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DELIVERABLE D7a: First EUG Event - Part 2: Briefing notes on assessment frameworks and knowledge gaps

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

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

This document represents a summary of group discussions held between the ERICA End-users Group (EUG) and members of the ERICA consortium as part of the first EUG thematic meeting in Sweden, 7th May 2004. The subject of that meeting was Assessment Frameworks and Knowledge Gaps. The present document is based on the group discussions and on additional background material provided by EUG and ERICA members, and will represent an input to further discussions at forthcoming EUG meetings as well as the Deliverable D8 on decision-making guidance.

EUG members	
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Tim Parker	British Nuclear Fuels Ltd
Jan Pentreath	International Commission on Radiological Protection
Jill Sutcliffe	English Nature
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As a result from the group discussions, a number of comments were raised by the EUG to be addressed at the next two EUG events. In addition, a few preliminary observations and conclusions could be made to guide the ERICA project, based on the distributed material, discussions during the Event and the summarising of the briefing note.

Comments to be addressed

EUG event	Assessment Frameworks	Knowledge Gaps
France, Sept '04	Compare frameworks for radionuclide and other environmental stressors. Include expert participation on, for example, EC environment directives; EU White Paper on Chemicals; OECD on socio-economic analysis.	The discussion will cover: biological, ecological aspects; dose-response and effects analysis (including weighting factors and safety factors); risk characterisation and management. A draft briefing note (D7b) will be distributed prior to the EUG meeting, for review and comments at the meeting. A draft of D4 from WP2 will be distributed for comment and review.

EUG event	Assessment Frameworks	Knowledge Gaps
Germany, Apr '05	Using the UK Sellafield case study as a basis, one aim will be to revisit conclusions on ecological risk assessment frameworks, and ask which frameworks would have given different answers? What, why and does it matter? There will also be a chance for a general review of the present document (D7a-2), with the aim of producing a final briefing note and input into D8.	The discussion should aim for a stronger focus on the original aim of the theme, based on a clear list of knowledge gaps prepared from the meeting discussions and previously submitted materials, i.e. draft and published ERICA deliverables to date. Work will continue on demarcation of the different types of knowledge gaps and uncertainties. Other expert judgement methodologies (e.g. Delphi process) will be included for assessing the orders of magnitude of various uncertainties. Review of the draft outline of D8 from WP3.

Assessment Framework

	EUG Comments	Actions for ERICA
WP2	The risk characterisation stage may need to be further compared between different systems, there is a potential conflict between risk characterisation for radiation protection and risk characterisation performed elsewhere.	Comparison to be made in WP2 workplan.
WP1 and WP2	Be clear about potential differences in frameworks depending on whether top-down or bottom-up approaches are used.	ERICA extends the FASSET bottom-up approach. It is within the remit of WP2 to consider potential conflicts between the approaches.
Entire project	The assessment framework must be able to deal with knowledge gaps. Develop a pragmatic approach to decision-making. Ensure that decision-making allows the precautionary principle to be applied when taking into account knowledge gaps and uncertainties. Some EUG background materials make consideration regarding decision-making.	The project focuses on dealing with knowledge gaps through extrapolation and a limited number of experiments. WP3 to consider these points (e.g. introducing conservatism, precaution) in the development of the decision-making guidance. WP3 to consider material and incorporate components in the decision-making guidance, if appropriate. ERICA to seek further information from those specific EUG members.
	Alternative approaches used for other stressors may also be suitable for use within the radiation field. Address the issue of having to be very generic in a European approach, while at the same time communicating with people affected by decision-making. Use the ERA as the central approach for further development of the ERICA integrated approach.	Engage closely with the EUG to identify and test such alternative approaches. To be further discussed within ERICA and by engaging the EUG. Adopt potentially a non-prescriptive guidance approach to decision-making. This is already within the ERICA work programme, but account has to be taken of the points made above.

	EUG Comments	Actions for ERICA
Entire project (cont'd)	Continue with the dose-to-reference organism approach while maintaining an open mind towards alternative approaches. ERICA talks about environmental "risk". What is the definition of risk, for the purpose of ERICA. Risk has a multitude of meanings in different contexts and for different users of the term.	Consider how the use of references organisms can be extrapolated to real species. To be decided.

Knowledge Gaps

	EUG Comments	Actions for ERICA
WP1	Source terms, transfer and uptake are all aspects where the information is patchy, and there are shortcomings in our ability predict environmental radionuclide concentrations both under dynamic and steady-state conditions. Further complicating factors arise from seasonality and chemical speciation.	Additional information relating to these data gaps to be provided, to the extent they are available or may be generated (e.g. within case studies. Advice on how to deal with the assessment in absence of data to be provided. The development of a practical tool (software) to take these points into account.
WP1 and WP2	Dosimetry: most of the calculation problems have already been resolved to a sufficient level. Refinement may be needed for organ doses and also for a scientifically justified approach to dealing with RBE.	The issues to be considered as parts of the work programmes for WP1 and WP2.
Entire Project	Effects analysis is possibly an area where lack of knowledge greatly jeopardises interpretation of data. In particular, this concerns the extrapolation of data obtained for laboratory test organisms to field conditions on an ecosystems scale.	Extend the database within the programme of WP1. WP2 to consider the extrapolation issues, both theoretically and experimentally. Seek advice from the EUG to transform the information into decision-making guidance.
	A number of knowledge gaps have been identified within the various EUG background materials.	The project will consider and prioritise reported gaps, and address them where appropriate in each WP. A list of experiments will be proposed that could reduce some of these gaps. Seek further views from the EUG regarding knowledge gaps.

