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The ERICA Consensus Seminar

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ERICA 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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Dedication

This report is dedicated to the memory of Masahiro Doi who died on the 23rd July 2006 as a result of a cerebral haemorrhage he suffered during the Stavern seminar.

Masahiro was a new member of the EUG, bringing to the group a unique and valuable cultural outlook on protection of the environment. The stroke occurred immediately after he had presented a plenary lecture entitled “the Asian Perspective on the Management of Environmental Risk”. The lecture can be found on the ERICA website.

Masahiro will be missed as a colleague and friend, and our thoughts are with his family.

Acknowledgement

The ERICA Consortium would like to thank all speakers and EUG members for their time and contribution to making this EUG event a success.

Special thanks also go to the “drafting Committee” for their diligence in preparing the draft Consensus Document.

F Brechignac C Willrodt – EM Forsberg
M. Kaiser – J Sutcliffe – D Copplestone N Beresford – J Holmes

Figure: The Consensus Seminar Drafting Committee.

Executive Summary

The ERICA EUG Consensus Seminar was held in Stavern, June 27th – 30th 2006. The meeting was hosted and organised by the Norwegian University of Life Sciences and the Norwegian Radiation Protection Authority, with facilitation provided by the National Committee for Science and Technology (NENT). This was the sixth EUG event to take place during the ERICA project, and was attended by 23 EUG members and 15 ERICA participants.

The aim of this Seminar was for the EUG to agree and formulate a position paper on the implications of some assumptions and limitations within the ERICA approach, and to provide recommendations for the ERICA Consortium. This was to be achieved through a critical and focused evaluation of the ERICA integrated approach, highlighting strengths and weaknesses and identifying areas of consensus and dissent, as well as exploring reasons behind disagreements. The intention was to improve the robustness and reliability of the ERICA approach and its usefulness to end-users. The issues discussed have also a broader relevance to the protection of the environment from ionising radiation. They are related to areas where previous EUG events had identified a lack of consensus between EUG members—often reflected by disagreement between ERICA Consortium members; where there is disagreement between ERICA and EUG; or where there is agreement on the importance of an issue but uncertainty as to how best to deal with it. The issues discussed under each subheading in this document are those, which were raised as specific issues of concern. While the goal of the seminar was to reach consensus, this was not a requisite.

The workshop was divided into four thematic sessions, each starting with introductory lectures, continuing with discussions in breakout groups, and ending with plenary presentations of the group work. The themes for the four sessions were: reference organisms, dose-effect evaluation, assessment tool and management. The chairs and secretaries of the three breakout groups, under the guidance of two of the facilitators, formed a drafting committee that prepared a draft consensus document. This draft was discussed and revised during the final plenary session, leading to the seminar consensus document. A broad consensus was reached in most issues, and within the final consensus document, these are summarised as follows.

Reference organisms

The reference organism concept was designed to be generic, but could be applied to protected species if appropriately parameterised. The concept and approach are individual based and have been derived bearing in mind both radiological and chemical risk analysis processes. It does not fully capture ecosystem dynamics and the limitations need to be recognised and stated clearly. Reference organisms provide a good model especially for whole body dosimetry.

Dose-effect evaluations

Dosimetry (estimation of absorbed dose) is a less uncertain aspect of the assessment method given the large variability and uncertainty in transfer components. However, issues related to heterogeneous internal distribution of radionuclides in the body should be considered further.

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

Assessment tool
In response to uncertainty there is adequate conservatism built into the ERICA tool. The way this is done needs to be transparently documented and the assumptions recorded. The ERICA Consortium should test the tool to see whether there is an appropriate balance between conservatism and realism at the screening stages.

Management
There is a need for general management principles in the area of environmental protection to be harmonised internationally for all contaminants including radioactive substances. There should be a general aim to develop a common best practice with internationally agreed no-effect or exemption levels, in combination with generic assessment guidance. This may be less restrictive than dose limits. Involvement of stakeholders in ecological risk assessment and management is a welcome development. There is a need for a more critical evaluation of objectives and procedures, and 'stakeholder fatigue' and duplication of processes should be avoided.

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

The ERICA tiered approach is supported by the EUG.

This deliverable provides some background information on the issues discussed, an overview of the methods used and results from group discussions, and the final complete consensus document.

Recommendations for ERICA

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

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

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

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

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

- Glossary. During the plenary discussion a number of terms were highlighted as being important to include in a glossary. It was agreed that the existing ERICA glossary, to be published in the D-ERICA final report, would be checked for the following terms, and items either added or revised.

Finally, the "ERICA Consensus Document" [ERICA 2006b] has also been published as a separate document that summarises in detail the agreed statements, as stated in Chapter 6 of this report.

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1 Introduction

The ERICA EUG Consensus Seminar was held in Stavern, June 27th – 30th 2006. The meeting was hosted and organised by the Norwegian University of Life Sciences (represented by Deborah Oughton) and the Norwegian Radiation Protection Authority (represented by Per Strand). The consensus process was facilitated by Matthias Kaiser and Ellen-Marie Forsberg from The Norwegian Research Ethics Committees (NENT), with the additional support of William Fagerheim from Mind the Gap. This was the sixth EUG event to take place during the ERICA project, and was attended by 23 EUG members and 15 ERICA participants, see Appendix 1.

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

Discussions were divided four subject areas:

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

The specific issues selected for discussion reflect topics where previous EUG events had identified a lack of consensus between EUG members — often reflected by disagreement between ERICA Consortium members; where there was disagreement between ERICA and EUG; or where there was agreement on the importance of an issue but uncertainty as to how best to deal with it. Before the seminar, the EUG was asked to provide comments and suggestions for discussion issues.

As background reading, a document was prepared compiling material from previously published ERICA deliverables, including a number of comments and recommendations made at previous EUG events. A selection of material from this document has been included under the relevant section headings. Moreover, each group work session was introduced by keynote lectures describing relevant aspects of the issues to be discussed. PowerPoint presentations and the background information document are available to EUG members and the ERICA Consortium on the EUG protected area of the ERICA website at www.erica-project.org.

This deliverable presents the final position paper (the Consensus Statements) endorsed by the group in Sections 6 and 7. The statements have also been published as a stand alone report [2006b]. Sections 2 to 5 present background material to the issues, and the main areas of agreement and disagreement from the breakout group discussions. The section headings represent the four main thematic issues.

1.1 Seminar Procedures

The seminar was preceded by a demonstration of the ERICA assessment tool and the FREDERICA database.

The seminar was opened with a welcome by Per Strand (NRPA), and an historic overview of the development of the ERICA approach by Carl-Magnus Larsson (SSI). Thereafter, Deborah Oughton (UMB) presented the evolution of the issues to be discussed at the present workshop throughout

earlier EUG meetings and the purpose of the current meeting. Finally, Matthias Kaiser (NENT) introduced the consensus seminar procedure and the work plan in detail.

The choice of a consensus conference model for this meeting was based upon experiences from the Consensus Conference on Protection of the Environment, organised as part of an International Seminar on 'Radiation Protection in the 21st Century: Ethical, Philosophical and Environmental Issues' in 2001 (Strand and Oughton, 2002). At that conference a consensus on the need for protection of the environment from ionising radiation was established. At this seminar the organisers wished to establish some key elements of *how* to protect the environment from ionising radiation. From previous EUG events, it was expected that there may be some disagreement on this, and the organisers therefore chose to keep a stronger focus on uncovering disagreements. It was thought that specifying the *arguments* for disagreement (and agreement) would help make the discussion better structured and be more informative for the ERICA Consortium.

Due to this focus, a questionnaire was sent to the participants by e-mail in advance of the seminar to both EUG members and ERICA Consortium who were to attend the seminar. In this questionnaire participants were asked to indicate their degree of agreement or disagreement to a number of statements related to the main issues to be discussed at the seminar. They were also encouraged to indicate reasons for their opinions. 23 participants (out of 42) returned the questionnaire in advance of the seminar. Although this did not represent the attitudes of all participants at the event, this information was used as a starting point for the group sessions, and participants were encouraged to submit additional opinions. From the comments given by the respondents, general arguments for or against each of the proposed statement were prepared by the facilitators as an input material for the group discussions.

The plan for the group sessions was to bring out the main arguments in favour and against the statements, and then assess the strengths and validity of these arguments. A prioritisation of the importance of the arguments was to be done and, if possible, tentative conclusions on the statements were to be recorded. The justification of this plan was to ensure the respect for a diversity of attitudes and viewpoints, and not put too much pressure on reaching common standpoints. However, it turned out that there was strong motivation within the groups to work constructively towards reformulating the initial statements into statements they all could agree on. Therefore the input pro and contra arguments were turned into instruments to formulate consensus. How the groups used these arguments in their discussions varied across the groups and also across the sessions.

