EUROPEAN COMMISSION

Community Research

ERICA

(Contract Number: FI6R-CT-2004-508847)

D-ERICA:

An INTEGRATED APPROACH to the assessment and management of environmental risks from ionising radiation

Description of purpose, methodology and application

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Date of issue of this report: **01/02/07**

Start date of project: **01/03/04** Duration: 36 Months

Project co-funded by the European Commission under the Euratom Research and Training Programme on Nuclear Energy within the Sixth Framework Programme (2002-2006)		
Dissemination Level		
PU	Public	PU
RE	Restricted to a group specified by the partners of the [ERICA] project	
CO	Confidential, only for partners of the [ERICA] project	

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ERICA (Environmental Risk from Ionising Contaminants: Assessment and Management) concerns 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 ended by February 2007.

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Contract No: **FI6R-CT-2004-508847**

Project Co-ordinator: **Swedish Radiation Protection Authority**

Contractors:

Swedish Radiation Protection Authority	SSI
Swedish Nuclear Fuel and Waste Management Company	SKB
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Foreword

This report, referred to as *D-ERICA*, summarises the developments in the ERICA project (Environmental Risks from Ionising Contaminants: Assessment and Management, EC Contract FI6R-CT-2004-508847). It also describes the *ERICA Integrated Approach* to the assessment and management of environmental risks from ionising radiation, and introduces the reader to the *ERICA Tool*, which is a software programme with supporting databases, that together with its associated help will guide users through the assessment process. Most assessors should find all the information they require within D-ERICA and the ERICA Tool in order to undertake an assessment. In some instances, particularly when uncertainty is high or the environmental risks are of substantial concern, the user may wish to consult the complete project documentation, available at www.erica-project.org.

More than 60 European scientists, regulators, policy makers and environmental experts have contributed to the ERICA Integrated Approach through the ERICA project. The contributors are listed below. In addition, a large number of experts in different areas have contributed views on the Integrated Approach and its associated Tool from the user's perspective, through participation in the End Users Group. While this input has been extremely valuable, the final design of the ERICA Integrated Approach and the ERICA Tool remains entirely the responsibility of the ERICA Consortium.

Carl-Magnus Larsson
ERICA co-ordinator
Stockholm, February 2007

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Executive Summary

Purpose and structure of the ERICA Integrated Approach

The purpose of the *ERICA Integrated Approach* is to ensure that decisions on environmental issues give appropriate weight to the environmental exposure, effects and risks from ionising radiation with emphasis on ensuring the structure and function of ecosystems. To fulfil this objective, elements related to environmental management, risk characterisation and impact assessment have been integrated (hence the *Integrated Approach*) into one common structure, illustrated in Figure I.

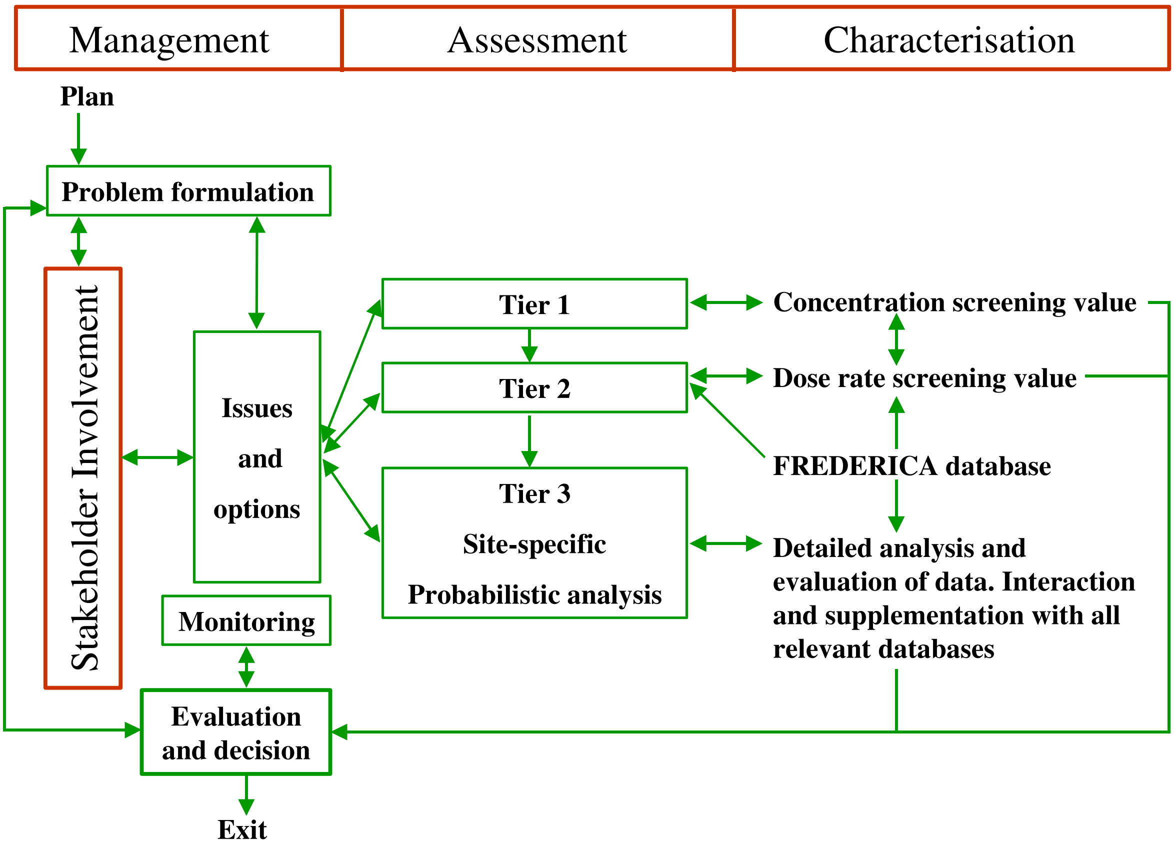

Figure I: Structure of the ERICA Integrated Approach

Assessment refers to the process of estimating exposure of biota, which involves estimating or measuring activity concentrations in environmental media and organisms, defining exposure conditions, and estimating radiation dose rates to selected biota.

Characterisation includes estimation of the probability and magnitude of adverse effects in biota, together with identification of uncertainties. Within the ERICA Integrated Approach published effects data are used as the basis of the assessment with risk characterisation performed by evaluating the output data from the assessment (estimates of exposure) against an effects analyses.

Management is used here as a general term for the process of taking decisions before, during, and after an assessment. The term covers such diverse aspects as decisions on specific technical issues associated with the execution of the assessment, general decisions relating to the interaction with stakeholders, and post-assessment decisions.

Using the ERICA Integrated Approach

The ERICA Integrated Approach advises the user on how to formulate the problem (involving stakeholders if appropriate), perform an impact assessment and evaluate data. It outlines the issues and options available to the user (and requiring decisions) before, during, and after an assessment.

The ERICA Integrated Approach is supported by the *ERICA Tool*, which is a software programme that guides the user through the assessment process, keeps records and performs the necessary calculations to estimate dose rates to selected biota. A detailed help is provided to assist the user in making appropriate choices and inputs, as well as interpret the outputs. The Tool interacts with a number of databases and other functions that help the assessor to estimate environmental media activity concentrations, activity concentrations in biota, and dose rates to biota. The databases consider the majority of the radionuclides included in Publication 38 of the International Commission on Radiological Protection (ICRP). The ERICA Tool also interfaces with the FREDERICA radiation effects database, which is a compilation of the scientific literature on radiation effect experiments and field studies, organised around different wildlife groups and, for most data, broadly categorised according to four effect umbrella endpoints: morbidity, mortality, reproduction, and mutation.

The databases of the ERICA Tool are built up around a number of reference organisms. Each reference organism has its own specified geometry and is representative of either terrestrial, freshwater or marine ecosystems. The approach is compatible with that used by ICRP; some of the geometries proposed for the ICRP 'reference animals and plants' are used as defaults in the ERICA Tool.

The assessment element of the ERICA Integrated Approach is organised in three separate *tiers*, where satisfying certain criteria in Tiers 1 and 2 allows the user to exit the assessment process while being confident that the effects on biota are low or negligible, and that the situation requires no further action. Where the effects are not shown to be negligible, the assessment should continue to Tiers 2 and 3. Situations of concern should be assessed further in Tier 3, by making full use of all relevant information available through the Integrated Approach or elsewhere.

Formulating the problem and interacting with stakeholders

Problem formulation is the first step of any risk assessment and includes consideration of ecological, political and societal issues when deciding on procedures and methods, who to involve, and any benchmarks or assessment criteria that the outcome will be compared to. Problem formulation also represents the first stage of the assessment where an assessor might exit the process. A decision *not* to proceed might be made on technical grounds (for example, no direct exposure route) or societal grounds (such as a veto on the discharge of radionuclides regardless of risks to biota). Stakeholder participation procedures vary and there is no single procedure or group of stakeholders that is likely to suit each purpose. In practice, and if participation is deemed important to a decision, a variety of methods are likely to be adopted.

The problem formulation and participation procedures may largely be regulated by legislation. The ERICA Integrated Approach provides information and advice for complying with such legislation and lists additional elements to consider should the user wish to do so. In the process of coming to a decision the problem may need to be re-formulated several times, with the involvement of stakeholders if appropriate, in the light of new information as the assessment proceeds. The ERICA Tool helps the user to consider relevant aspects and record decisions taken with regard to these issues.

Tier 1 assessment

The Tier 1 assessment is designed to be simple and conservative, requiring a minimum of input data and enabling the user to exit the process and exempt the situation from further evaluation, provided the assessment meets a predefined screening criterion. The default screening criterion in the ERICA Integrated Approach is an *incremental dose rate of 10 µGy* h^{-1}, to be used for all ecosystems and organisms. This value was derived from a species sensitivity distribution analysis performed on chronic exposure data in the FREDERICA database and is supported by other methods for determining predicted no effect values. However, the user can change the default screening dose rate within the ERICA Tool, For Tier 1, the predefined screening dose rate is back-calculated to yield Environmental Media Concentration Limits (EMCLs) for all reference organism/radionuclide combinations. The Tool compares the input media concentrations with the most restrictive EMCL for each radionuclide and determines a risk quotient (RQ). If the RQ is less than one, then the tool suggests that the user should exit the assessment process. If the RQ is greater than one, the user is advised to continue with the assessment.

Tier 2 assessment

Tier 2 allows the user to be more interactive, to change the default parameters and to select specific reference organisms. The evaluation is performed directly against the screening dose rate, with the dose rate and RQs generated for each reference organism selected for assessment. A 'traffic light' system is used to indicate whether the situation can be considered:

(i) of negligible concern (with a high degree of confidence);

(ii) of potential concern, where more qualified judgements may need to be made and/or a refined assessment at Tier 2 or an in-depth assessment in Tier 3 performed;

(iii) of concern, where the user is recommended to continue the assessment either at Tier 2 if refined input data can be obtained or at Tier 3.

Decisions to exit an assessment given outcomes (ii) and (iii) should be justified, for example by using information from FREDERICA provided in the Tool as 'look-up effects tables' for different wildlife groups.

Tier 3 assessment

Situations, which give rise to a Tier 3 assessment, are likely to be complex and unique, and it is therefore not possible to provide detailed or specific guidance on how the Tier 3 assessment should be conducted. Furthermore, a Tier 3 assessment does not provide a simple yes/no answer, nor is the ERICA-derived incremental screening dose rate of 10 μGy h^{-1} appropriate with respect to the assessment endpoint. The requirement to consider aspects such as the biological effects data within the FREDERICA database, or to undertake ecological survey work, is not straightforward and requires an experienced, knowledgeable assessor or consultation with an appropriate expert.

Tier 3 is a probabilistic risk assessment in which uncertainties within the results may be determined using sensitivity analysis. The assessor can also access up-to-date scientific literature (which may not be available at Tier 2) on the biological effects of exposure to ionising radiation in a number of different species. Together, these allow the user to estimate the probability (or incidence) and magnitude (or severity) of the environmental effects likely to occur and, by discussion and agreement with stakeholders, to determine the acceptability of the risk to non-human species.

Post-assessment considerations

Since the aim of the ERICA Integrated Approach is to aid decision-making so that adequate weight is given to the environmental effects of ionising radiation, the Integrated Approach is non-prescriptive and does not specify decisions that *must* be taken. This flexibility is necessary because of the diversity of environmental legislation. Nevertheless, the Integrated Approach offers guidance on a number of issues and options, and a structure for reaching a decision. However, a decision taken to justify exiting the assessment may not necessarily conclude the process. In most cases, where a decision has been taken via a full Tier 3 assessment, this may have to be revisited regularly on the basis of new information, or as part of licensing conditions.

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Annexes Published separately

1 Introduction

1.1 Objectives and background

The purpose of the *ERICA Integrated Approach* is to ensure that decisions on environmental issues give appropriate weight to the environmental exposure, effects and risks from ionising radiation with emphasis on ensuring the structure and function of ecosystems. It can be applied in planned and existing exposure situations, and although it is not primarily intended for emergency exposure situations, parts of the Integrated Approach would still be relevant.

Decision-making on activities, facilities, existing sites and contaminated areas of potential, perceived or actual environmental concern is normally governed by an environmental impact assessment (EIA). The procedure should ensure transparent decision-making, where all concerned parties (or 'stakeholders') have been consulted and allowed to comment on the impact of the situation. The ERICA Integrated Approach supports the EIA within the area of environmental radiation, which may be a major or minor concern within the overall EIA, depending on the circumstances.

The ERICA Integrated Approach uses a comprehensive method to address the ecological effects of ionising radiation on biota and ecosystems. A software programme, the ERICA Tool, supports the Integrated Approach. The Tool, together with this document, guides the user in:

- problem formulation;
- carrying out the impact assessment;
- assessing the level of uncertainty (or confidence) in procedures and results;
- taking decisions, in consultation with stakeholders if necessary, before, during and after the assessment.

The approach is generic, flexible and non-prescriptive, enabling users to formulate problems according to their specific needs. It also allows flexibility in the choice of parameters for the assessment. Likewise, it provides guidance on important issues and options available in decision-making, but does not prescribe which decisions are 'correct' or the radiation exposure and effects considered 'acceptable'.

The Integrated Approach is intended to be user-friendly. However, ecosystem functioning is complex and the Earth hosts a diversity of life forms. Thus, an overly simplistic approach would generate assessments without real scientific meaning and, of little value for decision-making. The ERICA Integrated Approach attempts to strike a balance between the simplification required for the method to be workable, and the complexity needed to generate useful information. This is accomplished via a *tiered approach*, enabling the early screening out of situations of negligible radiological concern, leaving only those of potential or real concern for more in-depth assessment. In particular, the highest tier (Tier 3) may require the assessor to be experienced or to consult external expertise.

1.1.1 The ERICA project and other recent international and national initiatives

The ERICA Integrated Approach and the ERICA Tool are both outcomes of the EC 6th Framework Programme (FP) ERICA project. Other deliverables from the project provide more information on the reasoning behind the ERICA Integrated Approach described here. The ERICA project incorporates, and expands upon, earlier EC projects FASSET (Framework for Assessment of Environmental Impact) and EPIC (Environmental Risks from Ionising Contaminants in the Arctic), briefly summarised in Appendix 3. Supplementary documentation from all three projects (available on www.erica-project.org) provides further scientific information supporting the ERICA Integrated Approach.

The development of the ERICA Integrated Approach has taken account of a number of national initiatives, such as those in the USA [US DoE, 2002], Canada [Environment Canada, 2001] and the UK [Copplestone *et al.*, 2001]. More than fifty organisations, brought together under the umbrella of the End Users Group (EUG), have provided comments and advice on the Integrated Approach in the course of its development, and have tested a prototype version of the ERICA Tool. As a result, a number of important changes and additions have been made, and the consortium responses to the EUG input have been tracked on the project website. Broad acceptance has been obtained on both technical and general issues (see, for example, the ERICA Consensus Seminar [ERICA D7f, 2006] and its resulting Consensus Document [ERICA Consensus Document, 2006]). While the interaction with end-users has been highly valuable, the final structure and content of the ERICA Integrated Approach and its associated Tool, databases and other documentation, remain entirely the responsibility of the consortium that developed it.

Development of the ERICA Integrated Approach has coincided with the work of the International Commission on Radiological Protection (ICRP) on protecting the environment against the harmful effects of ionising radiation [ICRP 2005; web version of the draft recommendations, http://www.icrp.org/docs/ICRP_Recs_02_276_06_web_cons_5_June.pdf]. The ERICA Integrated Approach and the ICRP approach are compatible. The databases have in both cases been developed with ecosystem representatives (reference organisms in ERICA; reference animals and plants or RAPs in ICRP), as further explained in Section 2.3.1. Indeed, the method developed by ERICA has been used extensively to build the ICRP databases.

1.2 The three elements of the ERICA Integrated Approach

To aid decision-making related to the environmental effects of ionising radiation, three main elements have been combined into the ERICA Integrated Approach. These are *assessment* of environmental exposure and effects using the ERICA Tool, *risk characterisation*, and *management* of environmental risks, as shown in Figure 1.1. Figure 1.1 demonstrates that the process of taking decisions is all but linear. It is recommended, and for complex assessment necessary, to reconsider all elements of the process described in Figure 1.1 through several iterations, involving stakeholders where appropriate. Also, post-assessment decisions on, for example, the acceptability of a specific project may need to be reviewed in the light of operating experience, monitoring data, or other information becoming available with time.

The Integrated Approach uses measured or predicted radionuclide activity concentrations in environmental media or biota as inputs into the ERICA Tool. Depending on intermediary results, the assessment then continues through a maximum of *three tiers* (see Box 1.1).

1.3 How to use this report and how it relates to the ERICA Tool

This report, D-ERICA, outlines the structure of the ERICA Integrated Approach. It provides the reader with information on the basic underlying assumptions and elements of the methodology, as well as with general advice on its application. The reader will become familiar with how the Integrated Approach deals with:

- problem formulation (Chapter 2);
- interaction with stakeholders (Chapter 3);
- calculation of radionuclide concentrations and dose rates (Chapter 4);
- assessments in Tiers 1, 2 and 3 (Chapters 5, 6 and 7 respectively);
- post-assessment considerations (Chapter 8).

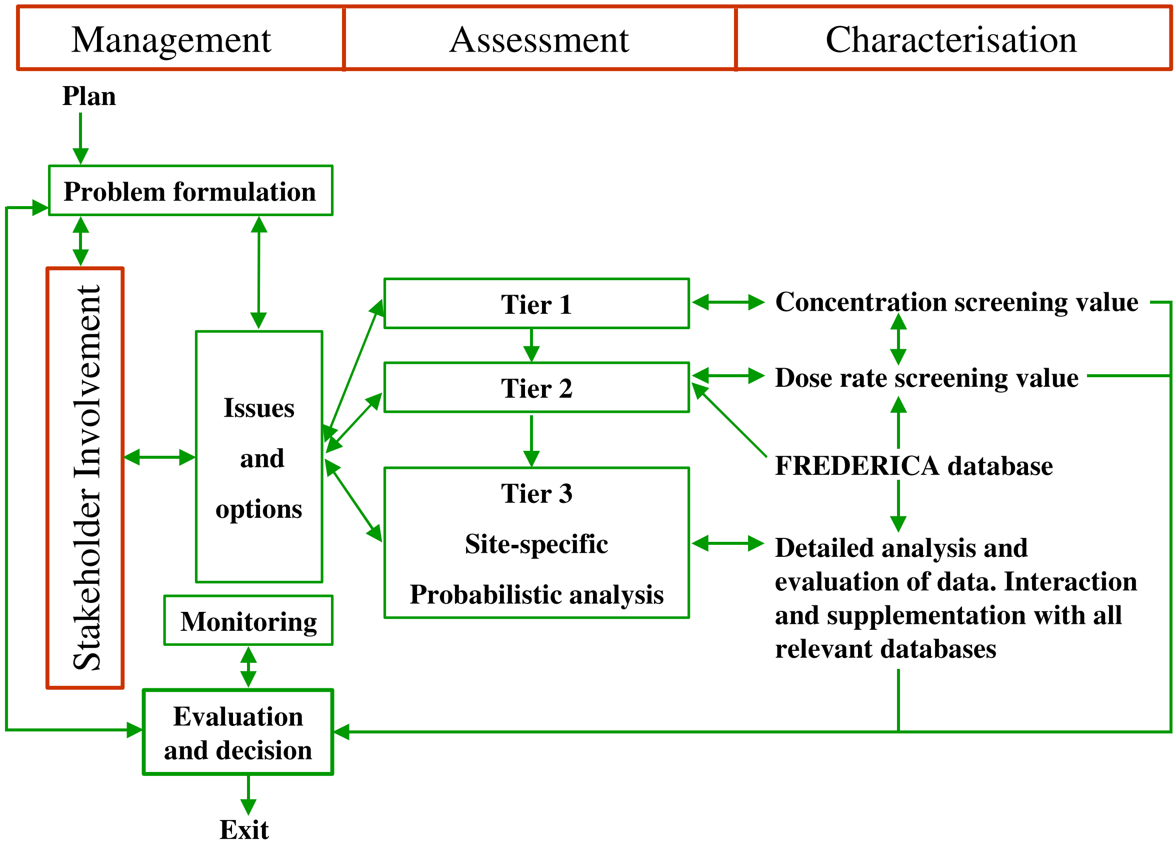


Figure 1.1: Overview of the ERICA Integrated Approach, outlining the interaction between assessment, risk characterisation and management.

Assessment refers to the process of estimating the exposure of biota. It involves estimating or measuring activity concentrations in environmental media and organisms, defining exposure conditions, and estimating radiation dose rates to selected biota.

Risk characterisation is 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. Published effects data effects data are used as the basis of the assessment with risk characterisation performed by evaluating the output data from the assessment with (estimates of exposure) against an effects analyses.

Management is used here as a general term for the process of taking decisions before, during and after an assessment. The term covers such diverse aspects as decisions on specific technical issues associated with the execution of the assessment, general decisions relating to the interaction with stakeholders, and post-assessment decisions. The ERICA Integrated Approach intends to aid such decisions, and does not prescribe what decisions *must* be taken.

D-ERICA serves as an introduction to the ERICA Tool, and demonstrates how the Tool and underlying science can be used to assess the environmental concern of a particular situation. The Tool can be downloaded free of charge from the ERICA website, www.erica-project.org. The user of the Tool can get help from the extensive Help incorporated into the Tool. An overview of the Tool in the form of a flowchart is given in Appendix 1, which highlights the information required at each step of the assessment. Appendix 2 lists the various points along the assessment route where a user needs to take decisions, together with some guidance on alternatives and their applicability.

For a full list of uncertainties governing assessments, the reader is advised to consult the uncertainty matrix laid out in Annex A to this report. The Glossary (Annex B) comprises not only terms, acronyms and abbreviations used in ERICA, but also those used in environmental assessments and decision-making generally.

Box 1.1 The Tiers of the ERICA Tool

Tier 1

- Highly conservative
- Requires minimal data input
- Simple and can be used by non-specialist users
- Maximum measured media concentrations suggested as input
- Compares input media concentrations to Environmental Media Concentration Limits calculated for the most limiting reference organism for each radionuclide
- If the Tool recommends that the assessment can be exited the situation can be considered to be of negligible radiological concern.