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1 Introduction

The main objective of this EUG thematic meeting was to consider two topics central to the future development of the ERICA integrated approach: Assessment Frameworks and Knowledge Gaps. The aim was to obtain a first broad overview of the two themes (i.e. what the differences and similarities between different frameworks are, and what the knowledge gaps are) and what possible practical problems, derived from these, may arise in developing the ERICA integrated approach. Each invited End-User Group (EUG) member was requested to submit background information on a selected topic, as described in Appendix 1.

The output of these discussions (i.e. this deliverable) will feed into the larger Generic Consultation Meeting on 24-27th April 2005, where participants will be asked to give a more in-depth critical evaluation of these and other selected issues, e.g. do they matter, why, what can be done.

1.1 Procedure

The participants were divided into two main groups (Group 1 and Group 2), consisting of a mixture of EUG members and ERICA consortium representatives. Each group discussed both themes, and the discussions were facilitated/moderated, but each group elected its own chair/rapporteur and, if desired, secretary. The agenda and composition of the groups is indicated in Appendix 2.

Prior to the meeting, EUG members were asked to prepare short summaries relevant to one of the two themes, and provide any supplementary background documents and references. A third smaller group of ERICA participants (Group 3) was given the task of reading and summarising this background material during the meeting and provide if necessary additional comments during the plenary sessions.

The present document represents a consolidation of those summaries together with conclusions and recommendations from the group discussions.

2 Assessment Frameworks - similarities and differences and experience in applying them

2.1 Objectives

The proposed ERICA integrated approach uses as a starting point the assessment framework developed as part of the EC-funded FASSET project (Framework for Assessment of Environmental Impact; documented on www.erica-project.org, see particularly the framework structure described in FASSET Deliverable 2 [Larsson and Jones, 2002] and FASSET Deliverable 6 [Larsson *et al.*, 2004]).

There are fundamental similarities but also some differences between the FASSET framework and alternative approaches adopted by different regulators to protecting the environment from ionising radiation. As part of the evaluation of the ERICA integrated approach, it is necessary to have a clear picture of what those disparities are (e.g. is it about terminology, methodology or deeper conceptual differences) and how they impact on the application of the various frameworks in practice. Therefore, for the present discussion, the ERICA Consortium:

- targeted selected EUG members who are experienced “users” of various frameworks (and specifically those experienced with protection from ionising radiation), to address basic concepts and application; and,
- placed the main focus of the discussion during this EUG Event on assessment, namely the part concerned with derivation of the *size of the risk*, or estimations of the probability that exposure to

radiation will bring about an effect of significance, and – if possible – extending the discussion to *how significant* this effect may be. This encompasses analysis of transfer, uptake and effects of exposure to ionising radiation, including the derivation of dose-effect relationships for various biological endpoints in exposed organisms.

2.2 Background Summaries

The assessment and management frameworks can be divided into generic approaches such as those developed by the ICRP, IAEA and FASSET, which are intended to be adaptable for use by various countries or for a range of applications, and specific frameworks actually applied within different countries. Ecological Risk Assessment (ERA) is usually divided into five main components: planning, problem formulation, risk assessment (or analysis), risk characterisation and risk management, see Figure 1.

However, a strict demarcation of assessment and management is rarely straightforward (nor particularly advisable) and such discussion will still need to be put into context with the other areas of ERA [Suter, 1993].