As in all other EUG events, the breakout group discussions formed a major part of the seminar. The participants were divided into three groups, with a focus on balance between ERICA and EUG members, between men and women, between nationalities, etc. The group work started by agreeing upon a chair and a secretary. The chair was to be responsible for reporting back in plenary, ensuring that no one dominated the discussions and for the quality of the output. The task of the secretary was to make notes of the discussions and to support the chair. The task of the facilitator was to help in reformulating the input statements and arguments into a form desired by the group, as well as help the chair keep track of time, etc. Each group session was followed by a plenary session where the chairs presented the results. Members of the group, as well as the other participants, were asked to supplement or comment the presentations of the chairs.

When all the group sessions were concluded, at the end of the second day, all the group plenary presentations were worked into a common document that were to be the input material for the *drafting committee*. The drafting committee consisted of the chair and the secretary from the three groups, as well as two of the facilitators. In addition, one of the organisers (Deborah Oughton) was present as an observer to provide technical support and answer questions from the committee.

The committee's task was to transform the results from the groups into statements that seemed to represent the common views of the groups. They worked during the evening of the second day and before breakfast on the final day of the seminar. The draft consensus document was made available to all participants in the morning of the final day. Carl-Magnus Larsson, on behalf of the ERICA Management Group, gave the first response to the document. Then there was a general plenary discussion. During the final plenary this draft document was revised into a form acceptable to all. Finally, evaluation forms were distributed at the end of the seminar, as during each EUG event, and responses summarised in Appendix 3.

2 Reference Organisms

This group session was introduced by a lecture given by Francois Brechignac (IUR).

2.1 Background Material

The reference organism concept is central to the ERICA Integrated Approach and Assessment Tool. The concept is similar to the Reference Animals and Plants (RAP) approach currently being developed by the ICRP, but it should be noted that ERICA includes a wider range of organisms than the ICRP.

2.1.1 Definitions

ERICA definition

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

ICRP 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.*"

2.1.2 List of the final radionuclides and reference organisms to be used within ERICA

Nuclides list:		Reference organisms:			
Ag	Silver	***Terrestrial***	***Origin***	***Freshwater***	***Origin***
Am	Americium	Soil Invertebrate (worm)	FASSET	Phytoplankton	FASSET
C	Carbon	Detritivorous invertebrate	FASSET	Vascular plant	FASSET
Cd	Cadmium	Flying insects	To represent protected spp. (e.g. butterflies)	Zooplankton	FASSET
Ce	Cerium	Gastropod	To represent protected spp. (snails)	Insect larvae	FASSET
Cl	Chlorine	Lichen & bryophytes	FASSET	Bi-valve mollusc	FASSET
Cm	Curium	Grasses & Herbs	FASSET	Gastropod	FASSET
Co	Cobalt	Shrub	FASSET	Crustacean	FASSET
Cs	Caesium	Tree	FASSET	Benthic fish	FASSET
Eu	Europium	Mammal	FASSET (amalgamation of three RO's)	Pelagic fish	FASSET
H	Tritium	Bird	Post D9 to represent protected spp.	Bird	FASSET
I	Iodine	Bird egg	FASSET	Mammal	FASSET
Mn	Mangenese	Reptile	To represent protected spp. (e.g. lizard & snake spp.)	Amphibian	FASSET
Nb	Niobium	Amphibian	Post D9 to represent protected spp.		
Ni	Nickel				
Np	Neptunium	***Marine***	***Origin***		
P	Phosphorus	Phytoplankton	FASSET	**Justification for the choices**	
Pb	Lead	Macroalgae	FASSET	**is being compiled by WP1**	
Po	Polonium	Vascular plant	FASSET	**to be provided in due course**	
Pu	Plutonium	Zooplankton	FASSET		
Ra	Radium	Polychaete worm	FASSET		
Ru	Ruthenium	Bivalve mollusc	FASSET		
S	Sulphur	Crustacean	FASSET		
Sb	Antimony	Benthic fish	FASSET		
Se	Selenium	Pelagic fish	FASSET		
Sr	Strontium	(Wading) bird	FASSET		
Tc	Technetium	Mammal	FASSET		
Te	Tellurium	Reptile	To represent protected spp. (marine turtles)		
Th	Thorium	Sea anemones/true corals	Key organism for protected habitat (cold water reef) see http://www.jncc.gov.uk/page-1449 and http://www.marlin.ac.uk/species/Lopheliapertusa.htm		
U	Uranium				
Zr	Zirconium				

2.1.3 The ICRP Approach

From ERICA D7a

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

From ICRP Draft Document

A deliberate emphasis has been placed on vertebrate animals but, in compiling the overall "set", consideration has also been given to the range of habitats covered, the variety of life histories and life spans represented, and the potential for extrapolating the basic "reference" animal or plant data to other forms of animal or plant, or to place them in other environments. The primary purpose is to use the reference animals and plants to relate exposure to dose, and dose to effect. To date, 12 reference

organisms have been proposed; deer, rat (pup and adult), duck (egg and adult), frog (egg, tadpole, adult), trout (egg and adult), flatfish (egg and adult), bee (larva, adult, colony), crab (egg, larva, adult), earthworm (egg and elongated), pine tree, grass and brown seaweed.

("The concept of use of reference animals and plants for the purposes of environmental protection": www.icrp.org/docs/Environm_ICRP_found_doc_for_web_cons.pdf.)

2.1.4 Previous Comments from EUG members

- In dosimetry at least, the term 'reference organism' might be reconsidered – it takes the focus onto individuals. For dosimetry 'reference geometry' might be better, although in the overall ERICA framework it was understood that reference organisms also carry with them assumptions as to life history, habitat and radionuclide uptake as well as geometry (ERICA D7e).
- 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 (ERICA D7c).
- 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. (ERICA D7c).

2.2 Group Discussions

2.2.1 The ERICA approach must be compatible with ICRP recommendations

α-group

The group endorsed arguments both for and against this statement, but seemed to have most focus on pro arguments. They stressed that the ERICA integrated approach should be compatible with ICRP recommendations for many practical scientific and pragmatic reasons, and it was underlined that this should explicitly relate to the ICRP concept of reference animals and plants. It was noted that compatibility is especially important for protected or rare species, due to their biological, ecological, physiological, genetic, etc. properties. Of the other arguments, it was noted that even if it should be compatible with ICRP, the ERICA integrated approach should be broad enough to cover the various situations (site specific biota) that may exist and require assessment. There should also be dialogue with other approaches like those taken by UNSCEAR and IAEA. A minority suggested that, although the need for compatibility was recognised, the ICRP concept of reference animals and plants puts too much focus on effects on organisms, and not enough on other aspects of the environment, and supported the claim that independent opinions are important.

β-group

In this group all agreed that the ERICA integrated approach should be compatible, but more sophisticated and wider, and that it should be a driving force for ICRP. Most agreed also that the approach should be practical and scientifically broad enough to cover the various situations that may exist and that require assessment, and that the ERICA integrated approach also should be compatible with other approaches, like those of the UNSCEAR and IAEA. A small majority of the group believed

that independent opinions are important and that site specific information on specific biota may be more relevant and of interest to stakeholders.

γ-group

This group noted that, as yet, there is no definitive ICRP approach, but still believed that the ERICA assessment tool should not be in conflict with ICRP. For practical, scientific and pragmatic reasons, harmonisation internationally was thought to be important, and something that would promote confidence and credibility in application at national level. There was less agreement about whether ICRP recommendations should be considered scientific or politically motivated. However there was a general consensus that independent science based opinions should be valued, and that the broader range of reference organisms in ERICA was important in addressing site-specific evaluations.

2.2.2 Reference organisms cannot represent protected species

α-group

The group reformulated the initial statement into the statement that "reference organisms cannot *necessarily* represent protected species." They contended that reference organisms *could* represent protected species if parameter values can be properly assigned. They supported the statement that protected species is a specific case which may be developed using the reference organism concept, and that reference animals and plants are chosen as a "reference" for environmental biota, but do not represent specifically protected ones. It was noted that benchmarks for reference biota are based on principles of protection of a population (and not individual biota). The group had some terminological qualms. It felt that the term "protected" should be better defined in order not to confuse it with the overall survival of the species, and also queried the meaning of the term 'represent'. Whether or not reference organisms can 'represent' protected species depends whether it is a modelling exercise or a field exercise.