Tier 2

- Less conservative screening tier
- User can edit transfer parameters
- Media and biota activity concentrations can be input (best estimate values are recommended)
- Estimated wholebody absorbed dose rates compared directly to the screening dose rate
- 'Traffic light' system indicates if situation is:
    - of negligible concern (with a high degree of confidence) - user is recommended to exit the assessment process
- of potential concern – user recommended to review and amend assessment
    - of concern – user recommended to continue the assessment
- Results can be assessed against summarised tables of effects and exposure due to naturally occurring radionuclides

Tier 3

- Not a screening tier – so no screening dose rate
- Not prescriptive and has no 'yes/no' answer
- Provides user with guidance, template and tool to help conduct more detailed assessment
- Probabilistic and sensitivity analyses
- Access to up to date on-line database of radiological effects

2 Problem Formulation

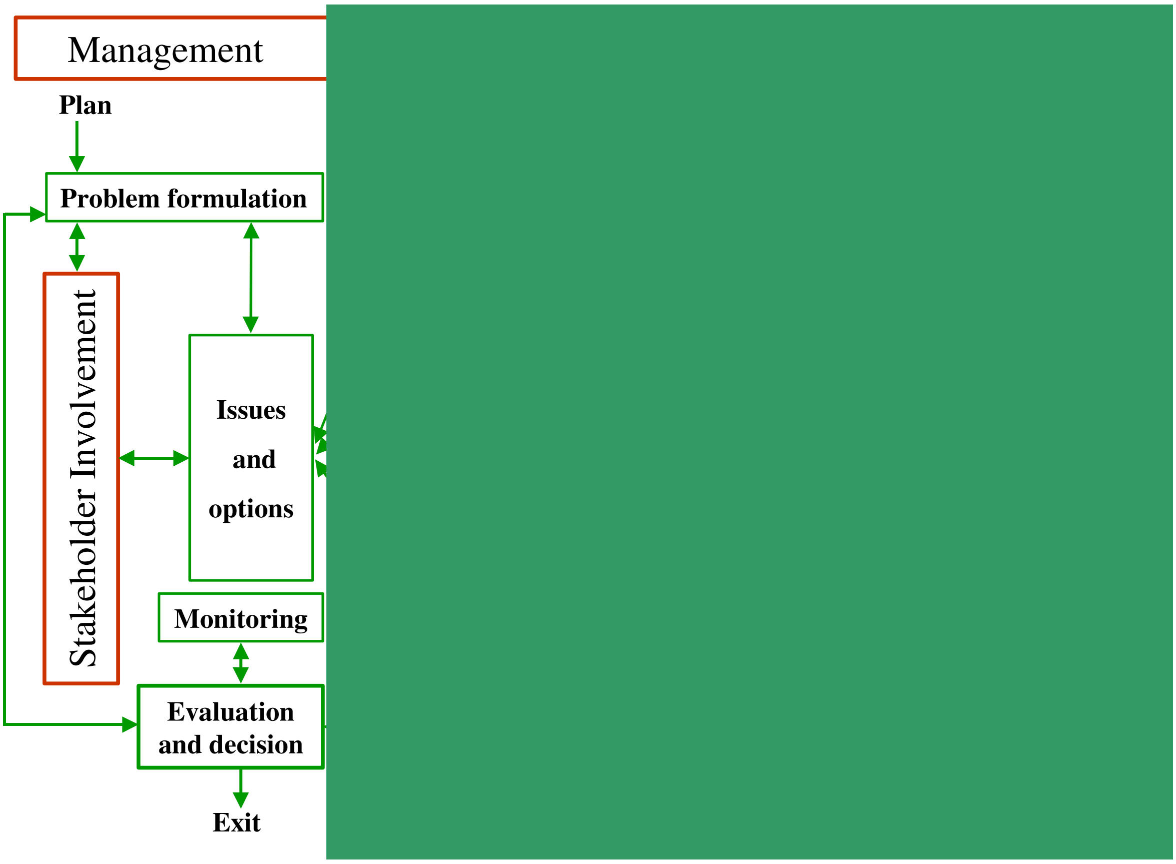


Figure 2.1: The ERICA Integrated Approach, highlighting the elements that relate to problem formulation.

2.1 Introduction

Problem formulation is the first step of any risk assessment, and within a tiered approach should be revised as new information becomes available or as decisions have to be reviewed. Problem formulation is used to identify the scope, context and purpose of the assessment. This should include consideration of ecological, political and societal issues, and should integrate the process of choosing assessment endpoints, identifying sources and describing the environment [Suter, 1993; Moore and Biddinger, 1995]. The user of the ERICA Integrated Approach may also wish to consider the three generic exposure situations for which the International Commission on Radiological Protection (ICRP) intends its forthcoming recommendations, due 2007, to be applied:

- *Planned exposure situations* - everyday situations involving planned operations, including decommissioning of nuclear facilities, disposal of radioactive waste and rehabilitation of radioactively contaminated land.
- *Existing exposure situations* - exposure situations that already exist when a decision on control has to be taken, including natural background radiation and residues from past practices.
- *Emergency exposure situations* - unexpected situations that occur during the operation of a practice, requiring urgent action.

The ERICA Integrated Approach can be used in most circumstances covered by these situations, as indicated by the examples shown in Table 2.1. However, the Integrated Approach does not fully consider the dynamic modelling necessary for non-steady state and transient scenarios associated with early emergency situations, although the method is nevertheless able to provide 'snapshots' of the situation. Furthermore, an emergency situation will eventually transform into an existing situation, where the Integrated Approach may be applied in full.

Table 2.1: Examples of exposure situations where the ERICA Integrated Approach may be used, either on its own or as part of a wider assessment which considers other issues.

Planned	Existing	Emergency
a) siting a new facility	a) exposure after an accident	a) accidents in nuclear facilities
b) re-assessing the authorisation of an existing facility	b) residues from past or existing practices	b) accidents in the transport of radioactive materials
c) decommissioning a nuclear facility and disposing of radioactive waste		c) deliberate/malevolent uses, including terrorism
d) remediation		
e) NORM/TENORM		
f) clearance		

The process of problem formulation in any of the above situations is crucial to conducting and interpreting the results of an assessment. Its purpose is to encourage the user to think carefully about the assessment to be conducted and to document any assumptions and decisions in a clear and transparent manner. For example, it is important to establish whether a full environmental risk assessment (selection of Tier 3) is appropriate or whether the legislative context calls for a Tier 3 assessment to be carried out, regardless of whether environmental risks can be deemed negligible or not.

Problem formulation also represents the first stage at which an assessor might exit the assessment process. For example, a decision **not** to proceed might be made on either technical grounds (for example, no direct exposure route) or social or economic grounds (such as if the local population says no to a practice that would discharge radionuclides for reasons other than the risk to biota).

2.2 Factors to consider in formulating the problem

A number of elements should be considered when formulating the problem to be assessed. These will also help justify the selection of the tier to begin the assessment at. Table 2.2 lists, and elaborates on, a number of fundamental factors to be considered.

It is crucial that the evidence collected during the problem formulation stage be documented in a transparent and understandable way. Commonly, a conceptual model is developed which describes what is known about the site, its geographical limits, radioactive substances of interest, potential pathways and receptors and the likelihood of exposure, along with any data gaps. Essentially, the conceptual model is a narrative summarising the site conditions, current knowledge and the problem faced. The level of detail required will be influenced by a number of factors but should comprise some, or all, of the information described in Table 2.2. Appendix 2 and the uncertainty matrix described in D-ERICA Annex A also provide information that the assessor may need to consider when formulating the problem.

The problem formulation should be reviewed as and when new information becomes available, for example as the assessment moves between tiers within the ERICA Integrated Approach.

Table 2.2: Elements of problem formulation for consideration.

Element	Explanation	Examples of questions to answer
Identification and characterisation of source	Identify anything that may cause radiation exposure, by emitting ionising radiation or releasing radioactive substances. Identify the type of radiation and/or radioactive substances. Identify the presence of other non-radioactive contaminants that might need to be considered (as part of the overall assessment).	Which radionuclide(s) and their activity concentrations should be included in the assessment? For prospective (and potentially retrospective) assessments, should you use a model to predict dispersion in the environment to determine media activity concentrations as inputs into the ERICA Tool? For retrospective assessments, what is the history of past discharges and does this need to be considered further?
Identification of the receiving media	Identify receptor(s), size and duration of exposure(s) and ecosystem(s) affected. Identify the spatial and temporal scales that need to be considered.	Is there a source-receptor pathway or can you exit the assessment? Which species and ecosystems should be included in the assessment? Does spatial or temporal averaging need to take place and if so how?
Legislative/regulatory requirements	Identify the legal framework governing the acceptability of the source in question. Identify any endpoints or assessment criteria that are listed in the legal framework.	What is the exit process (for example, is the source or exposure level acceptable or not)? Does the legal framework require an assessment to be carried out? What should be the level of stakeholder involvement? How should protection endpoints be defined, with reference to the legislation?
Stakeholder involvement	Take into account views of stakeholders. A stakeholder may be defined as anyone who has an interest in, or considers they have an interest in, the issue, which therefore goes beyond representatives of groups to include interested members of the public.	Which stakeholders should be involved? How to create awareness among stakeholders? At what stage, and what method of, engagement should be used? What results and actions from the consultation are to be implemented? Are there social or economic issues that should be considered in the assessment?
Assessment criteria	Preparation of a procedure for evaluating the results of the assessment against. This may incorporate management criteria specific to a particular assessment.	Which: (i) endpoints, (ii) dose rates or environmental concentrations, and (iii) screening values should be considered?

Element	Explanation	Examples of questions to answer
Outputs from the assessment	Depending upon the tier of the ERICA Integrated Approach, there will be different outputs available for review and evaluation.	What outputs should there be (such as risk quotients, dose rates, effects data, probability distributions)?
Uncertainties, knowledge or data gaps	Identify and record uncertainties related to the processes under evaluation within the assessment.	What are the uncertainties associated with: (i) the input data, (ii) calculations being used, (iii) effects data, (iv) underpinning radioecological data (such as concentration ratios), (v) data or knowledge gaps?
Risk characterisation	This is the synthesis of all the information obtained during the assessment for use in management decisions. This should include an estimation of the probability (or incidence) and magnitude (or severity) of the environmental effects likely to occur.	What are the levels of environmental detriment and risk? Should other contaminants be considered in the assessment? Should a sensitivity analysis be carried out?

2.3 Specific considerations in the ERICA Integrated Approach

The ERICA Tool (see Appendix 1) provides a number of initial screens for recording and justifying the problem formulation within the computer file for the assessment. The Tool prompts the user to:

- provide a detailed description of the assessment;
- list the transfer pathways and assessment endpoints;
- upload a conceptual model;
- select the ecosystem to be considered (freshwater, marine or terrestrial);
- within Tiers 2 and 3, select the reference organisms to consider (see Section 2.3.1);
- select radionuclides to include in the assessment;
- provide information on media activity concentrations;
- select the screening dose rate against which the results from Tiers 1 and 2 will be compared.

The ERICA Tool will prompt the user to provide input for the above points (see also Appendix 2). The identification of pathways and reference organisms (Section 2.3.1) may be assisted by uploading conceptual models for each of the ecosystems considered, that is terrestrial, freshwater and marine ecosystem (see example in Figure 2.2). The default radionuclides included in the Tool are listed in Table 2.3, but at Tiers 2 and 3 the Tool has the capability to undertake assessments for all but a few of the radionuclides listed in ICRP Publication 38 [ICRP, 1983]. Chapter 4 gives information on how to estimate media and biota activity concentrations. Chapter 5 describes the rationale for deriving dose rate screening values; the Tool, by default, uses 10 μGy h^{-1} as a screening incremental dose rate, but the assessor can modify this. The problem formulation may also be affected by the input from different stakeholders, as further dealt with in Chapter 3.

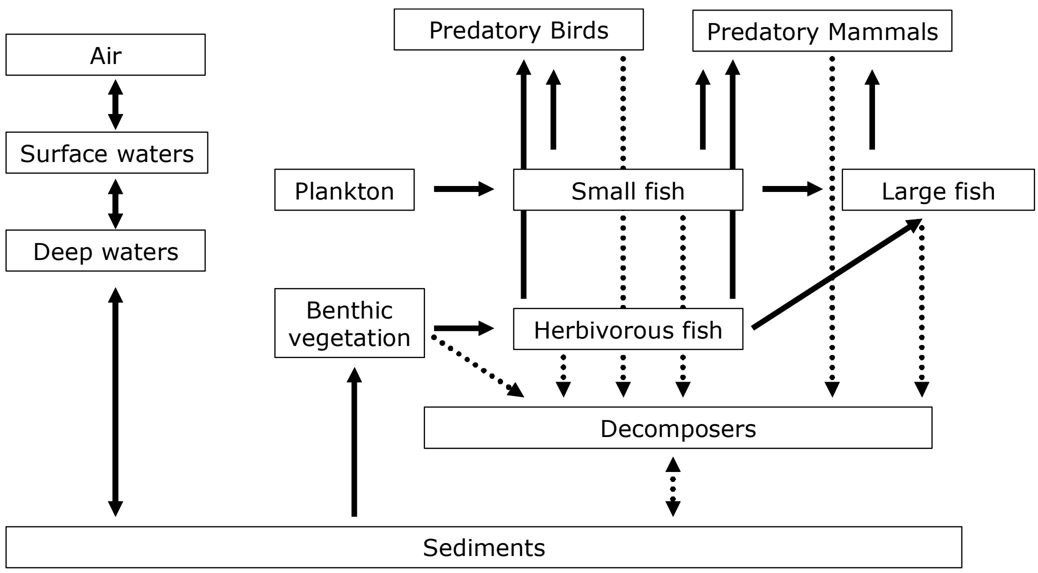


Figure 2.2: Example of a method to visualise a conceptual model (in this case, for a marine generic ecosystem).

Table 2.3: Default radionuclides for which databases are included in the ERICA Tool.

Element		Isotopes	Element		Isotopes
Ag	Silver	Ag-110m	P	Phosphorus	P-32, P-33
Am	Americium	Am-241	Pb	Lead	Pb-210
C	Carbon	C-14	Po	Polonium	Po-210
Cd	Cadmium	Cd-109	Pu	Plutonium	Pu-238, Pu-239, Pu-240, Pu-241
Ce	Cerium	Ce-141, Ce-144	Ra	Radium	Ra-226, Ra-228
Cl	Chlorine	Cl-36	Ru	Ruthenium	Ru-103, Ru-106
Cm	Curium	Cm-242, Cm-243, Cm-244	S	Sulphur	S-35
Co	Cobalt	Co-57, Co-58, Co-60	Sb	Antimony	Sb-124, Sb-125
Cs	Caesium	Cs-134, Cs-135, Cs-136, Cs-137	Se	Selenium	Se-75, Se-79
Eu	Europium	Eu-152, Eu-154	Sr	Strontium	Sr-89, Sr-90
H	Tritium	H-3	Tc	Technetium	Tc-99
I	Iodine	I-125, I-129, I-131, I-132, , I-133	Te	Tellurium	Te-129m, Te-132
Mn	Mangenese	Mn-54	Th	Thorium	Th-227, Th-228, Th-230, Th-231, Th-232, Th-234
Nb	Niobium	Nb-94, Nb-95	U	Uranium	U-234, U-235, U-238
Ni	Nickel	Ni-59, Ni-65	Zr	Zirconium	Zr-95
Np	Neptunium	Np-237			

2.3.1 The concept of reference organisms

The ERICA Integrated Approach concerns the assessment of radiation effects in biota, and provides a basis for decisions governing environmental protection. Given the variation between species, it is not generally possible to develop species-specific assessment systems (*cf.* human radiation protection). The ERICA Integrated Approach is based on generalised ecosystem representations, termed reference organisms. The definition of a reference organism (originally formulated in the FASSET project) is:

"a series of entities that provide a basis for the estimation of radiation dose rate to a range of organisms which are typical, or representative, of a contaminated environment. These estimates, in turn, would provide a basis for assessing the likelihood and degree of radiation effects".

The reference organisms selected for the ERICA Integrated Approach are listed in Table 2.4 below. They have been defined and used for the derivation of geometric relationships between radiation sources and organisms, as well as for considerations of the dosimetry of both external and internal exposure. The reference organisms can be grouped into three general ecosystem categories, namely terrestrial, freshwater and marine ecosystems. Furthermore, they can be used for pooling some of the effects data generated for a range of species. The selection of reference organisms makes it possible to address all protected species within Europe.

This reference organism approach is compatible with the ICRP approach, in which reference datasets are organised around 12 reference animals and plants (or RAPs)[1]. The ERICA Tool uses, for some of the reference organisms, the proposed ICRP geometries as indicated in Table 2.4.

Table 2.4: Reference organisms for each ecosystem in the ERICA Tool. The corresponding ICRP RAPs, for which the ERICA Tool uses the proposed ICRP geometries as default, are indicated in italics within brackets.

Freshwater	Marine	Terrestrial
Amphibian *(frog)*	(Wading) bird *(duck)*	Amphibian *(frog)*
Benthic fish	Benthic fish *(flat fish)*	Bird *(duck)*
Bird *(duck)*	Bivalve mollusc	Bird egg *(duck egg)*
Bivalve mollusc	Crustacean *(crab)*	Detritivorous invertebrate
Crustacean	Macroalgae *(brown seaweed)*	Flying insects *(bee)*
Gastropod	Mammal	Gastropod
Insect larvae	Pelagic fish	Grasses and herbs *(wild grass)*
Mammal	Phytoplankton	Lichen and bryophytes
Pelagic fish *(salmonid/trout)*	Polychaete worm	Mammal *(rat, deer)*
Phytoplankton	Reptile	Reptile
Vascular plant	Sea anemones/true corals	Shrub
Zooplankton	Vascular plant	Soil invertebrate (worm) *(earthworm)*
	Zooplankton	Tree *(pine tree)*

The reference organisms are used to calculate the EMCLs used in Tier 1, and they can be selected individually for Tier 2 assessments. They also form the basis for assessments at Tier 3.

[1] The proposed RAPs currently under study by the ICRP are: Deer, Rat, Duck, Frog, Trout, Flat fish, Bee, Crab, Earthworm, Pine tree, Grass, Brown seaweed.

3 Guidance on interactions with stakeholders

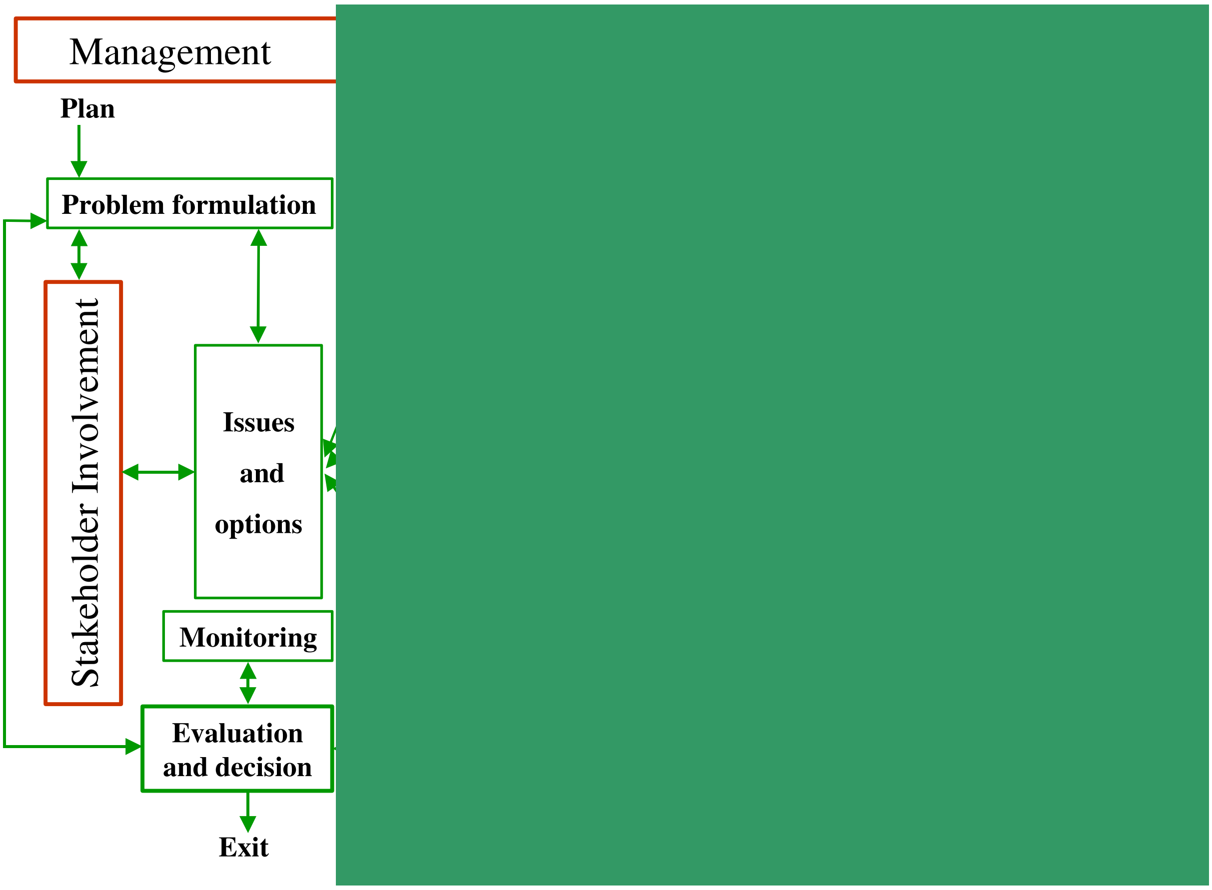


Figure 3.1: The ERICA Integrated Approach, highlighting the elements that relate to stakeholder involvement.

3.1 Introduction

The ERICA Integrated Approach does not determine whether or not the assessor should engage with stakeholders because:

- the need to involve stakeholders is specifically covered by national legislation in many countries;
- the Integrated Approach might be part of a wider environmental impact assessment that has its own broader stakeholder engagement process.

However, the involvement of stakeholders is considered to be good practice and should be encouraged.

The ERICA Tool allows the assessor to openly record stakeholder issues so that if anyone reviewed the outputs from the assessment, all relevant information would be available. The Tool also allows the assessor to review and revise the stakeholder engagement as they progress through a tiered assessment.

The word stakeholder originates from considerations of a company's obligation to its shareholders, but has since been expanded to cover any person or organisation that could either be affected by, or interested in, the outcome of a decision. Hence, stakeholder participation procedures vary according to the objective of the assessment (information gathering or decision-making), participants (experts or laypersons, elected, selected or volunteers), and processes. Such processes can include the simple provision of information (one-way communication), expert review or full public consultation procedures. There is no one procedure or group of stakeholders that may suit each purpose. In practice, and if stakeholder participation is deemed important to a decision, a variety of methods may be used in the course of evaluating an environmental issue.

3.2 Factors to consider and record when involving stakeholders

The ERICA Tool initially allows the user to select whether stakeholders will be involved or not.

If the assessor selects *no*, the Tool will ask them to provide a brief justification for their decision not to include stakeholders. This could be as simple as stating that there is a wider ongoing consultation.

If the assessor selects *yes*, the Tool will ask them for a brief summary of the stakeholder involvement (such as who is involved, how they are involved, what the aims and outcomes of the involvement are).

