EUROPEAN COMMISSION
Community Research

ERICA

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

DELIVERABLE 5:

Derivation of Predicted-No-Effect-Dose-Rate values for ecosystems (and their sub-organisational levels) exposed to radioactive substances

Editors: Garnier-Laplace J and Gilbin R (IRSN)

Authors: Agüero A (CIEMAT), Alonzo F (IRSN) Björk M (SUC) Ciffroy Ph (EDF), Copplestone D (EA), Garnier-Laplace J (IRSN), Gilbin R (IRSN), Gilek M (SUC), Hertel-Aas T (UMB), Jaworska A (NRPA), Larsson C-M (SSI), Oughton D (UMB), Zinger I (SSI)

Reporting period: March 2004 – February 2006

Date of issue of this report: **28-02-2006**

Start date of project : **01/03/04** Duration : 36 Months

Project co-funded by the European Commission under the Euratom Research and Training Programme on Nuclear Energy within the Sixth Framework Programme (2002-2006)		
Dissemination Level		
PU	Public	PU
RE	Restricted to a group specified by the partners of the [ERICA] project	
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Contract No: **FI6R-CT-2004-508847**
Project Coordinator: **Swedish Radiation Protection Authority**

Contractors:

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Executive Summary

Background

The ERICA Ecological Risk Assessment approach requires risk assessment benchmark values for risk characterisation within Tiers 1 and 2. Generally, a benchmark value designates any value that is used for a comparison purpose. It becomes a screening value when it is used for screening purpose. Such values can be derived by methods that aim to ensure the protection of generic freshwater, marine and terrestrial ecosystems from detrimental effects (on structure or function) under accidental (acute) or chronic releases of radionuclides. These benchmark values guide risk assessors at various decision points in the tiered approach. More precisely, they are:

- In Tier 1, screening values that correspond to limiting activity concentrations in media (Predicted No-Effect Concentration (PNEC, in Bq/L or Bq/kg) obtained by back-calculation from the dose(rate) screening values used in Tier 2;
- In Tier 2, dose (rate) screening values that correspond to Predicted No-Effect Dose (PNED, in Gy) and Predicted No-Effect Dose-Rate (PNEDR, in µGy/h) for acute and chronic scenarios respectively;
- In Tier 3, no predefined benchmark values are proposed. Instead, examples of methods that can be used to derive refined PNED(R) for a specific ecosystem, community, endpoints, etc, are presented, including a probabilistic approach.

Two main methods are used for effect analysis and the subsequent derivation of risk assessment benchmarks. The first, namely the Safety Factor method, uses expert judgement to define assessment/safety factors that ensure a margin of safety. These factors usually vary from 10 to 1000 depending upon the quality and quantity of the available effects data, and combine multiple sources of uncertainty with an unclear degree of conservatism. The second method is based on the construction of Species Sensitivity Distributions (SSDs) and the derivation of benchmarks according to a clearly defined set of rules. Although this method has the potential to provide a more transparent approach to dealing with uncertainty, it requires that the knowledge on dose-effects relationships is adequate with respect to the problem formulation.

Methodology used to derive ERICA risk assessment screening values

The ERICA risk assessment screening values used within Tiers 1 and 2 were derived on the basis of data taken from the FASSET Radiation Effects Database (FRED. The methods applied follow EC recommendations for the estimation of PNEC for chemicals (EC, 2003). A three-step methodology was used. 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 reconstruct dose(rates)-effect relationships and to estimate critical toxicity endpoints. For acute exposure, the critical toxicity endpoint is the estimated ED_{50} (in Gy) or Effect Dose giving a 50 % change in observed effect. For chronic exposure, the critical toxicity endpoint is the estimated EDR_{10} (in µGy/h) or Effect Dose Rate giving rise to a 10% change in observed effect. The third step of the methodology consists in using these estimated critical toxicity data to derive a Predicted No-Effect Dose (PNED) or Predicted No-Effect Dose Rate (PNEDR). In accordance with recommendations detailed in the TGD, and depending on the available data set in terms of number of data and biodiversity, screening dose (rate) values were then estimated for application in Tiers 1 and 2 using either the Safety Factor method or the Species Sensitivity Distribution method (SSDs). The Safety Factor method simply divides the lowest obtained ED_{50} or EDR_{10} with a nominal safety factor ranging from 10 to 1000, using rules defined in the TGD based on the quality and quantity of the data available. 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 or Hazardous Dose Rate giving 10% effect to 5% of species) were estimated. The final dose (rate) screening values (PNED or PNEDR) for application in Tiers 1 and 2, are then obtained by applying a safety factor of between 1 and 5 to allow for remaining extrapolation uncertainties (*e.g.* the irradiation pathway that could lead to a dominant internal dose by α or β emitters).

