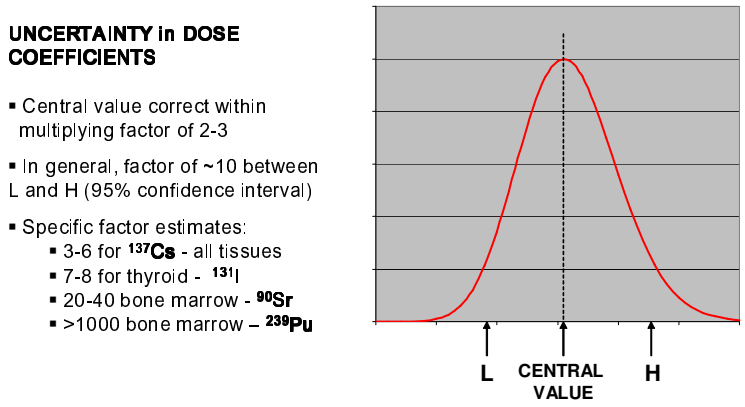

Figure 3.2: CERRIE conclusions on uncertainty in dose coefficients [CERRIE, 2004].

The following additional sub-categories of uncertainty have also been established to allow (the largely quantifiable) uncertainties to be identified in a more systematic fashion (these have been discussed in both CERRIE [2004] and further elucidated in the NDAWG, [2006]).

- *Measurement uncertainty* refers to the uncertainty in field or laboratory data on which models are based. This includes lack of precision, inaccuracy, sampling and analysis errors.
- *Scenario uncertainty* refers to uncertainty in the states of the system where the exposure occurs, including not only the situation at the moment of the assessment, but also the situation in the past (for retrospective assessments) and in the future (for prospective assessments). It includes uncertainty in the environmental properties and how these change, in the sources of contamination, etc. This type of uncertainty is usually dealt with by making assessments for several alternative scenarios.
- *Conceptual Uncertainties* arise from construction of a conceptual model (*e.g.* of environmental or biological processes) – its overall structure, components and inter-connections – and the extent to which the simulated processes and mechanisms in the model are considered to be an appropriate, accurate or complete representation of those considered to take place in reality. The amount of process-level detail within a conceptual model – and the corresponding uncertainties – will depend upon the assessment context, the type of information available to represent these processes and the extent to which extrapolation is necessary. For example, the assumption that absorbed energy in bulk tissue (radiation dose) may be used as a measure of 'harm' is based on a series of complex conceptual models – derived from a range of scientific evidence – which indicate that the probability of a biological

[5] In human dosimetry, the effective dose is only to be used for evaluation of *prospective* risk assessment, weighting factors apply only to cancer risk and have no uncertainty attached [ICRP, 2004].

effect being expressed is related to the energy deposited within biological matter. There are, however, uncertainties related to the conceptualisation of the biological target and the processes that lead to a biological effect. An example of conceptual uncertainty is that resulting from the use of compartment models to represent a real system. Compartment models assume that the contaminant is uniformly distributed in the compartment and transfers are proportional to the inventory of contaminant in the donor compartment. It is possible to reduce uncertainty to some extent, by choosing compartments carefully, but no real system behaves entirely like a compartment model.

- *Model (mechanistic or computational) uncertainties* arise from the (simplified) mathematical representation of the conceptual models and the imprecision in numerical solutions implicit in mathematical models. It includes model structural errors. This type of uncertainty is usually assessed by performing inter-comparisons between alternative models and between model predictions and empirical observations.
- *Data* or *Numerical Uncertainty* arises from uncertainties in the values of physical quantities used in calculations, most obviously in the data input into models, but also in the parameters used within the models themselves, for example for calculation of the dose rates (distribution coefficients, the concentration ratios, the radiation weighting factors, the occupancy factors, etc) and in the input data (concentrations in soil, water, sediments and the organisms). This category also includes intrinsic characteristics of the organisms such as their size and weight and intrinsic characteristics of the environment.

The methods for characterisation of data or numerical uncertainty are well documented in the literature; see for example IAEA [1989] and Morgan and Henrion [1990]. This type of uncertainty can be represented by assigning probability distributions to the parameters and the input data. The parameter/data uncertainties can then be propagated through the models by performing probabilistic simulations.

3.2 Approaches to dealing with uncertainties

The choice of the appropriate approach for dealing with uncertainties will be critically dependent upon the context. For example, a subgroup of the UK National Dose Assessment Working Group (NDAWG) considered the treatment of uncertainties and variability in radiological assessments and recognised that the management of uncertainty is not just a technical exercise and includes subjective judgements. It is therefore recommended that those carrying out such assessments should consider the following issues before commencing:

- Who is the assessment being carried out for?
- What decisions will be made based on the assessment? Will inclusion of uncertainty and variability improve those decisions?
- Will incorporation of uncertainty and variability improve the assessment?
- What are the major sources of uncertainty and variability? How will these be kept separate in the analysis?
- What are the time and resource implications of including uncertainty and variability? Is this effort justified?
- Are the necessary skills and experience available?

- What methods of incorporating uncertainty and variability are to be used? Have the strengths and weaknesses of those methods and other methods that could potentially be used been evaluated and compared?
- How will the results be communicated to the public and decision makers?

van der Suijs [in press] has proposed an approach for uncertainty management which provides a framework for considering such issues in a more systematic manner.

This approach has been extended to allow the quality of uncertainty information in decision-making to be considered. This is briefly described below, followed by an introduction to quantitative methods of analysis.

3.2.1 Dealing with qualitative aspects (considerations of quality)

Uncertainty management, or multidimensional approaches to Knowledge Quality Assessment, include the checklist approach recently adopted by the Netherlands Environmental Assessment Agency (RIVM/MNP), and the NUSAP system. The RIVM/MNP Guidance for Uncertainty Assessment and Communication aims to provide the basis for systematic consideration of uncertainties throughout the whole scientific assessment process [van der Sluijs *et al.*, 2005; Petersen *et al.*, 2003; Jansen *et al.*, 2005]. It is structured around six foci: problem framing, stakeholder participation, indicator selection, appraisal of the knowledge base, mapping and assessment of relevant uncertainties, and reporting of the uncertainty information, Table 3.2.

Table 3.2: Foci and key issues in Knowledge Quality Assessment [van der Sluijs, in press].

Foci	Key Issues
Problem Framing	Other problem views; inter-woven with other problems; system boundaries; role of results in policy process; relation to previous assessments
Involvement of stakeholders	Identifying stakeholders; their views and roles; controversies; mode of involvement
Selection of indicators	Adequate backing for selection; alternative indicators; support for selection in science, society and politics
Appraisal of knowledge base	Quality required; bottlenecks in available knowledge and methods; impact of bottlenecks on quality of results
Mapping and assessing relevant uncertainties	Identification and prioritisation of key uncertainties; choice of methods to assess these; assessing robustness of conclusions
Reporting uncertainty information	Context of reporting; robustness and clarity of main messages; policy implications of uncertainty; balanced and consistent representation in progressive disclosure of uncertainty information; traceability and adequate backing

The objective of the guidance is to help make choices about the type of uncertainty analysis required and the extent of stakeholder involvement that is appropriate.

Some key features of each of these stages are outlined below for ease of reference:

1. Problem framing includes an identification of the 'problem structure' – which is related to the level of agreement on the knowledge needed to understand or deal with the problem and on the level of consensus on norms and values used to judge it[6].

   The decision-stakes are also relevant in determining the form of uncertainty analysis that is appropriate. If stakes are low and uncertainties are low, then the problem is a purely technical issue, while if both aspects are high the problem is one of 'post-normal science' [van der Sluijs *et al.*, 2003; Funtowicz and Ravetz, 1993]. Value-ladenness uncertainties and (recognised) ignorance are key and stakeholder involvement is likely to be essential. In general terms, the socio-political context of the problem and the relative importance of the following types of uncertainty are identified: scientific; legal; moral; societal; institutional; proprietary and situational.

2. Stakeholder involvement involves an assessment of the process, and identification of the extent of agreement or conflict existing between the different parties. The following types of difference may exist: ideological; problem-setting; and differences in attitudes to problem solving and to the fairness of the analysis.

3. The selection of indicators and appraisal of the knowledge base relates primarily to the environmental assessment models: the importance of identifying uncertainties at each stage of an assessment is highlighted.

4. Mapping and Assessing Relevant Uncertainties. The uncertainty matrix presented above – and illustrated in Appendix 2 – provides a framework for considering the types of uncertainty relevant to a particular assessment and for providing an inventory of where the uncertainties that are most relevant for decision or policy-making are likely to arise for a specific assessment.

5. Reporting, review and evaluation: involves a review of the robustness of the results with respect to the critical aspects of the results and taking account of the extent to which they are likely to be contested or to which the results and conclusions would be modified by alternative assumptions. The form of reporting will depend upon why uncertainties are being reported; reporting guidelines may exist for regulatory reporting. Otherwise the level of presentation will depend upon the way in which uncertainties have been addressed in the assessment.

With respect to the appraisal of the knowledge base, the assessment needs to consider the adequacy of the available knowledge, its strong and weak points and contested issues (i.e. the extent to which it is subject to scientific and societal controversies). Here, the NUSAP system proposed by Funtowicz and Ravetz [1990] can help in producing an analysis and diagnosis of uncertainty. Briefly, NUSAP is a notational system that effectively uses the following qualifiers Numerical, Unit, Spread, Assessment and Pedigree. The Pedigree Analysis is particularly applicable to knowledge base appraisal, wherein

[6] An unstructured problem is one where there is little agreement and no consensus on norms and standards– in such situations the (recognised) ignorance and value-ladenness of uncertainties will be highlighted and it will be necessary to include public debate and reflexive science; A well-structured problem, on the other hand, is one where there is good agreement and consensus on norms, in which case normal scientific uncertainty analysis likely to be sufficient;

the strength of the number is evaluated by looking at the background history by which the number was produced, and the scientific status of the number, Table 3.3.

Table 3.3: Pedigree Matrix for Evaluating Models [Refsgaard *et al.*, 2006].

Score	Supporting empirical evidence		Theoretical understanding	Representation of understood underlying mechanisms	Plausibility	Colleague consensus
	Proxy	Quality and Quantity				
4	Exact measures of the modelled quantities	Controlled experiments and large sample direct measurements	Well established theory	Model equations reflect high mechanistic process detail	Highly plausible	All but cranks
3	Good fits or measures of the modelled quantities	Historical/field data uncontrolled experiments small sample direct measurements	Accepted theory with partial nature (in view of the phenomenon it describes)	Model equations reflect acceptable mechanistic process detail	Reasonably plausible	All but rebels
2	Well correlated but not measuring the same thing	Modelled/derived data Indirect measurements	Accepted theory with partial nature and limited consensus on reliability	Aggregated parameterized meta model	Somewhat plausible	Competing schools
1	Weak correlation but commonalities in measure	Educated guesses indirect approx. of rule of thumb estimate	Preliminary theory	Grey box model	Not very plausible	Embrionic field
0	Not correlated and not clearly related	Crude speculation	Crude speculation	Black box model	Not at all plausible	No opinion

3.2.2 Quantitative uncertainty analysis

The text below provides an overview of existing methods for undertaking analyses of the numerical uncertainties within an environmental assessment - by probabilistic approaches to propagate uncertainties through an assessment using probability distributions assigned to uncertain variables.

Assigning probability distributions to input data and parameters

Probability distributions are a convenient instrument for representing quantitative uncertainty in the inputs and parameter values to enable the use of existing probabilistic techniques for uncertainty and sensitivity analyses. It is necessary to select the appropriate distribution type on a case-by-case basis using one, or a combination of several, of the established methods identified below.

According to the principle of maximum entropy, a normal distribution should be adopted in cases when only the mean and standard deviation are known, with the additional constraint that the values

should be positive. However, experience shows that the uncertainty of radioecological data, *e.g.* activity concentrations, and parameters, concentration ratios and distribution coefficients, are often well fitted by lognormal distributions. Several explanations for the frequently observed good fit to the lognormal distribution have been put forward [Aitchison and Brown, 1957; Crow and Shimizu, 1988]. One possible explanation is the fact that the values of radioecological parameters are the result of multiplication of many factors and according to the multiplicative version of the central limit theorem this should lead to lognormal distributions. In addition, it is likely to be prudent to assume a lognormal distribution given that normal distributions, and associated statistics, do not behave so conveniently when uncertainties span several orders of magnitude – as is often the case for environmental parameters.

A range of different methods exists for assigning probability distributions to variables, as outlined below.

Distribution fitting

When sufficient empirical data are available, the probability distribution of the inputs and parameters can be directly estimated using standard statistical techniques [Taylor, 1993].The task of choosing a specific parametric probability distribution is twofold: first optimal parameters are found for each type of probability distributions and then the fit is assessed for each type of distribution to find the most appropriate distribution. The Maximum Likelihood Estimate (MLE) and the Least Squares Method (LSM) are among the most commonly used methods to find optimal distribution parameters. The precision of a parametric approximation method can be assessed using one of the so-called 'goodness of fits statistics', examples are the χ-test statistics, the Kolmogorov-Smirnov statistics and the Anderson-Darling test.

Maximum entropy method

The principle of using the entropy concept to derive probability distributions was introduced by Jaynes [1957]. The principle infers a distribution function that preserves the maximal level of uncertainty (entropy) given pre-supposed constraints on the modelled variable. This means that the choice of any other distribution will require making additional assumptions unsupported by the given constraints. The maximum entropy (ME) distribution thus constitutes a mathematically well-founded choice of distribution where there is a lack of knowledge and data. The most commonly encountered sets of constraints yields the maximum entropy distributions presented in Table 3.4 [Harr, 1987].

Table 3.4: Constraints and corresponding maximum entropy distributions [Harr, 1987].

Case	Available constraints	Maximum entropy distribution
1	Mean	Exponential
2	Lower bound = 0 and a fractile	Exponential
3	Lower bound > 0 and a fractile	Shifted exponential or gamma
4	Range	Uniform
5	Range and mean	Beta
6	Mean and standard deviation	Normal
7	Range, mean and standard deviation	Beta
8	Mean rate of occurrence	Poisson

Bayesian inference

When few or no data are available, Bayesian techniques can be used for deriving probability distributions by using available prior information for similar situations. An example is the case when there are only few data on concentration ratios for the element of interest. In this case, data available for analogue elements can be used to derive an *a priori* distribution, which can then be updated with the data available for the element of interest to obtain an *a posteriori* distribution. Bayesian techniques provide a framework for continuous updating of probability distributions as data become available. A comprehensive description of Bayesian techniques can be found in Gelman *et al.* [2003].

Expert elicitation

The data available for a given parameter are often limited both in quality and quantity. Moreover, some of the existing data may not be consistent with the assessment context. The process of deriving probability distributions is therefore largely subjective, and requires specialised knowledge and judgement of each parameter. Principles for the formal collection and use of expert opinion have received considerable attention [Hofer, 1986]. Formal techniques have, for example, been developed to study risks of reactor operation [Hora and Iman, 1989]. However, formal expert elicitation is an expensive and time-consuming procedure.

Some pitfalls and pointers

The UK National Dose Assessment Working Group (NDAWG) identified a number of pitfalls that may arise in setting up an uncertainty analysis.

- Parameter values chosen by the people carrying out the study are susceptible to bias - this problem is reduced by expert elicitation.
- For many parameters there is insufficient information to fully characterise a distribution of possible values and it may not be possible to distinguish between uncertainty and variability.
- Experts or analysts carrying out the uncertainty study may only feel happy to estimate a maximum and minimum value for a parameter together with the best estimate – often interpreted as a triangular distribution (influencing the distribution of outputs).
- Experts may not correctly interpret information requested – *e.g.* providing full range rather than best estimates.
- There is often a tendency to concentrate on the area of the distribution that will give the highest doses – with consequent skew in the resulting analysis.
- It is difficult to allow for correlation between parameter values.
- In studies considering uncertainty in dose assessments, the range in the estimated doses can often be found to be narrow due to the tendency for different factors to cancel each other out.
- Demonstration of rigorous quality control of the models and the data, effective checking and peer review is important.
- There are difficulties in expressing uncertainties in regulatory contexts, which are often defined in terms of single value targets or limits.
- Concentrating on the uncertainties due to lack of knowledge of parameter values can lead to other aspects such as methodological or scenario uncertainty being overlooked.
- Effort can be expended unnecessarily on eliciting distributions for parameters that do not significantly affect the result – demonstrating the importance of sensitivity analysis to focus assessments.

- Interpretation of the extremes of the distributions of results may represent the combination of unlikely circumstances.
- The use of uncertainty distributions can mask compounded pessimisms and cause unnecessary concerns.

Undertaking uncertainty and sensitivity analyses

Once parameters have been assigned suitable distributions, an uncertainty or sensitivity analysis may be undertaken. There are a number of methods available for undertaking analyses of this type –some of these are outlined below.

To estimate the uncertainty of the endpoints of the exposure assessment, the uncertainties in the inputs and parameters must be propagated though the model. A good discussion on this subject can be found in IAEA [1989]. When simple analytical expressions for the probability distributions are available, variance propagation can sometimes be applied for propagating the uncertainties [Morgan and Henrion, 1990; Hoffman and Hammonds, 1994].

Monte Carlo analysis

When analytical methods cannot be applied, Monte Carlo analysis may be used to propagate uncertainties in input data and model parameters through the model to provide a probability distribution of the endpoints. This may be used as a quantification of the uncertainties of the estimations. The bases of the Monte Carlo method are relatively straightforward (see Vose [1996]): point estimates in a model equation are replaced with probability distributions, samples are randomly taken from each distribution, and the results tallied usually in the form of a probability density function or cumulative distribution. This process is illustrated in Figure 3.3 for the case of a simple model with one input, one parameter and one endpoint.

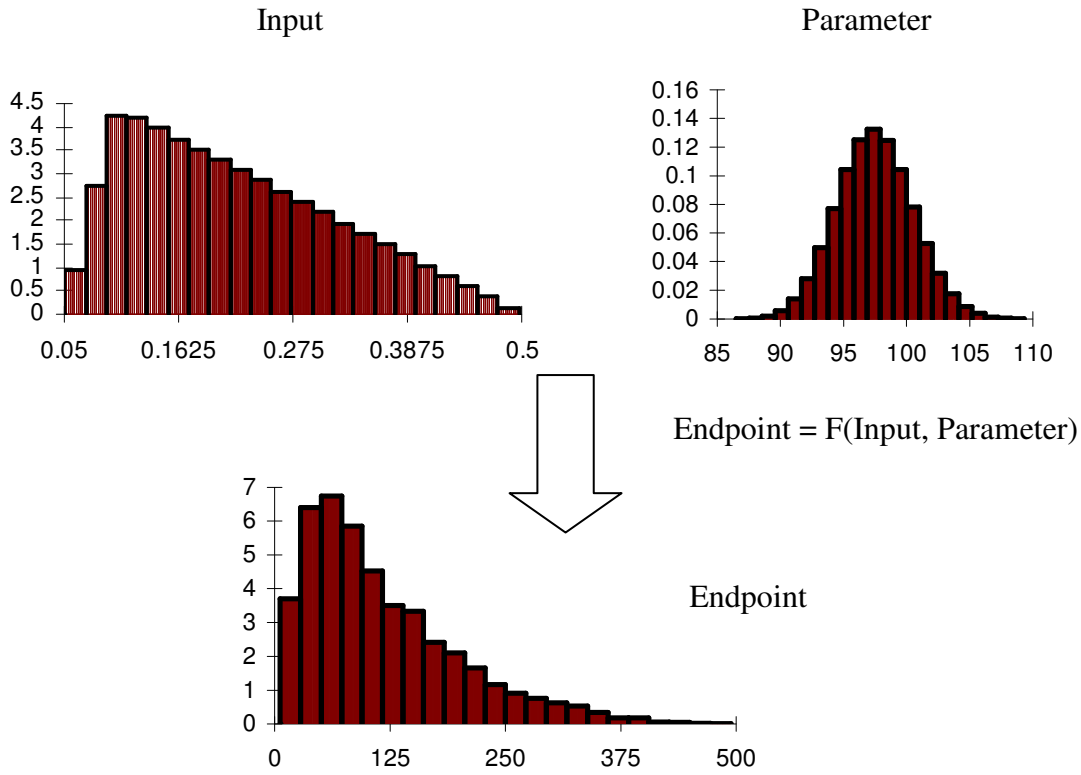

Figure 3.3: Illustration of the use of Monte Carlo probabilistic simulations.

The results of the probabilistic simulations may be presented as frequency histograms, a bar chart which approximates the probability density function. Statistics such as the mean, the median, given percentiles and the standard deviation are useful for describing the results of such analyses.

Refinements of the Monte Carlo method have been developed to try to ensure that all parts of the probability distribution are sampled, by dividing the distribution into sub-ranges of equal probability and ensuring that each sub-range is sampled (*e.g.* Latin Hypercube Sampling). These methods can help to reduce the number of simulations needed, but do not affect the fundamental methodology.