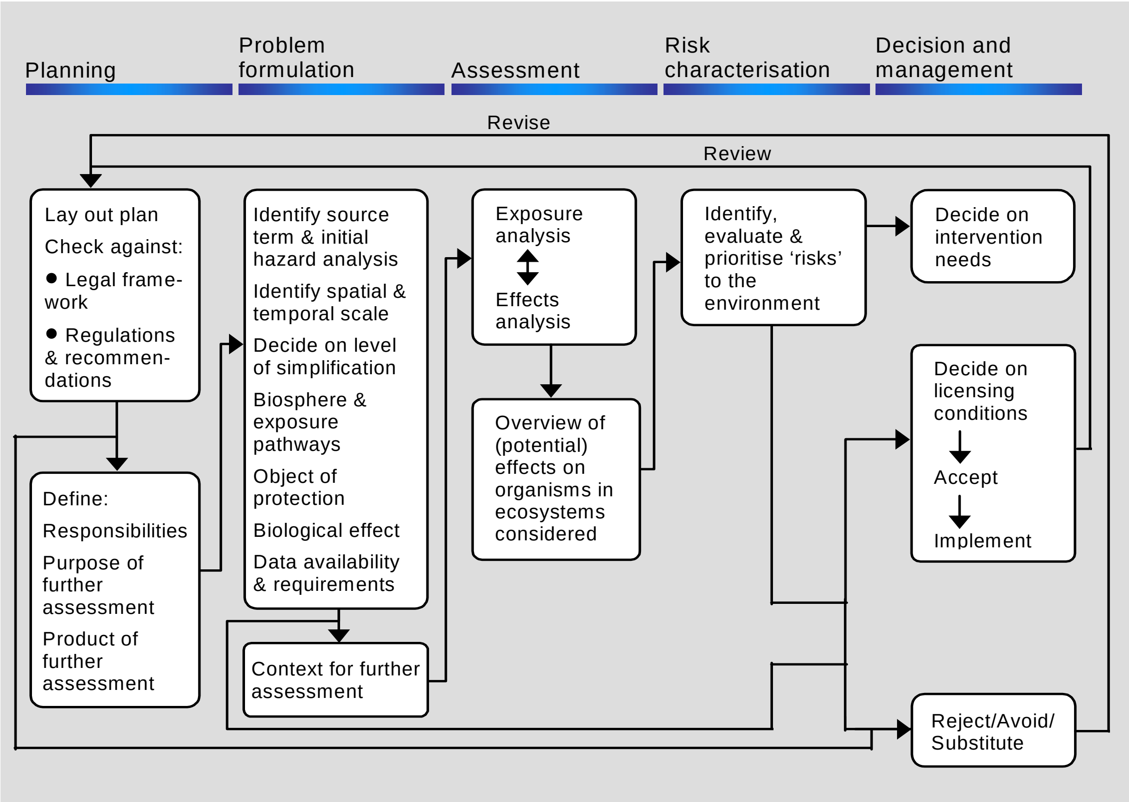

Figure 1: Ecological Risk Assessment (ERA) [Larsson *et al.*, 2004]. Note that, somewhat confusingly, there is a separate "assessment component" within the overall ERA. This component is often defined as the "scientific" evaluation or analysis of exposure and effects whereas ERA refers to the entire system, including risk characterisation, management and sometimes regulation [Suter, 1993][Benefanti et al., 2002]. In the following discussion, we will use assessment to refer to that component of the framework related specifically to exposure and effect analysis, and ERA to denote the whole framework.

2.2.1 Generic Frameworks: Examples

International Commission on Radiological Protection (ICRP): The ICRP system is centred on the reference plants and animals approach originally proposed by Pentreath [1999] and supported by the International Union of Radioecology (IUR), see [IUR, 2002] and FASSET. This is essentially a systematic approach to the collation of information on dose-effect relationships for individuals of selected types of animals and plants. The assessment system builds on the widely accepted approach used for human radiological protection, recognising that it will not be possible to provide data for all organisms and endpoints. To date, 12 reference organisms have been proposed, including, for example, a rat, a bee, a duck, and a frog. The system would allow both an assessment of dose received (but not of the pathway by which the dose was received) and a "management judgement" to be made. This judgement will clearly depend on the problem in question, which may vary from country to country and case to case. Possible approaches to risk characterisation (ranking of risks, and putting radiation risks into a multi-contaminant context) that have been suggested are comparison with background radiation or "bands of concern", and potential management guidelines include derived concentration factors or environmental quality standards. The ICRP does not intend, at the present, to recommend dose or dose rate limits [ICRP, 2003].

International Atomic Energy Agency (IAEA): The IAEA has a long history in the field of environmental protection, publishing a number of reports, supporting exchange of information and international conferences, and recently releasing its "Action plan on the protection of the environment from the effects of ionising radiation" [IAEA, 2004]. The objectives of that action plan are "to assist IAEA Member States in their efforts to protect the environment by development of a framework and methodologies to assess the impacts and review the corpus of radiation safety standards related to releases of radionuclides to the environment, revising as appropriate". Note, however, that the IAEA's remit is concerned more with the *implementation* of proposed assessment frameworks, specifically that of the ICRP, rather than in their actual development. With respect to management, this includes the development of appropriate guidance for protection and the administrative arrangements that countries might elect to use at a national level, such as a technical framework and methodology for implementing Safety Requirements.

FASSET: The FASSET framework is based on ERA and includes: source characterisation and initial hazard analysis, ecosystem description and selection of reference organisms; exposure analysis including conversion to dose rates; effects analysis; and guidance for interpretation. Extensive details of the framework and its compatibility with other ERA frameworks can be found in the project deliverables and articles (consult the Final Report at www.fasset.org for the reference to the project documentation). The FASSET framework is being extended within the ERICA integrated approach, to include risk characterisation, management and decision-making guidance.

2.2.2 Specific Frameworks: Examples

Australia – The Ranger Mine Assessment Framework: The Ranger Mine framework was developed by the Department of Environment and Heritage in 2003, with the aim of controlling and monitoring the radiological impact of uranium mining on the environment. The environmental protection objectives were based on conservation of biological diversity, protection of rare and endangered species and the precautionary principle. The assessment included modelling the dispersion of radionuclides in the aquatic environment to obtain water and sediment concentrations and calculation of dose rates using site-specific concentration factors for local native species. Risk characterisation was based on chemical toxicity assessment, using cumulative frequency distribution vs. NOEL (No Observed Effect Level) to determine dose rate limits. These were compared with a default value of the limit specified to achieve the objectives, i.e. 400 µGy/hr (~ 1 mGy/d). For actual discharges over the life of the Ranger mines, the maximum dose rate has been about 3 µGy/hr over the background rate of

30 µGy/hr [Johnston, 2004].

