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DELIVERABLE D7c: Transcripts from The First Generic EUG Event

Ecological Risk Assessment and Management

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

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Executive Summary

This report (deliverable D7c) is a transcript from the First Generic EUG Event. The report summarises presentations and group discussions that were held during the event. According to the ERICA work packages (WP), topics discussed were:

– WP1: the ERICA assessment tool;
– WP3: communication and decision-making – past events, the skeleton of deliverable D8 "decision-making guidance" and responses to questionnaires;
– WP4: deliverable D9 "Application of FASSET framework at case study sites";
– WP2: aspects of deliverable D4 "An interim method for the ERICA integrated approach"; developing environmental criteria and standards; and development and application of benchmarks in ERICA ecological risk characterisation.

Background summaries from most of the presentations were distributed prior to the meeting, together with a questionnaire, which was intended to highlight the main areas of consensus and controversy, and used as a source of discussions during the event.

During the meeting, WP participants, and an invited keynote speaker from the Environment Agency of England and Wales, gave presentations reflecting the ERICA work to date and direction for the future. Each of the presentations was then followed by smaller group discussions with ERICA Consortium participants (representing each ERICA WPs) and EUG members. A number of questions were distributed at each discussion session to help initiate the dialogues. All groups then reported in plenary sessions followed by further discussion.

This deliverable D7c, as well as D4 and D9, have been placed on the public/results area of the ERICA website: www.erica-project.org. Presentations and the D7c – Annex 1 have been posted on the EUG protected area of the website, as the material is under development and discussion by the ERICA Consortium.

We have endeavoured to ensure that all EUG comments and suggestions have been included and reproduced accurately in this document. Drafts have been sent to all EUG members present at the Event for comment. The report concludes with a summary of the main points raised by the EUG, together with the action to be taken by the ERICA Consortium.

The EUG organisations participating in the Event, detailed in Appendix 2, included:

OECD Nuclear Energy Agency;
EC – DG environment;
Greenpeace International;
World Nuclear Association;
International Union of Radioecologists;
Australian Nuclear Science and Technology Organisation (ANSTO), Australia;
Centre d'Étude de l'Énergie Nucléaire (SCK-CEN), Belgium;
International Sakharov Environmental University, Belarus;
McMaster University, Canada;
IMI Zagreb, Croatia;
AREVA, France;
CEA, France;
Ministère de l'Écologie et du Développement Durable, France;
Ministry of the Environment, Finland;
BfS, Germany;
Utrecht University, Netherlands;
Jozef Stefan Institute; Slovenia;
SPA "TYPHOON", Russia;
University of Oxford, UK.

The main conclusions and comments from the EUG members are highlighted in the table below. A special ERICA Management Group was called for as a result of this EUG event to discuss the recommendations from the EUG.

	EUG Comments
WP1	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 according as indicated in Section 2, 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.
WP2	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.
WP3	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.
WP4	Ensure the ERICA guidance and outputs have a clear scope, are user friendly and transparent. Define the possible applications of the ERICA integrated approach. Provide different EUG members with the same case study to test at the same time as WP4 the ERICA integrated approach.

Actions from that meeting, together with actions derived from this D7c document, and its Annex 1, will be incorporated in the Progress Report No. 3 on "EUG inputs and resulting ERICA actions", and posted on the EUG protected-area of the ERICA website www.erica-project.org. The deliverable D7c will be available to all on the results page of the ERICA website.

Next Meeting	**Location**	**Date**
EUG Thematic Event	Madrid, Spain	29-30 September 2005

Acknowledgements

In addition to the valuable contribution made by all EUG participants, the ERICA Consortium would like to thank the main contributors who have helped in generating the D7c text.

– Speakers: Justin Brown, Magnus Ramstedt, Jacqueline Garnier-Laplace, David Copplestone, Brenda Howard, Irene Zinger, Paul Whitehouse.
– Group Chairs: Hildegarde Vandenhove, John Holmes, Paul Whitehouse, Eric Vindimian, Branko Kontic, Christine Willrodt, Simon Carroll, John Ferris, Jeroen Van der Sluijs, François Bréchignac, Ted Lazo.
– Group and plenary discussion secretaries: Ingrid Bay-Larsen, Hanne Breivik, Nick Beresford, David Copplestone, Riitta Hänninen, Brit Salbu, Justin Brown, Deborah Oughton, Steve Jones, Brenda Howard.

Gerhard Pröhl and other GSF staff members, as well as the staff of the Kardinal-Döpfner-Haus in Freising, are gratefully acknowledged for their practical arrangements and help during the Event.

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1 Introduction

On the evening of the 24th April, Brenda Howard, representing the Consortium and acting on behalf of the project co-ordinator, gave a brief description of the ERICA project, emphasising the work done to date and the role of the EUG members within the project. Irene Zinger then provided basic information regarding the access for EUG members to ERICA information and guidance for repayment to EUG members.

On the 25th April, Brenda Howard welcomed all participants and Deborah Oughton presented the procedures to be followed for the whole three-day event.

1.1 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.

EUG members were requested to fill in a questionnaire prior the event as a guide for some of the discussions, and an evaluation questionnaire at the end of the meeting to help the ERICA Consortium improve future events.

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".

Deliverable D7c and all presentations have been placed on the public/results area of the ERICA website: www.erica-project.org. Presentations have been posted on the EUG protected area of the website, as the material is under development and discussion by ERICA participants.

1.2 Procedure to follow during the discussion groups

Deborah Oughton explained the process and procedures for the meeting.

In addition to the plenary presentations, time was allocated to small, breakout group discussions, to enable a more focused dialogue between EUG and ERICA participants. The division of the groups for each day is shown in Appendix 3. A list of questions for each group session was provided to help focus discussions.

Each group was to elect their own chairperson, and the Consortium would provide a secretary and a facilitator. Comments provided during the group discussions were not to be attributed to individuals; citation, or any other form of revelation, by one group member of another group member's opinion or assertion expressed during this part of the procedure would not be allowed. Members had the choice of representing themselves or their organisations. These rules were intended to promote a free exchange of views.

During the plenary sessions, which followed presentations and group discussions, each participant was identified and his or her name reported in this report. To differentiate between EUG members and ERICA participants, ERICA participant names are reported as initials only. "Q" refers to question and "A" to answer.

1.2.1 Roles

- Chair/Rapporteur (EUG member). A group elected EUG member to guide discussion, keep to time, sum up, and report in plenary session.
- Secretary (ERICA consortium participant). To take notes during discussion to provide any required support and assistance to the Chair in summing up and to assist in drafting the current report.
- Facilitator (ERICA consortium participant). To get the discussion started, aid the chair if necessary, ensure every person has an opportunity to speak and keep track of time.

The name of each person taking one of the above roles for each group and plenary sessions is indicated in Appendix 3.

2 WP1. The assessment tool

2.1 Summary of presentation

WP 1 is working on a number of tasks, which together will deliver an assessment tool, with supporting software.

2.1.1 Task 1: Modification and extension of the new FREDERICA database

EPIC data have been reformatted and submitted for integration into FRED and post 2001 articles have been added to the database. Some issues with the EPIC data structure remain and it has not yet been possible to construct dose-response curves.

The new database "FREDERICA" will be hopefully online in mid April. The front end is similar to FRED but amendments to the structure of FREDERICA will be made including: (i) provision of new search outputs; (ii) provision of new search flexibility; (iii) links to assessment tools.

2.1.2 Task 2: Transfer assessment

Three problems have become apparent from initial work within WP4: (i) missing information in the existing radionuclide - reference organism matrix; (ii) some radionuclides identified in assessments were not included in FASSET; and (iii) protected species are not always covered by existing reference organism list

Due to lack of ecosystem/species specific radioecological parameters the pragmatically based recommendation is to rationalise the ecosystems and organisms used in FASSET. In practice this means to reduce the number of terrestrial ecosystems, combine terrestrial mammals into one, remove bacteria. However, the reference organism list should encompass European protected species and the ICRP list of reference animals and plants. The identified radionuclides not covered by FASSET are: ^{35}S, ^{32}P, ^{33}P, ^{41}Ar, ^{85}Kr, ^{57}Co, ^{58}Co, ^{60}Co, ^{54}Mn, ^{95}Zr, ^{95}Nb, ^{110m}Ag, ^{123m}Te, ^{99m}Tc, ^{124}Sb, ^{125}Sb, ^{125}I, ^{154}Eu ^{141}Ce, ^{144}Ce, ^{228}Ra.

2.1.3 Task 3: Development of complex geometry dose models

A software utility has been developed, which computes dose conversion coefficients (DCCs) for given nuclide and irradiation conditions and for an arbitrary organism. The utility integrates dosimetric data from the FASSET framework and provides a capability to interpolate between FASSET geometry sizes.

The utility operates on a database of radionuclide emissions as published in the electronic version of the ICRP Publication 38. This encompasses most of radiologically important radionuclides and has data for 838 radionuclides.

The utility is compiled as a stand-alone executable thus making it possible to be accessed from within the assessment tool being developed.

2.1.4 Task 4: Dosimetry - reconstruction and experimental support

A number of papers where it is possible to reconstruct doses for radiation effects to biota have been identified, in which the effects are not related to a dose but to an activity concentration. These papers will be used to estimate the corresponding exposure. Quality assurance routines and scoring criteria have been introduced to allow errors to be minimised and the usefulness of papers to be ascertained

2.1.5 Task 5: Development of environmental assessment tool, including the prototype software

An early prototype of the software tool programmed in Java has been developed. The programme is based on a flexible and easily expandable structure and has an attractive user interface and will include wizards for user-friendliness. The final prototype will have all equations of the FASSET framework, for all ecosystems and scenarios incorporated. Some implemented features are: an assessment browser, a report generator, support for input as time series and graphs and tables output.

Screening transport models (i.e. IAEA SRS-19 and MARINA II marine transport model) have been identified and provided in programme code. The models cover transport in atmosphere (short distance model), rivers, estuaries, lakes, coastal and marine waters and are appropriate for continuous or prolonged releases under equilibrium or quasi-equilibrium conditions. Ongoing work is focussing on integrating these models into the assessment tool.

2.2 Clarifications after the presentation

John Holmes. Does the software track uncertainties through the calculations? Answer (A). No, not yet, but it should be implemented.

Tatiana Sazykina. The software should take into consideration the climatic zone when the ecosystem is specified. The software should make calculations for a set of organisms, e.g. 5 or 6, not just one reference. A. The software allows you to select a number of organisms for an ecosystem type, but not a pre-set number representative of a given climatic zone.

Simon Carroll. Is it possible to have interconnected ecosystems? A. Not for the present. This could be implemented later perhaps. As for now you would have to run the tool one time for each ecosystem.

John Ferris. Is the software able to take output from one section (e.g. a transport model) and input the data into another, e.g. dose calculation? A. Not for now, could perhaps be implemented later.

Eric Vindimian. Is speciation in nature considered? A: No, the approach is based on distribution coefficients and concentration ratios.

2.3 Group discussions

2.3.1 Q1. Do you agree or disagree with the proposed list of additional nuclide?

Group 1

It was generally agreed that the radionuclide list proposed was acceptable, and that the list was considered only from the 'addition' viewpoint and not from the view of potentially 'subtraction'. A few additional nuclides were suggested, e.g. isotopes of Se, Cd, Au and Ba - as being of particular relevance for specific applications. The point was stressed that for dosimetry it is important to have information on the radiological parameters of the isotope in question (e.g. half-life, radiation type) but for transfer it is the chemical properties of radionuclide that is important.

Group 2

In principle the suggested amended list of radionuclides to be considered by the ERICA project was accepted as being appropriate. The group felt that only the chemical element was important in determining a list for deriving transfer parameters, i.e. no need for separate CR values for isotopes of the same element. For dosimetry the group felt that the ability to consider all radionuclides should be

given; it was noted that this function had already been developed by GSF for inclusion in the ERICA tools.

Five additional radionuclides were considered for inclusion: (i) for high-level waste assessments – Se, Cd, Pa; (ii) for medical usage Re, Au.

However, concern was expressed that there would be very few data for many of the additional suggested radionuclides. It was stressed that the ERICA outputs must acknowledge where there were gaps in knowledge. The group expressed the opinion that they would prefer to see data gaps filled by experimentation and not expert judgement.

Group 3

A question was raised as to where did the FASSET list originally come from? A: These were known nuclides from real sites. The proposed additions are nuclides found in later case studies.

Several voiced the opinion that the list is impressively long already and that no more additions are desirable. The list should be simplified somehow, e.g. to group speciation properties or other similarities. It was pointed out that this is difficult because nuclides with similar chemical behaviour may have very different radiological properties.

A question was raised as to whether noble gases should be kept in the list. A: Yes we have to at least give the opportunity to consider them.

New energy technologies may lead to releases of other nuclides, it should be therefore possible to make additions to the list later.

2.3.2 Q2. Is the use of probability analyses in the ERICA assessment acceptable?

Group 1

Not discussed in any detail. In general it was considered one of a number of possible approaches that might be utilised. The key question was considered to be "how" it would be use, rather than if its use could be acceptable.

Group 2

The suggestion of using probabilistic modelling/uncertainty analyses within ERICA was thought to be the correct approach by most members of the group: "there is variability/uncertainty so single numbers should not be presented". It was also observed that the variation between predictions and observations within ERICA D9 demonstrated the requirement for this approach. The members raised the question of how much uncertainty was 'acceptable' and questioned at what stage data had to be obtained if knowledge was poor.

There was some reservation expressed on how probabilistic assessments could be conducted when there was little/no knowledge of variation in a parameter. The suggestion of WP1 that flat distributions be used (for conservatism) in this circumstance was thought to be acceptable. However all assumptions and uncertainties should be acknowledged.

It was generally felt that the level of sophistication of the use of probabilistic/uncertainty analyses would increase from Tier 1 to Tier 3. It was also commented that the level of knowledge needed (and likely to be had) by assessors would also increase up the tiers. For Tier 1 a more conservative value should be selected from the distributions with realism increasing at Tiers 2 and 3. A suggestion that uncertainty/variability could be incorporated in the values used to set Tier 1 'failure values' was made – this was felt to require a prior decision on how many false positives are acceptable, then using available data from site assessments, and different values from probabilistic ranges generated, select parameter values for Tier 1, which result in approximately this number of false positives.

Group 3

The probabilistic method was discussed in terms of uncertainties and confidence.

The interesting range of doses is one order of magnitude that means even small uncertainties make the results useless. Because of this it is important to decrease uncertainties in concentration factors. Decreasing uncertainties could also be done with more site-specific information or by just noting the climatic zone when choosing ecosystem. A: this complicates calculations. A better approach than introducing many default parameters to choose from is to keep the tool flexible and open to input.

Uncertainties need to be explicit and traceable, they can't be ignored. A way to minimise uncertainties might be to use either conservative default values or better data. To link uncertainties to tiered approach, use conservative default values for Tiers 1 and 2 and use more refined value in Tier 3.

Q. Is it even possible to estimate the uncertainties? A. One needs qualifiers of the data, the state of knowledge or confidence. May also need expert judgment. The possibility to choose which probability function to use could be built into the software.

One way to look at uncertainties is to start from the question "what range of uncertainties will be acceptable", find the most sensitive parameter and improve this, if financially acceptable.

It is a fact that higher uncertainties are accepted at lower dose rates.

2.3.3 Q3. Is it acceptable to reduce the number of ecosystems from seven to three?

Group 1

The plans to reduce the complexity of the assessment tool by, for example, reducing the number of ecosystem types to 3 (terrestrial, marine and freshwater) and the consequent changes to the reference organisms list were briefly discussed. This raised questions over the interconnectivity of the ecosystems and how one would deal with assessments at the interface between two or more ecosystems within the tool.

It was generally felt that a robust and simple tool is needed but at the same time the existing data gaps should be acknowledged in a transparent way. Simplification may hide the data gaps. It was pointed out that one way of handling missing data is using the conservative Tier 1 assessment.

Group 2

The group agreed with this recommendation noting it had the advantage of being consistent with assessments for chemicals. However, there needs to be advice on how to assess ecosystems, which do not readily fall into one of the three categories, e.g. estuaries.