Performing sensitivity analyses

Sensitivity analysis is used to apportion the relative effect of the uncertain inputs and parameters on the variation and uncertainty of the simulation endpoints. This is achieved by varying input parameters and determining the impact on the model output. This could be done manually – for single parameters (for example, in doing deterministic calculations for 'worst case' or 'best estimate' etc) or by varying a number of parameters simultaneously by sampling values from distributions. In the latter case, statistical procedures are needed to make sense of the results – these are outlined below.

Several sensitivity analysis methods of varying degree of complexity have been proposed in the literature [Sartelli *et al.,* 2004]. The choice of an appropriate method depends on several factors, such as the time needed for performing a simulation with the model, the number of uncertain parameters and the type of dependency between the inputs/parameters and the simulation endpoints of interest. For linear dependencies, simple methods based on correlations are generally sufficient; while for complex non-monotonic dependencies more advanced methods, based on decomposition of the variance, are required.

The two most commonly applied measures of correlation between the inputs/parameters and the endpoints in sensitivity are the Pearson Correlation Coefficient (CC) and the Spearman Rank Correlation Coefficient (SRCC).

The Pearson Correlation Coefficient is the normalized covariance between the input and output data sets and can take values between -1 and +1. The CC is equal in absolute value to the square root of the model coefficient of determination R^2 associated with the linear regression. The CC measures the linear relationship between two variables without taking into account of the effect that other possible variables might have. Hence, it can be used as a sensitivity measure if the dependency between the inputs and the outputs is linear. For example, this sort of correlation is likely to be sufficient to describe the sensitivity of predicted dose rates to a given organism and the corresponding dose conversion factors.

Where there are non-linear dependencies between the inputs/parameters and the outputs, it is necessary to use rank correlation coefficients as a measure of sensitivity (*e.g.* if the concentrations in water are not available and are estimated from the concentrations in sediments or the reference organisms). Rank transformation of the data is used to transform a nonlinear but monotonic relationship to a linear relationship. When using rank transformation, the data is replaced with their corresponding ranks. The usual correlation procedures are then performed on the ranks instead of the original data values. The Spearman Rank Correlation Coefficients are calculated in the same way as the CC, but on the ranks. The model coefficient of determination R^2 is also computed with the ranked data and measures how well the model matches the ranked data. Rank-transformed statistics are more robust, and provide a useful solution in the presence of input-output distributions with long tails (such as lognormal distributions). The SRCC will perform well as a sensitivity measure as long as there is a monotonic dependency between the inputs/parameters and the simulation endpoints.

The results of the sensitivity analysis may be presented as tornado plots, as illustrated in Figure 3.4. These are simple bar graphs where the sensitivity statistics, i.e. the CC or the SRCC, are visualized vertically in order of descending absolute value. The longer the bar the larger is the effect of the parameter on the simulation endpoint. The parameters that have positive values of the sensitivity measures have a positive effect on the endpoint, while the ones with negative values have a negative effect.

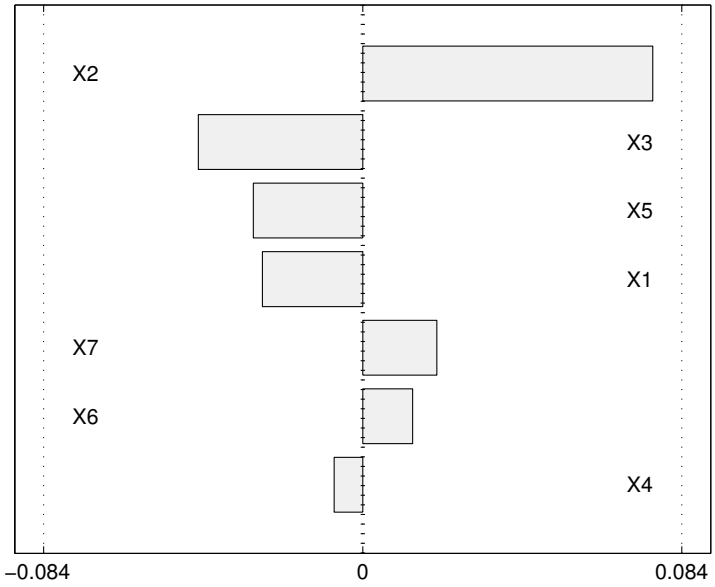

Figure 3.4: Example of a tornado plot representing the sensitivity statistics (values of the correlation coefficients given in the x-axis).

3.3 Uncertainties associated with thresholds and screening values

3.3.1 Extrapolation to a threshold

The aim of effects assessment is to determine the likelihood that effects will occur as a result of a given activity concentration or dose rate. For chemical contaminants, this is often achieved by the identification of a threshold dose below which adverse effects are not predicted to occur. For radionuclides, this threshold would most likely be expressed as a predicted no effect dose rate (PNEDR).

It is impossible to fully understand all the effects that either chemical or radiological hazards might have on all the species that could be exposed. From a practical viewpoint, there is an information gap between the effects data we are able to collect by experimentation ('assessment endpoint') and the much wider range of species, exposure periods and biological processes we might seek to protect in the field ('protection endpoint'). That gap is narrowed if data are available for a large number of species, or from experiments covering a wide range of exposure periods, but some residual uncertainty will always remain. In practice, this gap is bridged by a process of **extrapolation**, effectively making allowances for the areas of uncertainty shown in Figure 3.5 and giving the benefit of doubt caused by this uncertainty to the environment.

There are two main approaches for undertaking numerical extrapolations from the available test data to estimate a PNEDR. These are:

a) Critical data/safety factor paradigm;

b) Species sensitivity distribution (SSD) models.

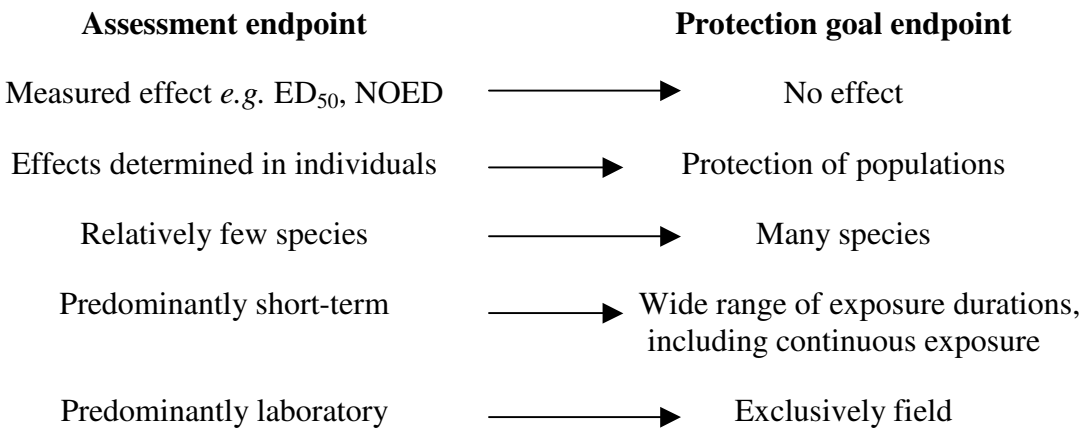

Figure 3.5: Areas of uncertainty in deriving environmental thresholds

A brief description for each approach is given below, along with an assessment of their strengths and limitations. A fuller description of these approaches is given in ERICA [ERICA D5, 2006].

Critical data/safety factor

For many years the critical data/safety factor paradigm has been the predominant approach for estimating thresholds for chemicals in aquatic and terrestrial environments. The principle is simple. It involves collecting available data for the substance of interest, ranking them according to sensitivity, identifying the lowest credible effects (or no effects) concentration - the critical data - and applying a safety factor to this value. In practice, a good deal of effort is expended in quality assessing the data to identify the critical data and several studies may actually contribute to the final decision. For a full critique of this approach, the reader is referred to a useful review by Chapman *et al.* [1998].

The most widely used scheme of this type was developed for risk assessment of existing chemicals and is described in the EU Technical Guidance Document [EC, 2003]. This has also been adopted for deriving environmental standards for Priority Substances under the Water Framework Directive [Fraunhofer Institute, 2002]. A safety factor is intended to account for the uncertainties listed in Figure 3.5 but the choice of factor (between 10 and 10,000) is strongly influenced by the quantity of data available, especially chronic toxicity data, Table 3.5. If the critical data/safety factor approach was used to derive radiological thresholds, the critical data are most likely to be reproductive endpoints in mammals since these appear to be the most radiosensitive [Copplestone *et al.*, 2001].

The main strengths of this approach are its simplicity and applicability to even very small datasets. There can be some flexibility in the size of the safety factor chosen *e.g.* depending on the availability of field data, but experience shows that application of the guidance given in the EU TGD tends to yield lower (i.e. more stringent) outcomes compared to SSD approaches [Whitehouse *et al*, 2002]. Furthermore, although the choice of safety factors is transparent, the scientific basis may be difficult to

justify. Nevertheless, the approach is consistent with those used for deriving thresholds for the protection of human health and remains the mainstay of much chemical risk assessment throughout the world.

Table 3.5: Safety factors used for the derivation of a PNEC using the EU Technical Guidance Document

Data available	Factor*
Lowest acute LC_{50} from small dataset	1000
Lowest acute LC_{50} from extensive dataset	100
Lowest of two chronic no-effect concentrations	50
Lowest of three chronic no-effect concentrations	10
Lower 5 percentile from SSD based on 10 NOECS from 8 taxa	*1-5*
Mesocosm/field data	Case by case

*an additional factor of 10 is used when deriving thresholds for the marine environment. This is to account for the greater uncertainty about the sensitivities of marine organisms to chemicals, especially given the much greater taxonomic diversity found in saltwater compared to freshwater.

Species sensitivity distribution (SSD) models

To construct an SSD, the available toxicity data are ranked and plotted – as a cumulative frequency distribution – against dose (or concentration), as illustrated in Figure 3.6 In this diagram, the sensitive species are to be found in the lower tail of the resulting distribution and the most tolerant species toward the upper part of the distribution. A model (*e.g.* log-normal or log-logistic) is then applied to the data (Figure 3.6). Where data are plentiful, an additional technique may be used to apply a line of best fit that makes no assumptions about the underlying distribution of species tolerances [Newman *et al.*, 2000].

From the line of best fit, the dose (or concentration) corresponding to a given percentile on the vertical axis (the proportion of species at risk) may be estimated. Usually, this is the lower 5 %ile of the distribution, i.e. a dose below which we would not expect to see adverse effects in more than 5% of species. This is referred to as the HC_5 (chemical concentration) or HDR_5 (radiological dose rate). An SSD may be constructed using either acute or chronic data. If acute data are used, the resulting HDR_5 is the dose at which no more than 50 % effect on 5 % of species is predicted. For chronic data, the corresponding HDR_5 would be one at which no more than 10 % effect in 5 % of species is predicted.

Because the precision of the HDR_5 can be quantified (confidence intervals can be estimated), it is possible to choose the median value as the PNEDR or, for additional precaution, the lower 95 % confidence interval about this estimate. Where data are plentiful and confidence intervals narrow, the difference between these may be small but where this is not the case, the difference between the median and lower 5% confidence interval about the HDR_5 can be substantial.

The EU Technical Guidance Document also sets out guidance for the construction and use of SSDs. However, at least 10 independent datapoints from a range of taxa are required; for non-radioactive chemicals these minimum data requirements are only infrequently met. However, since data from a wide range of studies may be combined to construct SSDs for radionuclides, these minimum data requirements are quite likely to be met. Indeed, if an SSD approach was adopted for deriving PNEDRs, specific studies may be commissioned with the intention of meeting those requirements or filling gaps of concern *e.g.* particular taxonomic groups. ERICA D5 [2006] provides a detailed

account of the construction of SSDs using radiological effects data for wildlife contained in the FRED database.

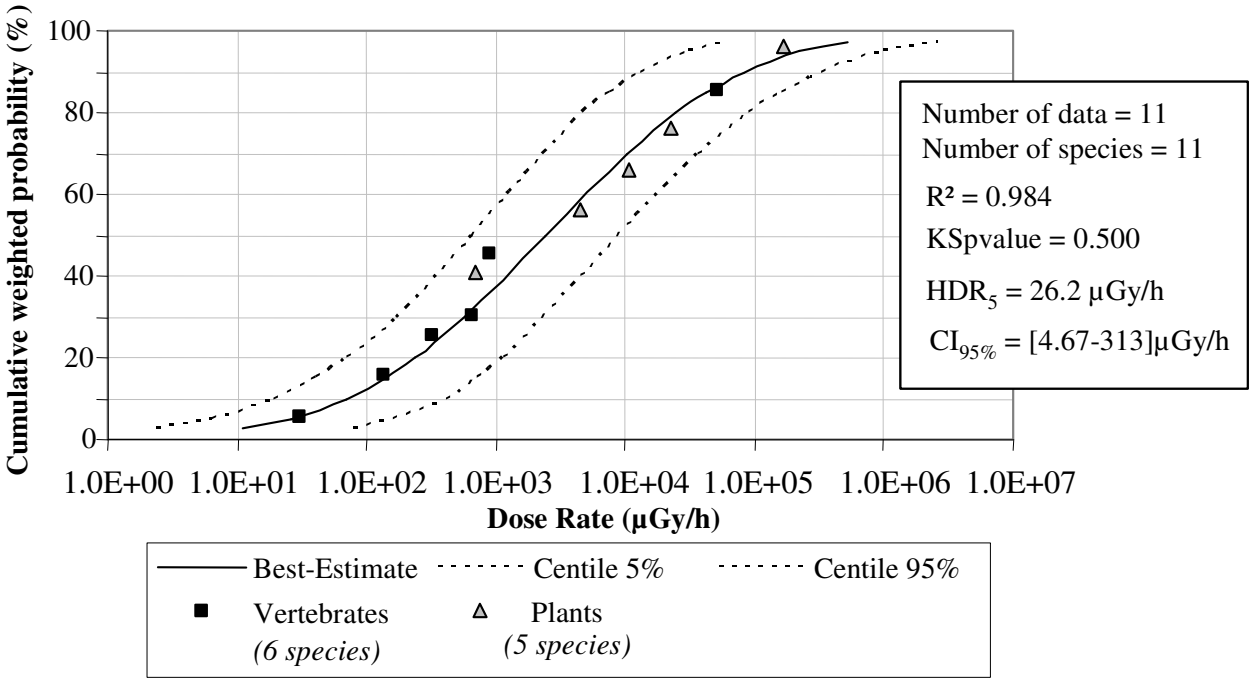

Figure 3.6: SSD for terrestrial ecosystems and chronic external irradiation exposure conditions

Clearly, decisions made on the basis of SSDs have a fundamentally different basis to those based on the critical data/safety factor paradigm. Whilst some of the weaknesses of the critical data/safety factor paradigm are addressed *e.g.* more effective use of the data, quantification of uncertainty, there are also limitations of the SSD approach, Table 3.6. The most notable limitations are that the method only deals with interspecies differences in sensitivity, an assumption that adequate protection is provided by the lower 5 percentile and questions about the validity of the model fitted to the data. The use of this percentile has little ecological justification, although experiments with pesticides suggest SSDs can provide a reasonable prediction of effects in the field [Van den Brink *et al*., 2000]. It is essential that the data used to construct the SSD are consistent – it would be inappropriate to combine acute and chronic toxicity data for example. Different SSDs may also result for different taxa, especially when the toxicant exhibits a specific mode of action, *e.g.* an herbicide or insecticide [Van den Brink *et al*., 2000].

It is perhaps significant that the EU TGD makes provision for additional safety factors to be applied to the HC_5 to account for unknown uncertainties in the derivation process. ERICA D5 [2006] also advocates a further safety factor to be applied to the HDR_5 when the expected irradiation pathway is one that would lead to a particularly high internal dose by α or β emitters. In practice, therefore, the SSD approach retains an element of the critical data/safety factor approach.

A detailed consideration of the SSD approach can be found in Posthuma *et al.* [2002] whilst a thoughtful review by Forbes and Calow [2002] draws attention to some of the limitations of using

SSDs in chemical risk assessment, particularly the ecological assumptions that must be made when fitting models to laboratory data.

Table 3.6: Strengths and limitations of the two approaches for deriving environmental thresholds

Approach	Strengths	Weaknesses
Critical data/safety factor	Process is simple and transparent	Over-reliance on default values can mean scientific understanding is overlooked - 'one size fits all'
	Experience indicates default factors are protective	Safety factors for soil organisms difficult to justify
	Low minimum data requirements – may be used where available data would not permit another approach	Poor use of the available information
		Can discourage data generation
		Provides no information on possible impact of a particular concentration
Species Sensitivity Analysis - SSD	Uses all the available data	'Data-hungry'
	Numerical uncertainties are quantified (possible to estimate confidence intervals)	Only deals with interspecies differences
	Resulting standards are less influenced by any particular dataset -less risk of basing decision on spurious data	Assumes that: • fitted model is valid • Lower 5 percentile provides adequate protection • toxicity tests data are random, independent trials
	Consequences of a particular environmental concentration can be predicted	

3.3.2 Deriving screening values in ERICA

There are a range of uncertainties associated with the derivation and application of dose-effects information in FRED. For example, information on chronic effects is limited and largely dominated by external γ irradiation exposure conditions such that only external γ irradiation dose effects data were quantitatively adequate to be mathematically processed in terms of dose-effect relationships and then on a SSD-type processing. The associated assumptions and limitations of the derived screening values for Tiers 1 and 2 can be split into two categories as follows.

1. Main assumptions and limitations linked to the methodology applied (see ERICA D4b [2005] Table 3.6 for further details)

   - **Main assumptions:** The species for which results of ecotoxicological tests are known are representative, in terms of sensitivity, of the totality of the species constituting a specific taxon, a selected species assemblage and/or a natural community.

     Interaction between species do not influence the sensitivity distribution

     All species are weighted equally

     Ecosystem structure is the target of protection

   - **Main limitations:** The need to adopt a cut-off value as level of protection. There may be keystone species among the 5 % that are "unprotected". Accordingly, it is recommended

that an assessor should identify the trophic level and taxonomic group(s) and the effect endpoint(s) present in the lowest quartile of the distribution and consider whether this is significant within their assessment.

2. Limitations due to the quality and the quantity of ecotoxicity data.
   - **Screening values to be applied for acute exposure conditions.** For both marine and continental ecosystems, the data set was adequate in terms of quality and quantity with a good representation of biodiversity. Their limitation is due to the fact that all these data refer to effects induced by external γ irradiation pathway. This limitation was taken into account through the application of a Safety factor of 5 to the HD_5. This value is the highest recommended by the EC for chemicals when predicted no-effect concentrations can be derived by SSD methodology.
   - **Screening values to be applied for chronic exposure conditions.** Available chronic ecotoxicity data sets cover a limited number of taxonomic groups with lack of information on primary producers for both freshwater and marine ecosystems, and lack of data on some taxonomic groups that appeared among the most radiosensitive under acute external exposure (*e.g.*, amphibians, reptiles, no mammals in the marine database). Since the radiosensitivity was not different on a statistical point of view between the species allocated to the three ecosystems, a unique SSD was build for "generic ecosystem", finally allowing an acceptable representation of biodiversity (still missing amphibians and reptiles). Their main limitation is that all these data refer to effects induced by external γ irradiation pathway. This limitation was taken into account through the application of a Safety factor of 5 to the HR_5. This value is the highest recommended by the EC for chemicals when predicted no-effect concentrations can be derived by SSD methodology.

3.4 Decisions in the ERICA Tool

Throughout an assessment using the ERICA assessment tool a number of decisions are required. At each stage of an assessment, various uncertainties or gaps in data or knowledge may arise in association with the decisions that are taken. Such decisions could include:

- Selection of appropriate data entry (screening Tiers 1 and 2) for retrospective or prospective assessments;
- consideration of multi-contaminants (including non-radioactive substances);
- consideration of multiple sources arising in different environments;
- selection of dose-rate screening values (Tiers 1 and 2);
- selection of EMCLs (Tier 1);
- selection of DCCs (Tier 2);
- application of risk quotients based on EMCLs (Tier 1) or dose rates (Tier 2);
- selection and revision of radiecological parameters (k_ds and CRs), occupancy factors and radiation weighting factors (Tier 2);
- Selection of appropriate uncertainty factors (Tier 2);
- Selection of suitable distributions for radiecological parameters (k_ds and CRs), occupancy factors and radiation weighting factors (Tier 3);
- Selection of suitable probabilistic simulation settings (Tier 3);
- Selection of appropriate effects data to place the calculated dose rates into context (Tier 3).

Appendix 1 describes in details where decisions need to be taken in the ERICA Tool, and for each decision what options exist supported by strengths and weaknesses arguments.

It is also important to recognise that there are uncertainties implicit in the application of default data within the tool. Some key issues are outlined below in Tables 3.7 and 3.8.

