



ERICA

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DELIVERABLE D7:

Summary of all ERICA EUG Events

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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.



Erica tetralix L.

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Project Coordinator: Swedish Radiation Protection Authority

Contractors:

Swedish Radiation Protection Authority	SSI
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Foreword

The ERICA project has acknowledged and supported the importance of stakeholder engagement in environmental policy making. In addition to including stakeholder involvement within the ERICA Integrated Approach, the ERICA consortium has consulted with a wide range of stakeholders (i.e., the End-Users Group) throughout the entire duration of the project. This report summarises the output of those consultations and gives a brief introduction to processes involved.

At the beginning of the ERICA project, as set out in the ERICA Technical Annex, an End-Users Group (EUG) was formed, with the following terms of references.

- To provide views, external to the ERICA Consortium, for the consortium to consider and incorporate into the ERICA framework.
- To attend a minimum of one ‘generic’ meeting of 2-3 days, plus at least one other more thematic, consisting of a smaller number of experts to discuss more specific assessment or managerial topics.
- To provide expert judgment on scientific and regulatory issues and to identify where further work is needed.
- To critically evaluate the applicability and acceptability of the framework developed within the ERICA project.
- To provide comment on ERICA’s draft deliverables.
- To disseminate project results to a wide range of other external end-users representing different views on the subject within Member States, within Candidate Member States, and internationally.

A total of 53 organisations and 60 people have participated actively in the EUG (Appendix 1). A number of EUG events were organised during the duration of the ERICA project, these included small thematic meetings (to discuss a specific issues) and generic events (Table 1). A variety of engagement procedures were employed, with the main aim being to facilitate two-way dialogue between the ERICA Consortium and the EUG. Consultation procedures used included focus groups, web-consultation and a consensus seminar. The EUG members were asked to contribute with their own experience, as well as to review ERICA outputs, and information was provided by ERICA through the website and newsletters. An overview of the various meetings is given below. After every event a publicly available deliverable report was produced, detailing the objectives and outcome of each event. These individual D7 deliverables (D7a-D7i) are available on the ERICA website (Table 2).

Time	Place	Thematic meetings	Generic meetings
2004	6-7 May	Sweden ASSESSMENT FRAMEWORKS <ul style="list-style-type: none"> • Experiences • Similarities and differences • Interaction with legislation and management SCIENTIFIC KNOWLEDGE GAPS <ul style="list-style-type: none"> • Experimental studies • Monitoring needs 	
	13-14 Sept	France IONISING RADIATION AND OTHER CONTAMINANTS Criteria and standards – comparison of different legislative frameworks <ul style="list-style-type: none"> • Reference animals and plants • Bands of concern/natural background 	





Time	Place	Thematic meetings	Generic meetings
2005	24-27 Apr	Germany	ECOLOGICAL RISK ASSESSMENT: CRITERIA AND STANDARDS <ul style="list-style-type: none"> Assessment and management frameworks Information needs Knowledge gaps and uncertainties Setting criteria and standards (endpoints, levels etc)
	29-30 Sept	Spain	DECISION-MAKING AND STAKEHOLDER INVOLVEMENT <ul style="list-style-type: none"> Stakeholder and public participation, Available methods EUG experience Aarhus convention Problems and guidance

Time	Place	Thematic meetings	Generic meetings
2006	27-28 Mar	Slovenia	SCIENTIFIC UNCERTAINTIES <ul style="list-style-type: none"> Dealing with uncertainties in practical management Extrapolation and safety factors Probabilistic risk assessment Precautionary principle
	27-30 Jun	Norway	CONSENSUS SEMINAR Critical review of the assumptions and limitations of the ERICA Integrated Approach
	14-15 Nov	Finland	MANAGEMENT, COMPLIANCE AND DEMONSTRATION <ul style="list-style-type: none"> Problem formulation and post-assessment decisions. Review of stakeholder web consultation
	8 Dec	Denmark	ERICA TOOL TESTING DAY Added event to test and improve the prototype of the ERICA Tool amongst end-users
Throughout the project	UK	LOCAL STAKEHOLDER EVENT Added event(s) to test the FASSET framework and the ERICA Integrated Approach on a real case scenario and local stakeholders	

To enhance transparency and accountability of the EUG process, a progress report was compiled that detailed the Consortium's decisions to address, or not, specific issues raised by EUG members either directly or during each EUG event. The progress report, updated regularly, has been available to EUG members on the EUG protected area of the ERICA website www.ERICA-project.org, and the final version of the progress report is included within this report in Appendix 2.

Feedback questionnaires were distributed during each EUG event, related to the procedures and running of each event. Based on the responses, the Consortium tried to improve the structure of the following events. On the whole the response from participants was positive and improved as the project progressed.





Finally, the ERICA Consortium wishes to acknowledge the inputs from all EUG members and to thank them for their valuable contributions throughout the whole duration of the project.

Table 2: EUG Event Deliverables.

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 Workplan. ERICA Deliverable D7a – Part 1. EC project Contract N°FI6R-CT-2004-508847.
D7a – Part 2	Oughton D, Zinger I, Bay I and Larsson CM (2004) First EUG Event - Part 2: Briefing notes on assessment frameworks and knowledge gaps. ERICA Deliverable D7a – Part 2. EC project Contract N°FI6R-CT-2004-508847.
D7b	Oughton D, Zinger I and Bay I (2004) Briefing Notes from The Second Thematic EUG Event Part 1: Ionising Radiation and other Contaminants and Part 2: Contribution to Deliverable D4 on Risk Characterisation. ERICA Deliverable D7b. EC project Contract N°FI6R-CT-2004-508847.
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.
D7d	Copplestone D, Zinger I and Oughton D (Eds) (2005) Transcript from the Third Thematic EUG Event: Decision-making and stakeholder involvement. ERICA Deliverable D7d. EC project Contract N°FI6R-CT-2004-508847.
D7e	Oughton D and Breivik H (Eds) (2005) Scientific Uncertainties: Transcript from the EUG Workshop. ERICA Deliverable D7d. EC project Contract N°FI6R-CT-2004-508847.
D7f	Forsberg ME and Oughton D (Eds) (2006) The ERICA Consensus Seminar. ERICA Deliverable D7f. EC project Contract N°FI6R-CT-2004-508847.
Consensus Document	Consensus Document (2006). EUG Event – Stavern June 2006. EC project Contract N°FI6R-CT-2004-508847.
D7g	Zinger I, Vetikko V, Sjöblom KL, Jones S, Hubbard L, Copplestone D, Michalik B, Prlic I and Momal P (2007) Summary of the EUG event on: Management, Compliance and Demonstration. Deliverable D7g. EC project Contract N°FI6R-CT-2004-508847.
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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I. D7a: First EUG Event

D7a Part 1: Discussion of ERICA Workplan

A first presentation focused on the transition from the FASSET project, which covered the impact assessment framework (i.e. from source term to assessing radiation effects in individual organisms) to the ERICA integrated approach, which will include risk characterisation, management and decision-making guidance. A general overview of the planned EUG meetings, their expected dates, locations and subject areas was also given.

Introduction

A general overview was provided for EUG discussion procedures for both the ERICA workplan and, briefly, the thematic meeting to take place the following day. The procedure for the first day was as follows.

Each WP leader gave a plenary presentation of the workplan, followed by short questions of clarification. Two breakout group discussions occurred during the day: the first to discuss WPs 1 and 2, and then WPs 3 and 4. For the ERICA workplan discussions, the EUG members were split into two groups, without ERICA participants. Both groups discussed all WPs. Following each breakout session, the groups reported their conclusions in plenary to ERICA participants, after which a discussion took place and further comments/questions from the floor were taken. For the thematic discussions, taking place the next day, the EUG and ERICA participants were mixed.

An important procedural point highlighted during the presentation was that the EUG breakout discussions were “closed”. *What* was said would be reported, but *who* said it would not. For this part of the dialogue, EUG members could chose to represent themselves or their organisations; EUG participants would not be permitted to attribute an opinion or information submitted by *another* participant during discussion.

Summary

The EUG provided a comprehensive evaluation of the workplans for the four ERICA Work Packages (WPs), submitting many useful comments and suggestions. Many of the inputs related to clarifications of the plans, largely to ensure that the ERICA project defines clearly its intentions and choices. While the FASSET Framework and the ERICA Technical Annex form an explicit basis for the work to be done under ERICA – and thereby set the boundaries to the proposed activities - it is clear that the choices made by the Consortium should be as transparent as possible. This means that ERICA needs to define the choices made and describe the rationale behind each decision, state clearly the assumptions and uncertainties in all parts of the project and above all do its best to be accountable to the EUG. Some of the main points made by the EUG, and the proposed action by the ERICA Consortium have been summarised in the following Table.

	EUG COMMENTS
WP1	Set boundary of assessment tool (e.g. work mainly from equilibrium state). Code development needs to be clearly stated
WP2	Define clearly the selected choices, supported by rationales for the choices.
WP3	Update EUG list regularly. Keep EUG informed of ERICA developments.





EUG COMMENTS	
WP4	Define clearly the purpose of the testing of the FASSET and ERICA methodologies on the case-studies. Timing is critical to WP4 success, and based on good interaction with the other WPs.
EUG	EUG inputs/responses/continuity lie with EUG members. EUG are welcomed to more than two meetings, at their own expenses in principle.

D7a Part 2: Briefing notes on assessment frameworks and knowledge gaps

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.

The output of these discussions fed into the larger EUG Generic Event in 2005, where participants were 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.

Summary and Suggestions

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.

Assessment Framework

EUG Comments	
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.
WP1 and WP2	Be clear about potential differences in frameworks depending on whether top-down or bottom-up approaches are used.
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. 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.





EUG Comments	
	<p>Continue with the dose-to-reference organism approach while maintaining an open mind towards alternative approaches.</p> <p>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.</p>

Knowledge Gaps

EUG Comments	
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.
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.
Entire Project	<p>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.</p> <p>A number of knowledge gaps have been identified within the various EUG background materials.</p>

Suggestions for Next Two EUG Events

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.

Knowledge Gaps

Thematic meeting, France

ERICA

(D7) Compilation of all EUG events contributions

Dissemination level: PU

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- 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.





II. D7b: Briefing Notes from The Second Thematic EUG Event

Objectives

This second EUG event had two main objectives:

1. to provide a general discussion on risk assessment and management of ionising radiation and other environmental stressors (i.e. Day 1); and
2. to review a draft of the ERICA project Deliverable D4 on “Risk Characterisation Methodologies” (i.e. Day 2).

This meeting, which was the second of a planned total of seven EUG events, consisted of EUG members, invited speakers and a limited number of ERICA Consortium participants, who represented all ERICA WPs. Those EUG members who previously expressed a wish to attend this meeting have been prioritised, but the meeting was also open to other EUG members, as space permitted.

This report, D7b, which summarises both presentations and group discussions, will help the ERICA project in producing guidance on how decision-makers and authorities might approach the assessment and management of radiation contamination, i.e. Deliverable D8 on “Decision-Making Guidance”.

D7b Part 1: Ionising Radiation and other Contaminants

Objectives

The purpose was to identify areas of consensus and dissent regarding the alleged similarities and differences in the assessment and management of ionising radiation and other stressors. The discussions on ionising radiation and other contaminants focused on a comparison of environmental stressors and their interactions, within three main themes.

1. Biological and toxicological effects:
 - a. biological effects of radioactive substances and other chemical stressors in the low dose range;
 - b. comparative environmental toxicology: towards an understanding of effects across levels of organization and complexity.
2. Dose-response models and risk characterisation:
 - a. assessing the environmental risks of radioactive substances - a comparison with approaches for non-radioactive substances;
 - b. the use of Species Sensitivity Distributions to derive predicted No-effect concentrations for stable chemicals. First applications to radionuclides and effects data from FRED;
 - c. quantification of environmental risks.
3. Management and socio-economic issues:
 - a. risk management: general comparison of regulation of environmental pollution; and
 - b. EC Chemicals Policy: from a European to a national point of view? Case study: the Water Framework Directive - is there an implication for radioactive contaminants?

Summary

Work on Day 1 generated a number of ideas, which could be investigated further. Some of the main points made by the EUG have been summarised in the following Table.

Table: Ideas and suggestions derived from the various discussions held.





	EUG COMMENTS
Biology and ecotoxicology	<ul style="list-style-type: none">• Summarise criteria for similarities and differences between chemicals and radioactive substances from cell to individual levels.• Revisit and examine in more detail the issue of dose modifying phenomena and synergistic effects.• Use of experiments and modelling as tools for extrapolation.• Use of other tools for extrapolation, e.g. biomarkers.
Risk assessment and risk characterisation	<ul style="list-style-type: none">• Which main parameter, e.g. effects, doses, concentrations, should be used to set standards?• Is there a difference between reference organisms and ICRP's reference animals and plants?• Are mammals the most sensitive species for all biological and/or ecological endpoints?• What criteria would form the basis for derivation of test species for radionuclides?• Select an approach to estimate risk that satisfy different stakeholder needs.
Risk management and socio-economic issues	<ul style="list-style-type: none">• Discuss whether the case has been made for regulation and control of radionuclides, and the role of ERICA within the risk management rather than risk assessment (i.e., scientific) aspects part of ERA.• Discuss socio-economic aspects, e.g. OECD report, which was due to be discussed in Aix, but speaker couldn't attend.• Decide on whether dose or/and concentration should be used as a basis for regulation (also stated above in risk assessment and risk characterisation).• Decide on how to treat background in the ERICA integrated approach.• Debate the advantages and disadvantages of relying on a single value vs a range/band of values.
Additional considerations	<ul style="list-style-type: none">• Agree on terminology, e.g. effect, endpoint, risk, harm.

D7b Part 2: Contribution to D4 on Risk Characterisation

Objective

WP2 has been working on their first deliverable, D4: "Critical Review on Methodologies for Risk Characterization and for Effects Testing Strategies", due to be published in March 2005. The WP Leader was to present their efforts to date, which centres on three areas:

1. D4 overall structure and content;
2. proposed tiered approach to risk characterisation; and
3. overview of plans for experimental work at NLH/NRPA and IRSN institutions.