Group 3

A reduced number of ecosystems can still represent more than three systems by using transfer values.

More systems may be reinstated in later projects if ERICA has provided the basic framework.

Three systems are consistent with the way chemicals are treated.

There should be a help button or similar guidance in the software, to give advice on how to apply the ecosystems in specific situations, e.g. brackish waters.

2.3.4 Q4. Do you have any comments with regards to the ERICA assessment tool?

Group 1

The discussion focused on what the purpose of the tool was, whether it would inform decision-makers, test compliance, assess management issues and whether it would be robust and user-friendly. The main question raised was whether the tool would encompass extrapolations from the individual to the

population level. The point here was that if the tool did not address extrapolation from individual to population then it would not be possible to use the tool to make decisions in a legal/scientific context because it would not be possible to compare the effects of exposure to ionising radiation with other stressors.

There was some debate over the primary function of the assessment tool (i.e. to assess the risk from the ionising radiation) and whether incorporation of extrapolation from individual to population was actually taking the requirements of the tool beyond the scope of the ERICA project. It was also noted that the extrapolation issues that are being addressed in WP2 are looking to establish advice/guidance on methods that can be used to extrapolate from individual to population level, but whether this would be incorporated into the tool itself was questioned. The point was made that lack of extrapolation from individual to population weakened the tool and that the tool should not then be allowed to drive the policy. It should be that the policy drives the development of the tool.

In order to determine what was missing, the previous points about the end-use of the tool and what it will provide was reiterated, with the point being made that it was difficult to judge the proposed list of radionuclides for addition within the tool when the ability to be able to evaluate the risks from ionising radiation against other stressors had not been demonstrated. The point was made again that this may well be outside the scope of the ERICA assessment tool and that the proposed list of amendments/alterations was to address the ability of the tool to determine the risk to non-human species from ionising radiation.

Group 2

Some comments were made on the assessment endpoint.

- Should the assessment endpoint be at the level of individual? Some members of the group wanted to see population level predictions in the ERICA tool.
- Guidance should be given for understanding the impact of dose 'limit' being exceeded for one ecosystem component on the ecosystem in general.
- Regulate to the most sensitive component and ecosystem.

There was some discussion of the importance of speciation being acknowledged within ERICA outputs, an opinion being expressed that not accounting for speciation may result in underestimates of exposure. People were, however, of the view that the use of available measurements (which would incorporate effects of speciation) was acceptable for retrospective assessments. Whilst acknowledging that speciation was important it was suggested that it was not logical to try to incorporate it into a model, which already had a high degree of uncertainty. It was recommended that the assumptions made on speciation and their potential impact be made obvious to the user.

Group 3

The tool should above all be robust, this could be ensured by testing by non-experts unfamiliar with the tool.

Possibility to import data, e.g. time series, rather than typing them in.

Interface with other programs, build a shell around it.

Possible to input specific data when known, instead of default values.

Should have flexibility to add custom nuclides or ecosystems, but at the same time one should be very certain that the database can handle this.

There is a wish for dynamic modelling, but the restraining time frame is recognised.

2.4 Plenary session

Eric Vindimian. One has to accept variability and distinguish it from uncertainty. There may be a narrow range of uncertainty if there is low variability. Sometimes uncertainties may increase if you have more measurements.

Sylvain Saint-Pierre. Extrapolation in the first presentation's objectives was not covered satisfactorily in the "future work". It is important for the industry how big the uncertainty is. The industry does not understand the logics on: risk characterisation leading to criteria/standards *without* the extrapolation being included. Should extrapolation not be included in the risk assessment? It is a *key* for the assessment from the industry's point of view.

Justin Brown (JB). In the presentation we did say it was an area that needed to be addressed.

Brenda Howard (BJH). Can't implement it before it's available. We agree that this issue is important and relevant , but methods to actually carry this out have not yet been fully developed.

Irene Zinger (IZ). It's only the prototype.

Jaqueline Garnier-Laplace (JG-L). To be addressed tomorrow, brainstorming on development of assessment tool and its applicability. It is here that the interaction between WP1 and WP2 is important.

Simon Carroll. At which point will the input from the EUG shape the ERICA tool? Agree on Sylvian Saint-Pierre's concern about EUG being kept out for too long while the tool is being developed and essentially designed. Any other alternative?

Deborah Oughton (DHO). Maybe some of the concerns from Sylvian Saint-Pierre are that EUG members are not going to be consulted until it is too late.

BJH. Discuss when/how implemented in the assessment tool.

IZ. Discussion of the tiered approach in Spain will include how to incorporate EUG feedback.

Branko Kontic. Additional endpoints should be implemented in the tool. Authorities and managers need some information on population data to make decisions.

Sylvain Saint-Pierre. The tiered approach will have the same problem. If one thing is affected, everything will be affected. Look to fisheries, radionuclides are ignored as an environmental concern. We need to think not only bottom-up, but also from a management point of view.

John Ferris. Using the tool to re-assess some or all the case studies (published in D9) would represent a valuable test of the assessment tool's efficacy and should provide some guarantee that it works.

BJH. The decision-making guidance will need to address this point.

Simon Carroll. Such guidance is critical for the tool. It needs to give a clear input on how to use the tool/assessment in relation to all other factors included in decision-making.

Sylvain Saint-Pierre. IAEA will have a policy on these issues very soon, the weakness of the tools cannot set the criteria for the policy. Have to feed in data on population level.

2.5 Conclusions

Most people agreed that the list of radionuclides as adequate. Although some extra were suggested, concern was expressed that there would be very few data for those new ones. The tool should indicate where the gaps existed.

The suggestion of using probabilistic modelling was generally accepted, but perhaps more suited at the Tier 3. The presence of uncertainties raised the issue of acceptability at various tiers.

The EUG appeared to be in favour of reducing the number of ecosystems to three, which reflects its use in chemical assessments. Guidance should however be given to deal with other ecosystems, e.g. estuaries.

A number of suggestions were given on how to improve the ERICA tool, e.g. not limit the number of radionuclides or reference organisms. There was a need to define the purpose of the tool and where it would and would not be appropriate to use it.

Concerns were raised because the tool didn't address extrapolation issues and impacts of chemicals.

The ERICA Consortium agreed to re-visit all suggestions and extend the tool if necessary to include the extra features. A list of actions will be drawn based on all comments, including from D7c-Annex 1.

3 WP3. Communication and decision-making

3.1 Summary of presentation

A questionnaire was designed and circulated prior to the Freising EUG event to try and capture EUG views on a number of issues raised in the two previous EUG Thematic events, which produced Deliverables D7a and D7b:

- D7a - Transcript from the First EUG Event, Stockholm, May 2004:
  - Part 1: Discussion of ERICA Workplan
  - Part 2: Briefing notes on assessment frameworks and knowledge gaps; and
- D7b - Briefing Notes from the Second Thematic EUG Event, Aix-en-Provence, September 2004:
  - Part 1: Ionising Radiation and other Contaminants,
  - Part 2: Contribution to Deliverable D4 on Risk Characterisation.

WP Leaders also added a number of questions, which related to their work progress and publications of their latest deliverables, i.e. D4 and D9.

A presentation of the results from the questionnaires was given based on the initial 11 responses. The analysis enclosed in the report has been extended to include all 26 received EUG questionnaires. Note that the EUG includes 52 organisations in total. Appendix 5 reproduced the blank questionnaire.

EUG members were invited to re-visit their answers at the end of the meeting. Only three EUG members opted to amend their answers, mainly in the form of additional comments.

IRSN analysed the results using the software "SHAREPART". The tool is aimed at better visualising the responses, and identify clearly the "yes", "no" and controversial issues.

3.1.1 General questions

These included Yes/No, fairly straightforward questions but also asked for developments, see Figure 3.1. The following aims at giving an indication of the EUG's global view.

Consensus

Of the EUG respondents all but three say that they will use ERICA. They are unanimous to say the tiered approach is useful. They see no problem in having different indicators and units at the different tiers. This amounts to a encouraging support for ERICA.

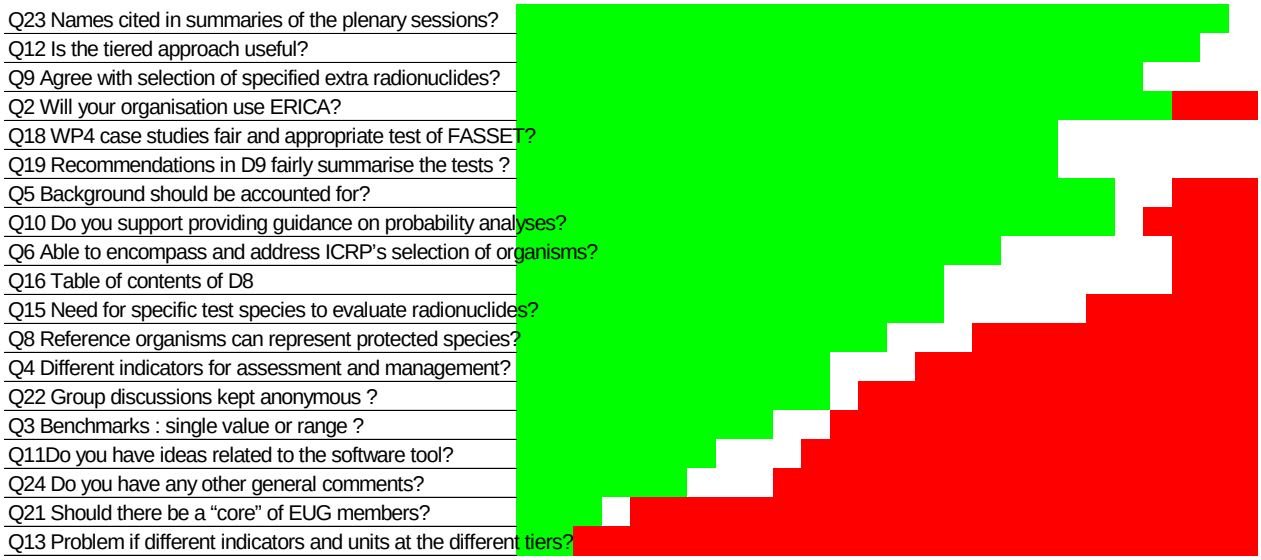
They unanimously agree with the proposed selection of specified extra radionuclides. A few others were suggested (Calcium, Xe-133, K-40, Rn-222, particularly for terrestrial animals living in soil, and radionuclides from new nuclear technologies especially nuclear medicine). However, a number of answers point to the fact that the list already appears to be quite long.

The EUG strongly believe background should be accounted for. When asked "*How should background best be considered in assessments, e.g. incremental or absolute levels?*" the answer seems to be incremental, although comments show that the question was perceived as somewhat ambiguous.

The group also feels that the ERICA approach is able to encompass and address ICRP's selection of organisms although it is less unanimous about this (20 % abstentions).

The EUG strongly support providing guidance on probability analyses.

Feedback on deliverables D8 and D9 was globally quite favourable.



Legend: *green = yes; red = no; blank = no answer.*

Figure 3.1: Sorted items to the Yes/No part of the questionnaire.

Mixed opinions

Is there a need for specific test species to evaluate radionuclides? 23 % say no, 15 % don't know and 62 % answer yes. But those who answered yes had different criteria in mind for the tests and the species; one group favoured alignment on the procedures used for evaluating chemicals, while others pointed out that this approach has been criticized and that radiosensitivity and practicality should guide choices in that field.

Can reference organisms represent protected species? 38 % feel they cannot, 54 % think they can. One person suggested "*a mapping should be provided that links the red list to the reference organisms*". That could, perhaps, help the EUG have a clearer position on this topic.

Should benchmarks take the form of single values or ranges? 58 % favoured ranges while 35 % preferred single values.

Should indicators be different for assessment and management? 46 % said no and 42 % said yes

One person's questionnaire included 3 no's with all other answers blank or unexplainable, and comments generally boiling down to negative and ironic remarks. Apart from this atypical return, there were no marked differences in the way the EUG responded to the yes/no questionnaire except that some offered extensive comments, while others didn't. Therefore, the main results above appear fairly reliable.

3.1.2 Knowledge gaps

Global comments on the answers

Many abstentions

There were many abstentions to these 16 questions. Technical reasons related to the questionnaire may account for some of these. For example, these questions appeared after 16 other questions, some of which asked for expanded answers. Some respondents may have felt "tired". The presentation was fairly

lively with choices to be made on a colour scale (on the positive side); but two answers were to be provided on each line, one on uncertainties and one on the best way to handle these uncertainties.

However, globally it seems that a number of respondents did not feel qualified to comment on knowledge gaps. Some 20 % of respondents did not answer at all. Those who answered had an average of 34 % abstentions. One question totalled more than 60 % abstentions while every question had at least 23 %.

Figure 3.2 is a picture of the answers ranging from green, meaning that the item is not considered a major knowledge gap, to red, meaning that, on the contrary, it involves very high uncertainty.

Differences in weighing uncertainty

Another global comment is that reds dominate: the proposed knowledge gaps are felt to be serious, as far as the group is concerned. There are clear differences, however, between respondents (which was not the case for the Yes/No answers): some are more inclined towards "conservative answers", others are somewhat more "optimistic".

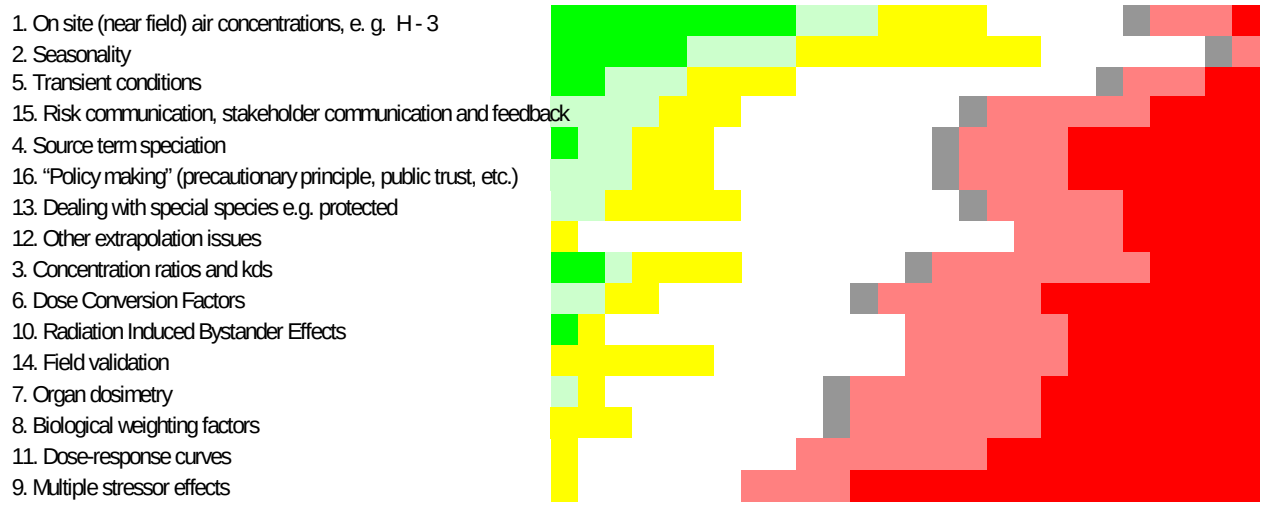
Therefore the following results deserve a balanced and prudent interpretation. Perhaps some respondents were very scrupulous and preferred not to answer if they were not sure, while others considered they should answer anyway and interpreted the items differently from the experts.

Groups of knowledge gaps

The first three items on the above Figure 3.2 are clearly believed to be less serious knowledge gaps than the others, namely: on site (near field) air concentrations, e. g. H-3; seasonality; and transient conditions.

At the other end of the range, two knowledge gaps were considered by the group to be extremely serious: dose-response curves and multiple stressor effects.

The other items are comparable, it seems, as far as the EUG tell us through this questionnaire, refer to Figure 3.3.



Legend:	Not a major gap	Gap with low uncertainty	Gap with moderate uncertainty	Gap with high uncertainty	Gap with very high uncertainty	I do not know	I do not want to answer

Figure 3.2: Knowledge gaps sorted according to level of uncertainty.