Table 3.7: Parameters used in the tool at Tier 1 and how uncertainty is accounted for

Tier	Parameter (Generic)	How uncertainty is accounted for
1	DCC*	Uncertainty not accounted for – values used are considered to be mathematically precise for the selected reference geometry
1	W	Default values of 10 for alpha, 3 for low energy beta and 1 for γ,β used. These might be considered "conservative values" – recent reviews on the subject suggest that a weighting factor for α of around 5 might be most appropriate for populations-relevant deterministic and stochastic endpoints (Chambers *et al*., 2006).
1	Occ	The occupancy factors are set to defaults representing the location within the reference organism habitat where the biota will be maximally exposed.
1	CR	In cases where an extensive data set exists, arithmetic mean, standard deviation and probability distribution functions are defined. In cases where a limited data set exists, an expected value is used in conjunction with an exponential function. This information is used in the derivation of the EMCL.
1	K_d	Expected values have been provided in all cases – an exponential distribution has been applied to this value. This information is used in the derivation of the EMCL.
1	D_{lim}	Derived using Species Sensitivity Distribution approach and application of an uncertainty factor (outlined below);
1	EMCL	Derived from the other parameters listed above – calculations are run probabilistically and the 5th percentile is selected.

*** includes internal and external DCCs.**

Table 3.8: Parameters used in the tool at Tier 2 and how uncertainty is accounted for

Tier	Parameter (Generic)	How uncertainty is accounted for
2	DCC*	**Default – as for Tier 1** Some uncertainty can be accounted for by selecting a user-specified geometry (create new organism module). DCCs specific to the assessors' studied organism can be selected (at least in the form of a sphere or ellipsoid). Uncertainty still exists because of non-homogeneous contamination and idealised geometries (ellipsoid as oppose to true organism geometry)
2	W	**Default – as for Tier 1** These values can be altered if justified – the assessor may enter radiation weighting factors specific to a particular species, endpoint etc.
2	Occ	**Default – as for Tier 1** These values can be altered to be specific for the organisms in the assessment. If occupancy factors are well documented this should reduce the uncertainty in the dose-estimate
2	CR	If extensive user defined data are available these values can be used. The (default) expected value can be used (an uncertainty factor being applied to the dose estimate)
2	K_d	If extensive user defined data are available these values can be used. The (default) expected value can be used (an uncertainty factor being applied to the dose estimate)
2	D_{tot}	The dose rate is still a conservative estimate (95^{th} percentile to be consistent with Tier 1) based on the application of uncertainty factors

For each issue arising, an assessor is encouraged to review the available options and the strengths and weaknesses associated with these to derive the option that is most appropriate for a particular assessment. The actual uncertainties, their, location, level and nature will be case and context dependent, and will vary with radionuclide, ecosystem and source. An uncertainty matrix provides a useful framework for achieving this – and for taking account of uncertainties located both within and external to the model. For example, a CR may not be available for a particular organism-radionuclide combination. The possible options for dealing with such a data gap at each assessment tier are outlined below. It is unlikely that applying the options outlined will eliminate all forms of uncertainty, but they can be used as a means of reducing them in the most appropriate way.

3.4.1 Practical options for dealing with data gaps

The most appropriate practical approaches for dealing with uncertainties and gaps in data will depend upon the assessment context and on the form of the type of uncertainty concerned – whether it primarily arises from incomplete knowledge (which can be addressed by additional research) or from natural variability (which cannot be reduced by additional research).

To assist the assessor, key practical options available for dealing with knowledge gaps and uncertainties, when applying the ERICA Tool, have been identified within matrix. The types of issues, options exist and their strengths and weakness are outlined. This detailed matrix is published under D-ERICA Annex A [Copplestone, 2007], and some of the main features are outlined below for ease of reference.

The options matrix

This matrix is intended to provide the user of the tool with options for dealing with uncertainties – its focus is thus on the application of the ERICA tool rather than on the uncertainties inherent in the development of the tool and the underlying models. The structure of the matrix is shown in Table 3.9.

Table 3.9: Structure of the options matrix.

Issue	Description	Type of uncertainty	Options	Strengths	Weaknesses
		U or V or DG*			

***Uncertainty (U):** arises from imprecision due to lack of information, expert judgement and/or measurement errors and could be reduced with increased knowledge and/or experimentation. **Variability (V):** otherwise referred to as natural variability and results from heterogeneity. Variability is inherent and cannot be eliminated in general. **Data Gap (DG).**

The types of issue for which decisions may be required have been grouped into the various steps involved in conducting an assessment:

- source characterisation, including source monitoring, radionuclide selection and discharge routes;
- ecosystem analysis, involving both biota and environmental characterisation;
- environmental transfer, which incorporates the transfer of radionuclides from environmental media to organisms and the subsequent assessment of internal and external dose rates;
- effects analysis; and,
- interpretation and evaluation.

Each issue has been classified in terms of the general type of uncertainty it represents. However, the type of uncertainty associated with an issue may vary depending on both the context of the assessment and the tier being applied.

The matrix information is intended to help the assessor to identify the practical options for coping with an incomplete data set – arising from uncertainty or variability – and to make choices on the basis of associated strengths and weaknesses (including issues such as stakeholder acceptance, resource implications and the extent of expert consultation likely to be required). The extent to which different options are applicable or feasible will be determined by the primary type and characteristics of uncertainty concerned. Some general considerations are outlined below.

- Measurement or data uncertainties – can be reduced by further measurement to a certain extent, although errors in measurement and uncertainties arising from natural variability will remain following additional measurements.
- Scenario uncertainties – or incomplete information about the situation to be assessed – may be reduced in some cases (for short-term retrospective assessments for example additional measurements may provide additional information). However, these types of uncertainty are generally accounted for by making alternative assumptions about the situation, *e.g.* maximising assumptions (as implied by the semi-quantitative treatment defined by the scenario sub dimension of the level of uncertainty defined by Walker and van der Sluijs).
- Conceptual uncertainties – arising from the conceptualisation of natural processes into simplified functions, *e.g.* the consideration of complex dynamic environmental processes as transfer coefficients between simplified environmental compartments. This type of uncertainty is fundamental to the process or situation being modelled and it is difficult to consider in a purely numerical way. It may correspond to uncertainties in the context of expert judgement – and relate to knowledge uncertainties, recognised ignorance.
- Model uncertainties – relate to uncertainties in the numerical implementation of the conceptual model – the uncertainties in the model may be studied (and to some extent reduced) by numerical means, for example by undertaking verification and validation exercises. The applicability of model parameters may be improved by additional measurements – but variability uncertainty will remain.
- Parameter (or data) uncertainty – is often difficult to distinguish from model uncertainty. Such uncertainties may be reduced by undertaking focused experimental work but uncertainties related to natural variability will remain.

The options for dealing with uncertainty referred to in D-ERICA Annex A provide practical alternatives for deriving specific parameters, in the absence of a full dataset. Some general features are summarised in Table 3.10.

Table 3.10: Summary of practical options for dealing with data gaps and uncertainties.

Options	Strengths	Weaknesses
Ignore process or source of uncertainty of concern	Easy to apply	Provides no information about the likely importance of process or uncertainty. Likely to be difficult to justify to stakeholder groups
Maximising assumptions about the relevant parameter	Easy to apply – provides an upper estimate of the likely influence of parameter or uncertainty	Could lead to significant overestimation and unnecessary concerns

Options	Strengths	Weaknesses
Additional literature research with application of single value parameters	Confidence in results of additional literature search.	Rather resource-intensive and requires specialist knowledge to make use of primary literature information. Does not necessarily reduce uncertainties arising from variability/site-specific issues or allow uncertainties to be quantitatively assessed.
Site-specific or relevant experimentation – to derive single value (site specific) parameters	Greater confidence that parameters are applicable to the site being considered – should reduce uncertainties primarily to intrinsic local variability.	Very resource-intensive; high level of expert input required to design and perform site-specific survey to provide representative input. Single-value parameter derivation does not provide for a sensitivity or uncertainty analysis.
Additional literature research to develop distribution of relevant parameters (for inclusion in sensitivity and uncertainty analysis)	Greater confidence that uncertainties are included as an intrinsic part of the assessment; provides basis for sensitivity analysis which could provide basis for focusing effort for more detailed uncertainty.	Resource-intensive and specialist input needed to undertake search and develop necessary distributions.
Application of expert elicitation techniques to derive a parameter distribution	When well structured – the approach can add to buy-in and increase confidence in results	Expert planning required ensuring consistency of results.
Site specific or relevant experimentation to derive distributions of relevant parameters (for inclusion in sensitivity and uncertainty analysis)	The most comprehensive treatment of parameter uncertainty possible – may add to confidence in results	Very resource intensive, the site-specific research, interpretation of experimental results and the application and interpretation of uncertainty analysis results will require detailed expert input.

3.5 Uncertainties associated with ERICA dose-rate derivations

In the derivation of ERICA internal Dose Conversion Coefficients we have assumed that radionuclides are homogeneously distributed within reference organisms. In reality, we know that this is not the case. Lots of radionuclides are concentrated in organs such as the liver (*e.g.* Ru, Ce), bone (*e.g.* Pu, Am) and thyroid (I). Here, we consider whether the non-homogeneity in radionuclide distributions is likely to make an impact on DCC values through the selection of several example situations. In this way (i) an indication of the uncertainty associated with the assumption of uniform distributions of radionuclides in reference organisms can be made and (ii) bounds on the upper limit on expected differences between heterogeneous and homogeneous cases can be established. Furthermore, simple methods for correcting for this phenomenon (if required) have been derived.

3.5.1 Introduction

Dose conversion coefficients (DCC) to assess absorbed dose rates in reference organisms due to internal and external exposure to gamma and beta emitters have been calculated and published

assuming three dimensional ellipsoids with different dimensions and some representative irradiation geometries [Taranenko *et al*., 2004; Vives i Batle *et al.,* 2004; Ulanovsky and Pröhl, 2006].

Although the differences found in the absorbed fractions depending on the energy made necessary the calculation of DCCs for reference organisms of various sizes and shapes, the huge number of possible situations also made it necessary to assume some simplifications concerning both the geometric models and the radionuclide distributions. In particular, homogeneous distribution of emitters has been assumed in all the cases, to calculate DCCs for monoenergetic photons and electrons in the range 10 keV – 5 MeV. Thus, the absorbed dose rate in a given organism for a given radionuclide is:

$$\dot{D}_{body} = DCC^{internal} \times A_{M,body} + DCC^{external} \times A_{M,outside}$$

where $A_{M,body}$, $A_{M,outside}$ are the activity concentrations in the body and the surrounding medium, respectively.

Because the assumed homogeneity is not be valid for some radionuclides, two general situations have been analysed in more detail: (i) the calculation of whole body doses for non-homogeneous distributions of incorporated radionuclides (and the uncertainty associated to the use of a homogeneous distribution to calculate whole body doses); (ii) the calculation of organ / whole body dose rates due to accumulation of radionuclides in a critical organ.

Rather than provide new sets of numbers, the purpose is to calculate the uncertainty associated to the possible non-homogeneous distribution within the body as well as to indicate some simple methods to estimate organ doses, based on the relationship between whole body and organ doses. Obviously, the uncertainty thus calculated does not take into account the simplistic nature of the reference organisms compared with actual animals and plants.

Appendix 3 details the uncertainties in the dosimetry methods applied in ERICA - essentially linked to the assumption of homogeneity in the distribution of radionuclides within reference organisms. The conclusions are re-iterated below.

3.5.2 Summary

Whole body dose rates in reference organisms due to internal exposure can be calculated using the DCCs for homogeneous distribution and the average whole activity concentration:

$$\dot{D}_{body}^{internal} = \left[DCC_{homogeneous}^{internal} \pm u\left(DCC_{homogeneous}^{internal}\right)\right] \times A_{M,body}$$

For photons, the uncertainty due to a possible non-homogeneous radionuclide distribution is lower than 20-25%, in the considered cases (these being a central point source (maximum absorbed fraction), homogeneous distribution, and eccentric point source; energy in the range 10 keV – 3 MeV and for geomteries representing woodlouse, mouse, mole, rabbit, and fox). For electrons, uncertainty is negligible below a threshold energy, depending on the size of the organisms. This is approximately 0.5 MeV for a woodlouse-sized geometry and 5 MeV for fox-sized geometry).

When the radionuclide is concentrated in a given organ, organ dose rate can be higher than whole body dose rate. In a general case:

$$\dot{D}_{organ} = E \times AF_{organ}(E, m_{organ}) \times A_{M,organ}$$

where AF_{organ} is a smooth function of the energy and the mass of the organ. If the absorbed fraction in the organ is close to one, then a simple relationship can be used:

$$\frac{\dot{D}_{organ}}{\dot{D}_{body}} \approx \frac{m_{body}}{m_{organ}}.$$

In simple terms this means that for low penetrating radiation types (alpha and beta particles for large parts of the expected energy range), the dose-rate in a low mass organ can be very much greater than the dose-rate in the whole-body (if the radiation emitter is located in the organ as oppose to being homogeneously distributed throughout the body). Using reference man as an example, selecting liver (of mass 1.8 kg) and whole-body (of mass 70 kg), application of the equation above would result in an organ (emitter located in the organ) dose-rate 39 times higher than the corresponding whole body dose-rate (homogeneously distributed emitter).

4 Issues and Options

In addition to considerations for uncertainties, the following questions need answering before proceeding to the risk assessment:

- What assessment criteria should be used?
- Should you consider natural radiation?

This Chapter provides some of the options available to the assessor. The list is not exhaustive and some considerations may be found in other ERICA Deliverables, *e.g.* D4 [2005] and D5 [2006].

4.1 Setting risk assessment criteria and standards

Section 3.3 concentrated on the uncertainties surrounding the derivation of threshold values. This Section focuses on the ERICA Integrated Approach and the particular status of radioactive substances compared to chemicals.

Environmental criteria and standards can be considered as tools for further actions within the framework of ecological risk assessment (for both categories) and its regulatory use (only for the second category). They are most frequently expressed as numerical values that represent threshold doses to organisms or concentrations in the environment for specific substances below which unacceptable effects are not expected to occur. Unlike criteria, standards always refer to regulatory purposes.

Within the ERICA Tiered Approach, an Ecological Risk Assessment tiered approach has been adopted [D4, 2005]. This approach requires risk assessment screening dose (rate) values for the risk characterisation within Tiers 1 and 2 and for an understanding of the effects of ionising radiation on reproduction, mortality and morbidity within Tier 3 [D5, 2006]. These screening dose (rate) values typically fall into the category of criteria with a precise use for screening within an ERA. Methodologies to derive such values have been reviewed in detail [D4, 2005]. This review led us to adopt a version of the methodology proposed for chemicals in the Technical Guidance Document adapted for radioactive substances [EC 2003]. Other values (or criteria) expressed as expected "no-effect" levels of exposure for non-human species come from expert judgement based on critical literature reviews in the field of radiobiology performed by several organisations: NCRP, IAEA or UNSCEAR [NCRP, 1991; IAEA, 1992; UNSCEAR, 1996]. Strictly speaking, none of these values has a regulatory relevance. However, a number of national initiatives has used them as screening values to evaluate the ecological risk in a regulatory context *e.g.* [Copplestone *et al.,* 2001; Environment Canada 2001; Bird *et al.,* 2002; Sazykina and Kryshev, 2002].

The following sub-section is devoted to the description of what a standard could be used for, illustrated on chemicals since no environmental standards for radioactive substances exist explicitly. Then, the methodologies used to determine ecological screening values are briefly reviewed in a comparative way between chemicals and radioactive substances. The method developed and applied in ERICA is summarised and alternative options to select a screening value are discussed.

4.1.1 Existing standards

Standards are important regulatory tools that are widely used to protect the environment and human health from chemicals or other agents released by human activity. At present, the majority of standards used in environmental regulation relate to hazardous chemicals. Most standards have been developed in response to national or international legislation or convention. For example, in Europe, the water policy started from a need for protecting water quality to allow the use of resources by man in the 1970's. It then moved in the 1990's to the importance of protecting structure and function of

biological communities. At first, the approach was chemically-based then turned to a non stressor-specific regulation within the Water Framework Directive. Water bodies are now considered as environmental goods and not only resources to be exploited. The objective of protection is the ecological status in terms of biodiversity not a concentration of chemicals. However, for practical reasons of management and control, Environmental Quality Standards have been derived and applied for Priority Hazardous Substances. These EQS are threshold concentration or doses adopted as legally enforceable numerical limits in water. Other standards may not be numerical, but instead specify improvements to processes (*e.g.* the introduction of catalytic converters on new vehicles, or buffer strips in nitrate vulnerable zones) that will bring about benefits for the environment or human health.

Clearly, there are different types of standard and they may be used in a variety of ways. This is illustrated in Figure 4.1, where we see that standards may be applied at:

- the point of production of a substance (*e.g.* technologically driven process standards);
- the point of release to the environment (limits on the quantity of a substance that may be released);
- in the environment itself (this covers the majority of standards and they are typically expressed as ambient concentrations of substances) or, rarely,
- a biological receptor, where the standard could be expressed in terms of an absorbed dose, or even, a biological effect.

The majority of environmental standards are of the third type.

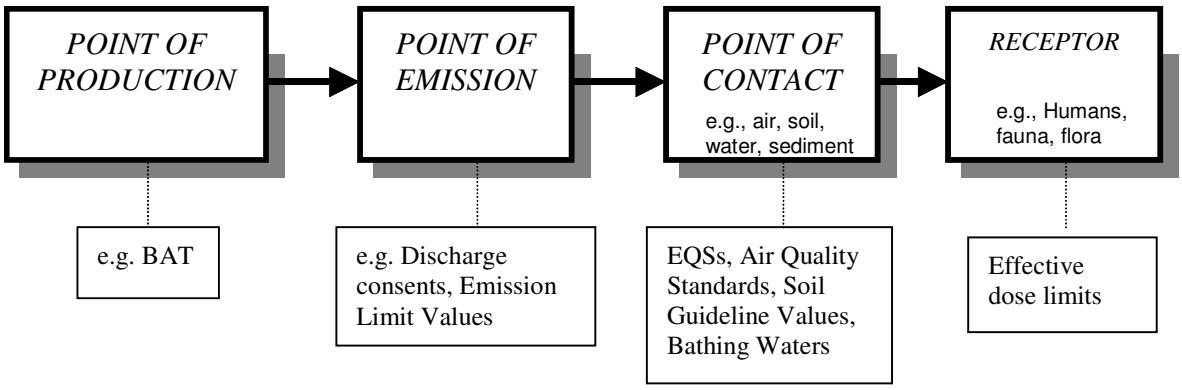

Figure 4.1: Points at which standards may be applied.

In practice, standards developed at one level may be translated into another but only from right to left in Figure 4.1. For example, EQSs for the protection of aquatic life are routinely used to calculate site-specific discharge permits that take account of local emission and dilution characteristics.

Whilst some standards are set by governments, many others are not but carry authority for other reasons, especially the scientific eminence or market power of those who set them (*e.g.* World Health Organisation guidelines). This is the case for radioactive substances in some countries where, for radiological protection of the environment, the most commonly referred values are those quoted by the IAEA [1992]. The values are actually listed as guideline values (and therefore do not carry any legally enforceable weight) that may be used when considering regulatory issues related to protection of the environment. For example, the Environment Agency in the UK has adopted a value equal to 5% of the guideline value from IAEA [1992] as a screening value in the first tier of an ERA-type approach. The

aim is to identify whether the discharge authorisation presents a risk for Natura 2000 sites [Copplestone et al., 2001]. When those values are used in such context, they can be assimilated as an example of the fourth type of standards, see Figure 5.1. In the same way, consents on emissions containing radionuclides are expressed in such a way as to prevent the critical dose limit being exceeded in organisms that may become exposed, or at the point of production expressed as a maximum quantity discharged per year.

4.1.2 Methodologies to derive radiological criteria for environmental protection and comparison with chemicals

This section is concerned with the derivation and expression of the radiological thresholds to be used within tiered approaches. These thresholds will be expressed as numerical limits (typically as concentrations or doses) in the environment. Because they are to be used as triggers for further action rather than compliance criteria, there is no need to consider compliance assessment (*e.g.* sampling frequency and compliance statistics) issues at that stage.

Assessing the risks to the natural environment from synthetic chemicals has much in common with environmental risk assessment for radionuclides but the underlying principles also differ in a number of important respects, all reviewed in details in [ERICA D4b, 2005] and summarised in Table 4.1. Most important is the difference in the way toxicity is determined and expressed but other associated differences are also evident.

In both cases, the risk assessment requires an understanding of the effects (toxicity) of chemicals or radionuclides to a range of species. In practice, these toxicity data are generated in laboratory tests using a range of plant, invertebrate and vertebrate species, which are effectively surrogates for those organisms we wish to protect in the field. All existing approaches for the derivation of screening values to be used in the first Tiers of an ERA-type approach are based on available ecotoxicity data arising from ecotoxicity tests, typically EC_{50} for acute exposure conditions (short-term) and EC_{10} for chronic exposure conditions (long-term).

Whereas the basis for chemical assessment is the chemical concentration to which organisms are exposed, dosimetry considerations are needed in the radiological assessment. There is a further distinction from chemical toxicity in that radiological assessment also considers a time element (*e.g.* μGy/h). The absorbed dose rate is estimated on the basis of:

(a) organism geometry, and

(b) radiation quality.