United States Department of Energy (DOE) Graded Approach for Biota Dose Evaluation: The DOE graded approach arose from a need to provide standardised evaluation approaches for demonstrating compliance and flexibility to apply site-specific information. It consists of three parts: 1) a data assembly phase where radionuclide data for soil, water and sediment are assembled; 2) a general screening methodology that compares data with Biota Concentration Guides (BCG); and 3) an analysis phase that, if required, consists of more detailed site-specific screening, analysis and dose assessment [USDOE, 2002; 2004][Higley *et al.*, 2003]. BCG represent derived concentrations in environmental media that are, in turn, calculated from dose limits representing safe levels of exposure as based on No Observed Adverse Effects Levels (NOAEL). At present the DOE has in place a dose limit of 10 mGy/dy for native aquatic organisms, and has proposed dose limits for terrestrial plants, at 10 mGy/d, and animals, at 1 mGy/d. In 2002, the methods, models and guidance within the DOE graded approach was applied at 65% of DOE facilities requested to prepare an annual site environmental report. In many ways the DOE approach is consistent and complimentary with the generic framework elements of FASSET. However, the DOE method uses an initial, prudently conservative, screening stage to quickly distinguish potential areas of concern [Higley, 2004].

The Canadian Approach: In 2000, the creation of the Canadian Nuclear Safety Commission from the former Atomic Energy Control Board saw major new regulations on licensing, including a new mandate in environmental protection. The Canadian approach has been driven largely by environmental legislation and public consultation, drawing on the existing federal framework for environmental protection (e.g. [Canadian Environmental Protection Act, 1999]; [Canadian Environmental Assessment Act, 2003]; [Environment Canada, 2004]). The present assessment and management methodology has its origins in US ERA, but aims for a unified approach for nuclear and other hazardous substances, drawing from ecological and ecotoxicology developments. Another trend has been the use of well-supported Lowest Observed Adverse Effect Levels (LOAEL) for interpretation of risk, with less emphasis on No Observed Adverse Effect Levels (NOAEL) or equivalent ENEV (Expected No Effects Values – with safety factors applied to estimated critical toxicity values). Practical issues in implementation include industry's reluctance to accept the ERA as a mature science and challenges to the scientific validity of toxicity benchmarks. Public acceptance of the concept of reference or surrogate organisms is also often an issue [Mihok, 2004].

2.3 Group Discussions

2.3.1 Group 1

The discussion focused on both assessment frameworks and regulation and management issues. Comparison of the various frameworks recognised similarity within the risk analysis and assessment parts. The frameworks tended to use the same types of transfer and dosimetry models, and similar criteria for selection of reference or critical organisms (even if the actual choice differs). The main differences arose within the risk characterisation stage, particularly with regard to the interpretation of effects data (e.g. the choice of NOEL, LOEL, EC_x, as well as selection of the biological endpoint of concern and judgements about "adversity"). Not surprisingly, it was here that problems for management and regulation started to appear. Specifically, there was a conceptual difference in the top-down and bottom-up approach, for example, the FASSET focus on producing realistic estimates of effects as compared to a more compliance driven approach adopted by the DOE. In other words a difference between regulation driven by "numbers in pipes" as a pose to "numbers in the environment". The area of risk characterisation was also mentioned as an important difference between the generic 'framework' being developed within ERICA integrated approach and that of the ICRP. The discussion touched on the difference between radionuclides and other stressors and here there was less agreement within the group, although the issue was not addressed in great depth. However, it was suggested that the ERA approach did have the potential to create harmonisation between radionuclide and other risk assessment and management approaches for environmental pollutants.

2.3.2 Group 2

The discussion started with a consideration of terminology, particularly the definition of "risk" and problems with the different interpretations in assessment, management and public perception. Thereafter the focus was on two main issues: 1) the assessment framework itself and 2) comparison between radionuclides and other environmental stressors. Regarding the framework itself, it was suggested that even though there may be a consensus regarding similarity between the assessment frameworks actually used in practice (i.e. the models, tools and assumptions used in dose-effect analysis), it did not necessarily follow that this framework was the most appropriate alternative. In particular, it was claimed that there were approaches used for other environmental stressors that may be more suitable. However there was disagreement among the group on this point – some claiming that ERA for radionuclides and other stressors is compatible, some that it can't and shouldn't be compatible, some that it isn't but should be more compatible. Thereafter there was a more general discussion of radiation and other stressors focusing both on biological mechanisms, the use of dose and dose effect analysis, as well as risk assessment, characterisation and management and public perception. What makes radiation special? Is risk assessment simpler for chemicals? Are we more worried about uncertainties and extrapolation for radionuclides as compared to chemicals? The relevance of "dose" was questioned; one response being that dose is the radiation protection approach of harmonising over different radionuclides. Finally, the importance of problem formulation was raised—namely that ERICA needs to consider broad application, whereas national frameworks have a focused problem formulation, as well as the fundamental problem of how to communicate and explain all this to the public.

In a conclusion, the group proposed that the ERICA consortium should continue with the dose-to-reference-organisms approach to risk assessment, but also include more focused comparison of the method with other dose assessment and management approaches, particularly with reference to their compatibility with methods used for other environmental stressors. Will different approaches give different answers?

3 Knowledge Gaps - what are they, why are they there, do they matter?

3.1 Objectives

For the past few years, every international meeting on protection of the environment had some time dedicated to "identification of knowledge gaps". The aim of this meeting was not to repeat this old theme, but to encourage a sharper and more critical evaluation of these supposed knowledge gaps and their origins. For example: which gaps can be reduced by research and how?; which are fundamental and only likely to be widened by more knowledge?; which represent diverging or incommensurable paradigms?; where can models help?