Each line is sorted from green to red; sorted lines are then reordered, the "greener" ones at the top of the list, the "redder" ones at the bottom.

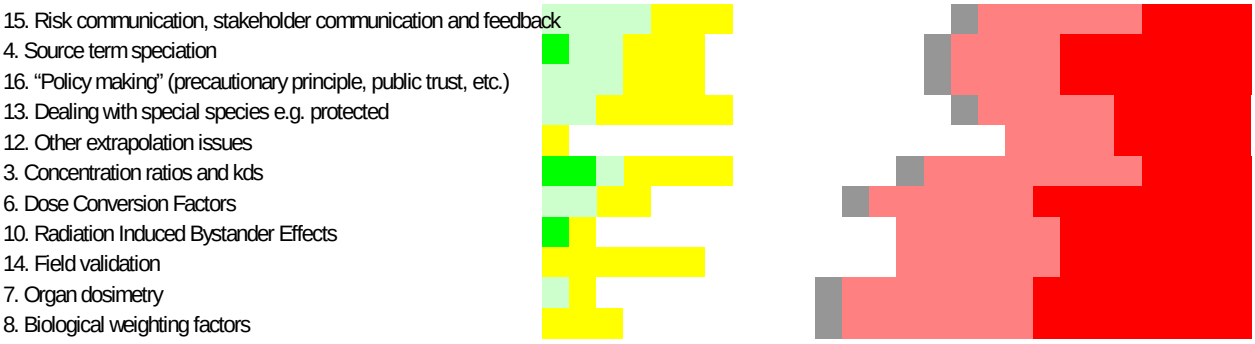


Figure 3.3: Eleven knowledge gaps area judged fairly similarly (same legend as for Figure 3.2).

3.1.3 Handling knowledge gaps

Respondents answered this question ticking possibilities including: expert judgement, modelling and experimentation. They generally chose to tick several. Therefore the answers are given in percentages, which do not add up to 100 %. We have outlined in Figure 3.4 the items for which the answers do seem to point to a preferred handling method.

	expert judgement	modelling	experimentation
1. On site (near field) air concentrations, e. g. H - 3	18%	29%	53%
2. Seasonality	18%	29%	6%
3. Concentration ratios and kds	35%	65%	65%
4. Source term speciation	41%	53%	41%
5. Transient conditions	12%	47%	24%
6. Dose Conversion Factors	24%	47%	47%
7. Organ dosimetry	12%	47%	41%
8. Biological weighting factors	24%	41%	53%
9. Multiple stressor effects	41%	82%	47%
10. Radiation Induced Bystander Effects	24%	24%	47%
11. Dose-response curves	47%	47%	47%
12. Other extrapolation issues	41%	29%	35%
13. Dealing with special species e.g. protected	53%	29%	29%
14. Field validation	24%	35%	59%
15. Risk communication, stakeholder communication and feedback	59%	12%	6%
16. "Policy making" (precautionary principle, public trust, etc.)	59%	0%	0%

Figure 3.4: Handling knowledge gaps

No clear links generally appear between these responses and the above concerning the seriousness of the uncertainties. However, "*Seasonality*" receives very few answers, probably because respondents didn't feel this was a serious knowledge gap. Perhaps because most respondents were scientific experts, a number also abstained answering for "*Risk Communication*" and "*Policy making*"; and those who answered opted for expert judgement. For similar reasons, probably, "*Dealing with special species*" is the only other item to be treated, preferably, by expert judgment.

Modelling is a clear winner for "*Transient conditions*" and "*Multiple stressor effects*".

Finally "On site concentrations", "*Radiation induced Bystander Effects*" and "*Field validation*" seem to be best handled through experimentation. Other items show no one preferred choice.

3.1.4 Additional written comments

Some EUG members gave a number of additional comments. All raw data were assembled and produce the Annex 1 of D7c, with over 15 pages of individual comments. This document will remain restricted, as will all individual responses to the questionnaire. The Annex will be read by the ERICA Management Group and derived actions identified and incorporated in the Progress Report No. 3 on "EUG inputs and resulting ERICA actions", in the EUG protected area of the website.

3.1.5 Table of Content for D8 "Decision-making guidance"

The table of content was circulated following the Aix EUG event in September 2004 and comments sought via the e-newsletter.

It was provided once again prior this event as an item for discussion, available in Appendix 6.

3.2 Group discussions

3.2.1 Q1. Questionnaire responses indicate that most EUG members feel that dose conversion coefficients (DCCs) are a greater source of uncertainty than are transfer coefficients. What is the justification for this?

Group 1

Firstly there was a general discussion over the questionnaire and it was noted that perhaps a little more background/description for each question was needed to help to understand the question being asked.

When discussing the specific questions, the point was made that individuals may feel more certain about certain aspects/concepts where they were more familiar. So for example with the dose conversion coefficients (DCCs) issue, most of the group felt that they were unfamiliar with the concept and it's application and therefore felt more uncertain about its application. This is in contrast with the use of transfer factors, which people are familiar with and have used and therefore felt more certain about. In discussion it was pointed out that actually in terms of numeric uncertainty the DCCs are more certain than the transfer factors and this was accepted but demonstrates the importance of asking the question in the right way and in the provision of supporting information.

There was limited discussion on the content and structure of D8 and the issues surrounding the extrapolation issues were again raised and how these might be addressed within the decision-making guidance. It was accepted that the structure of D8 needs further evolution and more notes on the issues to enable the readers to better understand what will be present in each chapter and how this relates to the objective of D8.

Group 2

The group discussed the problem without reaching a good explanation. Some of the group indicated that the response could be related to problems in converting Bq to Gy and then to Sv for biota, as we do for man. Biological endpoints for man (reflected in the Sv) are different for biota. The group generally agreed that the conversion from Bq to Gy should be straightforward and be accepted based on physical laws (energy, in Joules, absorbed per kg tissue). It was noted that ERICA DCCs estimated Gy and not Sv. Some of the group also expressed reservations with regard to assuming homogenous distribution of radionuclides in organisms when applying DCCs.

Several persons stated that the use of distribution coefficients, transfer factors, transfer coefficients, aggregated transfer factors concentration factors, bioconcentration factors are commonly applied in the

literature. The fact that most of these factors require that equilibrium conditions are attained, seems not to be taken into consideration when uncertainties are estimated.

The suggestion was made that transfer estimates can be validated whereas DCCs cannot and that this may have influenced the answers to the questionnaire.

Group 3

Need to be clear about the definition – the coefficients are based on the calculation of absorbed dose (energy deposited per unit mass in a given volume of tissue).

Dose conversion coefficients (and doses) are calculated quantities – only in exceptional circumstances can they be measured directly.

The calculations as implemented in FASSET/ERICA make a number of simplifying assumptions – geometric shapes for organisms, uniform distribution of radionuclides within organisms and in the surrounding environmental media, dose averaged over the whole volume of the organism is calculated.

These assumptions can be changed in principle; dose coefficients can be calculated for any arbitrary distribution of radionuclides relative to specified 'target' volumes. However it is difficult to implement such 'one-off' calculations in a general methodology; the simplifying assumptions allow a manageable number of dose coefficients to be 'pre-calculated' and tabulated for use in an assessment.

The use of absorbed dose averaged over a relatively large volume may not be appropriate if a specific, and small, sensitive volume is important in determining harm. This factor assumes particular potential importance when the range of the radiation in tissue is small compared to the volume of the organism.

Overall, the question is more about the relevance of the quantity calculated to the assessment of harm rather than uncertainty in the quantity – within the terms of the definition of the quantity, uncertainties are probably quite small.

Transfer coefficients are almost invariably derived empirically – measurements of radionuclide concentrations in an organism are simply related to concentrations in a chosen environmental medium (usually, the soil or water of the organism's habitat) and the resulting ratio used as a means of calculating radionuclide concentrations in that type of organism for a given concentration in the chosen environmental medium.

Choice of media and organisms to relate is important, e.g. relate benthic organisms to water or sediment: if sediment, surface or depth; if water, filtered or water plus suspended sediment …

It is accepted that transfer factors will be subject to spatial and temporal variability due to changes in the characteristics of the environment – salinity, temperature, soil and sediment mineralogy, etc.

Transfer coefficients represent the empirical sum total of many different processes and factors – the habits of the organism in terms of its location; the food chain through which the organism takes up radionuclides, any bio-magnification through the food chain, the dynamics of radionuclide uptake and clearance, etc.

The key problem is that it is not practicable to derive empirical transfer factors for all of the radionuclide/ecosystem/reference organism combinations. Moreover, because there is relatively little quantitative information or understanding of the processes and mechanisms involved, extrapolating from the purely measured values becomes a source of substantial uncertainty.

In relation to the question – 'which type of factor is the greatest source of uncertainty' – the group decided 'It depends'. Particular circumstances can be envisaged in which either is the more important.

It was also noted that if an individual understood dosimetry (DCCs) or radioecology (transfer factors) they would have a good intuitive understanding of where assumptions were reasonable, and where they were weak, in their own area of expertise – but would be inclined to place more weight on the uncertainties in the field with which they were less familiar.

The group recommended that:

- dialogue between dosimetry and radioecology specialists should be encouraged;
- dose conversion coefficients for more complex geometries should be developed (recognising that matching information on radionuclide distributions would be needed if these were to be used); and
- efforts should be made to better understand the mechanisms of radionuclide transfer to organisms so that extrapolations can be more reliably made.

3.2.2 Q2. Stakeholders in the case study exercise felt it important that the assessment framework should be able ensure that particular protected species (specific to study sites) were not harmed. How can this be achieved in practice?

Group 1

With regard to protected species, there was some debate as to whether the reference organism concept could adequately address these concerns with some of the group feeling that this was not the case and others feeling that it could. Again it was felt that a better definition of the question and provision of more background material would have helped in the interpretation and answering of this question. It was felt important to provide clear guidance on how the protected species could be addressed using the reference organisms concept especially as protected species may be the method used in a legal instrument. It was felt that there might be a communication issue over the use of reference organisms.

Group 2

After a long discussion on reference organisms, the need to make the strategy simple (few reference organisms) and the need to reduce uncertainties (need for many reference organisms representing biodiversity), the group finally agreed that protected species, especially those of concern for local stakeholders, should be included in the assessments to maintain the credibility of the whole assessment process. “No harm statements” based on a total different biological species will not be considered relevant and credible for a red list species of concern for stakeholders.

Whilst some members of the group felt that as scientists they could accept that protected species could be assessed within a reference organism approach they had some reservations as to if the lay public would accept this. The group was in general agreement that this was more an issue of communication (with openness and transparency) than science. Some group members felt that a non-radiological environmental monitoring assessment (i.e. statement that the ecosystem was ‘healthy’) accompanying any radiological assessment would be beneficial.

Group 3

The group endorsed the conclusion that sets of reference organisms should be extended to ensure that generic organism types are available which can reasonably be used to represent all protected species, e.g European Red List.

In considering their protection at a specific site, care should be taken to consider all relevant threats, not just radiation in isolation.

Some consideration of regulatory requirements for protection, to clearly define the level of protection required, would be helpful.

If the tiered approach can be shown to be sufficiently conservative, it may be possible in many cases to assure the well being of protected species at an early stage of the procedure, i.e. that no organisms, including protected species, could conceivably be harmed.

Where this is not possible, the group did not expect the ERICA integrated approach to provide a ‘complete answer’ to the assessment of protected species. So long as these organisms can be fitted into the generic integrated approach, the basis exists for further investigation on a site-specific basis.

Where concerns have been raised by particular groups of stakeholders involved in the site specific investigations, local knowledge and/or the specialist knowledge of regional or national nature conservancy organisations is likely to be an effective means of resolving the issue and reaching balanced management decisions.

3.3 Plenary Session

Q1 and issues relating to the questionnaire itself

BJH. People were clearly having problems understanding the meaning of DCCs; we need to go back to better explain the basic methodology of the approach.

Nick Beresford (NAB). Not necessarily a lack of understanding of dose, people were not sure about the way the question should be interpreted.

IZ. Add definition to glossary?

BJH. Yes, but not enough, I think.

DHO. There are two communication problems for ERICA. 1) how ERICA presents issues to the EUG and 2) how ERICA explains these issues in the decision-making guidance (D8).

Branko Kontic. What are behind the questions? Drop out of the sky? We know the terms, but not the context in which they are asked.

IZ. The list of knowledge gaps did not drop out of the sky: it was derived from the very first EUG meeting as explained in D7a.

Eric Vindimian. Can understand the misunderstanding, the need for the right equation to be sure that we answered the right question. It depends on the depth of knowledge.

Simon Carroll. The challenge is how the project interprets the questionnaire and responds to the findings obtained. How will the EUG's input be used?

John Ferris. The conceptual basis of dose conversion and transfer coefficients need to be understood by a wide range of people with differing levels of technical expertise.

Brit Salbu (BS). Put content on the net to be sure that the terms are equally understood. Value of material is very high.

BJH. Would condensed information be useful in a simple form outlining the approach and put on web site?

Gerhard Pröhl (GP). Many of the things are written in the executive summaries of the FASSET reports.

BJH. Yes but we need to make them more accessible.

John Ferris. It is important to integrate the potential effects of radiation with all the other environmental concerns; habitat protection etc.

IZ/DHO. The issues will be addressed continuously during the next 18 months of the project. We can address what has been touched upon earlier in the forthcoming EUG events.

Simon Carroll. My concern is how are these questions framed? The ways they are framed, in some cases, appear to be driven by the Consortium in a way to state its major concerns. The framing process is essential. Where do the inputs to framing the questions come from and how does this framing influence the outcome?

DHO. I understand that concern. But this is not the definitive ERICA questionnaire; it was intended to serve as an aid for this meeting. Perhaps we could make a similar questionnaire for the next meeting that focuses more on D8, and give the EUG chance to comment on the questions before they have to answer them.

Branko Kontic. I understand what a dose is, but I do not understand these questions. Let us have the opportunity to express ourselves. I would like to contribute, but you expect certain answers, don't do that, and let us answer without expecting something particular.

What is the integrated approach; nevertheless the story is repeatedly going on; compliance is the conclusion for every group.

D8

Branko Kontic. We don't have a definition of decision-making that is the basis for this document. Explain very briefly what ERICA are trying to suggest. The "cookbook" content misses in the D8 overview. How can this document help the decision-makers? Need to include and clarify certain issues.

Miliza Malmelin. D8 comments: title is not very good. Guidance? On what/where to put a plant? The heading is not telling us guidance on what?

Chapter 2 comments: technical requirements are not reflected anywhere, should be noted that they are not here.

Branko Kontic. What about the planning of installations: if you want to reserve a site, how can you get it in the space of spatial planning (which leads to long term consequences)? This is not further explored.

Sylvain Saint-Pierre. The group I represent is not here to discuss guidance and on how we make decisions. We are only interested in guidance regarding the scientific tools. It does not preclude us to give inputs into the discussions, but we are not to take guidance for decision-making.

Eric Vindimian. Guidance is not a cookbook, but a key to where to find information, analogue to travel-guides. The D8 gives you the same it should not take the decisions. This is very different from a cookbook, as Branko Kontic described it earlier.

IZ. I agree with Eric Vindimian's approach to D8.

Simon Carroll. This is not a "pure" science document. It incorporates value judgements, assumptions, etc. If you look at the tool, you have to recognise where these values are coming from.

3.4 Conclusions

The answer to the DCCs vs. transfer question seemed to depend on the knowledge and area of expertise of the person questioned. Simple tutorials, which extend beyond a glossary, may help bridge this gap. This becomes important to understand issues such as uncertainties and extrapolation. Giving examples also helps in understanding difficult concepts.

The reference organism concept should be able to represent protected species. Adding some guidance may help, especially at Tier 3. Stakeholder involvement at that Tier is also highly recommended (also discussed in Section 5).

More background information should be provided when asking to fill-in a questionnaire. The creation of a questionnaire raised many discussions and EUG have expressed an interest to be part of the process of setting questions.

A clearer objective is needed for D8, with possible revision of its structure and title. EUG members would like to spend more time on this document. Monitoring issues should for instance include verification and not only compliance.

