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Scientific Uncertainties: Transcript from the EUG Workshop

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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.



Erica tetralix L.

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Executive Summary

The workshop on Scientific Uncertainties was held in Ljubljana, Slovenia from 27th-28th March 2006. This was the fifth EUG event to take place during the ERICA project, and was attended by 16 EUG members, three invited speakers and 12 ERICA participants.

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

The workshop was divided into three sessions:

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

In addition to presentations by ERICA participants, invited keynote speakers introduced sessions. In Session 1, Jeroen van der Sluijs (Utrecht University, Netherlands) gave an introduction to the many dimensions of uncertainty associated with risk assessments of complex environmental problems, arguing that Knowledge Quality Assessment is essential to achieve a better awareness of the limits of science in policy debates. Philip Day (University of Manchester, UK) provided an overview of work carried out by the UK Committee Examining Radiation Risks from Internal Emitters (CERRIE). Mark Crane (Watts and Crane, UK) gave a general introduction to both Session 2 and 3, presenting an overview of uncertainties in Ecological Risk Assessment, together with examples from pesticide management. Finally, Eric Wright focused on the biological basis of radiobiological uncertainty, discussing the sources of biological variability in the response of cells, tissues and individual organisms to exposures of ionising radiation, and proposing that a better understanding of the underlying mechanisms would help inform risk assessment.

The Uncertainty workshop stimulated a lot of discussions and views. Preferences by EUG members regarding what to include in the ERICA tool related to uncertainties are recorded here. The ERICA Consortium will review suggestions and incorporate, as and if possible, some of the suggestions. A selection of comments is presented below

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

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





- There is a distinction to be made in the ERICA tool as to its usage: i.e. as a conceptual tool and as a computational tool. ERICA should address not only data issues (i.e. parameters and input data) but also the uncertainties inherent in the ERICA tool (i.e. model assumptions).
- ERICA should develop a framework or guide for uncertainty analysis: consider adapting the uncertainty matrix presented by Jeroen van der Sluijs.

The Tiered Approach

- Problem formulation and stakeholder involvement also need to consider uncertainties. For example, the definition of the assessment context and object of protection has important implications for the way uncertainties are addressed.
- Make the difference between conservatism/pessimism, simplification and realism clearer. Realism increases from Tier 1 to Tier 3; the high degree of conservatism in Tier 1 means that uncertainty is not so relevant.
- Provide clarification on how to handle the basic uncertainties due to temporal change (in the ecosystems or in some compartments) during the period assessed, and due to locality.
- Consider revision of Tier 2 to make the distinction from Tier 1 more obvious. For example, include sensitivity analysis, refined dose estimation and organism specific screening values.

Screening Values

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

Uncertainty in dose estimation and effects analysis

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





Management and Precautionary Principle

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





Table of contents

Executive Summary	4
1 Introduction	9
1.1 Meeting Objectives and Procedures.....	9
2 Categorisation of Uncertainties	10
2.1 Keynote Lectures	10
2.1.1 Knowledge Quality Assessment in the Science Policy Interface	10
2.1.2 Uncertainty in Assessment of Human Radiation Dose from Internal Emitters: Problems of Extension to Non-Human Organisms.....	13
2.1.3 Options for dealing with data-gaps and uncertainties: the ERICA Uncertainty Spreadsheet.....	16
2.2 Breakout Group Discussions	16
2.2.1 Group 1: Source Characterisation and Ecosystem Analysis.....	16
2.2.2 Group 2: Environmental Transfer	17
2.2.3 Group 3: Effects analysis, interpretation and evaluation.....	18
3 Environmental Transfer and Dose Calculation: The ERICA Assessment Tool	19
3.1 Keynote Lectures	19
3.1.1 Uncertainty in ecological risk assessment for pesticides.....	19
3.1.2 The ERICA Tiered Approach and Risk Assessment Tool	22
3.2 Breakout Group Discussions	24
3.2.1 Group 1: Environmental Transfer	24
3.2.2 Group 2: Uncertainty in Dose Estimation	25
3.2.3 Group 3: The Assessment Tool Flowchart	27
4 Uncertainties in Dose-Effect Evaluation: Risk Characterisation	28
4.1 Keynote Lectures	28
4.1.1 The Biological Basis of Radiobiological Uncertainty	28
4.1.2 Derivation of predicted no-effect dose rate values for ecosystems exposed to radioactive substances – associated uncertainties.....	30
<i>Jacqueline Garnier-Laplace (IRSN, France)</i>	30
4.2 Group Discussions	33
4.2.1 Group 1 – The Biological Basis of Uncertainty	33
4.2.2 Group 2: Effects analysis in the tiered approach	35
4.2.3 Group 3: Precautionary Principle	36
5 Recommendations for ERICA	38





6 Reference List..... 41

Appendix 1: List of Participants 43

Appendix 2: Discussion Groups..... 44

Appendix 3: Results from Feedback Questionnaire 46





1 Introduction

The workshop on Scientific Uncertainties was held in Ljubljana, Slovenia from 27th-28th March 2006. The meeting was hosted and organised by the Norwegian University of Life Sciences and the Norwegian Radiation Protection Authority, with local support from Branko Kontic at the Josef Stefan Institute. This was the fifth EUG event to take place during the ERICA project, and was attended by 16 EUG members, three invited speakers and 12 ERICA participants (see Appendix 1).

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

Feedback questionnaires were distributed, as during each EUG event, and responses summarised in Appendix 4. Responses indicate that this thematic EUG event has been the most positive by far.

This deliverable provides a brief summary of keynote presentations and transcripts of group discussion feedback. Additional background information and PowerPoint presentations are available to EUG members on the EUG website at www.ERICA-project.org.

1.1 Meeting Objectives and Procedures

The workshop was opened by Deborah Oughton, responsible for EUG co-ordination within the ERICA project, who gave a short introduction to the meeting objectives and plan. Although scientific uncertainty was the focus of the workshop, it was not intended to mean that this is the only uncertainty relevant to risk assessment and management. ERICA appreciated the multi-dimensional nature of uncertainty, and was aware of the need to address uncertainty at all stages of the risk assessment (problem formulation, stakeholder involvement, model parameters and assumptions, etc.). ERICA also recognised that there are limits to which uncertainty can be "tamed", but acknowledged that risk assessors would need to document assumptions and choices transparently.

The workshop was divided into three sessions.

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

It was intended that Session 2 should concentrate on the radionuclide transfer and dose calculation part of the assessment, whilst Session 3 would focus on the uncertainties related to evaluation of the effects of exposures, including the derivation of benchmarks and relevance to the precautionary principle in risk management.

As in all other EUG meetings, a major part of the time was allocated to small group discussions. These breakout discussions were split into parallel sessions with different groups addressing different issues. For the first session participants were allocated to groups, in the following sessions participants were able to choose which group they would join. Each group had an EUG chair and rapporteur, and an ERICA secretary.





2 Categorisation of Uncertainties

2.1 Keynote Lectures

Two invited speakers presented keynote lectures as generic background to uncertainties and risk assessment. Jeroen van der Sluijs gave an introduction to the many dimensions of uncertainty associated with risk assessments of complex environmental problems, arguing that Knowledge Quality Assessment is essential to achieve a better awareness of the limits of science in policy debates (see van der Sluijs, in press). Philip Day provided an overview of work carried out by the UK Committee Examining Radiation Risks from Internal Emitters (CERRIE). While the CERRIE remit concerned the assessment of human radiation dose, most of the analysis of uncertainty in dose estimation is relevant non-human organisms. This was followed by a brief introduction to the ERICA Uncertainty Spreadsheet by Carol Robinson, which was sent out as background material to meeting participants.

2.1.1 Knowledge Quality Assessment in the Science Policy Interface

Jeroen van der Sluijs (Utrecht University, Netherlands)

Funtowicz and Ravetz (1993) describe complex environmental risks as a *post-normal* class of problems, epitomised by a number of typical characteristics. For example, political decisions need to be made before conclusive evidence is available, the potential impacts of “wrong” decisions can be high, and there is often dispute over the values that guide the decision making process. The knowledge bases are characterised by large (partly irreducible, largely unquantifiable) uncertainties, multi-causality, knowledge gaps and imperfect understanding. Assessments are dominated by models, scenarios, assumptions and extrapolations, and unforeseen complexities often make it the case that more research will not result in less uncertainty. Finally, there are a number of hidden value loadings residing in problem frames, the indicators chosen and the assumptions made (van der Sluijs, in press).

It is possible to identify three paradigms that describe approaches to dealing with uncertain risk. The *Deficit View* sees uncertainty as provisional and reducible—as long as ever more complex models can be devised. Standard tools are quantification, Monte Carlo, and Bayesian belief networks. The *Evidence Evaluation View* focuses on comparative evaluation of research results, focusing on robust findings and appealing to scientific consensus building and multi-disciplinary expert panels. The *Complex Systems View* and *Post-normal View* take uncertainty to be intrinsic to complex systems and something that can be a result of knowledge production, acknowledging that not all uncertainties can be quantified. They stress the need to deal openly with the deeper dimensions of uncertainty using, for example, Knowledge Quality Assessment and deliberative regulated management of risk. Dimensions of uncertainty include technical uncertainty (inexactness), methodological uncertainty (unreliability), epistemological uncertainty (ignorance) and societal uncertainty (limited social robustness). Often the perceived uncertainty is lowest in those users or managers of the knowledge bases that are committed to institutional and research programmes, and higher in persons either directly involved in the production of knowledge or alienated from the research programmes (McKenzie, 1990).

Two examples of multidimensional and reflexive approaches to Knowledge Quality Assessment are the checklist approach recently adopted by the Netherlands Environmental Assessment Agency (RIVM/MNP), and the NUSAP system. The RIVM/MNP Guidance for Uncertainty Assessment and Communication aims to facilitate systematic reflection on uncertainties throughout the whole scientific assessment process (Van der Sluijs et al., 2003; Petersen et al., 2003; Jansen et al., 2005). It is structured around six foci: problem framing, stakeholder participation, indicator selection, appraisal of the knowledge base, mapping and assessment of relevant uncertainties, and reporting of the uncertainty information (Table 2.1).





Table 2.1 Foci and key issues in Knowledge Quality Assessment (van der Sluijs, in press).

Foci and key issues in knowledge quality assessment (ref. 9)

Foci	Key issues
Problem framing	Other problem views; interwovenness with other problems; system boundaries; role of results in policy process; relation to previous assessments
Involvement of stakeholders	Identifying stakeholders; their views and roles; controversies; mode of involvement
Selection of indicators	Adequate backing for selection; alternative indicators; support for selection in science, society, and politics
Appraisal of knowledge base	Quality required; bottlenecks in available knowledge and methods; impact of bottlenecks on quality of results
Mapping and assessing relevant uncertainties	Identification and prioritisation of key uncertainties; choice of methods to assess these; assessing robustness of conclusions
Reporting uncertainty information	Context of reporting; robustness and clarity of main messages; policy implications of uncertainty; balanced and consistent representation in progressive disclosure of uncertainty information; traceability and adequate backing

With respect to the appraisal of the knowledge base, the assessment needs to consider the adequacy of the available knowledge, its strong and weak points and which parts are contested (i.e, subject to scientific and societal controversies). Here, the NUSAP system proposed by Funtowicz and Ravetz (1990), can aid in producing an analysis and diagnosis of uncertainty. Briefly, NUSAP is a notational system that qualifies quantities using the five qualifiers of Numerical, Unit, Spread, Assessment and Pedigree. The Pedigree Analysis is particularly applicable to knowledge base appraisal, wherein the strength of the number is evaluated by looking at the background history by which the number was produced, and the scientific status of the number (Table 2.2).