The adaptations needed to enable derivation of ecotoxicity screening values for radioactive substances and the ERICA Integrated Approach were presented in [ERICA D5, 2006]. Briefly, the available effects data in the FRED database was critically analysed and used to (re)construct dose(rate)-effect relationships in a systematic approach to provide estimates of critical ecotoxicity values for both acute (ED_{50}) and chronic (EDR_{10}) external γ irradiation exposure conditions. Finally the method used to obtain the screening values for Tiers 1 and 2, the so-called *PNED(R)*, was based on the construction of Species Sensitivity Distributions and the application of a safety factor to take account for the remaining extrapolations, see ERICA deliverable D5 for further details.

Table 4.1: A comparison of environmental risk assessment for chemicals and radionuclides.

	Chemical Risk Assessment	Radionuclide Risk Assessment
Problem Formulation	• Potentially vast range of contaminants • Simplified compartments at risk defined • Implicit focus on population protection • Assumed that structural (species) protection will afford functional protection	• Defined range of radionuclides and radiation types • Ecosystems defined • Explicit focus on population protection • Reference organism types defined – based on available information about radiation effects, ecological relevance and dosimetric considerations
Exposure Assessment	• Ambient concentrations (PEC) estimated, based on expected releases and fate in the environment • Local or regional with standardised or site-specific exposure scenarios • Background exposure may be accounted for (metals)	• Radionuclide transfer estimated, based on expected releases and fate in the environment • Additional focus on external and internal radiation doses experienced by reference organisms • Natural background radiation exposures routinely considered
Dosimetry	• Does not feature at all; chemical doses and uptake pathways rarely known • Decision-making based on ambient concentrations (relate effect to exposure)	• Toxicity is determined by amount of radiation energy absorbed by organisms, not concentration of radionuclide • Absorbed dose estimated on basis of organism geometry and radiation quality (Relative Biological Effectiveness, RBE) • Definition of critical dose requires understanding of toxicokinetics
Effects Assessment	• Based on adverse effects at individual level with emphasis on demographic endpoints (mortality, morbidity, reproduction) • Empirical approach to species selection (but consider representation by different taxa and trophic levels) • Extrapolation to account for biological uncertainties – to cover all conceivable species/ecosystems at risk • Effects data expressed in terms of ambient concentration	• Based on adverse effects at individual level with emphasis on demographic endpoints (mortality, morbidity, reproduction) • Effects data extracted from species represented in FRED database • Reference species are those most likely to receive highest radiation dose by virtue of geometry, habitat, feeding characteristics, bioaccumulation potential • Extrapolation to population-level effects [Garnier-Laplace *et al.*, 2006] • Effects data expressed in terms of absorbed dose
Risk Characterisation	• Deterministic (PEC:PNEC ratio) to judge acceptability or requirement for refinement (reduce uncertainty through additional data) • Probabilistic approaches also possible where data sufficient	• Deterministic (PED(R):PNED(R) ratio expressed in dose(rate) for Tier 2 or in back-calculated activity in media for Tier 1) to judge acceptability or need for refinement • Probabilistic (Tier 3)

4.1.3 Issues and options for selecting the screening value to be applied in the ERICA tool

Before selecting the methodology to derive the screening values associated to the ERICA Integrated Approach, a critical survey of existing methodologies for developing ecological screening values to be used in ERA was performed [ERICA D4, 2005]. Table 4.2 summarises the main limitations of each methodology amongst those based on:

(i) ecotoxicity data manipulation (Species Sensitivity Distributions (SSD), SSD + Safety Factors, Safety Factors),

(ii) comparison to background levels, and

(iii) comparison to existing guidelines.

Table 4.2: Main strengths and weaknesses of some commonly applied methodologies to derive screening values for ERA. References in ERICA deliverables are given for further details. Also refer to Table 3.6.

Methodology	Strength	Weakness	Reference in ERICA deliverables
Toxicity testing and safety factors	Easy to implement Adapted to small data sets Consistent with the European methodology for chemicals	Lack of transparency Make use of the lowest ecotoxicity value Selection of the magnitude of the SF to be applied not scientifically based Highly conservative	D4b – Sections 3.2.4 and 3.4.3 D5 - Sections 2.1.2 and 4.2.5
Toxicity testing and SSD	Make use of the whole range of ecotoxicity data Allow the identification of the most sensitive groups of organisms Possible to combine with the application of a Safety Factor varying from 1 to 5 to take account for the remaining extrapolation Consistent with the European methodology for chemicals	Strongly dependant on the quality of the ecotoxicity data set Need to select an appropriate level of protection (*e.g.* 95 % of the species) Issues on "unprotected" species Need a data set ideally representative of biodiversity of the ecosystem	D4b – Sections 3.2.4 and 3.4.3 D5 - Sections 2.1.2 and 4.2.5
Background levels	Easy to categorize the output of an ERA into bands of concern with associated management actions In line with the ICRP reasoning	Which value to use as representative of background at the site (local or regional) Differences in bioavailability and route of exposure between the added fraction and the natural background	D4b – Section 3.2.2 D5 – Section 4.2.6
Existing guidelines	Justifications under the responsibility of the primary reference	Sources justifications mainly narrative based on effects observations and on expert judgment	D4b – Section 3.2.5 D5 – Section 4.2.7

Finally, the methodology adopted by the ERICA Integrated Approach was the SSD + SF and this selection was reinforced by comparing the obtained screening values for Tiers 1 and 2 with those from the application of other methodologies, see Table 4.3. This table constitutes an exhaustive list of the values that could be selected by an assessor for screening purpose (Tiers 1 and 2). To our knowledge, no value exists to be compared with the values proposed for chronic exposure to radioactive substances by the ERICA Consortium.

Table 4.3: Screening dose rate values (in µGy/h) proposed by various organisations/programmes and associated methods for deriving them for chronic exposure to radioactive substances. (This table is the same as Table 16 in ERICA D5. All the data included could be used to adopt a screening value by any assessor who has a good justification to do so.)

Targeted protected level as described in the source	Method	Dose rate (µGy/h)	Reference
Terrestrial ecosystems			
Generic ecosystems	SSD-95% species protected plus SF of 5	10	ERICA D5 [2006]
Generic ecosystems	SF method	0.6	ERICA D5 [2006]
Plants	Background	0.02-0.7	UNSCEAR [1996]
Plants	Review, SF on the lowest critical radiotoxicity value	110	Environment Canada [1997] Bird *et al.* [2002]
Plants	Review based on NCRP [1991]; IAEA [1992]; UNSCEAR [1996]	400	ORNL [1998] USDoE [2002]
Plants	Critical review for screening purpose from IAEA [1992]	400	Environment Agency [2002]
Organisms	Background –external irradiation and non weighted	0.01-0.1	Gomez-Ros *et al*, [2004]
Animals	Background	0.01-0.44	UNSCEAR [1996]
Animals	Review based on NCRP [1991]; IAEA [1992]; UNSCEAR [1996]	40	ORNL [1998] USDoE [2002]
Animals	Critical review for screening purpose from IAEA [1992]	40	Environment Agency [2003]
Small mammals	Review, SF on the lowest critical radiotoxicity value	110	Environment Canada [1997] Bird *et al.* [2002]
Invertebrates	Review, SF on the lowest critical radiotoxicity value	220	Environment Canada [1997] Bird *et al.* [2002]
Vertebrates and cytogenetic effects	Review Contaminated environments	4 – 20	Sazykina *et al.* [2005]
Vertebrates and effects on morbidity	Review Contaminated environments	20 – 80	Sazykina *et al.* [2005]
Vertebrates and effects on reproduction	Review Contaminated environments	80 – 200	Sazykina *et al.* [2005]
Aquatic ecosystems			
Generic freshwater ecosystems	SSD-95 % species protected plus SF of 5	10	ERICA D5 [2006]
Generic freshwater ecosystems	SF method	10	ERICA D5 [2006]
Generic marine ecosystems	SSD-95 % species protected plus SF of 5	10	ERICA D5 [2006]
Generic marine ecosystems	SF method	3.7	ERICA D5 [2006]
Freshwater organisms	Background	0.022-0.18	UNSCEAR [1996]

Targeted protected level as described in the source	Method	Dose rate (µGy/h)	Reference
Freshwater organisms	Background–external irradiation and non weighted	0.02-6	Brown *et al.*[2004]
Aquatic algae/macrophytes	Review, SF on the lowest critical radiotoxicity value	110	Environment Canada [1997] Bird *et al.* [2002]
Aquatic animals	Review based on NCRP [1991]; IAEA [1992]; UNSCEAR [1996]	400	ORNL [1998] USDoE [2002]
Freshwater and coastal marine organisms	Critical review for screening purpose from IAEA [1992]	400	Environment Agency [2003]
Amphibians/Reptiles	Review, SF on the lowest critical radiotoxicity value	110	Environment Canada [1997] Bird *et al.* [2002]
Benthic invertebrates	Review, SF on the lowest critical radiotoxicity value	220	Environment Canada [1997] Bird *et al.* [2002]
Fish	Review, SF on the lowest critical radiotoxicity value	20	Environment Canada [1997] Bird *et al.* [2002]
Marine organisms	Background–external irradiation and non weighted	0.03-1	Brown *et al.[* 2004]
Marine mammals	Critical review for screening purpose from IAEA [1992]	40	Environment Agency [2003]
Deep ocean organisms	Critical review for screening purpose from IAEA [1992]	1000	Environment Agency [2003]
Aquatic and terrestrial flora and fauna	Review concluded that few indications for readily observable effects at chronic dose rates below	<100	FASSET [2003]

The purpose of the refinements made in Tier 3 is to obtain more realistic estimates of exposure and effects to reduce the uncertainty in the risk assessment. A number of options have been illustrated in details in D5 as follows:

(i) to use SSD methodology while introducing more ecological realism (more conservative levels of protection, trophic/taxonomic weightings, statistical analysis restricted to a particular endpoint and/or a particular trophic/taxonomic group);

(ii) to refine the effects analysis by focusing on the protection of keystone species and/or endangered species; and

(iii) to refine the effects analysis to address situations when knowledge of effects is scarce with regard to the problem formulation, and when additional studies may be required.

Outstanding issues

The principles of added risk, already applied for metals risk assessment, also seem appropriate for radiological risk assessment. Indeed, the understanding of background radiation is probably superior to that for metals in many cases. Added risk would probably be applied at a site-specific level, making use of local background radiation to inform the assessment of exposure rather than modify the threshold.

The use of dual thresholds as opposed to a single value has some appealing features, notably the discretion it provides in prioritising risks and the opportunity to refine understanding about the actual risks (*e.g.* through further monitoring or modelling of exposure). However, the existence of two thresholds could be difficult to communicate.

With the use of SSD as recommended in ERICA-D5, there may be keystone species among the 5 % that are "unprotected". Accordingly, it is recommended that an assessor should identify the trophic level and taxonomic group(s) and the effect endpoint(s) present in the lowest quartile of the distribution and consider whether this is significant within their assessment. This information needs to be kept in mind when using the protection goals and screening levels for a given ecosystem. Moreover, cautious interpretation is needed when the aim of the assessment is to protect an object other than the structure of the ecosystem (*i.e.* an endangered species). In this case, a proposed screening dose (rate) value derived from a SSD type approach using a generic ecosystem is unlikely to be valid. Further guidance was proposed in D5 to solve this problem.

4.2 Risk Quotients

EMCLs (Environment Media Concentration Limits) can be derived and risk quotients summed using different approaches. Some of the methods that have been considered in the course of the project are described below.

4.2.1 Approach A: "No organism approach"

In this approach, the highest CR and the highest DCC values among all values for a specific radionuclide are selected. Aquatic organism configuration using Approach A is shown in Figure 4.4. For example, in the aquatic environment, the limiting water concentration is calculated using this information for each nuclide assuming 100 % occupancy in sediment. For the terrestrial environment the organism would be assumed to live entirely in soil.

There are differences with currently used methodologies such as the USDoE's Graded Approach [USDoE, 2002].

1. ERICA could use largest reference organism size for internal DCC and smallest reference organism size for external, instead of infinitely large (for internal) or small (for external) in the case of the USDoE [2002] Graded Approach.
2. ERICA could assume 100 % occupancy in, for example, sediment (in the marine ecosystem gives the highest exposure for all K_d>1, i.e. Cl is a special case), instead of assuming 100 % occupancy in each habitat.

Taking the example of the aquatic environment and assuming a 100 % occupancy in sediment, the limiting concentration in water for Approach A, can be derived using the following equation:

$$D_{lim} = C_{w-lim}\left[DCC_{int} \cdot CR + DCC_{ext} \cdot K_d\right] \qquad [4.1]$$

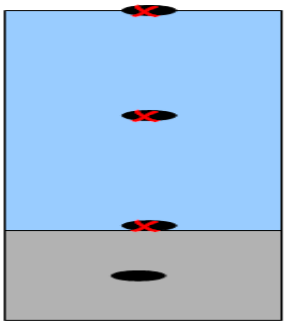

Figure 4.4: Aquatic organism configuration using Approach A. Crosses indicate that the configuration is not selected.

4.2.2 Approach B: single EMCL per nuclide approach

In this approach, the suite of ERICA reference organisms are treated separately, i.e. the full reference organism versus radionuclide EMCL matrix is computed. The limiting habitat for each of the reference organism is initially identified, Figure 4.5. For example, in the case of a bird in the terrestrial environment this would be identified to be the soil-air interface and for crustaceans in the marine environment the sediment-water interface. The limiting soil (terrestrial) or water concentration is then calculated using appropriate equations, *e.g.*

$$\text{For marine crustaceans : } EMCL_{crus} = \frac{D_{lim}}{\left[DCC_{int} \cdot CR + 0.5 \cdot DCC_{ext}^{M}\left(1 + K_{d}^{M}\right)\right]} \quad [4.2]$$

$$\text{For terrestrial bird } EMCL_{bird} = \frac{D_{lim}}{\left[DCC_{int} \cdot CR + DCC_{5,vol}^{T}\right]} \quad [4.3]$$

Where: D_{lim} = limiting dose-rate (default = 10 µGy h^{-1} for ERICA)

DCC = Dose conversion coefficient (µGy h^{-1} per Bq kg^{-1})

CR = Concentration ratio (Bq kg^{-1} f.w. organism per Bq kg^{-1} or Bq l^{-1} soil or water)

K_d = Distribution coefficient (l kg^{-1})

The Risk quotient for a specific radionuclide is defined by:

$$RQ_n = \frac{M_n}{EMCL_n} \quad [4.4]$$

Where: RQ_n = Risk quotient for radnionuclide "n"

M_n = measured activity concentration for radionuclide "n"

$EMCL_n$ = Environmental Media Concentration Limit fro radionuclide "n"

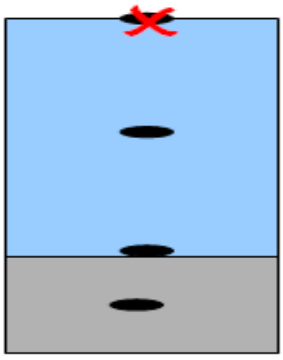

Figure 4.5: Aquatic organism configuration using Approaches B and C. Crosses indicate that the configuration is not selected.

In summing RQs, the lowest radionuclide specific EMCL value (which will return the highest radionuclide specific RQ value) is selected for each radionuclide. Although this approach might also be deemed overly-conservative, we can argue that Approach B is *fairly* consistent with other

assessment approaches (*e.g.* USDoE [2002]), provides only a single EMCL value for each radionuclide and does not imply that we have a greater detail of information than we actually have, especially since for some of the radionuclide_reference organism combinations we have very little data. Approach B is depicted in Figure 4.6.

This approach differs from USDoE [2002] in that:

1. Organism-specific DCCs are used, instead of infinitely large (for internal) or small (for external).
2. 100 % occupancy in the habitat giving the highest dose is assumed, instead of assuming 100 % occupancy in each habitat.

	RQs			Σ RQ
	Cs-137	Po-210	Ra-226	
Zooplankton	0.10	0.20	0.35	
Bivalve mollusc	0.12	0.36	0.02	
Polychaete worm	0.41	0.01	0.02	
Vascular plant	0.14	0.03	0.05	
	0.41	0.36	0.35	1.12

Figure 4.6: Summing of RQs across radionuclides for Approach B. The highest radionuclide-specific RQ is selected in each case.

4.2.3 Approach C: EMCLs for every reference organism versus radionuclide combination

As for Approach B, the suite of ERICA reference organisms are treated separately and the limiting habitat for each of the reference organism is initially identified before appropriate calculations are made for each radionuclide reference organism combination.

The Approach differs at the stage involving the summing of RQs. In Approach C, reference organisms are treated independently when summing across radionuclides. The assessor can test whether RQ is greater or less than 1 for every reference organism, see Figure 4.7.

	RQs			Σ RQ
	Cs-137	Po-210	Ra-226	
Zooplankton	0.10	0.20	0.35	0.65
Bivalve mollusc	0.12	0.36	0.02	0.50
Polychaete worm	0.41	0.01	0.02	0.44
Vascular plant	0.14	0.03	0.05	0.22

Figure 4.7: Summing of RQs across radionuclides for Approach C. RQ are summed across radionuclides on an individual reference organism basis.

Summing the RQs in this way avoids the problem of combining data from different organism types. However, the approach is complicated by the fact that there a numerous EMCLs for each radionuclide the number of which corresponds to the number of reference organism present in the selected ecosystem.

4.2.4 Other methods of combing RQs

In addition to the approaches identified above it should be noted that in some approaches RQs are combined for more than 1 limiting media. Taking the example of the USDoE [2002] graded approach, RQs in the aquatic environment are derived as specified in the following equation:

$$\sum RQ = \left[\frac{C_A}{BCG_A} + \frac{C_B}{BCG_B} + ... + \frac{C_N}{BCG_N} \right]_{WATER} + \left[\frac{C_A}{BCG_A} + \frac{C_B}{BCG_B} + ... + \frac{C_N}{BCG_N} \right]_{SEDIMENT} \quad [4.5]$$

Where: C_N = Activity concentration of radionuclide "n"

BCG = Biota concentration Guide (corresponds to ERICA's EMCL) for radionuclide "n".

This approach is conservative because there is an implicit assumption that, for the given example, an organism is spending 100 % of the time immersed in water and 100 % of the time immersed in sediment. In other words, the organism is assumed to be in 2 places at once. Using simplifying assumption relating to occupancy factors for reference organisms removes the requirement to invoke this overly conservative (arguably unrealistic) RQ-summing methodology. Furthermore, the approach is simplified by eliminating the necessity to provide EMCLs for more than 1 media type.

4.3 Natural radiation

The IAEA [2000] has two definitions of relevance.

- **Background.** "The *dose* or *dose rate* (or an observed measure related to the *dose dose rate*), attributable to all *sources* other than the one(s) specified.

  Strictly, this applies to measurements of *dose rate* or count rate from a sample where the *background dose rate* or count rate must be subtracted from measurements. However, *background* is used more generally, in any situation, which a particular *source* (or group of *sources*) is under consideration, to the effects of other *sources*. It is also applied to quantities other than *doses, dose rates*, such as *activity concentrations* in environmental media.

- **Natural background**. The *doses*, *dose rates* or *activity concentrations* associated with *natural sources* or any other *sources* in the environment, which are not amenable to control.

  This is normally considered to include *doses*, *dose rates* or *concentrations* due to *natural sources*, global fallout (but not local from atmospheric nuclear weapon tests and the Chernobyl accident.

All living organisms are exposed to ionising radiation from natural sources. Background radiation originates from both cosmic radiation and from radionuclides in the environment. It does not include exposure from natural radionuclides due to human activities. So, the doses absorbed by biota from natural radiation sources can be quantified, and thus one can measure whether exposure caused by human activities may, or not, add a significant increment of the background dose level.

Currently, most estimates of background exposures refer to humans in the terrestrial environment [UNSCEAR, 2000]. However, the exposure conditions for biota are much more variable. Background exposure to biota is the result of the complex interaction of habitat, exposure route, size and shape of the organism, radionuclide accumulation in the organism and the geometrical relationship of radiation source and target. Furthermore, exposure to background radionuclides may change with life stage as the geometry and ecological niche alters.

In view of the enormous variability of life-forms, it is clearly impossible to consider all species of flora and fauna and it is advisable to consider a limited set of reference organism that are representative for large components of common ecosystems.

Natural background exposures for terrestrial and aquatic biota are estimated by Gomez-Ros *et al.* [2004] and Brown *et al.* [2004] respectively. For terrestrial biota, the radionuclides ^{40}K, ^{210}Pb, ^{210}Po, ^{226}Ra, $^{228/232}$Th, and $^{234/238}$U were taken into account. Depending on organism and habitat, the external exposure varies in a range of 0.01-0.1 µGy/h. The main contributors are ^{40}K, ^{228}Th and ^{226}Ra (including daughter nuclides). The variation of internal exposures from natural radionuclides is wider. Depending on organ, weighted internal doses are estimated in the range from 0.02–2 µGy/h. The lower limit of this range is determined by the levels of ^{40}K, which vary relatively little. In organs as bone or liver that accumulate α-emitters, internal dose might be 1 µGy/h or more. The resulting total background exposures are summarised in Table 4.6. There are several other natural radionuclides as *e.g.* ^{3}H, ^{7}Be, ^{14}C, ^{22}Na, ^{26}Al, ^{32}Si, ^{35}S, and ^{87}Rb. Their contribution to the dose is very low; *e.g.* the exposure due to ^{14}C in activities of 0.21 Bq ^{14}C/g ^{12}C is in the order of 10^{-3} µGy/h.