4 WP4. Deliverable 9 - Application of FASSET framework at case study sites

4.1 Summary of presentation

In April 2005 WP4 published Deliverable D9: Application of FASSET framework at case study sites (Editors: NA Beresford and BJ Howard); the deliverable is available from the outputs page of the ERICA website. The presentation summarised the findings and recommendations of the report, the executive summary of which is reproduced below.

The assessment tools, which will be the outputs of the ERICA project, will be based on the FASSET framework for assessing the environmental impact of ionising radiation. This deliverable describes the application of the FASSET framework to five different case study sites. The case study sites were selected to test all of the components of the FASSET framework and included: (i) sites contaminated by anthropogenic releases of radioactivity and technologically enhanced natural radionuclides; (ii) regulated sites; (iii) contaminated areas where potential radiation induced effects had been observed; (iv) marine, freshwater and terrestrial ecosystems. The case study sites were: Sellafield, Loire River, North Sea oil and gas platforms, the Chernobyl exclusion zone and areas of enhanced natural radionuclides in the Komi Republic. The objectives of the case study applications were:

- to assess of the applicability of the FASSET framework methodology;
- to compare predicted and observed activity concentrations in biota (and water/sediments for aquatic ecosystems);
- to identify data gaps;
- to compare, where possible, observed radiation induced effects with estimated doses and predicted effects;
- to make recommendations to the ERICA project to guide developments of the ERICA assessment tools.

The process of applying the FASSET framework to different case studies has been valuable in highlighting areas of improvement for consideration during the ERICA project resulting in the following recommendations:

- ERICA should consider the scenarios it expects its tools to address. ERICA should be clear in its output when the methodology will and will not be applicable, considering: equilibrium, site specific factors and historic discharges.
- The guidance produced by ERICA must be user friendly and concise, it needs to clearly guide the assessor through the conduct and interpretation of all stages of the assessment, providing: interpretation of results at the various stages, guidance on how to proceed if required data or parameters are missing, guidance on how to take background exposure into account and guidance on chemical toxicity
- The ERICA tool and other outputs presenting guidance must be consistent, and their purpose and status clear. A consistent terminology must be used. Consideration should be given to providing guidance on how to present the assessment process and results to an interested but non-technical audience.
- The ecosystems and reference organisms considered by ERICA should be rationalised and consideration given to interface between different ecosystems. The reference organism list should encompass protected species, for instance, terrestrial birds and amphibians. The additional radionuclides identified in the case study assessments need to be prioritised for inclusion within ERICA.

Many aspects of the FASSET framework, which could be improved during the development of the ERICA tools, were identified. It will not be possible to address all of these within the resources and timescale of the ERICA project. We therefore need to agree and prioritise the recommendations. A fundamental question to ask during this prioritisation is: *how (and where) do we envisage the ERICA tools will be applied by end-users and what will they expect of it?* Interaction with end-users within the ERICA project may help in addressing this important question.

During the presentation, a number of slides summarised priorities, which were then discussed during the group sessions.

1. ERICA should consider scenarios its tools will address.

2. ERICA should be clear in its output when the methodology will and will not be applicable, considering:
    - equilibrium; site specific factors; historic discharges.
3. Guidance produced by ERICA must be much more user friendly (and one document), it needs to clearly guide the assessor through all stages of the assessment:
    - interpretation of results at ALL stages
    - how to proceed if required data or parameters are missing
    - how to take background exposure into account
    - on chemical toxicity
4. The ERICA methodology must not include assessment steps it does not provide guidance on how to conduct and interpret.
5. A consistent terminology must be used.
6. The ERICA tool and other outputs presenting guidance must be consistent and their purpose and status clear.
7. FASTer model validation.
8. The reference organism list should encompass protected species (e.g. terrestrial birds and amphibians).
9. Additional radionuclides identified need to be prioritised for inclusion within ERICA.
10. The ecosystems and reference organisms considered by ERICA should be rationalised and consideration given to interface between different ecosystems.
11. If ERICA is to continue the FASSET recommendation that uncertainty analyses be conducted as part of the assessment process it should provide the ability to do this.
12. ERICA should consider providing guidance on how to present the assessment process and results to an interested but non-technical audience.
13. The ecosystems and reference organisms considered by ERICA should be rationalised and consideration given to interface between different ecosystems.

4.1.1 Clarifications after the presentation

Marianne Calvez. Marianne Calvez. Will the FASTER tool be improved to help assessment in case of missing data? A. The ERICA project plans to check the tool for usability. At present FASTER has not been validated. If the tool is to be included in ERICA methods, it will be validated.

Sylvain St-Pierre. What impact zones were used for the sites where the FASSET methodology was tested? Which were the criteria used to define the zones to be assessed? A. The sites were of very different nature. The characteristics of the sites and their activities and information available on their contamination influenced the selection of examined areas. For instance at Sellafield the area encompassed a protected site which would need to be included in an assessment whereas for the marine platforms expert judgement was used to define the zones.

4.2 Group discussions

4.2.1 Q1. To help us prioritise the recommendations of D9, how and where do you envisage using the ERICA tools and what will you expect of it?

Group 1

In order to determine how the assessment tool might be used a list of end-user applications was generated and recorded. The were a wide range of possible applications proposed and it was agreed that

the ERICA Consortium should consider these and assess whether the tool could provide the output necessary to achieve these requirements. The following lists some of the issues raised:

- understanding links between emissions and effects;
- to advise and demonstrate links between discharges and effects;
- tool for analysing population (not individual) level effects;
- assessing on-going releases;
- assessing compliance;
- prospective assessments;
- as a regulatory tool (prospective and retrospective);
- emergency response (to a lesser extent);
- what if scenarios for remedial activities;
- OSPAR and Habitats assessments;
- planning regulations;
- technology assessments for comparing energy options, etc., to address say climate change; and
- comparison of risks for different options.

There was also a discussion and vote of the prioritisation of the recommendations from WP4. WP4 priorities are taken from the slides from the presentation. We numbered these 1 - 13 (the last bullet point on the third recommendation slide is a duplicate). It was then agreed that bullet points 3, 4, 6 and 12 were all essentially the same and related to guidance being clear, transparent and communication issues.

Points that came out were, in order:

- Point 2. ERICA should be clear in its output when the methodology will and will not be applicable considering equilibrium, site specific factors and historic discharges.
- Point 3. Guidance produced by ERICA must be much more user-friendly.
- Point 11. Provide the ability to include uncertainty analyses in the assessment.
- Points 9 and 10 both got one vote each, with point 9 on additional radionuclides needing to be prioritised for inclusion and the interface between ecosystems also considered.

Group 2

The group split this into two questions: (i) to prioritise the D9 recommendations on the slides as presented at the meeting; (ii) how and where they would use the tool.

After discussion each group member (including ERICA participants) selected the three most important recommendations from their point of view. The overall ranking of the importance of the recommendations was as follows.

1) Guidance produced by ERICA must be user friendly, allowing interpretation of all stages, guiding the assessor when required data/parameters are lacking, providing advice on chemical toxicity and background exposure (10 votes).
2) ERICA outputs should be clear, the limitations acknowledged, consistent, and purpose clearly stated (6 votes); include uncertainty analyses (6 votes).
3) Consider scenarios that ERICA tools will address (2 votes); provide guidance on presenting outputs to non-technical audiences (2 votes); rationalise ecosystems and reference organisms and consider ecosystem interface (2 votes).
4) Reference organisms list should incorporate protected species (1 vote).

The potential uses that the EUG members would have of the ERICA tools were: contaminated site assessment; teaching; compare various scenarios.

It was stated that the ERICA tool would not be used if the users did not have enough knowledge of the assumptions and approaches used to enable them to defend the findings within the assessments they conducted. It was also requested that the tool have greater flexibility such that the user could add radionuclides and/or ecosystems. The group expressed the view that it would be too much to expect that the ERICA tools also considered chemical risk. However, they felt that guidance on chemical toxicity during TENORM/NORM assessments should be provided (e.g. including tabulated toxicity values).

The group suggested that the ERICA tool and guidance is made available to the EUG for testing, with information so that they can also conduct a case study assessment.

Group 3

Industry will not use the tool in the short-term, they want to see results from other uses and let the system mature. It is too much responsibility to use a new, unproven 'framework'. They are waiting for go-ahead from IAEA, not wanting to invest in something untried. Need to be careful.

A number of uses for the tool was mentioned, such as: a need to invest in science to ensure clean environment for regulating purposes and predict impact from planned activities, prospective assessment; to prove to the public that the decisions are made with scientific confidence; as a prediction tool, and also in case studies, for looking for site for waste disposal and needs arguments to present to the public to select the site; current need for a tool to assess radioactivity as well as other pollutants.

FASSET works best in retrospect, weakest for predictions. The same may be the case for ERICA. This must be considered when deciding where the tool is applicable.

A question was raised to whether ERICA was more on the assessment than on the management side? A: The goal is an integrated tool to make management decisions. The software only helps with assessment, but the output from ERICA should be guidance on both assessment and management. The tool should be relevant.

The tiered approach is using the tool in management decisions, giving basis for decision combined with other frameworks.

Politically there is the need for transparency towards the public and ERICA might help with this. Some disagree that this need is real.

4.2.2 Q2. What level of agreement between observations and predictions is acceptable?

Group 1

It was considered that there is not one answer to this question. It is more important to understand where the disagreement comes from than only looking at the level of how much it is. Possible reasons include site-specific values, equilibrium/non-equilibrium case, model characteristics etc. The uncertainty of the assessment and measurements should be understood and explained. Also significance of disagreement may be different e.g. if the results are far below or near a reference level. The steepness of the effect curve may also be one factor in the acceptance of disagreement. Further, it was felt that the acceptance of disagreement could be different at different Tiers 1-3. In any case it is important to have confidence in the tool.

One possible way to improve assessments could be taking advantage of existing chemical models and in general sharing information with chemical field.

Group 2

It was agreed that the level of agreement depends upon the estimated dose and impact. For instance, if the estimated dose is trivial then the level of agreement does not have to be high. However, if estimated doses are approaching any 'limit' or requirement for intervention then the level of agreement must be good. Similarly it was recognised that the level of agreement between predictions and observations was most critical at Tier 3.

However, the group felt that the level of agreement accepted by scientists and the public would not be the same: the public expecting a high level of agreement if they are to give credibility to predictions. Presentation of uncertainty to the public needs to be addressed.

Group 3

Regulations should be aware of local variations e.g. in background, this needs to be considered in ERICA.

There was a strong preference for measurements over predictions.

Statistics say the confidence should be inside 90 %.

Uncertainty of four orders of magnitude for one nuclide when the other nuclides in the same calculation are in good accordance is not actually a problem in dose calculations, but might seem like a big problem to non-experts.

Take care how the success of the predictions from the model is presented to the audience.

It is not always possible to compare calculations to observations. What experience is there with agreement in retrospective cases, do they suggest the predictions are reliable?

One should have a good idea of the possible variation in uncertainty, to make the decision on what uncertainty is acceptable.

What is the domain of validity of the tool? The software should raise a flag when not really being applicable.

Is observation subjective (looking and interpreting, human factor) or objective (measurement error)? This gives rise to different types of uncertainties.

The level of acceptance depends on what tier we are on, higher uncertainties in lower tier, narrower range in Tier 3.

There is no general rule for what uncertainty is acceptable; it always depends on the scenario.

4.3 Plenary Session

Q1

DHO. As a general summary from the group discussions it appears that there is a wide interest among the participants to use ERICA methodology for various purposes. Should also remind you that the approach is still under development, and that ERICA Consortium has solicited involvement of the EUG participants already in this early in order to get views and advice how to improve the methodology.

John Ferris. After seeing the more developed assessment tool it would be possible for the EUG to give more informed comment on the content than at this early stage.

Simon Carroll. The ERICA tool should not be used in isolation. It should be kept in mind that there are other tools available and that the results of application of the ERICA tool will almost certainly be used in conjunction with other approaches.

Paul Whitehouse. There is a need to apply ERICA assessment approach shortly in the UK, e.g. Habitats Directives. ERICA is suitable also for deriving standards to implement Water Framework Directive.

Sylvain St-Pierre. Concerning radioactive substances it is the Euratom treaty that is valid.

Branko Kontic. Standards can be developed on the basis of this ERICA tool. However, this tool does not include technical, economic and other such aspects. Also note the last slide for Criteria talk on too wide to encompass within ERICA.

IZ. The slide refers to a generic presentation on setting criteria and standards, and be given tomorrow.

Q2

DHO. I noted that all groups mentioned the tiered approach and seemed to suggest that it may help in this issue.

Eric Vindimian. With four orders of magnitude differences between calculated and measured values the origin and reasons of the differences need to be understood. Possible reasons may be that site-specific data should have been used instead of generic data, effects of speciation etc.

DHO. Yes, differences need to be accounted for, but they may also help us understand why we got the observation wrong in the first place. Can be used to improve the tool.

Hildegarde Vandenhove. It is important to be able to explain the deviations of the calculated data from the measured values. A scenario should be developed and made available so that the EUG members could test ERICA method.

BJH. Site tests and responses of the EUG are part of a learning process in the project. The suggestion of having the case study available to the EUG for testing will be considered by the ERICA Management Group.

4.4 Conclusions

The ERICA guidance and outputs must have a clear scope, be user friendly and transparent in order to have confidence and credibility in the ERICA integrated approach. Chemical toxicity should also be addressed, perhaps as an appended set of tables for comparison purposes.

Improvements to the assessment tool were suggested, including adding uncertainty analyses, not restrict the number of radionuclides, reference organisms, be able to cope with inter-connecting ecosystems. This was also mentioned in Section 2.

A wide range of possible applications of the ERICA integrated approach was identified, e.g. pre-planning stage for the siting of installations, emergency releases. Some EUG members felt that ERICA may be limited if no data are available, e.g. when dealing with prospective assessment. For others, it was difficult to say whether they will use the ERICA integrated approach without knowing what it can do. A possible solution would be to provide different EUG members with the same case study to test at the same time as WP4 the ERICA integrated approach.

Regarding the level of agreement between predictions and observations, it was generally felt that it depended on how close to the target you are, i.e. how much deviation can be tolerated. Whilst disagreement is greater in Tier 1, agreement is most critical at Tier 3. Guidance is therefore needed on how to deal with differences between predictions and observations.

5 WP2. An interim tiered methodology for the ERICA integrated approach

5.1 Summary of presentation

WP2 published in April 2005 Deliverable D4a: Ecological Risk Characterisation: An Interim Method for the ERICA Integrated Approach (Editors: D Copplestone, M Björk, and M Gilek). The presentation summarised the findings and recommendations of the report, and its executive summary is reproduced below.

Ecological Risk Assessment (ERA) is an increasingly important component of any decision-making process that aims to provide transparent management decisions on environmental practices and associated problems. It is the method of risk assessment being applied and developed as part of the ERICA integrated approach, including the various aspects of planning, problem formulation, assessment, risk characterisation and decision and management. One of the challenges in developing risk assessment guidelines is to provide a method that can be applicable to different cases and contexts, for example, historical and ongoing activities (retrospective risk assessment), future activities (prospective risk assessment), as well as evaluation of both chronic (or routine) and acute (or accidental)

releases. In this respect, ERICA is proposing a more flexible approach to risk characterisation, in the form of a tiered approach, which allows for greater integration between the assessment, characterisation and decision-making aspects of ERA.

This document introduces the tiered assessment as an interim method for the ERICA integrated approach, which focuses on the technical aspects of the actual risk assessment/characterisation method but does not consider in any great detail how the ERICA integrated approach will handle the stakeholder and decision making aspects. This will be discussed and expanded by other participants in the ERICA project. This part of the deliverable (D4a) provides general guidelines and principles to demonstrate how ecological risk assessment and management processes can be applied across the range of activities that use radioactive substances. These guidelines and principles have been derived on the basis of the review presented in Deliverable Part b.

Although the method has not been fully developed, there are a number of reasons for introducing this interim approach at such a relatively early stage in the project. First, the good practice guidance for risk characterisation (deliverable D6) is not due until month 34 (out of 36) of the ERICA project. The ERICA consortium felt that this left too little time for detailed interaction with the ERICA end user group (EUG). Hence the risk assessment guidelines described in the following sections have been drafted to facilitate, and stimulate, discussion between the EUG and other interested stakeholders and the ERICA participants as an interim stage in the development. Second, the ERICA consortium needs to agree on a basic approach in order to test and apply the assessment and modelling tools being developed in other parts of the project, as well as the basic guidelines for decision-making.