Mapping and assessment of relevant uncertainties needs to highlight uncertainties in typology and set priorities for uncertainty assessment. Uncertainty can be classified along the following dimensions (Walker et al., 2003): its *location* (where it occurs), its *level* (whether it can best be classified as statistical uncertainty, scenario uncertainty or recognised ignorance) and its *nature* (knowledge related uncertainty or inherent variability). In addition, the typology includes dimensions on the *quantification of knowledge base* (what are weak and strong parts in the assessment) and *value-ladenness of choices* (what biases may shape the instrument). The typology is presented as a matrix (Table 2.3), and can be linked to available uncertainty assessment tools such as sensitivity analysis, scenario assessment etc. (van der Sluijs, in press).





Table 2.2. Pedigree Matrix for Evaluating Models (Refsgaard et al, 2006).

Score	Supporting empirical evidence		Theoretical understanding	Representation of understood underlying mechanisms	Plausibility	Colleague consensus
	Proxy	Quality and quantity				
4	Exact measures of the modelled quantities	Controlled experiments and large sample direct measurements	Well established theory	Model equations reflect high mechanistic process detail	Highly plausible	All but cranks
3	Good fits or measures of the modelled quantities	Historical/field data uncontrolled experiments small sample direct measurements	Accepted theory with partial nature (in view of the phenomenon it describes)	Model equations reflect acceptable mechanistic process detail	Reasonably plausible	All but rebels
2	Well correlated but not measuring the same thing	Modelled/derived data Indirect measurements	Accepted theory with partial nature and limited consensus on reliability	Aggregated parameterized meta model	Somewhat plausible	Competing schools
1	Weak correlation but commonalities in measure	Educated guesses indirect approx. rule of thumb estimate	Preliminary theory	Grey box model	Not very plausible	Embrionic field
0	Not correlated and not clearly related	Crude speculation	Crude speculation	Black box model	Not at all plausible	No opinion

Table 2.3. Uncertainty matrix (van der Sluijs, 2006).

UNCERTAINTY MATRIX		Level of uncertainty <i>(from determinism, through probability and possibility, to ignorance)</i>			Nature of uncertainty		Qualification of knowledge base (backing)			Value-ladenness of choices		
		Statistical uncertainty (range+chance)	Scenario uncertainty (range as 'what-if' option)	Recognized ignorance	Knowledge-related uncertainty	Variability-related uncertainty	Weak -	Fair 0	Strong +	Small -	Medium 0	Large +
Location ↓												
Context	Ecological, technological, economic, social and political representation											
Expert judgement	Narratives, storylines; advices											
Model	Model structure	Relations										
	Technical model	Software & hardware implementation										
	Model parameters											
	Model inputs	Input data; driving forces; input scenarios										
Data (in general sense)	Measurements; monitoring data; survey data											
Outputs	Indicators; statements											





In conclusion, complex environmental problems have characteristics that require an approach in which uncertainty assumptions and value loadings are subject to explicit and systematic analysis and communication. Knowledge Quality Assessment can promote a better awareness of the limits of science in relation to the task of knowledge producers to provide a scientific basis for policy debate. Approaches such as diagnostic uncertainty checklists and NUSAP can structure the tasks of uncertainty management, force a deliberative choice on how uncertainty and risk can be handled, promote reflection and help avoid the pitfalls and misunderstanding of risks.

2.1.2 Uncertainty in Assessment of Human Radiation Dose from Internal Emitters: Problems of Extension to Non-Human Organisms

Philip Day (University of Manchester, UK)

The UK Committee Examining Radiation Risks from Internal Emitters (CERRIE) was a government appointed committee given the remit “to consider the present risk models for radiation and health that apply to exposure to radiation from internal radionuclides in the light of recent studies and any further research that might be needed”. The Committee's report was published in October 2004, and is freely available (together with supporting documents and references) at www.cerrie.org. With respect to Uncertainty, the principle conclusions of the report were as follows: 1) The uncertainty of dose estimates is much greater than generally recognised, and whenever possible dose estimates should include specific reference to uncertainty; 2) Traditional dosimetry is unable to account fundamentally for the varying biological effects of certain radiations (i.e., alpha, low energy beta, Auger), and the use of radiation weighting factors is a source of uncertainty; 3) Microdosimetry, whilst giving more fundamental insight, is not yet sufficiently advanced to replace RBE methodology, but should inform conclusions and may reduce uncertainty; and 4) Newly discovered effects of radiation (namely genomic instability; bystander effects; minisatellite mutations) are real biological events that need further research and which undoubtedly create uncertainty in the results of traditional dosimetry.

While the CERRIE report focuses on *human* dose assessment, most of the analysis of uncertainty is relevant to the consideration of the biological effects of radiation doses to organisms other than humans. The standard dosimetry model for human dose assessment consists of four stages in a sequential calculation: *Environment, Physiology, Dosimetry* and *Risk* (Figure 2.4).

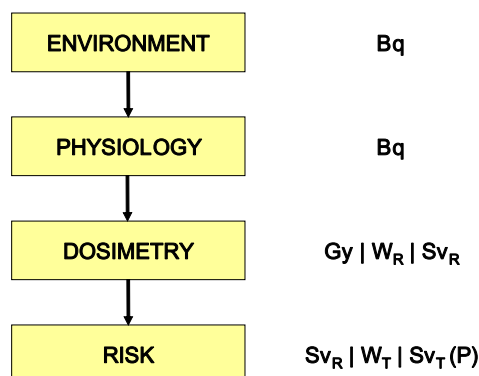


Figure 2.4. Standard dosimetry model for internal emitters and humans





Environment – pathways leading to exposure. Assessment of radionuclide inputs, environmental concentrations, intake by ingestion, inhalation or uptake by direct absorption. Radionuclides quantified by radioactivity (Bq), and types and energies of radiations, i.e. by definable, physical units. Uncertainties occur in input data and in the application of environmental models.

Physiology – uptake and internal distribution. Assessment of radionuclide uptake (following intake by inhalation or ingestion), and transfer to tissues using physiological and biokinetic models. Radionuclide content still quantified in acceptable units (Bq), but major uncertainties arise from the use of biological models, which are often poorly defined and/or parameterised.

Dosimetry – calculation of absorbed radiation dose. Calculation of absorbed dose in tissues, as energy deposition per unit mass (i.e. a definable physical unit, the gray, Gy). There is very little uncertainty in this step, but subsequent calculation of radiation-weighted dose for each radionuclide within each tissue introduces *radiation weighting factors* to calculate the so-called *equivalent dose*, in sieverts (Sv_R). Summation of radiation-weighted doses in each tissue, and the addition of any external dose, gives the equivalent dose for the tissue. ICRP radiation weighting factors are subjective judgements based on RBEs derived from experiments, usually on animals and for a variety of end-points, and clearly lead to major and largely unquantifiable uncertainties.

Up to this point, traditional dosimetry can be applied to non-human organisms, but presumably with at least as much uncertainty as for the human model.

Risk - The next step is applicable to humans only, and involves the use of specific risk factors for each tissue (namely *tissue weighting factors*, W_T , to derive *effective dose* for each tissue (Sv_T). Summation of Sv_T over all tissues gives the whole body *effective dose*. It must be emphasised that the tissue-weighted sievert is non-definable as a physical unit, as it has involved the introduction of subjective risk factors for the onset of cancer and other detriments. The use of tissue-weighting factors in organisms other than humans is not envisaged, nor indeed is it clear how it could be practicable.

The application of so-called risk factors to estimate the risk of contracting cancer (or other detriment) from effective dose is the second half of a circular argument, as the tissue weighting factors, on which effective dose estimates are founded, are based on the self-same cancer risk factors. Effective dose should, therefore, not be regarded as in any sense a scientific quantity, but as a convenient single-ended quantity of use to regulators in the control of nuclear operations and environmental discharges.

Uncertainties at each step of the calculation lead to a combined uncertainty in the overall estimate of risk.¹ The quality of the data and model parameters lead to different degrees of uncertainty in dose calculations for different radionuclides (Figure 2.5). This type of assessment assumes that uncertainty can be quantified and expressed as an error, and that the quantity has a central value within a definable range.

Data or Numerical Uncertainty arises from uncertainties in the values of physical quantities used in calculations, most obviously in the data for input to models, but also in the parameters used within the models themselves. Examples include that the source term may be variable or not known precisely, or that the input data for a given segment of calculation is generally output of previous segment, and thus subject to accumulated error. Error itself may be random or biased. Random errors may be estimated and treated statistically. Bias is often generated by use of subjective judgements, e.g. deliberate “pessimism”, “conservative estimation”, “caution”, etc., introduced with, no doubt, the best of intentions but scientifically, the worst of consequences (i.e. subjective judgements introduce confusion, obfuscation and the possibility of double counting). Estimates of data values should be the

¹ In human dosimetry, the effective dose is only to be used for evaluation of *prospective* risk assessment, weighting factors apply only to cancer risk and have no uncertainty attached (ICRP, 2004).





best values available and a “precautionary” approach to data estimation, however well meaning, is not appropriate. (Any “precautionary” bias should be applied - by regulators - to the conclusions of the dose calculation, in the light of estimated uncertainties, and not to the scientific assessment of dose.)

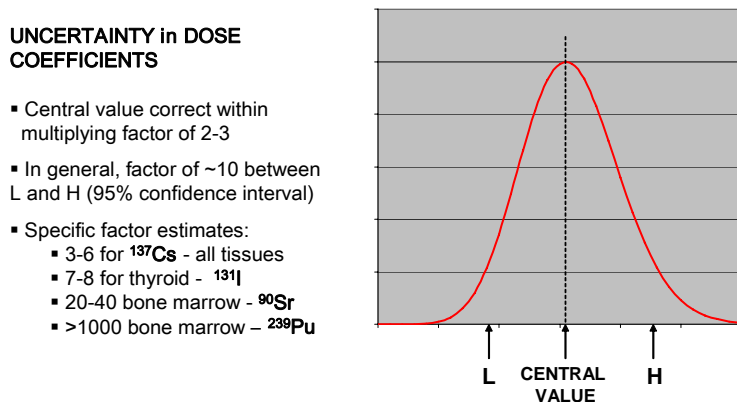


Figure 2.5. CERRIE conclusions on uncertainty in dose coefficients (CERRIE, 2004)

Mechanistic Uncertainties arise largely from the use of numerical/mathematical models to represent physical systems, both environmental and biological. Models are imperfect representations of real systems, and problems arise because the model structure may be inadequate, there may be a mismatch between model and reality, or the model may be over-complex in relation to knowledge. Furthermore, a model's parameters are an integral part of a mathematical model. A model may produce uncertainty in its predictions from flaws in its structure, including parameter values, or from inadequacies in its concept. Any model must be regarded as a theoretical representation of a real system, and has value only as a predictive tool. Consequently, a model can only be tested by attempts to disprove it – it can only be validated for circumstances in which it has not been falsified, and can never be proved correct outside such limits. Most importantly, as this is a common pitfall, since a model *cannot be falsified by testing it against the same data from it was initially created*, any such supposed test is not a test and must be discounted.

Conceptual Uncertainties arise if the overall structure or components of the standard model itself come into question. Conceptually inadequate models may apparently work quite well within limited ranges of data values or circumstances, but not necessarily outside this range. Sub-components (i.e. individual models) may be linked incorrectly, important interactions or pathways may not have been included, or the basic concepts may be inadequate (or just plain wrong). For example, the basis for radiological protection in humans is the use of absorbed energy in bulk tissue (radiation dose) as the parameter of harm. This concept may well be too simplistic, as biological effects take place at cellular level or below. Again, “Harm” from radiation of different types is made comparable through use of RBE and radiation weighting factors: this empirical concept has no fundamental basis, and may well have outlived its usefulness, even for human radiological protection.

In summary, uncertainty in dose assessment will arise from variability in environmental input data, models that are faulty in structure or inadequately parameterised, and flawed concepts on which the models are built. Uncertainties can only be estimated statistically if enough quantitative information on variability is available - in other cases one has to rely on informed guesswork. With relation to regulatory measures, dose calculations, or procedures for dose calculations, should be made on the basis of the best science and should make a full and understandable statement of the estimated



uncertainty. Any recourse to a precautionary principle should be made at the regulatory not at the scientific level, and should take account of the stated uncertainties.