The two methods can be summarised as follows:

$$PNED = \frac{LowestED_{50}}{SF} \text{ and } PNEDR = \frac{LowestEDR_{10}}{SF} \text{ when the Safety Factor method is applied}$$

or

$$PNED(R) = \frac{HD(R)_5}{SF} \text{ when the SSD method is applied.}$$

For Tier 3, it is possible to perform a quantitative uncertainty analysis whilst selecting a given likelihood of effect for a given assessment endpoint. The problem formulation-driven effect analysis could deal with:

(i) a particular target of protection such as well-known ecosystem, a specific wildlife community or a keystone species;

(ii) particular effects such as reproduction, and/or

(iii) particular extrapolation issues such as from individual to population, or external to internal irradiation effects.

The more detailed assessment in Tier 3 needs to be supported by a robust evaluation of experimental and modelling data related to the relevant endpoint. As an illustration, these points were supported both by theoretical developments (modelling) and by experiments under controlled conditions to simulate how effects observed at the individual level propagate at the population level and how effects observed during external irradiation exposure change when the dose is delivered by internal irradiation exposure.

Screening values recommended for Tiers 1 and 2

ERICA has proposed the screening values to be used in the first two tiers of the tiered approach for ecological risk characterisation that can be applied across the range of activities that use radioactive substances. These proposals are based on the following reasoning.

Object of protection. Generic ecosystems (freshwater, marine and terrestrial) should be protected from effects on structure and function under accidental (acute exposure) or chronic releases of radionuclides.

Specific methods. Species Sensitivity Distributions (SSD) built on ecotoxicity data obtained from the mathematical processing of the effects data within the FRED, and averaging per umbrella effect for each species (geometric mean per umbrella effect for each species, species weighted in the distribution, no weight per taxonomic group). The cut-off value is fixed at 95 % of species to be protected (as recommended in the EC TGD) and the likely distribution is used for the derivation of the $HD(R)_5$ with the associated confidence intervals (95 % CI). The application of the method will be extended to FREDERICA effects data once ready.

Ecotoxicity data were grouped according to ecosystem: freshwater (FW), marine (SW), and terrestrial (TER), and per exposure regime (acute or chronic). For **acute** exposures, there was a statistical difference between the sensitivity of species from the marine ecosystem and species from freshwater. Thus, species from aquatic ecosystems were not merged to construct a SSD. On the contrary, there was no difference between freshwater

and terrestrial species sensitivity, thus allowing construction of a common SSD for a generic continental ecosystem (FW+TER). For **chronic** exposures, there was no difference between the radiosensitivity of species from marine and freshwater ecosystems. The two sets were then grouped into a unique aquatic ecosystem. The difference between aquatic species and terrestrial species sensitivity was not statistically different. This finding allowed the construction of a unique SSD for generic ecosystems (SW+FW+TER) chronically exposed to external γ irradiation.

ERICA dose(rate) screening values for Tiers 1 and 2.

For **acute** exposure situations, the HD_5 and associated 95% confidence interval were as follows:

- marine ecosystems: 4.84 Gy [0.64; 12.7];
- terrestrial and freshwater ecosystems: 1.86 Gy [1.16; 2.98].

To derive the screening values, a Safety Factor (SF) of 5 was applied, giving the value rounded down and expressed with one significant digit. This resulted in:

Acute exposure screening values - 900 mGy for marine ecosystems and 300 mGy for terrestrial and freshwater ecosystems.

For **chronic** exposure situations, the HDR_5 and associated 95 % confidence interval are as follows:

- generic ecosystems (terrestrial, freshwater and marine): 81.8 µGy/h [23.8; 336]

To derive the screening value, a SF of 5 is applied, giving the value rounded down and expressed with one significant digit. This resulted in:

Chronic exposure screening value - 10 µGy/h for all ecosystems.

At the ecosystem level, the no-effect values lie in the dose range giving rise to minor cytogenetic effects or minor effects on morbidity in vertebrates. Those effects are not expected to be directly relevant at higher organisational levels, such as the structure and functioning of ecosystems.

Tier 3 Effect analysis and illustrations

When a lower tier assessment indicates a potential risk, then a risk management decision is made to warrant an additional Tier 3 assessment. The purpose of the refinements made in Tier 3 is to obtain more realistic estimates of exposure and effects in order to reduce the uncertainty in the risk assessment. The following questions and corresponding guidance on the sorts of approaches that may be applied for refined effect analysis in Tier 3 were addressed in the report.

- To use SSD methodology and to introduce more ecological realism: different approaches were explained such as (1) using 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).
- To refine the effects analysis by focusing on the protection of keystone species and/or endangered species: guidance was given to search in the updated FREDERICA database, produced during the ERICA project.
- To refine the effects analysis to address situations when knowledge of effects is scarce with regard to the problem formulation, and when additional studies may be required. Two examples were given to

illustrate possible ways of addressing extrapolation issues of concern, *i.e.* individual to population and external to internal irradiation effects.