Table 3.1 contains a generic list of stakeholders that can be used to help to group stakeholders into different classes. The ERICA Tool will record different types of information including timing options, where consideration should be given to whether engagement:

- is required only at the problem formulation stage;
- is required throughout the process;
- should serve as a source of knowledge and/or data for a particular purpose;
- should involve review of the assessment;
- should be requested for any other reason.

Table 3.1: List of generic stakeholder classes.

• Decision makers	• Non-human species*
• General public	• Other NGOs
• Independent experts (research and academia)	• Other No. 1, then No. 2 and so on
• Industry No. 1, then No. 2 and so on	• People/organisations ‘who care’
• International representatives (for transboundary questions)	• Regulators
• Local authorities and/or government representatives	• Risk bearers
• Media	• Users of the environment (for recreation, food production, and so on)
• Next generation*	• Worker representatives
• NGOs (particularly environmental and nature organisations)	

*The groups would be represented by appropriate organisations/individuals.

Once the stakeholders have been identified, it can be helpful to assign them to categories based on whether they have a high or low influence on the assessment process and/or decision and whether they have a high or low interest in its outcome. This categorisation may help to identify the best methods for engagement and the likely level of interest. For example, stakeholders with low influence and low interest may be harder to reach and may not need to be involved, but those with a high interest and high influence would normally be targeted. Potential methods of engagement are summarised in Table 3.2.

Table 3.2: Potential methods for stakeholder engagement for different purposes.

Information provision	Straightforward and can be considered as a one-way process (although the stakeholders might also provide specific information). Dissemination of information related to the project may involve the use of leaflets, websites, public relations and media, open house, exhibitions, seminars and announcements (usually in newspapers).
Consultation	Can be used for the purpose of discussion and gaining agreement on, for example, appropriate input values for the assessment and for gaining an understanding of the stakeholders' points of view and arguments.
Consensus building	Process aimed at reaching agreement on particular points through informed debate and discussion. This is different to consultation where areas of disagreement are likely to remain, because consultation is about identifying different views so that decision makers can consider all possible aspects. In contrast, consensus building attempts to bring all parties to some form of agreement. Whilst the aim of the process might be to come to some form of consensus, this may not always be possible. In these cases, the reasons for disagreement should be recorded, as they might shed light on key issues for consideration by decision-makers.

Once stakeholder engagement is completed, the ERICA Tool asks the user to record the results. The information recorded relates to the influence of stakeholders' comments on the assessment process. The Tool poses the following questions:

- *Have stakeholders been engaged as defined in the problem formulation?*
- *Did the assessor do as intended?*
- *Where is the supporting documentation?* This allows the assessor to record the physical or electronic location of any files that might be useful or should be associated with the assessment using the ERICA Tool or as part of a wider consultation process.
- *Did the stakeholder involvement impact on how the assessment was carried out?* This allows the assessor to record how the assessment problem formulation might have been, or was, modified in consultation with stakeholders.
- *How did the stakeholder involvement impact on the final decision?* This allows the assessor to record any stakeholder involvement in the decision regarding the final outcome. Decisions need to be documented in an open and transparent way, which is particularly important in cases where consensus is limited or absent.

4 Media and biota activity concentrations and dose rates

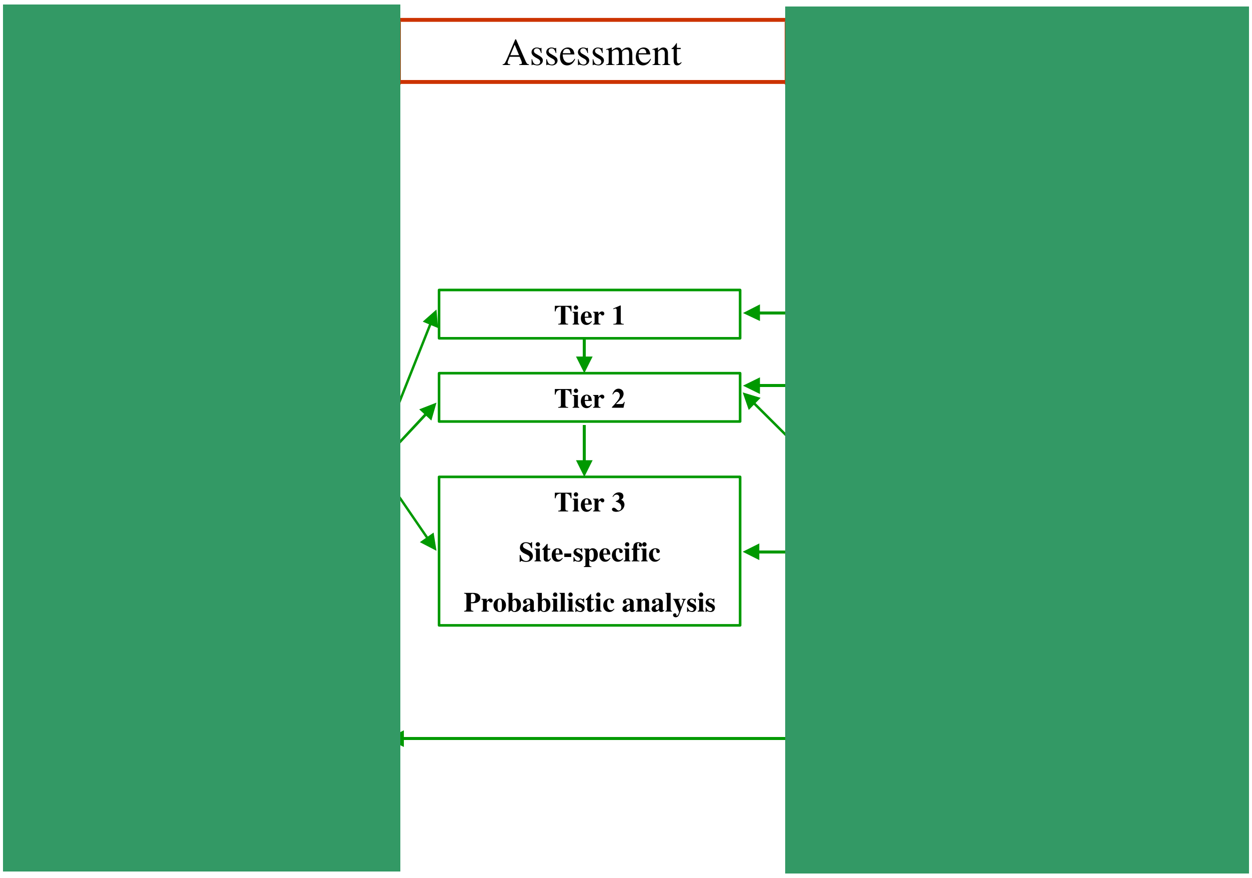


Figure 4.1: The ERICA Integrated Approach, highlighting the elements that relate to estimation of media and biota activity concentrations and absorbed dose rates.

4.1 Introduction

Exposure to radiation is estimated as the absorbed dose rate (the quantity of energy imparted by ionising radiation to a unit mass of an organism per unit time, with µGy h^{-1} used within the ERICA Tool). To determine this, the activity concentrations in both media and biota are required, together with the ability to convert these into estimates of external and internal exposure. Radionuclide activity concentration in media and/or biota may be known, or they may need to be estimated.

This chapter provides an overview of the methods used within the ERICA Tool to estimate radionuclide activity concentrations in media and biota and, from these, whole body absorbed dose rates. Advice on conducting complex assessments, such as those involving multiple sources or transitional ecosystems, is also provided.

4.2 Radionuclide concentrations in environmental media

The radionuclide activity concentrations in media (water, sediment, soil or air) are the basic inputs required in all three tiers of the ERICA Tool. However, sufficient data may not always be available from environmental monitoring. If this is the case, media activity concentrations need to be estimated using dispersion models (for assessments of proposed facilities, this will always be the case). The assessor may have their own models which can be used to derive these inputs. If not, screening transport models adopted from IAEA [2001], subsequently referred to as the SRS-19 models, have been built into the

ERICA Tool and can be used to estimate media concentrations for various scenarios. The SRS-19 models were developed for the purpose of screening radioactive discharges for either new or existing practices in the context of human radiological protection. The models incorporated within the ERICA Tool are generic and account for dilution and dispersion in the environment, using a minimum of site-specific input data. The following SRS-19 models for the three ecosystems are available in the ERICA Tool:

- Small lake (freshwater)
- Large lake (freshwater)
- River (freshwater)
- Estuarine (freshwater and marine)
- Coastal (marine)
- Air (terrestrial)

The SRS-19 models are designed to minimise the possibility that the calculated media concentrations will underestimate doses (to humans) by more than a factor of 10. They can estimate average concentrations in water or air from continuous releases from a single source assuming that an equilibrium, or quasi-equilibrium, has been established between released radionuclides and the environmental medium. The models and their uncertainties are summarised within the ERICA Tool help and a full description is available from the International Atomic Energy Agency (IAEA) website (www-pub.iaea.org/MTCD/publications /PDF/Pub1103 _scr.pdf).

4.3 Activity concentrations in biota

Radionuclide activity concentrations in biota are required for Tier 2 and 3 assessments. As for radionuclide concentrations in environmental media, sufficient data may not be available. If this is the case, the ERICA Tool provides the user with the ability to estimate them. Users of Tiers 2 and 3 need to have some understanding of the approaches used, as they will need to decide on the acceptability of default parameters or provide alternative values. Assessors using only Tier 1 of the ERICA Tool do not need to decide on these issues.

Whole body activity concentrations of radionuclides in biota within the ERICA Tool are predicted from media activity concentrations using equilibrium concentration ratios (CRs). For aquatic environments, the distribution coefficient (K_d) is used to relate equilibrium activity concentrations in sediments with those in water. Concentration ratios and K_d for the ERICA ecosystems are defined in Box 4.1.

The ERICA Tool has three default radioecology databases (one for each ecosystem) containing a complete set of CR and K_d values for all reference organisms and default radionuclides (see Table 2.3) within ERICA. By preference, values of CR were empirically derived from reviews of original publications. Various manipulations of reported data were necessary, as they were often not in the format required (for example, organ-specific rather than whole body activity concentrations). The manipulations and assumptions used in the derivations are fully documented, together with details of statistical analyses used, within the Tool's help. The default databases contain arithmetic mean values together with standard deviations, minimum and maximum values, probability distribution functions (pdfs), number of data entries, comments (such as notes on the data used), and date of last update for each value. The calculation of biota activity concentrations of radioisotopes of H, C, P and S using air concentrations rather than soil is common practice for human assessments.

For many of the reference organism-radionuclide combinations, there were no reported data from which to derive empirical CR values. Various options were used to populate the default CR databases in the absence of reported values for Tier 1 assessments (which require a complete set of default CR values to derive EMCL values; see Section 5.2.2). Values derived by these methods are identified within the default databases. The options used are summarised in Box 4.2 and described in more detail within the Tool help. By preference, the first four options were used wherever possible. With the exception of the last two options, which were used as a last resort, the remaining options were applied depending on availability of information. These approaches could be used by the assessor to help select CR values for newly defined reference organisms or for radionuclides added within Tier 2 and 3 assessments (as the Tool will not contain CR values for these).

Box 4.1 Definition of CR and K_d

Terrestrial ecosystems

$$\text{CR} = \frac{\text{Activity concentration in biota whole body (Bq kg}^{-1}\text{ fresh weight)}}{\text{Activity concentration in soil (Bq kg}^{-1}\text{ dry weight)}} \quad (4.1)$$

Exceptions are for chronic atmospheric releases of ^{3}H, ^{14}C, ^{32,33}P and ^{35}S where:

$$\text{CR (m}^{3}\text{ kg}^{-1}) = \frac{\text{Activity concentration in biota whole body (Bq kg}^{-1}\text{ fresh weight)}}{\text{Activity concentration in air (Bq m}^{-3})} \quad (4.2)$$

Aquatic ecosystems

$$\text{CR (l kg}^{-1}) = \frac{\text{Activity concentration in biota whole body (Bq kg}^{-1}\text{ fresh weight)}}{\text{Activity concentration of filtered water (Bq l}^{-1})} \quad (4.3)$$

$$K_d\ \text{(l kg}^{-1}) = \frac{\text{Activity concentration in sediment (Bq kg}^{-1}\text{ dry weight)}}{\text{Activity concentration in water (Bq l}^{-1})} \quad (4.4)$$

Within Tiers 2 and 3, it is possible to edit CR and K_d values and input measured activity concentrations for biota (all default values derived using the methods in Box 4.2 are clearly identified). A recent comparison of site-specific data to generic data (specifically, soil-plant concentration ratios), however, concluded that generic data may often constitute the best choice, owing to the very large inherent variability in transfer parameters, which a few site-specific measurements may not encapsulate [Sheppard, 2005]. The ERICA Integrated Approach is not prescriptive on the use of site-specific data, and the assessor is advised to consider carefully whether the quality of any available site-specific data justifies its application. Site-specific data will always provide a useful comparison with predictions generated using the Tool's generic parameters. A reasonable level of agreement would be for predicted and observed data to fall within an order of magnitude of each other (consistent with the approach taken in the development of the SRS-19 screening models). However, if there is consistent under- or over-prediction at a given site, alternative transfer parameters should be considered or sufficient measurements of biota conducted. It is also likely that the default CR and K_d databases included within the ERICA Tool will not be applicable to certain ecosystems (such as saltmarshes).

In situations where radioactivity concentrations are decreasing (such as decommissioning or remediation scenarios), the assumption of equilibrium between radioactivity in the medium and in the biota (the concentration ratio) may result in significant underestimation of the dose to organisms. Organisms retain some radionuclides in their bodies over timescales that can range from days to years. Alternative methods have been developed to derive biota activity concentrations under non-equilibrium conditions [for example, Thomann, 1981] although parameterisation of the models used in such assessments is often difficult, requiring resource-demanding experimental work [Vives i Battle *et al*., 2005; Wilson *et al*., 2006]. If such information or models are lacking, the use of allometric approaches (based on the observation that many metabolic parameters, including ingestion rates, radionuclide biological half-lives and so on, are proportional to a simple power function of organism mass) should be considered [see US DoE, 2002; Avila *et al.,* 2004; Brown *et al*., 2004].

Box 4.2 Approaches used to derive default CR values in the absence of empirical data

Use an available CR value for an organism of similar taxonomy within that ecosystem for the radionuclide under assessment (a preferred option) – for example, a value for marine pelagic fish was assumed to be applicable to marine benthic fish.

Use an available CR value for a similar reference organism (a preferred approach) – for example, available CR values for one vertebrate reference organism were applied to other vertebrate reference organisms.

Use CR values recommended in previous reviews or derive them from previously published reviews (a preferred approach) **-** in some instances, it was necessary to use broad reviews of stable element concentrations in media and biota to derive CR values or adopt previously recommended values without being able to go back to the source reference to confirm these.

Use specific activity models for ^{3}H and ^{14}C (a preferred approach) - specific activity models were used to derive ^{3}H and ^{14}C CR values for all reference organisms in terrestrial ecosystems (no values were based on observed data).

***Use an available CR value for the given reference organism for an element of similar biogeochemistry* -** for instance, available CR values for transuranic and lanthanide elements were used if CRs were not available for another member of these series.

***Use an available CR value for biogeochemically similar elements for organisms of similar taxonomy* -** for instance, actinide element CRs for marine reptiles were assumed to be the same value as for marine birds.

Use an available CR value for biogeochemically similar elements available for a similar reference organism - for instance, Nb CRs for marine vertebrates were derived from available Zr values.

Use allometric relationships, or other modelling approaches, to derive appropriate CRs - for instance, CRs for wild bird eggs were derived from available CRs for wild birds and published relationships between radionuclide concentrations in eggs and meat of domestic poultry.

Assume the highest available CR **(a least preferred option) - this option was used on a few occasions only to provide Po and Tc CR values for terrestrial invertebrate reference organisms and a small number of Ru and C CRs for freshwater reference organisms.**

For aquatic ecosystems use (if justified) an appropriate CR value for the reference organism in a different ecosystem *(*a least preferred option*)* - in the ERICA freshwater database, CR values for the same reference organism in the marine ecosystem (from the ERICA marine database) were assumed for a limited number of freshwater CR values.

4.4 Dosimetry

4.4.1 Basic concepts

The estimation of absorbed dose rate (µGy h^{-1}) is an essential step within the ERICA Integrated Approach, enabling media/biota activity concentrations to be interpreted in terms of potential effect. Radionuclides in the environment lead to plants and animals being exposed both externally and internally to ionising radiation. Internal exposure arises following the uptake of radionuclides by the organism via pathways such as ingestion or root uptake; it is determined by the activity concentration in an organism, the size of the organism, and the type and energy of emitted radiation. External radiation exposure depends on various factors including contamination levels in the environment, the geometric relationship between the radiation source and the organism, habitat, organism size, shielding properties of the medium and the physical properties of the radionuclides present.

The geometric relationship between radiation source and the exposed organism is an important factor in relation to the received absorbed dose rate. The intensity of the radiation field around a source decreases with distance and is influenced by the media between the radiation source and the target. The number of possible source/target configurations is infinite, therefore a set of limited and representative situations need to be considered.

The relationship between the activity concentration of an organism or media and internal or external absorbed dose rates is described by the dose conversion coefficient (DCC; µGy h^{-1} per Bq kg^{-1} fresh weight) (see Box 4.3). The method used to derive DCC values within the ERICA Tool is that described by Pröhl *et al*. (2003). A key quantity for estimating internal absorbed doses is the absorbed fraction (ϕ), defined as the fraction of energy emitted by a radiation source that is absorbed by an organism. Within the ERICA Integrated Approach, the absorbed fractions for photon and electron sources assumed to be uniformly distributed in spheres/ellipsoids immersed in infinite aquatic medium have been calculated using Monte Carlo simulation. The calculations for ERICA default geometries (see Table 2.4) cover an energy range from 10 keV to 5 MeV, a mass range from 1 mg to 1000 kg, and shapes from sphere to ellipsoids with varying degrees of non-sphericity [Ulanovsky and Pröhl, 2006]. From the computed absorbed fractions, a set of 're-scaling factors' have been derived and interpolated to allow user-defined organisms to be defined within certain limitations of size (see the Tool help for more details).

BOX 4.3 Dose conversion coefficients

In the simplest case, an organism is assumed to be in an infinite homogeneous medium of the same density and elemental composition as itself, and have radioactivity distributed homogenously throughout its body or in the medium. Under these conditions, both internal (DCC_{int}) and external (DCC_{ext}) ***dose conversion coefficients*** (defined as absorbed dose rate (µGy h^{-1}) per unit activity concentration in organism (Bq kg^{-1} fw) or medium (Bq kg^{-1} or l^{-1} media fw)) for mono-energetic radiation can be expressed as a function of the absorbed fraction:

$$DCC_{\mathrm{int}} = 5.77 \times 10^{-4} \times E \times \phi_E \qquad (4.5)$$

$$DCC_{ext} = 5.77 \times 10^{-4} \times E \times (1 - \phi_E) \qquad (4.6)$$

where:
E (MeV) is the energy of a mono-energetic source
ϕ_E is the absorbed fraction for a given energy
5.77×10^{-4} is a conversion factor

Equation 4.6 is an approximation that assumes the organism and the surrounding medium are of the same density and elemental composition.

For aquatic organisms, which are immersed in water, there is no substantial difference between the density of water and the organism and therefore the assumptions made within Equations 4.5 and 4.6 are justified. However, for terrestrial organisms the estimation of external exposure is more complex. Soil, air and organic matter differ considerably in composition and density. Consequently, radiation transport cannot be adequately taken into account by applying analytical solutions. Instead, the derivation of DCCs is based on radiation transfer simulated for mono-energetic photons using Monte Carlo techniques. Generalised, representative cases as defined by radiation energy, contaminated media and organism size were selected for detailed consideration. Exposure conditions, for which detailed calculations were not available, were then deduced by interpolation between these cases. The source–target relationships taken into account are presented in Box 4.4.

Box 4.4 Terrestrial source-target relationships

Source-target combinations for calculations of DCCs for external radiation:

- External exposure of on- and above- soil organisms to a uniformly contaminated volume with a thickness of 10 cm (µGy h^{-1} per Bq kg^{-1} soil fresh weight).
- External exposure of organisms that live in the middle of a uniformly contaminated soil layer with a thickness of 50 cm (µGy h^{-1} per Bq kg^{-1} biota fresh weight).

From the calculations for mono-energetic radiation sources, nuclide-specific dose conversion coefficients (DCCs) are derived for external and internal exposure, taking into account the type of radiation as well as energy and intensity of the emission for most radionuclides included in ICRP Publication 38 [ICRP, 1983]. Radioactive daughter nuclides are included in the calculation of the DCCs, if their half-lives are shorter than 10 days.

The simplifications made when estimating whole body DCC values in the ERICA Approach are comparable with those made in other approaches to estimating exposure of non-human biota [Beresford et al 2005]. The ERICA project has assessed the uncertainty associated with the heterogeneous distribution of some radionuclides and this is discussed in full in the Tool help. In summary, it can be concluded that: (i) for photons, the uncertainty due to a possible non-homogeneous radionuclide distribution is lower than 20-25 per cent in the considered cases; (ii) for electrons, uncertainty is negligible below a threshold energy dependent on the size of the organisms.

4.4.2 Dose rate calculation

The dose conversion coefficients can be used to estimate the unweighted absorbed dose rate from media and organism activity concentrations (see Box 4.5). However, radiation effects depend not only on unweighted absorbed dose, but also on the type of radiation. For example, for a given unweighted absorbed dose rate, α-radiation may result in a more significant effect than β- or γ-radiation. Therefore, radiation weighting factors are introduced to account for the relative biological effectiveness of the different types of radiation (see Box 4.5). Default radiation weighting factors of 10 for alpha radiation and 3 for low beta radiation are assumed within Tier 1, in line with suggested values in the FASSET project [Pröhl *et al*., 2003]. This is also consistent with the upper bound on the range of variation reported by Chambers *et al.* [2006] for α-radiation weighting factors in relation to deterministic endpoints (mainly mortality). At Tiers 2 and 3, whilst these values are provided as the defaults, they can be altered by the user.

4.5 Complex assessments – considerations for all tiers

The ERICA Tool allows assessments to be conducted for terrestrial, marine or freshwater environments. It does not address situations where an organism may inhabit more than one ecosystem (such as amphibians, sea birds or aquatic mammals), or where a radioactive release may impact upon more than one ecosystem (for example, flooding events may contaminate terrestrial ecosystems with aquatic discharge) or transitional environments (such as saltmarshes, sand dunes and other estuarine ecosystems). Similarly, the Tool does not allow for multiple input sources into an area (such as for an assessment site downstream of several facilities discharging into a river catchment).

As the ERICA Tool does not explicitly deal with these issues, it is recommended that the assessor undertake a series of linked assessments within the Tool. A key issue for this type of assessment is the need to consider whether the default ERICA data is appropriate to some of these specialised ecosystems. For example, chemical forms and contamination pathways of radionuclides within saltmarshes are likely to differ from those of other terrestrial ecosystems, affecting CR values. Below, two example scenarios illustrate how such assessments may be conducted using the Tool.