2.1.3 Options for dealing with data-gaps and uncertainties: the ERICA Uncertainty Spreadsheet

Carol Robinson (on behalf of Environment Agency, England and Wales)

The scope of the spreadsheet is related to the uncertainties and data gaps inherent in the ERICA assessment tool, and the primary focus is on the application of the ERICA tool by a third-party (i.e. not development within Consortium). For the sake of consistency, the definition of uncertainties and data gaps, given in ERICA Deliverable 4b (cf. p. 49) is used:

- *Uncertainty (Type I uncertainty)* – lack of scientific knowledge about specific factors, parameters or models (that can partly be reduced through further study). Includes parameter, model and scenario uncertainties. The uncertain belief about the likelihood of the variable (random variable) having different values represented by probability distribution.
- *Variability (Type II uncertainty)* – natural variability arising from true heterogeneity that is not usually reduced through further study (also Type I uncertainty about variability – where insufficiently sampled for example). Variability is characterised by frequency distribution (discrete random variable) or through a probability density function.

At present the spreadsheet represents a first attempt to collate information on sources of uncertainties and data-gaps that might affect application of the ERICA assessment tool, and the strengths and weaknesses of possible options for dealing with these uncertainties. The focus is primarily on uncertainty sources within the assessment tool (i.e., input data and model parameters), and has been divided into different stages of assessment, namely Source Characterisation, Ecosystem Analysis, Exposure Analysis, Environmental Transfer, Concentration or Dose Assessment, Effects Analysis and Interpretation and Evaluation. Since the Tiered Approach has different degrees of conservatism and realism at the different tiers, different options have been identified for different tiers. The spreadsheet is work in progress and the present format was chosen for simplicity in drafting purposes, and is not necessarily the final output.

2.2 Breakout Group Discussions

The groups were asked to consider the generic challenges raised by uncertainty in risk assessment and management and give some general feedback on the ERICA spreadsheet (i.e., whether any issues were missing and whether additional categories of uncertainties were needed). Groups were divided to focus on different sections of the spreadsheet: Group 1 — Source Characterisation and Ecosystem Analysis; Group 2 — Environmental Transfer; Group 3 — Effect Analysis and Interpretation and Evaluation. However, most of the discussion reflected overarching issues.

2.2.1 Group 1: Source Characterisation and Ecosystem Analysis

The group started by addressing the generic challenges raised by uncertainty in risk assessment, and appreciated the way that the introduction talks gave a chance to step back and think about the bigger questions associated with uncertainty. A number of points were noted:

- *Pessimism within the tiered approach and concerns that too much conservatism will lead to an inbuilt bias in the assessment.* It was recognised that the early tiers are pessimistic; particularly Tier 1 which is intended to be pessimistic, whilst some of the pessimism would be taken out when moving to Tier 2. There was a concern that there would be an unnecessary aggregation of pessimism. For example whether to use peak discharges for assessment or





some high average. There were also concerns about how decisions would be justified, and a feeling that choices needed to be made more transparent.

- *Separation of assessment and decision-making.* It was proposed that the assessment tool represented the scientific part of the process, and that scientists needed to provide the best information for decision-making, and that should include uncertainties. It was noted that chemical risk assessments include uncertainties as part of the assessment. However, the question was raised as to whether extrapolation factors (safety factors) were part of risk assessment or risk management. It was pointed out the ERICA approach includes both assessment and management.
- *Qualitative and quantitative uncertainties.* The group discussed the merits in expressing uncertainties in qualitative manner, so as to avoid giving a false impression of accuracy. For example if the screening value is 100 units, the information that the assessment gives 50 units should be accurate enough for the decision-maker. For the screening exercise the decision-maker would have to decide how good is good enough. This raises a further question on the difference in handling uncertainties in Tiers 2 and 3. It was concluded that there was a need for a framework or guide for uncertainty analysis.
- *Approach to uncertainties depends on protection objectives.* The group tried to identify actual situations where radioactivity had harmed non-human biota. Clear examples are big accidents, such as those at Kyshtym and Chernobyl (and possibly past industrial releases such as from Mayak and Sellafield). However, it was noted that no habitats were known to be destroyed and the need for developing a framework for protection non-human biota from radiation is rather based on the recognised conceptual gap when compared with the protection from other pollutants. It was noted that the required depth and breadth of understanding of uncertainties depends on the situation, e.g. the regulator needs to know what the data gaps are in the assessment and how this will influence the result.

Regarding the spreadsheet, it was suggested that the terms needed more clarification and that there needed to be a better link between the assessment tool, tiered approach illustration and the uncertainty spreadsheet that was distributed. There was a proposal that the classification should include “knowledge gap” (rather than “data gap”) and a distinction between uncertainty (reducible) and variability (which can’t be reduced). Data gaps include two different types; lack of understanding and lack of data (see paper by Calvez et al.). On the other hand it was questioned how complex the spreadsheet should be (already 186 lines). The group suggested that the uncertainty matrix presented by Jeroen van der Sluijs gave a richer picture of the dimensions of uncertainty for decision-makers.

2.2.2 Group 2: Environmental Transfer

The group’s discussion focused on the uncertainty spreadsheet and the information within, together with the way uncertainties are dealt with within the ERICA assessment tool and tiered approach. The main points were:

- The spreadsheet focuses on uncertainty within the method, not of the method. The categorisation needs to be expanded to include other types of uncertainties. DG/U is a false distinction as there is always a data gap, it is the relevance of the data to the problem that is the issue. The assessor needs to know what level of data would be adequate, and when there is sufficient data collection.
- We should not lock in on data issues (i.e., the data available and parameter assumptions), we need to also consider the uncertainty that is inherent in the ERICA tool (e.g. the model and its assumptions). If it does not reflect reality adequately who cares about the adequacy of the data within.





- There was little experience in application of the tool in the group, and it was unclear which procedure had been used to generate the spreadsheet or what its purpose was.
- While building in conservatism/safety factors was recognised to be a legitimate approach this must be transparent. While Tiers 1 and 2 capture uncertainty by a conservative approach, Tier 3 is not free of conservatism, this will still be embedded in the scenarios, although it does allow a more sophisticated uncertainty analysis. There is a need for traceability and transparency in the way the ERICA tool deals with uncertainty. Proposed that Tier 3 would show the degree to which Tier 1 is conservative enough.
- Although Tier 1 can be seen as a way of dealing with uncertainty, it also represents an aggregated approach. It isn't always clear where the uncertainty is. If you stop at Tier 1 you have to show how you have adequately dealt with uncertainty and need to record all assumptions (i.e. why it is safe). Tier 1 is supposed to be simple, however, the inclusion of dispersion models at this tier is complex.
- Reducing conservatism from Tier 1 to Tier 3 – main issue is *simplification* which is not necessarily the same as *conservatism*. The degree of *realism* increases from Tier 1 to 3. Tier 3 tries to be more explicit in where and why uncertainty occurs (e.g. inclusion of SSDs, parametric/probabilistic uncertainties)
- A number of assumptions are made because of uncertainty, but these are not taken account of within the spreadsheet. These assumptions can be addressed with pedigree analysis and sensitivity testing. Within the whole ERICA tool (i.e. all tiers) each value and assumption should be traceable. This will provide information on the degree of conservatism used.
- The spreadsheet is not doing all that is needed to meet the challenges, adaptations and/or additions are needed to the table.

2.2.3 Group 3: Effects analysis, interpretation and evaluation

The group started by discussing generic issues of uncertainty, and the main sources of uncertainty in protection of the environment. Taking as a starting point the large uncertainties in the supposedly simple case of humans, what hope do we have of assessing effects on non-humans if the environment is so complex? But the reality is that, despite these complexities, society does need to make decisions, hence we need a pragmatic approach to environmental risk assessment. The following questions were addressed:

- *What is the object of protection?* What does ERICA mean by “protection of the environment”? It was noted that the protection endpoint usually stems from legislation and this can cover entire ecosystems (e.g., biodiversity), as well as protected species or sites. If the object were global protection then that may be too large for ERICA. The difference between preservation (unwanted interference) and protection was discussed. It would not be possible to protect ecosystems from change, so ecosystem function would be the main goal. It was noted that the output of the model was dose, which was then converted to effects. Thus the biological endpoint for the assessment tool was different to the object of protection, so extrapolation would be needed. The level of uncertainty in this extrapolation would depend on what endpoint one was extrapolating to.
- *How should uncertainties be expressed within the tool?* The group was unanimously in favour that the tool should as a minimum estimate the order of magnitude in uncertainties included. It is important that the users are aware of uncertainties so that they do not rely too heavily on uncertain data. In addition, the tool could list the main sources of uncertainty, and give some background information including what one can do about uncertainties. There is a need to





distinguish between ERICA as a conceptual and a computational tool, and between input data and tool parameters. The distinction between data gap and uncertainty in the spreadsheet was not sufficient to capture the different types of uncertainty. In all cases transparency is of major importance.

- *What are the main sources of uncertainty?* Issues raised included the inherent uncertainty in the Predicted No Effect Dose (PNEC), hormesis or beneficial effects or radiation, effects of low chronic exposure on individuals (let alone whole ecosystems) and general lack of data. Data gaps are impossible to quantify.

3 Environmental Transfer and Dose Calculation: The ERICA Assessment Tool

The session opened with two keynote lectures. The first by Mark Crane (Watts and Crane, UK) was a general introduction to both Session 2 and 3, presenting an overview of uncertainties in Ecological Risk Assessment. This was followed by a presentation summarising the ERICA Tiered Approach and Assessment Tool by David Copplestone (Environment Agency, England and Wales).

3.1 Keynote Lectures

3.1.1 Uncertainty in ecological risk assessment for pesticides

Mark Crane (Watts and Crane, UK)

Pesticides risk assessment is among the best-developed regimes for assessing the risks of chemicals in the environment, because of the inherent toxicity of pesticides and their application directly to the environment. Directive 91/414/EEC requires risk assessment of new and existing pesticides. Comparison of toxicity and pesticide exposure data is generated within a tiered risk assessment (RA) and risk is expressed as a Toxicity Exposure Ratio (TER), which is in essence a back-to-front PEC:PNEC Hazard Quotient. Advancement through RA tiers occurs if there is an insufficient margin of safety between predicted exposure and predicted effects. The margin of safety should be large at lower tiers (e.g., 100) but can be low (e.g. 1 or 2) at higher tiers. Risk mitigation measures (e.g., buffer zones and restrictions in usage) may be part of the authorisation and subsequent risk management of a pesticide.

Areas of uncertainty in pesticide RA include legislation and regulation, stakeholder and public values, problem formulation and conceptual modelling and extrapolation to the natural environment. Directive 91/414/EEC states “...it is necessary, at the time when plant protection products are authorized, to make sure that, when properly applied for the purpose intended, they are sufficiently effective and have no unacceptable effect on plants or plant products, no unacceptable influence on the environment in general, and, in particular, no harmful effect on human or animal health or on groundwater.” But what is unacceptable, and to whom? This is currently decided largely by technocrats in government and business while public and other stakeholder values are not explicitly and formally taken into account (Crane and Giddings 2004). So what do the public and informed stakeholders think about the acceptability of pesticide risks?