3.2 Background Summaries

3.2.1 Knowledge Gaps and Uncertainties – definition

There are different types of knowledge gaps and uncertainties that are relevant in risk assessment. These range from statistical error on parameter values, biological or environmental variation, true "gaps" in knowledge (i.e. missing or insufficient data and extrapolation), conceptual uncertainties arising from model assumptions and choices, as well as situations of ignorance and indeterminacy (e.g. [Day and Roache, 2003] [Wynne 2002]). Whereas the main subject of the meeting was "knowledge gaps" rather than "uncertainties", implying that we are dealing with situations where there is some knowledge rather than no knowledge, these issues need to be put into context with the other types of uncertainty (note that a specific EUG event in March 2006 will be dedicated to "uncertainty and extrapolation").

As an illustrative example, Table 3.1 shows the current state of knowledge on biological effects in a number of wildlife groups – clearly, there are significant gaps in the knowledge, but the challenge lies in how existing knowledge can be used *per se*, and also for bridging the knowledge gaps through extrapolation.

Table 3.1: Overview of knowledge on effects data resulting from chronic exposure. Based on the FRED (FASSET Radiation Effects Database) [Real *et al.*, in press].

Wildlife Groups	Umbrella Endpoints			
	Morbidity	Mortality	Reproduction	Mutation
Amphibians	Too few data to derive dose-effect relationships	No data	No data	Too few data to derive dose-effect relationships
Aquatic invertebrates	Some data	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships
Aquatic plants	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships	No data	No data
Bacteria	Too few data to derive dose-effect relationships	No data	No data	No data
Birds	No data	No data	Some data	Too few data to derive dose-effect relationships
Crustaceans	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships	No data
Fish	Some data	Too few data to derive dose-effect relationships	Some data	Some data
Fungi	Too few data to derive dose-effect relationships	No data	No data	No data
Insects	Some data	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships
Mammals	Some data	Some data	Some data	Too few data to derive dose-effect relationships
Molluscs	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships	No data
Moss/Lichens	Too few data to derive dose-effect relationships	No data	No data	No data
Plants	Some data	Some data	Some data	Some data
Reptiles	No data	No data	No data	Too few data to derive dose-effect relationships
Soil fauna	Too few data to derive dose-effect relationships	Too few data to derive dose-effect relationships	No data	Too few data to derive dose-effect relationships
Zooplankton	Too few data to derive dose-effect relationships	No data	Too few data to derive dose-effect relationships	No data

Legend:
No data (black)
Too few data to derive dose-effect relationships (grey)
Some data (white)

3.2.2 Major Issues

This section is a compilation of the knowledge gaps identified during Group 2 discussions, background material provided by the EUG members and previously published material such as FASSET deliverables, conference proceedings and articles, e.g. [UNSCEAR, 1996]; [IUR, 2002]; [Garisto, 2002]; [Garisto and Weismer, 2004]; [Brechignac *et al.*, 2003]; [Mothersill and Seymour, 2004]; [Whicker and Hilton, 2003]; [CERRIE, 2004]. The list concerns primarily knowledge gaps and uncertainties associated with data variations and limitations, rather than conceptual uncertainties related to model assumptions and choices. For clarity, the issues have been grouped into four areas: 1) source terms, transfer and uptake; 2) dosimetry; 3) dose response and effects analysis; and 4) risk characterisation and management. However, it should be clear that there are interactions between all these areas. For example, gaps in knowledge in transfer and uptake of radionuclides in ecosystems will have knock-on effects for uncertainties in dosimetry calculations, and lack of data for dosimetry will influence the reliability of effects analysis.

Source Terms, Transfer and Uptake

- **On site (near field) air concentrations**, e.g. H-3, C-14.
- **Seasonality**, for example, data collected in one season and applied at a different season. Other environmental variables such as temperature, rainfall. (Note this is also important for dose response and effects analysis).
- How to fill data gaps on **transfer factors** for specific biota and specific radionuclides? It will be important to determine (on a site specific basis, perhaps using a sensitivity analysis) whether this should be done by using conservative estimates or measurements.
- Source term **speciation** and its influence on the transfer and uptake of radionuclides, including metabolism and internal distribution within biological organisms.
- **Transient conditions.** There is a lack of experience with the methodology for estimating radioecological impact under transient conditions, such as those caused by a spill, upset conditions, accidental releases. This includes the dynamics of radionuclide uptake, dosimetry under time dependent conditions (e.g. a growing egg), and effect evaluation. This is also related to uncertainty/knowledge gaps with respect to temporal and spatial averaging.

Dosimetry

- Missing gaps in **Dose Conversion Factors.** Need to review whether these can make a difference in the results of radioecological assessments.
- **Organ dosimetry.** Is there a need for organ-based dosimetry for biota? In which cases would this be important? What about cases where the effect benchmark for organ dose is different to that of the whole body (e.g. reproduction effects)? There are data gaps in transfer factors to specific organs.
- **Biological weighting factors** for alpha radiation, tritium and Auger emitters. Robust weighting factors require information on the Relative Biological Effectiveness (RBE) under a variety of conditions. Experimentally derived RBEs may vary with species, life cycle stage, biological and/or ecological endpoints, radiation type, dose and dose rates. Note that this issue is of similar importance to dose response and effects analysis.