Some of the material related to the above was circulated prior to the event.





Summary

Work on Day 2 generated a number of ideas, which could be investigated further. Some of the main points made by the EUG have been summarised in the following Table.

Table: Ideas and suggestions derived from the various discussions held.

	EUG COMMENTS
Interim ERICA tiered approach	<ul style="list-style-type: none">• Define benchmark• Draft a document related to benchmarks in relation to decision making situations for stakeholders to comment• Further develop the tiered-approach.

	EUG COMMENTS
Feedback questionnaire	There is a need to make more use of the ERICA website to improve visits and disseminate material prior to the events.
	Distribute material prior to event in time for people to read.
	Increase time for discussion.
	More focused presentations and topics to be addressed by the groups.
	Improve questions to better focus discussion





III. D7c: Transcripts from the First Generic EUG Event: Ecological Risk Assessment and Management

Overall Objectives

This first generic EUG event had three main objectives:

1. to summarise WP work and achievements to date;
2. to revisit past EUG events and actions for the Consortium, and
3. to discuss ecological risk assessment and management in the ERICA context, with an emphasis on how criteria and standards are derived.

This meeting was the first generic EUG event to which all EUG members were invited. A limited number of ERICA Consortium participants were also invited to represent each ERICA WP. The agenda for the whole Event is shown in Appendix 1, and the list of participants can be found in Appendix 2.

This report, D7c, which summarises both presentations and group discussions, will help the ERICA project in producing guidance on how decision-makers and authorities might approach the assessment and management of environmental radioactive releases and/or contamination, i.e. Deliverable D8 on “Decision-Making Guidance”.

Overall conclusions and recommendations

Following the EUG event, a special Management Group meeting has been called, to take place on the 27th and 28th June 2005, to address the comments from the EUG listed below, and if needed re-direct some of the work for the remainder of the project to accommodate EUG’s inputs.

EUG Comments	
WP1	<p>Finalise the list of radionuclides, and indicate where gaps exist.</p> <p>Use probabilistic modelling at Tier 3. Deal appropriately with uncertainties in all tiers.</p> <p>Reduce the number of ecosystems to three, but provide guidance for dealing with other ecosystems.</p> <p>Improve the ERICA tool according as indicated in Section 2, including uncertainty analyses, and indicate when it would and would not be appropriate to use it.</p> <p>Address extrapolation issues and impacts of chemicals in the tool.</p>
WP2	<p>The tiered approach is generally accepted as a way forward to develop the ERICA integrated approach, but certain issues must be addressed, e.g. it must be flexible to allow entrance at any tier; more guidance for Tier 3 in terms of stakeholder involvement, how to go back to earlier tiers or exit from Tier; address chemical assessment in parallel to the radioactivity assessment, perhaps as an appended set of tables for comparison purposes.</p> <p>Set the screening levels using the traffic light system, but justify the choice of the values.</p> <p>Use SSD as a method to characterise risk, but debate the 95 % range. Give added guidance to cope with special cases where species don’t fit in the range but need protection</p> <p>Give proper guidance to add credibility to the system.</p> <p>Agreement between predictions and observations depends on how close to the target you are; agreement is most critical at Tier 3. Guidance is therefore needed on how to deal with differences between predictions and observations.</p>





EUG Comments	
WP3	<p>Give extended definitions and examples of certain issues, e.g. DDC, uncertainties, as to help stakeholders and assessors understand difficult concepts.</p> <p>A clearer objective is needed for D8, with possible revision of its structure and title.</p> <p>Add “monitoring for verification purposes” into D8 skeleton.</p> <p>EUG have expressed an interest to be part of the process of setting questions in any future questionnaire designed by the project.</p>
WP4	<p>Ensure the ERICA guidance and outputs have a clear scope, are user friendly and transparent.</p> <p>Define the possible applications of the ERICA integrated approach.</p> <p>Provide different EUG members with the same case study to test at the same time as WP4 the ERICA integrated approach.</p>





IV. D7d: Transcript from the Third Thematic EUG Event: Decision-making and stakeholder involvement

Introduction

The meeting had three main objectives:

1. to provide general information on the nature of, and reasons for, stakeholder involvement in environmental policy making;
2. to determine the range of methods that may be employed and to establish which methods work well;
3. to determine how stakeholders may be involved within the ERICA integrated approach and in particular to provide input and advice on the issues that may be encountered, the options available to address these issues, identify particular procedures that may be employed at different stages of the integrated assessment and to highlight potential problems that may be encountered.

The meeting output summarised the presentations and the group discussions held during the meeting along with the background material provided by the EUG participants in advance of the meeting. The report has contributed to the “engaging with stakeholders” section within Deliverable D8, which is on “Decision-making guidance”. Stakeholder involvement will be a key component of the ERICA integrated approach that is being developed within the ERICA project.

Overall Conclusions and issues for ERICA to consider

It is evident from the range of EUG inputs that the extent to which stakeholders should or may be involved first depends on each country’s legal framework and then how each country's experience with stakeholders has evolved through trial and error. It is also important to recognise that the scale of stakeholder involvement should be appropriate to the size of the project/decision to be made at hand. How this fits with the ERICA integrated approach has been questioned as it is likely that the ERICA tool will be used within a wider environmental impact assessment process. Having said that stakeholder involvement within environmental assessment processes often does not specifically address the protection of humans, or biota. Some countries have already adapted the process of stakeholder involvement to address protection of biota from ionising radiation. It should be noted however that there are now legal requirements for engagement now. For example, for any environmental policy, the Aarhus convention would demand the provision of information to the general public as an absolute minimum of stakeholder involvement, i.e., that the general public is informed about the issues, the decisions taken and why, and that the information was freely available.

It was clearly recognised that stakeholder involvement is becoming more important nowadays and is already part of some regulatory frameworks. In general the direction and concerns of the stakeholders should be allowed to develop over time and it is important for ERICA to recognise that their interests may not specifically cover protection of the environment. The ERICA integrated approach should therefore allow for the assessor to choose whether or not to involve stakeholders. If chosen, then the ERICA integrated approach should provide guidance as to how stakeholder involvement may be approached and which methods would be the most appropriate at the different stages of the assessment process.

Given the wide range of methods that can be used for stakeholder involvement, from passive dissemination of information to extended engagement processes, there is a need to recognise that, whilst the process can be very productive, the time and resources involved in particular methods can be very demanding, so a balance must be reached.





While the definition of a stakeholder was generally accepted, it was clear that this was a term that could cause confusion. One of the most common misunderstandings is when the term stakeholder, or stakeholder engagement, is taken as being synonymous with PUBLIC consultation only (i.e. the provision and gathering of information with the general public); whereas other persons use the term to refer to non-lay people and the elicitation of expert opinion such as committee consultation or expert review. Furthermore, cultural differences may make it even more difficult to define and in some cases there is no translation of the word stakeholder. The meeting participants agreed that stakeholder can be defined as: *"anyone who has an interest in or considers themselves to have an interest in the issue and therefore it goes beyond "representatives" of groups to include "interested members of the public"*. It should be noted that stakeholders should also encompass those who are affected by a decision. The participants also agreed that stakeholder categories (additional to those who are affected by a decision) could be summarised as follows:

Hi influence/low interest e.g. civil servants	Hi influence/hi interest e.g. the developer/proposer, regulator
Low influence/low interest e.g. members of the public	Low influence/high interest e.g. local NGOs, protest groups

ERICA therefore needs to be clear that stakeholders can include a wide range of groups and that engagement can vary according to the group in question. Although extended stakeholder engagement needs not necessarily include the general public (bearing in mind that public participation methods are available). It was recognised that cost constraints may limit participation in extended procedures, and the question of representation and selection of participants needs to be addressed. Therefore ERICA could provide some guidance on the selection of stakeholders and appropriate methods to use.

A number of lessons have been learned by those engaging with stakeholders. Some of these are summarised below.

- Lack of trust may develop in public consultation processes that are very institutionalised (i.e. via regulatory regimes) and that leave very little room for flexibility. It is suggested that a better approach would be to engage the public initially in the design of the consultation processes prior to their implementation.
- Acceptance of both the process and eventual decision starts with getting all the relevant information together and making it available. It is therefore vital to ensure that information is widely available or can be made available if requested during the stakeholder process.
- A more complex interaction is now taking place among players at national, regional and especially at local levels as large industrial projects are highly dependent on siting and other local considerations, and a broader, more realistic view of decision making is taking shape.
- A keyword in the process is partnership i.e. lay out clearly what the benefits, both social and financial, of engagement are at an early stage to guarantee good faith and commitment. Gaining trust, especially for governmental organisations, is very important.
- Public consultation should be used not only for gaining acceptance but also so that the public can inform the decision-makers about their points of view and arguments. This should lead to better-founded decisions that are eventually more acceptable. It is therefore important, before beginning to involve stakeholders, to recognise how much influence the stakeholders can have in the assessment and the decision-making process.
- Assessments of real case studies are very helpful for formulating practically-applicable procedures for environmental protection from ionising radiation and other contaminants but it should be noted that the public's previous experience with nuclear installations may strongly influence the attitudes encountered.





- Understanding of people's values is of paramount importance, and should be articulated as early as possible. This will help to establish a long-term relationship between local communities and those putting forward the agenda.
- Frequently gaining the interest of those who are willing to co-operate and then to maintain that interest will build confidence and develop public support. It should be noted that public support could also be influenced by the provision of benefits for the community, with emphasis on maximising joint gains, which leaves them better off, but without compromising fundamental principles such as safety.
- There will always be dissension irrespective of the public consultation. Public consultation should not be aimed at gaining consent (this may be unrealistic) but at creating discussion of the different views, the results of which can be considered by the decision-makers.

Pulling this together suggests then that any stakeholder engagement within the ERICA integrated approach needs to consider when stakeholders should be engaged with, how they should be engaged with (and at what level) bearing in mind that there may be other wider stakeholder engagement processes ongoing associated with the planned development. The issues need to be identified and recorded. Early notification should be used to entice participation and thus allow potential stakeholders to identify themselves and their interest. In this way, providing a fair, open, continuous and patient process will help to develop trust, promote local acceptance and support for implementing the results and decisions made from the assessment process.

An assessor using the ERICA integrated approach may not consider that a full stakeholder/public consultation is needed for each and every assessment but there is a need to ensure that the assessment process is transparent and that all the necessary information has been provided and the justification of decisions made recorded. In this way, the question of stakeholder engagement may become how much and who should be involved within a given assessment. Flexibility would appear to be key to this approach. ERICA should provide some guidance on these issues.

There will always be dissension irrespective of the public consultation - thus the public consultation should aim not at gaining unrealistic consent but at creating diverse discussion with different views for the consideration of decision-makers. Understanding of people's values, and trying to illustrate by example, will help facilitate communication.

Implications for ERICA

A number of key issues for consideration within the ERICA integrated approach have been identified and are summarised as follows: ERICA should:

- provide definitions related to stakeholders involvement for the ERICA glossary;
- provide a list of stakeholders (e.g. Table 2.2) and reasons why they might be engaged with;
- provide a list of methods to involve stakeholders (it is suggested that this should be considered in relation to the tier at which the engagement is being used and/or the purpose of the assessment). It was noted that different tools may be required at different points in the engagement process and advice on their application should be provided;
- should give an overview of how to get the most from the stakeholder engagement process, e.g. what works and what to avoid;
- should consider problem formulation and how stakeholder engagement may be used to define what issues are to be addressed and what assumptions are to be made;
- consider the role of stakeholder engagement within the ERICA integrated approach and how this should be captured - generally there was agreed that ERICA should provide a mechanism for capturing the decisions regarding whether stakeholder engagement was required or not and to





provide an opportunity for the assessor to record in the assessment tool who should be involved, to what extent and what contribution can they provide.

- ERICA should consider the stakeholder processes (some required by national legislation) which will be occurring for other aspects of assessment of permissions for existing or planned licensed sites (to avoid duplicating effort) and should provide guidance on assessing the need for additional stakeholder engagement when considering biota assessments.





V. D7e: Scientific Uncertainties: Transcript from the EUG Workshop

Introduction

The aim of the workshop was to evaluate the various sources of uncertainty in evaluating the impact of ionising radiation on non-human species (data gaps, statistical variation, conceptual uncertainties, etc) and provide guidance on how one might deal with them in risk assessment. As background material, participants were asked to consult a number of documents in preparation for the meeting, including published ERICA reports (D4a and D5) and work in progress (the ERICA Uncertainty Spreadsheet and Assessment Tool Flowchart).

The workshop was divided into three sessions.

- Session 1 was a general introduction to types and sources of uncertainty in Risk Assessment and Management.
- Sessions 2 and 3 addressed uncertainties within the ERICA Tiered Approach and Assessment Tool.

Session 2 concentrated on the radionuclide transfer and dose calculation part of the assessment, whilst Session 3 focused on the uncertainties related to evaluation of the effects of exposures, including the derivation of benchmarks and relevance to the precautionary principle in risk management.

Recommendations for ERICA

The Uncertainty workshop stimulated a lot of discussions and views. Preferences by EUG members to what to include in the ERICA tool related to uncertainties have been recorded here. The ERICA Consortium will review suggestions and incorporate, as and if possible, some of the suggestions.

Comments directed at “Sources of Uncertainty” in the ERICA tool and the Uncertainty Spreadsheet

- It must be made clear to the users that ERICA has several types of intrinsic uncertainties and that some conservatism already is built-in to compensate for those. It is important that the user neither doubles the conservatism nor trusts the result too uncritically.
- Users require information on the sources, and at least the order of magnitude, of uncertainties in the assessment. There is a need for transparency and traceability in the way the tool deals with uncertainty and a justification of the choices and assumptions made in selection of model and parameters.
- There is a distinction to be made in the ERICA tool as to its usage: i.e. as a conceptual tool and as a computational tool. ERICA should address not only data issues (i.e. parameters and input data) but also the uncertainties inherent in the ERICA tool (i.e. model assumptions).
- Terms used in the uncertainty spreadsheet need more clarification. The distinction between uncertainty and variability should be included, and the term “data gap” should be replaced with “knowledge gap” where appropriate.
- Make the link clearer between the uncertainty spreadsheet, the assessment tool and the tiered approach illustration. A review of the content of the Uncertainty Spreadsheet was difficult at the workshop: deal with specific comments separately.
- ERICA should develop a framework or guide for uncertainty analysis: consider adapting the uncertainty matrix presented by Jeroen van der Sluijs.





