

# ERICA (Contract Number: FI6R-CT-2004-508847)

# **Consensus Document**

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ERICA Consensus Document, EUG Event – Stavern, June 2006 Dissemination level: PU Date of issue of this progress report: 31-08-06





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



Erica tetralix L.

# Contract No:FI6R-CT-2004-508847Project Coordinator:Swedish Radiation Protection Authority

## **Contractors:**

Swedish Radiation Protection Authority	SSI
Swedish Nuclear Fuel and Waste Management Company	SKB
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# ERICA EUG EVENT Consensus Seminar Stavern, June 27<sup>th</sup> – 30<sup>th</sup> 2006 CONSENSUS DOCUMENT

This document is dedicated to the memory of Masahiro Doi who died tragically from a cerebral haemorrhage he suffered at the Stavern seminar. Masahiro will be missed as a colleague and friend, and our thoughts are with those he left behind.

# 1. Introduction

The aim of the ERICA project is "to provide an integrated approach to scientific, managerial and societal issues concerned with the environmental effects of contaminants emitting ionising radiation...The final outcome of the project will be the ERICA integrated approach to assessment and management of environmental risks from ionising radiation, using practical tools" (www.erica-project.org).

The aim of this Seminar (Stavern, June  $27^{th} - 30^{th} 2006$ ) was for the EUG to agree and formulate a position paper on the implications of some assumptions and limitations within the ERICA integrated approach, and to provide recommendations for the ERICA Consortium. The issues debated related to areas where previous EUG events had identified a lack of consensus. The issues discussed under each subheading in this document are those that were raised as specific areas of concern. While the goal of the seminar was to reach consensus, this was not a requisite.

This document provides an overview of the consensus areas identified by the participants at the Stavern Seminar. This document will be part of the ERICA deliverable D7f (ERICA, 2006), which will record the Stavern discussions and areas of agreement and disagreement in greater detail.

# 2. Summary overall viewpoints

A seminar was held to explore assumptions and limitations within the ERICA integrated approach and a broad consensus was reached on most issues. These are summarised as follows.

## Reference organisms

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

## Dose-effect evaluations

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

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

ERICA Consensus Document, EUG Event – Stavern, June 2006 Dissemination level: PU Date of issue of this progress report: 31-08-06





### Assessment tool

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

#### Management

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

#### In general

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

The ERICA tiered approach is supported by the EUG.

## 2.1 Reference organisms

#### Compatibility of the ERICA approach with ICRP recommendations

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

#### Representation of protected species by reference organisms

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

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

<u>Reference organisms as a basis for the estimation of dose rates</u> Reference organisms provide a good model for whole body dosimetry. Further consideration of internal heterogeneous distribution of radionuclides is needed.

Consensus Document, EUG Event – Stavern, June 2006 Dissemination level: PU Date of issue of this progress report: **31-08-06** 



**ERICA** 



# 2.2 Dose-effect evaluation

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

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

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

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

#### Adequacy of the FREDERICA database for the assessment of ecological effects

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

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

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

## 2.3 Assessment tool

#### Conservatism within the ERICA tool

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

#### Treatment of prospective versus retrospective assessments within the ERICA tool

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

**ERICA** 

Consensus Document, EUG Event – Stavern, June 2006 Dissemination level: PU Date of issue of this progress report: **31-08-06** 





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

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

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

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

# 2.4 Management issues

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

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

#### Application of the precautionary principle

The precautionary principle does not necessarily imply zero release or zero exposure. Application of the precautionary principle is mainly a matter for decision-makers. However, precaution is incorporated in the ERICA integrated approach. ERICA should specify how the precautionary principle could be applied in the management scheme.

Stakeholder involvement in ecological risk assessment

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

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

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

# Reference

This document is an extract from:

ERICA deliverable D7f: "The ERICA Consensus Seminar". Ellen-Marie Forsberg (NENT) and Deborah Oughton (UMB) (Eds), <u>www.erica-project.org</u>, European Commission, 6th Framework, Contract N°FI6R-CT-2004-508847. August 2006.



Consensus Document, EUG Event – Stavern, June 2006 Dissemination level: PU Date of issue of this progress report: **31-08-06** 

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