β-group

The group held that reference organisms *can* represent protected species if parameter values can be properly assigned. Protected species is a specific case, which may be developed using the reference organism concept, but it needs to be supplemented with a well-designed research program to support findings (from individual to population). However a large majority of the group endorsed the contra argument that reference organisms do not capture the dynamism of ecosystems (with regard to protected or sensitive species).

γ-group

The group noted that rare species are by definition rare and that the whole ecosystem therefore should be considered. They held that protected species is a specific case which may be developed using the reference organism species concept (e.g. a modelling exercise). Indeed, the ERICA reference organism list has been reviewed against European protected species at a generic level. The group also noted that protected species are protected in a special (legislative) context – so generic methodology is not necessarily appropriate. Moreover, the group stressed that reference organisms have to be amenable to research.

2.2.3 The use of reference organisms is not compatible with the approach used in chemical assessment

α-group

The group disagreed: they are not the same (the reference organisms approach is more complex), but compatible. There are moves afoot to bring the two systems in line with each other. Some aspects are already similar, and the reference organism concept is currently being looked at for chemicals. Test

laboratories used to derive no effect concentration limits are similar to the reference organism approach and chemical ecological toxicity tests have commonalities with the ERICA integrated approach.

β-group

The group claimed that the concepts/approaches are somewhat different, but should be integrated in the future.

γ-group

The group claimed that they are not the same, but compatible. In fact, the chemical approach has been considered throughout development of ERICA (e.g. no effect doses). Nevertheless, a key difference is metabolism – which is often more important for chemical assessment.

2.2.4 Reference organisms are a good basis for the estimation of radiation dose rates

α-group

This group agreed that reference organisms are a good basis for the estimation of radiation dose rate because the concept is thorough and well-defined. Furthermore, dosimetric models can be extended to other organisms

As a general comment to this group session, the group recommended that one should clarify in detail the ERICA understanding of the term compatibility, and the relation between radiation and chemical assessment, as well as the relation to ICRP.

β-group

A majority of the group believed that dose rate is a crucial physical quantity regarding radiation protection (and effects from ionising radiation exposures). Therefore it is very important to evolve a dosimetric model for reference organisms. In due time, we can extend this experience on developing dosimetric models for other organisms. Still, the group noted that the model's adequacy depends on the endpoint you are looking at because the dose/radioactivity may not be uniformly distributed.

γ-group

This group did not have time to discuss this statement, besides noting the general agreement that reference organisms were a good basis for estimating dose.

3 Dose-Effect Evaluation

This group session was introduced by two lectures. Christian Streffer from Essen University, and chairman of the ICRP Committee on Dose spoke about 'RBE and Weighting Factors: Scientific Background and Use in Radiological Protection'. David Copplestone (Environmental Agency, UK) spoke about the FREDERICA database.

3.1 Background Material

Discussion of dose-effect evaluation at previous EUG events has raised questions in two main areas: first the applicability of RBE data for the derivation of weighting factors used in *dose* calculation; and, second, the relevance of existing data in FREDERICA for the evaluation of ecological *effects*.

For example, in ERICA D7e it was noted that the principle uncertainties in the estimation of dose were:

- *Concentrations in the organism and surrounding environmental media.* Uncertainty in concentrations arises from the transport and uptake modelling component of ERICA, rather than dosimetry *per se.*
- *Choice of weighting factors.* Uncertainty in the weighting factors is key to the comparison with FREDERICA database results, most of which are based on external gamma, or X-ray photon irradiation. However the inclusion of a weighting factor for low energy beta radiation, and the segregation of dose coefficients according to radiation type (which allows weighting factors to be easily amended) were noted as positive features of the approach.
- *The assumption of uniform distribution within the organism.* Non-uniformity of distribution within the organism would affect the estimation of dose averaged over the whole volume of the organism, although this has been addressed in the ERICA project and the effect is not large. More importantly, non-uniformity of distribution between organs on a scale comparable with the range of the radiation in tissue could have very significant consequences on the risk of effects – risk would be increased (relative to ERICA estimates) if radionuclides concentrated in an organ which was critical for one or more of the relevant endpoints, or decreased if concentration were in an organ that is relatively insensitive.
- *Dose estimation in the FREDERICA database.* Proper understanding of the basis of dose estimation in the FREDERICA database studies is necessary to ensure comparability with estimates from the ERICA assessments. Overall, for a given set of radionuclide concentration values in the organism and the surrounding environmental media, it was felt that estimation of radiation dose *in terms of the quantities as defined* was probably the least uncertain part of the ERICA assessment part.

The principal points leading to uncertainties in estimating effects include the following elements.

- The lack of information in the FREDERICA database for many species (data gaps).
- The linearity between dose and effect (it was noted that end-points considered by ERICA are likely to be non-stochastic in nature, and a sigmoid or threshold type of dose response is assumed).
- The difference between acute and chronic exposures in determining the risk of effects. What duration of exposure marks the boundary between acute and chronic and what is the relationship to stages in the life cycle.
- Are sensitivities at different stages in the life cycle adequately covered by FREDERICA?
- The basis of dose estimation in FREDERICA (it was noted that the project has reviewed, and where necessary re-constructed, dose estimates in all the FREDERICA effects studies).
- Extrapolation from individuals to populations remains problematic and will need to be carefully justified.

3.2 Group Discussions

3.2.1 The majority of the RBE data available for non-human organisms are inappropriate to the formulation of weighting factors

α-group

The group holds that there are some relevant data in the literature and these can be used to derive values within a range – but we should observe the uncertainties, for instance that there is a lack of coverage of different organisms and a lack of coverage of endpoints. The majority of the data are only

available for a small subset of all organisms and are therefore inappropriate for extrapolation. It also notes that although there is very credible data, their interpretation is more difficult. It was proposed that weighting factors are politically negotiable, and queried why weighting factors should be a limiting term for ERICA.

β-group

The group formulated a new statement: "Weighting factors are based on credible, but limited data". It specified that there are credible data for mammals and mortality, but not for other organisms and other endpoints.

γ-group

The group proposed that where RBE are available for non-human organisms, that data are highly appropriate for the formulation of weighting factors. However, RBE data are not available for a sufficiently wide range of organisms and endpoints. RBE values are mainly obtained for mammals and different endpoints (a large number of in vitro experiments). RBE values depend both on the life stage and the endpoint. Few available data for population-relevant deterministic endpoints related to reproduction. Taking into account population effects as endpoints for biological protection, the most appropriate basis for RBE determination is experience on deterministic effects and cell death. RBE for alpha emitters needs to address differences in tissue sensitivity and non-uniformity of radionuclides distribution within the organism

3.2.2 Transfer factors and concentration ratios represent the major sources of uncertainty within dose assessment; the estimation of absorbed dose (Gray), for a given radionuclide concentration within an organism, is the least uncertain part of the dose assessment

α-group

The group agreed that dosimetry is the most certain (but not fully certain) part of the assessment. This was supported by referral to the reliability of the measurement, and the relatively low error on dose-conversion factors, as compared to the extreme errors associated with transfer factor approaches

β-group

The group proposed a new statement that "dose conversion factors are the least uncertain parts of dose assessment". They also specified that measurements reduce uncertainties, and the reliability of dose conversion coefficients due to their being based on physical parameters. However, they also noted that in some cases differences in assumptions can lead to differences in dose estimates.

γ-group

This group supported the statement, adding that preliminary international intercomparison of biota models have shown that the variability and uncertainty in the transfer component of the tool, is much greater than in dosimetry component. They also agreed with the other two groups on the physical aspects of dose conversion coefficients and the importance of differences in assumptions. However, they also noted that there are some uncertainties that arise from the fact that internal distributions of radionuclides are not uniform. Dose to targeted/specific organ/tissue may be more important than dose to the whole body.

3.2.3 The derivation of benchmarks for ecological risk assessment is undermined by the fact that a large part of the data in FREDERICA was not collated for the purpose of assessing ecological effects

α-group

This group made a new statement: “The lack of ecological effects data undermines/limits the assessment approach”. They agreed that umbrella effects related to individual growth and reproduction had been reviewed by FREDERICA, and that these would be related to the viability of the population and sustainability of the ecological system.

β-group

The group felt that it was correct that the majority of the source literature for FREDERICA was designed for other purposes. They supported that FREDERICA is a database gathering experiments on effects on individual species; and that the available data do not provide sufficient information on ecological effects. They thought it important that only a few tens out of thousands for entries in FREDERICA "passed" criteria for SSD, and noted that this is probably no worse than benchmarks derived for chemicals. They also pointed out that it is necessary to focus on what is missing and how best to fill gaps.