The Tiered Approach

- Problem formulation and stakeholder involvement also need to consider uncertainties. For example the definition of the assessment context and object of protection has important implications for the way uncertainties are addressed. Stakeholders can influence the outcome of an assessment and the description of pathways and conceptual model needs justification of the choices.
- Make the difference between conservatism/pessimism, simplification and realism clearer. Realism increases from Tier 1 to Tier 3; the high degree of conservatism in Tier 1 means that uncertainty is not so relevant. There is a need however to avoid “double accounting of uncertainty”.
- Provide clarification on how to handle the basic uncertainties due to temporal change (in the ecosystems or in some compartments) during the period assessed, and due to locality (disparity between the areas evaluated/ influenced and the area of population spread).
- Consider revision of Tier 2 to make distinction from Tier 1 more obvious. For example, include sensitivity analysis, refined dose estimation and organism specific screening values.

Screening Values

- Identify data gaps associated with the estimation of the proposed screening values.
- Make clear the justification and assumptions behind the 95 % cut-off. For example does this mean that the screening level set at 5 % of species will certainly result in harm to those 5 % species? Or that we are reasonably sure that 95% won't be harmed (but not so sure about the other 5 %)?

Uncertainty in dose estimation and effects analysis

- Proper understanding of the basis of dose estimation in the FREDERICA database is necessary to ensure comparability with ERICA assessments. The database should be scrutinised for its ability to provide accurate information, and it must be made clear to users that much of the data have been produced for another objective.
- Uncertainty in the weighting factors is key to the comparison with FREDERICA database, most of which are based on external gamma, or X-ray photon irradiation. This includes non-uniformity of distribution between organs, which could have very significant consequences on the risk of effects. One option may be to work on the basis of unweighted doses, but still separate out the three dose components and take specific account of localisation.
- Clarification is needed on the applicability of the ERICA integrated approach to retrospective or prospective assessments.
- Many of the uncertainties reflect unreliability/ignorance. We do not know that the approach is complete because of the biological uncertainty – multiple stressors, trans-generational effects, delayed and non-targeted effects. This is valid for non-radioactive as for radioactive assessments. “We know we don’t know” needs to be appreciated in the assessment. These kinds of uncertainties cannot be dealt with by probabilistic risk assessment. The ERICA approach cannot reliably conclude a negative effect. This needs to be emphasised to end-users.

Management and Precautionary Principle

Application of the Precautionary Principle is a matter for decision-makers not for the ERICA integrated approach itself. The ERICA integrated approach must be absolutely clear about where, why, how and to what extent conservatism has been included – so that decision-makers do not take the ERICA output and apply further precaution, and un-knowingly double-count the degree of conservatism/precaution, in their decisions.





VI. D7f: The ERICA Consensus Seminar

Introduction

The aim of this Seminar was for the EUG to agree and formulate a position paper on the implications of some assumptions and limitations within the ERICA approach, and to provide recommendations for the ERICA Consortium. This was achieved through a critical and focused evaluation of the ERICA integrated approach, highlighting strengths and weaknesses and identifying areas of consensus and dissent, as well as exploring reasons behind disagreements. The intention was to improve the robustness and reliability of the ERICA approach and its usefulness to end-users. While the goal of the seminar was to reach consensus, this was not a requisite.

Discussions were divided four subject areas:

- 1) Reference Organisms;
- 2) Dose-Effect Evaluation;
- 3) The Assessment Tool; and
- 4) Management Issues.

As background reading, a document was prepared compiling material from previously published ERICA deliverables, including a number of comments and recommendations made at previous EUG events.

Consensus Statements

The consensus statements draw on the main areas of consensus from the above group discussions. These were the areas agreed upon by the EUG in plenum – with only slight revision for consistency following the plenary session. In large the level of agreement in plenary was rather good, with the majority of revisions reflecting language and terminology. The following chapter (Chapter 7) summarises these points into the key recommendations for the ERICA Consortium.

Reference organisms

Compatibility of the ERICA approach with ICRP recommendations

The reference organism concept used within ERICA should be compatible with the ICRP framework, for good pragmatic and scientific reasons. However, the broader range of reference organisms in ERICA should be retained. The scientific independence of the ERICA project and radiological research in general, can add value within the processes of ICRP and the wider radiological protection organisations.

Representation of protected species by reference organisms

The term reference organism refers to a generic concept, which could be applied to protected species with appropriate parameter selection. The application of reference organisms to protected species needs testing. The reference organism concept is individually focused using reference values and does not fully capture ecosystem dynamics. The reference organism concept needs to be communicated carefully.

Compatibility of the reference organism concept with the approach used in chemical assessment

The use of the reference organism concept is compatible with the approach used in chemical assessments, and the approaches should become more similar given further development. We envisage a future state with a high degree of compatibility between the systems, but this does not imply that they will be identical (for instance with respect to metabolism and dosimetry). The overall ERICA





integrated approach has considered the principles used in chemical risk assessment throughout its development.

Reference organisms as a basis for the estimation of dose rates

Reference organisms provide a good model for whole body dosimetry. Further consideration of internal heterogeneous distribution of radionuclides is needed.

Dose-effect evaluation

The appropriateness of using the RBE data available for non-human organisms as the basis for formulating weighting factors

Where Relative Biological Effectiveness (RBE) data are available for non-human organisms, the data are highly appropriate for the formulation of weighting factors. However, RBE data are not available for a sufficiently wide dose range, range of organisms, life stages and endpoints. RBE values are mainly available for mammals. RBE is a specifically defined concept whilst the weighting factors are not exclusively derived from RBE data. Where population effects are used as endpoints for biological protection, the most appropriate basis for RBE determination is experience on deterministic effects and cell death. RBE values for alpha emitters need to address differences in biological endpoints, in tissue sensitivity and non-uniformity of radionuclide distribution within the organism.

Sources of uncertainty: absorbed dose compared to transfer factors and concentrated ratios

Dosimetry (estimation of absorbed dose) is the least uncertain part of the ERICA assessment methodology. There are some uncertainties that arise from the fact that internal distributions of radionuclides are not uniform, for example, dose to specific organs and tissues may be more important than dose to the whole body. These uncertainties are being addressed by the ERICA integrated approach. The variability and uncertainty in the transfer component of the ERICA assessment methodology is greater than in the dosimetry component.

Adequacy of the FREDERICA database for the assessment of ecological effects

There are insufficient direct data within the FREDERICA database for assessing ecological effects, which limits the scope of the assessment. However, this does not undermine the possibility of deriving benchmarks for ecological risk assessment, provided additional data are supplemented. The benchmarks are not derived from the current ecological effects data, but are based on mortality, morbidity and reproduction endpoint data, which are population relevant.

The basis for evaluation of the impact of radiation exposure: effects of individual organisms versus predicting population consequences

Given the database available, effects on individual organisms may form the initial basis for evaluation of the impacts of radiation exposure of the ecosystem. It is important to gain information about endpoints such as reproduction that could influence the population dynamics. Where protection of the population is the objective, extrapolation from effects on individuals to a population is necessary, but may not be straightforward.

Assessment tool

Conservatism within the ERICA tool

In response to uncertainty there is adequate conservatism built into the ERICA tool, but the way this is done needs to be transparently documented and the assumptions recorded. In the early tiers conservatism is preferred to the possibility of a false positive and the conservatism is gradually replaced as the user inputs site-specific data. The ERICA Consortium, and others, should test the tool further to see whether there is an appropriate balance between conservatism and realism at the screening tiers.

Treatment of prospective versus retrospective assessments within the ERICA tool





The ERICA tool can be applied both to prospective and retrospective assessments. The data requirements will vary for the two situations (for instance site-specific data in the retrospective case) and this should be identified in the problem formulation. Uncertainties will increase when applying the tool to very long term prospective assessments and therefore caution is appropriate when selecting parameters. Quality of input data may limit the reliability of retrospective assessments.

Use of probabilistic analysis to account for uncertainty in the risk assessment

There will be probabilistic analysis and sensitivity analysis in ERICA to account for uncertainty. As much as this is appreciated there are other ways to address uncertainty, which should be considered by the ERICA Consortium. Probabilistic analysis is “data hungry” and difficult to explain, but may be more environmentally realistic.

The adequacy of the risk quotient as an indicator of environmental risk

The risk quotient is an appropriate and simple indicator of environmental risk for screening purposes. It is easy to understand and simple to explain. The ERICA integrated approach needs to make clear to users that there is a slight difference in calculation in its use in Tiers 1 and 2, and that the risk quotient is not intended to be used in Tier 3.

Management issue

Harmonisation of the general principles for management of the protection of the environment for all contaminants

General management principles should be harmonised for all contaminants including radioactive substances, leading to a ‘multi stressor’ approach in the future. However, implementation will vary. There should be a general aim to develop a common best practice, and not adopt inappropriate principles in radioecological management. The ERICA project should make these principles explicit for its own purpose.

Application of the precautionary principle

The precautionary principle does not necessarily imply zero release or zero exposure.

Application of the precautionary principle is mainly a matter for decision-makers. However, precaution is incorporated in the ERICA integrated approach. ERICA should specify how the precautionary principle could be applied in the management scheme.

Stakeholder involvement in ecological risk assessment

The involvement of stakeholders in ecological risk assessment and management is a welcome development (e.g. EUG). There is a need for a critical evaluation of objectives and procedures for stakeholder involvement. ‘Stakeholder fatigue’ and duplication of processes should be avoided. A high level of transparency and traceability is desirable.

The need for internationally agreed dose limits for protection of non-human species

There is a need for international harmonisation in the area of environmental protection. This might be achieved through less restrictive instruments than dose limits. Internationally agreed ‘no effect’ or exemption levels in combination with generic assessment guidance might be sufficient. Having harmonised approaches may facilitate interaction with stakeholders and addressing trans-boundary effects. Regional flexibility, which allows the setting of more stringent standards, is important.

Recommendations for ERICA

Reference organisms

The reference organism concept and approach do not fully capture ecosystem dynamics and the limitations need to be recognised and stated clearly.





Dose-effect evaluations

Issues related to heterogeneous internal distribution of radionuclides in the body should be considered further.

Assessment tool

The ERICA Consortium should test the tool to see whether there is an appropriate balance between conservatism and realism at the screening stages.

Management

There is a need for a more critical evaluation of objectives and procedures related to stakeholder involvement, and 'stakeholder fatigue' and duplication of processes should be avoided.

In general

It is essential that the ERICA integrated approach bases its judgements on scientific data and societal input. ERICA needs to maintain transparency and quality assurance concerning its publications, methods, terminology, assessment tool, data, uncertainties and assumptions. An example is that the ERICA software of the assessment tool should be dated, so that any relevant changes can be tracked.

Glossary

During the plenary discussion a number of terms were highlighted as being important to include in a glossary, including the following terms.

It was agreed that the existing ERICA glossary, to be published in the D-ERICA final report, would be checked for those selected terms, and items either added or revised.





VII. D7g: Summary of the EUG event on: Management, compliance and demonstration

The meeting represented the fifth and last thematic EUG event to take place before the ERICA project comes to a close in February 2007.

The overall objective of the event was to clarify the process of integrating an environmental assessment with a management decision. The focus was on two areas of decision-making, which underpin the ERICA integrated approach, as illustrated in Figure 1 below.

1. Problem formulation, which can be defined in the Ecological Risk Assessment (ERA) paradigm as the first step of any risk assessment intended to identify the context and purpose of the assessment framework. This should include ecological, political and societal issues related to questions being addressed, and integrate the process of choosing appropriate assessment endpoints, identifying sources and describing the environment.
2. Decision-making post assessment, or in other words: what options are there once you have the results of the assessment?

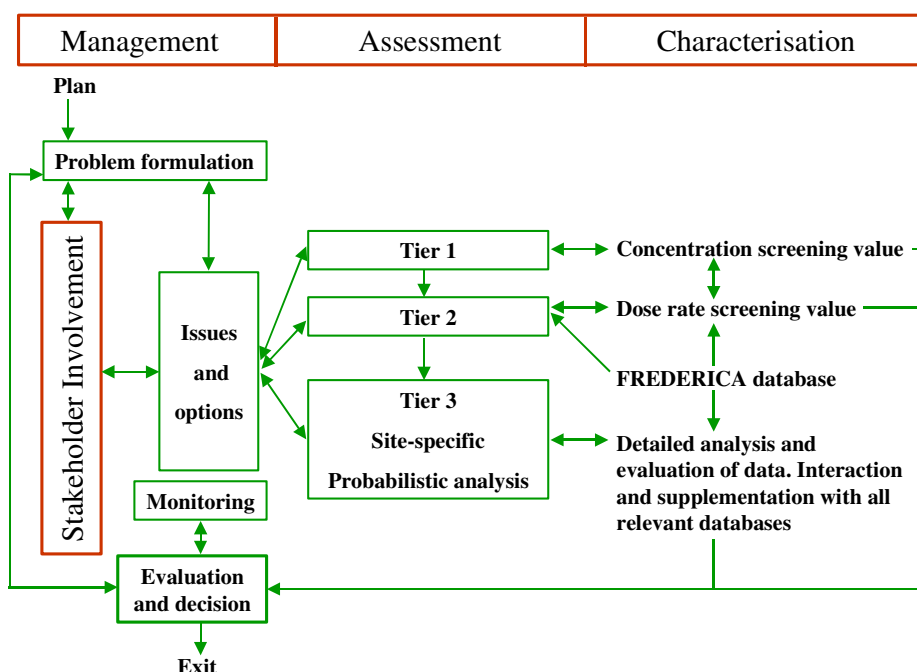


Figure 1. Overview of the ERICA Integrated Approach, outlining the interaction between assessment, risk characterisation and management (as amended following the EUG event).

Another objective was to help review and input into the D-ERICA, i.e. the final deliverable that describes the ERICA integrated approach. For this purpose the current draft of sections on problem formulation and decision-making post assessment were distributed prior to the meeting.