Table 4.6: Background exposures to selected organisms and tissues in the terrestrial environment

Organism/Tissue	Exposure (µGy/h)[a]	Main radionuclides	Main exposure route
Freshwater			
Crops (above ground)	0.05-0.1	^{40}K, ^{226}Ra	Internal
Muscle (cattle)	0.03-0.06	^{40}K, ^{226}Ra	Internal
Bone (cattle)	ca. 1-2	^{226}Ra	Internal
Kidney (cattle)	0.02-0.05	^{40}K	Internal
Liver (cattle)	0.05-0.2	^{210}Po,	Internal
Egg (hen)	1	^{210}Po	Internal
Burrowing animals (lung)	100-10000[b]	^{222}Rn++	Internal
Arctic animals (bone)	1-30	^{210}Po	Internal

[a] weighting factor for α-radiation = 10

[b] depending on time spent in burrow, radon concentration, equilibrium factor

Under specific circumstances, much higher internal exposures may occur. Grazing animals in Arctic regions may be more highly exposed to ^{210}Pb and ^{210}Po that accumulate in lichens which is the main feed for some species. ^{210}Pb and ^{210}Po are daughter nuclides of ^{222}Rn which emanates from the soil and decays subsequently to ^{210}Pb and ^{210}Po in the atmosphere. Macdonald *et al.* [1996] found in tissues of Canadian caribou in some herds, mean activities of 500 and 1000 Bq/kg fresh weight for ^{210}Pb and ^{210}Po respectively. Assuming a weighting factor for α-radiation of 10, such ^{210}Po levels cause weighted internal doses of up to 30 µGy/h.

Even higher doses occur for small burrowing mammals that live in soil and which are exposed to high radon levels in soil [Macdonald and Laverock, 1998]. For ^{222}Rn in soil air, levels in the order of 10000 Bq/m³ are not untypical. Dependent on the organisms and their time spent in burrow, out of burrow or

hibernating, this causes unweighted lung exposures in the order of some tens to some hundreds of µGy/h.

Typical ranges for the exposure of aquatic biota from natural sources are summarised in Table 4.7. The exposures are generally higher than for terrestrial organisms. Internal exposure dominates by far; the main contributors are ^{210}Po, ^{226}Ra, ^{228}Ra and ^{228}Th. Doses are higher for freshwater organisms, with broader ranges reflecting enhanced variability of radionuclide concentrations and associated uncertainties in freshwater. For both, marine and freshwater organisms, typical values for weighted exposures are in the order of a 1 µGy/h. However, the variations are considerable and some organisms are exposed at levels of some tens of µGy/h.

Table 4.7: Natural background exposures for freshwater and marine organisms

Habitat/Organism	Exposure (µGy/h)		Main radionuclides	Main exposure route
	Total	Range		
Freshwater				
Phytoplankton	2.5	0.94-30	^{210}Po, ^{226}Ra	Internal
Macroalgae	4.2	1.3-57	^{226}Ra, ^{210}Po	Internal
Mollusc	3.5	1.1-25	^{210}Po, ^{226}Ra	Internal
Crustacean	1.7	0.65-23	^{226}Ra, ^{210}Po	Internal
Pelagic fish	0.36	0.12-6.7	^{226}Ra, ^{210}Po	Internal
Benthic fish	1.9	0.68-31	^{226}Ra, ^{210}Po	Internal
Marine water				
Phytoplankton	0.75	0.31-6	^{228}Ra, ^{228}Th	Internal
Zooplankton	0.87	0.36-2.6	^{210}Po, ^{228}Th	Internal
Macroalgae	0.26	0.16-0.95	^{210}Po, ^{228}Th	Internal
Molluscs	0.15	0.88-5.2	^{226}Ra, ^{228}Th	Internal
Crustacea	1.7	0.27-27	^{210}Po, ^{226}Ra	Internal
Fish	0.14	0.08-0.71	^{210}Po, ^{40}K	Internal
Mammals	0.62	0.49-3.2	^{210}Po, ^{40}K	Internal

4.3.1 Management options

There are several options to use background exposures as a basis from which to set up limits for regulation. A summary of these options with its advantages and disadvantages is given in Table 4.8.

The first three options are all oriented on the variation of the background exposure. The idea is to allow additional exposures to organisms that are a fraction or a small multiple of the natural background exposure. Exposures within the variation of the background dose assumed to be insignificant which ensures that no adverse effects due to the additional exposure have to be expected. However, the background is very variable and covers a range of about 2 orders of magnitude.

One option is to use a fixed ratio to background radiation for the region, *e.g.* 10 % (i.e. insignificant). The additional dose is small and therefore, no adverse effects due to the additional exposure are expected. However, due to the large variations of background exposures, organisms in different habitats would have different base lines. This is also the case for the concept the derived consideration levels (DCL) that is proposed by ICRP [2003]. The DCL refers to the background exposure of a specific reference organism in a specific habitat. In ICRP 91, it is suggested that concern on the exposure might be indicated, if the additional dose is about a factor of 10 above the specific background exposure of a reference animal or plant.

However, due to the pronounced variability of background exposure, this would imply that the DCLs that indicate possible concern vary largely the with reference organism considered. This is very impractical, since the background exposures for the different reference organisms vary at least over

one order of magnitude. Furthermore, the effects data base set up in FASSET and ERICA gives no indication that the radiosensitivity of the reference organisms varies in a similar matter as the background exposure. This does not justify the application of species specific background levels for the derivation of allowable radiation levels from anthropogenic activities.

The application of site-specific background levels for the derivation of allowable additional exposures could imply that in areas with high natural background, higher additional exposures could be acceptable if the additional exposure is defined as a fixed fraction of the background exposure. So it might be more appropriate to use average global rather than the site-specific background exposure as criterion. This would avoid that on highly contaminated sites higher exposures would be acceptable than on sites with low natural contaminations.

The clearest approach is probably to introduce a fixed limit that is derived from the upper range of natural background for all organisms and habitats (Option 4). Natural background exposures vary from less than 0.1 µGy/h to some tens of µGy/h (excluding radon). In the FREDERICA effects data base, only minor effects are reported for dose rates less than 100 µGy/h. So, there is no concern that biota are affected if exposed to background levels, even if the exposure as at the upper bound of the background range of, say 10 µGy/h. Furthermore, the FREDERICA data base gives no indication about pronounced differences in radiosensitivity between the different organisms; this means there is no reason to apply different limits to different classes of biota.

The background exposure of soil animals due to radon and daughters is a specific issue. In comparison to other radionuclides, lung exposures of burrowing animals from ^{222}Rn and its daughters are very high and dominating by far all other exposure routes. The lung exposures are in the order 10-1000 µGy/h depending on the circumstances. Whole body exposures above 100 µGy/h cause statistically significant effects to biota [Real *et al.,* 2004]; this means, the use of radon exposures as a base for evaluation of exposures to biota could lead to allowable exposures that cause significant radiation effects at least to a part of the animal and plant species. Therefore, it is thought that radon background exposure is an inappropriate yardstick to evaluate anthropogenic exposures.

Table 4.8: Options for using natural background exposures to biota.

Option	Strength	Weakness
Allow the increase of the natural background exposure by a fixed percentage of the region	Additional dose is a small fraction of the natural which is assumed to cause, if any, minor effects only	Difficult to implement, since background varies with organism, habitat and geology
Limit for additional doses to biota proportional to the variation of natural background exposure	Exposures within the variation of the background dose assumed to be insignificant	Variation of the background between different ecosystems much larger than between species in a given ecosystem Effects data do not indicate pronounced differences in radiosensitivity for all species
Derived consideration levels (DCL): Concern might be indicated if additional dose is more than a factor of 10 higher than the background	Orientation on the background avoids exceptionally exposures	Due to the variability in background exposures with concern would vary largely with the organism considered. Effects data do not indicate that radiosensitivity varies in a similar matter as the background
Constant dose rate limit of 10 µGy/h to organisms derived from the upper range of the observed background exposures (excluding radon)[a]	Clear and transparent approach Effects data base does not indicate relevant differences in radiosensitivity According to the effects data base FREDERICA, no adverse effects are observed for chronic exposure levels of 10 µGy/h.	In areas, where exposures to biota in the order of 10 µGy/h are induced by man-made radionuclides, the exposure to the population has to be carefully checked to ensure compliance with human radiation protection standards

[a] Radon induces weighted lung doses to burrowing mammals in the order of 100 µGy/h [MacDonalds and Laverock, 1998], which is in the range for which radiation effects may be observed in case of whole-body irradiation.

5 Accidental Scenarios

Accidental scenarios involve the release of radioactivity into the environment over a short period of time. As the ERICA assessment methodology and Tool use transfer factors from environmental media to organisms that assume concentrations in environmental media and organisms are in equilibrium, the methodology cannot be applied directly to the very dynamic situation that pertains in the immediate aftermath of a major nuclear accident.

Accidental releases of radioactivity can occur both to the atmosphere and to the aquatic environment. However, both historically and in terms of hazard analyses for nuclear facilities, releases to atmosphere are of greater significance.

The immediate aftermath of an accidental release of radionuclides to atmosphere will be characterised by high activity concentrations on vegetation due to deposition of particulates and reactive vapours (e.g. iodine radioisotopes) from the atmosphere. Initially, this deposit will be present largely as external contamination on foliage surfaces; the external contamination will decline quite rapidly due to weathering processes, with a removal half-life in the order of 10 to 15 days. For short-lived radionuclides, which make a very important contribution to initial contamination levels following a nuclear reactor accident, radioactive decay will make an additional contribution to the reduction in concentrations.

Radionuclides removed from vegetation by weathering accumulate in soil; for most radionuclides accumulation will initially be confined to the top 5 cm or so of the soil profile, with subsequent relatively slow downward migration at a rate largely controlled (in undisturbed soils) by the sorption coefficient.

Experience from past major nuclear accidents (Khystym and Chernobyl) indicate that during the initial phase of high concentrations on vegetation early adverse effects may be observed in plants, particularly in trees because of the high efficiency of the canopy in intercepting airborne particulates and vapours. Appendix 4 provides an overview of atmospheric dispersion and deposition modelling, which will permit estimates to be made of the initial concentrations of radionuclides in and on vegetation. By treating these concentrations as internal contamination within the ERICA methodology for dose calculation, estimates can be made of the initial radiation doses to plants and hence the likelihood of early effects[7].

There are no models currently available that can be used to predict the concentrations in fauna during the immediate aftermath of a nuclear accident. However, it is reasonable to assume that concentrations in fauna during this early phase will be less than the concentrations in vegetation, estimated as outlined above.

Twelve months after the initial deposition of radionuclides, the bulk of the deposited inventory that remains after radioactive decay will have been transferred to the upper 10 cm or so of the soil profile, with little remaining external contamination of vegetation. By this stage the ERICA methodology and tool can be considered applicable to the estimation of radiation doses and consequent effects for both vegetation and fauna. Of course, it will be possible to supplement calculated concentration of radionuclides in organisms with the results of actual measurements.

[7] It should be noted that this approach is most relevant for beta and gamma emitting radionuclides. In the case of alpha emitters, doses to vegetation will be over-estimated as much of the contamination will be external and so contribute little to dose to the plant.

During the first twelve months following deposition, the only reliable method of estimating internal concentrations of radionuclides in fauna would be to make actual measurements.

Of course, the management activities in the immediate aftermath of a major accidental release of radioactivity will focus on dose assessment for humans, and on the analysis and implementation of appropriate countermeasures to mitigate the radiological consequences. In this phase, the management options for limitation exposures to biota are marginal and of lower priority. Nonetheless, should the necessary resources be available, making systematic measurements of radionuclide concentrations in environmental media and biota as the affected ecosystems progress towards equilibrium would both enable the early assessment of any adverse effects on biota, and also contribute significantly to radioecological knowledge and the ability to better predict effects in the future.

6 Monitoring for Compliance and Verification

6.1 Introduction

There are a large number of options for managing the environmental risks, developed for different purposes and applying different methodologies. These programmes can be grouped into different categories, as follows:

- management through pathway based analyses of exposure, often involving environmental standards expressed in terms of concentrations or dose/dose rates;
- management through process standards relevant to (a) specific source(s) based on best available technology (BAT) or similar criteria of technical status or performance;
- certification schemes or systems to ensure that positive actions are taken to protect the environment and where continuous performance improvements are sought [IAEA, 2003].

Whereas all of these programme categories are relevant to actions directed to protect the environment, management through pathway-based analysis of exposure is closest to the assessment methodology of ERICA.

Demonstration of compliance with regard to the limitation of radiation exposure to non-human biota can and should be carried out as far as possible with the same monitoring programmes, which are traditionally carried out for human exposure.

Monitoring is the tool by which both implementers and regulators can routinely review the performance against the regulatory standards. Such monitoring could include:

- the quantity of radionuclides released;
- the concentration of radionuclides in environmental materials;
- the absorbed dose/dose rate (actual or estimated) received by non-human biota;
- the presence/absence in a species of a "biological marker" or "indicator" of some form of potential radiation effect;
- direct measurement of the "health" of a particular species or groups species (as expressed in total numbers, breeding success etc.). The "health" could also be affected by other factors.
- direct measurement of the characteristics of a particular habitat, which, again, could be affected by other factors [IAEA, 2003].

In case of planned exposure, preoperational monitoring programme is carried out to establish "baseline" environmental radiation levels and activity concentrations for the purpose of subsequently determining the impacts of the source.

6.2 Responsibilities for monitoring

Table 6.1 lists responsibilities for environmental and source monitoring for the purposes of protection of non-human biota.

Table 6.1: Responsibilities for environmental and source monitoring for the purposes of protection of non-human biota [IAEA, 2005].

Exposure category	Type of source	Responsible body	
		Registrant or licensee	**Regulatory body or designated organisation**
Planned	Excluded, exempted or cleared	No monitoring required	
	Registered sources	Source monitoring	Control measurements and review/verify dose assessments, as appropriate
	Licensed sources	Source and environmental monitoring; dose assessment	
	Multiple sources	Source and local environmental monitoring	Environmental monitoring and dose assessment
Emergency		Source monitoring, near field environmental monitoring	Large scale and near field environmental monitoring
Existing exposure		Source and local environmental monitoring	Large scale and near field environmental monitoring; dose assessment, measurement of the health of species

6.2.1 Combining human and biota monitoring

Discharge and environmental monitoring programmes are traditionally implemented for protection of humans, especially in the case of planned exposure situations. These programmes provide much information that can be used in the monitoring of non-human exposure. Complementary monitoring is needed for specific routes of biota exposure and types of biota not directly related to human exposure. Indicator organisms that accumulate radionuclides readily are used for early detection of increased radiation levels in the environment. Alternativly, radioecologically or radiobiologically sensitive organisms would give early detection of impact on biota.

6.3 Programmes for monitoring of non-human biota

The objectives for monitoring could be to:

- verify compliance with the licence (releases, concentrations of media, doses/dose rates etc.);
- verify assumptions made in risk assessment estimations (activity description, dose calculation models, effects from doses/dose rates);
- check effectiveness of actions to reduce risks;
- provide early warning of unexpected deviation from the normal exposure situation;
- provide data for improved risk assessment;
- provide information for the public.

6.3.1 Planned situations

Source related monitoring programmes should be defined according to the specific source and environmental characteristics. A systematic programme should be defined to cover radiation dose rates, radioactive discharges and relevant exposure pathways of biota with sufficient intensity. Environmental monitoring points and frequencies, types of samples of environmental media and biota and radionuclides to be measured in the programme should be selected based on information derived from the safety assessment. Application of Erica reference organisms in local conditions will guide the selection of species to be monitored. In addition, local species expected to accumulate radionuclides or to be particularly sensitive and those living in places where high exposure can occur should be considered in planning of monitoring programmes. Also, local protection goals such as protection of specific species or habitats may have influence on the design of the programme.

Monitoring of the health status of ecosystems can be used to complement radiological monitoring programmes. Specific more extensive surveillance than regular monitoring can be used to acsertain the radiological conditions and status of ecosystems in more detail. Results from these programmes will enable a better understanding of the situation and can be used to redirect existing monitoring programmes.

Generic large area or nationwide monitoring programmes are needed in addition to local source related monitoring programmes to provide reference information on the radiological and health status of the environment and to comply with international responsibilities. Large area monitoring will also inform on the situation resulting from multiple sources.

6.3.2 Emergency situations

Combining monitoring for the protection of both human and non-human biota is especially relevant in emergency situations. However, in planning the emergency monitoring programmes in advance, consideration should be given to acquiring information on the risks to the biota. The methods (sampling, measurements, calculations, pre-prepared tables etc.) of obtaining this information should be simple to be useful in emergency situations. This information could aid in decision making related to countermeasures.

6.3.3 Existing exposure situations

In existing exposure situations monitoring the health of certain species or populations can be used as a decision aid for possible remedial actions. In the next step, when making decisions on intervention, it should be taken into account that in many cases the physical and ecological consequences of remediation are more detrimental for biota populations and habitat than living in an environment with elevated radioactivity.

6.4 Use of monitoring programme results as part of risk assessment

There are two principal ways of using monitoring results. The first is simple and straightforward, namely to check monitoring results with licence requirements or other criteria. In this case no special expertise and only limited resources are needed. The process is suitable for demonstrating compliance with the regulations. Figure 6.1 illustrates the generic principles for organising monitoring.

More information could be obtained by an iterative approach in the risk assessment. It involves a combination of measurement results from regular environmental surveillance, observed trends, data from specific, more extensive research projects, calculations using separate models, studies on effects and observations of the status of the environment. This procedure requires multiple expertise and extra resources. This sort of analysis would be suitable for development of a monitoring programme and enhancement of the risk assessment.

6.4.1 Reporting and record keeping

The operator should report the radioactivity monitoring results periodically to the regulatory body in radiation safety issues following the same procedure that is applied for radiological protection of human. In reporting and record keeping, numerical information, such as activity concentrations or dose rates, is preferable as they allow simple comparison with safety criteria. In addition, reporting to environmental safety authorities (if separate) together with other environmental data should include assessment of the impact of radioactivity on the health of the ecosystem. Records should be kept, as usually stated in national regulations.

Open availability for the public of the monitoring results is preferable as it supports stakeholder involvement. In this way information from several sources can be combined.

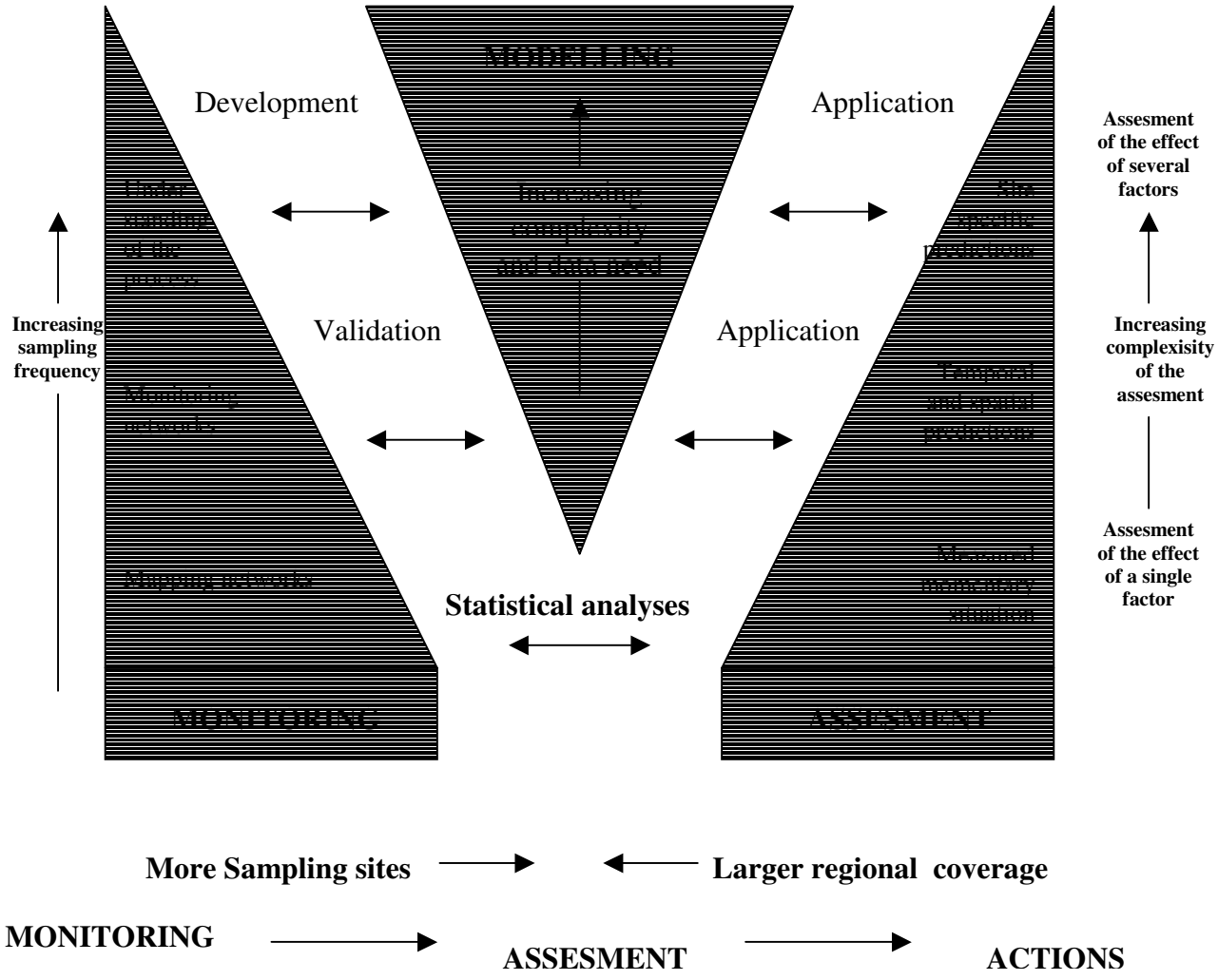

Figure 6.1: Generic principles for organising monitoring. Modified from CLRTAP ICP IM Convention for Long-Range Transboundary Air Pollution, United Nations Economic Commission for Europe [1998].