Dose Response and Effects analysis

- **Multiple stressor effects**. How to assess multiple stressor effects? (including chemical, physical, biological)? How to assess radioecological impact in the presence of multiple stressors? How to account for habitat change, climate change, chemical contaminants, impingement/entrainment? How to delineate cause and effect?
- How to extrapolate **laboratory results on biological harm to a practical effect level**? How to use results of research on biomarkers? What are the implications of radiation biology research to radioecological risk assessment?
- How to account for **Radiation Induced Bystander Effects** (RIBE) and genomic instability? The relevance of genetic and genotype variability in sensitivity or response.

- Uncertainty in **dose-response curves**, particularly at low doses. Dose-rate dependencies, secondary (indirect) responses, and on-going recovery and repair. These knowledge gaps are related also to uncertainty in the determination of NOELs, LOELs or EC_x.
- Other **extrapolation issues.** For example, how to extrapolate data from one biological species to another? How to extrapolate between chronic and acute situations? Or from molecular to individual to population to ecosystem effects?

Risk characterisation and management

- How to deal with **special species** such as endangered species, listed species, pets, livestock, crops? Links with environmental policy questions of biological diversity and species and habitat conservation.
- Lack of experience with **field validation**, effects monitoring and assessment of habitat damage (or lack of damage). This would include measurements of concentration, biomarkers and bioindicators as well as knowledge on natural variability and background radiation doses. An example of a possible effect of tritium on mussels was mentioned.
- **Risk communication, stakeholder communication and feedback to stakeholders.**
- Have knowledge gaps influenced **policy**? For example, the precautionary principle, public trust in expert evaluation, questions of liability and compensation for alleged damage.

3.2.3 Approaches to Dealing with Knowledge Gaps

A number of different methods for dealing with knowledge gaps have been proposed. These include a stronger focus on frequency and probabilistic analysis of data, species sensitivity analysis, increased use of expert judgement and consultation (including structures procedures such as the Delphi technique), and a more systematic approach to the collection and interpretation of data (e.g. the FASSET/EPIC approach and the ICRP reference animals and plants approach). In most cases, both the significance and the possible response to knowledge gaps will depend on the problem being addressed and the case in question. For example, uncertainties in radionuclide transfer and uptake might be less important in situations where models can be verified by sample analyses. For management, one may be able to live with large uncertainties if levels are well below those expected to cause adverse ecological effects. Finally, regarding regulatory action, the precautionary approach can offer a possible means of recognising and accounting for limitations in scientific evidence [Santillio *et al.*, 1998] [Stirling, 1999].

3.3 Group Discussions

3.3.1 Group 1

The group started by identifying and listing the main sources of knowledge gaps, see Section 3.2.2. Regarding overarching issues, the following areas were identified.

- “The largest uncertainty is uncertainty itself”. There was agreement that there is a need for a systematic estimate of uncertainties and gaps. There are methodologies for doing this (e.g. probabilistic assessment, parameter distribution functions). However, there has not been a detailed implementation, particularly for ERICA.
- There is also a need for a systematic evaluation of the sensitivity of the assessment results to specific uncertainties. This would provide a list of priorities.
- Uncertainties in this context include: data gaps, uncertainty caused by model assumptions and uncertainty in data (parameter) values.

Finally, some members are not convinced that the importance of knowledge gaps on assessment and management has been sufficiently well documented to justify experimental work. Others think it has, but are not in agreement that the most important knowledge gaps are being addressed. And some acknowledge that even though all knowledge gaps will not be filled, the experimental work in ERICA will contribute to help to fill some relevant gaps.

Conclusion: encourage ERICA Consortium to use a variety of systematic approaches to the identification of main knowledge gaps (statistical methods such as probabilistic and deterministic assessments, sensitivity analysis and "expert judgement").

3.3.2 Group 2

The group divided the issues into transfer, dose and effect. They considered what the knowledge gaps at the various stages were, but focused on their importance and how they might be resolved. A distinction was made between the relevance for the assessment stage (transfer, dose, effect analysis) and the management stage (policy, standards, regulation). For transfer, there is clearly plenty to do but it is less straightforward to see how one might go about doing it. For example, there is a need to consider migration and accumulation, under dynamic and equilibrium states. However, the real issue for risk assessment is the *consequences* of predicted or measured concentrations in environmental media. The basic gaps within dose and dosimetry calculations were deemed to be largely solved, or at least possible to solve. Effect analysis was considered to be the most important area, and the source of the major problems within ERA. For example, there is a need to go from individual to ecosystem level, and one could choose between ecological models and physics-chemistry-biology based models to achieve this. Nevertheless all extrapolations are "leaps in the dark". Thus there is a requirement for a clear methodology for the management of uncertainty (and bias in uncertainty estimates). In this respect there will be a difference in approach depending on whether one is aiming to demonstrate that exposures are below pre-defined limits or to assess the real impact of exposures. Finally, there is a need for an interim working assumption/paradigm (e.g. the FRED database), which in turn requires data on chronic and acute exposures for relevant dose rates.

4 Summary and Suggestions

4.1 Summary of Issues and Actions

A few preliminary observations and conclusions could be made to guide the ERICA project, based on the distributed material, discussions during the Event and the summarising of the briefing note.