The Consortium was seeking EUG members with management experience in terms of: protection of human and or biota from radiation, or/and protection of humans and / or other species from chemical contaminants. Therefore Work Package 3 targeted this small thematic event to bring together both regulators and operators.





The event was prompted by the result of the web-consultation, which took place in October 2006.

Goals of the event

The one and a half day event was divided into three sessions, with set goal for each:

- Session 1: Results from the web-consultation
 - Goal: Focus discussions on areas of difference of opinions
 - Method: Presentation of results followed by parallel sessions to consider findings and then by plenary to report findings.
- Session 2: EUG experiences
 - Goal: Capture any extra information not already addressed.
 - Method: Presentations by End-Users followed by parallel sessions to complement experiences members from each group using the received summaries. Plenary to amalgamate different views.
- Session 3: D-ERICA
 - Goal: Quality check that the aspects of the document are practical and useable.
 - Method: Brief summary of what is in the draft, then discussion on EUG expectations followed by a plenary to summarise views.

Conclusions

A total of 19 EUG members answered the web-consultation. However some respondents skipped several questions as they felt the questions were not appropriate or that they did not feel they had the relevant expertise or experience. For this reason questions during the event were aimed at clarifying some of these points.

Session 1

The group suggested that “emergency situations” in the ICRP exposure situations should be replaced by “post-emergency situations”, and that the purpose of biota assessments in this situation. This was explained by the fact that in an acute emergency action will be taken primarily to protect the human population. Changes in the phrasing of some of the text within problem formulation should be addressed.

Session 2

The ERICA Integrated Approach needs to be able to deal with the impact of NORM / TENORM through the provision of underpinning data for naturally occurring radionuclides which should be included in the assessment tool.

Numerical criteria of some form are needed, but there was no consensus on exactly what form these numbers should take or what they should be called. Observation of the ecological status of a potentially affected site is an important adjunct to any assessment based on numerical dose or radionuclide concentration criteria. A potential way forward might be for the EC to issue a guidance, rather than a legal, document, e.g. a Directive. Units should also be specified. Some of these points, will be passed on to the EC project PROTECT - Protection of the Environment from Ionising Radiation in a Regulatory Context, see www.ceh.ac.uk/protect.

Session 3

Decision-making post assessment should be renamed decision-aiding.

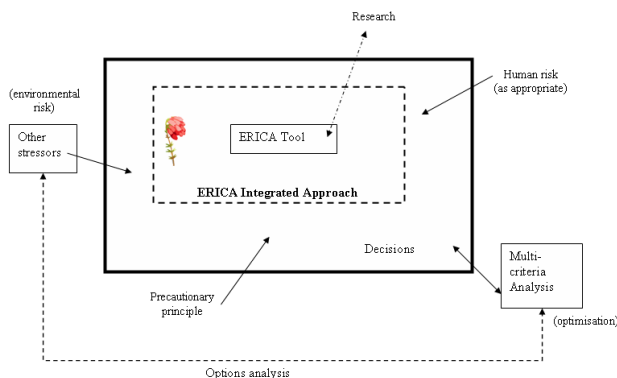
A specific sub-section of D-ERICA should be dedicated for Tier 3 at the problem formulation giving a reminder of what the results are from the tool. Special explanation/guidance of how the benchmark could be determined would also be useful to inexperienced users.





Once an assessment is done, it should be noted that reviewing the problem formulation and the chosen assessment criteria can help increase the confidence in the interpretation of the assessment results.

Problem formulation and decision-making post assessment are closely linked and a number of external factors to the assessment will dictate the context/purpose of the assessment, as illustrated below.



ERICA = Risk of Radioactivity on the environment (non-human biota)
- individual
- population
- non-living environment } extrapolation

Illustration of factors affecting decisions – not exhaustive

The majority of ERICA recommendations from the groups will be implemented in both the D-ERICA and the D8- “Considerations for applying the ERICA Integrated Approach” document, to be published in early 2007.

Globally, feedback of the event was positive and answers more positive than the feedback questionnaires of previous events.





VIII. D7h: Summary of the EUG Tool Testing Day

Introduction

A one-day workshop dedicated to testing the ERICA integrated approach, i.e. the ERICA assessment tool prototype and the draft deliverable D-ERICA, was held on the 8th December in Copenhagen, as it was concluded during the September Consortium workshop that:

- EUG members find it difficult to squeeze in time for testing the ERICA Assessment Tool in their normal working environment; and
- the prototype tool, as provided since June 2006, did not have in-built guidance in the form of help files, making it difficult to use fully.

Consortium and targeted EUG members spent the day testing and providing comments on the ERICA Assessment Tool and the draft Deliverable D-ERICA using two scenarios. People from the IAEA EMRAS biota Working Group (BWG) were also approached due to their known technical expertise in tool testing.

On the day, all EUG members were asked to use the scenarios as examples and to:

- navigate through the tool
- refer to D-ERICA for further guidance
- Make use of the FREDERICA database if needed
- report bugs as they went along
- provide feedback on use of the tool and accompanying guidance.

Conclusion

The day was very successful for the Consortium, as it provided valuable inputs into the process of using the ERICA assessment tool and its guidance. Note that all EUG actions identified are to be implemented within the tool, except for the future improvements.

It became clear during the day that people prefer to use the in-built help guidance, rather than the D-ERICA. As a result, D-ERICA would be revisited and modified. D-ERICA will now focus more on the overall principles, while the in-built help guidance will provide more information on reasoning and assumptions related to the use of the ERICA assessment tool.

A small editorial group met in January 2007 to finalise D-ERICA following interaction with the Consortium to take on board the above modification of emphasis.





IX. D7i: Local Stakeholders Event

The UK case study has considered semi-natural coastal (dune and saltmarsh) and agricultural ecosystems in the vicinity of the Sellafield reprocessing plant, Cumbria, UK. The study has involved a group of local stakeholders with an interest in the sites. The aim of involving stakeholders was twofold; firstly to investigate how input from stakeholders could most usefully be integrated into the assessment process, and secondly to elicit feedback as to the overall credibility and acceptability of the assessment process to an interested and well informed group of lay people. This note summarises the work to date, key outputs and learning points.

Two case studies have been conducted on the site. The first (Phase 1), conducted in late 2004 and early 2005, applied the methods and data developed by the FASSET project, with the principal objective of identifying gaps and uncertainties that needed to be addressed during the course of the ERICA project. The second (Phase 2), conducted in early 2007, had the principal objective of testing the ERICA methodology and tool in application to a site for which conservation interests are an important consideration.

Timescales for the Phase 2 case study were compressed by delays in the completion of the ERICA tool, and the processes used for stakeholder engagement in this second phase needed to be adapted as a result. Consequently this summary is presented as a sequential narrative, describing the process as it developed in parallel with the scientific work of the ERICA project.

Reflections and learning points from the exercise

- The involvement of stakeholders has been beneficial both in assisting with site characterisation and providing a lay perspective on the whole assessment process.
- Involvement of this kind should lead to much greater acceptance of the findings from a 'real assessment'.
- Some of the most useful outputs can emerge from discussions which deviate from the expected agenda; 'structured flexibility' is needed. Flexibility is also needed to accommodate timing issues in the project overall (e.g. Phase 2 in this exercise).
- The time demands of involving stakeholders are substantial and should not be underestimated; it is necessary to produce a substantial amount of briefing material and correspondence; simply keeping in contact, arranging meetings, and securing comments can be very time consuming; there are significant extra demands in terms of presentation and report writing.
- Stakeholders are being asked to give their time voluntarily; particularly where this is not part of their normal professional duties efforts need to be made to generate enthusiasm for engagement and the assessment team need to ensure that participation is made as easy as possible. Stakeholders suggested that making a series of presentations to potentially interested groups, or holding public meetings, to publicise a project such as this would generate more general interest as a pre-cursor to engagement by individuals.
- A review of the recommendations made during the Phase 1 engagement indicates that virtually all of the recommendations that could reasonably be addressed either generically by the ERICA methodology or specifically during the Phase 2 case study re-assessment have been adequately addressed. Recommendations could perhaps be highlighted as useful suggestions to those undertaking a 'real' site assessment; they could not be addressed within the scope of the ERICA case studies.
- Recommendations concerning explanation of the approach to lay people have not as yet been adequately addressed. One clear conclusion from the Phase 2 experience reported here is that the ERICA methodology is complex; considerable thought is needed when trying to explain it





clearly and concisely to an audience of non-specialists. Individuals with a good knowledge of the ERICA methodology should be able to do this, but more help in the form of pre-prepared material would be very useful.

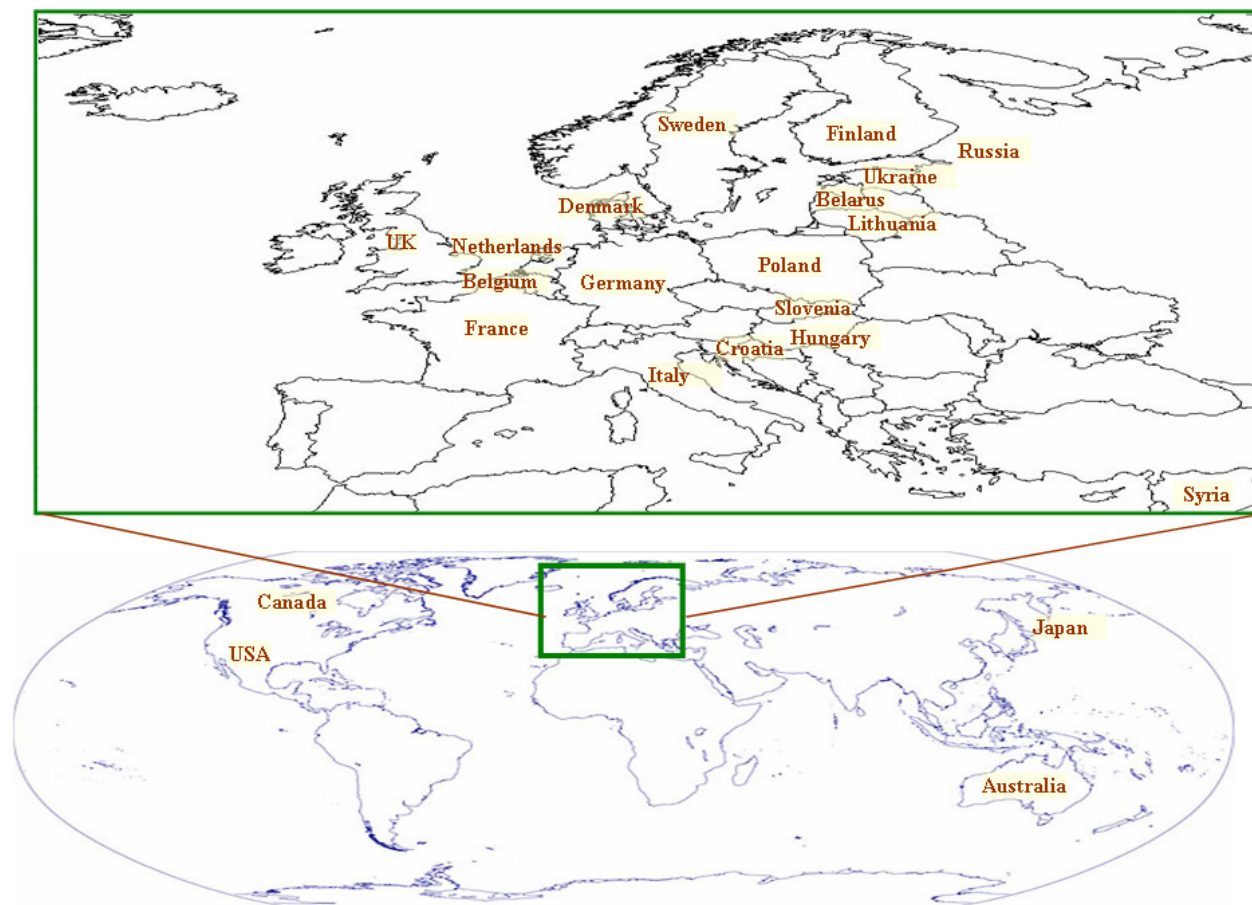
- Finally, it is worth re-iterating the comment made about ‘trusting the experts’. Although it may be time consuming to do so, engaging openly and face to face with individuals who have an interest in the site being assessed is, ultimately, the best way of building trust and laying the foundation for co-operation. In this case engagement undoubtedly helped Liverpool University secure the permissions needed for sampling on a sensitive conservation site.