6.4.2 Uncertainties

Monitoring activities should be such as to provide the necessary data for the analysis and evaluation of environmental contamination and compliance with the regulations. Monitoring results have associated uncertainties that arise from technical uncertainties, the non-representativeness of samples and/or measurements, and human errors. These uncertainties cannot be eliminated but they should be reduced as far as possible by means of quality assurance procedures.

The technical uncertainties in the monitoring data arise mainly from the spatial and temporal variability of the quantity monitored (*e.g.* dose rate and activity concentration), the variability of procedures for sampling, processing and measurement, and the statistics of counting in the case of low-level radionuclide activity. Representativeness in sampling and/or in field measurements can be optimised by appropriate sampling and measurement schemes and by intensifying monitoring activities. Human errors are difficult to quantify but since they often can be foreseen and simulated, adequate training of personnel and quality assurance procedures should be used to reduce their number.

The uncertainties should be reported together with the monitoring results and taken into account in dose assessment procedures and in the interpretation of monitoring data [IAEA, 2005].

Multiple dimensions of uncertainties are involved when monitoring is considered as part of the assessment process *e.g.* to verify the assessed consequences to the biota or the relevance of the scope and assumptions of the assessment. The impact of radiation exposure is difficult to assess and monitor in complex environmental situations with many factors affecting the health status of biota. In addition to technical inexactness there are qualitative dimensions of uncertainty such as methodological (unreliability *e.g.* due to assumptions), epistemological (ignorance due to limited knowledge and understanding) and societal (limited social robustness) [Jeroen van der Sluijs, personal communication].

The uncertainties of the entire assessment are discussed in Chapter 3.

6.5 Selecting monitoring options

Table 5.2 highlights the strengths and weaknesses of the potential types of monitoring programme for planned activities. Usually, the monitoring programme should be a compilation of source and environmental monitoring, supplemented with measurements of ecosystem health, as appropriate. The nuclides and materials subject to monitoring, as well as monitoring frequencies are not dealt with.

Table 5.2: Strengths and weaknesses of different monitoring options

Biota or environmental media concentration as screening value (e.g. Tier 1)		
Description	**Strengths**	**Weaknesses**
Monitoring of releases at source *Regulatory limit: Release*	• monitoring easy, can be automatic and include screening alarm or be based on sampling at source • serves simultaneously for protection of human and non-human species	• environmental dispersion and transfer calculations needed, either screening or site specific calculations

Biota or environmental media concentration as screening value (e.g. Tier 1)		
Description	**Strengths**	**Weaknesses**
Environmental monitoring *Regulatory limit: Release* Monitoring of environmental media concentrations	• environmental transfer calculations only from media to biota (no dispersion calculation needed) • usually serves simultaneously for protection of human and non-human species	• link from releases to environmental media concentrations needs modelling • monitoring may be difficult due to low concentrations
Monitoring of biota concentrations	• no transfer calculations	• link from biota concentrations back to environmental media + releases needs modelling • monitoring may be difficult due to low concentrations
Environmental monitoring *Regulatory limit: Environmental media concentrations* Monitoring of environmental media concentrations	• no transfer calculations • usually serves simultaneously for protection of human and non-human species	• monitoring may be difficult due to low concentrations
Monitoring of biota concentrations		• link from biota back to environmental concentrations needs modelling
Environmental monitoring *Regulatory limit: Biota concentrations* Monitoring of environmental media	• environmental transfer calculations only from media to biota • usually serves simultaneously for protection of human and non-human species	• monitoring may be difficult due to low concentrations • link from environmental concentrations to biota needs modelling
Monitoring of biota	• no transfer calculations • might serve simultaneously for protection of human and non-human species	• monitoring may be difficult due to low concentrations
Biota dose/dose rate as screening value (e.g. Tiers 2 and 3)		
Description	**Strengths**	**Weaknesses**
Regulatory limit: Release **Monitoring of releases at source**	• monitoring easy, can be automatic and include screening alarm or be based on sampling at source • serves simultaneously for protection of human and non human species	• environmental transfer and media to biota + dose rate calculations needed

Biota or environmental media concentration as screening value (e.g. Tier 1)		
Description	**Strengths**	**Weaknesses**
Regulatory limits Release **Environmental monitoring** Monitoring of environmental media concentrations	• monitoring of environmental concentrations easier than monitoring of dose rates • usually serves simultaneously for protection of human and non-human species	• link from releases to environmental concentrations needs modelling + dose rate calculations • monitoring may be difficult due to low concentrations
Monitoring of biota concentrations	• only dose rate calculations needed	• link back from biota concentrations to releases needs modelling • monitoring may be difficult due to low concentrations
Regulatory limit: Environmental media concentrations **Environmental monitoring** Monitoring of environmental media concentrations	• usually serves simultaneously for protection of human and non-human species	• monitoring may be difficult due to low concentrations • link from environmental media concentrations to biota needs transfer modelling + dose rate calculations
Monitoring of biota concentrations	• only dose rate calculations needed	• link back from biota concentrations to regulatory limit of environmental media concentrations needs modelling
Regulatory limit: Biota concentrations **Environmental monitoring** Monitoring of environmental media	• only dose rate calculations needed • might serve simultaneously for protection of human and non-human species	• link from environmental concentrations to biota needs modelling + dose rate calculations
Monitoring of biota	• only dose rate calculations needed	• often does not serve simultaneously for protection of human and non-human species
Regulatory limit: biota dose rates **Individual monitoring**	• actual (external) dose rates measured	• practical problems with the recovery of fauna wearing dosimeters • often does not serve simultaneously for protection of human and non-human species
Protection of populations and ecosystems		
Description	**Strengths**	**Weaknesses**
Measurement of the health of particular species or group of species, including so called indicator organisms (expressed in total numbers, breeding success etc.)	• measurement often carried out for other than radiation protection purposes	• influence of other factors is difficult to distinguish from that of radioactivity • very resource consuming if carried out solely for radioactivity

Biota or environmental media concentration as screening value (e.g. Tier 1)		
Description	**Strengths**	**Weaknesses**
Detection of so called "biological marker" of some form of radiation effects in a species	• direct information of effects to certain species	• could be resource consuming • has to be interpolated to other populations and/or ecosystem
Direct measurement of the characteristics of a particular habitat	• measurement often carried out for other than radiation protection purposes	• influence of other factors is difficult to distinguish from that of radioactivity

7 Concluding an Assessment

Once a risk assessment is completed, three outcomes exist:

- the risk is below concern;
- there is insufficient confidence that the risk is below concern ; or
- the risk is of concern.

This is dependant on the pre-defined problem formulation criteria. For each of these outcomes, a number of possible statements can be derived, **based solely on the assessment of biota**. Table 7.1 merely offers a range of possible actions for each of the ICRP exposure situations. A wider context may subsequently change the overall decision.

Table 7.1: Examples of possible conclusions, based on the results of the assessment to non-human biota. *ICRP quotes "emergency exposures" – for the purpose of ERICA, post-emergency exposures are more appropriate

Outcome	ICRP exposure situations		
	Planned	**Existing**	**Post-Emergency**
Risk is of concern	Say no to the practice or: Reconsider the proposal Another site Reconsider decision Perspective of other risks Would more site specific (or appropriate) data help? Are there other external over-riding priorities that mean that the practice should be started? Shut down practice Consider changes of current practice to re-optimise the process	Consider ecological value of present site Would remediation do more good than harm? Cost benefit analysis is needed	Consider ecological value of present site Would remediation do more good than harm? Socio-economic (e.g. cost-benefit) analysis is needed
Insufficient confidence that the risk is below concern	Would more data be helpful? Or available? Ask experts for help Proceed with additional controls imposed and review practice/assessment after defined time intervals Say no to the practice Re-iterate the assessment Undertake a multi-criteria decision analysis Shut down existing practice Consider changes of current practice to re-optimise the process Proceed with additional controls imposed and review practice/assessment after defined time intervals Say no to the practice	Ecological restoration Consider assessment of other stressors Consider ecological value of present site Would remediation do more good than harm? Cost benefit analysis is needed Onus of proof is on operator	Consider ecological value of present site Would remediation do more good than harm? Socio-economic (e.g. cost-benefit) analysis is needed Timescales and observe
Risk is below concern	Proceed but consider other factors *e.g.* cost, BAT, human exposure and optimisation	No intervention for biota Consider if controls for human exposure are required	Biota will be fine consider other factors

In the ERICA Integrated Approach, the ERICA Tool does not provide decisions for the assessor to take. For Tiers 1 and 2 the ERICA tool indicates whether the risk quotients are below or above 1. If above 1, the tool recommends that the assessor should move to the next tier – solely on the effects observed on environmental grounds, i.e. data provided and effects calculated on biota. In Tier 3, information will be provided at the end of the assessment:

1. dose rates;
2. effects data for those dose rates are mainly for individuals not populations;
3. probability distributions of dose rates; and
4. guidance for deriving benchmarks, for a given endpoint or organism.

7.1 Extrapolation

In ERA, the common way to deal with uncertainty is to propose extrapolation rules, see D4b [ERICA, 2005]. Extrapolations over time, space, taxa, stressors, and level of biological organisation are common practice to produce ERAs. This can apply for exposure and effects analyses, and for risk characterisation. This is generally done while using more or less refined conceptual mechanistic models (transport and fate models, multimedia models, biokinetics models), empirical "black box" models based on regression relationships (allometric scaling, phylogenetic extrapolation etc), and/or less elaborate "safety" or uncertainty factors" and/or statistical models based on probability distributions. The two first categories are mainly used for exposure assessments while the latter two have been developed as methods for effect and risk. ERICA D5 and its Annexes explore this issue in detail, via, for example, experimentation. In this report, extrapolation has been used at various stages of the assessment, and referred to within Chapter 3 and 4.

Once an assessment is complete and the results are given based at the individual level, there may be a need to determine whether populations or ecosystems are being protected. During the EUG Consensus Seminar [D7f, 2006], it was concluded that:

> "While there is a lack of direct data identified as ecologically relevant within FREDERICA, conservative screening benchmarks have been derived based on available data for mortality, morbidity and reproduction endpoints, which are population relevant. Where protection of the population is the objective then extrapolation from effects on individuals to a population is necessary, but may not be straightforward."

The problem when assessing the effect at population level is the complexity of the system coupled by the availability of data as well as knowledge gaps that are present at both population level (*e.g.* population size to population growth rate relationship [Silby *et al.*, 2005]) and at the lower level of organisation (*e.g.* individual). Linking effects across levels of biological organisation is, however, a well-known problem to adequate assessments of ecological risk [Hinton *et al.*, 2004].

During the ERICA EUG event [ERICA D7b, 2004], there was a general agreement that extrapolation was a matter of immense complexity, and that endpoints differ in human and ecological risk assessment. There was doubt as to the usefulness of the application of biomarkers as an extrapolation tool. In groups and plenary discussions, modelling was proposed as the most feasible unified approach, both regarding chemicals and ionising radiation and for individual and ecosystem effects. There was some disagreement as to whether protecting at the individual level would be the most pragmatic approach.

Extrapolation is a matter of immense complexity, and endpoints differ in human and ecological risk assessment. For non-human biota, the aim is to avoid deterministic effects at the population level. Several studies suggest that at a dose rate of lower than 1 mGy/d for the most exposed individuals,

there would be no detrimental effects at the population level [USDoE, 2002]. Hence, the system for man is more stringent than for non-human biota, a situation that has some similarity with regulations of chemicals, where the criteria for drinking water (aimed at man) are much stricter than for surface water. A number of other factors might have a greater impact than extrapolation. For example, food intake may be more important than exposure itself.

7.1.1 Factors to consider

A number of parameters are known to be of importance when extrapolating from individual to population level [Garnier-Laplace *et al.*, 2004]. In addition, knowledge gaps related to these parameters add to the uncertainty of extrapolation. Table 7.2 summarises the issues and also provides some way of dealing with those parameters during extrapolation.

Table 7.2 Parameters of importance at population level to be considered during extrapolation

Parameter	Knowledge Gap	Solution
Different life stages	Which life stage is the most important to maintain the population? The most sensitive life stage may not be the one studied.	Add margin of safety if there is a lack of data. The best, however, is to integrate the effects on various life stages via population growth rate analysis. This may not be possible due to lack of data.
Different life cycles for different species - different reproductive strategies respond differently to the same degree of radiation effect.	Which population dynamic features may result in increased sensitivity at the population level?	Taking life-cycle characteristics should be considered to increase the reliability of the risk assessment, *e.g.* Woodhead [2003].
Density dependent factors	Do density dependent factors, *e.g.* temperature, competition of resources, render the population less sensitive than its individuals?	Hard to draw general conclusions on how those factors may influence extrapolation.
Effects of DNA damage	In the case of increased mutation rates due to radiation, which other accelerating factors would lead to reduced fitness and population decline?	Less concerned except for large mammals.

7.1.2 Methods to extrapolate effects from the individual to the population level

Current extrapolation methods assume that the variability in toxicant sensitivity among species ignores life history characteristics [Hinton *et al.*, 2004]. Basic physiological and life history trait differences should be taken into account as they determine the individual response to changes in contaminants [Hinton *et al.*, 2004]. There are two current approaches to extrapolating: use of safety factors and modelling.

- **Safety factors.** Chapman *et al.* [1998] defines a safety factor as a means by which known data are extrapolated to deal with situations for which there are no data. The use of safety factors has also been widely used as a method of introducing conservatism into the estimates, whereby the size of the safety factor increased as uncertainty increases [ERICA D7b, 2004].

  The magnitude of the extrapolation factors is determined on the basis of the quality, quantity, and relevance of the available ecotoxicity test data. Extrapolation factors often vary from 1 to

1000, and are routinely used and accepted by regulatory agencies in both Europe and North America [Hinton *et al.*, 2004; Garnier-Laplace *et al.*, 2004].

- **Modelling.** A population model is simply a mathematical representation of the biological processes that take place within an identified population, based on individual attributes, with a number of assumptions and constraints. Modelling should focus on reproduction endpoints [ERICA D5, 2006]. Calow *et al.* [1997] developed an approach to catalogue a series of simplified life-history scenarios to demonstrate how individual level effects propagate to population dynamics, based on ecotoxicological test results.

  Woodhead [2003] specify two classes of models that can be used to study the effect of contaminants at population level.

  - Metabolic models. These depend on the availability of detailed information on the effects of the contaminant on the basic biochemistry and metabolism of the organism, and integrate this information into a model of future population reproduction and growth. These have primarily been applied to investigate the effects of xenobiotic chemical compounds, *e.g.*, pesticides, PCB etc.
  - Leslie matrix models. These models employ life table (age-specific) information on birth, morbidity and death rates to project the future evolution of the population structure. They appear to be more appropriate to the information available on the effects of radiation on individuals and are amenable to use in experimental scenarios.

Woodhead [2003] developed a Leslie matrix population model approach to investigate how the effects of radiation on individuals may propagate to produce (or not) a response at the population level. It has been applied to two fish species with different life cycles and reproductive strategies - the plaice (*Pleuronectes platessa*) and the thornback ray (*Raja clavata*). The results appear to confirm the relative sensitivities of the two populations, as might have been predicted on the basis of their life cycles and reproductive strategies, to possible effects of radiation on individual fertility, fecundity and mortality. The female plaice can produce thousands of eggs, while the thornback ray produces fewer (but more protected) eggs and more highly developed neonates. Although the model, as currently implemented, probably lacks full biological realism, it has generated some interesting and useful information. It appears that rather small radiation-induced reductions in egg production and embryonic survival, and increases in age-dependent mortality could aggregate to produce significant effects at the population level [Woodhead and Zinger, 2003].

In ERICA D5 [2006], population models were used to extrapolate toxic effects on various combinations of individual life-cycle variables (i.e. survival, reproduction, and maturation) to effects on population dynamics. This was done using population models to extrapolate toxic effects on various combinations of individual life-cycle variables to effects on population dynamics. The ERICA experiments clearly showed that in any species, changes in life history traits due to radionuclide exposure could induce a variable impact on population dynamics. The growth rate of the population is most sensitive to effects on (in order) age of reproduction, on fecundity and adult mortality. However, the relative importance of each life history trait also varies between species, depending on the type of reproductive strategy and generation time. Thus, when assessors need to address individual-to-population extrapolation, we recommend following these successive steps:

1. collect data describing the life history traits of the species under investigation;
2. implement theoretical population dynamic models to rank the sensitivity of the population growth rate to individual 'vital' rates or endpoints;
3. search in the literature, or conduct experiments where knowledge gaps exist to obtain dose(rate)-effect relationship(s) for those individual effect endpoints inducing a substantial reduction in the growth rate of the population.