The proposed risk assessment guidelines are based on a tiered design as outlined in Figure 5.1. The following text pulls out some of the key requirements/processes that are associated with each tier of the assessment and discussed in detail within this document.

Problem formulation

- Defines the scope, endpoints and purpose of the assessment;
- will consider what is already known about the site, its historic use and the proposed or operational practice being assessed;
- some stakeholder engagement is required in the problem formulation to ensure that all aspects are considered;
- uses a conceptual model to lay out the issues in a clear and transparent manner;
- defines any source – pathway – receptor linkages present.

Tier 1 (Screening)

- Evaluates the risks using a conservative approach;
- uses maximum environmental activity concentrations derived from measured or modelled predictions (of dispersion from the source) – takes no account of spatial or temporal variation;
- compares the measured/modelled activity concentrations for each radionuclide being considered against the activity concentration for the most sensitive reference organism which would give rise to a dose rate that was considered unacceptable;
- has the advantage of identifying which radionuclides present at the site would contribute most to the exposure of the reference organisms which might be useful in guiding where resources need to be directed to find out additional information if the assessment proceeds to the higher tiers.

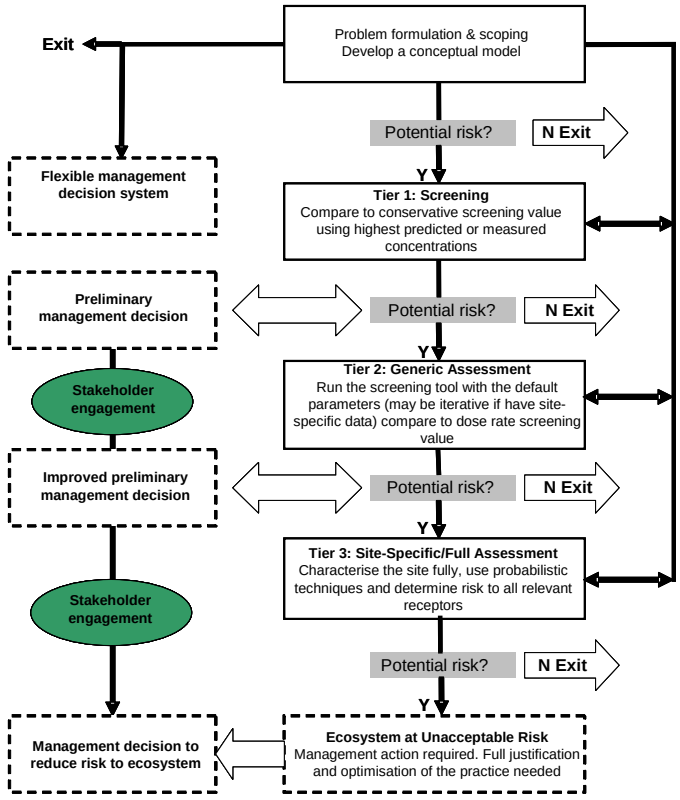


Figure 5.1: Overview of the interim ERICA tiered approach to risk assessment.

Tier 2 (Generic assessment)

- Introduces dispersion modelling techniques (using site-specific models or default models that will be made available within the ERICA assessment tool);
- introduces available site-specific data or encourages its collection;
- compares the predicted dose rates to the same dose rate considered as unacceptable in Tier 1 but by using dose rates introduces the flexibility to use different, but justified, radiation weighting factors for different radiation types;
- may involve evaluation of the likely biological effects of the exposure to ionising radiation by comparing the predicted dose rates to the data held on effects for example within the FREDERICA database;
- some, but probably more limited, stakeholder engagement at this stage.

Tier 3 (Detailed assessment)

- Full site-specific assessment, requires gathering of additional data as necessary – this may include ecological survey work, measurement of radionuclide concentrations, measure (air kerma) dose rates using TLDs and monitors etc;
- evaluates all the key impacts on the site including non-radioactive contaminants (although there is limited consideration of this in the earlier tiers);
- consider the background radiation levels in the area being assessed;
- introduction of probabilistic techniques to aid in the assessment;

– no defined prescribed screening level but involvement of stakeholders to agree whether the practice is acceptable in terms of its environmental impact versus the economic and social benefits.

5.1.1 Clarifications following the presentation

Steve Jones. What does Tier 3 look like? For prospective use it does not allow to get more site-specific data. The operator might give up and ask for a better model. A: Find out anything about the site, e.g. soil type, then stakeholders can comment. Human risk evaluation already drives this. Any new information will improve the model in the further project.

Sylvain St-Pierre. Assume calculations show that chemicals contribute more than radioactivity. There may also be natural variation in populations, not necessarily from stressors.

JG-L. You should know the natural cycle beforehand.

DC. If not important, go to Tier 1, if unacceptable, go to Tier 3.

EricVindimian. The stakeholders are important in the decision on what is important.

Branko Kontic. Is a yes/no for screening level? A: Yes. Screening level involves acceptability. The number you compare to is the criterion. A "yes" brings you to Tier 2.

DC. Tier 1 is used to focus effort on the biggest problems. It is a risk-based assessment.

5.2 Group discussions

5.2.1 Q1. Is the overall tiered approach acceptable, flexible enough and which aspects need more consideration?

Group 1

The tiered approach was generally accepted as an overall approach. Some refinement was needed and the point was made that it was good to see the EUG comments from Aix being addressed. Generally it was felt to be an obvious way to go, provides good consistency with the approaches adopted in chemicals risk assessment and the approach adopted asks the right questions in terms of burden of proof. Practically needs more description of the Tier 3 and in particular what constitutes a termination of the Tier 3, advice on stakeholder discussions and the depth of assessment/number of reiterations etc that are required. It was pointed out that problem formulation can be and should be carefully considered and that this could address potential problems with the assessment and clear/transparent reasoning behind the layout of an assessment.

Separate guidance is needed at each tier for a prospective or retrospective assessment. Within Tier 1 the point was made that it is not always possible to compare the measurement in the environment because it is a limit of detection value (although the two points were made on the use of modelled data and on the fact that there is likely to be a low dose if the value is an LOD one).

Group 2

The group agreed that the tiered approach was acceptable and useful for screening out sites which do not need a more rigorous assessment. Several persons thought that the approach might be difficult to apply, and questioned if the approach was practical in use.

The group stressed that it was essential that the approach was flexible, allowing direct entrance into Tiers 2 and 3 if needed. This was important for the credibility of the system, not wasting time with Tier 1 if a thorough investigation was needed to assure the public.

Several of the members stressed that it was essential that chemical assessments were made parallel to the ERICA radioactivity assessment, and that environmental problems were not excluded if radioactivity was of no concern. Furthermore, effects due to multiple stressors may be overlooked if radionuclides were the only stressors assessed.

The group agreed that uncertainties in the risk assessments need more consideration and should be taken into account at an early stage. Some people suggested that uncertainties (how large uncertainties can be tolerated) should be included in the problem formulation.

Some group members expressed the opinion that public acceptability may always result in larger, high profile sites requiring higher tier assessments. There was a request that ERICA consider how available measurements, which are below limits of detection (as many will be for operating nuclear sites) be used in Tier 1 assessments.

Group 3

There was general consensus that the approach was acceptable although further examples and practical application were required before a definitive answer could be provided.

Communication could be an issue – a concern was raised relating to the fact that if maximum concentrations were used in Tier 1, this might suggest that there was a problem if the assessment failed. The conservatism of the system was deemed important – a fine balance was required so that screening levels would be acceptable. A calibration of the tiered system through prior testing seemed a sensible solution to this. Stakeholder dialogue was also considered important in this respect.

The flexibility of the system was underlined – the tiers need not be applied sequentially, the assessor can enter at any tier in accordance with requirements. However, there were individual concerns about this relating primarily to the issue of guidance – if there is a free choice, then how will the assessor know which tier should be accessed?

A comment was made on the necessity to not take radioactivity "out of context" i.e. to treat in a holistic appraisal. In this respect it was emphasised that this type of tiered approach is used in other types of environmental impact assessments. There was a brief discussion on extrapolation issues from individual to populations of wild organisms – a view was expressed that the applied benchmarks should relate to the latter. Furthermore, background levels needed to be considered. There was some discussion as to whether this might be addressed as part of problem formulation or in deriving the benchmark.

5.2.2 Q2. Is use of screening levels/benchmarks at the Tiers 1 and 2 and not at Tier 3 acceptable?

Group 1

The basic agreement was there for the proposed approach, however they wanted flexibility in Tier 3, i.e. guidance on the approach to Tier 3 and the decision-makers/stakeholders involvement and the possibility to refer to screening levels/other reference/recommended guidelines/standards etc.

Group 2

The group agreed that a screening level was needed for Tiers 1 and 2. The screening level at Tier 1 is important for the credibility of the approach. It is essential that the screening level at Tier 1 is conservative, to avoid underestimation of risks. The group had a vote on if a benchmark should be included at Tier 3: 10 said no; 1 abstention. However, some members pointed out several problems with conservative benchmarks, that Tier 3 then would apply for most cases even for natural background situations. Some of the members would also see a screening level at Tier 3, however the levels should not be conservative but reflect realism.

Tier 1 is linked to monitoring data. The group agreed that measurement uncertainties (uncertainties associated with representative sampling, inhomogeneous distributions, measurement uncertainties) must be taken into account when compared to screening levels (and uncertainties) for Tier 1. It is essential that the screening levels/benchmarks are not associated with large error bars. Questions were also raised with respect to how we can treat " less than" data.

During the discussion on flexibility of the approach, several members raised the question – what purpose has Tier 1 and for which cases can Tier 1 be used? The group agreed that Tier 1 can be used to

exclude variables of concern, exclude biological species of concern, exclude radioactivity as a key problem of concern at a specific site. One of the members questioned the usefulness of the approach during a planning process for new installations, before decisions have been made and a new plant had been sited. Questions were also raised as to if the tiered approach could be used for incidents, or short time after an accident. It was agreed that contamination long time after an accident release would be covered by the approach. The group agreed that cases illustrating the tiered approach should be given. A suggestion was made that members could be willing to test the approach if a specific case could be outlined in detail.

Group 3

Clarification was provided by emphasising that at Tiers 1 and 2 numerical benchmarks are used to judge whether the assessment passes or fails. At Tier 3 there is no default numerical criterion for reaching a decision. At this tier, a variety of criteria and/or benchmarks could be refined in relation to problem formulation and methodologies such as probabilistic analyses employed. Furthermore, testing such as new experiments, data collation could be applied in Tier 3. There was some concern expressed regarding guidance, e.g. how do the loops in the system provoke the assessor to go back to higher tiers work and what are the criteria for undertaking various tasks in Tier 3? A further concern was expressed that without specific criteria in Tier 3 there may be "no way out" of the assessment, e.g. continual loop of refining data, experimental work. Very clear guidance in Tier 3 was considered essential to avoid such problems. Having argued the case for clear guidance, a view was also expressed that the guidance should not be overly prescriptive. ERICA need not take all decisions but should be a tool to aid decision-making.

The approach was generally acceptable but clearly practical application and demonstration of the approach was needed to address concerns.

5.3 Plenary Session

Simon Carroll. The flowchart looks sequential. The truth is that it is more flexible than this – a different way of presening the flow-cart could make this more obvious.

Eric Vindimian. Is ERICA an assessment tool or a decision making tool? It seems it is meant as a way to bring good science to stakeholders. The clarification is needed and seems forgotten in the groups.

BS. Problem formulation should also encompass a judgment on what uncertainty is acceptable.

Sylvain St-Pierre. Industry is only involved [within ERICA] in the assessment tool, they are not mandated to be involved in a management tool.

Branko Kontic. There is no benchmarking in Tier 3. A suggestion for formulation is "The acceptability is dynamic".

5.4 Conclusions

The tiered approach was generally accepted as a way forward to develop the ERICA integrated approach. The tiered approach should in addition be flexible to allow entrance at any tier. More explanation is however needed to better understand Tier 3. Several members stressed that it was essential that chemical assessments were made parallel to the ERICA radioactivity assessment.

Proper guidance should be given, especially at Tier 3 and the decision-makers/stakeholders involvement, the possibility to refer to screening levels/other reference/recommended guidelines/standards etc., how to go back to earlier tiers or exit from Tier 3. Furthermore setting of the Tier 1 screening level was seen as very important with regards to the credibility of the approach.

6 Setting criteria and standards

6.1 Summary of presentations

6.1.1 General overview

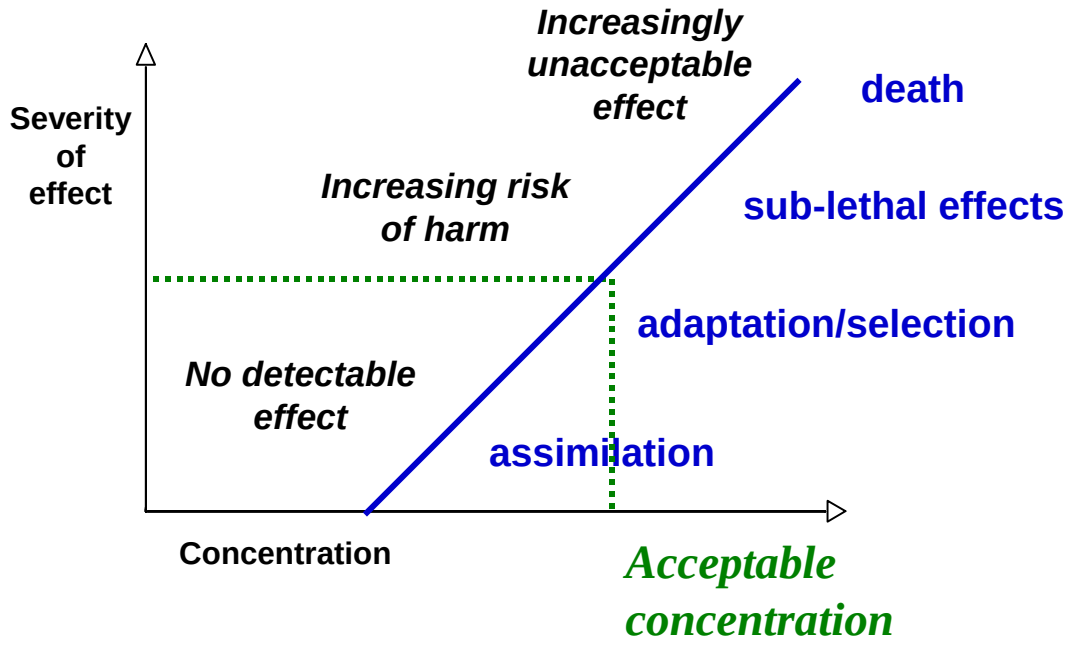
Paul Whitehouse from the Environment Agency was invited to give a presentation on "Developing Environmental Criteria and Standards", which the content is summarised below.

Environmental standards have played a key regulatory role in controlling chemicals and physical parameters (e.g. pH, temperature) for many years, and this situation is likely to prevail for the foreseeable future. Indeed, major legislation such as the Water Framework Directive is stimulating new programmes of standard setting.

The presentation introduced some principles that are applicable to all criteria and standards intended to protect the natural environment. It drew mainly on experience gained from efforts to control chemical contamination of the environment but also identified some ways in which standard-setting might develop in the future.

The presentation covered important aspects.

- Different types of standards - points at which they can be used to control chemical impacts between the source and environmental receptor.
- How standards are used – screening criteria in a tiered assessment regime vs. compliance targets:
  - effects-based thresholds - based on hazard,
  - to control …chemicals, physical parameters, microbes, ionising radiation,
  - to protect … human health, flora and fauna,
  - thresholds below which we do not expect adverse impacts to occur,
  - standards ~ criteria ~ thresholds ~benchmarks: standards are benchmarks but not all benchmarks are standards.
- Protection goals – do we know what the protection goals are and what are tolerable risks.