APPENDIX 1: List of all EUG members

ERICA End-Users Group (EUG)



Internal Organisation	Participant
European Commission	George Neale Kelly
European Commission	Eberhardt Henrich
Greenpeace International	Simon Carroll
International Atomic Energy Agency	Mikhail Balonov Didier Louvat Rodolfo Cruz Suarez
International Commission on Radiological Protection	Lars-Erik Holm Christian Streffer
International Union of Radioecology	Francois Brechignac
Nuclear Energy Agency	Edward Lazo
United Nations Scientific Committee on the Effects of Atomic Radiation	Malcolm Crick
World Nuclear Organisation	Sylvain Saint-Pierre
World Wide Fund for Nature, Arctic Branch	Brettania Walker





Country	Organisation *	Participant
	* Members who registered but didn't participate actively, as in the terms of references.	
Australia	* Australian Radiation Protection and Nuclear Safety Agency	John Loy
Australia	Department of Environment and Heritage	Arthur Johnston
Australia	Australian Nuclear Science & Technology Organisation (ANSTO)	John Ferris
Belarus Republic	International Sakharov Environmental University	Golubev Alexander
Belgium	Centre d'Étude de l'Énergie Nucléaire (SCK-CEN)	Hildegarde Vandenhove Geert Olyslaegers
Canada	Canadian Nuclear Safety Commission	Patsy Thompson Steve Mihok Guy Riverin
Canada	SENES Consultants Limited, Risk and Radioactivity Studies	Nava Garisto Douglas B. Chambers
Canada	McMaster University Medical Physics and Applied Radiation Sciences Unit	Carmel Mothersill
Canada	Atomic Energy of Canada Limited	Sohan Chouhan Tamara Yankovitch
Croatia	Institute for Medical Research and Occupational Health (IMI)	Ivica Prlic and Lady Sanja-Milkovic Kraus
Denmark	Risø National Laboratory	Sven P Nielsen
France	Commissariat à l'Énergie Atomique (CEA)	Marianne Calvez Valérie Moulin
France	Agence Nationale pour la gestion des Déchets Radioactifs (ANDRA)	Lise Griffaut
France	COGEMA-AREVA	Patrick Devin
France	Nuclear Safety Authority (ASN)	André Jouve
France	Ministère de l'écologie et du développement durable	Eric Vindimain
Finland	Posiva Oy	Ari Ikonen
Finland	Ministry of the Environment	Miliza Malmelin Jaana Pennanen
Germany	German Federal Office for Radiation Protection (Bfs)	Christine Willrodt
Germany	University of Duisburg-Essen Institute for science and Ethics	Christian Streffer
Hungary	Public Agency for Radioactive Waste Management (PURAM)	Peter Ormai
Hungary	University of Veszprem, Department of Radiochemistry	Bela Kanyar
Italy	University of Milan and National Institute of Nuclear Physics	Marie Claire Cantone
Japan	National Institute of Radiological Sciences	Doi Masahiro
Lithuania	Radioactive Waste Management Agency (RATA)	Stasys Motiejuna Vitold Filistovic
Netherlands	VROM Ministry of Housing, Spatial Planning and the Environment	Theo Klomberg
Netherlands	Utrecht University Copernicus Institute for Sustainable Development and Innovation	Jeroen van der Sluijs
Norway	* Institute for Energy Technology	Gordon C. Christensen

ERICA

(D7) Compilation of all EUG events contributions

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Country	Organisation *	Participant
	* Members who registered but didn't participate actively, as in the terms of references.	
Poland	Central Laboratory for Radiological Protection Department of Radiation Hygiene	Pawe Krajewski Michalik Boguslaw
Russia	SPA "TYPHOON"	Tatiana Sazykina
Russia	Russian Institute of Agricultural Radiology and Agroecology, Head of Plants Ecotoxicology Laboratory,	Stanislav A. Geras'kin
Slovenia	Institut Jozef Stefan - Energy Efficiency Centre	Branko Kontic
Sweden	Kemakta Konsult AB	Celia Jones-Johansson
Sweden	Karita Research	Kjell Andersson
Syria	* Atomic Energy Commission of Syria	Riad Shweikani
UK	The Centre for Environment Fisheries and Aquaculture Science (CEFAS)	Kins Leonard
UK	University of Reading	Jan Pentreath
UK	Institute for European Environmental Policy	Andrew Farmer
UK	University of Oxford	John Holmes
UK	Natural England	Jill Sutcliffe
UK	British Nuclear Fuels, (BNFL)	Tim Parker
UK	Scottish Environment Protection Agency	Paul Dale Ian Robertson
UK	Enviros	Carol Robinson
Ukraine	International Radioecology Laboratory	Sergiy Gashchak
Ukraine	* State Nuclear Regulatory Committee of Ukraine	Dr Ryazantsev
USA	Oregon State University	Kathryn A. Higley
USA	United States Environmental Protection Agency (US EPA)	Mary Clark
USA	Savannah River Ecology Laboratory (SREL)	Tom Hinton
USA	Argonne National Laboratory	Sunita Kamboj
USA	U.S. Department of Energy (US DOE)	Stephen Domotor Ernest Antonio
USA	US Nuclear Regulatory Commission	Tim Harris Donald Cool Gregory Suber





UK Local Stakeholder Organisations (D7i)

Organisations from which stakeholders were drawn:

Ravenglass Coastal Partnership
National Park Authority
Landowners
National Farmers Union
English Nature
Cumbrian Wildlife Trust
Herpetological Conservation Trust
Parish Councils
District Councils
Environment Agency (not involved in ERICA)
British Nuclear Group
Nuclear Decommissioning Authority
UK Nirex Ltd
Nuclear industry supply chain





APPENDIX 2: EUG inputs and resulting ERICA actions

This document summarises information collated by the ERICA Consortium from a number of sources, including:

- information exchange during EUG events;
- Consortium actions derived from minutes of meetings;
- specific queries requested by WP leaders to EUG members, e.g. via the e-newsletter;
- Stakeholder queries received via the ERICA information e-mail; and
- EUG queries received via the dedicated EUG e-mail.

Table 1 extracts from ERICA deliverables the various actions which the Consortium agreed to address, and records when each action was taken. For example, one of the first EUG's request was for the ERICA Consortium to illustrate how information provided by them would influence the project. Figure 1 illustrates this point, and the information was placed on the ERICA website, within the EUG Area.

Due to continual updating this current report has functioned as a working document throughout the ERICA project, and has been updated regularly to show how the ERICA Consortium interacts with external stakeholder interests in the project. At the end of the project, the information collated here was incorporated into the required EC report on: Summary of activities according to the Consortium Action.



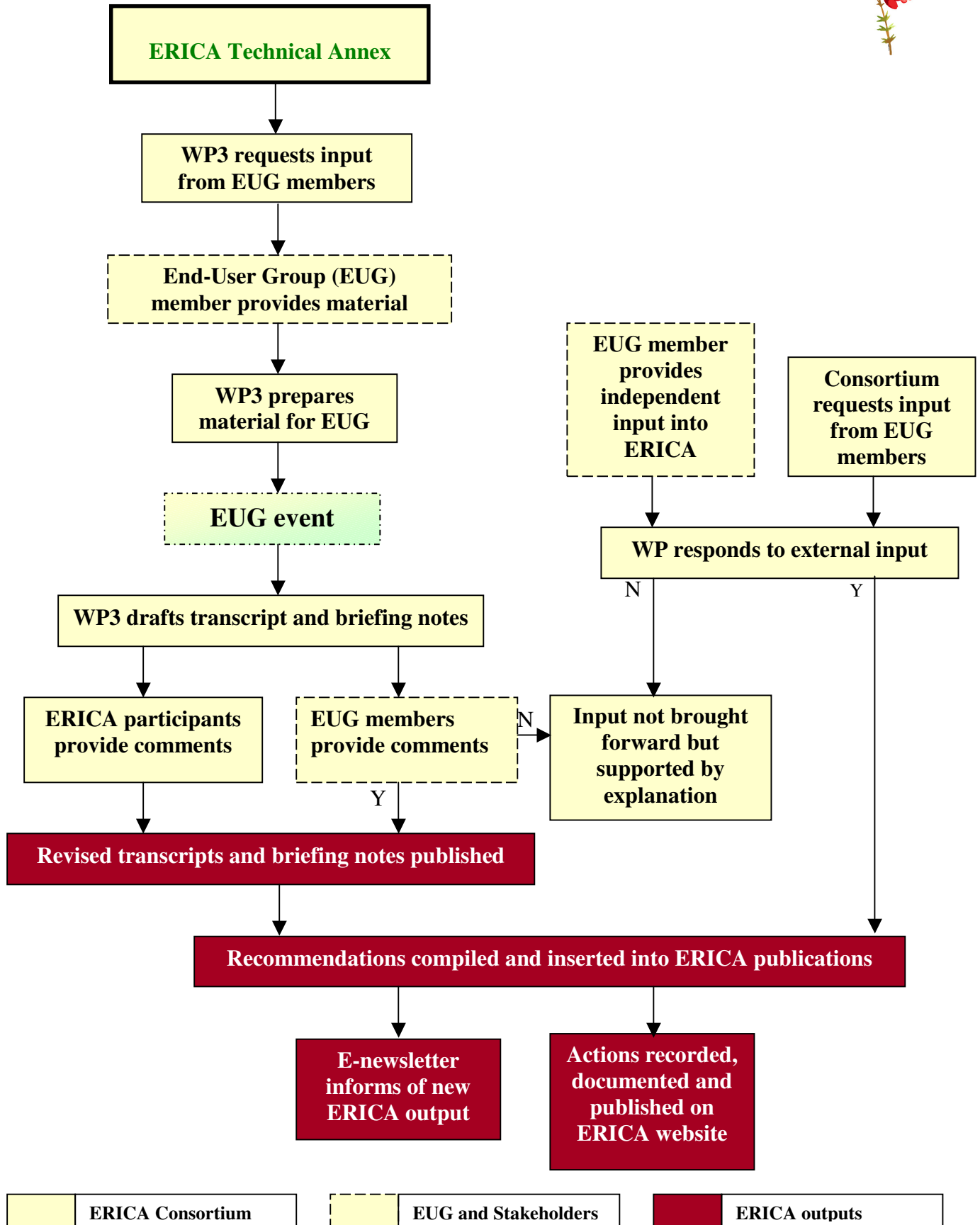


Figure 1: Flowchart illustrating the way information from external stakeholders (mainly the EUG) is dealt with within ERICA





Table 1: Summary of EUG queries, ERICA actions, and recorded actions taken by ERICA

SOURCE	EUG COMMENTS		ACTION FOR ERICA	FINAL OUTSET
D7a – Part 1: First EUG Event - Part 1: Discussion of ERICA Workplan	WP1	Set boundary of assessment tool (e.g. work mainly from equilibrium state). Code development needs to be clearly stated	Contact EUG for inputs on tool development – via WP3.	Inputs requested via the first issues of the ERICA e-newsletter, August 2004
	WP2	Define clearly the selected choices, supported by rationales for the choices.	Clearly define the reasoning for selection of experimental organisms in deliverable D5.	Reasoning given in D5-Annex B. Briefly: “Both the organisms and the methods chosen reflect the limited resources and time for experimentation, but demonstrate the type of methodology that could be applied to a variety of organisms and within a variety of case studies.”
			Provide EUG with list of experiments, which would help ERICA	Experimental protocols distributed for Second EUG event (and presented at the event), and posted on the EUG protected area of the website
	WP3	Update EUG list regularly. Keep EUG informed of ERICA developments.	Provide outline on how EUG inputs will be taken into consideration within ERICA.	Flowchart put on the EUG Area of the ERICA website, July 2004.
Revisit EUG structure after the next EUG meeting.			EUG categories developed and EUG inputs sought at the Second EUG event. Comment sought in the second issue of the e-newsletter	





SOURCE	EUG COMMENTS		ACTION FOR ERICA	FINAL OUTSET
	WP4	Define clearly the purpose of the testing of the FASSET and ERICA methodologies on the case-studies. Timing is critical to WP4 success, and based on good interaction with the other WPs.	Revisit number of case studies at Month 13.	Done, following publication of D9. A number of case studies were dropped and new ones added. More experimental work is to be done at some case study sites. WP4 is also participating in the IAEA EMRAS biota working group exercises and scenarios. Prototype tool and D-ERICA need to be preferably by Sept 06 to allow testing of the ERICA integrated Approach by WP4.
	EUG	EUG inputs/responses/continuity lie with EUG members. EUG are welcomed to more than two meetings, at their own expenses in principle.	Propose potential EUG candidates to WP3	This is on-going, e.g. new organisations came forward at the ECORAD 2004.





SOURCE	THEME	EUG COMMENTS		ACTIONS FOR ERICA	FINAL OUTSET
D7a – Part 2: First Thematic EUG Event - Part 2: Briefing notes on assessment frameworks and knowledge gaps	Assessment Framework	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.	Issue addressed in Aix, on the first day of the Second EUG event. Results incorporated in the deliverable D7b: Ionising Radiation and other Contaminants.
		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.	Considered in Deliverable D4b
		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.	WP2 experimental protocol addresses these issues. Methods have also been developed in WP1 to fill knowledge gaps with regards to environmental transfer.
			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. EUG event on uncertainties to address this.	Dealt with partly in D7e, and as a statement in the D7f derived from the Consensus Seminar in Stavern, June 2006.
			Some EUG background materials make consideration regarding decision-making.	WP3 to consider material and incorporate components in the decision-making guidance, if appropriate – D8 to address	Materials incorporated via the D7 EUG event reports.
				ERICA to seek further information from those specific EUG members.	First EUG generic event in Freising is planned for this purpose.





SOURCE	THEME	EUG COMMENTS		ACTIONS FOR ERICA	FINAL OUTSET
			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.	No action - ERICA will only deal with effects of radionuclides as other stressors. Remit too wide otherwise to be covered in the time span of the project.
D7a – Part 2: Cont'd	Assessment Framework: Cont'd	Entire project: Cont'd	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. – D8 to address	D8 is generic and does not prescribe what decisions to take. It enumerates options, and presents strengths and weaknesses. It also provides justifications where decisions are taken for ERICA.
			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.	ERA forms a central pillar to the ERICA integrated approach.
			Continue with the dose-to-reference organism approach while maintaining an open mind towards alternative approaches.	D-ERICA will provide guidance to select the best surrogate species if the actual species is not among the list of the ref. organisms	D-ERICA and the assessment tool allow assessments to be made for both reference organisms and user-defined organisms. In this way the flexibility desired by the EUG is maintained.