A recent study attempted to answer this question by consulting a variety of stakeholders (Crane et al., 2006). Focus groups were used to establish areas of consensus and disagreement on criteria for determining an unacceptable environmental influence. Long-term effects on populations of non-target organisms were deemed unacceptable. For vertebrates it was stated “*Ideally there should be no adverse effects on individuals, including behavioural effects. However, one, or a few, dead or otherwise affected animals may be acceptable, while death of a large group (e.g. a flock) is not, irrespective of any population effects.*” In the case of invertebrates, plants and microbes it was stated





that “Loss of species richness both in- and off-crop compared with what ‘should’ occur at a site is unacceptable. Off-crop organisms should receive greater protection than in-crop organisms. In general, there should be an intolerance of off-field effects on either species richness or abundance of individuals within species. Any secondary poisoning effects are unacceptable.” When, in the same study, the public were asked their opinion on acceptable effects of pesticides in an opinion poll of more than 2000 UK residents, their views were substantially more conservative than those of stakeholders interviewed in focus groups. It is clear that uncertain regulatory drivers and limited understanding of public values lead to uncertain interpretation of what is required by regulators and industry. This, in turn, leads to wasted effort and arbitrary and inconsistent risk management decisions, with potential for over- or under-precaution, lack of trust in the process by stakeholders and the public, and consequent deep public conservatism.

The problem formulation in pesticides risk assessment is also uncertain. Directive 91/414/EEC fails to specify some important factors: What are we trying to protect from pesticides? Where are we trying to protect it? When are we trying to protect it (e.g., over what seasons, what is the allowable return frequency)? How much of it are we trying to protect? Protecting “the environment” from “unacceptable influences” must be operationalised in the problem formulation and conceptual model. A lack of clear problem formulation or conceptual modelling in pesticide RA leads to several uncertainties about the severity, timing and location of potential effects, about the most important sources, pathways and receptors for pesticide exposure, about the balance between environmental costs and agronomic benefits and about the size of assessment (safety, uncertainty) factor required.

Pesticide and other chemicals RA frameworks use a hierarchy of assessment factors depending on quantity and quality of data: 100-1000 for acute single species tests in lower tiers, 10 for chronic single species tests in higher RA tiers, and 1-5 for mesocosm and semi-field tests and for an HC₅ from a species sensitivity distribution. The factors are arbitrary and intended to account for acute-to-chronic, inter-specific and lab to field. If arbitrary assessment factors are used, this leads to uncertainty about what assessment factors are accounting for, (is there double counting, or are items missed?), about what is irreducible natural variability and what is reducible uncertainty, about the most sensitive inputs and about the degree of over- or under-protection.

The Precautionary Principle (PP) can be formulated as ‘*preventative action must be taken when there is reason to believe that harm is likely to be caused, even when there is no conclusive evidence to link cause with effect: if the likely consequences of inaction are high, one should initiate action even if there is scientific uncertainty.*’ The EC wants to apply the PP when scientific evaluation has shown a potential danger and efforts have been made to reduce scientific uncertainty and fill gaps in knowledge that could allow a scientifically-based decision to be made. Measures should be proportional, non-discriminatory, consistent, cognisant of costs and benefits, subject to review and capable of assigning responsibility for producing the scientific evidence necessary for altering conclusions based upon the PP. However, some environmental NGOs argue that the Commission’s approach is just an excuse for delaying a decision and that it weights risks of taking action *now* too heavily. But some of the same critics also argue against the process of RA itself, and in favour of a simple hazard assessment. Probabilistic RA (Figure 3.1) is one approach that may allow precaution to be reduced in a scientifically and socially defensible way, consistent with the PP.

The majority of ecological RAs are deterministic and deliberately precautionary. Application of the PP on the basis of a deterministic RA is therefore likely to lead to conservative results. However, the degree of conservatism is opaque, undefined, uncontrolled and often cumulative and it is difficult to characterise risk accurately with a deterministic RA, except in extreme situations (Crane et al., 2003). In contrast, probabilistic RA (PRA) answers the important question “How likely are the outcomes?” This produces better understanding of risk distributions, allows separation of uncertainty from variability, provides more integrated options for sensitivity analyses and helps to focus further work





more accurately on important uncertain and sensitive parameters. Guidance and tools that forces us to formulate and conceptualise the problem we wish to address are now widely available (e.g. EUFRAM, WEBFRAM and USEPA guidance; Crystal Ball and @Risk software). Second order Monte Carlo is likely to be recommended as the main preferred method by the EU's EUFRAM project on pesticide RA. The objective is to separate variability from uncertainty: Variable parameters are themselves drawn from statistical distributions intended to represent uncertainty about true values. The result is a distribution of distributions.

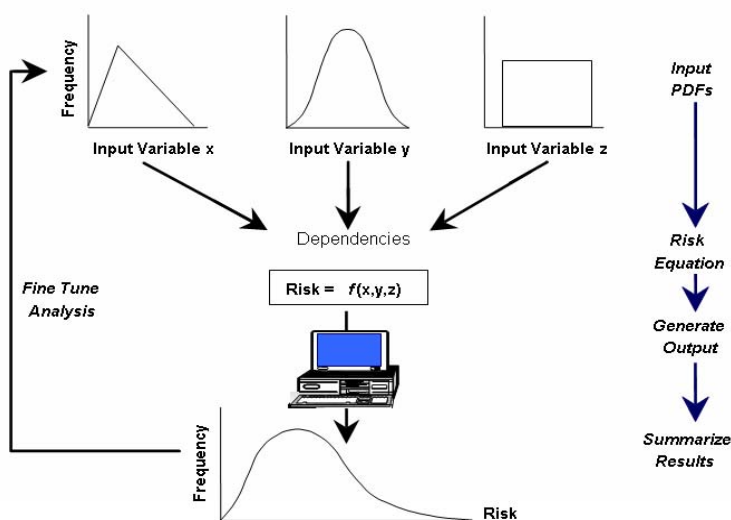


Figure 3.1 Steps involved in probabilistic risk assessment

Although PRA has substantial advantages for expressing uncertainties, important data are sometimes missing, so PRA must still use assumptions, and important (and contentious) assumptions can still remain opaque. Confidence intervals are often very wide and “unknown unknowns” still cannot be accounted for. The interpretation of probability can be difficult (e.g., what does a 20 % chance of an exceedance of the EC₅₀ of 30 % of species in a species sensitivity distribution actually mean for the environment?). Regulators ultimately need to make binary decisions (“pass” or “fail”), and PRA does not easily lend itself to a “bright line” decision-making process.

In conclusion, developers of RA frameworks need truly to understand the social and regulatory context within which their framework will operate. Uncertain wording of regulations and ignorance of public values leads to confused and contentious implementation of risk assessment approaches. Experts representing a range of views can form a consensus despite uncertainty when provided with clear evidence and context. However, a significant proportion of the public is more conservative than the “experts”, and is very unlikely to change their views once they have made their minds up that something is dangerous, and want to base decisions on hazards rather than risks. In addition, it is difficult to formulate and conceptually model a problem accurately unless we know what entities the regulations want to protect in time and space, and to what protection level. Arbitrary assessment factors obscure the causes and influence of variable and uncertain input parameters, and may lead to non-transparent over- or under-protection of the environment. PRA can help to replace arbitrary precaution with more realistic distributions of data, and is consistent with the European Commission’s interpretation of the precautionary principle. It is the best available approach for dealing with and separating uncertainty and variability in ecological RA. But it is not a panacea and its data-hungriness



and difficulty of interpretation is leading to resistance from a substantial number of pesticide regulators and businesses who need to make a “pass/fail” decision.

3.1.2 The ERICA Tiered Approach and Risk Assessment Tool

David Coppelstone (Environment Agency, England and Wales)

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 3.2). 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.

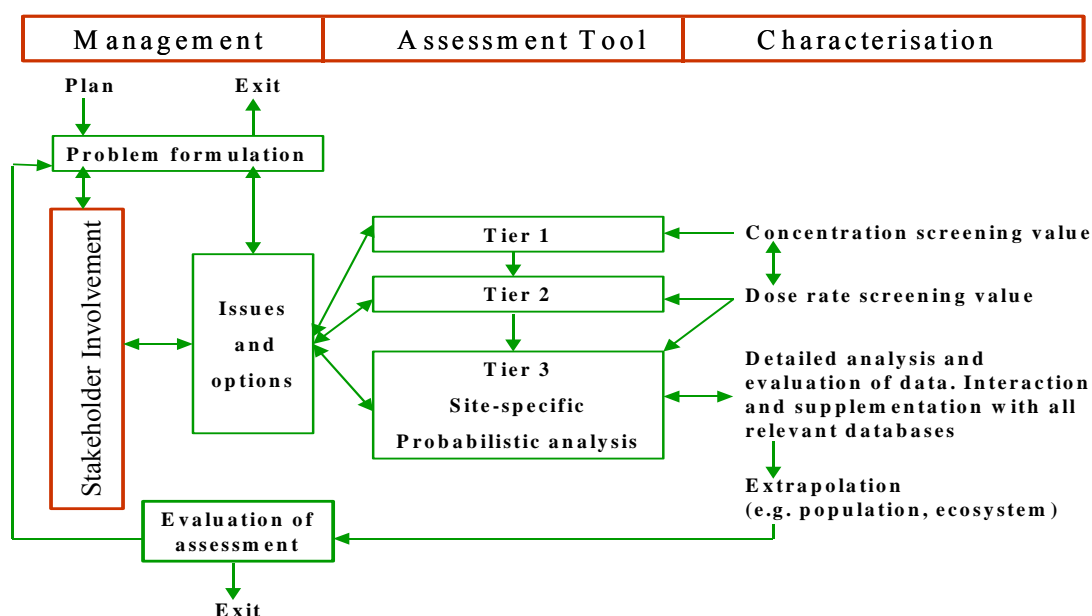


Figure 3.2. Working model of the ERICA Integrated Approach, depicting its three main integrated features: An assessment tool, methodology for risk characterisation and guidance for stakeholder involvement and decision-making (management), April 2006.

While programming of the assessment tool is still in progress (a prototype will be available in mid June), the basic structure of the approach and the processes associated with each tier have been described in detail in ERICA Deliverables 4a and 5 (all available from www.ERICA-project.org), and the overall process illustrated in the draft Assessment Tool Flowchart. Briefly, the various stages of the assessment, the differences between the tiers, data requirements and sources of uncertainty can be summarised as follows:





Problem formulation

- Defines the scope, purpose and endpoints of the assessment;
- Considers what is already known about the site, its historic use and the proposed or operational practice being assessed;
- Considers whether stakeholder engagement is required in the problem formulation to ensure that all aspects are considered;
- Uses a conceptual model to lay out the issues in a clear and transparent manner, including the main uncertainties (scientific, societal, conceptual, etc);
- Defines any source – pathway – receptor linkages present;
- Represents the stage at which the assessor can choose which tier to start, including the option to exit the assessment (e.g., if not necessary because there is no source-pathway-receptor link, or if an alternative approach required), and includes guidance for recording and justifying the decisions made.

Tier 1 (Screening)

- Evaluates the risk using a conservative approach;
- 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 Section 4.1.2 and ERICA D5);
- Has the advantage of identifying which radionuclides present at the site would contribute most to the exposure of the reference organisms. This can then guide decisions of resource allocation for acquisition of additional information if the assessment needs to proceed to the higher tiers;
- 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;
- Considers the involvement, albeit probably limited, of stakeholders at this stage.
- 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;
- Considers the background radiation levels in the area being assessed;
- 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.

3.2 Breakout Group Discussions

Groups were divided to address different sources of uncertainty in the assessment tool and tiered approach. Group 1 were asked to consider Environmental Transfer, Group 2 Dose Estimation, and Group 3 the overall assessment and assessment tool flowchart.

3.2.1 Group 1: Environmental Transfer

The group found the Uncertainty Spreadsheet difficult to review in a discussion meeting. The spreadsheet (and the intended guidance) is not well connected to the ERICA Tool Flowchart. There seems to be too much unstated qualification behind each uncertainty item and the options given for how to deal with it. A more effective way would be to ask the EUG members to provide their specific comments in writing. Note that Calvez et al (available from www.ERICA-project.org) provided specific writing comments on the content of this spreadsheet. After that the discussion turned to more generic issues.