Box 4.5 Estimation of unweighted absorbed dose rates

$$\dot{D}_{\text{int}}^{b} = \sum_{i} C_{i}^{b} * DCC_{\text{int},i}^{b} \quad (4.7)$$

Where:

$\dot{D}_{\text{int}}^{b}$ is the absorbed internal dose rate for reference organism *b*

C_{i}^{b} is the average concentration of radionuclide *i* in reference organism *b* (Bq kg^{-1} fresh weight)

$DCC_{\text{int},i}^{b}$ is the radionuclide-specific dose conversion factor (DCC) for internal exposure defined as the ratio between the average activity concentration of radionuclide *i* in the organism *b* and the dose rate to the organism (µGy h^{-1} per Bq kg^{-1} fresh weight)

$$\dot{D}_{\text{ext}}^{b} = \sum_{z} v_{z} \sum_{i} C_{zi}^{\text{ref}} * DCC_{\text{ext},zi}^{b} \quad (4.8)$$

Where:

v_z is the occupancy factor, the fraction of time that organism *b* spends at a specified location *z* in its habitat

C_{zi}^{ref} is the average concentration of radionuclide *i* in the reference media of a given location *z* (Bq kg^{-1} fw or dw (soil or sediment) or Bq l^{-1} (water))

$DCC^{j}_{ext,zi}$ is the dose conversion factor for external exposure defined as the ratio between the average activity concentration of radionuclide *i* in the reference media corresponding to the location *z* and the dose rate to organism *b* (µGy h^{-1} per Bq unit media)

Weighted total dose rates (in µGy h^{-1}) can be calculated as:

$$DCC_{\text{int}} = wf_{\text{low}\beta} \cdot DCC_{\text{int,low}\beta} + wf_{\beta+\gamma} \cdot DCC_{\text{int},\beta+\gamma} + wf_{\alpha} \cdot DCC_{\text{int},\alpha} \quad (4.9)$$

$$DCC_{\text{ext}} = wf_{\text{low}\beta} \cdot DCC_{\text{ext,low}\beta} + wf_{\beta+\gamma} \cdot DCC_{\text{ext},\beta+\gamma} \quad (4.10)$$

Where:

wf are the weighting factors for various components of radiation (low β, β + γ and α)

4.5.1 Example of an assessment of a transitional environment (a saltmarsh)

For a saltmarsh, the ERICA Tool should first be run to assess dose rates to each reference organism (and assessor-specified organisms at Tiers 2 and 3) in the terrestrial environment. The Tool should then be run to assess dose rates to each organism in the marine environment. In both cases, for a retrospective assessment, where sufficient measured data are available these should be used as input into the Tool.

If, at Tier 1, the risk quotients for both assessments are predicted to be well below unity – the qualification of 'well below' having been agreed by assessor and stakeholders – then there is no further need for assessment. If there is any doubt, the assessor may want to consider the proportion of time organisms of concern spend in terrestrial and aquatic locations within the saltmarsh ecosystem, and alter the occupancy factors at Tiers 2 and 3 of the assessment accordingly. For example, if a particular organism spends 50 per cent of its time in the terrestrial environment and 50 per cent in the marine environment, all occupancy factors could be reduced by 50 per cent to reflect this.

4.5.2 Example of an assessment of multiple sources discharging into a river catchment and impacting one site downstream

For multiple sources affecting one site, the key information required is the input activity concentrations for radionuclides discharged into the river that arrive at the site of interest.

In a retrospective assessment, measurement data, if available, should be used if the assessor is satisfied that the measurements adequately represent contamination levels at the site under study. This would address the need to take into account any transport or dispersion from the points of discharge. However, it may be difficult to determine the relative contributions of different sources to the doses predicted. If an impact on non-human species is predicted as a result of a multi-source assessment, the assessor will need to determine the contributions of individual discharges to the estimated dose rate.

In a prospective assessment (or where little measured data exist), the SRS-19 models provided (at Tiers 1 and 2) can be used to determine activity concentrations reaching the site of interest; other models could be used to provide these data if available, and would be needed in Tier 3. The assessor can thus estimate dose rates to biota from each source. Estimated dose rates can be compared against the screening levels, but the assessor must remember to add up the dose rates for each organism from each source. This needs to be done outside of the assessment tool, although an alternative would be to conduct an additional assessment inputting the total amount of radioactivity received by the site of interest from all the discharges.

Prospective assessments may also need to consider exposure from historical contamination of a site. This could be considered in a similar manner to the method described above, where doses from historical contamination (from measured data) and prospective releases could be assessed separately and then summed.

5 Tier 1 – a simplified screening tier

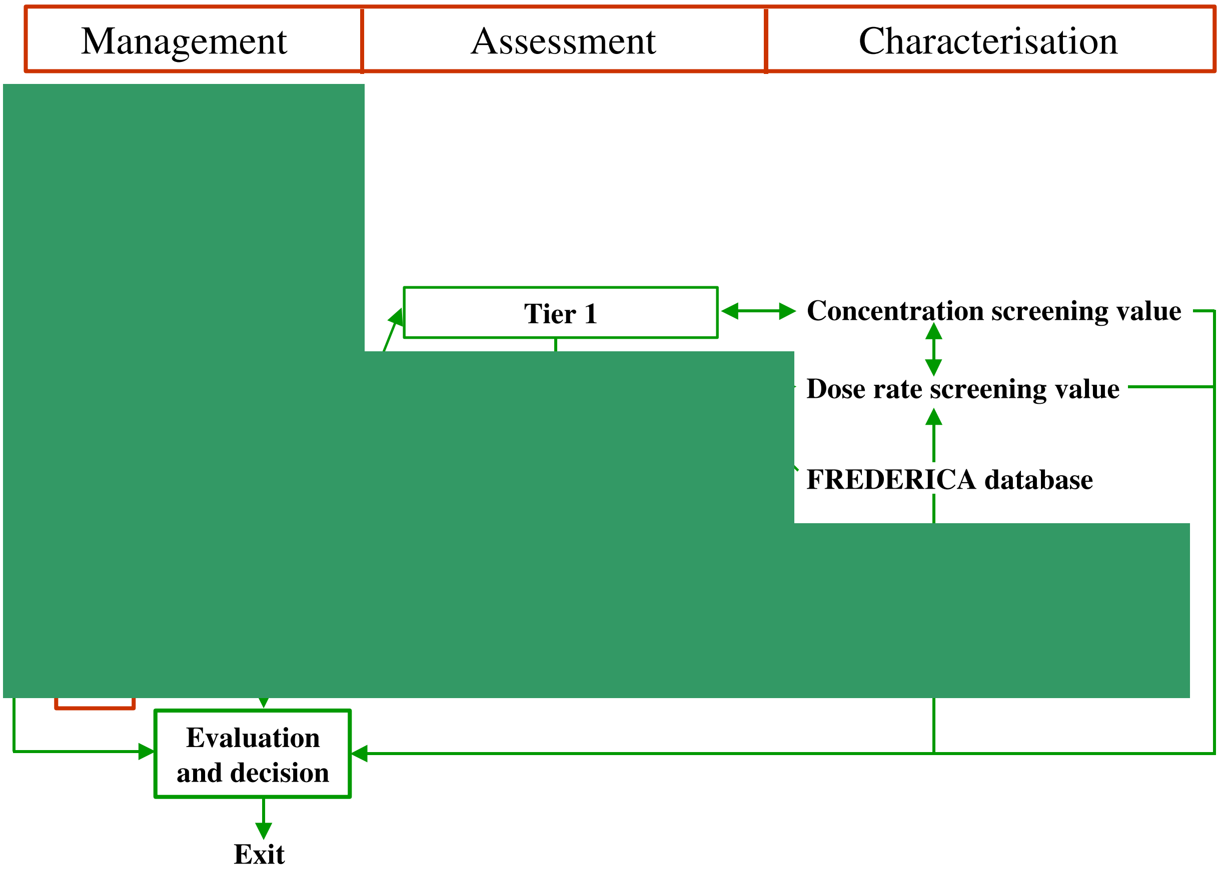


Figure 5.1: The ERICA Integrated Approach, highlighting the elements that relate to Tier 1.

5.1 Introduction

Tier 1 is designed to be relatively simple, so that non-experts can use it; it requires minimal input and is highly conservative. It is anticipated that many assessments will be screened out (that is, judged to be of negligible concern with a high degree of confidence) using this tier.

This chapter describes the main components underpinning Tier 1 and explains its results. Uncertainties associated with this tier are described within the uncertainty matrix in Annex A of this report.

5.2 The risk quotient

The risk quotient (RQ) method provides a simple means of assessing risk. Within the ERICA Integrated Approach, the risk quotient integrates exposure and effects data to determine ecological risk by calculating the quotient of estimated exposure and benchmark dose rate. The benchmark dose rate is the dose rate which is assumed to be environmentally 'safe'. The RQ is defined as:

$$RQ = \frac{predicted\ \ environmental\ dose\ rate}{benchmark\ \ dose\ rate\ assumed\ to\ be\ environmentally\ 'safe'} \qquad (5.1)$$

The ERICA Integrated Approach requires benchmark values for Tiers 1 and 2. Generally, a benchmark value designates any value that is used for the purpose of comparison. It becomes a *screening value* when it is used to screen out sites of negligible concern. For all organisms and ecosystems, ERICA has a screening incremental dose rate of **10 µGy h^{-1}** for chronic exposure to human activities that use radioactive substances and/or increase the levels of ionising radiation in the environment.

Within Tier 1, the RQ is simplified such that the screening dose rate is used to derive benchmark media activity concentrations which are compared to user input activity concentrations. The approach taken to estimating RQs in Tier 2 is described within the next chapter.

5.2.1 Deriving the ERICA Integrated Approach incremental screening dose rate

The aim of the ERICA Integrated Approach is for generic ecosystems (freshwater, marine and terrestrial) to be protected from effects on their structure and function from chronic exposure to radionuclides. The proposed 10 µGy h^{-1} screening dose rate has been derived from data on the effects of ionising radiation in non-human biota collated in the FRED effects database (see also Chapter 7). This database includes data from the original FASSET Radiation Effects Database (FRED), covering the period 1945-2001, plus data from new references up to the end of the ERICA project (early 2007). FREDERICA also contains the output from experiments conducted within the ERICA project and field data from the former Soviet Union [Sazykina et al 2003].

The 10 µGy h^{-1} incremental screening dose rate is the result of an analysis of chronic exposure data from amongst the 26,000 data entries in the original FRED database. The analysis conducted follows EC recommendations for estimating predicted no effect concentrations (PNEC) for chemicals [EC, 2003]. A three-step method was used:

- A data subset was extracted from each experiment, covering endpoints related to mortality, morbidity and reproduction.
- A systematic mathematical treatment was applied to reconstruct dose rate-effect relationships and to estimate critical toxicity endpoints. For chronic exposure, the critical toxicity endpoint is the estimated EDR_{10} (in µGy h^{-1}); that is, the effect dose rate giving rise to a 10 per cent change in observed effect.
- These estimated critical toxicity data were used to derive a predicted no effect dose rate (PNEDR) using the species sensitivity distribution method (SSD) [EC, 2003].

The SSD method was used to estimate the dose rates below which 95 per cent of species in the aquatic/terrestrial ecosystem should be protected: the HDR_5 or hazardous dose rate giving a 10 per cent effect to five per cent of species. After analysing the data for different ecosystems separately, there was no statistical justification to attempt to derive ecosystem-specific screening dose rates and all data were analysed together as a generic ecosystem. The resultant HDR_5 value was 82 µGy h^{-1} (with 95th percentile confidence intervals of 24 and 336 µGy h^{-1}). To derive the final dose rate screening (or PNEDR), a safety factor of five was applied to account for the remaining extrapolation uncertainties (such as the irradiation pathway that could lead to a dominant internal dose by α or β emitters) and the resultant number rounded down to the nearest one significant digit. This resulted in **the ERICA Integrated Approach screening dose rate for incremental exposure of 10 µGy h^{-1}**. The method used to derive this screening value is fully documented within ERICA D5, where the value is also shown to be similar to that derived using alternative methods to SSD.

At the ecosystem level, the ERICA Integrated Approach screening dose rate value lies in the dose range giving rise to minor effects [Woodhead & Zinger 2003; ERICA D5; Garnier-Laplace et al 2006]. These minor effects are not expected to be important at higher organisational levels, such as the structure and functioning of ecosystems. Furthermore, natural background dose rates may be in excess of 10 µGy h^{-1} for some organisms in some areas. The proposed screening dose rate is lower than the US Department of Energy (DoE) dose rate limit of 10 mGy d^{-1} (around 400 µGy h^{-1}) for native aquatic animals, and benchmarks of 400 and 40 µGy h^{-1} for terrestrial plants and terrestrial animals respectively (based on the intent of DoE orders as no statutory dose limits were in place as of 2006), as used in the US DoE's graded approach [US DoE, 2002].

5.2.2 The Environmental Media Concentration Limit

To simplify Tier 1, environmental activity concentrations are compared to the Environmental Media Concentration Limit (EMCL). The EMCL is derived for each radionuclide-reference organism combination by back-calculating from the proposed screening dose rate (see Box 5.1). Under the conservative assumptions used within Tier 1, only the minimum value obtained from the suite of reference organisms is used to provide the EMCL value for a given radionuclide. As a consequence, the user cannot select reference organisms within Tier 1. For the terrestrial environment, EMCL values always refer to soil activity concentrations, except for isotopes of H, C, S and P that refer to air concentrations. For aquatic systems, EMCL values are derived for both water and sediment activity concentrations. The derivation of the EMCL used within the ERICA Tool is fully described within the Tool help.

Box 5.1 Environmental Media Concentration Limit

For each radionuclide and each organism, the EMCL (in Bq l^{-1} or kg^{-1} (dry weight) or m^{-3} of medium) is defined as:

$$ECML = \frac{Screening\ dose\ rate}{F} \qquad (5.2)$$

Where:

F is the dose rate that a given organism will receive for a unit concentration of a given radionuclide in an environmental medium (µGy h^{-1} per Bq l^{-1} or kg^{-1} (dry weight) or m^{-3} of medium).

The value of F depends upon the reference organism type, which is defined by specific DCC values, position(s) within habitat and the radionuclide-specific DCC, CR and K_d values. Derivation of the F value is summarised below (and explained in full within the Tool help). An example equation to estimate F is shown in Figure 5.3 – equations for every reference organism can be found in the Tool help.

In deriving EMCLs, the default location within the habitat is based on the configuration that will result in maximum exposure of a given organism (see Figure 5.2 for the default habitats considered). For example, for the terrestrial soil invertebrate, the assumption is made that the organism spends 100 per cent of its time underground (when in reality it will also spend time on the soil surface).

To ensure defensible and conservative ECML values in this initial screening tier, the F values are calculated for each radionuclide-reference organism combination using all available information, including statistical information relating to CR and K_d by probabilistic methods. Data availability varies and can be summarised as follows:

- Well-defined datasets with arithmetic mean, standard deviations and (assumed) log-normal probability distribution functions. This is the case for some reference organism-radionuclide CR values.

- Poorly defined datasets with expected values only. This is the case for most K_d and many CR values. In this case, an exponential distribution is assumed.
- Precisely calculated values for which the uncertainty is assumed to be zero, namely the DCC values.

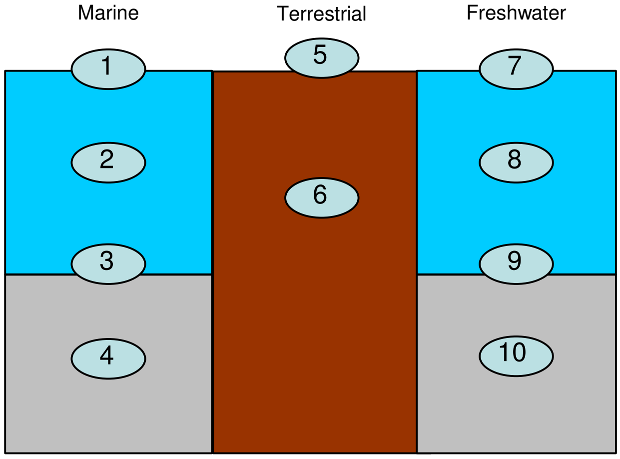


Figure 5.2: The ten habitats in the ERICA Integrated Approach.

The output of the probabilistic (Monte Carlo) simulation is a probability distribution for the F value which enables the calculation of any percentile of the ECML. The ERICA Tool uses conservative EMCL values, set at five per cent. An illustrative example of the probabilistic derivation of an F value is provided in Figure 5.3.

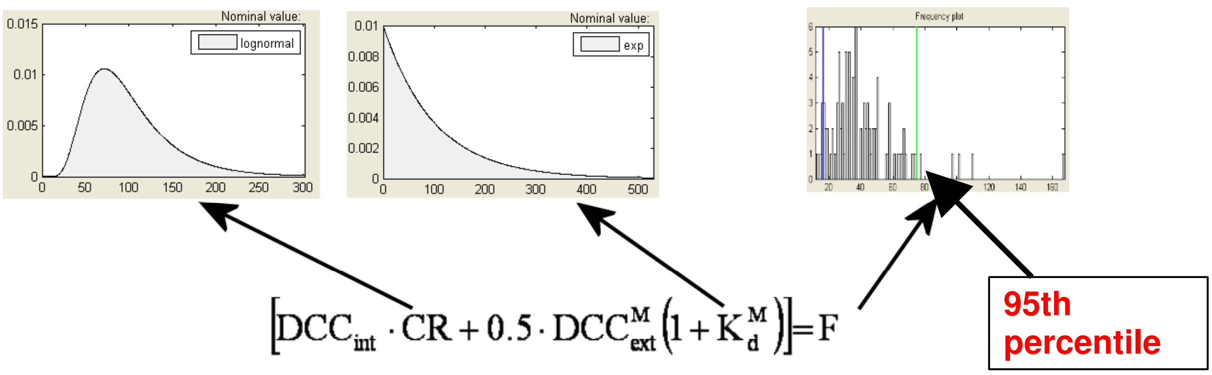


Figure 5.3. Example of the use of probabilistic calculations in the derivation of EMCLs. The equation shown here is for benthic organisms living at the water-sediment interface (habitats 3 and 9 in Figure 5.2).

In addition to having EMCL values calculated for the ERICA screening dose rate, the ERICA Tool allows the user to select two alternatives:

- Values of 40 µGy h^{-1} for terrestrial animals and 400 µGy h^{-1} for terrestrial plants and all aquatic species. It has previously been suggested that below these values of chronic exposure, no measurable population effects would occur [IAEA, 1992; UNSCEAR, 1996]. As already noted, these values also correspond to those used in the US DoE's graded approach [US DoE, 2002].

- User-defined value that enables the user to put in any number they consider justifiable. If this option is selected, the resultant RQ values are derived by scaling those for the ERICA screening dose rate of 10 µGy h^{-1} by the difference between the user input dose rate and the ERICA screening dose rate; for example, if the user defines a screening dose rate of 20 µGy h^{-1}, the tool simply divides the RQs by a factor of two.

5.3 Screening at Tier 1

At Tier 1, the assessor is prompted to enter the measured or modelled radionuclide activity concentrations for their site. The activity concentrations entered should be either the **maximum** values available or other justifiable values (for example, at the edge of the mixing zone rather than the end of a discharge pipe). The ERICA Tool compares the measured or modelled radionuclide activity concentrations with the EMCLs for the most limiting reference organism by calculating RQs for each radionuclide (see Box 5.2). The ECMLs are then summed to provide an overall RQ for the ecosystem being assessed.

Box 5.2 Calculation of RQ in Tier 1

$$RQ = \frac{M}{EMCL} \quad (5.4)$$

Where:RQ = Risk quotient for a given radionuclide;

M = Estimated or measured activity concentration for a given radionuclide in Bq l^{-1} for water, Bq kg^{-1} dry wt for soil/sediment or Bq m^{-3} for isotopes of C, H, P and S within the terrestrial environment;

EMCL = Environmental media concentration limit for a given radionuclide **for the most limiting reference organism** (same units as medium).

As the ERICA Tool only contains the EMCL value for the limiting reference organism, the sum of RQs may be derived from different reference organisms (see Table 5.1). This will result in the overall RQ being in excess of the total RQ for any one species.

Table 5.1. Approach used for summing RQs at Tier 1, where the limiting RQ is identified in red for each radionuclide. The overall RQ, which is used to decide the assessment outcome, is the sum of the three limiting RQ values. As the ERICA Tool only contains EMCL values for the limiting reference organism for each radionuclide, only the limiting RQs are reported (in this example, only the red values are reported by the Tool).

		RQs		**∑RQ**
	Cs-137	**Po-210**	**Ra-226**	
Zooplankton	0.10	0.2	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	
				1.12

5.3.1 Interpreting the Tier 1 RQ value

The outputs of a Tier 1 assessment are the RQ values for the limiting reference organism and the sum of the individual radionuclide RQs. These enable the user to decide whether to conclude the assessment or conduct a more detailed one, as follows:

- ***If the sum of the RQs is less than one*** there is a very low probability that the absorbed dose rate to any organism exceeds the screening dose rate, and the situation may be considered to be of negligible radiological concern. The ERICA Tool will recommend the user to conclude the assessment.
- ***If the sum of the RQs is greater than one*** the assessment dose rate to one or more organisms may exceed the screening dose rate, and there is insufficient evidence to conclude that the situation is of negligible radiological concern. The ERICA Tool will recommend the user to continue the assessment using Tier 2.

The default EMCLs used at Tier 1 can be considered conservative estimates, because a screening dose rate and the 95th percentile of the F value have been used in its derivation as described above. Furthermore, the lowest radionuclide-specific EMCL value from across the whole suite of ERICA reference organisms, which will result in the highest RQ value, is selected for each radionuclide. This means that when summing RQs for all radionuclides present in a given situation, the limiting or most 'affected' reference organism may not be the same for each radionuclide (see Figure 5.3). All of these considerations, together with the recommendation that the maximum measured or predicted media concentrations are generally used within Tier 1, allow for a very high degree of confidence in concluding that environmental effects are of negligible concern when being able to exit the assessment at Tier 1 (if the sum of RQs is less than one). Although the approach might be deemed overly conservative, it has nevertheless been selected because it:

- is reasonably consistent with other assessment approaches currently available (such as US DoE [2002]);
- reflects the uncertainty associated with the severe lack of data for some radionuclide-reference organism combinations;
- is simple and resource effective and does not require an expert user.