SOURCE	THEME	EUG COMMENTS		ACTIONS FOR ERICA	FINAL OUTSET
			<p>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.</p> <p>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.</p>	<p>To be decided. – D5 and D-ERICA to address</p> <p>Address issue at the EUG event in France, Sept’04</p>	<p>Topic addressed in D4b and D5.</p> <p>Definitions are given in the ERICA glossary and a tutorial dealing with risk characterisation has been posted on the web site. The subject is also covered in some detail in D-ERICA, the tool Help and D8.</p> <p>Issue addressed in Aix, on the first day of the Second EUG event. Results incorporated in the deliverable D7b: Ionising Radiation and other Contaminants.</p> <p>OECD presentation cancelled but relevant OECD document circulated to Consortium for consideration.</p>
D7a – Part 2 (cont’d)	Assessment Framework Cont’d	Entire project (cont’d)	<p>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?</p> <p>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.</p>	<p>Address issues at the EUG event in Germany, Apr’05</p> <ul style="list-style-type: none"> - As part of questionnaire to be distributed to all EUG members - Presentation by WP3 at the Freising EUG event; discussion to follow– D8 to address 	<p>Not done due to lack of time</p> <p>Data gaps dealt with as part of the Freising questionnaire</p>





SOURCE	THEME	EUG COMMENTS		ACTIONS FOR ERICA	FINAL OUTSET
	Knowledge Gaps	WP1	<p>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.</p>	<p>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).</p> <hr/> <p>Advice on how to deal with the assessment in absence of data to be provided. D8 to address</p> <hr/> <p>The development of a practical tool (software) to take these points into account. D-ERICA to address</p>	<p>The final derivation of transfer factors is covered in some detail in the ERICA Assessment tool Help. Where information is lacking the derivation of the Concentration ratio is reported clearly and transparently. Seasonality and speciation are not considered explicitly but where data are numerous empirical databases (with concomitant statistics) should encompass these effects to some extent. The ERICA transfer approach concerns steady state conditions only.</p> <hr/> <p>Example in D5. Details on this subject are also provided in D-ERICA and the help file of the assessment tool.</p> <hr/> <p>The tool and D-ERICA provide clear and transparent information with regards the derivation and limitations associated with the transfer derivations.</p>





SOURCE	THEME	EUG COMMENTS		ACTIONS FOR ERICA	FINAL OUTSET
		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.	D5 deals with the RBE issue. A statistical distribution of RBE has been established on the basis of existing data (done for alpha and beta particles). The validity field of this knowledge (mammals and mortality) is strongly pointed at. The tool in WP1 allows the user to enter their own values for radiation weighting factors. D8 considers the implications of radionuclide inhomogeneity on biota dose-rates.





SOURCE	THEME	EUG COMMENTS		ACTIONS FOR ERICA	FINAL OUTSET
D7a – Part 2: Cont'd	Knowledge Gaps: Cont'd	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.	FREDERICA published with limited extra data.
			WP2 to consider the extrapolation issues, both theoretically and experimentally. D5 to address	Example in D5 and also addressed in D5 Annex B.	
			Seek advice from the EUG to transform the information into decision-making guidance.	Dealt with at the EUG event in Madrid, see D7d	
		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. To be dealt with in EUG event on scientific uncertainties and D8	Dealt with with partly in the Freising questionnaire;	
		A list of experiments will be proposed that could reduce some of these gaps.	Not done directly, but information on setting experimental designs provided in D5 - Annex B.		
		Seek further views from the EUG regarding knowledge gaps.	Questionnaire dealing with this issue distributed prior to the Freising EUG generic event, and results in D7c		
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.	Address issues at the EUG event in France, Sept'04	Issue addressed in Aix, on the first day of the Second EUG event. Results incorporated in the deliverable D7b: Ionising Radiation and other Contaminants.			





SOURCE	THEME	EUG COMMENTS		ACTIONS FOR ERICA	FINAL OUTSET
D7a – Part 2: Cont'd	Knowledge Gaps: Cont'd	Entire Project (cont'd)	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.	Address issues at the EUG event in Germany, Apr'05	D7c published in June 2005
			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.	<ul style="list-style-type: none"> - As part of questionnaire to be distributed to all EUG members, but also in the EUG event on Uncertainties - As part of questionnaire to be distributed to all EUG members and discussed in Freising. Delayed until Madrid Workshop to input text. 	<ul style="list-style-type: none"> Done, reported in D7c D8 original skeleton modified as a result of EUG input in Freising.
Independent EUG input		WP3	Neale Kelly forwarded a copy of a special issue of Radiation Protection Dosimetry: "expert judgement and accident consequence uncertainty analysis"	Read document and incorporate if appropriate to ERICA.	Forwarded to GSF as background material.





SOURCE	THEME	EUG COMMENTS		ACTION FOR ERICA	FINAL OUTSET
D7b: Briefing Notes from The Second Thematic EUG Event	Ionising Radiation and other Contaminants	WP2	<p>Biology and ecotoxicology</p> <ul style="list-style-type: none"> • Summarise criteria for similarities and differences between chemicals and radioactive substances from cell to individual levels. • Revisit and examine in more detail the issue of dose modifying phenomena and synergistic effects. • Use of experiments and modelling as tools for extrapolation. • Use of other tools for extrapolation, e.g. biomarkers. <p>Risk assessment and risk characterisation</p> <ul style="list-style-type: none"> • Which main parameter, e.g. effects, doses, concentrations, should be used to set standards? • Is there a difference between reference organisms and ICRP's reference animals and plants? • Are mammals the most sensitive species for all biological and/or ecological endpoints? • What criteria would form the basis for derivation of test species for radionuclides? • Select an approach to estimate risk that satisfy different stakeholder needs. 	<p>Discussed in D4.</p> <p>Will be discussed to in EUG event Uncertainties and consensus conference, as a factor that can influence uncertainties. To be addressed in D5</p> <p>To be addressed in D4</p> <p>Addressed via questionnaire to be distributed to all EUG members prior to Freising EUG event.</p> <p>Addressed via questionnaire to be distributed to all EUG members prior to Freising EUG event</p> <p>No evidence to contrary. There are more factors to this.</p> <p>Addressed via questionnaire to be distributed to all EUG members prior to Freising EUG event. Not done - add question to web consultation</p> <p>To be addressed at the EUG event in Spain</p>	<p>D4 published in April 2005</p> <p>Done in D5</p> <p>Done and illustrated in D5</p> <p>D4 published in April 2005</p> <p>D7c published in June 2005 PNED(R) are recommended in D5 to be used at the screening tiers</p> <p>Done</p> <p>D7c published in June 2005</p> <p>This issue was discussed in D5 Annex A and Annex B</p> <p>e.g. a comparison was done (Safety Factors method and SSD) in D5. See also the related statements in the consensus conference outcomes</p>

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SOURCE	THEME	EUG COMMENTS		ACTION FOR ERICA	FINAL OUTSET
D7b: cont'd	Ionising Radiation and other Contaminants	WP 3	<p>Risk management and socio-economic issues</p> <ul style="list-style-type: none"> • Discuss whether the case has been made for regulation and control of radionuclides, and the role of ERICA within the risk management rather than risk assessment (i.e., scientific) aspects part of ERA. • Discuss socio-economic aspects, e.g. OECD report, which was due to be discussed in Aix, but speaker couldn't attend. • Decide on whether dose or/and concentration should be used as a basis for regulation (also stated above in risk assessment and risk characterisation). • Decide on how to treat background in the ERICA integrated approach. 	<p>The ERICA integrated approach will unavoidably address management issues and arguably, to be a useful practicable tool will need to consider such aspects.¹</p> <p>Considered by WP3 - To be addressed at the EUG event in Spain</p> <p>Repetitive – see above</p> <p>Addressed via questionnaire to be distributed to all EUG members prior to Freising EUG event. Recognised by WP2 and WP4, so to be also discussed in the ERICA workshop in Madrid. Both actions carried out. D-ERICA to cover</p>	<p>No action</p> <p>Wider aspects of assessments mentioned in D7d</p> <p>No action</p> <p>D8 provides a number of options.</p>

¹ This can be explored by considering certain cases. The ERICA approach is designed to be widely applicable allowing assessments to be made for prospective releases to the environment and accidents. For the former, It is incumbent upon authorities, by international law, and/or industries to conduct environmental impact assessment for any new facilities or planned operations that unavoidably includes issues related to decision making and management. For example decisions on licensing conditions would be inherent parts, inter alia, in any process for accepting new plant operations. Similar considerations are true under accident situations where decisions are required on intervention levels and exposure regimes under which countermeasure should be applied. ERICA is being designed to facilitate such management - decision making exercises. To separate the EIA from the management part of the overall approach would be impracticable and counterproductive in many cases





SOURCE	THEME	EUG COMMENTS		ACTION FOR ERICA	FINAL OUTSET
D7b: Cont'd	Ionising Radiation and other Contaminants	WP 3	<ul style="list-style-type: none"> Debate the advantages and disadvantages of relying on a single value vs a range/band of values. <p>Additional considerations Agree on terminology, e.g. effect, endpoint, risk, harm</p>	<p>Part of WP2 proposed tiered approach, D4. To be addressed via questionnaire to be distributed to all EUG members prior to Freising EUG event.</p> <p>D4 terminology and WP4 acknowledge. Chester will provide. And Theme for Madrid (terms which cause problems) - D-ERICA will provide a glossary for consistent terminology.</p>	<p>Results from Freising indicate a split in EUG's preferences. Traffic light approach suggested, with single value at Tiers 1 and 2 and traffic light at Tier 3.</p> <p>See the ERICA glossary</p>
	Risk Characterisation Contribution to D4	WP 2	<ul style="list-style-type: none"> Define benchmark Draft a document related to benchmarks in relation to decision making situations for stakeholders to comment Further develop the tiered-approach. 	<p>Discussion in ERICA Workshop in Spain. To be covered in D5 and D-ERICA</p> <p>Not a document but as part of ERICA. D4 intermediary tier approach, then in D-ERICA</p> <p>Discussed within D4 to D-ERICA; decision to be taken and justified.</p>	<p>Definitions in D5 and in the glossary</p> <p>D5 explains how to derive benchmarks. D8 and D-ERICA will develop their relation to decision making</p> <p>Done in D4, applied in the ERICA tool.</p>
	Feedback questionnaire	Entire Project	<p>There is a need to make more use of the ERICA website to improve visits and disseminate material prior to the events.</p>	<p>Structure of the website will be re-visited to make information more obvious.</p>	<p>New division of folders carried out. Revisited at periodic intervals.</p>





SOURCE	THEME	EUG COMMENTS		ACTION FOR ERICA	FINAL OUTSET
			Distribute material prior to event in time for people to read.	All documents to be posted on the website in advance of events. ERICA e-newsletter will remind EUG members and link to where documents are on the website.	Continuous improvement sought. Worked well for Madrid EUG event. The third e-newsletter had links to documents.
			Increase time for discussion.	Forthcoming events will make more time for discussion.	Worked in Madrid by restricting topics to be tackled; to be remembered at each EUG event.
			More focused presentations and topics to be addressed by the groups.	Number of topics to be covered in forthcoming events will be reduced.	Worked in Madrid by restricting topics to be tackled; to be remembered at each EUG event.
D7c: Transcripts from The First Generic EUG Event	Ecological Risk Assessment and Management	WP1	<ul style="list-style-type: none"> Finalise the list of radionuclides, and indicate where gaps exist. Use probabilistic modelling at Tier 3. Deal appropriately with uncertainties in all tiers. Reduce the number of ecosystems to three, but provide guidance for dealing with other ecosystems. Improve the ERICA tool, including uncertainty analyses, and indicate when it would and would not be appropriate to use it. Address extrapolation issues and impacts of chemicals in the tool. 	<p>For WP1 to do. Justification table to be drawn by WP1.</p> <p>Agreed, part of the tiered approach methodology, i.e. D-ERICA.</p> <p>Agreed. Other ecosystems to be addressed as a theme for Madrid ERICA Workshop. Not done in Madrid, but guidance to be given in D-ERICA</p> <p>Yes, on-going, part of the tiered approach methodology, i.e. D-ERICA.</p> <p>Extrapolation not to be dealt within the tool itself and in D5. Chemicals to be limited to radionuclides that have both toxicity, e.g. U.</p>	<p>Done and posted on ERICA website.</p> <p>Most of these recommendations have been included in the assessment tool</p> <ul style="list-style-type: none"> Radionuclides are listed and transfer data gaps are shown Probabilistic methods are available at Tier 3 Marine, freshwater and terrestrial ecosystems are considered. Sensitivity analyses are available in the tool – the help explains its application. Extrapolation has only been used in the context of dosimetry and transfer. Chemicals are not considered in the tool.





SOURCE	THEME	EUG COMMENTS		ACTION FOR ERICA	FINAL OUTSET
D7c: Cont'd	Ecological Risk Assessment and Management	WP2	<ul style="list-style-type: none"> • The tiered approach is generally accepted as a way forward to develop the ERICA integrated approach, but certain issues must be addressed, e.g. it must be flexible to allow entrance at any tier; more guidance for Tier 3 in terms of stakeholder involvement, how to go back to earlier tiers or exit from Tier; address chemical assessment in parallel to the radioactivity assessment, perhaps as an appended set of tables for comparison purposes. • Set the screening levels using the traffic light system, but justify the choice of the values. • Use SSD as a method to characterise risk, but debate the 95 % range. Give added guidance to cope with special cases where species don't fit in the range but need protection • Give proper guidance to add credibility to the system. • Agreement between predictions and observations depends on how close to the target you are; agreement is most critical at Tier 3. Guidance is therefore needed on how to deal with differences between predictions and observations. 	<p>Points addressed in D4 and as part of the tiered approach methodology, i.e. D-ERICA. Chemicals to be limited to radionuclides that have both toxicity, e.g. U.</p> <p>On-going, as part of the tiered approach methodology, i.e. D-ERICA.</p> <p>SSD will use 95% range, with added guidance given as part of the tiered approach methodology, i.e. D5 and D-ERICA.</p> <p>On-going, as part of the tiered approach methodology.</p> <p>On-going, as part of the tiered approach methodology, i.e. D-ERICA. WP3 to examine IAEA's Safety Series 100 on how to deal with uncertainty and variability.</p>	<p>D-ERICA published Feb'07</p> <p>Screening levels explained in D5</p> <p>Done in D5</p> <p>D-ERICA published Feb'07</p> <p>D-ERICA and D8 deal with Uncertainty issues.</p>