4.1.1 Assessment Framework

	EUG Comments	Actions for ERICA
WP2	The risk characterisation stage may need to be further compared between different systems, there is a potential conflict between risk characterisation for radiation protection and risk characterisation performed elsewhere.	Comparison to be made in WP2 workplan.
WP1 and WP2	Be clear about potential differences in frameworks depending on whether top-down or bottom-up approaches are used.	ERICA extends the FASSET bottom-up approach. It is within the remit of WP2 to consider potential conflicts between the approaches.

	EUG Comments	Actions for ERICA
Entire project	The assessment framework must be able to deal with knowledge gaps.	The project focuses on dealing with knowledge gaps through extrapolation and a limited number of experiments.
	Develop a pragmatic approach to decision-making. Ensure that decision-making allows the precautionary principle to be applied when taking into account knowledge gaps and uncertainties.	WP3 to consider these points (e.g. introducing conservatism, precaution) in the development of the decision-making guidance.
	Some EUG background materials make consideration regarding decision-making.	WP3 to consider material and incorporate components in the decision-making guidance, if appropriate. ERICA to seek further information from those specific EUG members.
	Alternative approaches used for other stressors may also be suitable for use within the radiation field.	Engage closely with the EUG to identify and test such alternative approaches.
	Address the issue of having to be very generic in a European approach, while at the same time communicating with people affected by decision-making.	To be further discussed within ERICA and by engaging the EUG. Adopt potentially a non-prescriptive guidance approach to decision-making.
	Use the ERA as the central approach for further development of the ERICA integrated approach.	This is already within the ERICA work programme, but account has to be taken of the points made above.
	Continue with the dose-to-reference organism approach while maintaining an open mind towards alternative approaches.	Consider how the use of references organisms can be extrapolated to real species.
	ERICA talks about environmental "risk". What is the definition of risk, for the purpose of ERICA. Risk has a multitude of meanings in different contexts and for different users of the term.	To be decided.

4.1.2 Knowledge Gaps

	EUG Comments	Actions for ERICA
WP1	Source terms, transfer and uptake are all aspects where the information is patchy, and there are shortcomings in our ability predict environmental radionuclide concentrations both under dynamic and steady-state conditions. Further complicating factors arise from seasonality and chemical speciation.	Additional information relating to these data gaps to be provided, to the extent they are available or may be generated (e.g. within case studies. Advice on how to deal with the assessment in absence of data to be provided. The development of a practical tool (software) to take these points into account.
WP1 and WP2	Dosimetry: most of the calculation problems have already been resolved to a sufficient level. Refinement may be needed for organ doses and also for a scientifically justified approach to dealing with RBE.	The issues to be considered as parts of the work programmes for WP1 and WP2.

	EUG Comments	Actions for ERICA
Entire Project	Effects analysis is possibly an area where lack of knowledge greatly jeopardises interpretation of data. In particular, this concerns the extrapolation of data obtained for laboratory test organisms to field conditions on an ecosystems scale.	Extend the database within the programme of WP1. WP2 to consider the extrapolation issues, both theoretically and experimentally. Seek advice from the EUG to transform the information into decision-making guidance.
	A number of knowledge gaps have been identified within the various EUG background materials.	The project will consider and prioritise reported gaps, and address them where appropriate in each WP. A list of experiments will be proposed that could reduce some of these gaps. Seek further views from the EUG regarding knowledge gaps.

4.2 Suggestions for Next Two EUG Events

4.2.1 Assessment Frameworks

Thematic meeting, France

- Comparison of frameworks for radionuclide and other environmental stressors: specifically the assessment, characterisation and management stages. Include expert participation on, for example, EC environment directives; EU White Paper on Chemicals; OECD on socio-economic assessments.

Generic Consultation meeting, Germany

- Using the UK Sellafield case study as a basis, revisit the ecological risk assessment frameworks and ask which frameworks would have given different answers? What, why and does it matter?
- General review of this document (D7a-2), and production of a final briefing note.

4.2.2 Knowledge Gaps

Thematic meeting, France

- Main area of discussion: “Radiation and other Environmental Stressors” covering biological, ecological aspects; dose-response and effects analysis (including weighting factors and safety factors); risk characterisation and management.
- Review of the draft briefing note on “Radiation and other Environmental Stressors” (D7b) to be distributed prior to this EUG event.
- Review of the Risk Characterisation draft deliverable D4 from WP2. This includes systematic methodology for identification and managing uncertainties in risk characterisation and experimental design.

Generic meeting, Germany

- Stronger focus on the original objective of this exercise: based on a clear list of knowledge gaps prepared from the meeting discussions and previously submitted materials (i.e. D7a/b and other draft ERICA deliverables).

- Work further on the demarcation of the different types of knowledge gaps and uncertainties. Try to incorporate other expert judgement methodologies for assessing the orders of magnitude of various uncertainties.
- Review of the outline draft of D8 on decision-making guidance from WP3.

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Appendix 1: EUG Material requested prior to the Thematic Event

Background summaries

A one page summary on a suggested, specific topic was requested from each participant, without the knowledge of what the other EUG members were asked to prepare. The participants were also free to propose their own topics for discussion.

For the Assessment Framework material, ERICA suggested a consistent format so that the information could be more easily compared.

- Name (and synonym if relevant).
- History – Why was it developed? When? By who and for whom? To serve what purpose?
- Schematic breakdown – for example, general approach (ERA/EA/etc); ecosystems; species (including critical and/or reference entities); biological endpoints; model(s) used; assumptions; data input and output; treatment of uncertainties; site and case specificity.
- Approach to risk characterisation: e.g. comparison with set dose guidelines; NOELs; natural; background radiation.
- Links with risk management.
- Applications and experience.