By using the tiered approach the Assessment Tool could be useful at very different complexity levels. The group felt, however, that the argumentation was missing for why the present assessment levels for Tier 2 and Tier 3 were selected. It was thought that the tool was not optimised, or anyway that it was





not seen that an effort had been made to minimise the workload or to evaluate the need for flexibility. For example, there should be a possibility to evaluate sensitivity in Tier 2.

There is a need for a general discussion on how to handle the basic uncertainties due to temporal change (in the ecosystems or in some compartments) during the period assessed, and due to locality (disparity between the areas evaluated/ influenced and the area of population spread). It is not clear how time variation or, for example, contaminated sites are considered within the ERICA approach. It seems that only some years are taken into account and not long term variation.

The group also expressed concern for:

- how the predators were dealt with – not including an ingestion pathway
- the approach to use a 95 % level as a cut off – can it withstand external criticism?
- how the variability is translated into conservatism – you should be able to see the maximum values

Members of the EUG requested that ERICA consider making underlying transfer datasets available, otherwise at Tiers 2 and 3 the user is in effect being asked to repeat the work of the consortium.

3.2.2 Group 2: Uncertainty in Dose Estimation

An overview of the ERICA assessment process informed the group's discussions. In essence the ERICA assessment process follows the steps:

- 1) Development of a description of the exposure scenario;
- 2) Use of environmental transport and uptake models, possibly in conjunction with measurements, to estimate activity concentrations (Bq kg^{-1}) in organisms and their surrounding environmental media;
- 3) Use of dose conversion factors to estimate dose rates (microGy h^{-1}) to reference organisms; and
- 4) Use of the FREDERICA effects database to establish what effects, if any, might be expected at the estimated dose rates based on dose rates and effects observed in effects studies within the database.

Key issues relating to uncertainty in the ERICA method of dose estimation are:

- The comparability of dose rates estimated by the ERICA assessment method, and those measured or assessed in the effects studies within the FREDERICA database.
- The majority of the results in the FREDERICA database relate to external exposure of organisms to X-rays or gamma-rays.

For clarity, the dose quantity calculated by ERICA was explained in the following terms:

- It is the sum of the absorbed dose rates from internally incorporated radionuclides and radionuclides in the surrounding environmental media;
- The dose rate is averaged throughout the whole volume of the organism;
- Organisms are represented as unit density ellipsoids with appropriately specified values for each of the three ellipsoid axes;
- Dose rates are segregated into contributions from: (1) beta particles and electrons less than 10 keV; (2) other beta particles, electrons and gamma ray photons; and (3) alpha particles.



- Default weighting factors of 3 for beta particles and electrons less than 10 keV, and 10 for alpha particles, are advised, but these factors can readily be amended by the assessor if required.

Following this clarification, the discussion turned to uncertainties in dose estimation. The group suggested that the principal uncertainties identified in the estimation of doses 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 methodology.

Discussion then turned to the relationship between doses (as defined) and effects. The principal points noted were:

- 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).

Particular points for consideration in taking ERICA forward are:

- Whether circumstances in which localisation into specific organs (e.g. iodine into mammalian thyroids) might be important, should be ‘flagged’ with some advice on how this should be dealt with;



- Whether this problem of non-uniform distribution might have been ‘disguised’ to some extent by the use of weighting factors – one option suggested was to work on the basis of unweighted doses, but still separate out the three dose components and take specific account of localisation.
- Clarification on the applicability of ERICA to retrospective or prospective assessments. It was noted that in human protection, the ICRP system of dosimetry – including radiation weighting factors – is intended essentially for prospective assessments and the planning of radiation protection. For retrospective assessments of individuals, and epidemiological studies, ICRP endorse the use of data specific to the situation being considered.
- 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.
- Extrapolation from individuals to populations remains problematic and will need to be carefully justified.

3.2.3 Group 3: The Assessment Tool Flowchart

The group was to look at uncertainties throughout the flowchart and flag them. They decided to work systematically through the flowchart. Some uncertainties are generic for the ERICA approach; some are specific to the context of each tier.

- The first uncertainty noted is in the very first step: when defining the assessment context one has to make assumptions for the complexity of the scope.
- The decision on level of stakeholder involvement will influence the outcome of the assessment. ERICA D5 covers derivation of no-effect levels with proposition of benchmark values for screening purpose in Tier 1 and Tier 2 and a method to perform quantitative uncertainty analysis for a given likelihood of effect and a given assessment endpoint in Tier 3.
- The description of pathways or conceptual model needs justification of the choices made, with the underlying assumptions. In a broad sense this is model completeness uncertainty.
- There is an uncertainty in the relationship between available data and complexity of the model.
- In Tier 1 the choices of nuclides, ecosystem, dose rate and concentration will contain both numerical uncertainties and uncertainties in the assumptions made.
- A question was raised on how to record the choices made and the reasoning behind them. In reply, it was noted that there is an underlying assumption that the user has good reason for the choices; therefore there will not be a text box for each screen. There could be one overall text box for this purpose, which could be placed at the end of each tier together with the “record decision” section. The concern here was traceability.
- In Tier 1 it was felt the transport model approach proposed was too advanced at this stage. However, to be able to run the assessment one needs some input. In Tier 1 it is recommended to use default values for all parameters. These parameters of course have some intrinsic numerical uncertainty. There should be a recommendation on how to choose the most conservative outcome.
- Tier 1 has to be able to demonstrate conservatism; therefore uncertainty is not that relevant here. Tier 2 is just adding a few steps to Tier 1.





- It is recommended to use generic information as long as you don't have any special circumstances for your site. However, stakeholders mainly will prefer the most site-specific option available.

4 Uncertainties in Dose-Effect Evaluation: Risk Characterisation

In all ERA, risk characterisation involves some form of extrapolation, either on effects (between endpoints, species, and life stages, or from individual to population) and/or types of exposure (high to low dose, acute to chronic, external to internal, low LET to high LET). Hence extrapolation is a fundamental source of uncertainty in effects analysis, and has consequences for risk characterisation at various levels. The two keynote lectures gave an introduction to two approaches to this subject. The first by Eric Wright focused on the sources of biological variability in the response of cells, tissues and individual organisms to exposures of ionising radiation, proposing that a better understanding of the underlying mechanisms would help inform risk assessment. Jacqueline Garnier-Laplace (IRSN, France) gave a presentation on the derivation of predicted no-effect benchmarks in the ERICA project.

4.1 Keynote Lectures

4.1.1 The Biological Basis of Radiobiological Uncertainty

Eric Wright (University of Dundee, UK)

Evaluation of dose-effect relationships and the prediction of effects of radiation exposure are subject to many sources of uncertainty. These include the validity of the linear extrapolation, the derivation of risks for internal, low level chronic exposures to alpha and beta emitters, assumptions in deriving doses using biokinetic and dosimetric models, and the RBEs used for internal radionuclides. All these sources of uncertainty are confounded by variability in the biological response to radiation exposure. A better understanding of the mechanisms underlying the response to radiation exposure may help explain some of this variability.

Biological responses in irradiated cells include damage repair, cell death, gene mutations, chromosome aberrations and neoplastic transformation. Conventionally, these effects have been attributed to radiation induced DNA damage producing irreversible changes during the processing and enzymatic repair of the damage or during DNA replication. Cellular responses lead to tissue responses and ultimately organism effects. Inter-cellular, inter-tissue and inter-individual differences in responses (biological variability) are an important source of uncertainty in predicting effects, particularly at the organism level.

DNA damage responses are linked to a complex interaction of gene activation and expression, and many factors interact to signal and modulate responses (Kutz and Lees-Miller, 2004). Activation of the p53 response by DNA damage is a key component regulating the biological consequences of exposure to ionising radiation, but it is only one of several transcription factors activated by DNA damage (Jen, 2003; Lane 1998). In normal cells exposed to ionising radiation p53 levels rise through post translation stabilisation and p53 becomes active, turning on the expression of genes such as p21 that induces a cell cycle arrest and Bax that promote apoptosis (Figure 4.1). Cell cycle arrest allows for repair, but ineffective repair increases the potential for pathological effects. Thus, apoptosis can more effectively eliminate unstable and potentially malignant cells. The degree of apoptotic response shows both genetic and tissue specific responses. For example, haemopoietic and intestinal cells show similar genotypic difference, but are mediated by different signalling processes.

Uncertainties in biological responses are further complicated by challenges to the "Nuclear Target Paradigm". Under this paradigm, cell death, chromosome aberrations and gene mutations are attributed to radiation-induced damage, and it is assumed that most of the changes take place at the time of radiation exposure and that genetic alterations are restricted to direct DNA damage. Recent

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28/46

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research suggests that the Nuclear Target Paradigm is inadequate, and that biological response to ionising radiation needs to account for a variety of additional effects, collectively described as *Radiation-Induced Genomic Instability* and *Radiation-Induced Bystander Effects* (Coates et al., 2004; Wright and Coates, 2006).

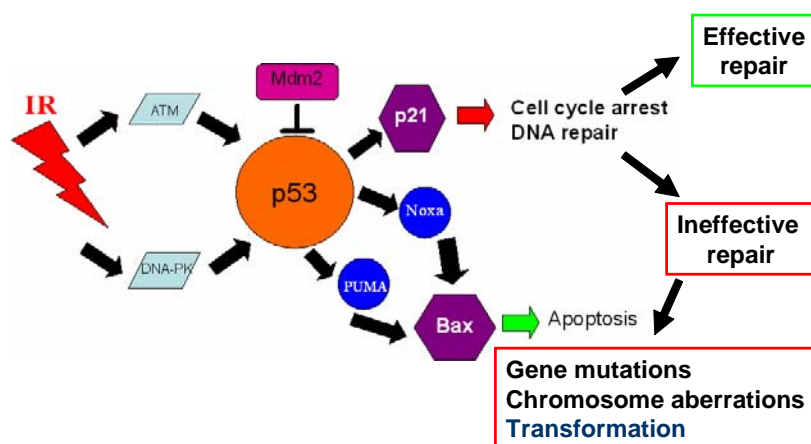


Figure 4.1 Biological Responses in Irradiated Cells: p53 is a transcription factor and tumor suppressor.

Radiation-Induced Genomic Instability (RIGI) refers to effects observed in cells that are not themselves irradiated but are the progeny of irradiated cells. Effects in progeny include cell death, genetic mutations and a wide variety of chromosome aberrations, all of which are regarded as consequences of destabilisation of the genome. RIGI is a genome-wide process induced at very high (epigenetic) frequencies, and persisting over many cell generations, perhaps indefinitely. The response appears to saturate at low doses, and observed lesions tend to have characteristics of “spontaneous” abnormalities. Most studies have been carried out on cell lines *in vitro*, and expression of aberrations is not universal, but influenced by cell type and genetic factors. Genetic studies indicate that the expression of RIGI is genetically recessive and that chromosomal instability is likely to be associated with the arrest/repair/misrepair versus apoptosis response described above. Compared to *in vitro* data, *in vivo* measurements show significantly less damage per cell and fewer cells demonstrating chromosomal instability, but confirm significant inter-individual variability. *In vivo* studies on pre-conceptional irradiated mice indicate that the effects are transgenerational—pre-meiotic exposure produced increased mutation rates in the germ line of two subsequent generations (Dubrova et al. 2002), and can affect the susceptibility of progeny to chemical carcinogen exposure. Pre-conception exposure of mice to plutonium reduced latency, increased incidence rate and induced pathological differences in leukaemias induced in their progeny exposed to MNU (Lord et al., 1998). At present the mechanism of induction of instability by ionising radiation is not understood, nor is it clear whether all endpoints reflect a common mechanism. Inter-cellular mechanisms have been implicated, as have mechanisms involving oxidative stress and free radical-mediation processes.