γ-group

The group formulated a new statement: “Data in FREDERICA were not collated for the purpose of assessing ecological effects”. The ERICA assessment within the tiers uses FREDERICA to assess effects at the individual level, and as such benchmarks are based on no effect levels for individuals, and the ecological context is not addressed until Tier 3. They agreed with the other groups on the lack of ecological endpoints in the database (98.3 % of the data of the database do not address ecological endpoints), but that the derivation of benchmarks was probably no worse than for chemicals. However they also pointed out that although the data may not be aimed at ecological effects, but that doesn't make it irrelevant. The relevance of the FREDERICA database for population effects can be improved if cytogenetic effects are excluded.

3.2.4 Since prognosis of consequences for populations is so complex, effects on individual organisms should form the primary basis for evaluation of the impact of radiation exposure

α-group

New statement: “Given the database available, effects on individual organisms may form the initial basis for evaluation of the impacts of radiation exposure of the ecosystem”.

β-group

The group basically agreed with the statement. As support they noted that we can make measurements at the individual level, and that it is currently more difficult at higher levels of organisation. Experimental data are achieved for individuals, but it is important to gain information about endpoints that could influence the population dynamics, such as reproduction. Protection of the population is the ultimate goal, and extrapolation from effects in individuals to population is necessary. A well-directed accumulation of knowledge about specific population-level effects of radioactive contamination is needed. If the object of protection is population, then there is a need for more focus on effects at individual level that are relevant for population dynamics (e.g. reproduction).

γ-group

The group claimed that this is not necessarily the best approach, but is a reality for the data available. They agreed that experimental data are obtained at an individual level, but noted that it was important to gain information about endpoints that could influence the population dynamics, such as reproduction. They also noted that this is an externally imposed constraint that is a generic problem for ecotoxicology (from chemicals as well), and not an inherent problem for the tool. The group also thought that some of the dissenting views were worth noting (even though one might not agree with them). Namely that the primary goal of environmental protection is at the level of populations, communities, ecosystems and biodiversity. This means that too much focus on individuals is potentially a much more controversial approach.

4 The Assessment Tool

This group session was introduced by two lectures. Justin Brown (NRPA) spoke about 'The ERICA Assessment Tool – Realism and Conservatism', and Steve Mihok (CNS) spoke about the Canadian experience.

4.1 Background Material

4.1.1 The ERICA Tiered Approach and Risk Assessment Tool

From ERICA D7e

The ERICA integrated approach to the assessment and management of environmental risks from radioactive substances consists of three integrated components: an assessment tool, a methodology for risk characterisation and decision-making guidance, Figure 2. These components are combined within a tiered approach, starting with problem formulation and continuing through a series of three assessment tiers. The general concept of a tiered approach to risk management is recognised within Ecological Risk Assessment (ERA), both for non-radioactive and radioactive substances (e.g. Canada). However, to produce a practical and workable assessment tool for the ERICA project, the various tiers need to be specified and characterised, and the overall tiered approach needs to be integrated with the risk assessment tool and risk characterisation methodologies. This has been done for Tiers 1 and 2 within the ERICA integrated approach and we are currently working on the description and implementation of Tier 3.

Briefly, the various stages of the assessment, the differences between the tiers, data requirements and sources of uncertainty can be summarised as follows, and detailed in ERICA D4a.

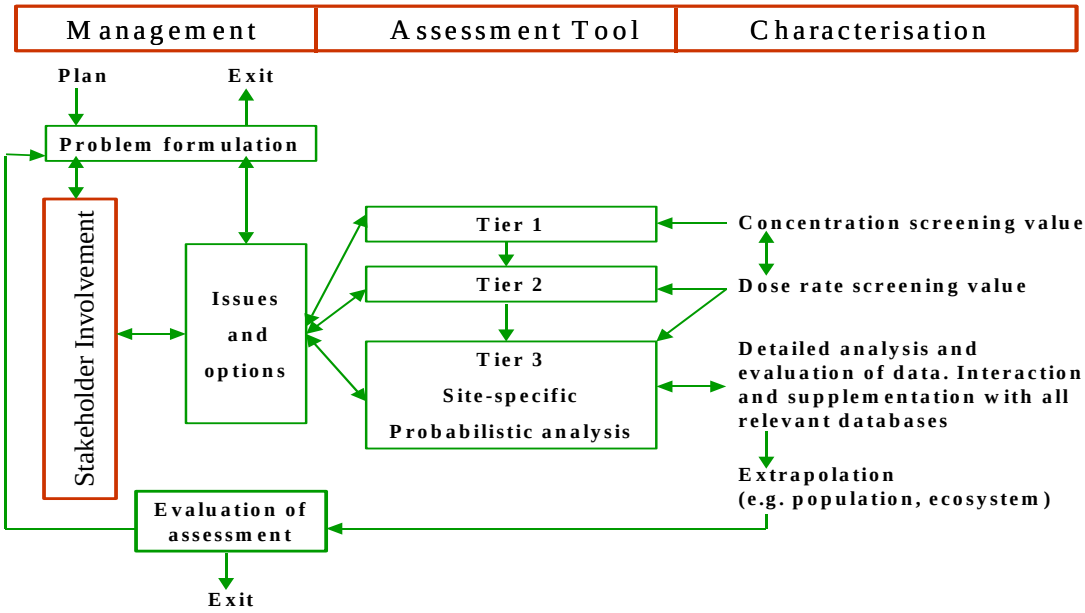

Figure 2. Working model of the ERICA Integrated Approach, depicting its three main integrated features: An assessment tool, methodology for risk characterisation and guidance for stakeholder involvement and decision-making (management), April 2006.

Tier 1 (Screening)

- Uses maximum environmental activity concentrations derived from measured or modelled concentrations in various environmental media (unless otherwise defined in the problem formulation) and takes no account of spatial or temporal variation. Simple transport models are provided within the assessment tool to assist the assessor in predicting environmental media concentrations if required.
- Compares the measured/modelled activity concentrations for each radionuclide being considered against environmental media limiting concentrations (EMLC) in Bq/l or Bq/kg for the main media (i.e., water, sediment, air, soil) and for each radionuclide.
- Derives the EMLC or screening values by back-calculating from Predicted No-Effect Dose Rates (PNEDR). Dose rate screening values can be selected by the user at the present time. For a given radionuclide, these screening values (one per medium) correspond to the *minimum* value for all reference organisms (see ERICA D5).
- The approach to uncertainties can generally be considered as hyper-conservative (maximum possible concentration compared with minimum acceptable dose) with main source of uncertainty in robustness of assessment likely to be in the applicability of the selected screening value.

Tier 2 (Generic assessment)

- Incorporates dispersion modelling techniques (using site-specific models (provided by the assessor) or default models that are available within the ERICA assessment tool).
- Introduces available site-specific data (e.g., media concentrations, site-specific Kds, CFs, occupancy factors) or encourages its collection.
- Compares the predicted dose rates to the same limiting dose rate (PNEDR) considered in tier 1, but using dose rates. This introduces the flexibility to use different, but justified, radiation weighting factors for different radiation types. It is also possible to carry out the calculation for all reference organisms, not only the one that led to the minimum value of the environmental media limiting concentration.
- May involve evaluation of the likely biological effects of exposure to ionising radiation by comparing predicted dose rates to look up tables on the biological effects caused by exposure to ionising radiation. These look up tables are being compiled from the FREDERICA database, which is also part of the assessment tool.
- There is debate currently over the amount of evaluation of the main sources of uncertainties in the assessment at tier 2 bearing in mind that whilst this tier allows you to refine the exposure pathway analysis (e.g. screening values, input data, model parameters, risk quotients) you are still comparing the exposure values to the PNEDR values and as such the uncertainties have been considered implicitly within this assessment.

Tier 3 (Detailed assessment - still under development)

- 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 depending in part on the revision of the problem formulation and the endpoints of interest.
- Evaluates all the key impacts on the site including non-radioactive contaminants, although there might be limited consideration of this through guidance given in the earlier tiers.
- Introduces probabilistic techniques to aid in the assessment evaluation.
- Has no defined prescribed screening level but includes involvement of stakeholders to consider whether the practice is acceptable in terms of its environmental impact compared with the economic and social benefits.
- Possibility for more detailed uncertainty and sensitivity analysis, including uncertainties in evaluation of effects data, species sensitivity and ecosystem functioning.
- Links directly to the FREDERICA database on radiation effects on non-human species.