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Appendix 1: Decisions to be taken within the ERICA Tool

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
Appropriate data entry (screening Tier 1) for Retrospective assessment	Screen 1 assessment context (Tier 1)	Use maximum media activity concentration value derived from an empirical dataset	Most robust defendable approach – empirical data therefore no assumptions required with respect to behaviour and fate of radioactivity in the environment. Provides an integrated view of contamination levels	There will be a cut-off where too few empirical data exist to perform a robust analysis using the user-defined option. A reasonable data coverage in time and space may be required to ensure that a maximum value is acquired.
		Select the tool default transport model (based on IAEA [2001])	Provides a quick and easy method to establish whether a problem might exist	Output from this generic screening model may not reflect the real contamination levels. Problems related to time-integrated contamination levels
		Select user-defined transport model and enter data based on simulation output.	May predict quite realistic activity concentration data	Problems related to time-integrated contamination levels although simulating over long time periods may mitigate the situation
Appropriate data entry (screening Tiers 1 and 2) for Prospective assessment	Screen 1 assessment context (Tier 1 and 2)	Select the tool default transport model (based on IAEA [2001])	Established, internationally-recognised methodology. Provides consistency allowing inter-comparison between different assessments	May be overly conservative

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
		Select user-defined transport model and enter data based on simulation output	User may feel more confident for this particular case. A site specific model should provide the best estimate of contamination levels for this type of assessment	Requires some consideration of the most appropriate scenario for prediction – in particular issues related to spatial and temporal averaging
		Enter proxy data that are based on expert judgement, *e.g.* comparison with the contamination surrounding existing sites with similar technical specification, authorisation limits and receiving environment	Based on real-world conditions. Reasonable semi-empirical approach.	Cannot be established as being a conservative, i.e. screening, approach.
Appropriate data entry (screening Tier 2) for Retrospective assessment	Screen 1 assessment context (Tier 2)	Use representative empirical activity concentration data for environmental media and biota.	Most robust defendable approach – empirical data therefore no assumptions required with respect to behaviour and fate of radioactivity in the environment.	Relatively complicated set of rules governing which data take precedence, *e.g.* data available for organism A, B and sediment : which value(s) should be used to derive water concentrations?
		Select the tool default transport model (based on IAEA [2001]) to derive media concentrations	Provides a quick and easy method to establish whether a problem might exist	Will tend to provide conservative activity concentrations in environmental media.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
		Select user-defined model and enter data based on simulation output.	May predict quite realistic activity concentration data	May be some confusion relating to consistency with the parameters used in ERICA. For example if the model uses a bespoke suite of transfer factors that bear little resemblance to the values used as defaults in the tool.
Assessor faced with multi-contaminants (including non-radioactive substances)	The assessment tool deals with radioactive contaminants only			
Assessor faced with multiple sources arising in different environments	Screen 1 assessment context	Run through the assessment numerous times in accordance with the more complicated scenario, then add all components.	Considers all sources and impacted environment. Allows identification of the dominant source and most vulnerable environmental receptor	Difficult to acquire all the necessary data
		Select the dominant/most relevant source and ignore the others.	Simplifies the problem.	May lead to an underestimation of the total risk

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
Selection of dose-rate screening value	Screen 1 assessment context	Use one of the default ERICA screening values	Values derived based on analyses of latest current available data and established statistical methods [Garnier-Laplace and Gilbin, 2006]	Data frozen in time and may be outdated by new research
		Select a user defined screening value	Dose-rate screening level might be more acceptable because it falls in line with national legislation or guidance and or internationally-accepted recommendations	Screening values may not account for the most up-to-date environmental radiobological data
		Do not use a screening value	May not be needed by assessor	Risk quotients cannot be derived and thereby no *exceedence* criteria can be defined.
Selection of EMCLs	Global database (provides all ERICA default parameter values)	Select ERICA default EMCLs	Derived using a well documented approach and supported by the extensive data-bases and methodologies constructed within ERICA	EMCLs have been derived using generic parameters. Although antecedent probabilistic calculations have been performed to account for variability (as well as uncertainty), the approach may be limited when the influence of site specific conditions is important, *e.g.* soil type and water chemistry can strongly affect biological transfer – using generic values cannot allow for this influence.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
		Select user defined EMCLs based on published methodologies	The assessor may be more familiar with (and thereby feel more comfortable with) EMCLs derived using a user-defined approach. The EMCLs may be more appropriate for use under the specific assessment conditions compared to the generic values provided by ERICA.	
		Decide not to use EMCLs -	In relation to the ERICA Tool, this would involve the avoidance of Tier 1. EMCLs are calculated from several generic parameters each of which is associated with uncertainties and numerous assumptions defined in their derivation. The EMCL itself is therefore a rather complex value, the derivation of which may be difficult to communicate.	Avoidance of EMCLs in Tier 1 invalidates the use of a simple screening approach and immediately necessitates a more involved screening analysis by the assessor.
Selection of DCCs	General acceptance of ERICA DCCs (or methods of deriving thereof) in performing any dose-rate calculation with the tool; global database	Select ERICA default DCCs	ERICA DCCs have been derived using state-of –the art methods as used within the field of ecodosimetry. The methods have been validated and are consistent with those being adopted by international advisory groups such as the ICRP	Use of default DCCs based on reference organism geometries may not be compatible with the actual organisms under study. This problem can be mitigated by using the DCC interpolation module in the tool if considered necessary.
		Select user-defined DCCs	The assessor may feel more comfortable with values that have been derived explicitly for his/her purposes using familiar methodologies	User-defined DCCs are unlikely to draw upon a similarly robust and extensive underpinning data set and documentation as that provided by ERICA.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
Application of risk quotients (Tier 1) - EMCLs		Use ERICA's method of summing over risk quotients	The ERICA RQ methodology calculates RQ for one reference media only. In summing RQs, the lowest radionuclide specific EMCL value (which will return the highest radionuclide specific RQ value) is selected for each radionuclide Although this approach might also be deemed overly-conservative, we can argue that this Approach is *fairly* consistent with other assessment approaches in that is provides only a single EMCL value for each radionuclide and does not lead to the suggestion that we have a greater detail of information than we actually have	The approach is not strictly conventional – differs slightly to approaches taken elsewhere.
		Use other methods to sum over risk quotients	Other RQ summation methodologies exist, *e.g.* those applied at Tier 2. Also others (*e.g.* USDoE [2002]; Garisto *et al.* [2005]) that add EMCLs for 2 reference media such as sediment and water.	Depends on approach but, for example, the practice of summing RQs for different media types is considered overly-conservative.
Application of risk quotients (Tier 2) – dose rates		Use ERICA's method of summing over risk quotients	The ERICA RQ summation methodology treats each reference organism on an individual basis testing whether the sum of all radionuclides for that particular organism is < 1. This approach is considered to promote the greatest realism to the assessment and avoid any unnecessary conservatism.	The approach is unconventional – differs somewhat to approaches taken elsewhere.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
		Use other methods to sum over risk quotients	Other RQ summation methodologies exist	When information is provided specifically in relation to the types of organisms present at a site, any approach that does not treat risk quotients on an organism by organism basis might be considered overly-conservative
Selection and Revision of radiecological parameters (K_ds and CRs)	Tier 2 – Dialogue screen entitled "Radiecological parameters"	Select ERICA default CRs and Kds	The CRs used as the ERICA default database are comprehensive drawing on an extensive review of publishes literature and characterised by statistical information. According to Sheppard [2005], the inherent variability of transfer parameters is so large that generic data may be the best choice for application in risk assessments.	In studies where the environment is characterised by parameters that clearly deviate from generic conditions (in the case of freshwater environment this might, for example, be for assessments involving extremely nutrient poor, oligotrophic or nutrient rich, eutrophic, lakes) the application of generic values will be inappropriate
		Input user-defined CRs and Kds	In cases where there are statistically-significant differences between site-specific and generic data, the application of site specific data may be justified. Especially for ERICA, site specific K_ds might be more suitable owing to the fact that ERICA K_ds are poorly define statistically – essentially recommended values have been provided and exponential functions probability distribution functions applied for due to lack of more detailed collated statistical information	The application of site-specific data is often not justified especially in cases where datasets are small.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
Selection and Revision of occupancy factors	Tier 2 – Dialogue screen entitled "Occupancy factors and radiation weighting factors"	Use ERICA default occupancy factors	Default occupancy factors have been selected to maximise the dose, *e.g.* selected for the location in the habitat where highest doses might be expected. In many cases the occupancy factors will be the most appropriate in any case, *e.g.* for sessile organisms such as macrolalgae, mollusc etc. changing the default would not be justified	The selection of the default occupancy factor will lead to an overestimation of the dose-rate in some cases. For example with mobile species that spend only a limited period at locations where maximum doses are expected.
		Input user-defined occupancy factors	Application of realistic occupancy factors, where appropriate, will lead to less conservative dose-estimates. This approach may also allow the user to modify the equations to account for time spent within contaminated areas.	Derivation of occupancy factors may be difficult without the application of considerable resources and time. As a first attempt, life history data for a given species can be collated via review.
Revision of radiation weighting factors	Tier 2 – Dialogue screen entitled "Occupancy factors and radiation weighting factors"	Use ERICA default radiation weighting factors	Default values of 10 for alpha, 3 for low beta and 1 for γ,β used. These might be considered "conservative values" – recent reviews on the subject suggest that a wα of around 5 might be most appropriate for populations-relevant deterministic and stochastic endpoints [Chambers *et al.*, 2006].	The radiation weighting factors are still under discussion in the scientific community.
		Input user-defined radiation weighting factors	The assessor can account for the most radiobiological research related to this theme. Furthermore the assessment can be tailored to a specific problem context. Radiation weighting factors are known to be *inter alia*, endpoint, species and dose-rate specific.	The choice of the radiation weighting factor needs to be justified. This may require substantial effort to review information and derive values for a specific case.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
Selection of Uncertainty factor	Tier 2 – Assessment context	Use the default values of 3 (tests the 5 % probability of exceeding the selected dose-rate screening level) or 5 (tests the 1 % probability of exceeding the selected dose-rate screening level)	The derivation is straight-forward and documented in the Help function	The application of the UF assumes that the underlying distribution in the Risk quotient is exponential. This is a conservative approximation that cannot account for the real underlying distributions that are associated with the parameters associated with the calculation
		Use a user defined UF	Allows the user to derive a UF that is specifically related to their particular situation – the variability (type II uncertainty) may be more rigorously characterised in this way.	The derivation of the UF value is complex and will normally rely on the implementation of probabilistic analyses software to account for the propagation of uncertainty through the derivation. It may be advisable to simply move to tier 3 as this will essentially involve the same type of analysis.
Selection of appropriate radioecological parameters, *e.g.* K_ds, CRs	Tier 3 – Dialogue screen entitled "radioecological parameters"	Selection of single values (default)	Straight-forward – requires very limited underpinning data	Use of single values defeats the purpose of employing a probabilistic method. If all values are deterministic then the calculation can be performed at Tier 2. Failure to address variability (type II uncertainty) for this component of the analysis.
		Selection of single values (user-defined)	As above but has the advantage of allowing a site specific calculation to be performed	As above.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
		Selection of distributions (default)	Accounts for uncertainty (Type II) in this component of the assessment. Allows a much larger data set (than that employed at lower tiers) to be employed in the analyses thereby contributing to the robustness of the assessment	The analysis becomes more complex. In a rigorous sense, data sets should be pre-analysed using various statistical methods to derive summary statistics and establish underlying probability distributions. Collating large enough data sets to allow robust statistical methods to be performed may be resource intensive.
		Selection of distributions (user-defined)	As above but has the advantage of allowing a site specific calculation to be performed	As above.
		Review of derivation methods for CRs, i.e. not blindly accepting the derived CR values.	Review of the CRs is preferable from the perspective of being able to defend the approach – provides insight into weaknesses in the approach and where resources might be best used to improve the analyses, *e.g.* CR derived using a "least-preferred" option – a few direct measurements in reference biota might improve the assessment considerably.	Can be resource intensive
Selection and revision of occupancy factors	Tier 3 - Dialogue screen entitled "Occupancy factors and radiation weighting factors"	**See Tier 2**		

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
Revision of radiation weighting factors	Tier 3 - Dialogue screen entitled "Occupancy factors and radiation weighting factors"	Selection of single values (default)	**See Tier 2.** Application is Straight forward.	**See Tier 2.** Use of single values defeats the purpose of employing a probabilistic method. If all values are deterministic then the calculation can be performed at Tier 2. Failure to address variability (type II uncertainty) for this component of the analysis.
		Selection of single values (user-defined)	**See Tier 2.** Application is Straight forward.	**See Tier 2.** Also - Use of single values defeats the purpose of employing a probabilistic method - Failure to address variability (type II uncertainty) for this component of the analysis.
		Selection of distributions (user-defined)	Accounts for uncertainty (Type II) in this component of the assessment. Allows a much larger data set (than that employed at lower tiers) to be employed in the analyses thereby contributing to the robustness of the assessment. **The assessor may wish to consider the data collated in ERICA D5.**	The analysis becomes more complex. Data sets should be pre-analysed using various statistical methods to derive summary statistics and establish underlying probability distributions. Collating large enough data sets to allow robust statistical methods to be performed may be resource intensive.
Appropriate data entry (Tier 3)	Tier 3 – Dialogue screen entitled "Inputs"	Selection of single values	Straight-forward – requires very limited underpinning data	Use of single values defeats the purpose of employing a probabilistic method. If all values are deterministic then the calculation can be performed at Tier 2. Failure to address variability (type II uncertainty) for this component of the analysis.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
		Selection of distributions	Accounts for uncertainty (Type II) in this component of the assessment. Allows a much larger data set (than that employed at lower tiers) to be employed in the analyses thereby contributing to the robustness of the assessment.	The analysis becomes more complex. Data sets should be pre-analysed using various statistical methods to derive summary statistics and establish underlying probability distributions. Collating large enough data sets to allow robust statistical methods to be performed may be resource intensive.
Selecting suitable probabilistic simulation settings	Tier 3 – Dialogue screen entitled "Probabilistic simulation settings"	Select all available inputs and parameters to be involved in the simulation	Most robust calculation of overall Type II uncertainty in the analysis.	The uncertainty in the calculation may be so large that confidence in the results is undermined.
		Select only some of the available inputs and parameters to be involved in the simulation	May allow a simple form of uncertainty analysis to be performed, i.e. measure of the effect that the variability for a selected parameter is having on the final output variability	Not all components of the known Type II uncertainty are accounted for in the analysis.
		Select a large number of simulation runs (i.e. >5000)	Provides robust statistics	In cases where there are a large number of input data and parameters (all reference organisms and radionuclides selected) the memory required to perform the simulation will be substantial – in some cases a large number of simulations will not be allowed (ERICA provides a warning message to this effect).
		Select a low number of simulation runs (i.e. <1000)	Provides less robust statistics.	There are no problems with the physical memory required and calculation time is very rapid.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
Selection of appropriate effects data to place the calculated dose-rates into context	Tier 3 – Results	Access the FREDERICA database	Provides a comprehensive overview of the studies undertaken and results obtained in relation to irradiation of plants and animals	Difficult to extract and synthesise information from the database for use in an environmental impact assessment. Methods are available to derived benchmarks such as predicted no effects dose-rates but these often require specialist knowledge.
		Decision not to access the FREDERICA database – await input from stakeholders/radiobiological review etc.	Reviews are available in the open literature in relation to effects on plants and animals (*e.g.* UNSCEAR [1996]). Conclusions from such reviews may be easy to apply.	The assessor can be left somewhat *in limbo* at T3 if the FREDERICA base is not utilised. The effort to extract and use data from the database may be considered worth-while if it subsequently leads to a more robust, defendable assessment.

Appendix 2: Illustration of the Uncertainty Matrix for the ERICA Assessment Tool.

The option matrix and the uncertainty spreadsheet are published under D-ERICA Annex A [Copplestone, 2007].

Location		**Type of uncertainty**			**Nature of uncertainty**		
		Statistical	**Scenario - range**	**Ignorance**	**Knowledge-related**	**Inherent variability**	**Quality of knowledge base**
Assessment Tool							
Model Parameters	CRs	Site specific concentration ratios (*e.g.* in Tier 3)			Conceptual and model uncertainties related to the use of simple equilibrium factors to model complex dynamic process - apply to any use of CRs	Appropriate sampling and analysis	Good - specific to situation being considered
		Generic data for Cs-137 and Sr-90 distribution data and statistics available			As above	Site-specific applicability unknown	Much of CR database related to human modelling requirements
			Choice of CRs based on expert judgement and extrapolation methods, *e.g.* on trace or chemically similar elements		As above	Significant - related to site-specific variation and variations in radionuclide/organism characteristics	Depends on radionuclide and organisms involved - may vary between moderate and poor

Location		Type of uncertainty			Nature of uncertainty		
		Statistical	**Scenario - range**	**Ignorance**	**Knowledge-related**	**Inherent variability**	**Quality of knowledge base**
				For many other radionuclides, or maximising assumptions			Poor knowledge base
	Kds	Site-specific data			Model and conceptual uncertainties related to use of distribution coefficient apply to use of site-specific and generic values	High degree of variability for different sites due to salinity, redox, sediment load etc.	Good knowledge base if site-specific analysis appropriate
			Single-value ranges of Kd values generally available (*e.g.* IAEA)			See above	Moderate-poor depending on radionuclide
	DCC		Organism-specific geometry applied (Tier 3)		Applicability of whole body coefficients due to heterogeneity in dose distribution for some radionuclides		Best available
			Application of generic geometry and DCC values			Significant - due to variations in size and shape of organism and target-source configurations	Applicability will depend on the organism concerned

Location		Type of uncertainty			Nature of uncertainty		
		Statistical	**Scenario - range**	**Ignorance**	**Knowledge-related**	**Inherent variability**	**Quality of knowledge base**
	Weighting factors	For gamma and beta radiation	For alpha - due to internal incorporation			Variation in biological effectiveness of different radiation types in inducing different biological endpoints	Knowledge base varies depending on organism and biological effect type
	Occupancy factors		Ranges of values based on observations for generic species	Applicability to specific species (and specific life stages) unknown		Significant variations with climate and organism	Generally unspecific database of information
Model inputs	Radionuclides	Discharge and monitoring information available for some sites and radionuclides			The chemical form of the radionuclide may not be known in detail	Temporal and spatial variability	Well known - scientific judgments
	Activities		Given incomplete information on radionuclides present - assumptions and ranges necessary		Exact origin of radionuclides may not be known		
	Reference organism		semi-quantitative judgments on reference organisms applicability to species of			Natural variability difficult to accommodate in simple assessment	Varies from good/moderate to poor - depending on information available for given species and organism.

Location		Type of uncertainty			Nature of uncertainty		
		Statistical	**Scenario - range**	**Ignorance**	**Knowledge-related**	**Inherent variability**	**Quality of knowledge base**
			concern				
Outputs	Effects analysis	For some effects and organisms			Related to type of effect - individual or population; use of laboratory information to the field;	Natural variation in sensitivity of different organisms and species; analysis of experimental protocols	Good for some species and endpoints - poor for others
			For some effects and organisms derived from information on analogue organisms		Information available for sub-set of organisms	See above	Poor for many organisms
	Derivation and application of dose rate or concentration benchmarks	For species where distribution information exists - possible to use species sensitivity distributions to derive 'no effects' levels			Multiple stressor or inter-organisms events may affect sensitivity that are not taken into account	Natural variability in sensitivity (see 'effects analysis')	Subjective valuation related to the percentiles used for benchmarks

Location		Type of uncertainty			Nature of uncertainty		
		Statistical	**Scenario - range**	**Ignorance**	**Knowledge-related**	**Inherent variability**	**Quality of knowledge base**
				Where effects information is sparse - uncertainties may be taken into account by application of safety factors		See above	Poor scientific basis for decisions

Appendix 3: Uncertainties associated with ERICA dose-rate derivations

1. Internal exposure due to non-homogeneous distributions of radionuclides

Dose conversion coefficients (DCC) to assess absorbed dose rates in reference organisms due to internal and external exposure to gamma and beta emitters have been calculated and published assuming three dimensional ellipsoids with different dimensions and some representative irradiation geometries [Taranenko *et al.*, 2004; Vives i Batle *et al.*, 2004; Ulanovsky and Pröhl, 2006].

Although the differences found in the absorbed fractions depending on the energy making necessary the calculation of DCCs for reference organisms of various sizes and shapes, the huge number of possible situations made it also necessary to assume some simplifications concerning both the geometric models and radionuclide distributions. In particular, homogeneous distribution of emitters has been assumed in all cases, to calculate DCCs for monoenergetic photons and electrons in the range 10 keV – 5 MeV. Thus, the absorbed dose rate in a given organism for a given radionuclide is:

$$\dot{D}_{body} = DCC^{internal} \times A_{M,body} + DCC^{external} \times A_{M,outside}$$

where $A_{M,body}$, $A_{M,outside}$ are the activity concentrations in the body and the surrounding medium, respectively.

Because the assumed homogeneity is not be valid for some radionuclides, two general situations have been analysed in more detail: (i) calculation of whole body doses for non-homogeneous distributions of incorporated radionuclides (and the uncertainty associated to the use of a homogeneous distribution to calculate whole body doses); (ii) calculation of organ / whole body dose rates due to accumulation of radionuclides in a critical organ.

Rather than provide new sets of numbers, the purpose is to calculate the uncertainty associated with the non-homogeneous distribution within the body as well as to indicate some simple methods to estimate organ doses, based on the relationship between whole body and organ doses. Obviously, the uncertainty thus calculated does not take into account the simplistic nature of the reference organisms compared with actual animals and plants

1.1 Uncertainties in the calculated whole body DCC for internal exposure associated to inhomogeneous distribution of internal emitters

New DCCs for the reference organisms [Taranenko *et al.*, 2004] have been calculated considering a monoenergetic point source located either in the centre of the ellipsoid and in the furthest point (closer to the surface), emitting photons (energy in the range 10 keV – 3 MeV) or electrons (energies in the range 10 keV – 5 MeV).

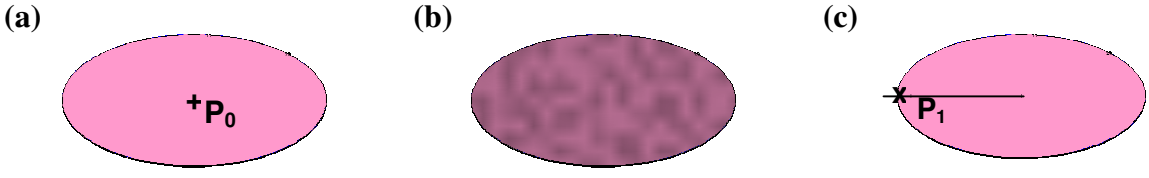

Figure 1: Schematic representation of the three considered cases: central point source (maximum absorbed fraction), homogeneous distribution, and eccentric point source (minimum absorbed fraction).

For geometrical reasons, see Figure 1, it is clear that central point source (a) and eccentric point source (c), amongst all the possible source distributions, give the maximum and minimum absorbed fraction respectively. This is the situation depicted in Figure 2 for photons and Figure 3 for electrons. The upper and lower borders of the shaded regions correspond to the central and eccentric point sources, respectively. The Continuous line has been calculated assuming a homogeneous distribution.