6 Tier 2 assessments

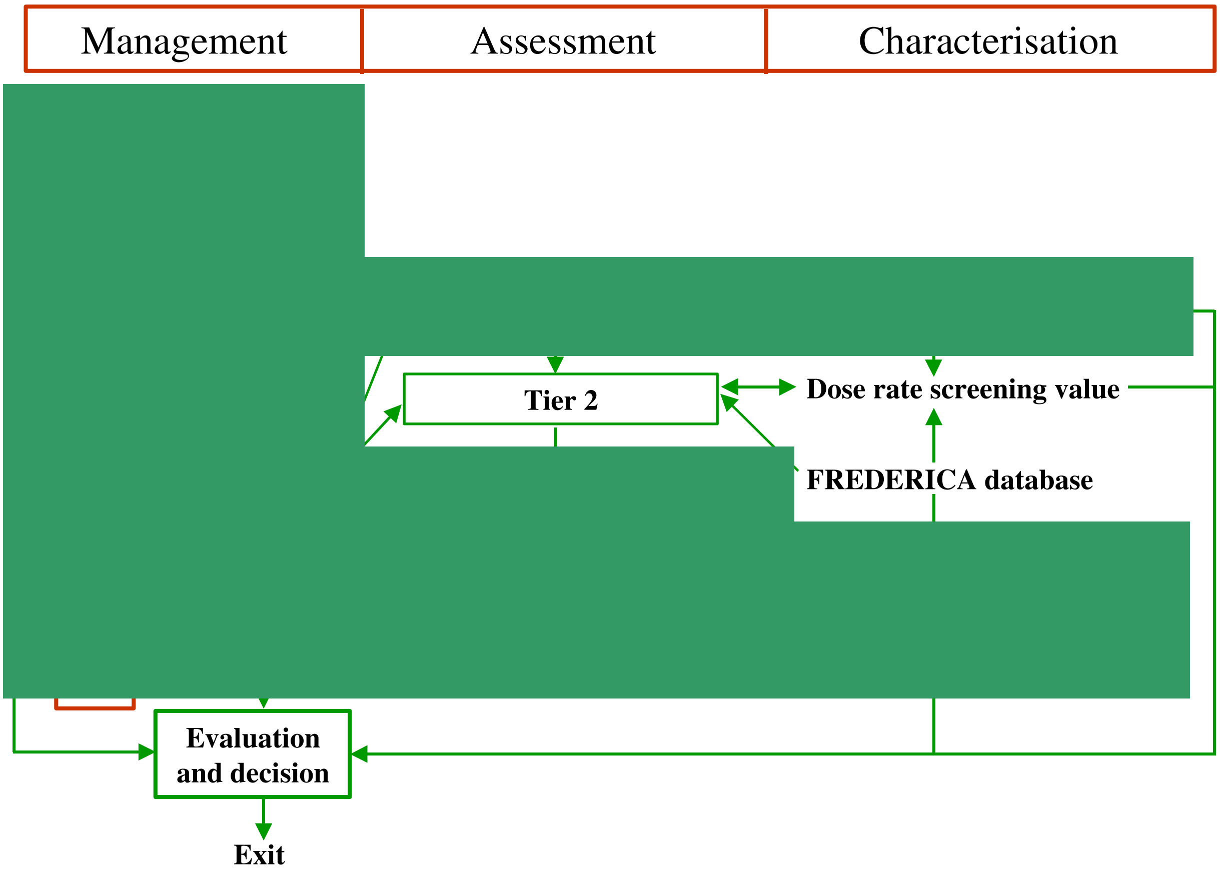


Figure 6.1: The ERICA Integrated Approach, highlighting the elements that relate to Tier 2.

6.1 Introduction

Tier 2 of the ERICA Tool is also a screening tier, but enables a more informed assessment and hence does not need to be as conservative in its approach as Tier 1. The objective of Tier 2 is to identify situations where there is a very low probability, for example a few percent, that the dose to any selected organism exceeds the adopted screening dose rate.

Within this tier the user can:

- obtain RQ values for the organisms of interest within their assessment (compared to the combined ecosystem worst case RQ output in Tier 1);
- define their own organism to represent species of interest;
- add additional radionuclides;
- provide their own CR and K_d values;
- put their results into context with effects data and typical background exposure rates.

Some of these additional functions may mean that some users start their assessment at Tier 2 (for example, if a radionuclide not considered within the ERICA default list needs to be assessed). The user-defined organism, addition of radionuclides and editing of CR and K_d values functions are all discussed in the Tool help. Further background is also provided in Chapter 4. This chapter concentrates on describing the Tier 2 RQ value and interpretation of results. Uncertainties associated with this tier are described within the uncertainty matrix in Annex A of this report.

Users who have progressed to Tier 2 on the basis of a Tier 1 assessment should review and refine their problem formulation as the first step of the Tier 2 assessment (see Chapter 2).

6.2 The Tier 2 Risk Quotient

In Tier 2, the ERICA screening dose rate of 10 µGy h^{-1} (see Section 5.2.1) is compared directly to the total estimated whole body absorbed dose rate for each individual organism:

$$RQ = \frac{\textit{Whole body absorbed dose rate}}{\textit{Screening dose rate}} \qquad (6.1)$$

The approach differs from that in Tier 1 in that, in effect, the RQ for a given organism equals the sum of the radionuclide-specific RQs for that organism, whereas in Tier 1 the overall RQ is the sum of the RQs for the most limiting reference organism for each radionuclide. The Tier 2 approach is less conservative than the approach used at Tier 1 (compare Tables 5.1 and 6.1) but justified because, at Tier 2, the assessor is more directly involved with selecting the reference organisms to include in their assessment.

Table 6.1: Representation of the Tier 2 RQ values.

	RQs			**∑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

In addition to media activity concentrations, at Tier 2 the user can input whole body activity concentrations for biota if they are available. Users may find the data manipulations used by ERICA to derive the CR database useful if only organism-specific activity concentrations are available – see the Tool help. In Tier 2, it is recommended that the user inputs best estimate activity concentrations for media and organisms (if available).

As with Tier 1, the user can chose alternative screening dose rates, being able to either: (i) select 40 µGy h^{-1} for terrestrial animals or 400 µGy h^{-1} for terrestrial plants and all aquatic species; or (ii) input a user defined value.

6.2.1 Uncertainty factors

As the aim of Tier 2 is to identify situations where there is a very low probability that the dose to any selected organism exceeds the adopted screening dose rate, the screening test is implemented as follows:

1. An **expected value** of the RQ is calculated using expected (or best estimate) values for the input data and the parameters;
2. The 95th or 99th percentile of the RQ is estimated by multiplying the expected value of the RQ by an uncertainty factor (UF) of 3 or 5 respectively (reported as the **conservative RQ** in the ERICA Tool). The uncertainty factor is defined as the ratio between the 95th or 99th percentile and the expected value of the probability distribution of the dose rate (and RQ). To estimate UFs, it is

assumed that the dose rate and RQ follow exponential distributions with means equal to the estimated expected values. In this case, the UFs corresponding to the 95th and 99th percentiles are equal to three and five respectively (the assessor can select which to use). This approach is explained and justified within the Tool's help.

The UFs also maintain conservatism between Tiers 1 and 2. With the same input values and default settings, the results for Tiers 1 and 2 should approximate to one another because the user will not have thought in more detail about the problem they are facing and may not have amended the problem formulation accordingly. The use of the UF value of three (95th percentile) results in conservative RQ estimates compatible with the results of Tier 1 (the EMCL being derived from the 95th percentile F value).

In addition to the UF values of three and five, the user can input their own number although this will need to be derived and justified (see Tool help).

6.3 Interpreting the Tier 2 Risk Quotient

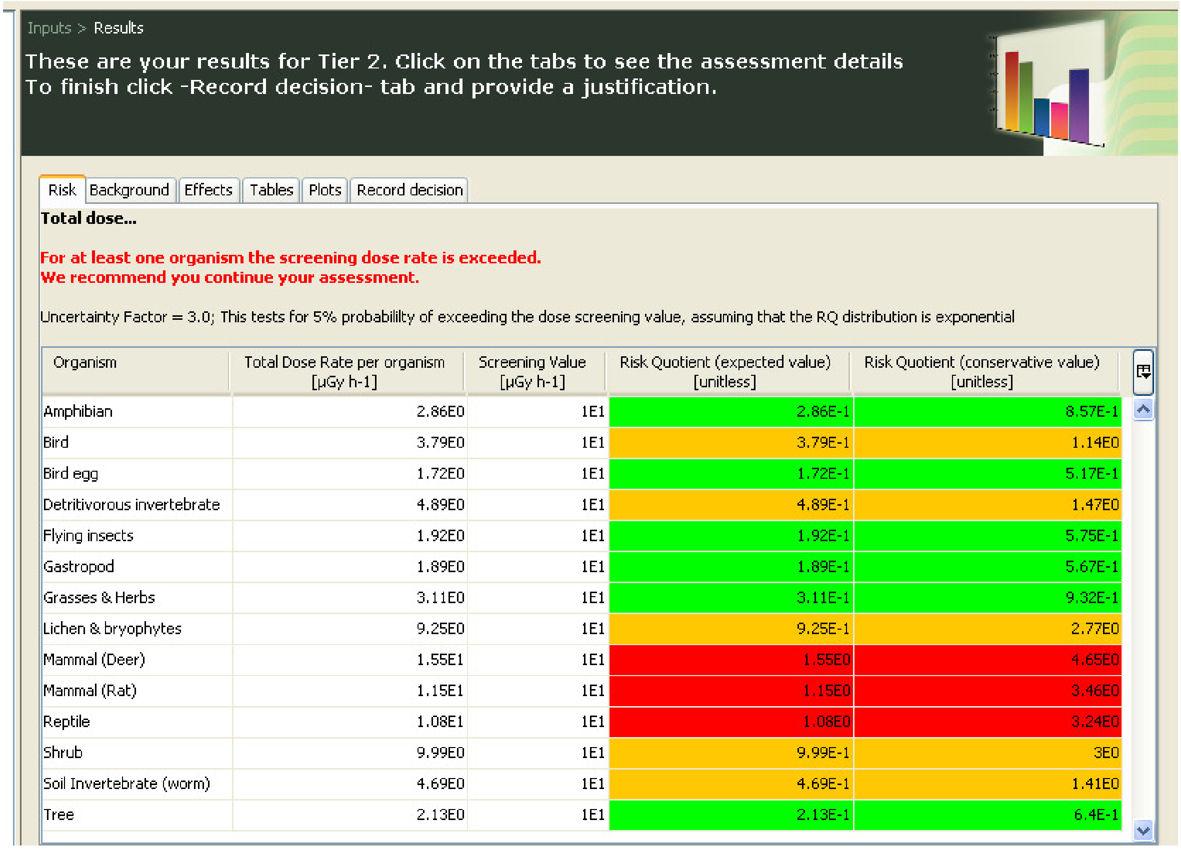
As described above, two RQs are reported in Tier 2 for every organism selected in the assessment: the best estimate RQ and the conservative RQ (see Table 6.1). Used in combination with other information provided within the Tier 2 assessment screens (as discussed below), these enable the assessor to make a decision on whether to conclude or continue the assessment:

- ***If the conservative RQs are below one*** for all organisms, then the assessment has not exceeded the screening level at Tier 2. If a UF of three or five (or higher) is used, there is low probability that the estimated dose rate to any organism exceeds the screening dose rate, but the resulting risk to non-human biota can be considered to be trivial (on the basis of the analyses of effects data conducted to derive the ERICA screening dose rate, as discussed in Section 5.2.1). The ERICA Tool will recommend the user to exit the assessment.

- ***If the conservative RQ is above one*** for any organism, then the probability of the assessment exceeding the screening value at Tier 2 is above that selected (as defined by the UF). However, if the expected value RQ is below one there is a possibility that (i) further work to reduce uncertainties in the estimate may result in the conservative RQ falling below unity or (ii) putting the results into context with the available effects data or background dose rates may lead to the assessor (and stakeholders) agreeing that the likely risk is minimal. The ERICA Tool will recommend that the assessment and results are reviewed.

- ***If the expected value RQ (and by implication the conservative RQ) is above one*** for any organism, then the assessment has exceeded the screening value at Tier 2 and the ERICA Tool will recommended that further assessment be conducted.

In those cases where is it recommended that the assessment be continued or that the assessment and results are reviewed, this does not necessarily mean an automatic progression to Tier 3. For instance, it may be possible to refine the input data or Tool parameters (for example, obtain CR vales applicable to the site) if justifiable and to then rerun the assessment at Tier 2. In instances where the conservative RQ is above one whilst the best estimate RQ is below one, interpretation of the results may lead to a decision that the assessment can be justifiable exited. These issues are expanded upon below.



Inputs > Results

These are your results for Tier 2. Click on the tabs to see the assessment details
To finish click -Record decision- tab and provide a justification.

Risk | Background | Effects | Tables | Plots | Record decision

Total dose...

For at least one organism the screening dose rate is exceeded.
We recommend you continue your assessment.

Uncertainty Factor = 3.0; This tests for 5% probability of exceeding the dose screening value, assuming that the RQ distribution is exponential

Organism	Total Dose Rate per organism [µGy h-1]	Screening Value [µGy h-1]	Risk Quotient (expected value) [unitless]	Risk Quotient (conservative value) [unitless]
Amphibian	2.86E0	1E1	2.86E-1	8.57E-1
Bird	3.79E0	1E1	3.79E-1	1.14E0
Bird egg	1.72E0	1E1	1.72E-1	5.17E-1
Detritivorous invertebrate	4.89E0	1E1	4.89E-1	1.47E0
Flying insects	1.92E0	1E1	1.92E-1	5.75E-1
Gastropod	1.89E0	1E1	1.89E-1	5.67E-1
Grasses & Herbs	3.11E0	1E1	3.11E-1	9.32E-1
Lichen & bryophytes	9.25E0	1E1	9.25E-1	2.77E0
Mammal (Deer)	1.55E1	1E1	1.55E0	4.65E0
Mammal (Rat)	1.15E1	1E1	1.15E0	3.46E0
Reptile	1.08E1	1E1	1.08E0	3.24E0
Shrub	9.99E0	1E1	9.99E-1	3E0
Soil Invertebrate (worm)	4.69E0	1E1	4.69E-1	1.41E0
Tree	2.13E0	1E1	2.13E-1	6.4E-1

Figure 6.2: Presentation of RQ values in Tier 2.

6.3.1 Effects data

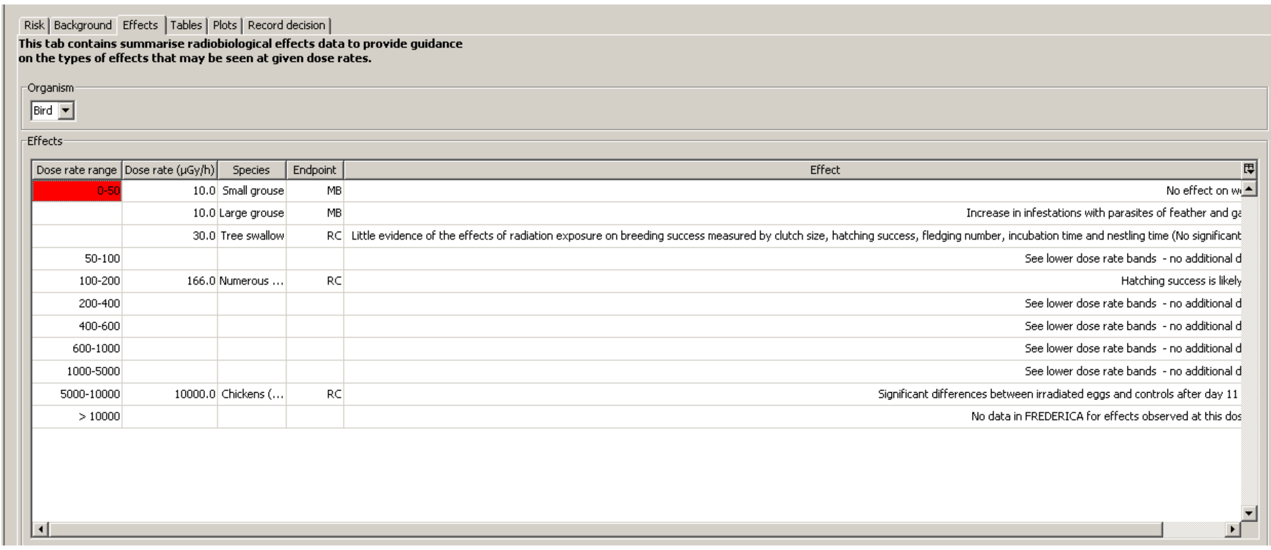
Predicted dose rates can be compared with dose rates known to cause biological effects in non-human species. For convenience, in Tier 2 the available data within the FREDERICA database (see Section 7.3) have been summarised in look-up tables based on 16 wildlife groups into which each reference organism has been categorised (Table 6.2). Users need to select a suitable wildlife group for their own defined organisms. An example of a look-up table is given in Figure 6.3. For each entry, the effect is categorised as: no effect, minor effect, moderate effect, major effect or severe effect).

The look-up tables enable the assessor to put their estimated dose rates into context with biological effects on the organism.

If there are no effects data for a specific wildlife group close to the estimated dose rate, options to progress the assessment (if either Tier 2 RQ is greater than one) could include: (i) accessing the FREDERICA database which may contain more recent data (see Section 7.3); (ii) conducting effects experiments for the organism. Either of these options could lead to a justifiable reassessment at Tier 2 rather than the need to progress to Tier 3. If the effects data for a given wildlife group are sufficient and demonstrate insignificant effects at the estimated dose rate then the assessment could be justifiably exited.

Table 6.2: Wildlife groups and their associated reference organisms used in the effects look-up tables at Tier 2.

Wildlife Group	Associated reference organism(s)
Amphibian	Amphibian
Aquatic invertebrate	Insect larvae, Polychaete worm
Aquatic plant	Macroalgae, Phytoplankton, Vascular plant
Bird	Bird, Bird egg, Wading bird
Crustacean	Crustacean
Fish	Benthic fish, Pelagic fish
Insect	Flying insect
Mammal	Mammal
Mollusc	Bivalve mollusc, Gastropod
Moss and Lichen	Lichen and Bryophytes
Plant	Grasses and Herbs, Shrub, Tree
Reptile	Reptile
Soil fauna	Soil invertebrate (worm), Detritivorous invertebrate
Zooplankton	Zooplankton



Dose rate range	Dose rate (µGy/h)	Species	Endpoint	Effect
0-50	10.0	Small grouse	MB	No effect on w
	10.0	Large grouse	MB	Increase in infestations with parasites of feather and ga
	30.0	Tree swallow	RC	Little evidence of the effects of radiation exposure on breeding success measured by clutch size, hatching success, fledging number, incubation time and nestling time (No significant
50-100				See lower dose rate bands - no additional d
100-200	166.0	Numerous ...	RC	Hatching success is likely
200-400				See lower dose rate bands - no additional d
400-600				See lower dose rate bands - no additional d
600-1000				See lower dose rate bands - no additional d
1000-5000				See lower dose rate bands - no additional d
5000-10000	10000.0	Chickens (...	RC	Significant differences between irradiated eggs and controls after day 11
> 10000				No data in FREDERICA for effects observed at this dos

Figure 6.3: Tier 2 biological effects look-up table for birds.

6.3.2 Natural background exposure

Tier 2 also provides ranges in background exposure rates due to naturally occurring radionuclides. As specified within Chapter 1, the ERICA Integrated Approach should be used to assess incremental doses from human activities only. If dose rates estimated within Tier 2 result in RQ values in excess of one, but are within or close to natural background exposure rates, the user could conclude that there is negligible cause for concern. If activity concentrations of naturally occurring radionuclides are available for the assessment site, the assessor could estimate site-specific absorbed dose rates for comparison to dose rates from exposure to radionuclides from anthropogenic sources. It is possible that within normal ranges of activity concentrations of naturally occurring radionuclides, the Tool will estimate dose rates for some organisms in excess of 10 $\mu Gy\ h^{-1}$ (which is compatible with the background exposure rates in the Tool summary table).

For sites being assessed for TeNORM contamination, the dose rates estimated will include a contribution from background levels of the radionuclides of interest. In this instance, the total dose rates should be compared to the summarised background dose rate provided within Tier 2, to determine if the incremental dose is likely to be of concern.

7 Tier 3 Assessments

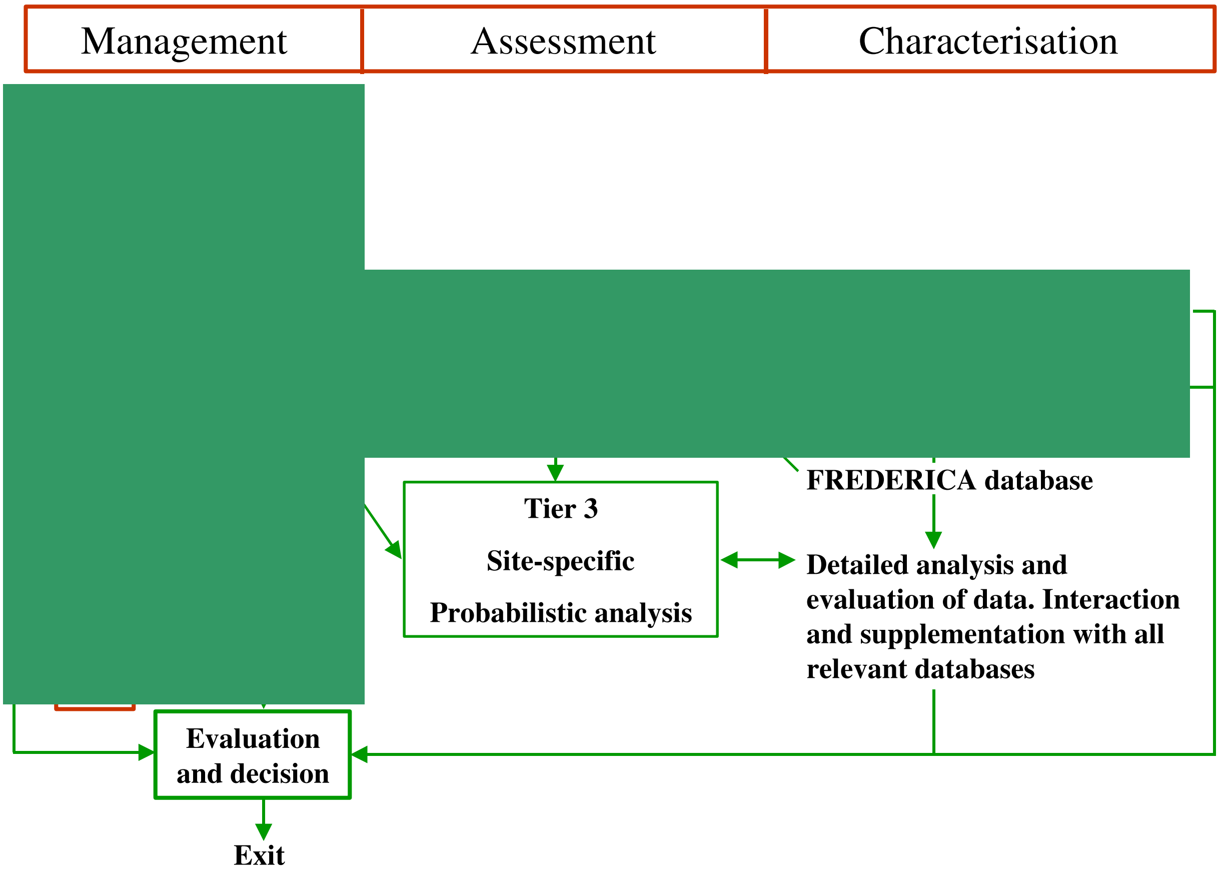


Figure 7.1: The ERICA Integrated Approach, highlighting the elements that relate to Tier 3.

Those situations that give rise to a Tier 3 assessment are likely to be complex and unique, and it is therefore not possible to provide highly specific guidance on how the Tier 3 assessment should be conducted. Furthermore, a Tier 3 assessment does not provide a simple yes/no answer, nor is the ERICA derived screening incremental dose rate of 10 µGy h^{-1} appropriate with respect to the assessment endpoint. The requirement to consider aspects such as the biological effects data contained within the FREDERICA database, or to undertake ecological survey work, is not straightforward and requires an experienced, knowledgeable assessor or consultation with an expert. The following sections explain how the ERICA Tool and the FREDERICA database can be used within a Tier 3 assessment.

7.1 Introduction

Within the ERICA Integrated Approach, environmental risk is characterised in a tier-specific manner and the previous two chapters have described how Tiers 1 and 2 can be used to estimate risk using a *deterministic* approach. Both Tiers 1 and 2 are valuable for screening out situations where the environmental risk from ionising radiation is such that the situation can be exempt from further action.