<u>Selected comments from previous EUG events on assessment</u>

- 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 (D7c).
- 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 (D7c). Guidance on dealing with the spatial scale should be considered somewhere within ERICA (D7a Part 1).

- Users require information on the sources, and at least the order of magnitude, of uncertainties in the assessment. There is a need for transparency and traceability in the way the tool deals with uncertainty and a justification of the choices and assumptions made in selection of model and parameters. (D7e).
- It must be made clear to the users that ERICA has several types of intrinsic uncertainties and that some conservatism already is built-in to compensate for those. It is important that the user neither doubles the conservatism nor trusts the result too uncritically (D7e).
- Use probabilistic modelling at Tier 3. Deal appropriately with uncertainties in all tiers (D7c).

4.2 Group Discussions

4.2.1 There is too much conservatism built into the ERICA tool

α-group

The group felt that there was not too much conservatism built into the ERICA tool, but that the conservatism that is there needs to be transparent so that users don't overcompensate. They thought that there is indeed much conservatism at the early tiers, but this is preferred to the possibility of a false positive (i.e. a failure that is not detected).

β-group

The group formulated a new statement: There is adequate conservatism built into the ERICA tool. The group held that conservatism should be balanced with uncertainty in the assessment. One should spell out caveats and assumptions in the assessment, and make clear that information is dated 2006 and understanding may change. The conservatism needs to be transparent so that users don't overcompensate. Still, the group held that should note that the assumption of equilibrium may not always be conservative.

γ-group

This group claimed that there is certainly conservatism in the tool - but probably to about the right extent as a starting point (i.e. at early tiers). The protocols in the model need to allow you to decide to reduce conservatism in the light of new data. They held that conservatism should be balanced with uncertainty in the assessment, and agreed with the other groups on the need for processes to be transparent to users and decision makers (so that they understand, don't overcompensate, etc.). The conservatism in the ERICA tool must be considered in combination with conservatism on the PNEDR in making management decisions. There is a particular need to be careful with the weighing factors for alpha particles. The group also pointed out that this question is difficult to answer as the tool is still under development and testing. Getting the balance right between conservatism and realism is important.

4.2.2 The ERICA tool needs to treat prospective and retrospective assessments differently

α-group

The group claimed that the ERICA tool is able to do prospective and retrospective assessments. Prospective and retrospective assessments should be treated just the same - although it needs to be recognised that getting site-specific data is more straightforward in the retrospective case. There are some differences in the two assessment situations and the tool should (and can) deal with these differences adequately.

β-group

The group formulated a new statement: The ERICA tool can be applied both to prospective and retrospective assessments. The group noted, however, that there are some differences in the approach and the tool should (and can) deal with these differences adequately. They agreed with group one that getting site specific data is more straightforward in the retrospective case, but suggested that there is a time scale limit to how prospectively the tool can be used Uncertainties in prospective assessments increase with time, hence examples of use and limits should be given.

γ-group

The group wanted to modify this statement in several ways. They claimed that there are different goals for prospective assessments and retrospective assessments (although management of contaminated sites could involve both). There are some differences in the approach and the tool should (and can) deal with these differences adequately. There are also differences in the degree of conservatism and realism because there are different amounts of data and differences in the quality of data, but the principles can still be the same. For the prospective assessments one would need reference values and models (e.g., reference organisms, weighing factors). For retrospective situations one need more detailed and site specific information where possible. In general, getting site-specific values is more straightforward in the retrospective case. But it is important to be aware that, in some cases, retrospective assessments can be limited by the quality of past measurement technologies. They also noted that the prospective and retrospective analyses are established practice in Ecological Risk Assessment. Finally, they thought it important to note that scientific practices, ideologies and regulations often change between the past, the present and the future, making it difficult to evaluate on an 'even' ground.

4.2.3 There should always be a probabilistic analysis in risk assessment to account for uncertainty

α-group

The group formulated a new statement: There should be *an option* for a probabilistic analysis to account for uncertainty. This is because probabilistic analysis isn't the only way of dealing with uncertainty. The group claimed that probabilistic analysis is useful when there is a range of parameter values encompassing the uncertainty in the analysis. However, sometimes, there is an uncertainty in the conceptual model that would also require running several scenarios.

β-group

The group preferred the following formulation: Probabilistic or sensitivity analysis should be required to deal with uncertainty. They also thought that sensitivity analysis would often be preferable, since it is simpler than probabilistic analysis to use, interpret and communicate. For probabilistic analysis you need to have the knowledge of distribution and sometimes this is lacking. This leads to problems in interpreting the uncertainties of the probabilistic analysis. However, probabilistic analysis (or any approach taking uncertainty into account) needs to be communicated effectively. Where issues are well below levels of concerns they are not necessary.

γ-group

The group claimed that risk assessment and probabilistic analysis (PRA) go hand in hand and that probabilistic analysis in ERICA is a valuable addition to the available tools. However, PRA is data hungry and it is a mistake to assume that it is not. The data are rarely available to achieve this goal. The challenge is also that the results of PRA are communicated effectively. Probabilistic analysis isn't the only way of dealing with uncertainty and options for managing uncertainties should be highlighted in the ERICA integrated approach. In practice one uses bounding conditions and alternative scenarios

to deal with uncertainty. For screening purposes (e.g. in a Tier 1 assessment), probabilistic analysis would not be required; however, as risk quotients approach the limit may become necessary.

4.2.4 The risk quotient is an overly simplistic indicator of environmental risk

α-group

The group formulated a new statement: "The risk quotient is an appropriate and simple indicator of environmental risk".

It commented that it is easy to understand, simple to explain, for screening it is a very effective way of evaluating risk. Simple can be useful, as long as the initial assumptions feeding into an assessment are adequately conservative. The degree of simplicity is consistent with the level of understanding of environmental risk. It is perfectly fine as a planning / regulatory tool, but it should not be over interpreted (i.e. it is "fit for purpose"). It should be used more cautiously at Tier 3.

β-group

The group preferred a statement that the risk quotient is easy to understand and simple to explain. For screening it is a very effective way of evaluating risk, however it should be used more cautiously at Tier 3 (there you would need additional information or use other techniques).

γ-group

The group also agreed that the risk quotient is in principle easy to understand and simple to explain. But the group stressed the differences in use in Tiers 1 and 2. It's not over-simplistic when used in Tier 1 with a lot of conservatism built in. For screening it is a very effective way of evaluating risk and appropriately is not used at Tier 3. The risk quotient is perfectly fine as a planning / regulatory tool, but it should not be over interpreted, for example when population effects have a dose effect threshold.

5 Management Issues

This session was introduced by two lectures. Solvår Hardeng, from the Norwegian Pollution Control Authority spoke about 'European Chemical Legislation', and Masahiro Doi from the National Institute of Radiological Sciences, Japan, spoke about 'Asian Perspective on the environmental protection'.

5.1 Background Material

Management issues have been discussed at a number of EUG events, including an event dedicated to the issue of stakeholder involvement in risk assessment. In addition to stakeholder involvement, other key issues have been integration with other management approaches and the applicability of the precautionary principle within the ERICA integrated approach. Regarding integration with approaches to management of chemicals one might argue that both stakeholder involvement and the precautionary principle are simply two specific examples of a variety of general management approaches and principles. But from EUG discussions, it is clear that both issues attract interest and also provoke a certain amount of disagreement. Questions have been raised about the appropriateness of involving stakeholders in the ERICA approach, and the implications of the precautionary principles. Already at the first meeting, the EUG had proposed that ERICA should "*Develop a pragmatic approach to decision-making. Ensure that decision-making allows the precautionary principle to be applied when taking into account knowledge gaps and uncertainties* (ERICA D7a Part 2)". While at a follow-up discussion of the precautionary principle at the EUG event on scientific uncertainties EUG members proposed that: "*Application of the Precautionary Principle is a matter for decision-makers not for the ERICA integrated approach itself* (ERICA D7e)". Other statements from EUG are detailed in Section 5.1.2.

It should be noted that the last EUG event, in November 2006, will deal specifically with management issues.

5.1.1 Definitions of Precautionary Principle

From ERICA D7e

Discussions about the use of the precautionary principle in risk management are complicated by the lack of agreement on what the principle actually is. Three possible examples are given below.

Rio Declaration (United Nations 1992)

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

EU communication on the PP (EU, 2000)

"The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU."

UNESCO-COMEST (2005)

"When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.

Morally unacceptable harm refers to harm to humans or the environment that is

- *threatening to human life or health, or*
- *serious and effectively irreversible, or*
- *inequitable to present or future generations, or*
- *imposed without adequate consideration of the human rights of those affected.*

The judgment of plausibility should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review.

Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm.

Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process."

Selected comments from the EUG on management issues

- Comparison of the various frameworks recognised similarity within the risk analysis and assessment parts. The frameworks tended to use the same types of transfer and dosimetry models, and similar criteria for selection of reference or critical organisms (even if the actual choice differs). The main differences arose within the risk characterisation stage, particularly with regard to the interpretation of effects data (e.g. the choice of NOEL, LOEL, EC_x, as well as selection of the biological endpoint of concern and judgements

about “adversity”). Not surprisingly, it was here that problems for management and regulation started to appear (D7a Part 2).

- It was agreed that the way ERICA would be used would be different in different countries because of legislative and cultural contexts (e.g. countries vary in their experience with stakeholder engagement, the role of NGOs varies from country to country). (D7d)
- It was suggested that even though there may be a consensus regarding similarity between the frameworks actually used in practice (i.e. the models, tools and assumptions used in dose-effect analysis), it did not necessarily follow that this framework was the most appropriate alternative. In particular, it was claimed that there were approaches used for other environmental stressors that may be more suitable (D7a Part 2)
- There was a conceptual difference in the top-down and bottom-up approach, for example, the FASSET focus on producing realistic estimates of effects as compared to a more compliance driven approach adopted by the DOE. In other words a difference between regulation driven by “numbers in pipes” as opposed to “numbers in the environment” (D7a Part 2).
- It is also important to recognise that the scale of stakeholder involvement should be appropriate to the size of the project/decision to be made at hand (D7d).
- It is important to note that stakeholder involvement should NOT be undertaken with the objective of to get people to AGREE. As with ‘who are stakeholders?' the question of why to involve them will be case specific (D7d).
- Given ERICA is likely to be embedded within other assessment processes, there will be overlap between stakeholders for ERICA and stakeholders for other parts of the assessment process (D7d).
- Application of the Precautionary Principle is a matter for decision-makers not for the ERICA integrated approach itself. The ERICA integrated approach must be absolutely clear about where, why, how and to what extent conservatism has been included – so that decision-makers do not take the ERICA output and apply further precaution, and un-knowingly double-count the degree of conservatism/precaution, in their decisions. (D7e).

5.2 Group Discussions

5.2.1 The same general principles for management of the protection of the environment should apply for all contaminants

α-group

The group modified the statement slightly: The same *(high level)* principles for management of the protection of the environment should apply for all contaminants.

They claimed that the framework of environmental risk management should be “harmonised” for all contaminants to meet the needs of the high level principles. We should be aiming for harmonisation in the future to ensure consistency

β-group

The group felt that we should be aiming for common general principles in the future to ensure consistency for all toxicants, but noted that implementation may vary. One should encourage/adopt a common best practice. Multiple stressor approach should be developed in the future.

γ-group

The group claimed that the same general management principles should apply in order to ensure consistency. The principles can be similar but the details will be different, for example external

irradiation or combined effect of radiation and chemical toxicity (e.g. uranium), radioactive decay versus chemical half-life. The group stressed that it is important that consistency should not be achieved by adopting inappropriate principles (e.g. lethal toxicity testing).

It also noted to what extent the same management principles apply to all contaminants, and that in future discussions it would be useful to define what these different/primary management principles are.

5.2.2 The precautionary principle (PP) suggests that radioactive releases to the environment should not occur at all

α-group

The group disagreed with the statement. It noted that this was a wrong interpretation of PP, although there could be some specific cases where PP would support no releases. Still, all activities imply releases. Moreover, it's important to take into account economic and social considerations as ICRP 60 recommended (ALARA principle). Still, applicability of PP is a matter for managers, not for the ERICA tool.

The PP applies in situations where there is insufficient data available to make other decisions. But this is not the case in the control of routine radioactive releases. Whilst there are gaps, there are sufficient data to justify controlled releases under authorisation. Effects of low-level radiation exposure should be controlled on the basis of scientifically plausible judgement. We should have regard to additional data gathering to address the gaps. Levels of releases should also be set with regard to the data gaps but it should not drive us to zero discharges. The group felt it is important to strike a realistic balance between the desirable outcomes and the less-than-desirable outcomes of anthropogenic activities, as opposed to taking extreme stances, such as zero releases. It is likely that regulatory guidelines, such as dose limits, can represent one means of setting the context for such balances. That said, it is important to conduct our activities in a manner that minimises the potential effects we may have.

β-group

The group referred to the COMEST 2005 definition of the precautionary principle (see above). The precautionary principle should apply in situations with uncertain knowledge and possibility for serious/irreversible risk of harm. The PP does not imply zero release, but aims at zero serious impact.

γ-group

The group referred to the UN Rio definition of PP, and claimed that the interpretation of PP in the statement was wrong. It noted that the precautionary principle exists along other principles like sustainable development, pollution prevention, ALARA, etc.. It was suggested that the applicability of PP is matter for decision makers, not the ERICA tool, but there was disagreement in the group about this point. Still, it is important that whatever the output of the ERICA tool is, the science needs to be transparent. Scientific knowledge is an important input to the use of the PP and effects of low-level radiation exposure should be controlled on the basis of scientifically plausible judgement (dissenting opinions). With regard to zero releases, the group noted that all activities imply releases and zero releases may not be achievable. There are many activities involving releases of radionuclides (e.g. medicine).

5.2.3 The involvement of stakeholders is an essential part of ecological risk assessment

α-group

The group wanted to specify the statement better:

3.a) the involvement of stakeholders can be *useful* in ecological risk *assessment*;
3.b) the involvement of stakeholders is *essential* in ecological risk *management*.

They commented that there should be involvement of stakeholders where needed and it should be considered for different purposes i.e. providing input into problem formulation (re. 3.a)), advice/information gathering, evaluating/decision making etc. All assessments should be conducted with the possibility that stakeholders may evaluate the output in the future.

Referring to 3.b) there is a need for a more critical evaluation of objectives and procedures. Must avoid "stakeholder fatigue". The group felt it is important to discuss who is involved and whether it is "informed".

β-group

The group reformulated the statement: "The involvement of stakeholders is an essential part of ecological risk assessment and risk management".

Involvement of stakeholders is both prudent and very often a legislative requirement. Still, the group felt that there is a need for a more critical evaluation of objectives and procedures and that "stakeholder fatigue" must be avoided. One should be aware that stakeholder involvement is probably ongoing as part of the process anyway. Therefore, stakeholders need not be included in each tier in ERICA if they are already engaged via other mechanisms (i.e. 'don't duplicate'). It is important that consultations are traceable and transparent. One should encourage best practice/common approach/ethical code with regard to stakeholder involvement and take account of developments in this area.

γ-group

The group agreed to the statement, but there were differences in the group on how best to do this. Stakeholder involvement should be used where appropriate – there would be different levels of involvement and different stakeholders at different stages. One must avoid "stakeholder fatigue". There are several reasons for involving stakeholders (practical, ethical, etc.). Moreover, stakeholder involvement is already legislated in some countries. However, it is broader than ERA and therefore may not need to be included in ERICA methodology.

5.2.4 There is no need for an internationally agreed dose limit for protection of non-human species

α-group

The group changed the term dose *limit* into the term dose *criteria* and had several arguments both for and against this statement. They thought there is no strict *need*, but without it will be very difficult to reach an international level of assessment with scientific and public acceptance. They agreed that there are several advantages of international-agreed upon dose limits. An agreed limit (or reference value) would ensure consistency of approach. For example, emissions are not necessarily limited to within-borders, but can also cross borders into other countries. In such cases, mutual understanding and respect could at least partly be achieved through consensus. In addition, energy production is often a global enterprise. Finally, development of international limits can lead to understanding, since different countries may be in varying positions with respect to their understanding of dose and its implications. Moreover, there is an advantage to have such a value especially in dealing with stakeholders. However, internationally agreed dose criteria (i.e., IAEA, ICRP) should come in time when the science is there to make decisions on the appropriate number to apply. There should also be a certain regional flexibility.

β-group

The group agreed that there is a need for an internationally agreed dose limit(s) for protection of non-human species. Currently we have advisory guidelines. These should be revised and internationally agreed upon. Dose limits should come in time when the science is there to make decisions on the

appropriate number to apply – there is a current lack of data. The derivation of the number should be transparent. Regional flexibility to set more stringent standards is also important.

γ-group

The group thought that there is a need for international harmonisation in the area of environmental protection; however, it might be achieved through less restrictive instruments than the dose limits. Trying to create an international number for dose limits may lead to more problems that it is worth. Internationally agreed "no effect" or exemption levels in combination with generic assessment guidance might be sufficient. There is an advantage to have such a harmonised approach, especially in dealing with stakeholders and trans-boundary effects.