Once the Consortium had received the background material, some clarifications and suggestions for revision were requested from the EUG members. Most EUG members provided those clarifications and additional information.

The final versions of the background summaries will be made available on the EUG protected Area of the ERICA website, following the event.

The following Tables list the various material requested by ERICA prior to the event.

Group 1: Assessment frameworks

EUG member	Material requested prior to EUG event
Jan Pentreath	ICRP summary
Kathryn Higley	US DOE summary
Arthur Johnson	Australian approach
Steve Mihok	Canadian summary
Simon Carroll	Precautionary approach
Tim Parker	Industry requirements: what does the framework need to provide?
Mary Clark	Comparison of ERA, PP and ecosystem approach
Didier Louvat	IAEA summary
Celia Jones	Summary from FASSET

Group 2: Knowledge gaps

EUG member	Material requested prior to EUG event
Jill Sutcliffe	What knowledge gaps are the public concerned about?
Francois Brechignac	IUR's view on knowledge gaps
Carmel Mothersill	What are the main knowledge gaps regarding bystander effects and genomic instability?
Nava Garisto	Experience from ERA in Canada
Neale Kelly	What do we know enough about already?
Brettania Walker	Overview of the main knowledge gaps from other environmental stressors

Appendix 2: Agenda for EUG event on Friday 7th May '04

0900-0930	Introduction to the day's work – Deborah Oughton
0930-1100	Group discussions
	Group 1 to discuss Assessment Frameworks (facilitator Deborah Oughton)
	Group 2 to discuss Knowledge Gaps (facilitator Graham Smith)
	Coffee
	Plenary report from the two groups, as well as additional views from Group 3
	Group discussions
	Group 1 to discuss Knowledge Gaps (facilitator Graham Smith)
	Group 2 to discuss Assessment Frameworks (facilitator Deborah Oughton)
	Lunch
1300-1330	Plenary report from the two groups, as well as additional views from Group 3
1330-1500	General discussion and drafting of meeting report and "briefing notes"

Procedural Notes

On the Friday, the EUG groups should be roughly divided into those with assessment framework application experience and those with something to say on knowledge gaps. The composition of each group is listed below. Here, ERICA members may join in the discussion groups. But it is important that the ERICA participants are in a minority in these groups, and also with more than 12 members the discussion won't be as focused.

Again, the groups should elect their own "chair" and "secretary" and Graham and Deborah should assume the role of rather "passive" facilitators, ready to help out the chairs and secretaries as needed, interrupting only to make sure that all voices are heard and if the discussion gets off track.

Both groups will get a chance to discuss both themes, but with more time for their "main expertise". The second group discussion should enable two groups to evaluate the other group's conclusions and make comments of their own. Graham will be minute-taker in the plenary sessions.

The EUG one page summaries should be handed in the day before, so that people will have had time to read them before the discussions on the day. The third group, consisting of ERICA participants, are to review the documentation and add comments into the plenary sessions. This documentation will help to give outsiders some insight into the basis of the group decisions. The one-page summaries should facilitate preparation of the final "briefing notes".

Participants to the EUG event on Assessment Framework and Knowledge gaps on the Friday 7th May '04.

Group 1 (facilitated by Deborah Oughton and Graham Smith, alternating)	
Name	**Affiliation**
Simon Caroll, *Secretary Assessment Framework*	Greenpeace international
Mary Clark	U.S. Environmental Protection Agency
Arthur Johnston, *Rapporteur Knowledge Gaps*	Australian Radiation Protection and Nuclear Safety Agency
Celia Jones	Kemakta Konsult AB
Kathryn Higley, *Rapporteur Assessment Frameworks*	Oregon State University
Didier Louvat	International Atomic Energy Agency
Steve Mihok	Canadian Nuclear Safety Commission
Tim Parker	British Nuclear Fuels Ltd
Jan Pentreath	International Commission on Radiological Protection
David Copplestone	ERICA Consortium
José-Maria Gomez	ERICA Consortium
Lynn Hubbard	ERICA Consortium
Carl-Magnus Larsson	ERICA Consortium
Gerhard Pröhl	ERICA Consortium
Per Strand, *Assessment Frameworks only*	ERICA Consortium

Group 2 (facilitated by Deborah Oughton and Graham Smith, alternating)	
Name	**Affiliation**
Kjell Andersson	Karinta Konsult
Frank Bruchertseifer	German Federal Office for Radiation Protection
Nava Garisto	SENES Consultants Ltd
Celia Jones	Kemakta Konsult AB
Neale Kelly	Independent expert
Carmel Mothersill	McMaster University
Jill Sutcliffe	English Nature
Brettania Walker	World Wildlife Fund, Arctic Branch
David Cancio	ERICA Consortium
Jacqueline Garnier-Laplace, *Knowledge Gaps only*	ERICA Consortium
Steve Jones	ERICA Consortium
Ulrik Kautsku	ERICA Consortium
Kristina Rissanen	ERICA Consortium
Irene Zinger	ERICA Consortium

Group 3	
Name	**Affiliation**
Kirsti-Liisa Sjöblom	ERICA Consortium
Leif Moberg	ERICA Consortium