Where it is not possible to state with confidence that the risk is below concern at Tiers 1 and/or 2, it is recommended that the assessment proceed to Tier 3. The assessor may choose to refine and repeat earlier tiers, depending on the case under evaluation, before moving to Tier 3. A Tier 3 assessment differs from the previous tiers in a number of respects, as outlined below:

- Tier 3 allows the assessor to carry out a detailed assessment of a given situation if there have been other drivers that have prevented the assessor from using Tier 1 or 2; for example, the requirements of stakeholders or legislation may have stated that a full detailed assessment be conducted.
- Tier 3 allows the assessor to refine the problem formulation (if Tier 1 or 2 have been used previously), although the SRS-19 models are no longer available because these are designed to be conservative; therefore, the assessor should use their own dispersion model.
- Tier 3 allows the assessor to input probability distribution functions for the different input data and parameters and thus allows the assessment to be run probabilistically. This provides the assessor with an estimate of the probability of exposure at a given dose rate.
- Tier 3 provides information on the uncertainties associated with the exposure assessment, by performing a sensitivity analysis. This is most useful when trying to understand the uncertainties associated with the derivation of total dose rate estimates, and can allow the assessor to target the need for additional work in a cost effective manner.
- Tier 3 generates information on the internal, external and total dose rate received by each organism and this can be compared directly with current data on the effects of ionising radiation on the species of interest. Whilst Tier 2 provides effects look-up tables, these have been created in January 2007 within the ERICA project whereas the FREDERICA database will be updated, through a quality controlled procedure, and may therefore contain information on species of relevance to the assessment.
- Tier 3 does not use a screening dose rate. Instead, Tier 3 provides access to the compilation of scientific literature on the effects of ionising radiation that is collated within the FREDERICA database. Instead of using a screening dose rate, the assessor is able to look at the available data and, with experience and/or expert support, make judgements on the likely consequences of the predicted dose rates for the species of interest. In addition, the assessor may wish to derive his or her own benchmark from the effects data. This will determine the likely magnitude of the adverse effects likely to occur in a population or environmental compartment.
- Tier 3 then provides a mechanism for determining the likely magnitude of, and probability of, exposure that the assessor can use, possibly in conjunction with stakeholders, to determine whether:
    - the risk is below concern;
    - there is insufficient confidence that the risk is below concern;
    - the risk is of concern.

Tier 3 is a probabilistic risk assessment in which uncertainties associated with the results may be determined using sensitivity analysis. It allows the assessor to access a compilation of up-to-date scientific literature (which may not be available at Tier 2) on the biological effects of exposure to ionising radiation in a number of different species. The assessor can then estimate the probability (or incidence) and magnitude (or severity) of the environmental effects likely to occur and, by discussion and agreement with stakeholders, to determine the acceptability of the risk to non-human species. The following sections describe how the ERICA Integrated Approach has incorporated these points.

7.2 Problem formulation for Tier 3

If the assessor is starting at Tier 3, then the advice provided previously (Chapter 2) should be reviewed and used in formulating the problem being assessed. The points made below regarding the revision of the problem formulation for Tier 3 should also be addressed.

If a Tier 1 and/or Tier 2 assessment has already been conducted, it is important to revisit and revise the problem formulation and the conceptual models, particularly with regard to the use of probability distribution functions on the input values (Section 7.2.1)

The refinements made in the Tier 3 risk assessment are anticipated to be driven primarily through the use of revised exposure estimates (by the use of site-specific exposure models and distributions of input data and parameter values instead of single values). Refinement of the effects analysis will probably be needed to increase its relevance with regard to problem formulation, especially by introducing ecological realism; this is covered in Section 7.3.

A full site-specific assessment may require the gathering of additional data. Rather than relying on a single approach, a battery of tests, modelling and/or field observations can be used to estimate risk. This may include ecological surveying, environmental monitoring and other work, depending on the revised problem formulation and the endpoints of interest. Obviously, there is a difference between prospective and retrospective assessments in the availability of data, and hence the lines of evidence. In the retrospective assessment, monitoring and field data are often available and can be supplemented with additional sampling as the assessment moves through tiers. Furthermore it may, for example, be possible to perform toxicity testing on contaminated media, or measure biomarkers and other effects directly in exposed populations. With prospective assessments, field data are usually unavailable or very limited and there is a reliance on modelling approaches and standard toxicity data to predict environmental exposure and effects. In cases where a practice is granted based on a prospective assessment, there may be a requirement to reassess data after a certain time to compare model outcomes with actual measured data.

The assessor, possibly with stakeholders, might predefine the assessment endpoint in terms of an acceptable dose rate (not the same as a screening dose rate) against which dose rate estimates from the ERICA Tool can be compared. Further information on how an acceptable dose rate might be defined is given in Section 7.3.

Appendix 2 describes other aspects that the assessor may wish to consider.

7.2.1 Dealing with uncertainty

Uncertainty in the results of an exposure assessment can arise from a number of sources, including:

- conceptual uncertainties in the models applied;
- uncertainty in the values of the model parameters;
- uncertainties in the empirical data due to natural variability;
- measurement errors;
- biases in the sampling.

The sources of uncertainty can be broadly categorised as follows:

- *Scenario uncertainty* refers to uncertainty related to the current, historic (for retrospective assessments) and future (for prospective assessments) situations and how this might influence the outcome of the assessment. This type of uncertainty is usually dealt with by considering several alternative scenarios. Performing several assessments for a given case can do this. However, the Tool does not support aggregation of a number of assessments.
- *Model uncertainty* arises from imperfect knowledge about ecological processes, which leads to imperfect mathematical models, which are often over-simplified. Uncertainty of default parameter values also falls into this category. This type of uncertainty is usually assessed by performing inter-comparisons between alternative models and between model predictions and empirical

observations. The ERICA Tool is being used in the IAEA Environmental Modelling for Radiation Safety (EMRAS) inter-comparison programme.

The assessor can consider the uncertainties associated with exposure parameters, such as distribution coefficients, concentration ratios and radiation weighting factors, and input data such as activity concentrations in soil, water, sediments and the organisms. However, uncertainties related to the effects analysis must be dealt with outside the Tool. Whilst there are a number of different methods for characterising uncertainty documented in the literature (such as IAEA [1989]; Morgan and Henrion [1990]), the ERICA Tool can quantitatively assess some of the modelling uncertainties by using probabilistic and sensitivity analyses.

7.2.2 Input data for Tier 3 – probability distribution functions (pdf)

Within Tier 3, the ERICA Tool supports the entry of single values or a probability distribution function (pdf) for each user-defined input parameter except soil/sediment dry weight and occupancy factors. However, there are no pdfs for the DCCs.

The ERICA Tool supports the most common pdf types, that is, uniform, loguniform, exponential, normal, lognormal, triangular and logtriangular. The properties of these distribution types are well documented in the literature (see, for example, IAEA [1989] and Evans *et al.* [2000]). Table 7.1 provides information on the parameters required by the supported distribution types. All parameters refer to untransformed data. For example, for the lognormal distribution the mean and the standard deviation of the sample data, without taking logarithms, should be used.

Table 7.1: Distribution types supported by the ERICA Tool and required parameters.

Distribution type	Distribution parameters
Uniform	Minimum, maximum
Loguniform	Minimum, maximum
Exponential	Arithmetic mean
Triangular	Mode, minimum, maximum
Logtriangular	Mode, minimum, maximum
Normal	Arithmetic mean, standard deviation
Lognormal	Arithmetic mean, standard deviation

There are a number of ways of assigning a probability distribution depending upon the availability and quality of data for example:

- Distribution fitting [Taylor, 1993]
- Maximum entropy method [Herr, 1987]
- Bayesian inference [Gelman et al., 2003]
- Expert elicitation [Hofer, 1986].

The probability distribution type should be selected on a case-by-case basis using one or more of these methods. However, experience has shown that the uncertainty of radioecological data, such as concentration ratios (CRs) and distribution coefficients (K_ds), are often well fitted by lognormal distributions. Several explanations for this have been given [for example, see Aitchison and Brown, 1957; Crow and Shimizu, 1988]. One possible explanation is that the values of the radioecological parameters are the result of multiplication of many factors and this should lead to lognormal distributions. For this reason, a pdf has been defined for each entry in the default CR and K_d databases within the ERICA Tool using the following simple rules:

- where a standard deviation could be determined from the raw data used to derive a particular parameter (for example for a CR), a lognormal distribution was applied;
- for all other cases, an exponential distribution was applied.

Assessors can therefore use the default probability distributions for each parameter in the ERICA Tool or they can define their own pdf for each parameter (or a combination of both), depending upon the availability and quality of the data. Assessors are advised to obtain expert help if needed to assign pdfs to the input values.

7.2.3 Propagating the uncertainties through the models

To estimate the uncertainty of the endpoints of the exposure assessment, uncertainties in the inputs and parameters must be propagated though the model. When analytical methods cannot be applied, the uncertainties can be propagated using the Monte Carlo analysis, which is the approach used in the Tool. The bases of the Monte Carlo method are 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 are combined, usually in the form of a probability density function or cumulative distribution. This process is illustrated in Figure 7.2 for the case of a simple model with one input, one parameter and one endpoint.

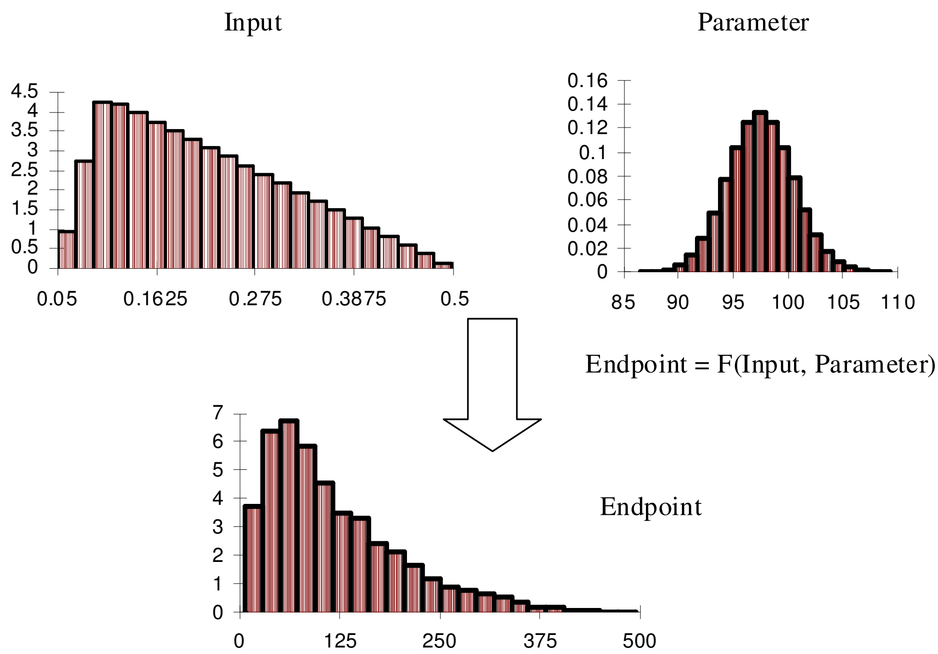


Figure 7.2: In the ERICA Tool, Monte Carlo probabilistic simulations are used for propagating uncertainties in the inputs and parameters through the model. As a result, a probability distribution of the endpoints is obtained, which can be used to quantify uncertainties in the estimations. In this example, the endpoint is calculated with a function F (the model) of one input and one parameter.

7.2.4 Sensitivity Analysis

Sensitivity analysis is used to identify the relative contribution of uncertainty associated with each input and parameter value to the endpoint of interest. There are several sensitivity analysis methods available [Saltelli *et al.,* 2004], but the choice of method depends on factors such as computing power and time needed, the number of uncertain parameters and the type of dependency between the inputs/parameters and the simulation endpoints of interest. For linear dependencies such as those found within the ERICA Tool, simple methods based on correlations are sufficient.

Within the ERICA Tool, sensitivity analysis is based on the correlation between the inputs/parameters and the endpoint. Two correlation coefficients are computed: the Pearson Correlation Coefficient (CC) and the Spearman Rank Correlation Coefficient (SRCC). Further guidance on the application of these analytical methods is provided in the help of the Tool.

The results of the sensitivity analysis are presented as a tornado plot, shown in Figure 7.3. These are simple bar graphs where the sensitivity statistics – the CC or the SRCC – are visualised vertically in order of descending absolute value. The longer the bar, the larger the effect of the parameter on the endpoint. Parameters that have positive values of sensitivity measures have a positive effect on the endpoint, while ones with negative values have a negative effect.

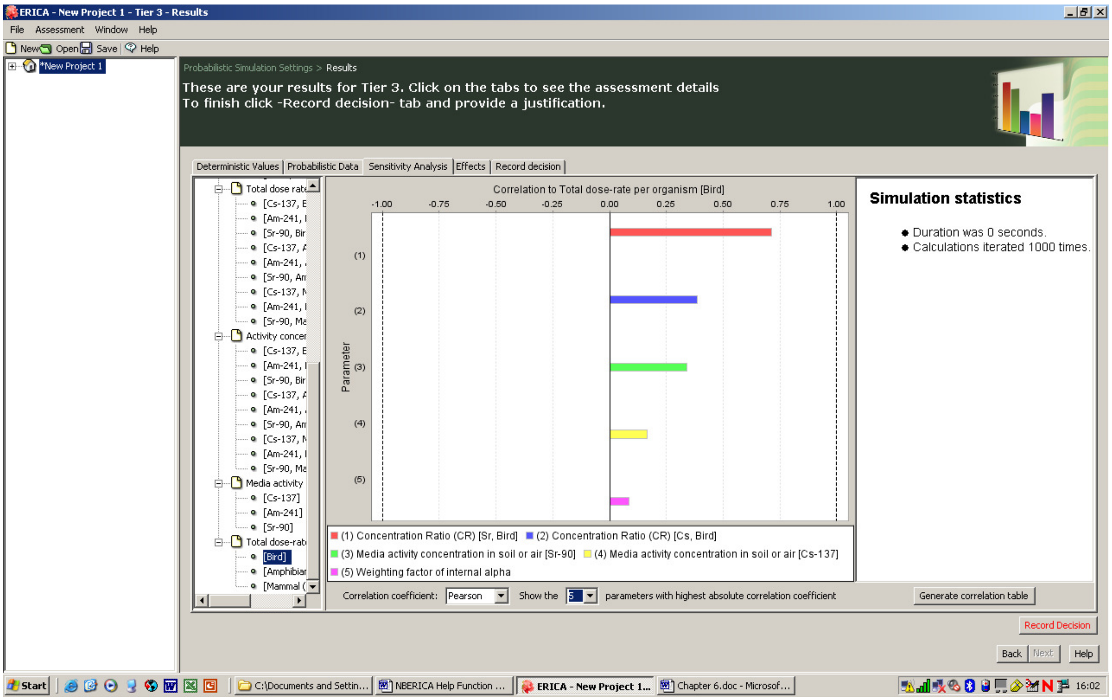


Figure 7.3: Illustrative example of a tornado plot for total dose rate to the bird reference organism. The longer the bar, the bigger the effect of the parameter on the endpoint. In this example, the parameters visible all have a positive effect on the endpoint.

7.2.5 Presentation of the results of the probabilistic assessment

Several methods are available in the ERICA Tool to construct the frequency histograms. The Tool provides several statistics for each endpoint, such as the mean, the median and the standard deviation. The Tool also allows the assessor to find the endpoint value corresponding to any given percentile and the percentile corresponding to any given endpoint value. The later functionality can be used, for example, to estimate the probability that the calculated dose rates fall above or below a benchmark value, or between two benchmark values and so on.

7.3 Biological effects and their relationships to dose rates

7.3.1 FREDERICA

Like Tier 2, Tier 3 generates information on dose rates and these can be used to interpret the available information on dose-effect and dose-response relationships. As briefly described in Chapters 4 and 5, the primary source of information to analyse biological effects in relation to dose rate within the ERICA Integrated Approach is the FREDERICA database (www.frederica-online.org), which may be searched either directly through the ERICA Tool (Tier 3) or as a stand alone package available online [ERICA D1, 2005]. FREDERICA contains information from the FASSET Radiation Effects Database (FRED), which covered the period 1945-2001, plus data from new references up to the end of the ERICA project (early 2007). FREDERICA also contains the output from experiments conducted during the ERICA project. Field data from the EC-funded EPIC project have also been included in the database. All these data have been used in three main ways:

1. to derive a chronic no effect benchmark used as a screening incremental dose rate, as described in Chapter 5;
2. to establish look-up tables for Tier 2 to obtain a qualitative description of the effects potentially induced within a given range of exposure, including information on background (Chapter 6);
3. for specific searches in FREDERICA by focusing on, for example, the protection of keystone species and/or endangered species, and/or on specific endpoints.

The database contains some 30,000 data entries from more than a thousand literature references. These data correspond to pairs of points (exposure level, biological effect) along with information on the conditions in which these data were experimentally obtained (such as the tested species and its life stage, the exposure regime defined by the duration and irradiation pathway, the effect endpoint). The information is broadly divisible into effects of acute and chronic exposures. The data are organised into different 'pseudo-taxonomic groups' called wildlife groups: amphibians, reptiles, aquatic invertebrates, aquatic plants, bacteria, birds, crustaceans, fish, fungi, insects, mammals, mosses/lichens, soil fauna, terrestrial plants and zooplankton. These are then allocated to one of three ecosystems: freshwater, marine and terrestrial. While this classification may appear taxonomically arbitrary, it reflects the way experiments or field observations have been performed, and thus represents a practical way of presenting and analysing the effects data.

In terms of biological effects, the vast majority of data come from effects observed at an individual level followed by sub-individual (such as genetic and molecular) levels. Biological effects were grouped into four categories of effects (called umbrella effects) for use on a population-wide level:

1. morbidity including growth rate, effects on the immune system, effects on behaviour linked to central nervous system damage;
2. mortality including the stochastic effects of mutation and the consequences for cancer formation, and the deterministic effects which alter mortality rates and life expectancy;
3. reproductive capacity including fertility, fecundity, embryo development;
4. mutations of somatic and reproductive cells.

Most effects data compiled in FREDERICA concern terrestrial ecosystems (73 per cent of all data) and for each ecosystem, there are roughly twice as many data on acute exposure, typically from an external γ irradiation source, than for chronic exposure. Chronic effect data information is limited and largely dominated by external γ irradiation exposure conditions. Currently, data devoted to effects induced by external γ irradiation are adequate to be mathematically processed in terms of dose-effect relationships.

FREDERICA data also includes about 400 records from the EPIC database from Russian/Former Soviet Union experimental and field studies relating to chronic dose rate effects for wildlife in ecosystems, including the Arctic. Radiobiological effects within the EPIC data range from stimulation at low dose rate to death from acute radiation effects at high doses. The effects data were grouped under the same umbrella endpoints as those used in FREDERICA, plus three additional endpoints: ecological (such as changes in biodiversity, ecological successions), stimulation and adaptation effects.

7.3.2 Refining the effect analysis

At Tiers 2 and 3, one of the outputs from the assessment tool is a predicted dose rate to the organism of interest. Predicted dose rates can then be compared with dose rates known to cause biological effects in non-human species. To do this, Tier 3 makes direct use of the FREDERICA database to identify available information for the dose rates and the non-human species considered, by running an online database search from within a screen window in the ERICA Tool.

At Tier 3, the assessment may concern a particular object of protection such as keystone species[2] or protected species. Protection may be directed at the individual level, against which adverse effects on various functions such as growth, reproduction and survival would be considered negative. In such cases, a specifically directed search can be undertaken within the FREDERICA database. The most appropriate ‘surrogate species’ or wildlife group would need to be selected if the actual species were not represented in the database.

There are a number of ways to search the data contained within the FREDERICA database and to generate results (by selecting which information the assessor would like to view). Searches can be conducted by:

- author
- keywords
- source of radiation (internal, external)
- specific type of radiation (alpha, beta and gamma)
- specific radionuclides as the source of radiation
- specific endpoints
- particular species (or all) from within a particular wildlife group
- wildlife group
- dose or dose rate steps
- umbrella endpoints.

The user can consult the FREDERICA database directly and use its search capability to locate information specific to the assessment being conducted. As well as online, the FREDERICA database can be accessed at Tier 3 by opening a web browser window, through which the assessor can request information on particular reference organisms and biological endpoints for the dose rates calculated within the Tool. The ERICA Tool provides information on the dose rates directly to the FREDERICA database after the user selects the reference organism(s) and endpoint(s) of interest. Access to the biological effects information contained within the FREDERICA database, either directly or through the Tool, requires an Internet connection.

The output of searches conducted in the FREDERICA database is initially displayed in the web browser. If more than one result is available, these can be browsed on the screen. There is the option to export the

[2] Keystone species is used here to describe species that influence the ecological composition, structure or functioning of their community far more than their abundance would suggest.

search output as a comma separated file (CSV) file that can be read directly into programmes such as Microsoft® Excel. There is a full help available online within the FREDERICA database, which describes how to conduct searches, view and export the outputs and add new biological effects literature to the database.

ERICA Deliverable D5 outlines methods that can be used to derive refined predicted no effect dose rates (PNEDR) for specific endpoints, such as;

- using SSD methodology and selecting more conservative levels of protection (moving from 95 per cent to 99 per cent of species being protected);
- using SSD methodology and introducing more ecological realism to describe a particular ecosystem or habitat by: (a) applying trophic/taxonomic weightings that better describe the structure of a specific ecosystem; (b) revising the FREDERICA database to set new benchmarks whilst restricting the statistical analysis to a particular endpoint (for instance, reproduction) and/or a particular trophic/taxonomic group (such as vertebrates or fish);
- refining the effects analysis by focusing on the protection of keystone species and/or endangered species;
- extrapolating particular issues, such as from individual to population, or external to internal irradiation effects;
- refining the effects analysis to address situations when knowledge of effects is scarce, and when additional experimental/modelling studies may be required.

The Tier 3 assessment may need to determine whether individuals, populations, communities or ecosystems are being protected. The ERICA EUG Consensus document [2006] states:

> "*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 effects at the population level, is the complexity of the system coupled with the lack of available data and knowledge gaps at both population (for example, population size to population growth rate relationship [Silby *et al.*, 2005]) and individual level. Linking effects across levels of biological organisation is, however, a well-known problem within ecological risk assessments [Hinton *et al.*, 2004]. A number of parameters are known to be of importance when extrapolating from individual to population level and these are summarised in Table 7.2 [Garnier-Laplace *et al.*, 2004].

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 most important.	Add margin of safety if there is a lack of data. The best solution, 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.	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 (see Woodhead [2003]).
Density dependent factors	Do density dependent factors such as temperature and competition of resources render the population less sensitive than its individuals? The opposite has been observed in some studies.	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?	Need to consider further, particularly for long-lived organisms.