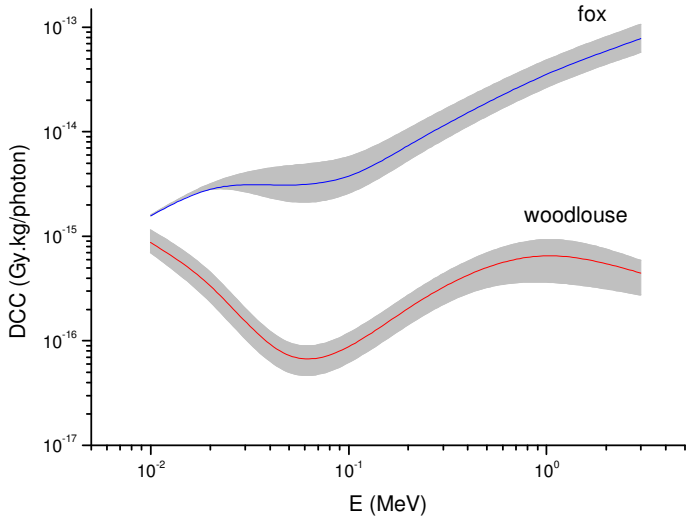

Figure 2: Energy dependence of photon DCC for the reference organisms 'woodlouse' and 'fox' considering the three distributions depicted in Figure 1.

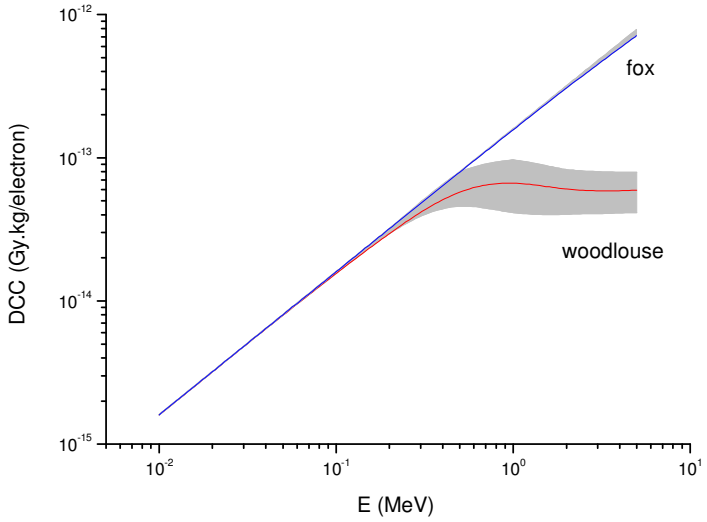

Figure 3: Energy dependence of electrons DCC for the reference organisms 'woodlouse' and 'fox' considering the three distributions depicted in Figure 1.

Therefore and considering a rectangular probability distribution of possible DCCs values between minimum and maximum values, the associated standard uncertainty for an homogeneous distribution values is [ISO, 1995; Kacker *et al.*, 2002]:

$$u(\,DCC^{internal}_{homogeneous}\,) = \frac{\left(DCC^{internal}_{central\ point} - DCC^{internal}_{excentric\ point}\right)}{2\sqrt{3}}$$

Then, whole body doses due to internal exposure could be calculated using the DCC value for homogeneous distributions with this uncertainty, i.e.:

$$\dot{D}^{internal}_{body} = \left[DCC^{internal}_{homogeneous} \pm u\left(DCC^{internal}_{homogeneous}\right)\right] \times A_{M,body}$$

The standard uncertainties for DCCs of selected reference organisms [Taranenko *et al.*, 2004], calculated assuming a rectangular distribution between the values of DCC obtained for central and eccentric point sources is listed in Tables 1 and 2. For photons, uncertainty does not change too much with E and it is lower than 20-25% for the considered reference organisms (woodlouse mass: 0.17 g, fox mass: 6.6 kg). For electrons and due to its finite range in tissue equivalent material, uncertainty depends very much on the organisms' size and energy and it is negligible below a given threshold (approximately 0.5 MeV for woodlouse and 5 MeV for fox). Assuming the same density for the reference organisms, the uncertainty is always lower for bigger and more massive organisms.

Table 1: Standard uncertainty for the photon DCC of selected reference organisms, calculated assuming a rectangular distribution between the values of DCC obtained for a central and an eccentric point sources, gamma emitters (photons).

photon	standard uncertainty				
E (MeV)	woodlouse	mouse	mole	rabbit	fox
0.010	14.0%	2.6%	1.9%	0.7%	0.4%
0.020	18.2%	16.4%	14.9%	6.5%	3.6%
0.050	18.3%	19.3%	20.5%	22.3%	21.5%
0.100	18.1%	18.2%	19.2%	21.5%	22.1%
0.200	18.2%	17.6%	18.2%	19.3%	19.4%
0.500	21.0%	17.4%	17.8%	17.9%	17.5%
1.000	25.1%	18.2%	18.3%	17.5%	16.9%
3.000	21.0%	22.1%	22.2%	18.6%	17.3%

Table 2: Standard uncertainty for the DCC of selected reference organisms, calculated assuming a rectangular distribution between the values of DCC obtained for a central and an eccentric point sources. beta emitters (electrons).

electron	standard uncertainty				
E (MeV)	woodlouse	mouse	mole	rabbit	fox
0.010	0.0%	0.1%	0.0%	0.0%	0.0%
0.020	0.1%	0.0%	0.0%	0.0%	0.0%
0.050	0.3%	0.1%	0.1%	0.1%	0.1%
0.100	0.7%	0.1%	0.1%	0.0%	0.0%
0.200	2.3%	0.2%	0.1%	0.0%	0.0%
0.500	15.5%	1.0%	0.7%	0.2%	0.1%
1.000	23.1%	2.8%	2.0%	0.7%	0.5%
2.000	19.8%	11.4%	5.1%	1.6%	1.1%
5.000	18.1%	21.0%	21.1%	4.4%	2.9%

2. Estimation of organ dose due to the accumulation of radionuclide in a critical organ

For low energy emitters (i.e. 'short range' electrons and 'low mean free path' photons), a significant dose gradient can be found surrounding the source. Therefore (and although the uncertainty in the whole body DCC can be very small since whole body dose does not actually depend on the point where the emitter is located), organ dose can be very high compared with whole body dose if the emitter is located in a given organ. This situation is illustrated in Figures 4 and 5, where organ / whole body dose ratios are presented for selected reference organisms, considering a cantered spherical organ, 5% total mass.

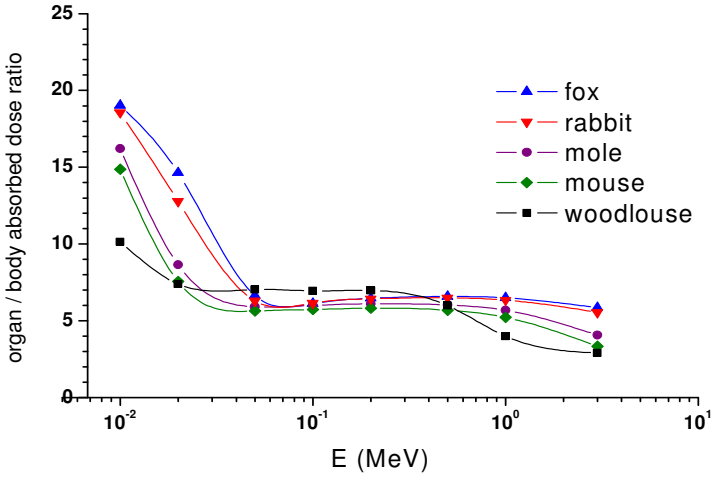

Figure 4: Energy dependence of organ / body dose ratio for a cantered spherical organ representing 5% total mass of the reference organism (photons).

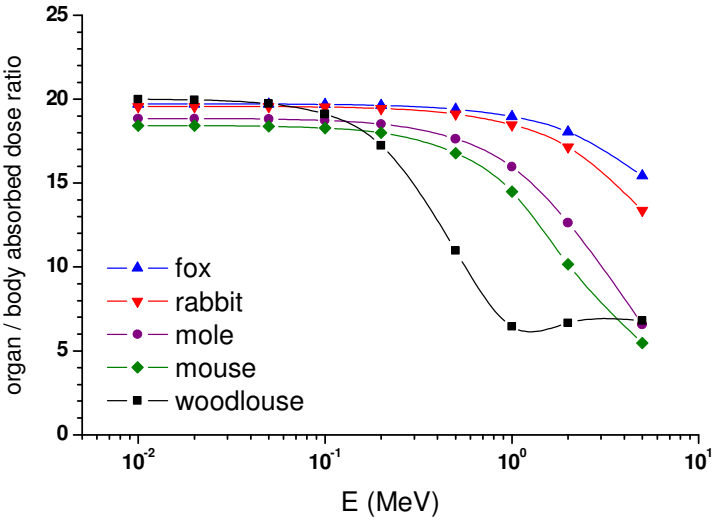

Figure 5: Energy dependence of organ / body dose ratio for a cantered spherical organ representing 5% total mass of the reference organism (electrons).

In general, the organ dose rate due to a given activity concentration in the organ, $A_{M,organ}$, is:

$$\dot{D}_{organ} = E \times AF_{organ}(E, m_{organ}) \times A_{M,organ}$$

where AF_{organ} is the absorbed fraction in the organ. Then, when $AF \approx 1$ (*e.g.* for electrons with E<0.5 MeV), it results:

$$\dot{D}_{organ} \approx \dot{D}_{body} \times \frac{m_{body}}{m_{organ}}$$

For a general case and due to the many possible cases, a conservative estimation can be obtained using the absorbed fraction, $AF_{organ}(E,m_{organ})$, calculated assuming a spherical organ in an effectively infinite media. As it can be seen in Figures 6 and 7, $AF_{organ}(E,m_{organ})$ is a smooth function of E and m_{organ}, thus interpolation methods could be applied.

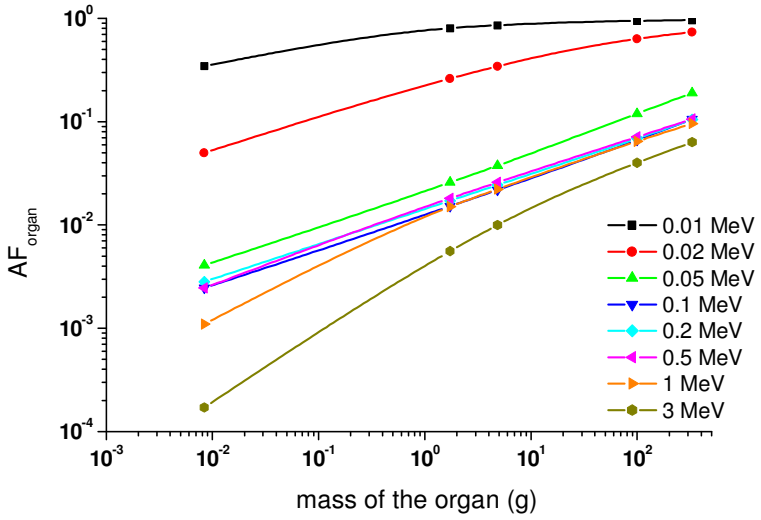

Figure 6: Energy and mass dependence of the absorbed fraction $AF_{organ}(E,m_{organ})$ for monoenergetic photons in a homogeneously contaminated organ, assuming spherical shape within an effectively infinite volume.

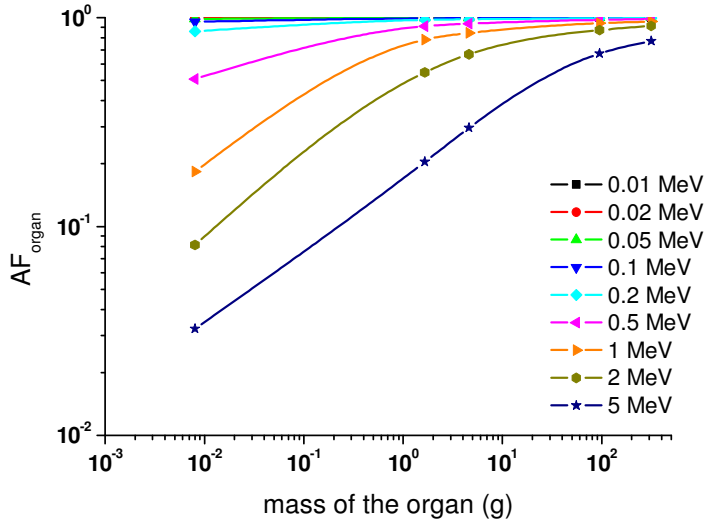

Figure 7: Energy and mass dependence of the absorbed fraction $AF_{organ}(E,m_{organ})$ for monoenergetic electrons in a homogeneously contaminated organ, assuming spherical shape within an effectively infinite volume.

For alpha radiation and taking into account its short range in water and soft tissue, it can be assumed that $AF \approx 1$. Then, the absorbed dose rate due to an activity density A_M (in Bq/kg) of a given alpha emitter is:

$$\dot{D} = A_M \sum_{\alpha} E_\alpha y_\alpha$$

where E_α and y_α are respectively the emission energy and emission yield for the radionuclide and the summation is extended to all the emission energies. For those organisms of size smaller than range, more specific calculations at microdosimetric level may be of interest (see for example Tung *et al.* [2004]).

3. Concluding remarks

Whole body dose rates in reference organisms due to internal exposure can be calculated using the DCCs for homogeneous distribution and the average whole activity concentration:

$$\dot{D}_{body}^{internal} = \left[DCC_{homogeneous}^{internal} \pm u\left(DCC_{homogeneous}^{internal} \right) \right] \times A_{M,body}$$

For photons, the uncertainty due to a possible non-homogeneous radionuclide distribution is lower than 20-25%, in the considered cases. For electrons, uncertainty is negligible below a threshold energy, depending on the size of the organisms.

When the radionuclide is concentrated in a given organ, organ dose rate can be higher than whole body dose rate. In a general case: $\dot{D}_{organ} = E \times AF_{organ}(E, m_{organ}) \times A_{M,organ}$

where AF_{organ} is a smooth function of the energy and the mass of the organ. If the absorbed fraction in the organ is close to one, then a simple relationship can be used: $\frac{\dot{D}_{organ}}{\dot{D}_{body}} \approx \frac{m_{body}}{m_{organ}}$.

Appendix 4: Estimation of doses to biota in case of nuclear accidents

Atmospheric dispersion

A simple Gaussian plume model is used to calculate the activity in air at a point subsequent to a short-term release. The key quantity is the dispersion factor χ, which is defined as:

$$\chi(x,y,z) = \frac{C_{air}(x,y,z)}{Q} \quad [1]$$

where:

Parameter	Unit	Description
χ	s/m³	Short-term dispersion factor
C_{air}	Bq/m³	Air concentration
Q	Bq/s	Release rate
X	m	Coordinate in wind direction
Y	m	Coordinate in vertical direction
Z	m	Height above ground

The dispersion factor χ can be calculated according to:

$$\chi_j = \frac{1}{\pi \cdot \sigma_{y,j}(x) \cdot \sigma_{z,j}(x) \cdot u} \cdot \exp\left(-\frac{H_e^2}{2 \cdot \sigma_{z,j}^2(x)}\right) \cdot \exp\left(-\frac{y^2}{2 \cdot \sigma_{y,j}^2(x)}\right) \quad [2]$$

where:

Parameter	Unit	Description
χ	s/m³	Short-term dispersion factor
π	[1]	
$\sigma_{y,j}(x)$	m	Dispersion coefficient
$\sigma_{z,j}(x)$	m	Dispersion coefficient
U	m/s	Wind speed at release height
H	m	Release height

The dispersion coefficients $\sigma_y(x)$ and $\sigma_z(x)$ are calculated according to

$$\sigma_{y,j}(x) = p_y \cdot x^{q_y} \quad [3a]$$

$$\sigma_{z,j}(x) = p_z \cdot x^{q_z} \quad [3b]$$

where:

Parameter	Unit	Description
p_y, p_z	unitless	coefficient
X	m	Distance to release point
q_y, q_z	unitless	exponent

The parameters p and q are empirically derived for different stability classes in the atmosphere. They are summarised in Table 1.

The stability class defines the status of the atmosphere. A is very unstable, this means the mixing is very well, whereas F is stable, this means it is a kind of an inversion.

The maximum concentrations of the near surface air decrease from stability class A to F; at the same time, the distance of the maximum from the release point increases drastically from some 100 m to some km and more.

For the default estimation the activity in air following uncontrolled releases, a stability class D and a release height of 100 m could be applied. In this case also, precipitation may be assumed which increases the deposition. Due to physical-meteorological reasons, precipitation is not possible for stability class A, B, E and F.

Assuming a wind speed of 4 m/s (average for inland areas in Germany), for the above conditions (the peak concentration at 1000 m does depend both on the 4 m s^{-1} wind speed and the other conditions on the preceding paragraph), the highest air concentrations are found at a distance of 1000m from the release point.

The wind speed u at release height H is estimated from the wind speed at the reference height z_1 (10 m) assuming an exponential wind profile:

$$u = u_1 (\frac{H}{z_1})^m \qquad [4]$$

The exponent m is given in Table 1. The mean annual wind speed for inland regions in Europe is in the order of 2-4 m/s. In Frankfurt (Germany) for example, in the period 1981-1990, the mean annual wind speed is 3.2 m/s. However, during accidents, the mean wind speed might be lower, and a value of about 1 m/s might be appropriate.

Table 1: Coefficients to calculate the dispersion coefficients $\sigma_y(x)$ and $\sigma_z(x)$

Release height (m)	Diffusion category	p_y	q_y	p_z	q_z	Exponent m (equation 4.9)
50	A	1.503	0.833	0.151	1.219	0.09
	B	0.876	0.823	0.127	1.108	0.2
	C	0.659	0.807	0.165	0.996	0.22
	D	0.64	0.784	0.215	0.885	0.28
	E	0.801	0.754	0.264	0.774	0.37
	F	1.294	0.718	0.241	0.662	0.42
100	A	0.17	1.296	0.051	1.317	0.09
	B	0.324	1.025	0.07	1.151	0.2
	C	**0.466**	**0.866**	**0.137**	**0.985**	**0.22**
	D	**0.504**	**0.818**	**0.265**	**0.818**	**0.28**
	E	**0.411**	**0.882**	**0.487**	**0.652**	**0.37**
	F	**0.253**	**1.057**	**0.717**	**0.486**	**0.42**
180	A	0.671	0.903	0.0245	1.5	0.09
	B	0.415	0.903	0.033	1.32	0.2
	C	0.232	0.903	0.104	0.997	0.22
	D	0.208	0.903	0.307	0.734	0.28
	E	0.345	0.903	0.546	0.557	0.37
	F	0.671	0.903	0.484	0.5	0.42

The activity in air is calculated as:

$$C_{air}(x,y,z) = Q \cdot \chi(x,y,z) \qquad [5]$$

Dry deposition

The dry deposition D_d to the ground is estimated by:

$$D_d = v_g \cdot C_{air}(x,y,z) \quad [6]$$

where v_g is the deposition velocity [m/s] (Table 2)

Wet deposition

The wet deposition D_w is estimated according to:

$$D_w = Q \cdot \frac{\Lambda}{\sqrt{2} \cdot \pi \cdot \sigma_{y,j}(x) \cdot u} \cdot \exp\left(-\frac{y^2}{2 \cdot \sigma_{y,j}^2(x)}\right) \quad [7]$$

Λ is the washout coefficient (s^{-1}), it depends on the precipitation intensity according to:

$$\Lambda = \Lambda_0 \cdot \left(\frac{I}{I_0}\right)^{0.8} \quad [8]$$

where I is the actual precipitation intensity (mm/h) and Λ_0 refers to the precipitation intensity I_0 of 1 mm/h (Table 2). As a default a precipitation intensity of 1 mm/h can be assumed.

Table 2: Default values for v_g and Λ are summarised below:

Chemical form	Deposition velocity v_g (m/s)	Washout coefficient Λ_0
Particles	0.0015	7E-05
Elemental iodine	0.01	7E-05
Organic iodine	0.0001	7E-07

Activity in vegetation

The time-dependent activity in vegetation due to direct deposition on the foliage is then calculated according to:

$$C_{veg}(t) = \frac{D_d + f_w \cdot D_w}{Y_{veg}} \cdot \exp[-(\lambda_w + \lambda_r) \cdot t] \quad [9]$$

where:

Parameter	Unit	Description
f_w	[1]	Interception fraction, a frequently used default value is: 0.3
λ_w	d^{-1}	Weathering rate constant, a frequently used default value is: 0.0495 d^{-1} (corresponds to a weathering half-life of 14 d)
λ_r	d^{-1}	Decay constant
t	d	Time since deposition
Y_{veg}	kg/m^2	Standing biomass (1kg/m²)

For the consideration of the consequences of accidents, the endpoint is probably the accumulated dose rather than the dose rate. This can be calculated from the time-integrated activity concentration in vegetation [Bq d/kg] which is:

$$C_{veg}(T) = \frac{D_d + f_w \cdot D_w}{(\lambda_w + \lambda_r) \cdot Y_{veg}} \cdot [1 - \exp[-(\lambda_w + \lambda_r) \cdot T] \quad [10]$$

where T is the time from the deposition to the end of the vegetation period. A default of 60 d can be used. A value of 0.95 would then result for the exponential built-up term in eq. 9.

The accumulated dose [Gy] is then calculated according to:

$$\text{Dose} = C_{veg}(T) \cdot DCC_{plant} \quad [11]$$

Additionally, there is a contamination of plants due to uptake from soil and subsequently of animals. This can be calculated according to the approaches already existing in FASSET. The total deposition is calculated as the sum of wet and dry deposition.