Radiation-Induced Bystander Effects (RIBE) include a variety of effects seen in cells that are not themselves irradiated but in the neighbourhood of irradiated cells or exposed to medium in which cells have been irradiated. RIBE have been demonstrated in a variety of cell types after exposure to both high and low-LET radiations. Effects may reflect at least two separate mechanisms for the transfer of damaging signals: gap junction-mediated intracellular communication, which stimulates a TP53-



mediated damage signalling pathway (cell-cell contact); or secretion of cytokines or other factors that act to increase intracellular levels of reactive oxygen species in unirradiated cells (soluble signals). Effects include increase or decrease in damage-inducible and stress-related proteins, increases or decreases in reactive oxygen species, cell death or cell proliferation, induction of mutations and chromosome aberrations and induction of an instability phenotype. Like RIGI, they are not universally expressed, but influenced by cell type and genetic factors, and the response also appears to saturate at high doses. Inter-cellular signalling, production of cytokines and free radicals are also features of macrophage activation and inflammatory responses that have the potential for context-dependent pathological consequences (Figure 4.2).

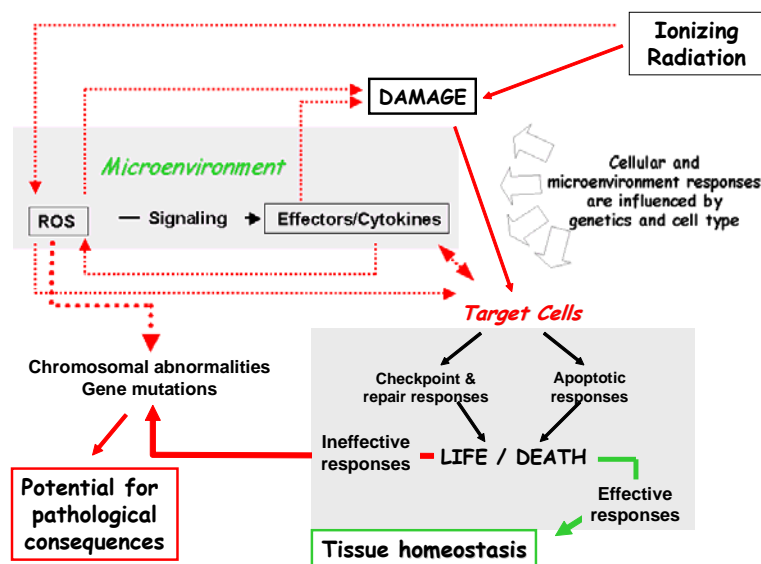


Figure 4.2 Microenvironment and Pathological Consequences of Ionising Radiation (Wright and Coates, 2006)

At low doses, untargeted effects may be associated with either increased risk due to mutational change or a decrease in risk due to either apoptosis or adaptive response. Inflammation has been implicated in the increases in cardiovascular, gastrointestinal and respiratory diseases reported in A-bomb survivors (Kodama et al., 1996; Shimizu et al., 1996; Hayashi et al., 2003). Clastogenic factors, indicative of the oxidative stress associated with inflammation, have also been demonstrated in the blood of the A bomb survivors, Chernobyl liquidators and children exposed at Chernobyl (Emerit et al., 1995, 1997).

In summary, RIGI and RIBE both have the potential to introduce discontinuity into dose-effect relationships at low doses. The effects show large inter-cellular, inter-tissue and inter-individual variation adding further uncertainty to extrapolation between and within species. The production of clastogenic factors, bystander effects and instabilities may all reflect inter-related aspects of a non-specific inflammatory response to radiation induced stress, and may be involved in a variety of the pathological consequences of radiation exposures, including delayed and trans-generational effects.

4.1.2 Derivation of predicted no-effect dose rate values for ecosystems exposed to radioactive substances – associated uncertainties

Jacqueline Garnier-Laplace (IRSN, France)

Uncertainty is associated with all the basic components in ERA. The common method for dealing with this is to propose extrapolation rules. For chemical ERA, the standard practice is to evaluate the ecological effects on the basis of results from species in standard toxicity tests and extrapolates over





time, taxa and level of biological organisation using assumptions and models. The ERICA deliverable D5 focuses on uncertainties in the effect analysis, with the aim of deriving predicted no-effect levels, and proposing benchmarks for use in the ERICA Tiered Approach (ERICA, 2006). These benchmarks need to reflect the various degrees of confidence that are needed through the 3 tiers, from conservative assumptions to more realistic ones. It is proposed that benchmark values for screening purposes are applied in Tier 1 and Tier 2, whilst in Tier 3 it is recommended that quantitative uncertainty analysis is carried out for a given likelihood of effect and a given assessment endpoint in Tier 3 (Figure 4.3).

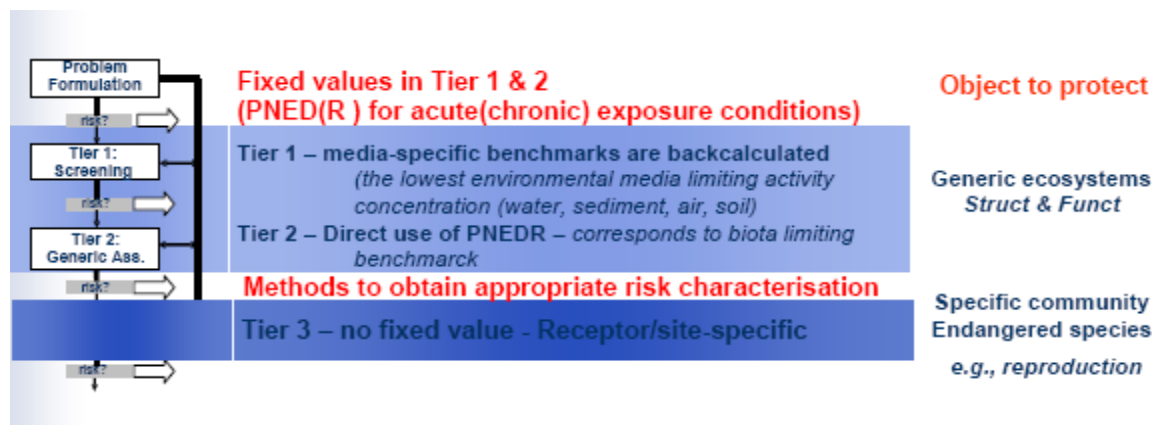


Figure 4.3. Risk Characterisation in the ERICA Tiered Approach

The screening values used within Tier 1 and 2 were derived from the FREDERICA database using a three step methodology recommended within the EC Technical Guidance Document for the estimation of PNEC for chemicals (EC, 2003a). First, a coherent data sub-set was extracted from each experiment, covering endpoints related to mortality, morbidity and reproduction. Second, a systematic mathematical treatment was applied to build dose(rates)-effect relationships and estimate critical toxicity endpoints. For acute exposure, the critical data are the estimated ED_{50} (in Gy) or Effect Dose giving a 50% change in observed effect. For chronic exposure, the critical endpoint was the estimated EDR_{10} (in $\mu\text{Gy/h}$) or Effect Dose Rate giving rise to a 10% change in observed effect (Figure 4.4). The third step of the methodology consists then in using these critical toxicity data to derive a Predicted No-Effect Dose (PNED) or Predicted No-Effect Dose Rate (PNEDR).

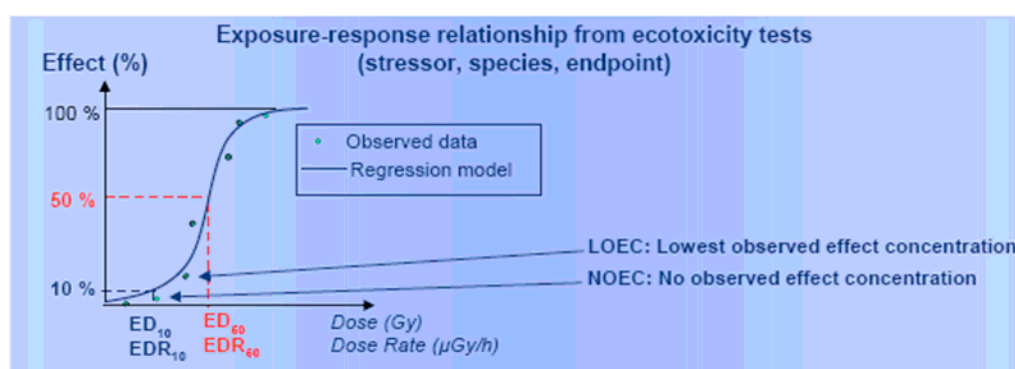


Figure 4.4 Derivation of ED_{50} (acute exposure) and ED_{10} (chronic exposure).



The SSD method estimates the doses (or dose rates) below which 95 % of species in the aquatic/terrestrial ecosystem should be protected (HD_5 or HDR_5 – Hazardous Dose giving 50 % effect to 5 % of species for acute doses or Hazardous Dose Rate giving 10 % effect to 5 % of species for chronic doses). The final benchmark screening values (PNED or PNEDR) are obtained by applying a safety factor of between 1 and 5 to take on board remaining extrapolation uncertainties (e.g. the irradiation pathway that could lead to a dominant internal dose by α or β emitters). The alternative to the SSD method is the Assessment Factor method, which simply divides the lowest obtained ED_{50} or EDR_{10} with a nominal safety factor ranging from 10 to 1000.

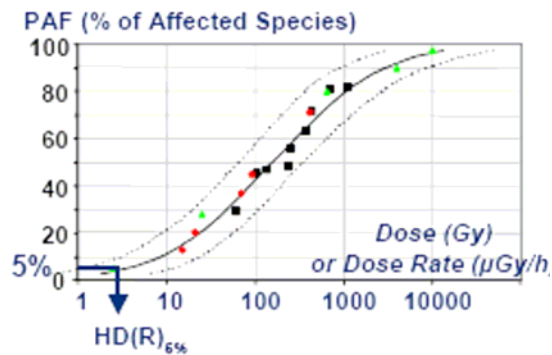


Figure 4.5. Derivation of HD(R) using the SSD Method.

The two methods can be summarised as follows:

Species Sensitivity Distribution (SSD)
$$PNED(R) = \frac{HD(R)_5}{SF}$$

Assessment Factor
$$PNED = \frac{LowestED_{50}}{SF} \text{ and } PNEDR = \frac{LowestEDR_{10}}{SF}$$

An example of the SSD results for chronic exposure taken from the FREDERICA database is given in Figure 4.5. As the data set showed no difference between the radiosensitivity of species from terrestrial, freshwater and marine ecosystems, it was possible to construct a unique SSD for generic ecosystems chronically exposed to external γ irradiation (Figure 4.6). For acute exposures there was a significant difference in radiosensitivity for marine and terrestrial organisms (see ERICA, 2006).

On the basis of these PNED(R), ERICA proposed screening values for the first tiers of the tiered approach. To derive the benchmark values for acute exposure, a SF of 5 is applied, giving the value rounded down to one significant figure, giving 900 mGy for marine ecosystems and 300 mGy for terrestrial ecosystems and freshwaters. To derive the benchmark value for chronic exposure situations, a SF of 5 is applied, giving the value rounded down to the nearest order of 10 of 10 μ Gy/h for all ecosystems.

Tier 3 must be a problem formulation driven and case specific assessment depending on the areas of potential risk and data gaps identified in the lower tier assessments. As such, the ERICA consortium decided that it was not appropriate to make specific recommendations. Rather, some guidance on the sorts of approaches that may be applied for refined effect analysis was exemplified. It is recommended to use SSD methodology and to introduce more ecological realism: Different possibilities were explained such as (1) using a more conservative levels of protection (i.e. moving from 95 % to 99% of





species being protected); (2) applying trophic/taxonomic weightings that better describe the structure of a specific ecosystem; (3) restricting the statistical analysis to a particular endpoint (for instance reproduction) and/or a particular trophic/taxonomic group (*e.g.* vertebrates or fish). It is proposed to refine the effects analysis by focusing on the protection of keystone species and/or endangered species and to refine the effects analysis to address situations when knowledge of effects is too scarce with regard to the problem formulation, and additional studies may be required.