8 Post-assessment considerations

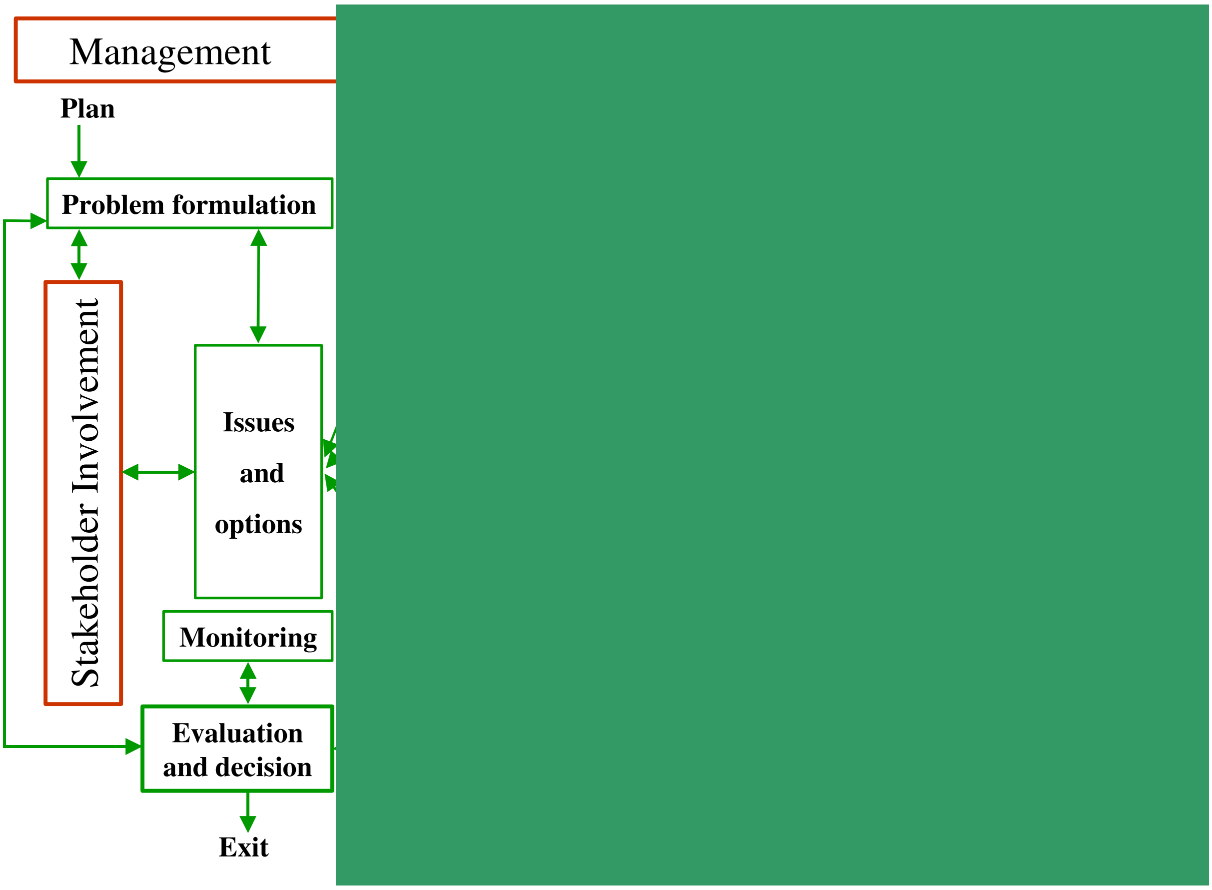


Figure 8.1: The ERICA Integrated Approach, highlighting the elements that relate to post-assessment considerations.

8.1 Introduction

Once an assessment is completed, three outcomes are possible:

- there is negligible concern (where an assessment has not exceeded the conservative screening criteria used for Tiers 1 and 2), or more qualifications can be provided that would make it possible to exempt the situation from further assessment or action;
- there is insufficient confidence that there is negligible concern (for example, a Tier 3 assessment indicates a significant probability that there are, or may occur, radiation effects of concern);
- there is concern.

It is evident that the second and third of the above outcomes, which most likely have required a full Tier 3 assessment, would be more difficult to handle in post-assessment decision-making. Since the ERICA Integrated Approach is intended to ensure that adequate weight is given to the environmental effects of ionising radiation, the ERICA Integrated Approach is non-prescriptive and does not specify decisions that *must* be taken post-assessment. Flexibility is necessary in view of differences between countries' legislation. Furthermore, there are at present no international criteria or standards that specifically address the protection of the environment from the effects of ionising radiation (although such criteria and/or standards may exist at a national scale). Approaches are under development by a number of international organisations, 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 emerging recommendations for the way in which ERICA is applied.

This chapter mainly covers factors that might need to be considered post-assessment (decisions to be taken as part of the assessment are listed, together with options, in Appendix 2). An in-depth account of factors governing decision-making can be found in D8 [ERICA D8, 2007]. Decisions taken post-assessment may not necessarily conclude the process. Most likely, in cases where a decision has been taken via a full Tier 3 assessment, the decision may have to be revisited regularly on the basis of new information or as part of licensing conditions, resulting in a new problem formulation and, potentially, less uncertainty. As this may change the rationale for the assessment as well as the outcome substantially, stakeholders may need to be consulted.

8.2 Evaluation of assessment results against criteria set up during problem formulation

Chapter 2 lists factors to be considered as part of problem formulation, and that has direct relevance to the way the assessment is carried out. During the assessment, these factors may have to be reconsidered and revised. Further guidance on this is given in Appendix 2. Following the assessment, and in particular if the assessment has to be carried all the way to Tier 3, which does not necessarily give a simple yes/no answer to the question under study, the user of the ERICA Integrated Approach might wish to examine the assessment results against some of the objectives of the international legal framework and/or binding agreements, as well as recommendations. Table 8.1 summarises the main factors affecting decision-making and how they are related to such drivers.

8.3 Socio-economic factors

Sustainable development forms the background to many environmental management decisions. This, by definition, requires environmental, social and economic development objectives to be balanced. The use 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*. If a Tier 3 assessment, using the ERICA Integrated Approach, results in concern over the environmental effects, there is obviously a need for considering the outcome of the assessments against a background of socio-economic factors. The ERICA Integrated Approach is only a component of the broader decision-making process, which is illustrated in Figure 8.2 (see further [ERICA D7g, 2007]).

8.3.1 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. The main aspects of such an analysis are as follows:

- establish a baseline (the health, social, environmental and economic conditions in the absence of the risk or environmental management measures under consideration);
- identify and assess the risks and benefits associated with the risk or environmental management measure and alternatives (for example, from application of ERICA);
- manage uncertainties and communication issues;
- consider the distribution of risks and benefits and the implications of this distribution;
- consider the time periods and assessment implications of this and other assumptions.

The type of objectives that underpin the decision-making process may be illustrated by the social criteria recently identified by the Environment Agency to inform its decision-making [Environment Agency, 2005], and earlier by Environment Canada for chemical risk management (see Box 8.1 and 8.2).

Table 8.1: Factors affecting decision-making derived from legal instruments and binding agreements. Based on [ERICA D8, 2007]

Driver	Factors affecting decision-making
General environmental protection	- 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	- The need to identify and designate species and areas of significance (such as 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 need to control emissions into transboundary media, including air, watercourses and lakes
Prospective and retrospective assessment of the impact	- 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	- The need to monitor compliance with emission limits and environmental objectives
Provision of information	- The need to exchange information with EU 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 for participation in decision-making
Decision-making	- 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 need to reduce and mitigate the impacts of any unusual event - The need to inform other EU 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

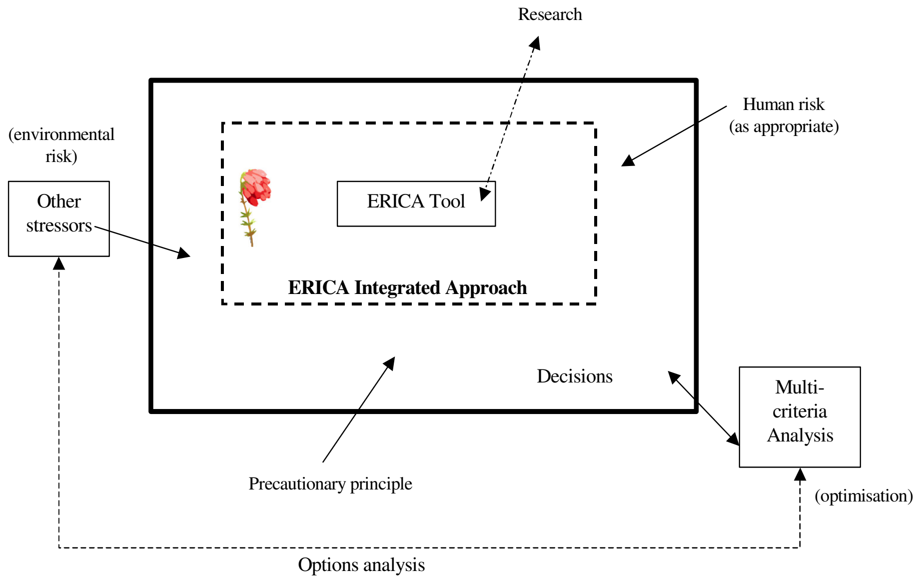


Figure 8.2: Illustration of factors affecting decisions, and the position of the ERICA Integrated Approach and Tool. From [ERICA D7g, 2006].

The selection of an appropriate approach for socio-economic analysis 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 costs and benefits that need to be considered and the nature of information available. The European Commission [EC, 1998] suggests that the form of analysis appropriate for developing risk reduction strategies will depend upon the factors summarised in Box 8.3.

Given the diverse range of considerations to be included in the decision-making process, and the need for transparency and stakeholder involvement, a range of tools have been developed for a systematic approach to including 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 summarised in Box 8.4.

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 minor, then a relatively simple analysis may suffice. However, there may be a 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 if there are controversial trade-offs between environmental impacts and human health. This approach is consistent with the ERICA Tiered Approach recommendations.

Box 8.1

Social criteria defined by the Environment Agency (England and Wales):

- promote health, safety and wellbeing (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 engagement, developing partnerships, supporting external activities);
- help develop a learning culture (capacity building) by increasing staff skills and knowledge of social issues and developing new areas of knowledge and practice.

Box 8.2

Criteria applied by Environment Canada for chemical risk management:

- the implications for competitiveness of the industry concerned (and minimisation of financial burden);
- the provision of incentives for creativity and innovation in the 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 on 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.

Box 8.3

EC rationale for developing risk reduction strategies:

- 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;
- the level of uncertainty surrounding the likely advantages and disadvantages.

Box 8.4

- *CEA* is based on the principles of economic appraisal. It may be used to identify the most cost-effective way of achieving a predefined 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 offers 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 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.

8.4 Outcomes of the assessment

Faced with the outcome of the assessment, the user of the ERICA Integrated Approach may wish to consider some or all of the factors reviewed above in the post-assessment decision-making. In doing so, it might be helpful to return to the generic ICRP exposure situations introduced in Chapter 2, that is, planned exposure situations, existing exposure situations (from past and current practices), and emergency exposure situations (from accidents). Table 8.2 lists a number of possible decisions or actions relating to hypothetical outcomes of the assessment. as well as to the above mentioned exposure situations for consideration and for further elaboration by the user of the ERICA Integrated Approach. The user may benefit from consulting ERICA D8 [2007] for further information.

Table 8.2: Examples of possible decisions or actions based on the assessment, organised according to the generic ICRP exposure situations.

Assessment outcome	Planned exposure	Existing exposure	Emergency exposure
Of concern	Are there overriding priorities that mean that the practice should be started (cost-benefit analysis)? Perspective of other risks Reconsider the proposal Reconsider decision Say no to the practice Select a different site Would more data help?	Consider changes of current practice to re-optimise the process Consider ecological value of present site Monitoring Perform cost-benefit analysis Shut down existing practice Would remediation do more good than harm?	Consider ecological value of present site Monitoring Perform cost-benefit analysis Would remediation do more good than harm?
Insufficient confidence	Ask experts for help/review Perform cost-benefit analysis Proceed with additional controls imposed and review the practice and/or assessment at defined time intervals Re-iterate the assessment Say no to the practice Undertake a multi-criteria decision analysis Would more data be helpful and are they available?	Consider assessment of other stressors Consider changes of current practice to re-optimise the process Consider ecological value of present site Monitoring Perform cost-benefit analysis Proceed with additional controls imposed and review practice/assessment after defined time intervals Say no to the practice Shut down existing practice Would remediation do more good than harm?	Consider ecological value of present site Consider timescales Monitoring Perform cost-benefit analysis Would remediation do more good than harm?
Negligible concern	Proceed but consider other factors such as cost, best available technique, human exposure, optimisation and monitoring	Consider if monitoring and controls for human exposure are required No intervention for biota	Monitoring No action from environmental point of view

ERICA Deliverables

D1 Copplestone, D (Ed) (2005) Progress on the production of the web-based effects database: FREDERICA. ERICA Deliverable D1.EC Contract N°FI6R-CT-2004-508847.

D2 The prototype of the ERICA Tool (2006) Available on www.erica-project.org. To be replaced by the final version of the ERICA Tool in February 2007, on the same website. EC Contract N°FI6R-CT-2004-508847.

D4a Copplestone D, Björk M and Gilek M (Eds) (2005) Ecological risk characterisation: An interim method for the ERICA Integrated Approach. ERICA Deliverable D4a. EC project Contract N°FI6R-CT-2004-508847.

D4b Björk M and Gilek M (Eds) (2005) Overview of ecological risk characterisation methodologies. ERICA Deliverable D4b. EC project Contract N°FI6R-CT-2004-508847.

D5 Garnier-Laplace J and Gilbin R (Eds) (2006) Derivation of predicted no effect dose rates values for ecosystems and their sub-organisational level exposed to radioactive substances. ERICA Deliverable D5. EC project Contract N°FI6R-CT-2004-508847.

D5 - Annex A Garnier-Laplace J and Gilbin R (Eds) (2006) Guidelines for the design and statistical analysis of experiments on chronic effects of radioactive substances. ERICA Deliverable D5 Annex B - Public. EC project Contract N°FI6R-CT-2004-508847.

D5 - Annex B Gilbin R and Oughton D (Eds) (2006) Experiments on chronic exposure to radionuclides and induced biological effects on two invertebrates (earthworm and daphnid). Results and discussion. ERICA Deliverable D5 Annex B - Public. EC project Contract N°FI6R-CT-2004-508847.

D7a – Part 1 Oughton D, Zinger I, Bay I, Børretzen P, Garnier-Laplace J, Larsson CM and Howard B (2004) First EUG event - Part 1: Discussion of ERICA work plan. ERICA Deliverable D7a – Part 1. EC project Contract N°FI6R-CT-2004-508847.

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D7c Zinger I (Ed) (2005) Transcripts from the first generic EUG event: Ecological risk assessment and management. ERICA Deliverable D7c. EC project Contract N°FI6R-CT-2004-508847.

D7c – Annex 1 Zinger I (Ed) (2005) Added written comments from the Freising questionnaire. ERICA Deliverable D7c Annex 1. EC project Contract N°FI6R-CT-2004-508847.

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D7e Oughton D and Breivik H (Eds) (2005) Scientific uncertainties: Transcript from the

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D7f Forsberg ME and Oughton D (Eds) (2006) The ERICA consensus seminar. ERICA Deliverable D7f. EC project Contract N°FI6R-CT-2004-508847.

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D7h Zinger I (Ed) (2007) EUG Tool Testing Event. Deliverable D7h. EC project Contract N°FI6R-CT-2004-508847.

D7i Jones S (Ed) (2007) Local Stakeholder EUG Event. Deliverable D7i. EC project Contract N°FI6R-CT-2004-508847.

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D8 - Annex A Copplestone D (Ed) (2007) Review of international legal instruments that may influence decision-making. Deliverable D8 Annex A. EC project Contract N°FI6R-CT-2004-508847.

D9 Beresford N and Howard B (Eds) (2005) Application of FASSET framework at case study sites. Deliverable 9. EC project Contract N°FI6R-CT-2004-508847.

D10 in progress, to be published in February 2007.

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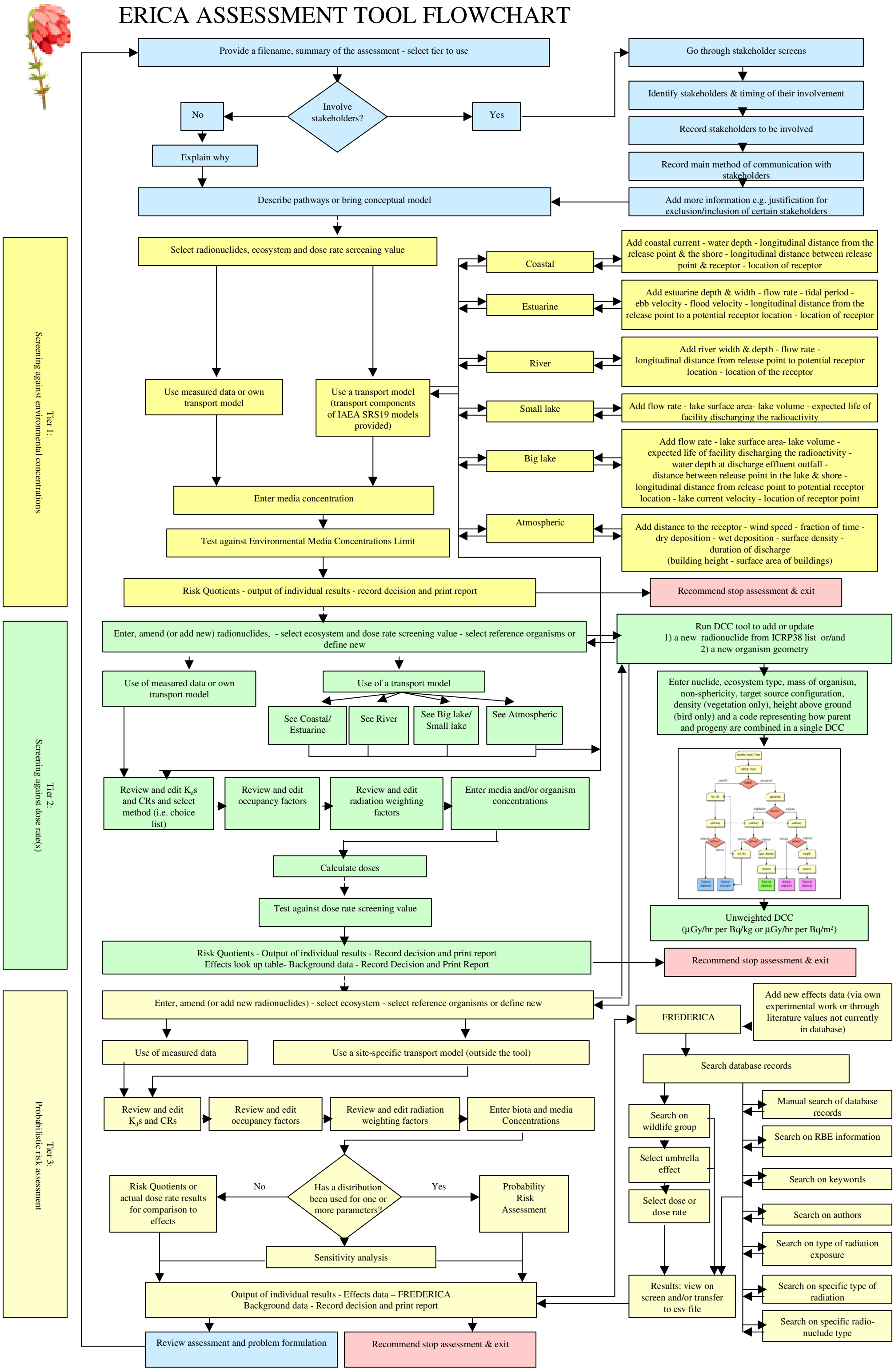
Appendix 1: ERICA Assessment Tool Flowchart



Appendix 2: Decisions to be taken within the ERICA Tool regarding parameter selection and data input

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 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 an analysis using the user-defined option. Reasonable data coverage in time and space may be required to ensure that a maximum value is acquired.
		Use input value based on activity concentrations at the edge of the dispersion zone.	Maximum measurement at the end of the discharge pipe is overly conservative.	May be perceived not to be as conservative as it might be.
		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 & 2) for prospective assessment	Screen 1 assessment context (Tier 1 & 2)	Select the tool default transport model (based on IAEA, 2001).	Established internationally recognised methodology. Provides consistency, allowing comparison between different assessments.	May be overly conservative.
		Select user-defined transport model and enter data based on simulation output as media activity concentration.	User may feel more confident for his 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.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
		Enter proxy data that are based on expert judgement, for example 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.	May be perceived not to be as conservative as it might be.
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. For example, data available for organism A, B and sediment: which value(s) should be used to derive water concentrations? A further weakness might be insufficient data.
		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.
		Select user-defined model and enter data based on simulation output.	May predict quite realistic activity concentration data.	
Assessor faced with multi-contaminants (including non-radioactive substances)	The assessment tool deals with radioactive contaminants only	Use the ERICA Tool and whatever method is appropriate for the other stressor and combine with the ERICA assessment.	Assessment can be conducted addressing both sets of stressors.	Difficult to interpret.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
Assessor faced with multiple sources	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. May not be credible to stakeholders.
Selection of dose rate screening value	Screen 1 assessment context	Use the default ERICA screening values.	Values derived based on analyses of latest current available data and established statistical methods [ERICA D5 Annex A, 2006].	Data frozen in time and maybe become 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 radiobiological data.
		Do not use a screening value.	May not be needed by assessor.	Cannot do a Tier 1 assessment using the ERICA Tool.
Selection of DCCs	Either through creating own organism or through the edit database option	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 may not be transparently documented as those provided. If you edit the default databases, it may become unclear which numbers are being used in the assessment.

What decision is taken?	Where is this in the ERICA Tool?	What are the choices	Strengths	Weaknesses
Selection of DCCs	Either through creating own organism or through the edit database option	Use the 'create' organism function.	Uses the ERICA method and may be more appropriate to the species being assessed.	
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, this approach is fairly consistent with other assessment approaches in that it provides only a single EMCL value for each radionuclide and does not lead to the suggestion that there is greater detail of information than actually available. Fulfils the criteria to be highly conservative within Tier 1.	No organism-specific assessment – may identify the most exposed organism.
		Use other methods to sum over risk quotients.	Other RQ summation methodologies exist, such as those applied at Tier 2. Also others (US DoE, 2002; Garisto et al., 2005) that add EMCLs for two 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	Tier 2	Use ERICA's method of summing over risk quotients.	The ERICA RQ summation method treats each reference organism on an individual basis, testing whether the sum of all radionuclides for that particular organism is less than one. This approach is considered to offer 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
Application of risk quotients (Tier 2) – dose rates	Tier 2	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. Would need to be done outside of the Tool.
Selection and revision of radioecological parameters (K_ds and CRs)	Tier 2 dialogue screen entitled "Radioecological parameters"	Select ERICA default CRs and K_ds.	The CRs used in the ERICA default database are comprehensive, drawing on an extensive review of published 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 is likely to be inappropriate
		Input user-defined CRs and K_ds.	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 mostly poorly defined statistically – essentially recommended values have been provided and exponential or probability distribution functions applied for want of more detailed collated statistical information.	The application of site-specific data is often not justified, especially in cases where datasets are small.
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, such as those selected for the location in the habitat where highest doses might be expected.	The selection of the default occupancy factor will lead to an overestimation of the dose rate in some cases.