6 Consensus Statements

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

6.1 Reference organisms

Compatibility of the ERICA approach with ICRP recommendations

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

Representation of protected species by reference organisms

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

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

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

Reference organisms as a basis for the estimation of dose rates

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

6.2 Dose-effect evaluation

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

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

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

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

Adequacy of the FREDERICA database for the assessment of ecological effects

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

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

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

6.3 Assessment tool

Conservatism within the ERICA tool

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

Treatment of prospective versus retrospective assessments within the ERICA tool

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

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

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

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

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

6.4 Management issue

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

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

Application of the precautionary principle

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

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

Stakeholder involvement in ecological risk assessment

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

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

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

6.5 Glossary

During the plenary discussion a number of terms were highlighted as being important to include in a glossary. It was agreed that the existing ERICA glossary, to be published in the D-ERICA final report, would be checked for the following terms, and items either added or revised.

Absorbed dose
Benchmarks
Endpoints
False positive
Precautionary principle
Precautionary approach
Probabilistic analysis
RBE
Reference organisms
Retrospective and prospective assessment
Risk quotient

7 Recommendations for ERICA

Reference organisms

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

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

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

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

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

Glossary

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

Absorbed dose
Benchmarks
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False positive
Precautionary principle
Precautionary approach
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It was agreed that the existing ERICA glossary, to be published in the D-ERICA final report, would be checked for the following terms, and items either added or revised.

8 Reference List

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Appendix 1: List of Participants

EUG Members
Ernest Antonio, Pacific Northwest laboratory and DOE, USA
Mikhail Balonov, IAEA
Francois Brechignac, IRSN and IUR, France
Marianne Calvez, CEA, France
Marie-Claire Cantone, University of Milan and INFN, Italy
Simon Carroll, Greenpeace International
Patrick Devin, AREVA, France
Masahiro Doi, INRS, Japan
Andrew Farmer, Institute for Environmental European Policy, UK
Nava Garisto, SENES, Canada
Stanislav Geras'kin, Ukraine
Alexander Golubev, International Sakharov Environmental University
John Holmes, Oxford University, UK
Steve Mihok, Canadian Nuclear Safety Comission, Canada
Sanja Mikovic-Kraus, IMI, Croatia
Ivica Prlic, IMI, Croatia
Ian Robertson, SEPA, UK
Carol Robinson, Enviros, UK
Tatiana Sazykina, SPA Typhoon, Russia
Christian Streffer, ICRP and Essen University, Germany
Jill Sutcliffe, English Nature, UK
Christine Willrodt, BFS, Germany
Tamara Yankovitch, Atomic Energy of Canada, Canada

ERICA Consortium
Boris Alfonso, Facilia, Sweden
Nicholas Beresford, NERC, UK
Hanne Breivik, NRPA, Norway
Justin Brown, NRPA, Norway
David Cancio, CEIMAT, Spain
David Copplestone, EA, England and Wales
Jacqueline Garnier-Laplace, IRSN, France
Turid Hertel-Aas, UMB, Norway
Stephen Jones, Westlakes, UK
Carl-Magnus Larsson, SSI, Sweden
Patrick Momal, IRSN, France
Deborah Oughton, UMB, Norway
Brit Salbu, UMB, Norway
Per Strand NRPA, Norway
Irene Zinger, SSI, Sweden

Facilitators
Matthias Kaiser, NENT
Ellen-Marie Forsberg, NENT
William Fagerheim, NENT

Preliminary Program

TUESDAY 27th

12.00 Lunch

14.00-17.00 Demonstration Session on ERICA "tools"

Optional session giving EUG members the opportunity to have hands-on exploration of the ERICA Assessment Tool and FREDERICA database (ERICA members will be available to advise). The FREDERICA database is already available online at www.erica-project.org. The testable version of the prototype of the Assessment Tool will be available to all online from the end of June until the end of September. The web-address will be made available in Stavern and posted on the ERICA website.

19.00 – 21.00 Buffet Reception

WEDNESDAY 28th

09.00 Welcome and introduction:

- Welcome	*Per Strand, NRPA*
- The road to the ERICA Approach	*Carl-Magnus Larsson, SSI*
- Earlier EUG events	*Deborah Oughton, UMB*
- About the process for this meeting	*Matthias Kaiser, NENT*

SESSION I: Reference Organisms
Chair: Jill Sutcliff, Co-Chair: Irene Zinger

10.00	Introduction on reference organisms Francois Bregniac, IUR (to be confirmed)	
10.20	Breakout Group Discussion	w/ coffee
12.00	Plenary presentation of group work	*Facilitator: Matthias Kaiser*

12.30/13.00 Lunch

SESSION II: Dose-Effect Evaluation
Chair: Nava Garisto, Co-chair: Brit Salbu

14.30	RBE and Weighting Factors: Scientific Background and Use in Radiological Protection	*Christian Streffer, ICRP/Uni. of Essen*
	The FREDERICA Database	*David Copplestone, Env. Agency, UK*
15.10	Breakout Group Discussions	
16.40	Coffee	
17.00	Plenary presentation of group work	*Facilitator: Matthias Kaiser*
17.30	End of day	

18.30 Boat trip w/dinner

THURSDAY 29th

09.00 The Oslo Consensus statement *Deborah Oughton*

SESSION III: Assessment
Chair: Mikael Balanov, Co-Chair: Brenda Howard

09.20	The ERICA Assessment Tool – Realism and Conservatism	*Justin Brown, NRPA*
	Canadian Experience	*Steve Mihok, CNS (to be confirmed)*
10.00	Breakout Group Discussion	w/ coffee
11.30	Plenary presentation of group work	*Facilitator: Matthias Kaiser*
12.00/12.30	Lunch	

SESSION IV: Management
Chair: Tatiana Sasykina, Co-Chair: Per Strand

13.30	Management of Chemicals	To be announced
	Title to be announced	*Marriane Calvez, CEA*
14.10	Breakout Group Discussion	
15.40	Plenary presentation of group work	*Facilitator: Matthias Kaiser*
16.10	End of day	
17.00-late	Drafting committee convenes	

FRIDAY 30th

08.30	Draft consensus statement available for all

SESSION V: Seminar Statement ***Chair: Matthias Kaiser***

09.15	Presentation of consensus statement	
09.30	Comments from ERICA Consortium on draft	*Carl-Magnus Larsson*
09.45	Plenary discussion on draft	
11.00	Coffee	
11.30	Plenary discussions continued	
12.30	Final reflections and feedback	
13.00	Lunch	

Appendix 2: Discussion Groups

ALPHA - α	**BETA - β**	**GAMMA - γ**
Matthias Kaiser - f	Ellen-Marie Forsberg - f	William Fagerheim -f
Ernest Antonio **Francois Brechignac - ch** Andrew Farmer Nava Garisto Ivica Prlic Carol Robinson Tatiana Sazykina Boris Alfonso **David Copplestone - s** Turid Hertel-Aas Carl-Magnus Larsson Patrick Momal Per Strand	Marie-Claire Cantone Patrick Devin Masahiro Doi Stanislav Geras'kin Sanja Mikovic-Kraus Ian Robertson **Jill Sutcliffe - ch** Tamara Yankovitch **Nick Beresford - s** Hanne Breivik Jacqueline Garnier-Laplace Brit Salbu Irene Zinger	Mikhail Balonov Marianne Calvez Simon Carroll Alexander Golubev **John Holmes - ch** Steve Mihok Christian Streffer **Christine Willrodt - s** Justin Brown David Cancio Stephen Jones Brenda Howard Deborah Oughton

f- facilitator; ch – chair; s – secretary

Appendix 3: Questionnaire Answers prior to the Seminar

A questionnaire was distributed prior to the Seminar together with background material. A total of 25 persons (EUG members and ERICA Consortium) answered the following 16 questions, and results are presented below:

To what extent do you agree/disagree with the following discussion statements

The full statements and background material can be found in the accompanying material.
Please note that the questionnaire is only intended as an initial stimulus to the group discussions