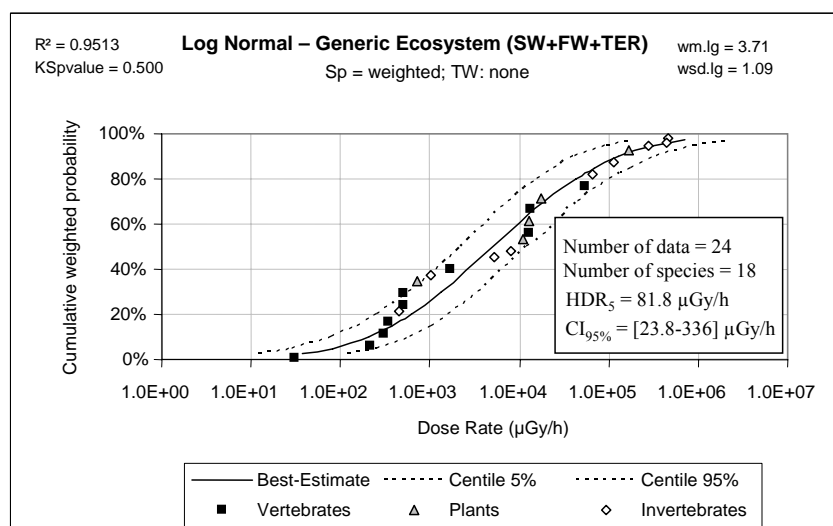


Figure 4.6. SSDs for generic ecosystems (FW+SW+TER) and chronic external γ irradiation exposure conditions. The log normal distribution with its associated 95 % confidence interval is fitted to geometric means per effect category for each species calculated on critical ecotoxicity data (EDR_{10}). (ERICA, 2006).

4.2 Group Discussions

The main background material for the group discussions was ERICA deliverable D5. The risk characterisation stage of risk assessment requires judgements about the possible effects of the exposures of organism to radiation. Are the exposures likely to be detrimental to organisms? Do benchmarks and screening values reflect a sufficient degree of protection? Or are the benchmarks over-conservative with regard to the likely ecological consequences? For this session, different groups considered different issues associated with dose-effect evaluation and risk characterisation. Groups were divided as follows: Group 1—Biological Basis of Uncertainty; Group 2—Effects Analysis in the Tiered Approach; Group 3—The Precautionary Principle.

4.2.1 Group 1 – The Biological Basis of Uncertainty

(Chair – Carmel Mothersill, Rapporteur—Philip Day, Secretary—Hanne Breivik)

The group started out by proposing four discussion issues/questions:

1. Trans-generational effects
2. Does understanding of the bio-mechanisms help or invalidate the ERICA approach?
3. If inflammatory response is the primary effect, is a dose-response plausible?
4. Multiple stressors: does ERICA consider interactions with other stressors?

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Dissemination level: PU

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The question was raised whether ERICA considered these types of uncertainties. The answer was that they are only considered rudimentarily as sources of uncertainties; the ERICA database is not mechanistic, it is a comparison of two black boxes (real life and experiment). The implications of this approach and the pros and cons for ERICA were discussed.

Pro ERICA: It is all a comparison with a database. We appreciate that there will be large uncertainties, but we are comparing apples and apples. The predictions suffer from inexactness, therefore contain some degree of unreliability, but for the task in question they are on the whole reliable. The non-targeted effect will also be arising in the experiments.

Con ERICA: What is the reliability of the database? Here the discussion focused on the methods for input of data to the database, the conclusion being that the database should be scrutinised for ability to answer the question being put to it. Recognise need to collate data, but need to appreciate that the data has been produced for another objective and may not be applicable for the ERICA purpose. For example:

- If the environmental effect is chronic, does the DB select a suitable sub-set of the data (i.e., are acute effects really screened out)? The definition of chronic exposure is one tenth of lifetime, but very few data meet this criterion, in any case these effects can be delayed across lifetimes.
- Are enough organisms and effects included for the relevant endpoints (e.g. no mammals in marine, much of research for cancer rather than ecological effects)?
- Is the time frame of the observations in the DB long enough to be relevant to long-term environmental effects? Specific issues mentioned were trans-generational effects (do they increase the spread of data or shift the whole distribution), delayed and non-targeted effects – example of the inflammatory responses now being picked up in bomb-survivors, delay between exposure and reproductive effect in earthworms.
- There will be a spectrum of gene-types in the population, a sub-group might be more or less radiosensitive
- Uncertainties are of two types:
 - Quantitative: Known uncertainty (inexactness and unreliability) in the genetic difference in response (positive/negative) will increase the spread of the data, intra-species, inter-species and tissue/cell differences. Can be dealt with by statistics, safety factors and probabilistic risk assessment. Inexactness if normal, unreliability if changes distribution and central value
 - Unreliability/ignorance: Unknown: we do not know that the approach is complete because of the biological uncertainty – multiple stressors, trans-generational effects, possibility of propagation of effects through generations. “We know we don’t know” needs to be appreciated in the assessment. These kind of uncertainties cannot be dealt with by probabilistic risk assessment

Conclusions

The ERICA approach cannot reliably conclude a negative effect. Answer is not “Effect – or no effect”, but “Effect or perhaps, we don’t know”. This needs to be emphasised to “end users” and regulators.



4.2.2 Group 2: Effects analysis in the tiered approach

(Chair/Rapporteur — John Ferris, Secretary — Nick Beresford)

Safety factor and derivation of the screening level

- Why reduce screening level to ‘1 significant figure’ and why use a value of 5 for the safety factor? ERICA Consortium members explained that ‘1 significant figure’ was to simplify the approach and acknowledge that the screening level was derived by rounding *down* to the nearest 10 and not by rounding to the nearest 10. The value for safety factor was adopted from those used by the chemical industry, which range from 1 to 5. The ERICA approach is reproducible.
- Some EUG members commented that it was an advantage for communication with the public to have the same approach as used for chemicals.
- It was explained that FREDERICA contains the entire set of base data from which the screening level was derived and that entries in the FREDERICA database are traceable back to the original reference. All papers entered into the FREDERICA database were read for accuracy and relevance.
- The opinion was expressed (by some EUG members) that ERICA had used a quality approach to derive the screening level.

The value of the screening level

- There was concern expressed that the 10 $\mu\text{Gy/h}$ may be seen as more than just a screening level and that the value may be too low as most raw data indicate no effects below 100-200 $\mu\text{Gy/h}$. What happens when a site is assessed to have dose rates in excess of 10 $\mu\text{Gy/h}$?
- Some EUG members felt that the proposed 10 $\mu\text{Gy h}^{-1}$ screening level seemed ‘reasonable’ compared to the 1 mGv y^{-1} limit used for exposure of the public (from practices).
- ERICA members explained that all documentation would clearly state that 10 $\mu\text{Gy/h}$ was a screening level for use within Tier 1 and 2 level assessment only. If Tiers 1 and 2 assessments estimate doses below 10 $\mu\text{Gy/h}$ then we can be reasonably confident that there will be no impact at a population level. Above the screening level we could not guarantee no effect. The US uses a screening level approach and does not seem to experience problems with regard to their screening level being seen as ‘the number’. The screening approach should focus effort to a few sites. If assessments estimate doses in excess of 10 $\mu\text{Gy/h}$ then agreement will have to be reached and no effect proved (e.g. by looking at biodiversity at the site).

Tiered approach

- The opinion was expressed that, whilst a single screening level was thought to be OK for use in Tier 1, sub-sets of data (e.g. organism or ecosystem specific values) should be used for Tier 2.
- ERICA members expressed their view that Tier 2 should be used to improve the exposure assessment. There are insufficient data (only 24 points) to derive more specific screening values for Tier 2. For single species assessments Tier 3 should be used when all the data from FREDERICA can be accessed. However, summary tables from FREDERICA can be accessed at Tier 2. Tier 2 is restricted to refining the exposure assessment to reduce the work required in the assessment.
- The EUG stated that the ERICA should clearly state the limitations of the available data. The comment was made that there were lots of uncertainties in models used etc., which may lead





to a problem in passing Tier 3. With regard to uncertainties at Tiers 1 and 2 it was felt that it could be demonstrated that the approach was sufficiently conservative to account for model uncertainty and not result in estimates of 10 µGy/h in reality being 100 µGy/h.. Tier 3 will be stochastic allowing the user to see the uncertainties and focus effort.

- Some EUG members felt that Tier 2 should contain more than a single screening value, otherwise there is a transition from a simple single value at Tier 2 to needing a lot of expertise at Tier 3. The advantage of having organism-specific values within FREDERICA is lost at Tier 2 by only having a single screening value. Would it be of value at Tier 2 to demonstrate that there is not a single screening value applicable to all species-ecosystems? Why use ecosystem-specific screening values at Tier 2?
- ERICA members explained that Tier 2 would enable comparison with tabulated effects data from FREDERICA. The users also had the ability to input their own screening values, however, it was accepted that this require considerable expertise. The summary tables are a method of presenting more information without the expertise required to derive alternative screening values. Ecosystem-specific screening values have been derived but were similar to each other.
- Some EUG members commented that the ERICA approach represents the first steps towards a process compatible with that used for chemicals and to protecting the environment as a whole with little argument for doing differently. Others requested more expert provision of effects information at Tier 2 to remove the requirement for the user to be the expert. Furthermore data gaps should be clearly identified and the 10 µGy/h screening level suggested by ERICA should not be put forward as ‘the number’.
- The potential to refine the screening value through analysis of new data added to FREDERICA was discussed with the EUG asking the ERICA Consortium to consider including the ability to conduct species-sensitivity analysis within the ERICA tool. Software is available on the EDF website, inclusion in the tool had been considered but rejected due to the complexity of the methodology. The Consortium agreed to re-evaluate this at the request of the EUG.

4.2.3 Group 3: Precautionary Principle

(Chair—Jeroen van der Sluijs, Rapporteur—Mark Crane, Secretary—Steve Jones)

As a departure point, the group discussions took the material presented by Mark Crane (see section 3.1.1) and a number of contemporary definitions of the precautionary principle.

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.”

During the discussions a number of points were made:

- It is important that the ERICA methodology should be clear as to how it relates to the Precautionary Principle, as regulators need to show how they have incorporated the principle into their decision making, and in any event NGOs are certain to raise the issue once the outcome of ERICA assessments are published or put out for consultation.
- All decision-making processes will be subject to some degree of scientific uncertainty. If uncertainties were relatively small and/or dealt with very robustly by the methodology, decisions made on the basis of an ERICA assessment could be seen as consistent with Prevention rather than Precaution. The feeling of the group was that the ERICA methodology stood somewhere between Prevention and Precaution.
- ERICA deals with uncertainty largely (in Tier 1 and Tier 2) through the introduction of conservatism. It is important to justify that the assumptions are indeed sufficiently (but not excessively) conservative.
- Regulators are likely to view the ERICA methodology as a pass/fail test to check that proposed authorised discharge levels are unlikely to cause environmental harm. In this context the robustness of the ‘screens’, particularly at Tier 1, are very important.
- The 5 % cut-off for setting screening dose rates is an area of vulnerability. Does this mean that at the screening level 5 % of species will certainly be harmed? If this is so, this is not obviously conservative and will probably not be acceptable to many stakeholders. If on the other hand it means that we are sure that 95 % won't be harmed (but not so sure about the other 5 %), that might be more acceptable. Clarity of meaning, and justification, are critical here.
- Application of the Precautionary Principle is a matter for decision makers not for the ERICA methodology itself. What the ERICA methodology must do is to 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, apply further precaution and un-knowingly double-count the degree of conservatism/precaution in their decisions.