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"	Input user-defined occupancy factors.	Application of realistic occupancy factors, where appropriate, will lead to less conservative dose estimates.	Need to obtain life history data.
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 α weighting factor of around 5 might be most appropriate for population deterministic and stochastic endpoints (Chambers et al., 2006).	The radiation weighting factors used in ERICA have been adopted from FASSET. They have always been considered provisional values, applied for demonstration purposes only – their application therefore is arguably unsubstantiated.
		Input user-defined radiation weighting factors.	The assessor can account for the most recent radiobiological research related to this theme. Furthermore, the assessment can be tailored to a specific problem context. Radiation weighting factors are known to be endpoint, species and dose rate specific. Could use published reviews (Chambers et al., 2006).	The choice of the radiation-weighting factor needs to be justified.
Choice of Tier 3 parameters		Choices as per Tier 2.		
Tier 3 probabilistic parameters	Tier 3	Use single values.	Pdfs may not be available.	Loose benefit of Tier 3 functionality.
		Use pdf.	Probabilistic analysis conducted with sensitivity analysis.	User has to be able to derive appropriate pdfs. Sufficient data may not be available.

Appendix 3: Information on three relevant projects

FASSET (2000-2003)

FASSET: Framework for Assessment of Environmental Impact

Executive summary of the FASSET Final Technical Report

Background and project organisation

Radiological protection has traditionally focused on the protection of man. For the past decade, the limitation to human health protection has been increasingly questioned and the requirement for an internationally agreed rationale to the protection of the environment to ionising radiation is now recognised, *for example* as reflected in the ongoing revision of the Recommendations of the International Commission on Radiological Protection. The FASSET project (contract N°: FIGE-CT-2000-00102) was launched in November 2000 under the EC 5th Framework Programme, to develop a framework for the assessment of environmental impact of ionising radiation in European ecosystems. It involved 15 organisations in seven European countries, and set out to organise radioecological and radiobiological data into a logic structure that would facilitate the assessment of effects on non-human biota resulting from known or postulated presence of radionuclides in the environment.

The FASSET project was divided into four work packages (WP), with the following broad objectives:

- WP1 – Dosimetry. To provide radiation dosimetry models for a set of reference organisms relevant to different exposure situations.
- WP2 – Exposure. To assess transfer, uptake and turnover of radionuclides in European ecosystems and identify components of the ecosystems where exposures (external and internal) may be high.
- WP3 - Effects. To critically examine reported data on biological effects on individual, population and ecosystem levels, as a point of departure for characterising the environmental consequences of, *for example*, a source releasing radioactive substances into the environment.
- WP4 - Framework. To review existing frameworks for environmental assessment used in different environmental management or protection programmes and to integrate project findings into an assessment framework.

In WP2, seven European ecosystems were considered, four of them terrestrial and three of them aquatic. A list of generic *reference organisms* was drawn up on the basis of expert judgement of exposure situations in the selected ecosystems. A number of novel modelling approaches were applied in the work, and resulted in a Handbook that compiles relevant information for the initial stages of the impact assessment.

The identification of reference organisms served as starting points for the development of dosimetric models in WP 1. For a variety of reference geometries, dosimetric conversion factors were computed, in several cases involving Monte Carlo calculations, and tabulated in the Handbook.

WP3 considered general 'umbrella' effects that, when manifested in an individual, may have an impact at population level or at higher levels of the organisational hierarchy. A database was also assembled, compiling data from the literature for a number of wildlife groups for each of these four umbrella effects (FRED – The FASSET Radiation Effects Database).

WP4's main task was to organise the work from the above three work packages into a framework for impact assessments, which would take into account experiences from existing systems for environmental risk assessment. The formulation of the FASSET assessment context was also part of this WP, which helped define the remit of the framework.

The FASSET project produced a total of six report deliverables, D1-D6. The final deliverable, D6, describes the FASSET framework and draws on information produced under the other five deliverables. Complete documentation on the FASSET project can be found on FASSET's website (www.fasset.org).

The progress and dissemination of results were further carried out by presentations at major international conferences and by publications into the scientific literature. It also help support the development of international initiatives, and lead to the commissioning of further research, *for example* under the EC 6th Framework Programme.

The FASSET Framework – an overview

The assessment framework developed under FASSET includes the following fundamental elements: source characterisation; description of seven major European ecosystems; selection of a number of reference organisms on the basis of prior ecosystem and exposure analysis; environmental transfer analysis; dosimetric considerations; effects analysis; and, as an integral part of the aforementioned steps, general guidance on interpretation, including consideration of uncertainties and possibilities to extrapolate from existing data to areas where data are absent or scarce. The project has used existing information, supplemented by the development of models, by Monte Carlo calculations, and by building an effects database (FRED, the FASSET Radiation Effects Database). An overview is given below, with reference to the different FASSET Deliverables (*cf*. also Figure 1).

Source characterisation

The initial phase of the assessment involves the characterisation of the radionuclide input in the environment. A set of radionuclides from 20 elements was selected for inclusion within the Framework, on the basis of being routinely considered in assessments and emergency planning for accidental releases; representing a range of environmental mobilities and biological uptake rates; being of both anthropogenic and natural radionuclides; and, being representatives of α-, β- and γ-emitters [D1].

Furthermore, a preliminary flowchart for the screening of radionuclides and a description of criteria useful in the process has been described. This guidance was based on a number of criteria used to define the source term, physical characteristics, environmental fate, biological activity and chemical characteristics, as discussed in [D2].

Ecosystem characterisation and selection of 'reference organisms'

The Framework includes information on seven European ecosystems to allow for identification of maximally exposed ecosystem components [D1]. The ecosystems considered were as follows.

- *Forests*: land with tree crown cover of more than 10 %, an area of more than 0.5 ha and with trees, which are able to reach a minimum *in situ* height of 5 m at maturity.
- *Semi-natural pastures and heathlands*: including mountain and upland grasslands, heath and shrub lands, saltmarshes and some Arctic ecosystems.
- *Agricultural ecosystems*: including arable land, intensively managed pastures and areas used for fruit production.
- *Wetlands*: areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish, or salt.
- *Freshwaters*: all freshwater systems, including rivers and lakes.

- *Marine*: the North-Eastern section of the Atlantic Ocean and its marginal seas.
- *Brackish waters*: the non-tidal, shallow Baltic Sea; organisms are immigrants from either marine or freshwater systems.

The ecosystems overview enabled identification of a number of reference organisms, based on habitat and feeding habits, as well as bioaccumulation and biomagnification [D1]. The Framework defines the reference organism as: *"a series of entities that provide a basis for the estimation of radiation dose rate to a range of organisms which are typical, or representative, of a contaminated environment. These estimates, in turn, would provide a basis for assessing the likelihood and degree of radiation effects"*. In total, *ca* 30 reference organisms have been chosen. It should be noted that these 'organisms' are not equivalent to specific species – they rather represent biological components of importance for the functioning of each ecosystem, and thus they are suitable targets for impact assessments.

Environmental transfer and dosimetry

A number of radionuclide transfer models developed for the seven major European ecosystems have been used for calculation of external and internal radionuclide concentrations. Furthermore, calculations and tabulations have been made to allow conversion of external and internal concentrations to absorbed dose (rate), including those resulting from natural background radiation for a number of ecosystems. The Conversion factors for estimates of dose rates have involved Monte Carlo calculations and the definition of a number of representative geometries for different reference organisms. Data have been compiled in a Handbook on the initial assessment stages [D5], as well as in a separate report on dosimetry [D3].

Effects analysis

The Framework centres the effects analysis on individuals, accepting that effects must materialise in individuals *before* they can become manifested within the ecosystems. In order to organise the available knowledge on radiation effects, it was decided that the Framework would concentrate on four effects categories, or 'umbrella effects'.

- *Morbidity* (including growth rate, effects on the immune system, and the behavioural consequences of damage to the central nervous system from radiation exposure in the developing embryo).
- *Mortality* (including stochastic effect of somatic mutation and its possible consequence of cancer induction, as well as deterministic effects in particular tissues or organs that would change the age-dependent death rate).
- *Reduced reproductive success* (including fertility and fecundity).
- *Mutation* (induced in germ and somatic cells).

[D4] reviews the current knowledge on radiation effects on biota, grouped under 16 wildlife groups, which are broadly comparable with the chosen reference organisms. The report is supported by the FASSET Radiation Effects Database (FRED). The database contains approximately 25 000 data entries from more than a thousand references. The reviewed effects data give few indications of readily observable effects at chronic dose rates below 100 µGy/h. However, it is advised that using this information for establishing environmentally 'safe' levels of radiation should be done with caution, considering that the database contains large information gaps for environmentally relevant dose rates and ecologically important wildlife groups. Assessors are encouraged to use the database as a starting point, and seek the original papers to extract more detailed information.

The FRED contains only limited data that enable the derivation – or even discussion – of radiation weighting factors. The recommendation is that assessors, as a part of a sensitivity analysis, make a judgment whether the weighting factor matters in each particular case.

Uncertainties and interpretation

The Framework contains general advice as to the interpretation and handling of uncertainties associated with the assessment. For a number of radionuclides, transfer and effects data are lacking or scarce, necessitating information to be extrapolated from 'known' data, and involving a substantial component of expert judgment.

Outlook

On the basis of the FASSET experience, and other recent projects, it can be concluded that there is substantial agreement in terms of conceptual approaches between different frameworks currently in use or proposed, and that differences in technical approaches can largely be attributed to the differences between ecosystems of concern, or to different national legal requirements. Furthermore, sufficient knowledge appears to be available to support robust, scientifically-based assessments following the FASSET framework structure, although significant data gaps exist, *for example* concerning environmental transfer of key nuclides and effects data for key wildlife groups at environmentally relevant dose rates.

Future challenges lie in the development of an integrated approach where decision-making can be guided by sound scientific judgements, which requires, *inter alia*: filling of gaps in basic knowledge of relevance to assessment and protection; development of risk characterisation methodologies; development of user-friendly assessment tools; and stakeholders involvement, including the development of supporting communication strategies.

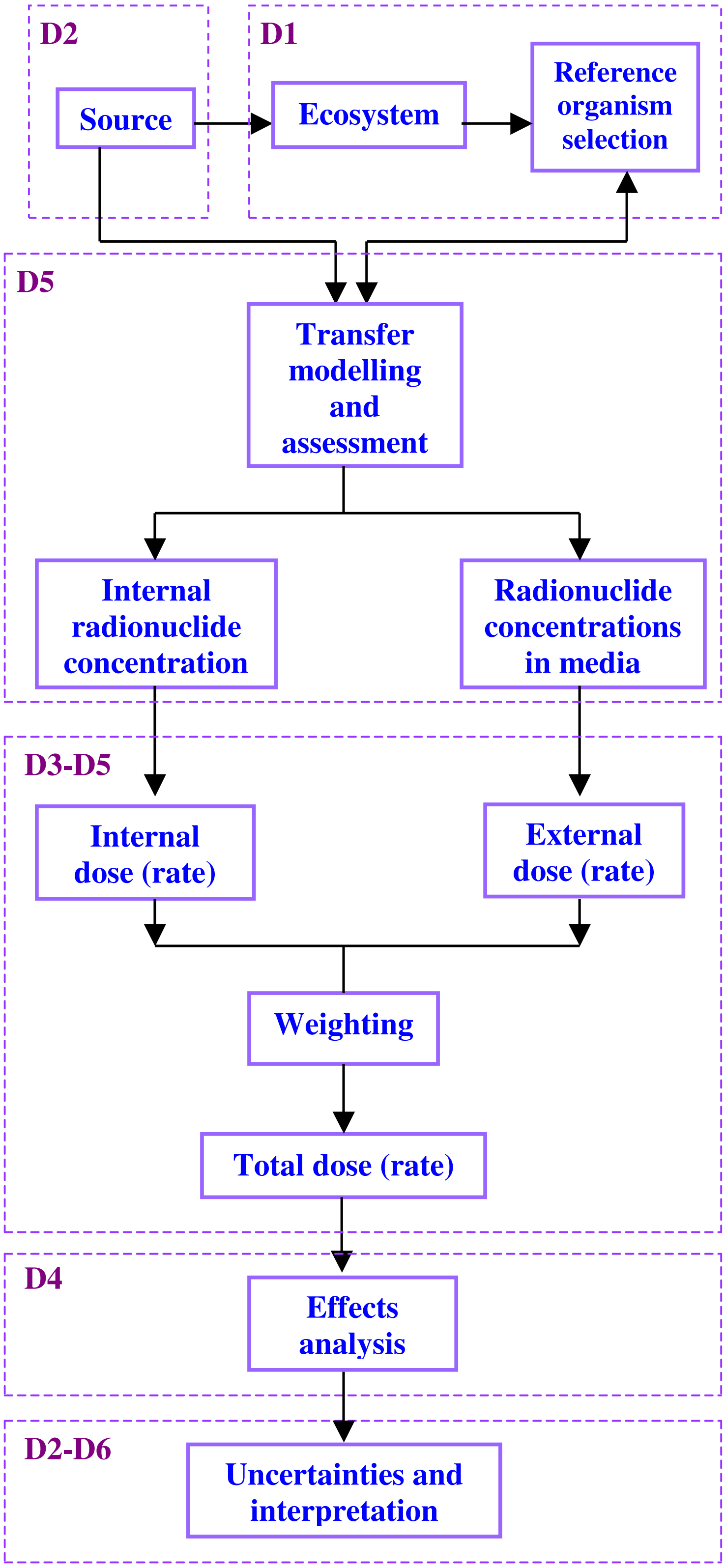


Figure 1 *Sequential organisation of the Framework elements, as developed by the FASSET Project, with reference to the sources of detailed information in the different FASSET Deliverables.*

EPIC (2000-2003)

EPIC: Environmental Protection from Ionising Contaminants in the Arctic

<u>Executive summary of D6</u>*: The "EPIC" impact assessment framework: Towards the protection of the Arctic environment from the effects of ionising radiation*

A Deliverable Report for EPIC (Environmental Protection from Ionising Contaminants in the Arctic). Funded under the European Commission's Inco-Copernicus Programme.Contract No: ICA2-CT-2000-10032. Edited By: JE Brown, H Thørring and A. Hosseini [2003].

This report provides an overview of the EPIC environmental impact assessment framework in its entirety and explores how the advances made in the project may provide input towards the development of criteria and standards ensuring protection of the Arctic environment from ionising radiation. Where relevant, the methodologies employed by environmental impact assessment systems for non-radioactive contaminants are discussed from the perspective of compatibility. In the introductory part of the report, the requirement for environmental protection is considered through an analysis of international conventions, agreements and legal issues. The need to relate the system to established underlying principles including conservation, sustainability and maintenance of biodiversity is also emphasised.

The EPIC system consists of problem formulation stage and primarily of an assessment methodology that will allow an assessor to quantify the probable effect of radiation exposure to selected biota following a defined release of radionuclides. Pure decision and management issues fall beyond the scope of our assessment as these involve judgements of a societal, political etc. nature. The considerations afforded the system development have also been limited in a geographical context, i.e. to the European Arctic, and to a suite of 13 radionuclides selected to be broadly representative of:

(i) routine release scenarios from power plants and reprocessing facilities,

(ii) accidental releases and

(iii) naturally-occurring or technologically enhanced naturally occurring (TENORM) radionuclides.

Three ecosystem types have been studied, i.e. terrestrial, freshwater and marine and the starting point for the assessment has been selected to be a unit concentration of a specified radionuclide in the environment with emphasis placed upon food chain transfer as oppose to physical transport processes.

Earlier in the EPIC project, lists of reference organisms were constructed based on the application of selection criteria including: Ecological niche, intrinsic radiosensitivity, radioecological sensitivity, distribution and amenability to research and monitoring. The generic reference organism lists have been used as a basis for deriving appropriate environmental transfer data information and selecting suitable target geometries/phantoms for dosimetric modelling. With respect to these points, it became apparent that the identification of actual species (or in some cases families or classes of organisms) representing each of the broadly defined groups would be helpful in some instances. Basic ecological information needs to be collated for each of the selected flora and fauna. The specific organism attributes that should be considered relate directly to the subsequent assessment of exposure. For example, information should be provided on habitat and, where applicable, the fractional occupancy of various organisms in their habitats. Guidance on the types of ecological information required for reference fauna has been provided in this report. For the purpose of illustration Life History data sheets have been presented in Appendix 1.

Several approaches have been employed in order to consider the transfer of radionuclides in the Arctic environment. In the first instance, datasets providing information on concentration ratios/factors (CR/CF) have been collated for reference organism types and the suite of EPIC radionuclides. This exercise has allowed data gaps to be identified. In cases where data coverage is poor or non-existent, other methodologies have been employed in the process of providing estimates. Such methods have included the application of allometric relationships and the biokinetic models. Recommended values have been provided for terrestrial and marine environments in Appendices 3 and 4, respectively. Limitations in the application of concentration ratios have been explored. These essentially relate to problems in applying the method where sources to a compartment are numerous and the unsuitability of applying the approach to non-equilibrium situations. In light of these problems, further work was conducted in the development of fully dynamic models as exemplified by the modification of an existing radiological model "ECOMARC" to allow activity concentrations in a herbivorous (reindeer) and carnivorous mammal (nominally a wolf) to be derived.

The method for deriving absorbed doses is based on an approximation describing the dose distribution defined using Dose attenuation function and Chord distribution functions. External doses to organisms from radionuclides present in soil or in the water column are calculated using a variant of a simple formula for a uniformly contaminated isotropic infinite absorbing medium: This approach neglects density differences between the organism and the medium. A two-step method has been used for the estimation of external exposures at the interface of environments with different densities. In the first step, the kerma in a specified location (above the soil/air interface, in soil at the given depth) is derived. In the second step, the ratio of the dose in an organism and the kerma is calculated for the different organisms and radionuclides. A computer model with a user-friendly interface has been developed to allow such calculations to be conducted. Radionuclide specific Dose Conversion Factors (DCFs) have been generated for all reference organism groups and a large suite of radionuclides including the 13 radionuclides selected within EPIC and radionuclides from ^{238}U and ^{232}Th decay series. Within this report, weighted DCFs have been derived using provisional weighting factors of 3 for 3H and 10 for alpha radiation. These DCF values are presented in Appendix 2 of this report.

The approach taken within EPIC with regards to analyses of dose-effects relationships was to collate and organise data around the reference organism categories and to focus on dose-rates and biological endpoints that are of relevance from the perspective of environmental protection. Data of dose-effects relationships on radiation effects in biota available from Russian and other former Soviet Union sources have been collated. The compiled data are concentrated on the effects in radiosensitive species in terrestrial and aquatic ecosystems, such as mammals, fish, and sensitive groups of plants (for example pines). Data have been organised under "umbrella" end-point categories, namely: morbidity, reproduction, mortality, cytogenetic effects, ecological effects, stimulation effects and adaptation effects. A general conclusion can be made, that the threshold for deterministic radiation effects in wildlife lies somewhere in the range 0.5-1 mGy d^{-1} for chronic low-LET radiation. However, although minor effects on morbidity in sensitive vertebrate animals are observed at the dose range specified above, populations of highly productive vertebrate organisms are viable at dose rates in the order 10 mGy d-1. Preliminary scales defining the severity of radiation effects at different levels of chronic exposure for different organisms groups have been constructed. In addition, background dose-rates have been calculated for reference organisms in terrestrial, freshwater and marine ecosystems although some of the values generated have been based on very limited data sets.

There are currently no radiation dose limits in place for Arctic environments. In order to assess the potential consequences of exposures to radiation on non-human biota, arguably, two points of reference may be used. These are (a) natural background dose rates and (b) dose rates known to have specific biological effects on individual organisms. The information collated within the EPIC project is consistent with this and, therefore, allows an evaluation of potential effects from a given dose-rate to be made without explicitly providing dose-limits. Furthermore, the generalised conclusions, within EPIC, regarding the threshold dose-rates at which various effects are observed are consistent with earlier studies. From the available information it is, therefore, not possible to justify any Arctic specific dose-standards at the present time. It should be noted, however, that the data set upon which such a conclusion is drawn is limited in scope and the hypothesis relating to whether there is a unique expression of radiation-induced biological damage under Arctic conditions remains to be properly tested.

The EPIC environmental impact assessment framework is generally compatible with systems being developed elsewhere including those applicable for non-radioactive substances. The reference organism approach has now been advocated by a number of international authorities on this subject including the International Commission on Radiological Protection (ICRP), the International Atomic Energy Agency (IAEA) and the International Union of Radioecology (IUR). Similar methodologies have also been applied in a recent EC study looking at impact of radionuclides in European marine areas, i.e. The Marina II study.

At the end of this report, areas of information deficiencies are identified and recommendation made for further development of this system. In particular, these relate to the development of better transfer data, through empirical data collation and modelling, in the Arctic environment, dose reconstruction of numerous data entries in the EPIC dose-effects database and the more detailed exploration of dose-effects on Arctic species (at present most of the available information relates to boreal species).

PROTECT (2006-2008)

PROTECT: Protection of the Environment from Ionising Radiation in a Regulatory Context

www.ceh.ac.uk/protect

The EC EURATOM funded **PROTECT** project (FI6R-036425) aims to evaluate different approaches to protecting the environment from ionising radiation.

We will compare these approaches with those used for non-radioactive contaminants, which will allow us to suggest numerical target values and develop standards for protecting the environment from ionising radiation. To achieve this we will work with the International Commission on Radiological Protection, the International Atomic Energy Agency, regulators, industry and other interested parties. The outputs will help to inform a future revision of the EC Basic Safety Standards.

Work Plan

There are four work packages associated with the project:

WP1: Environmental protection concepts

WP2: Assessment approaches: practicality, relevance and merits

WP3: Requirements for protection of the environment from ionising radiation

WP4: Management and progress assessment

During the course of the project we will run a number of workshops for interested parties from regulatory organisations, NGOs, industry and the research community.

Work Package 1

Drawing on the experiences of key stakeholders from regulatory organisations, NGOs and industry (nuclear and chemical) in different member states, this WP will:

- gather information on the current regulatory approaches to both chemical and radioactive substances in member states;
- critically review the biological and ecological endpoints of protection currently used and the similarities and differences between approaches for chemical and radioactive substances.

Work Package 2

This WP will bring together those organisations using or developing ways of protecting the environment from ionising radiation in order to:

- evaluate whether existing and developing approaches are practical;
- consider how acceptable and relevant the approaches are to regulators and industry (identified by WP1);
- apply numerical target values recommended by WP3 and others;
- assess the user-friendliness of the approaches to potential users;

Application of the available approaches to case studies will be used to help achieve these objectives.

Work Package 3

To propose numerical target values for protection of the environment from ionising radiation to ensure compliance with protection goals. This WP will:

- define appropriate levels of protection, taking into account European legal requirements and existing practices for other hazardous substances;
- propose target values for both dose and activity concentrations to ensure protection level compliance.

Consult with regulators, industry, NGOs and other experts to identify areas of consensus and make recommendations for numerical target values in the future.

Summary

PROTECT will:

- evaluate the current regulatory approaches to chemical and radioactive substances, recommend how standards should be set and establish how to assess these approaches;
- evaluate different approaches for protecting the environment from ionising radiation;
- propose an appropriate level of protection and numerical target values;
- record views from the consultation exercise
- make recommendations for the future.

Consortium

- Centre for Ecology and Hydrology: Co-ordinator of the project
- Swedish Radiation Protection Authority
- Environment Agency
- Norwegian Radiation Protection Authority
- Institute for Radiological Protection and Nuclear Safety

Note that all deliverables from the ERICA project will be transferred to the PROTECT website www.ceh.ac.uk/protect as of March 2007.