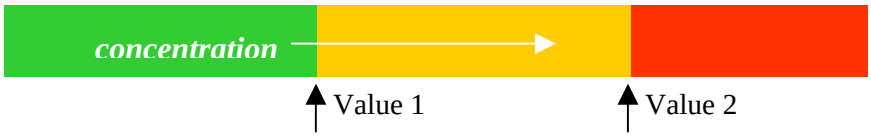
- Approaches for extrapolating from test data to a standard.

	Strengths	Weaknesses
Safety Factors (SF) Approach	Process is simple and transparent Experience indicates default factors are protective Low minimum data requirements - available data may permit no other approach	Over-reliance on default SFs can mean scientific understanding is overlooked - 'one size fits all' Only SFs for aquatic life can be justified Does not use all the available data Can discourage data generation No information on possible impact of a particular concentration
SSD Modelling Approach	Uses all the available data Uncertainty is quantified (can estimate CIs) Resulting standard is less influenced by any particular dataset -less risk of basing decision on spurious data Consequences of a particular environmental concentration can be predicted	'Data-hungry' Only deals with interspecies differences Assumes that: - fitted model is valid - 95 %-ile provides adequate protectio - toxicity tests data are random, independent trials

Data available	Safety factor to use (ref. EU TGD)
Lowest acute LC_{50} from small dataset	1000
Lowest acute LC_{50} from extensive dataset	100
Lowest of two chronic no-effect concentrations	50
Lowest of three chronic no-effect concentrations	10
Lower 5 %ile from SSD based on 10 NOECs from 8 *taxa*	1-5
Mesocosm/field data	case by case

- Some emerging issues, including dealing with background levels; bioavailability; and compliance assessment; and finally.
- A proposed Framework for Standards – a logical framework for developing new standards that explicitly deals with uncertainty, economic issues and the practicalities of implementation.

Paul Whitehouse described the "traffic light" system of setting of benchmarks/thresholds, i.e., where two values are used.



The presentation concluded on a comparison between benchmarks for chemical and radiological protection.

Similarities	Differences
Data - (dose) - ambient concentrations Similar RA paradigm: - tiered, and - conservative benchmarks, becoming more refined. Consistency in protection goals (% species affected) Dealing with background?	Concentration vs. dosimetry Radiological benchmarks not specific to particular radionuclides Mixtures more easily dealt with

Paul Whitehouse also made reference to a UK report called "Setting Environmental Standards, 21st report of the Royal Commission on Environmental Pollution", published by Her Majesty's Stationery Office. The RCEP website is: http://www.rcep.org.uk.

6.1.2 WP2. Development and application of benchmarks in ERICA ecological risk characterisation

Benchmarks are numerical values used to guide risk assessors at various decision points in a tiered approach. These values need to be provided by a transparent & scientific reasoning. They are concentrations, doses or dose rates that are assumed to be safe based on exposure – response information (e.g. ecotoxicity test endpoints – found in FREDERICA). In ERICA, they are intended to be used for screening purpose in Tiers 1 and 2, while only methods/principles to analyse effects and calculate risk are needed in Tier 3.

The three key tasks within ERICA to propose risk assessment benchmarks are:

(1) to specify the strategies for the PNEDR development and use;

(2) to specify guidelines on how to apply risk characterisation at Tier 3; and

(3) to secure consensus on their acceptance (values and methods) among end-users.

Risk assessment benchmarks are different from regulatory Environmental Quality Standards even though the methods to develop these values are in so far very similar. EQS are legally enforceable numerical limits that have been adopted from a criterion or an objective (e.g. the EQSs derived within the WFD).

All existing approaches are based on available ecotoxicity data, typically EC50 for acute exposure conditions (short-term) and EC10 (preferred to NOEC) for chronic exposure conditions (long-term). Whatever the method, the ecotoxicity data selection is of major importance as the benchmark values greatly depend on their relevancy, their quality and their quantity.

Two main methods, recommended by EC (TGD, revised in 2003) to derive PNEC for chemicals (note that they are also used to set QSs within the WFD).

(1) AF Method: based on the assessment/safety factors application to critical toxicity data (principally designed for small datasets); stringent method as the PNEC value is obtained by dividing the lowest critical data by an appropriate AF ranging from 10 to 1000.

(2) SSD Method: based on a statistical extrapolation model to address variation between species in their sensitivity to a stressor.

Examples of both approaches were presented, e.g. Figure 6.1.

It was concluded that it was feasible to derive PNEDR based on a rational and transparent process widespread in Europe for chemicals.

The SSD method allows to use all available information and data can be peer- reviewed to quantify uncertainties. It builds on acute external irradiation conditions and fits all EC recommendations and can be used to develop acute-to-chronic extrapolation rules to obtain robust benchmarks for long- and short-

term purposes. And, when performed on an adequate dataset, SSD produces less stringent PNEDR than the AF method.

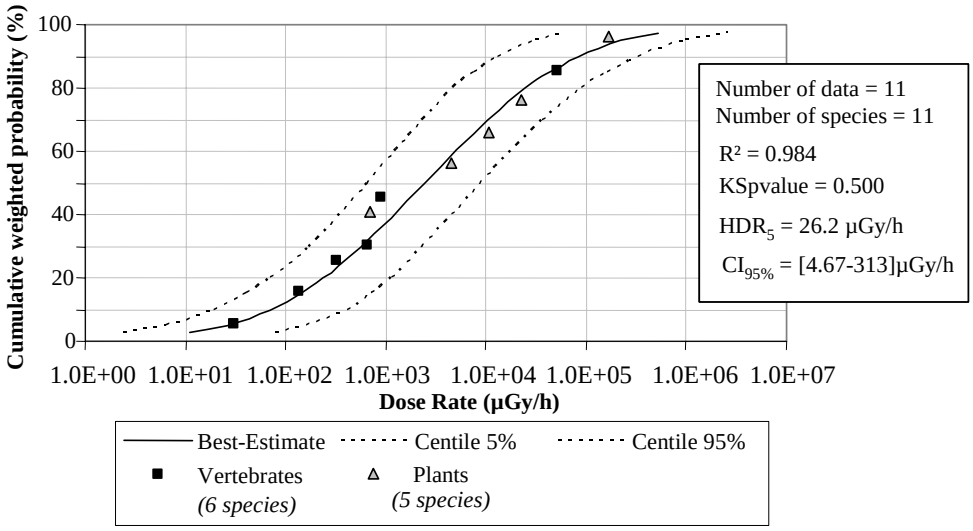


Figure 6.1: SSD for terrestrial ecosystems and chronic external irradiation exposure conditions.

The ERICA benchmarks will need to be:

- scientifically defensible, based on ecologically relevant endpoints, amenable to a weight of evidence evaluation;
- protective of ecological receptors at the level of population, community, ecosystem; and
- implemented with minimum reliance on unsupported safety factors to account for extrapolation.

6.1.3 Clarifications after the two presentations

Sylvain St-Pierre. I can understand no-effects threshold for chemicals, not for radiation. A: The situation is somewhat similar for radionuclides and metals, there is a locally varying background.

BS. When setting standards uncertainties must be small, this means directing research to work on the filling of knowledge gaps. A: Sometimes it means more research. Other times the uncertainties can be "glossed over".

Marianne Calvez. Why have you chosen the SSD method? A: This was chosen now for the demonstration, we will choose the more robust method in the end.

Sylvain St-Pierre. The dose rates corresponding to the protection of 95 % of species you have obtained are very close to the IAEA recommendations.

6.2 Group discussions

6.2.1 Q1. Should radiological benchmarks be expressed as a single value or range? Why?

Group 1

The group was more in favour of a range.

Pro's for range	Con's for range
Convey more information and reveals uncertainties and gaps Helps prioritise and focus	Increase demands on users Ease to screen out (if numbers "right")

Pro's for range	Con's for range
Ease to make comparisons (e.g. background) Not give false impressions of precision and ability to assess	

The group felt that a single value (using the range) would be good for Tier 1. The range would be used for Tiers 2 and 3.

In the discussion it was suggested that a set of single values might be used. First level: no effect below the level, second level: no serious effect below the level. One remark was that a range would not serve as a benchmark very well. A range would mean an uncertainty and it would not help in all cases to decide weather a case would be below or above benchmark value.

It would be useful to find out the experience concerning a range of values from Canada.

It might be useful to have a range if there are several sites. A range would allow prioritising the sites.

One aspect could be that several different values could be used for several different animals.

On the other hand there was a note that the meaning of benchmark is a generic value with no effects below it or a generic value with only acceptable effects below it (if there are always some effects).

One possibility could be that a single value could be used for Tier 1, and a range or multiple benchmarks (for Tier 3) to take into consideration dose and effect relationship.

Also some opinion was that only practice in using benchmark values would tell what is good. Case studies and examples would be helpful.

One opinion was that there should be information available so that the selection of benchmark value could be done for 1 or 2 % instead of 5 % of species being affected. So if there is one benchmark, it is important that it should be possible to select the desirable and corresponding "safety level".

Finally as a summary: one number for Tiers 1and 2, another number for Tier 3 can be used.

Again it was pointed out that test cases with one single value or two values etc should be presented.

One opinion emphasized that the main problem is that the system should be manageable in practice and should not lead to impossible situations.

Group 2

Quick vote around the table showed that three people would prefer a single value and the remaining seven preferred a range (note this 30:70 ratio differs than that found in the overall questionnaire results which were 50:50). This support of a range was linked to the tiered approach. Establishing a range for the no effect, clear effect and then the interface at later tiers was considered a good idea whilst it was recognised that it may be easier to use a single value for screening at Tier 1 particularly for the users of the assessment. Being flexible at Tiers 1, 2 and 3 was recognised as potentially useful but it was suggested that methods for handling range for the Tier 3 would be necessary. Tier 1 using the single value approach would depend on the degree of conservatism. Use of a range would assist reflecting discussions held, better address the uncertainties and might help to avoid misuse of the assessment tool.

The point was made that the Tier 1 screening value could encompass the range if it is suitably conservative. Another point made was that we should avoid being forced to give a single value because of lack of understanding about the range and what it means. It was indicated that an understanding of the range would help you to select a single number for screening because it would help you to adjust the value to use to help screen out additional sites. There was a question over whether this should be a flexible option within the tool i.e. that people can vary the number for the screening themselves but this could also lead to criticism if people amend the screening value purely to exclude/include sites in the assessment. Clear and sufficient guidance will be needed within the tool on its application.

It was pointed out that use of a range would allow you to compare more freely with issues such as background. In addition the following points about using a range were made:

- using a range would avoid the false impression of certainty by giving a single value;
- precision of the monitoring would be important in other words "how does measurement precision compare to that which we can predict?"; and
- would be consistent with the chemical risk assessment.

A general point was made that everything we can do to make the system more consistent to human radiological protection and chemical risk assessment would be good. However the question was asked that if you have ranges for 50 different chemicals and 20 radionuclides how do you compare their likely impacts. It was noted that a PNEC (or its radiological equivalent) might change for example because it will vary over life stage or as a consequence of other stressors. Furthermore, we may gain new data such that we would need to revise the PNEC over time.

Group 3

One should rely on previous experience from dealing with chemicals.

The more scientific approach is the range. For regulators the single value is easier to communicate. The public tends to pick the lower value in a range.

For screening you need yes/no, single value will be easier in Tier 1.

Range takes natural variation into consideration.

The choice between of single value or range is depending on what stage of the assessment you are in.

It could be possible to have a range as a baseline and take a single value as e.g. the average/50 % value.

Tier 1 should use single value, in Tier 2 a single value would be preferable, but perhaps a range could work and Tier 3 should definitely use a range.

One could use a single value plus/minus an uncertainty range.

It would be difficult to rationalise different choices of range for different sites, this would suggest unfairness to the public.

The variation inside a site already is a range.

In a range, how do you choose the screening value? Need to make a decision based on uncertainty.

Conclusion from the above: the choice of single value or range will depend on what tier we are in, but a range is more scientifically correct to reflect nature.

6.2.2 Q2. Is the proposed methodology (SSD) and protection level (95 %) to derive a radiological benchmark acceptable?

Group 1

The group generally supported SSD. There was more debate on the 95 % level. So, caveats were added: 1) which species would be under the 5 % level, and 2) which species were not in the database.

There was a suggestion of a distribution range within species, and to carry out a more detailed assessment for critical species.

One opinion already addressed in Q1 above: there should be information available so that the selection of benchmark value could done for 1% or 2 % instead of 5 % of species being effected. So if there is one benchmark, it is important that it should be possible to select the desired corresponding "safety level". A note on this opinion in the discussion was that uncertainties would be very large in the case of 1% or 2%.

There was an opinion concerning the acceptability of a protection level: it is important to ask - acceptable for whom? A remark was that it should be acceptable from the scientific point of view. Politicians will have their own opinions.

It was pointed out that 5 % might be difficult to justify to all stakeholders.

One point of view was that benchmarks mean scientifically derived values but risks take account of social and economic factors in addition.

For 5 % it was seen that it is valid from the population point of view but not valid if one is concerned about individuals. Basically 5 % is coming from chemicals. It was not selected here and no reasoning other than taking it from chemical guidance was given.

A remark on available data to derive benchmark: only little information on freshwater conditions: site-specific SSD could be done and it would need additional information.

An opinion concerning site-specific species: it can be thought that surrogate species (for which there is information available) represent e.g. some protected species (for which there is no information available).

Summary: Answer to the question is in principle “yes” but one must have confidence in the data, which are the bases.

SSD – many species, many nuclides, many environmental media (water, soil,..). Therefore one should think most sensitive species, most hazardous nuclide, etc.

Group 2

To protect a specific population of a species - how does this work for a 95 % level of protection given that there are other factors that apply pressure? What happens if there are protected species? It was generally felt that the proposed methodology was reasonable but has limitations particularly over the data requirements.

Also if the level of protection has been selected and there is a general feeling that there is still a problem with the acceptance of 95 % of species are protected. Adoption of the SSD approach would require the issues over the identification of which species are under the 5 % of the assessment to be addressed and the links highlighted about which species should be considered specifically within the assessment. It was pointed out that if you want 100 % species protection then you are heading towards a value of 100 % protection, which will be a single ultra conservative value. More description and justification for the 95 % protection level is needed.

Group 3

The 5 % integrates a lot of species.

For humans you consider individuals, in the ecosystem you consider populations.

It is known that an ecosystem can loose 5 % of its species without loosing functionality. But the presence of key species can invalidate this assumption.

Biodiversity: one needs to consider the functions in the ecosystem and make sure the ratio producers/consumers/reducers is maintained. If one key producer is eliminated because it is most sensitive, even within 5 % this can be a major problem.

One could analyse the specific site to see which is more sensitive and then decide if 5 % is acceptable.

99 % protection makes the lower end of the dose distribution very low, often unrealistic.

One should have an idea of the case specific curve.

It is customary in statistics to play around with % level to see what happens.

One needs to validate the assumption that the ecosystem is as robust as presumed in the model.

Tier 1 is conservative and generic, so 95 % may be a good choice.

One should take previous history of the site into account.

Conclusion: 95 % seems a good starting point.

6.3 Plenary session

Sylvain St-Pierre. Protection of the population is implicit in SSD but not in the estimation of exposure - we need to agree incompatibility.

JG-L. We need a benchmark.

Sylvain St-Pierre. I am talking about the legal basis. In Europe control of discharges by the nuclear industry comes under Euratom Article 35. The Habitats Directive is for industry and agriculture in general for Natura 2000 sites and presents no quantitative limits. How do you go from the Habitats Directive to a tool for ionising radiation. The integrated tool must include all other factors.

IZ. Only in England and Wales is it being taken forward. But the Waters Directive does not exclude ionising radiations. The problem in England and Wales is that English Nature insists that discharges can't be allowed unless the Natura 2000 sites are protected.

DC. Also I would like to point out that the radiological assessments are being conducted as part of assessments for all industries.

Sylvain St-Pierre. A UK decision is not all Europe.

IZ. It's an example of what is being done in one country. However, that does not mean it would not be applicable for other countries.

Q1

IZ. It looks like we are favouring the 'traffic light approach' as presented by Paul Whitehouse; it provides single numbers and a range.

Paul Whitehouse. I think that there is no taste for a range in Tier 1.