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SOURCE	THEME	EUG COMMENTS		ACTION FOR ERICA	FINAL OUTSET
D7c: cont'd	Ecological Risk Assessment and Management	WP3	<ul style="list-style-type: none"> • Give extended definitions and examples of certain issues, e.g. DDC, uncertainties, as to help stakeholders and assessors understand difficult concepts. • A clearer objective is needed for D8, with possible revision of its structure and title. Add “monitoring for verification purposes” into D8 skeleton. • EUG have expressed an interest to be part of the process of setting questions in any future questionnaire designed by the project. 	<p>Tutorials will be produced by WP Leaders on different aspects of risk assessment and posted on the website. Details described below. Two more tutorials (effects and dosimetry) to finish to be added to the website.</p> <p>Agreed, D8 will be revisited by WP3 and title potentially changed to “Decision-making options”.</p> <p>WP3 to consider for future EUG events.</p> <p>WP3 will involve stakeholders with clarification issues when designing the planned web-based questionnaire, to be done in 2006.</p>	<p>Two tutorials (transfer and risk) completed and posted on the ERICA website.</p> <p>New D8 structure created in Sept 05, for EUG members to comment via e-newsletter.</p> <p>Consultation process done for the EUG Consensus Seminar.</p> <p>Done as part of the process. D7g published.</p>
		WP4	<p>Ensure the ERICA guidance and outputs have a clear scope, are user friendly and transparent. Define the possible applications of the ERICA integrated approach.</p> <p>Provide different EUG members with the same case study to test at the same time as WP4 the ERICA integrated approach.</p>	<p>On-going, as part of the tiered approach methodology, i.e. D-ERICA.</p> <p>WP4 will consider, but as this will require extra resources, a decision will be taken after Year Two</p> <p>To be discussed and recommendation made at Sept. '06 Cambridge meeting – will depend on the state of the finances.</p>	<p>D-ERICA and the ERICA Tool published with those points in mind.</p> <p>Scenarios developed for Copenhagen EUG event partly based on case studies</p> <p>Done at the EUG testing day and then re-worked as part of the ERICA Open Event.</p>





SOURCE	THEME	EUG COMMENTS		ACTION FOR ERICA	FINAL OUTSET
		D7c Annex	Individual Comments from EUG members	WP Leaders to provide additional comments if issues not already addressed above.	WP leaders have taken on board some of the suggestions given by EUG members.
D7d: Briefing Notes from The Third Thematic EUG Event	Decision-making and Stakeholder Involvement	<ul style="list-style-type: none"> provide definitions related to stakeholders involvement for the ERICA glossary; provide a list of potential stakeholders and reasons why they might be engaged with; provide a list of methods to involve stakeholders (it is suggested that this should be considered in relation to the tier at which the engagement is being used and/or the purpose of the assessment). It was noted that different tools may be required at different points in the engagement process and advice on their application should be provided; should give an overview of how to get the most from the stakeholder engagement process, e.g. what works and what to avoid; should consider problem formulation and how stakeholder engagement may be used to define what issues are to be addressed and what assumptions are to be made; consider the role of stakeholder engagement within the ERICA integrated approach and how this should be captured. It was generally agreed that ERICA should provide a mechanism for capturing the decisions regarding whether stakeholder engagement was required or not and to provide an opportunity for the assessor to record in the assessment tool who should be involved, to what extent and what contribution they can provide. 		<p>To be provided, e.g. in D-ERICA.</p> <p>To be provided in D8</p> <p>To be provided in D8</p> <p>To be provided in D8</p> <p>To be provided in D8 and the assessment tool</p> <p>To be available within the assessment tool</p>	<p>Included in D7f following the Consensus Seminar. Also in D-ERICA Annex B - Glossary</p> <p>D8 addresses all the issues listed in the EUG Comments column and provides links to further literature.</p> <p>Done, as a series of recording Tables within the Assessment Tool prototype, from August 2006.</p>





SOURCE	THEME	EUG COMMENTS	ACTION FOR ERICA	FINAL OUTSET
D7d: cont'd	Decision-making and Stakeholder Involvement	<ul style="list-style-type: none"> ERICA should consider the stakeholder processes (some required by national legislation), which will be occurring for other aspects of assessment of permissions for existing or planned licensed sites (to avoid duplicating effort) and should provide guidance on assessing the need for additional stakeholder engagement when considering biota assessments. 	To be available within the assessment tool	Done, as a series of recording Tables within the Assessment Tool prototype, from August 2006.
	“Sources of Uncertainty” in the ERICA tool and the Uncertainty Spreadsheet	<ul style="list-style-type: none"> It must be made clear to the users that ERICA has several types of intrinsic uncertainties and that some conservatism already is built-in to compensate for those. It is important that the user neither doubles the conservatism nor trusts the result too uncritically. Users require information on the sources, and at least the order of magnitude, of uncertainties in the assessment. There is a need for transparency and traceability in the way the tool deals with uncertainty and a justification of the choices and assumptions made in selection of model and parameters. There is a distinction to be made in the ERICA tool as to its usage: i.e. as a conceptual tool and as a computational tool. ERICA should address not only data issues (i.e. parameters and input data) but also the uncertainties inherent in the ERICA tool (i.e. model assumptions). 	<p style="text-align: center;">D8 to address</p> <p>To be addressed in the ERICA tool, as description of assumptions and partly as quantification of uncertainties in Tiers 2 and 3.</p> <p>To be addressed in the ERICA tool</p>	<p>Uncertainty is now dealt with in the tool through the application of various methods including the use of uncertainty factors at Tier 2. Methods employed are described in some detail in the accompanying help file.</p> <p>The uncertainties associated with modelling (conceptual uncertainties) are considered in D8.</p> <p>Assumptions related to the tool are listed in the D-ERICA Annex,</p>





SOURCE	THEME	EUG COMMENTS	ACTION FOR ERICA	FINAL OUTSET
D7d: cont'd	“Sources of Uncertainty” in the ERICA tool and the Uncertainty Spreadsheet	<ul style="list-style-type: none"> • Terms used in the uncertainty spreadsheet need more clarification. The distinction between uncertainty and variability should be included, and the term “data gap” should be replaced with “knowledge gap” where appropriate. • Make the link clearer between the uncertainty spreadsheet, the assessment tool and the tiered approach illustration. A review of the content of the Uncertainty Spreadsheet was difficult at the workshop: deal with specific comments separately. • ERICA should develop a framework or guide for uncertainty analysis: consider adapting the uncertainty matrix presented by Jeroen van der Sluijs. 	<p>D8 to address</p> <p>D8 to address</p> <p>D8 to address</p>	<p>The terminology used in D8 has been refined and corresponds to the traditional meaning of the various terms used (detailed descriptions are provided in D8).</p> <p>The uncertainty matrix developed by Jeroen van der Sluijs is included in D8.</p> <p>The uncertainty matrix developed by Jeroen van der Sluijs is included in D8.</p>
World Nuclear Association (WNA)	Generic input 30 Sept'05	<p>The World Nuclear Association has chosen not to input into the ERICA assessment steps beyond the assessment tool, i.e. risk characterisation and decision-making.</p> <p>WNA has provided extensive comments related to the ERICA project, see Annex 1.</p>	<p>Comments have been made by the ERICA management Group in response to each WNA points. Text incorporated within Annex 1.</p>	<p>Refer to Annex 1</p>





SOURCE	THEME	EUG COMMENTS	ACTION FOR ERICA	FINAL OUTSET
D7e: Cont'd	The Tiered Approach	<ul style="list-style-type: none"> • Problem formulation and stakeholder involvement also need to consider uncertainties. For example the definition of the assessment context and object of protection has important implications for the way uncertainties are addressed. Stakeholders can influence the outcome of an assessment and the description of pathways and conceptual model needs justification of the choices. • Make the difference between conservatism/pessimism, simplification and realism clearer. Realism increases from Tier 1 to Tier 3; the high degree of conservatism in Tier 1 means that uncertainty is not so relevant. There is a need however to avoid “double accounting of uncertainty”. • Provide clarification on how to handle the basic uncertainties due to temporal change (in the ecosystems or in some compartments) during the period assessed, and due to locality (disparity between the areas evaluated/ influenced and the area of population spread). • Consider revision of Tier 2 to make distinction from Tier 1 more obvious. For example, include sensitivity analysis, refined dose estimation and organism specific screening values. 	<p>D8 to address</p> <p>D-ERICA top address</p> <p>Included within WP1 work.</p> <p>Clarification to be taken on board by WP1. Sensitivity analysis will only be available in Tier 3.</p>	<p>D8 makes reference to factors that influence problem formulation and decisions to be taken once the assessment is concluded</p> <p>D-ERICA discusses those points.</p> <p>Guidance is now provided in the Assessment tool “help” file explaining how Temporal and spatial data sets may be utilised. The uncertainties are not dealt with explicitly but the use, where possible, of empirical data sets with concomitant statistical information and probabilistic methods should account, to some extent, for the uncertainties associated with temporal change and locality referred to by the EUG. Tier 2 is quite distinct from tier 1 in the final version of the tool. At tier 2 the assessor can select particular reference organisms of interest and modify all parameters used in the calculation. This is not possible at Tier 1.</p>





SOURCE	THEME	EUG COMMENTS	ACTION FOR ERICA	FINAL OUTSET
D7e: Cont'd	Screening Values	<ul style="list-style-type: none"> Identify data gaps associated with the estimation of the proposed screening values. Make clear the justification and assumptions behind the 95 % cut-off. For example does this mean that the screening level set at 5 % of species will certainly result in harm to those 5 % species? Or that we are reasonably sure that 95% won't be harmed (but not so sure about the other 5 %)? 		<p>See D5</p> <p>See D5</p>
	Uncertainty in dose estimation and effects analysis	<ul style="list-style-type: none"> Proper understanding of the basis of dose estimation in the FREDERICA database is necessary to ensure comparability with ERICA assessments. The database should be scrutinised for its ability to provide accurate information, and it must be made clear to users that much of the data have been produced for another objective. Uncertainty in the weighting factors is key to the comparison with FREDERICA database, most of which are based on external gamma, or X-ray photon irradiation. This includes non-uniformity of distribution between organs, which could have very significant consequences on the risk of effects. One option may be to work on the basis of unweighted doses, but still separate out the three dose components and take specific account of localisation. Clarification is needed on the applicability of the ERICA integrated approach to retrospective or prospective assessments. 	<p>Work undergone by WP1. D-ERICA to address.</p> <p>WP1 to consider.</p> <p>D-ERICA to address.</p>	<p>D1 published.</p> <p>The assessment tool allows full flexibility with regards this point. Dose-rates are split into components of alpha, low beta and gamma-beta. Although default alpha and low beta radiation factors are used, assessors may enter their own values for these parameters (including distributions at Tier 3).</p> <p>D-ERICA addresses this as does the Help function in the assessment tool.</p>





SOURCE	THEME	EUG COMMENTS	ACTION FOR ERICA	FINAL OUTSET
D7e: Cont'	Uncertainty in dose estimation and effects analysis	<ul style="list-style-type: none">Many of the uncertainties reflect unreliability/ ignorance. We do not know that the approach is complete because of the biological uncertainty – multiple stressors, trans-generational effects, delayed and non-targeted effects. This is valid for non-radioactive as for radioactive assessments. “We know we don’t know” needs to be appreciated in the assessment. These kinds of uncertainties cannot be dealt with by probabilistic risk assessment. The ERICA approach cannot reliably conclude a negative effect. This needs to be emphasised to end-users.	D8 to mention	Tables with strengths and weaknesses within D8 try to fill these types of considerations.
D7e: Cont'	Management and Precautionary Principle	<ul style="list-style-type: none">Application of the Precautionary Principle is a matter for decision-makers not for the ERICA integrated approach itself. The ERICA integrated approach must be absolutely clear about where, why, how and to what extent conservatism has been included – so that decision-makers do not take the ERICA output and apply further precaution, and un-knowingly double-count the degree of conservatism/precaution, in their decisions.	D8 to address	Partly addressed in D7f





SOURCE	THEME	EUG COMMENTS	ACTION FOR ERICA	FINAL OUTSET
D7g: Summary of the EUG event: Management, compliance and demonstration		<p>The overall objective of the event was to clarify the process of integrating an environmental assessment with management decision.</p> <p>The outcome of the EUG event was to help the ERICA Consortium complete the D8 and input into D-ERICA's section on management.</p>	<p>The majority of ERICA recommendations from the groups will be implemented in both the D-ERICA and the D8- "Considerations for applying the ERICA Integrated Approach" document, to be published in early 2007.</p>	<p>Both D8 and D-ERICA contain the recommendations from D7g.</p>
D7h: Summary of the Copenhagen EUG Tool Testing Day		<p>EUG members were asked to provide feedback on use of the tool and its guidance. As a result, a list was collated containing comments, improvements and software bugs.</p>	<p>It was agreed that the "Urgent" items would be solved before the final version of the prototype is released. D-ERICA will be revisited and modified. D-ERICA will focus more on the overall principles, as the in-built help guidance provides more information on reasoning and assumptions related to the use of the ERICA assessment tool.</p>	<p>D-ERICA now reflects the change in emphasis expressed during the event. The ERICA Tool has taken on-board the majority of changes discussed during the event.</p> <p>A number of improvements to the tool will be implemented once the ERICA project is completed, after an agreement within the Consortium to sponsor extra work for the next three years is finalised. Updated versions of the tool will be available free of charge to registered users.</p>





ANNEX 1: World Nuclear Association Inputs September 2005

Sylvain Saint-Pierre, Director for Environment and Radiological Protection

Comments by ERICA Management Group in black italics text

Some of the Nuclear Industry's Current Key Concerns about the Erica Process and Work

*** For further context, some references to the “deliverable D7c” which reports on the first generic EUG event – ecological risk assessment and management – are made herein ***

As for all EUG meeting deliverables, a draft of D7c was distributed to EUG members as part of its review process. Comments on the draft were not received from WNA prior to its publication in October 2005.

1. What is the EUG real role?

The WNA and others are still seeking (e.g. deliverable D7c, p.16) at which point the EUG input will help shape the Erica tool? Until now, although some important issues such as those indicated further below have been already mentioned during previous Erica meetings, by and large, they have been left unaddressed with no obvious opportunities to really discuss them. We would like to know if Erica has a plan to rectify this key shortcoming?

The EUG was invited to comment on the work plan of all work packages in March 2004, and then more specifically on the assessment tool in the first e-newsletter, August 2004. At the March meeting, Tim Parker represented the WNA. Following the Freising event, it was decided that a number of specialised EUG members will be asked to comment on the prototype regarding specific aspects of the tool. A distinction also needs to be made between the assessment tool and the tiered approach. The tiered approach was first introduced at the second thematic EUG event in September 2005, where comments were also sought from the EUG members. The tiered approach focuses on effects to the individual, as guided by the FASSET framework, but will also provide guidance relate to extrapolation to population levels. The tool is being developed to be consistent with the tiered approach. By commenting on the tiered approach, the tool will encompass some of the EUG comments. Some of the EUGs' comments have already been incorporated into the developing tool (e.g. radionuclide list).