- The Precautionary Principle, if applied in isolation, could conflict with the principle of Optimisation (balancing potential harm against benefits and other factors). The UNESCO 2005 definition of the Principle is helpful here: “*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.*”
- Balance can be particularly important when uncertainty is high – if high uncertainty is dealt with by introducing extreme conservatism, very unbalanced decisions can result.
- The scientific plausibility of potential harm must be influential. It is worth emphasising that past experience, in most cases, gives no expectation whatsoever that controlled releases of radioactivity into the environment will cause any harm to ecosystems. An example would be a proposal to construct a new PWR reactor – here, it is arguable that past experience (of planned releases) would not indicate that the proposal is at all likely to “*lead to morally unacceptable harm that is scientifically plausible but uncertain*”, and that therefore the Precautionary Principle should not require any special action to protect ecosystems
- Likewise, it should be remembered that the FASSET and ERICA projects were not initiated as a result of concern that currently regulated radioactive releases were causing ecological harm. Arguably, the projects could be seen as an implementation of the Precautionary Principle to test the unsupported hypothesis of ICRP that protection of humans to their recommended standards would also ensure that ecosystems would not be harmed.

5 Recommendations for ERICA

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

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

- It must be made clear to the users that ERICA has several types of intrinsic uncertainties and that some conservatism already is built-in to compensate for those. It is important that the user neither doubles the conservatism nor trusts the result too uncritically.
- Users require information on the sources, and at least the order of magnitude, of uncertainties in the assessment. There is a need for transparency and traceability in the way the tool deals with uncertainty and a justification of the choices and assumptions made in selection of model and parameters.
- There is a distinction to be made in the ERICA tool as to its usage: i.e. as a conceptual tool and as a computational tool. ERICA should address not only data issues (i.e. parameters and input data) but also the uncertainties inherent in the ERICA tool (i.e. model assumptions).
- Terms used in the uncertainty spreadsheet need more clarification. The distinction between uncertainty and variability should be included, and the term “data gap” should be replaced with “knowledge gap” where appropriate.





- Make the link clearer between the uncertainty spreadsheet, the assessment tool and the tiered approach illustration. A review of the content of the Uncertainty Spreadsheet was difficult at the workshop: deal with specific comments separately.
- ERICA should develop a framework or guide for uncertainty analysis: consider adapting the uncertainty matrix presented by Jeroen van der Sluijs.

The Tiered Approach

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

Screening Values

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

Uncertainty in dose estimation and effects analysis

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





kinds of uncertainties cannot be dealt with by probabilistic risk assessment. The ERICA approach cannot reliably conclude a negative effect. This needs to be emphasised to end-users.

Management and Precautionary Principle

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





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Appendix 1: List of Participants

EUG Members

Marianne Calvez, CEA, France
Marie-Claire Cantone, University of Milan and INFN, Italy
Sohan Chouhan, Atomic Energy of Canada, Canada
John Ferris, ANSTO, Australia
Tom Hinton, University of Georgia, USA
John Holmes, Oxford University, UK
Ari Ikonen, Posiva Oy, Finland
Matthias Kaiser, NENT, Norway
Branko Kontic, Josef Stefan Institute, Slovenia
Carmel Mothersill, McMaster University, Canada
Ivica Prlic, IMI, Croatia
Ian Robertson, SEPA, UK
Carol Robinson, Enviro, UK
Hildegard Vandenhove, Belgian Nuclear Research Centre, Belgium
Jeroen Van der Sluijs, University of Utrecht, Netherlands
Christine Willrodt, BFS, Germany

Invited Speakers

Philip Day, University of Manchester, UK
Eric Wright, University of Dundee, UK
Mark Crane, Watts and Crane, UK

ERICA Consortium

Almudena Agüero, Ciemat, Spain
Nicholas Beresford, NERC, UK
Hanne Breivik, NRPA, Norway
David Copplestone, EA, England and Wales
Jacqueline Garnier-Laplace, IRSN, France
Rodolphe Gilbin, IRSN, France
Riitta Hänninen, STUK, Finland
Robert Smith, EA, England and Wales
Stephen Jones, Westlakes, UK
Tönis Papp, SKB, Sweden
Deborah Oughton, UMB, Norway
Kirsti-Liisa Sjöblom, STUK, Finland
Henning von Maravic, European Commission
Irene Zinger, SSI, Sweden





Appendix 2: Discussion Groups

Session 1: Categorisation of Uncertainties

Plenary: Deborah (Chair); *Hanne and Rodolphe* (scribes)

Group 1 Source Characterisation; Ecosystem Analysis	Group 2 Environmental Transfer and Exposure	Group 3 Effects Analysis; Interpretation and Evaluation
John Holmes (ch/rp) Mark Crane Matthias Kaiser Philip Day Ian Robertson Marianne Calvez Henning von Maravic	Hildegarde Vandenhove (ch) Sohan Chouhan Marie-Claire Cantone John Ferris Jeroen van der Sluijs (rp) Ivica Prlic Robert Smith	Tom Hinton (ch/rp) Eric Wright Carmel Mothersill Marianne Calvez Carol Robinson Ari Ikonen Christine Willrodt Branko Kontic
Irene Zinger Steve Jones Tonis Papp Kirsti-Liisa Sjöblom (s)	Nick Beresford Almudena Aguero Riitta Hanninen Rodolphe Gilbin (s)	Deborah Oughton Jacqueline Garnier Laplace David Copplestone Hanne Brevik (s)

ch – chair; rp – rapporteur; s – secretary

Session 2: Environmental Transfer and Dose Calculation: The ERICA Assessment Tool

Plenary: Irene (chair); *DHO and Tonis* (scribes)

Group 1 Environmental Transfer	Group 2 Dose Estimation	Group 3 Tool Flowchart
Hildegarde Vandenhove (ch) Sohan Chouhan Ivica Prlic Robert Smith (rp) Marie Claire Cantone Marianne Calvez Henning von Maravic	Tom Hinton (ch/rp) Philip Day Eric Wright Carmel Mothersill Ari Ikonen Matthias Kaiser Christine Willrodt Mark Crane	John Ferris (ch/rp) John Holmes Jeroen van der Sluijs Carol Robinson
Nick Beresford Riitta Hänninen Tönis Papp (s)	Deborah Oughton Almuenda Aguero Steve Jones (s)	Irene Zinger David Copplestone Kirsti-Liisa Sjöblom Hanne Brevik (s)



Session 3: Dose-Effects Analysis: Risk Characterisation

Plenary: DHO/IZ, secretary NB

Group 1 Biological Basis – Extrapolation	Group 2 Tiers	Group 3 Precautionary Principle
Carmel Mothersill (ch) Tom Hinton Eric Wright Philip Day (rp) Christine Willrodt	John Ferris (ch/rp) Ari Ikonen John Holmes Carol Robinson Hildegarde Vandenhove	Jeroen van der Sluijs (ch) Mark Crane (rp) Sohan Chouhan Marie Claire Cantone Ian Robertson Ivica Prlic Marianne Calvez
Deborah Oughton Alicja Jaworska Almudena Aguero Kirsti-Liisa Sjöblom Hanne Breivik (s)	Irene Zinger Jacqueline Garnier Laplace Rodophe Gilbin David Copplestone Nick Beresford (s)	Steve Jones (s) Tönis Papp





Appendix 3: Results from Feedback Questionnaire

The following illustration is a colored rendering of the responses to the feedback questionnaire distributed and completed at the end of the EUG event in Ljubljana, Slovenia.

The feedback questionnaire was answered by 14 participants (i.e. 87,5 % EUG participants) on a five level scale from “poor” to “excellent”. In the translation, green renders “excellent” while red renders “poor”. The full red was not used by respondents; light red, i.e. answer 2, appeared only in three places. In the table, questions have been re-ordered according to “the excess of greens over reds”.

Globally, answers are very positive. Three sets can be distinguished.

- The first set of questions shows a positive consensus: answers are fairly unanimously green.
- In the second group, answers are also very positive, overall, but there is more diversity among opinions; there are some dissenting voices. In particular, some doubts seem to be expressed about the timely manner in which the background material was provided. However, it should be noted that for this event all material was placed on the website two weeks before the event, as it should be.
- Dissenting voices are close to half the answers in the third group. Therefore, the group average is less than “excellent”. The source of this (mild) criticism seems to be the relevance and clarity of the objectives in the group discussions.

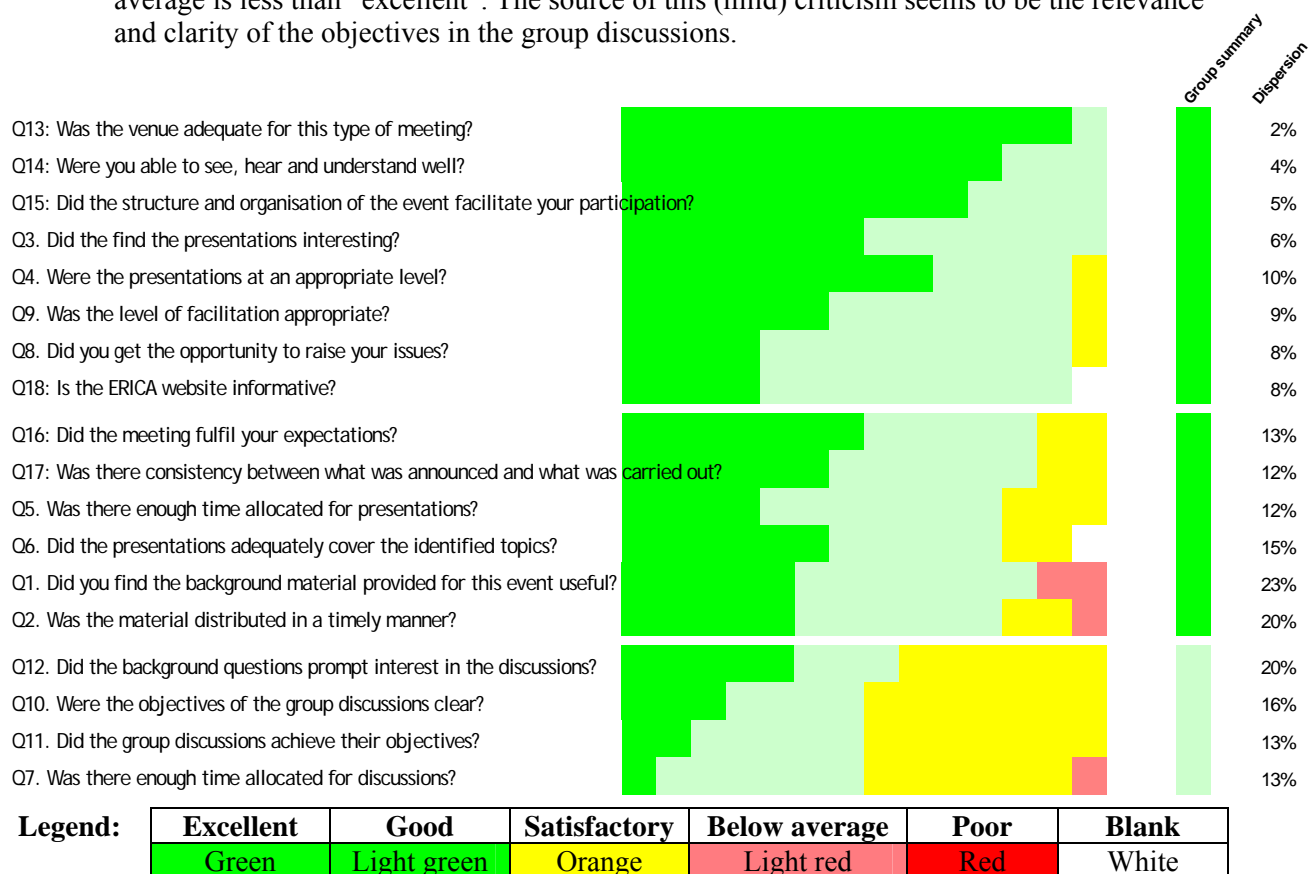


Figure 1: Summary of the responses from the questionnaires.