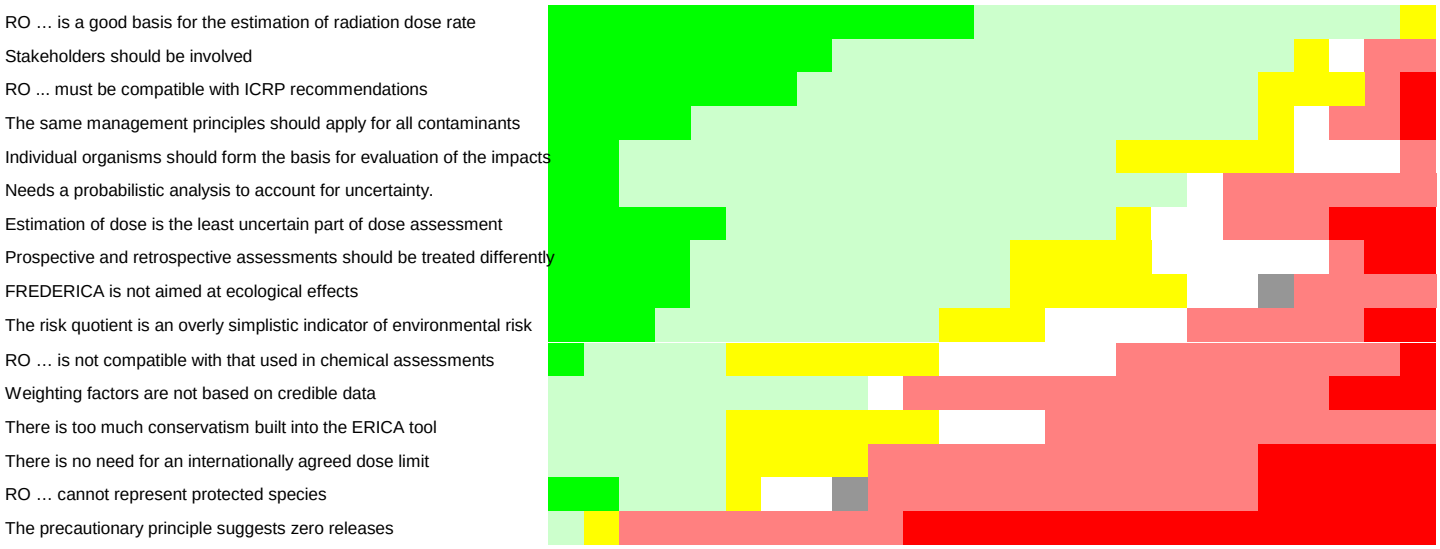
Green	**Strongly agree**	X						
Light green	**Agree**		X					
Orange	**Indifferent**			X				
Light red	**Disagree**				X			
Red	**Strongly disagree**					X		
White	**Blank**						X	
Grey	**I do not want to answer**							X

Please tick the corresponding color

¤

The ERICA approach to Reference Organisms							
... must be compatible ICRP recommendations							
… cannot represent protected species							
… is a good basis for the estimation of radiation dose rate							
… is not compatible with that used in chemical assessments							
Dose/effect evaluation							
Weighting factors are not based on credible data							
Estimation of dose is the least uncertain part of dose assessment							
FREDERICA is not aimed at ecological effects							
Individual organisms should form the basis for evaluation of the impacts							
The proposed assessment tool?							
There is too much conservatism built into the ERICA tool							
Prospective and retrospective assessments should be treated differently							
Need a probabilistic analysis to account for uncertainty.							
The risk quotient is an overly simplistic indicator of environmental risk							
Management of protection of the environment							
The same management principles should apply for all contaminants							
Stakeholders should be involved							
There is no need for an internationnaly agreed dose limit							
The precautionary principle suggests zero releases							

The following shows sorted answers:



Prior to the seminar, the two statements attracting the greatest consensus were that:

- there is strong agreement that the ERICA approach to Reference Organisms "is a good basis for the estimation of radiation dose rate";
- there is strong disagreement that the precautionary principle suggests zero releases.

Three other statements carry a relatively strong degree of agreement:

- "Stakeholders should be involved";
- "The ERICA approach to Reference Organisms must be compatible with ICRP recommendations";
- "The same management principles should apply for all contaminants".

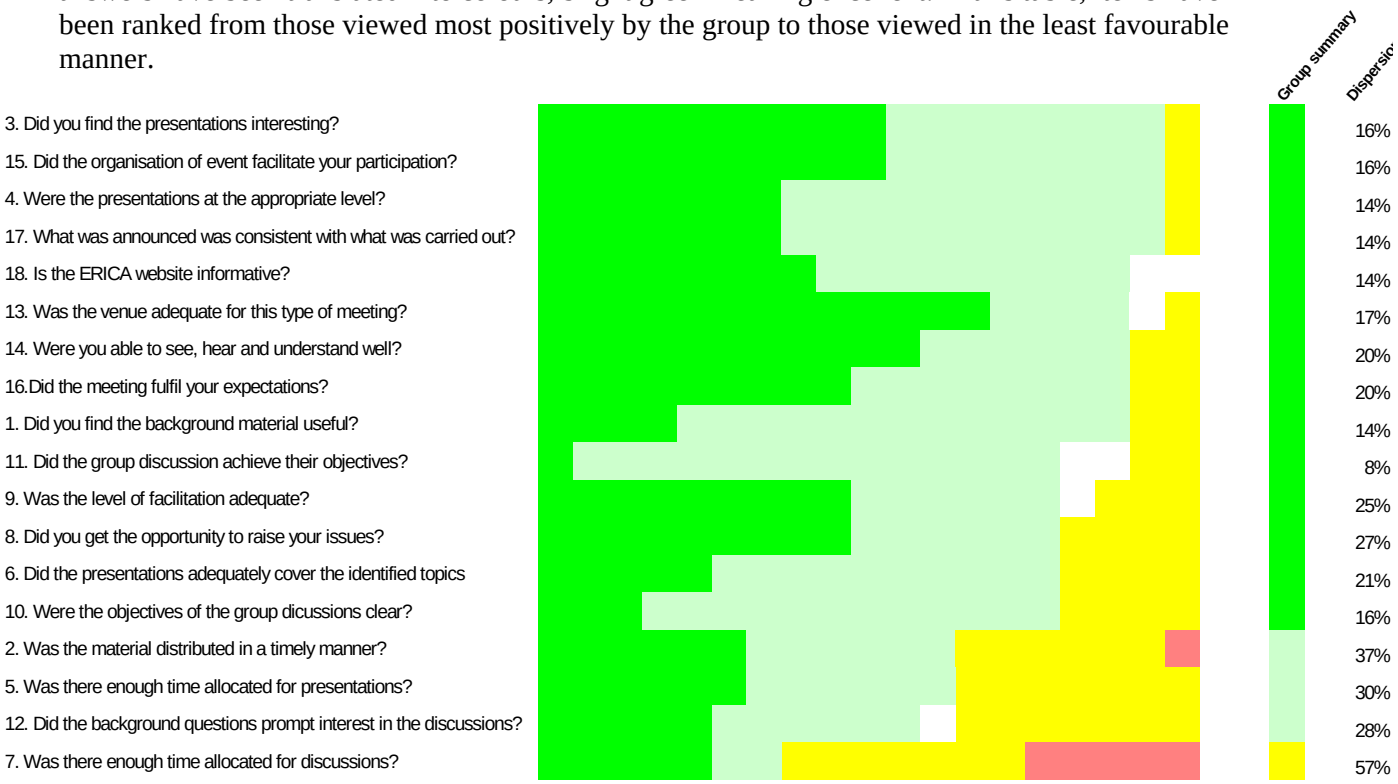
For all other statements, there are mixed opinions within the group. Prior to the seminar, the most controversial statements were:

- "Estimation of dose is the least uncertain part of dose assessment";
- "The ERICA approach to Reference Organisms cannot represent protected species"
- "The risk quotient is an overly simplistic indicator of environmental risk".

Appendix 4: Results from Evaluation Questionnaire

As usual, a feedback questionnaire was distributed at the end of the event. Responders were asked to rank the following items from 1 (poor-red) to 5 (excellent-green).

19 persons answered the questionnaire. The results are summarised in the following table where answers have been translated into colours, bright green meaning excellent. In this table, items have been ranked from those viewed most positively by the group to those viewed in the least favourable manner.



Globally, there are very few “red cards”: no bright reds and only six light red answers. Of the 18 items, 14 appear as excellent at the group level.

One item obviously stands out, question *7. Was there enough time allocated for discussions?* Given the globally polite character of the answers, the above table suggests that the answer to this question is: no. Perhaps the participants would have preferred to spend more time on a shorter list of items and/or on items more close to their concerns and formulated in clearer language. One way to improve this aspect could be to arrange pre-seminar consultations on the items.

Globally however, the answers show that the participants were quite happy with the event – an appreciation they largely expressed orally on site.