We would like to be more constructive but we are sceptical about the possibility of addressing these issues with sufficient depth as part of the upcoming two-day long meeting in Madrid. However, we would welcome another opportunity in the near future to adequately discuss these issues.

While the ERICA project does allow for interaction with EUG members, it is not only a debate forum: the project has a research plan and deliverable schedule. Decisions must be taken at given times so that the outputs can be delivered on time. A number of the comments presented below (e.g., the management and assessment issue) were discussed at both the EUG meeting in Aix (see deliverable D7b) and extensively in Freising and Madrid. This provides us with the foundation to move forward with the project in a timely manner.

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2. Prematurely moving beyond the development of an (scientifically-based) assessment tool

We believe that there is value in developing an international framework, based on robust scientific and practical foundations that will ultimately help assessing the potential health effects on non-human species from exposure to ionizing radiation. The question of what should be done from that point is a totally different matter.

It is worth emphasizing here a few key points about the current international context:

- The scientific work from leading international authoritative bodies (UNSCEAR and ICRP) in the specific field of radiological protection of non-human species that aims to provide a sound scientific basis, is currently under development and is not expected to be completed for a few years.
ERICA consortium members are part of the ICRP Committee 5 on the environment and therefore both ICRP and ERICA developments will be in parallel and will not be contradictory. Current working versions of the UNSCEAR documents rely heavily on the FASSET/ERICA outputs and both projects continue to be major contributions to UNSCEAR.
- The current international consensus at the IAEA level – as indicated in a draft plan of activities (June 2004) - is that the Member States:
 - Have agreed on the need to develop an “assessment framework” and on the broad steps of this development (which integrates the upcoming effort from key scientific authoritative bodies such as UNSCEAR and ICRP over the next few years)
 - Have agreed “to develop an international consensus on the need for, and if necessary the form and content of standards that address the protection of non-human species.”

We would like to point out that the WNA has expressed its support for the above IAEA draft plan as we believe that an international assessment framework can, ultimately, be helpful for dealing with situations where the exposure of humans is not the predominant concern.

We see value in Erica informing all its members of this IAEA draft plan, and if possible, we encourage Erica to indicate where its on-going work can potentially best contribute to this IAEA draft plan. At this early stage of development, we believe that the harmonization and pooling of efforts at the international level towards a sound international assessment framework is important.

The IAEA Board of governors agreed in Sept 2005 to:

“Promote collaborative work by relevant international organisations that enhances current approaches in radiation protection by taking explicit account of non-human species in developing an approach for the assessment and management of radionuclides entering or present in the environment”.

And,

“Provide assistance to IAEA Member States in their efforts to protect the environment and review its corpus of radiation safety standards...”.

The ERICA project has been awarded under EC sixth Framework. The Consortium is aware of developments in the IAEA and some of its participants work in close collaboration with the IAEA (including providing the co-chairs for its Biota Working Group). Furthermore the IAEA is

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represented in the EUG and presented their draft plan at the first EUG meeting (see deliverable D7a). All efforts under ERICA will constitute a prime input to the IAEA Action Plan, which the Action Plan already acknowledges.

- Erica and many others recognize that there is a whole range of key gaps in scientific knowledge that remains to be addressed. One good example is the key issue of extrapolation of the effects at the individual level to effects at a higher level of organizations (populations, ecosystems, etc.) (e.g. deliverable D7c, p.14-17). Without such linkage and without addressing the other key outstanding gaps, it is easy to anticipate that an assessment tool can only be of little help in practice. We agree that to be practical, the aim of the protection should be at the population level or at a higher organizational level and that the Specific Sensitivity Distribution (SSD) method seems a step into the right direction (e.g. deliverable D7c, p.42, 44). It would be equally important to include relevant guidance in the step on problem formulation so that the definition of exposure scenarios to be considered becomes compatible as well.
The ERICA project is aware of these issues, and is addressing them as part of its work programme. The assessment tool will be, in practice, of use for assessors that wish to gain knowledge about the effects and risk of ionisation at the individual level. The tiered approach will also give guidance on extrapolation. Knowledge gaps are always going to be present and how to pragmatically deal with them will be addressed, via uncertainties. The problem formulation stage is included in the tiered approach, and will be present in the assessment tool to record decisions taken by the assessors as they progress through the assessment. Problem formulation also needs to address management as well as assessment issues.

In the current international context of limited scientific knowledge that is scheduled to be addressed over the next few years, we have difficulties in understanding what Erica's rationale is for attempting to reliably address, at this early stage, major steps (such as: risk characterisation, criteria/standards, management, and communication/decision-making) to the (scientific) assessment tool.

The scope of the ERICA project has been awarded on the basis of addressing risk characterisation and management issues. Furthermore, the work plan has been discussed in the first EUG event, and all EUG members were asked for comments. As the way forward was deemed acceptable by the EUG, the ERICA project will deliver its obligations to the Commission.

Alternatively, if the global intent here rather relates to some kind of an academic exercise (as opposed to a practical exercise – that potentially bears real implications) which genuinely attempts to explore various possibilities, we would agree that the conceptual ideas and methods put forward by the scientific community on some of the subsequent steps may help envision the kinds of practical developments that may be worth considering in the future. This flagging issue should be examined closely.

It is unclear what the difference is between an academic and practical exercise. Part of the reason for addressing management issues is that these will help in developing the overall approach.

Overall, the general sentiment is that Erica is tending to by-pass too easily important and difficult scientific issues, for which it is well qualified and expected to contribute, and instead try to prematurely cover a whole range of other topics that rather pertain to the major steps (e.g., risk characterisation, criteria and standards, management, and communication/decision-making, etc.) subsequent to the (scientific) assessment tool.

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As stated above, the development of a practicable assessment tool requires that the management issues are addressed. We do not agree that the scientific issues are being bypassed.

3. What is really meant by an integrated approach or an integrated tool?

If we have understood correctly, it seems that in Erica, the meaning of an “integrated approach” or “integrated tool” covers the whole spectrum from planning, problem formulation, risk characterisation, and decision and management (e.g. deliverable D7c, p.31-32). Should this be the case, we would like to point out some key shortcomings:

The nature of the ERICA integrated approach is now emerging, as clearly specified in the summary of the Mid-Term review, published on the project’s website.

- Considering the effects of ionizing radiation, as mentioned earlier, the issue of weak and incomplete scientific bases is of great concern, and especially when one tries to address the major steps subsequent to the assessment tool. Also, assuming that these bases will be fully developed, we wonder how the apparent integration would come into play in practice? For example, imagine a newly constructed hospital (with all relevant approvals) but that could not operate on the grounds that the potential radiation effects to non-human species would be too great? How would the impact on non-human species during operations be weighted against those during construction, and against the benefits to humans? In our view, these are important issues that an “integrated” approach would need to account for.

These issues are precisely the reason why the integrated approach needs to go beyond a simple assessment to address also management issues. The ERICA integrated approach will highlight the wider context and the involvement of stakeholders, which in the case would bear to a wider context than just effects to biota. The ERICA integrated approach is not meant to be used in isolation but as part of a wider context. If an assessor wishes to investigate effects to biota, then it can use this approach, with all its assumptions and limitations. The information provided by the tool on effects will be one of many issues upon which decisions should be based.

- Considering the effects of ionizing radiation – in isolation of all other factors that impact the health of non-human species - is also a great concern and can lead to a gross misallocation of resources. It should be taken well into account that the framework for the assessment of radiation effects on non-human species will inevitably have to be part of an overall assessment framework for the well being of non-human species – with a fairly good chance that low dose of ionizing radiation might not even figure when compared to the prevailing factors such as climate change, urban developments, agriculture, fisheries, and predator-prey relationships in the food web. For example, consider the current climate change predictions that forecast a substantial increase in sea levels in a few decades with a corresponding dramatic impact on non-human species – especially along coastlines. How this would be accounted for in an integrated approach is crucial. Similarly, how would the increasing burden of urban developments, agriculture and fisheries (not to mention all other industries) be weighted in an integrated approach?

The ERICA integrated approach is not intended to be run in isolation of other assessments. The approach will enable assessment of the relative size of environmental impact, and allow comparisons between different environmental

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stressors. The ERICA integrated approach is instead directed to guide sound environmental management without wasting resources.

We note that the “interim method for the Erica integrated approach focuses on the technical aspects of the actual risk assessment/characterisation method but does not consider in an great detail how Erica integrated approach will handle the stakeholder and decision-making aspects” (e.g. deliverable D7c, p.32). We generally agree that the approach focuses on the technical aspects and that addressing the outstanding scientific gaps in order to end up with a scientifically robust and practical assessment tool is key for Erica. We remain unconvinced that the Erica approach should handle any major steps (e.g. risk characterisation, criteria and standards, stakeholder involvement and decision-making) subsequent to the assessment tool. Others also seem to question this important distinction (e.g. deliverable D7c, p.36).

At the time of the deliverable in question (D4), stakeholder involvement had not been fully addressed within the context of the integrated approach. This has now been discussed in length in Madrid. It was considered to be highly relevant and is being integrated into the assessment too, recognising that this should not be repetitive of stakeholder involvement which will be on-going in other parts of an assessment. The ERICA integrated approach also makes reference to stakeholder involvement throughout the assessment, characterisation and management stages.

As stated above in point two, the agreed work plan is to address risk characterisation, criteria and standards, stakeholder involvement and decision-making.

4. Evaluation of the success and legitimacy of the process

It is worth recalling here that Erica itself should be aware of the key issue of its limited competence for addressing major steps subsequent to the assessment tool. For example, while discussing risk communication and policy making aspects with the EUG, it was noted that “most respondents were scientific experts, a number also abstained answering for “Risk Communication” and “Policy Making”;...” (e.g. deliverable D7c, p.20). This flagging issue should be examined more closely.

We invited a number of organisations to join, which represent a wide range of end-users. Furthermore, the partners within the consortium represent a wide range of expertise, which cover all steps of assessment process, including risk characterisation and policy-making. . EUG members with particular experience of communication and stakeholder engagement were present at the Madrid event. A domination of scientific and technical expertise does not mean that only scientific expertise can be addressed.

We are also concerned that, by and large, this rather scientific representation may also be dominant for most of the other major steps subsequent to the assessment tool.

In connection with this, one could therefore question if the attendees to the EUG meetings are sufficiently compatible with the scope of the Erica discussions (for example, their competence and whether or not they represent their organizations at the right hierarchy level). A further issue is that when someone does not express his/her views verbally at the EUG meetings, it is often interpreted as a voice in favour of what Erica is proposing. It seems that several EUG players have experienced similar situations during the EUG meetings and that they did not feel comfortable with this. This flagging issue should be examined more closely.

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All EUG members are treated equally and no preference is given to any member. The ERICA project continually invites comments and inputs, both at websites and through questionnaire, and not only verbally at EUG meetings. The project also asks each EUG participant to provide material prior to the meetings where their experience is described. However, such consultation is only part of the ERICA development. The project has a number of milestones to deliver and must proceed according to contractual obligations, which limits the Consortium. EUG comments have been taken on board and can shape but not completely override the work plan.

For our part, the WAN has clearly indicated at the EUG meetings that we are interested in the development of the scientific assessment tool and of the related scientific guidance, but that we do not believe that Erica is a proper forum for discussing the major subsequent steps (e.g. criteria and standards, management, decision-making, etc.) and that we have not been mandated by our members to do this (e.g. deliverable D7c, p.15, 25, 36). In fact, we would like to add that this is also the case for the representatives of individual nuclear companies that participated in the EUG meetings.

The ERICA integrated approach can accommodate a number of end-users needs. The flexibility of the approach will allow different users to either utilise only the assessment tool, or continue into risk characterisation etc. Thus, we allow for the possibility that some users may not wish to use the whole approach.

5. Regulatory Context

As for the other major subsequent steps, it seems that Erica experienced difficulties in adequately laying out the regulatory context. For example, the link between the EC Habitat Directive and the apparent (legal) need for a framework to assess the health effects of radiation exposure to non-human species (in isolation of all other factors that impact on the well being of non-human species) seems unclear. The apparent (legal) need for any major subsequent steps such as setting standards and controlling radioactive discharges on the basis of the protection of non-human species is even more remote at this early stage of development.

It should be borne in mind that the EC Habitat Directive generally aims at the industry (at large) and the agricultural sector in the specific context of the Natural 2000 sites. It does not specifically aim at ionizing radiation or at the nuclear industry, and it does not contain any related quantitative guidance. It therefore appears that any integrated methods (see item 4 above) that does not account for all predominant factors that impact on the well being of non-human species would be ill-conceived and inadequate in view of the broad objectives of this Directive (e.g. deliverable D7c, p.44).

For information, in the European Union, the legal basis for the control of radioactive discharges associated with the nuclear industry is set under the Erratum Treaty (art.37). Despite the discussions that Erica had on the topic of European legislation and on criteria and standards for the control of radioactive discharges, it is striking that the Erratum Treaty has not yet been mentioned nor accounted for in the Erica project. For example, the two presentations on the European legislation that we had at the EUG meeting in April did not mention it, and it is not mentioned in the brief outline for this meeting in Madrid. Again, this may simply indicate that discussing regulatory matters is beyond the scope of Erica or at the very least, that the competence (in this field of expertise) of some Erica players may not be sufficient.

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ERICA is funded under the ERRATUM Treaty. We have representatives of both industry and Regulators within the ERICA Consortium, who believe this work is needed to respond to their daily requirements. Indeed, such requirements exist on a national level within several of those countries active in ERICA.

Also for information, the EC draft Thematic Document on the European Marine Strategy that is planned to be converted into a Framework Directive well acknowledged that the control of radioactive discharges for the nuclear industry is a matter that directly pertains to the Erratum Treaty (e.g. deliverable D7c, p.30, 44).

Individual countries' interpretation of the EC Directives is outside the scope of the ERICA project. Please note, however, that some countries have decided to interpret the Directive in such a way that the assessment of radioactive substances is being incorporated in the process.

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