IZ. But the yellow to red value could be the single value in Tier 1.

Sylvain St-Pierre. You need to demonstrate the effect of the different numbers.

DC. I agree we will try to do that.

Ted Lazo. You can have your cake and eat it – use the range to set the Tier 1 single value.

Q2

IZ. It seems that the SSD methodology is considered to be ok, but that the 5 % level is being questioned. But one can go back to the data to look at which species are within the 5 %. The approach needs to be, and can be, transparent.

Sylvain St-Pierre. Need to average your input data. For instance, would you use injection water from oilrigs or collect from the end of a discharge pipe to obtain maximum values in water.

JG-L. I don't understand your point.

Sylvain St-Pierre. You need to consider populations not the highest of the highest.

JG-L. We are only using this approach in Tier 1.

Sylvain St-Pierre. If you sample from the actual oilrig rather than integrating over a radius of 10 km you would fail Tier 1.

DC. Whole purpose of Tier 1 is to avoid effort.

Paul Whitehouse. This is part of the exposure assessment.

Sylvain St-Pierre. We need population-orientated exposure.

Paul Whitehouse. Have to estimate dose to the most sensitive organisms and in Tier 1 we would not know the distribution. It is the worst case. We could pick a different % value from the SSD but we do not have that level of sophistication.

DC. That is Tier 3.

Sylvain St-Pierre. It's simple – if we assume an animal at the discharge pipe we would have to move to Tiers 2 and 3.

John Holmes. Can I ask whether it worked in England and Wales.

DC. Yes we screened out 90 % of sites. For a lot of them that failed at the screening level, it was often because we used the total authorised discharges, which were much higher than the actual discharges.

6.4 Conclusions

Most EUG members were in agreement of using a single value in Tier 1 but otherwise use a range. Both systems have pro's and con's, but setting a number in Tier 1 is really important, because it may lead to "do nothing" action. The traffic light system may provide a good way forward to address benchmarks.

Whilst SSD may be generally accepted as a method to characterize risk (also used for chemicals), there was more debate on selecting the 95 % range. What about the species falling out (i.e. remaining 5 %), the organisms without data, distribution range within species, key species etc? There is a need to be flexible as to understand the uncertainty and sensitivity of these data. Proper guidance should be provided to give credibility to the system.

6.5 Exercise for the EUG on setting a benchmark

The Consortium asked the EUG to think of suitable numeric screening values, following the two WP2 presentations. An anonymous ballot was held, based on the following background information.

The Consortium made it clear that the information would remain anonymous and only enable the ERICA Consortium to start on their discussions on the way to providing benchmark values within the ERICA tiered approach. The background information was circulated on the ballot sheet, and is reproduced below.

From IAEA, NCRP and UNSCEAR, no effect expected at population level is presented as:

- 1000 µGy h^{-1}: deep ocean organisms,
- 400 µGy h^{-1}: aquatic organisms,
- 400 µGy h^{-1}: terrestrial plants, and
- 40 µGy h^{-1}: terrestrial animals.

From FASSET D4 no significant effect below:

- 100 µGy h^{-1}: all organisms.

Currently the EA of England and Wales is using:

- 5 % of IAEA values for screening purposes, i.e.
- 20 µGy h^{-1}: aquatic organisms and terrestrial plants, and
- 2 µGy h^{-1}: terrestrial animals.

Provisional data to protect 95 % of species using the SSD method:

- 26 µGy h^{-1}: terrestrial organisms (range of 2 orders of magnitude), and
- 400 µGy h^{-1}: freshwater organisms (range of 3 orders of magnitude).

6.6 The results from the ballot

Table 7.1 summarises the 15 responses to the ballot, i.e. from the EUG members still present at the end of the morning session, on the 27th April 2005. Note that some people answered "don't know" but also provided numbers.

Table 7.1: Suggestions for benchmarks

Information on ballot	Results	Comments
Single value Yes or No	Yes = 9 No = 1	Two answers specified a yes at Tier 1
What number would be acceptable?	6 answers	15 µGy h^{-1} aquatic ecosystems 10 µGy h^{-1} and preliminary site-specific understanding of uncertainty 20 µGy h^{-1} aquatic and 2 µGy h^{-1} terrestrial 100 µGy h^{-1} 100 µGy h^{-1} 1 mGy/d for all organisms
Range value Yes or No	Yes = 5 No = 1	One answer specified a yes at Tiers 2 and 3 One answer specified a yes at Tier 3
What range would be acceptable?	4 answers	1 - 6 µGy h^{-1} 100 - 400 µGy h^{-1} Traffic light approach with discrete values Three orders for preliminary assessments
Don't know because I don't have enough information to answer (please tick box)	5 answers	One answer specified for terrestrial ecosystems One answered not an expert One answered not enough to be specific One answer specified too limited information to get a true ecological effect
Don't want to answer (please tick box)	3 answers	One answered don't like SSD approach and worry this "number" might get accepted by default One feared the number would start to live and be used as justification for ERICA – different approaches, scenarios, etc, should be analysed by ERICA and threshold justified.

7 Final EUG session

Irene Zinger gave a presentation to explain the process to get inputs from EUG members prior to the delivery of the deliverable D7c. In brief:

- compile all notes from discussions and plenary sessions, to be ready by mid May, i.e. receive notes ASAP;
- distribute to EUG chair persons, WP leaders and note takers by the 16th May to be returned by the 24 May;
- add questionnaire analysis, conclusions and recommendations by the end of May;
- circulate draft by the end of May for return by 10th June; and
- publication on to the website by mid-June.

Reminder was also given to fill-in the feedback questionnaire and instructions given to EUG members for claiming repayments for attending the event.

The First EUG event was then concluded, inviting EUG members to join the ERICA project in Madrid on the 29th and 30th September 2005 for the third EUG Thematic Event on "Decision-making and Stakeholder Involvement".

7.1 Feedback Questionnaire

EUG members were also requested to fill in a feedback questionnaire on the event to help the ERICA Consortium improve future events. The questionnaire was similar to that from the 2nd EUG event and can be found in Appendix 5. Fifteen participants returned the questionnaire.

7.1.1 Summary of feedback

Figure 7.1 summarises the responses from the 15 feedback questionnaires.

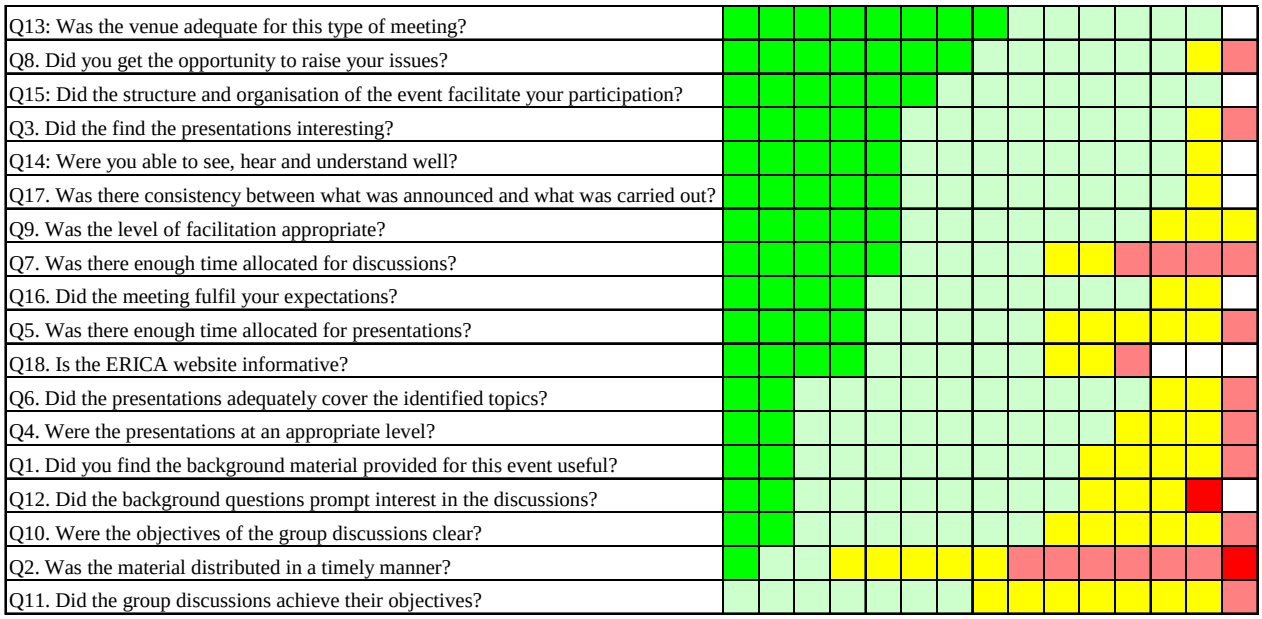


Figure 7.1: Feedback summary from the First generic EUG event.

Legend:	excellent	good	satisfactory	below average	poor	no answer

It is clear that documents were not distributed in a timely manner.

The most polarised response came from the question: "Was there enough time allocated for discussions?" Some really thought there was and some really thought there was not. The course of action to follow is not clear from the received feedback. Everyone, but one, felt that the objectives were at least satisfactorily achieved.

The following questions received a positive answer:

- Q13: Was the venue adequate for this type of meeting?
- Q15: Did the structure and organisation of the event facilitate your participation?
- Q14: Were you able to see, hear and understand well?

– Q17. Was there consistency between what was announced and what was carried out?
– Q8. Did you get the opportunity to raise your issues?
– Q3. Did you find the presentations interesting?
– Q9. Was the level of facilitation appropriate?
– Q16. Did the meeting fulfil your expectations?

The following received mixed answers:

– Q6. Did the presentations adequately cover the identified topics?
– Q4. Were the presentations at an appropriate level?
– Q12. Did the background questions prompt interest in the discussions?
– Q1. Did you find the background material provided for this event useful?
– Q5. Was there enough time allocated for presentations?
– Q10. Were the objectives of the group discussions clear?
– Q18. Is the ERICA website informative?

One person answered extremely negatively. Another four had fairly mixed answers. The remaining 10 people were globally very positive about the meeting.

7.1.2 Additional written comments

Most of the EUG members had comments, with a few recurring ones on the late arrival and content of the material (including the detailed agenda) and the short time allocated to discussions. Although apologies were given regarding the lateness of the arrival of the material, the timing of producing some of the deliverables was on time from the ERICA technical annex viewpoint. It future, it may be advisable to ensure that the timing of output delivery is kept well in advance from the timing of EUG events.

With regards to presentations and discussions, a number of wide ranging views were reported:

- couldn't hear some of the speakers;
- it would have been interesting to have more detailed presentations with examples of ERICA tool;
- some slides were hard to read;
- interesting to gather all plenary technical sessions in order to have the a overview of the topics before the discussion groups;
- discussions were diffuse;
- more time should be given to questions both after presentations and discussions.

One EUG member felt that the event was too technically driven for the EUG and that wider issues ought to have been discussed. Another noted that other important items came out during the discussions for which there were no time to expand. Also, an EUG member said that language was a difficulty as far as understanding all the details of the discussions.

Positive comments and suggestions were also received, such as:

- discussions would have been difficult without the questions, which were circulated prior to each discussion session;
- request to have presentations on the website;
- website could be improved with more information to help understand better the development of the project;
- I think the questionnaire was a good idea, as it helped to prepare for the meeting, but the presentation of the results would have been more appropriate at the end of the meeting;

- love the venue and proximity to airport.

8 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.

Actions from that meeting, together with actions derived from this D7c document, and its Annex 1, will be incorporated in the Progress Report No. 3 on "EUG inputs and resulting ERICA actions", and posted on the EUG protected-area of the ERICA website www.erica-project.org. The deliverable D7c will be available to all on the results part of the ERICA website.

	EUG Comments
WP1	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 according as indicated in Section 2, 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.
WP2	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.
WP3	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.
WP4	Ensure the ERICA guidance and outputs have a clear scope, are user friendly and transparent. Define the possible applications of the ERICA integrated approach. Provide different EUG members with the same case study to test at the same time as WP4 the ERICA integrated approach.

Appendix 1: Final Agenda for the Freising EUG Event

1st Generic EUG Event: Ecological Risk Assessment and Management 24 –27 April, 2005

Sunday 24th April

18:30-19:30 Welcome cocktail and buffet

19:30-20:30 Optional pre-Session
- Background information on ERICA
- Review of EUG past events and guidance for payment

Monday 25th April

09:00-09:30 Welcome and Introduction to Procedure

09:30-12:15 WP1 – prototype assessment tool
- Presentation (total time 30 mins including questions)
- Groups discussion (at least 1 hour)
- Plenary feedback

13:15-17:00 WP3 – Communication and Decision-Making - D7a, D7b and D8
- Presentation (total time 1 hr max including questions)
- Groups discussion
- Plenary feedback
- Questionnaire

Tuesday 26th April

09:30-12:15 WP4 – Case studies and D9
- Presentation (total time 30 mins including questions)
- Groups discussion
- Plenary feedback

13:15-17:00 WP2 – Risk Characterisation: D4 and the tiered approach
- Presentation (total time 30 mins including questions)
- Groups discussion
- Plenary feedback

18:00-onwards Cultural walk and EUG Bavarian dinner

Wednesday 27th April

09:00-12:15 Setting criteria and standards
- Two Presentations with one invited speaker (total time 60 mins including questions)
- Groups discussion
- Plenary feedback

13:15-15:00 EUG session
- EUG activities, evaluation, questionnaire

Lunch served every day at 12:15.

Appendix 2: List of participants

EUG members

Surname	First name	Organisation
Brechignac	Francois	IUR (International)
Calvez	Marianne	CEA (France)
Carroll	Simon	Greenpeace International (International)
Devin	Patrick	AREVA (France)
Ferris	John	ANSTO (Australia)
Golubev	Alexander	International Sakharov Environmental University (Belarus)
Henrich	Eberhardt	EC – DG environment
Holmes	John	University of Oxford (UK)
Kontic	Branko	Jozef Stefan Institute (Slovakia)
Lazo	Edward (Ted)	OECD Nuclear Energy Agency (International)
Malmelin	Miliza	Ministry of the Environment, (Finland)
Mothersill	Carmel	McMaster University (Canada)
Moulin	Valerie	CEA (France)
Prlic	Ivica	IMI Zagreb (Croatia)
Sazykina	Tatiana	SPA "TYPHOON" (Russia)
St-Pierre	Sylvain	World Nuclear Association (International)
Van der Sluijs	Jeroen	Utrecht University (The Netherlands)
Vandenhove	Hildegarde	SCK-CEN (Belgium)
Vindimian	Eric	Ministère de l'écologie et du développement durable (France)
Willrodt	Christine	BfS (Germany)

EUG members that registered but couldn't attend:

IAEA, University of Georgia (USA), Russian Institute of Agricultural Radiology and Agroecology, Institute for Energy Technology (Norway), Central Laboratory for Radiological Protection (Poland), US DoE

ERICA Consortium Participants

Surname	First name	Organisation
Whitehouse	Paul	EA – guest speaker
Copplestone	David	EA
Ramstedt	Magnus	Facilia
Pröhl	Gerhard	GSF
Garnier-Laplace	Jacqueline	IRSN
Momal	Patrick	IRSN
Beresford	Nick	NERC
Howard	Brenda	NERC
Bay-Larsen	Ingrid	NLH
Oughton	Deborah	NLH
Salbu	Brit	NLH
Breivik	Hanne	NRPA
Brown	Justin	NRPA
Zinger	Irene	SSI
Hänninen	Riitta	STUK
Jones	Steve	WSC
Maravic	Henning	EC project officer

Appendix 3: Division of Discussion Groups for Each Day

Monday 25th April WP1 and WP3

Group	EUG members and guest speaker		Facilitator	WP1	WP2	WP3	WP4
1	Sylvain St-Pierre Branko Kontic Simon Carroll * John Ferris #	Marianne Calvez Christine Willrodt Alexander Golubev Henning Maravic	Ingrid Bay-Larsen	Gerhard Pröhl	David Copplestone ~	Riitta Hänninen	Brenda Howard +
2	Paul Whitehouse * Hildegarde Vandenhove Ivica Prlic	Eric Vindimian # Valerie Moulin	Irene Zinger +	Magnus Ramstedt	Brit Salbu ~	Patrick Momal	Nick Beresford ~
3	Miliza Malmelin Carmen Mothersill John Holmes *# Jeroen Van der Sluijs	Tatiana Sazykina Francois Brechignac Patrick Devin Eberhardt Henrich	Deborah Oughton	Justin Brown	Jacqueline Garnier-Laplace	Hanne Breivik ~	Steve Jones ~

* Group Chair person for WP1 # Chair person for WP3 ~ secretary (taking notes) + Plenary Chair person

Tuesday 26th April: WP4 and WP2

Group	EUG members and guest speaker		Facilitator	WP1	WP2	WP3	WP4
1	Simon Carroll John Ferris Paul Whitehouse # Eric Vindimian	Miliza Malmelin Jeroen Van der Sluijs * Patrick Devin	Ingrid Bay-Larsen	Gerhard Pröhl	David Copplestone ~	Riitta Hänninen	Brenda Howard
2	Branko Kontic # Marianne Calvez Alexander Golubev Eberhardt Henrich	Hildegarde Vandenhove * Carmen Mothersill Tatiana Sazykina	Irene Zinger +		Brit Salbu ~	Patrick Momal	Nick Beresford ~
3	Sylvain St-Pierre Christine Willrodt # Henning Maravic	Ivica Prlic Valerie Moulin John Holmes François Bréchignac *	Deborah Oughton +	Justin Brown ~	Jacqueline Garnier-Laplace	Hanne Breivik ~	Steve Jones

* Group Chair person for WP4 # Chair person for WP2 ~ secretary (taking notes) + Plenary Chair person

Wednesday 27th April – Setting criteria and standards

Group	EUG members and guest speaker		Facilitator	ERICA Consortium
1	Miliza Malmelin Sylvain St-Pierre Tatiana Sazykina	Hildegarde Vandenhove * Eberhardt Henrich Paul Whitehouse	Ingrid Bay-Larsen	Gerhard Pröhl Riitta Hänninen ~ Brenda Howard
2	Jeroen Van der Sluijs Patrick Devin Simon Carroll *	Carmen Mothersill John Holmes John Ferris	Irene Zinger +	Patrick Momal Brit Salbu David Copplestone ~
3	Alexander Golubev Marianne Calvez Christine Willrodt Ivica Prlic	Valerie Moulin Francois Brechignac Ted Lazo *	Nick Beresford	Justin Brown Jacqueline Garnier-Laplace Hanne Breivik ~

* Group Chair person for the day ~ secretary (taking notes) + Plenary Chair person

Appendix 4: Questionnaire to be filled-in prior to the event

ERICA - First Generic EUG event
Ecological Risk Assessment: Criteria and Standards
Freising, 24 – 27 April 2005

Questionnaire to all EUG members

The ERICA project is interested in your views on a number of topics. We have decided to survey the opinions of all our EUG members, whether attending or not the event.

Most questions require a "yes" or "no" answer, or a ranking, and on certain occasions ask for an explanation. The questionnaire reflects on the ERICA first year's progress, its published deliverables, and information available from its website, i.e. www.erica-project.org, in both public and in the area restricted to the EUG.

The questionnaire is designed to be answered rapidly to so not take too much of the EUG's time. Responses to this questionnaire will remain anonymous, and the compilation of results will not be attributed to the EUG organisations – it is important that we get the personal opinion of EUG members rather than the 'official' opinion by organisations.

Please fill-in the questionnaire and return before the 20th April to: irene.zinger@ssi.se and patrick.momal@irsn.fr

Q1	Name:	

Input into the project

The ERICA integrated approach is to be developed for another two years.

Q2	Do you foresee your organisation making use of the ERICA integrated approach?		**Yes / No**
	Q2a	If not, what would you specifically like the ERICA integrated approach to do?	Expand

Input into "Setting criteria and standards"

In existing frameworks both "single value" and "a range of values" have been used when setting standards and benchmarks.

Q3 Would you prefer a single value or a range of values for benchmarks to be used in the ERICA integrated approach? **Single / Range**

Q4 Do you think that different risk indicator or benchmark value(s) should be used for risk assessment and risk management? **Yes / No**

Natural background radiation should be accounted for when calculating radiation doses to biota and in protecting the environment.

Q5 Do you agree with this statement? **Yes / No**

Q5a	If yes, then how should background best be considered in assessments, e.g. incremental or absolute levels?	Expand

The ERICA integrated approach will use the FASSET reference organism concept:

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

The ICRP are developing a set of Reference Animals and Plants:

> "A **Reference Animal or Plant** (RAP) is a hypothetical entity, with the assumed basic characteristics of a specific type of animal or plant, as described to the generality of the taxonomic level of Family, with precisely defined anatomical, physiological, and life-history properties that can be used for the purposes of relating exposure to dose, and dose to effects, for that type of living organism."

Q6	Is the ERICA integrated approach able to encompass and address ICRP's selection of organisms?	**Yes / No**
Q7	If not, what do you see as the main differences between the two?	Expand
Q8	Do you think that the use of reference organisms can represent protected species?	**Yes / No**

Input into WP1

The Consortium intends to expand the FASSET list of radionuclides, which included the elements: H , C, Cl, Ni, Sr, Ru, Tc, I, Nb, Cs, Po, Pb, Ra, Th, U, Pu, Am, Np, Cm.

The suggested nuclides include: ^{32}P, ^{33}P, ^{35}S, ^{41}Ar, ^{54}Mn, ^{57}Co, ^{58}Co, ^{60}Co, ^{85}Kr, ^{99m}Tc, ^{110m}Ag, ^{124}Sb, ^{125}I, ^{141}Ce, ^{144}Ce, ^{154}Eu, ^{95}Zr, ^{95}Nb, ^{123m}Te, ^{125}Sb, ^{228}Ra.

Q9	Are you in agreement with the selection of these extra radionuclides?	**Yes / No**
Q9a	What other radionuclides should we be considering? Which ones should be deleted? List and give rationale.	Expand

We are moving in the direction of providing guidance on probability analyses (building on the initial work conducted in FASSET).

Q10	Does the EUG support this approach?	**Yes / No**

The underlying structure of the software has been created for the assessment tool. The EUG was invited, via the e-newsletter, to provide inputs on expectations about the software basic functionality.

Q11	Do you have ideas related to the software tool in general, and more specifically about: - assessment scenarios of interest - input and output requirements/user friendliness	**Yes / No**

Q11a If so, please describe Expand

Input into WP2

Based on its review of existing frameworks, ERICA intends to adopt a tiered approach to risk characterisation. Very briefly, **Tier 1** corresponds to a risk screening exercise based on radionuclide concentrations in environmental media (*i.e.* water, sediment, soil, air). **Tier 2** is a refined Tier 1 wherein screening is based on exposure analysis. Tiers 1 & 2 use the Predicted-No-Effect-Dose-Rate (PNEDR in *µGy/h*) derived from knowledge on radionuclide effects on non-human species. Tier 1 proposes a retro-calculation of corresponding screening values to give biota limiting concentration for each radionuclide. At Tier 2, the PNEDR is used directly and is compared to the calculated dose rate for the set of reference organisms. **Tier 3** will consist of a more extensive risk calculation using site specific data and probabilistic methods.
If required, more information on the approach can be found in the D4 summary and its ful document (to be posted by 18th April).

Q12 Do you agree this is a useful approach? **Yes / No**

Q12a If not, suggest any suitable alternative method: Expand

In Tier 1 of the risk characterisation process, concentration, i.e. Bq/l, is used as a simple indicator for risk screening purposes while in Tiers 2 and 3 dose rate, i.e. µGy/hr, is used for more detailed risk characterisation.

Q13 Do you see any major problem with the use of different indicators and units at the different tiers? **Yes / No**

Q13a If yes, please expand and say which you would prefer? Expand

A number of methods have been already used for chemical substances to derive effect benchmarks.

Q14 Which of the following method(s) would you prefer to use in the ERICA integrated approach, and why? Expand
Expert judgement, safety factors, species sensitivity distributions, other (specify)

In toxicology, standard test species are often used for evaluating environmental risk from chemicals (e.g. daphnia).

Q15 Is there a need for specific test species to help evaluate ecological risks associated with radionuclides? **Yes / No**

Q15a If so, what criteria could be used to select them?

Input into WP3

The draft Table of Content for the deliverable D8: "Decision-making Guidance" has been circulated. *Refer to the D8 table of content..*

Q16 Does the draft cover all the main issues? **Yes / No**

Q16a If not, which other components should be included? Expand

A number of knowledge gaps were identified during the first year of the ERICA project. In developing its assessment tool, the project needs to prioritise the gaps, specifically in terms of the level of uncertainty and variability the various gaps contribute to the final assessment. It must also decide how to deal with the most important gaps and uncertainties, e.g. by using expert judgement, modelling, probabilistic analysis, performing experiments or monitoring measurements.

See deliverables D7a – part 2 and D9 on the website.

Q17 Please indicate how you rank the level of uncertainty related to the gaps below and how you think the gap should be dealt with, e.g. Jud - expert judgment, Mod – modelling and/or probabilistic analysis, Exp – use of experiments/measurements/monitoring, Other – list another method.

Green	(Not a major gap)	X						
Light green	(Gap with low uncertainty)		X					
Orange	(Gap with moderate uncertainty)			X				
Light red	(Gap with high uncertainty)				X			
Red	(Gap with very high uncertainty)					X		
White	(I do not know)						X	
Grey	(I do not want to answer)							X

Shoudl be dealt through	Jud	Mod	Exp	Please describe
Expert judgement	X			
Modelling		X		
By experimentation			X	
Others (please list)				

Please tick the corresponding answers

	Not a major gap	Low uncertainty	Moderate	High	Very high uncertainty	Don't know	Don't want to answer	Expert Judgment	Modelling	Experimentation	Other - describe
Source Terms, Transfer and Uptake											
1. On site (near field) air concentrations, e. g. H-3											
2. Seasonal variation											
3. Concentration ratios and kds											
4. Source term speciation											
5. Transient conditions											
Dosimetry											
6. Dose Conversion Factors											
7. Organ dosimetry											
8. Biological weighting factors											
Dose Response and Effects analysis (exposures)											
9. Multiple stressor effects											
10. Radiation Induced Bystander Effects											
11. Dose-response curves for various organisational levels (sub-cell->ecosystem)											
12. Other extrapolation issues											

Risk characterisation and management	**Not a major gap**	**Low uncertainty**	**Moderate**	**High**	**Very high uncertainty**	**Don't know**	**Don't want to answer**	**Expert Judgment**	**Modelling**	**Experimentation**	**Other - describe**
13. Dealing with special species, e.g. protected											
14. Field validation											
15. Risk communication, stakeholder communication and feedback											
16. "Policy making" (precautionary principle, public trust, etc.)											

Have we left out other important gaps?

If so list and tick the corresponding answers

Input into WP4

The FASSET framework has been applied to five case studies, as part of WP4 contribution to the project. The results have just been published in the deliverable D9.

Q18 Did the evaluations of case studies in D9 constitute a fair and appropriate test of the FASSET methodology? **Yes / No**

Q18a If not please specify how it could have been improved? Expand

Q19 Did the recommendations fairly summarise the main points arising out of the tests of FASSET? **Yes / No**

Q19a If not, where do you think the deficiencies lay? Expand

Q20 Which recommendations did you feel were most important? Please specify here Expand

Input into EUG events

WP3 has run so far two EUG events. As a follow up to questions arising at the first event (*see deliverable D7a*), WP3 would like to ask members for their opinions on the following issues.

Q21 Should there be a "core" of EUG members to represent the whole EUG? **Yes / No**

Q22 Do you prefer participants' contributions within the **group discussions** are kept anonymous, both in the meeting summaries and deliverables? **Yes / No**

Q23 Do you agree to having names of contributors cited in the deliverable summaries of the the **plenary sessions**? **Yes / No**

Q24 Do you have any other general comments? **Yes / No**

Q24a If so, please list: Expand

On behalf of the ERICA Consortium, many thanks for your time and for providing the ERICA project with valuable contribution.

Appendix 5: Feedback Questionnaire for EUG Members

1st Generic EUG Event: Ecological Risk Assessment and Management

In order to help us improve our future EUG events, would you please rank your answers to each question as follows:

1. poor 2. below average 3. satisfactory 4. good 5. excellent

Preparations

Q1. Did you find the background material provided for this event useful?	1	2	3	4	5
Q2. Was the material distributed in a timely manner?	1	2	3	4	5
• *Comments:*					

Plenary sessions

Q3. Did the find the presentations interesting?	1	2	3	4	5
Q4. Were the presentations at an appropriate level?	1	2	3	4	5
Q5. Was there enough time allocated for presentations?	1	2	3	4	5
Q6. Did the presentations adequately cover the identified topics?	1	2	3	4	5
Were there any particular issues that were missed?					
• *Comments:*					

Group discussions

Q7. Was there enough time allocated for discussions?	1	2	3	4	5
Q8. Did you get the opportunity to raise your issues?	1	2	3	4	5
Q9. Was the level of facilitation appropriate?	1	2	3	4	5
Q10. Were the objectives of the group discussions clear?	1	2	3	4	5
Q11. Did the group discussions achieve their objectives?	1	2	3	4	5
Q12. Did the background questions prompt interest in the discussions?	1	2	3	4	5
• *Comments:*					

Organisation

Q13: Was the venue adequate for this type of meeting?	1	2	3	4	5
Q14: Were you able to see, hear and understand well?	1	2	3	4	5
Q15: Did the structure and organisation of the event facilitate your participation?	1	2	3	4	5
• *Comments:*					

General feedback

Q16: Did the meeting fulfil your expectations?	1	2	3	4	5
Q17: Was there consistency between what was announced and what was carried out?	1	2	3	4	5
Q18: Is the ERICA website informative?	1	2	3	4	5
• *Comments:*					

Appendix 6: Table of content for D8 - Decision Making Guidance - initial structure for discussion

Chapter and Sections	Heading
	Executive Summary
1	Introduction *What is the aim of this report, how was it originally described in the Technical Annex, how does i fit with the rest of the project, how has the content been compiled and developed (mention of EUG events etc….)*
2	Factors Affecting Decision-making – International law and binding agreements – Socio-Economic considerations – Local politics *state that local/national 'politics' is not in this report* – Public concerns *point to the stakeholder involvement, to be dealt with later in this guidance* – Radiation protection guidance *review briefly the relatively meagre guidance that already exists in the 'world of radiation protection'*
3	Guidance for Decision Makers *Compilation of all the main elements in the next Chapters*
4	The Assessment of Radiation Effects
4.1	Frameworks
4.2	How to deal with knowledge gaps and uncertainties related to the effects assessment when you need to take decisions
4.3	Stakeholder views and recommendations (from EUG event)
5	Effects of Ionising Radiation in Relation to Other Contaminants
5.1	Contaminant differences based on sources – biological and toxicological effects; – risk assessment and dose-response models; and – management issues
5.2	Stakeholder views and recommendations (from EUG event)
6	Setting of Criteria and Standards for Radionuclides Contamination
6.1	Factors affecting selection and quantification – purpose of criteria and standard *e.g. compliance, intervention, remediation, prospective regulation, scientific evaluation* – dose rates *vs* medium concentrations – reference organisms – bands of concerns – the multicontaminant context
6.2	Natural radiation issues
6.3	Stakeholder views and recommendations (from EUG event)

Chapter and Sections	Heading
7	Decision-making and Stakeholder Involvement
7.1	Stakeholder involvement: problems and guidance – communication strategies to involve stakeholders – public perception – public participation – timing and purpose
7.2	Stakeholder views and recommendations (from EUG event, including the local Sellafield stakeholder event))
8	Scientific Uncertainties and Extrapolation
8.1	Pragmatic approach to dealing with uncertainties
8.2	Extrapolation issues and management
8.3	Stakeholder views and recommendations (from two EUG events) – scientific uncertainties – consensus conference on uncertainty and extrapolation
9	Management Compliance and Demonstration
9.1	Monitoring for compliance
9.2	Stakeholder views and recommendations (from EUG event)
10	Conclusions and Recommendations