Concerning the individual-to-population extrapolation, the question is to estimate stress effects on demographic characteristics. SSD techniques thus become inappropriate as they totally ignore the inter-species variability due to variability in life-cycle characteristics. A better approach is to use population models to extrapolate toxic effects on various combinations of individual life-cycle variables (i.e. survival, reproduction, and maturation) to effects on population dynamics. This was done while using population models to extrapolate toxic effects on various combinations of individual life-cycle variables to effects on populations dynamics. The ERICA experiments clearly showed that in any species, changes in life history traits due to radionuclide exposure can induce a variable impact on population dynamics. The growth rate of the population is most sensitive to effects on (in order) age of reproduction, on fecundity and adult mortality. However, the relative importance of each life history trait also varies between species, depending on the type of reproductive strategy and generation time. Thus, when assessors need to address individual-to-population extrapolation, we recommend following these successive steps:

(1) collect data describing the life history traits of the species under investigation;

(2) implement theoretical population dynamic models to rank the sensitivity of the population growth rate to individual vital rates or endpoints;

(3) search in the literature, or conduct experiments where knowledge gaps exist to obtain dose(rate)-effect relationship(s) for those individual effect endpoints inducing a substantial reduction in the growth rate of the population.

Concerning the extrapolation from gamma external irradiation to internal irradiation effect (alpha or beta emitters), the data evaluated within this project support the main conclusions and recommendations of Chambers *et al.* (2005; 2006). The statistical analysis performed gave a best estimate of 3.9 for RBE of alpha particles and deterministic endpoints, with a 95 % confidence interval from 3.2 to 4.7. Note that the upper bound to the confidence interval is in line with the safety factor value of 5 applied to derive the PNEDR. However, these values are mainly valid for mammals and mortality and do not take account of the influence of the life-cycle. Statistical analysis of RBE for beta particles provided values up to 1.8 (upper bound of the 95% confidence interval of the best estimate).

More generally, this review on RBE values underlines that there is an important gap on umbrella effects other than mortality, particularly reproduction. This lack of knowledge also concerns the way the life traits of a given species may modulate the response at the population level as the sensitivity to ionising radiation and the RBE value depend on both the life stage and the endpoint. As a first start, the ERICA experiments with daphnids generated new RBE values for alphas (Am-241) and demonstrated that a robust estimation needs a well-established dose-effect relationship, covering the whole range of effects from no-effect to that where 100% of the effect is observed and that RBE must be viewed as a function of the effect value rather than as a single value.

D5 is associated with two stand alone reports: D5-Annex Part A giving guidelines for the design and statistical analysis of experiments carried out within WP2, and D5-Annex Part B reporting on obtained experimental results.

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Associated reports -

D5-Annex Part A. Guidelines for the design and statistical analysis of experiments on chronic effects of radioactive substances on non-human biota. Garnier-Laplace J. and Gilbin R. (Eds). ERICA, European Commission, 6th framework, Contract N°FI6R-CT-2004-508847.

D5-Annex Part B. Experiments on chronic exposure to radionuclides and induced biological effects on two invertebrates (earthworm and daphnid). Results and discussion. Gilbin R., Alonzo F. and Hertel-Aas T. (Eds). ERICA, European Commission, 6th framework, Contract N°FI6R-CT-2004-508847.

1 Scope and background on effect extrapolation issues in Ecological Risk Assessment (ERA)

1.1 Introduction

1.1.1 The ERICA tiered approach, risk assessment benchmarks

In D4a (ERICA, 2005b) and after several discussions during EUG events (ERICA, 2004; ERICA, 2005c), the ERICA Consortium has adopted a tiered approach to assess and characterize ecological risk for radioactive substances as summarized in Figure 1. Briefly, the approach uses an initial problem formulation step followed by a three-tiered assessment, where tiers become increasingly more complex and resource intensive. As for any tiered approach, uncertainty needs to be incorporated into the exposure and effect analyses in various ways that are tier-specific. Generally, the uncertainties are large and poorly specified in the preliminary problem formulation and scoping, so that any quantitative uncertainty analysis is impossible. For tiers corresponding to screening and generic assessments (Tiers 1 and 2), a number of conservative assumptions are therefore required, related both to the derivation of appropriate screening dose (rates) and to the expected environmental concentrations and exposures. These assumptions result in a worst-case estimate of risk, and therefore make the assessment conservative at these tiers.

For the effect analysis and the derivation of risk assessment benchmarks[1], two main methods can be used. The first (namely the Safety factor method) simply takes the lowest observed effect dose or concentration (*e.g.* ED_{50} or EC_{50}) and divides it by a nominal safety factor or extrapolation factor to guarantee a margin of safety. These factors are usually selected by expert judgement based on the quality and quantity within the available effects data, and typically vary from 10 to 1000 combining multiple sources of uncertainty with an unclear degree of conservatism (Forbes and Calow, 2002a). The second method is to construct Species Sensitivity Distributions (SSDs) that can be applied when knowledge on dose-effects relationship is adequate with regard to the problem formulation. The rules used to select the benchmarks can be clearly defined and thus provide a more transparent and robust approach to dealing with uncertainty. Finally, for Tier 3, a quantitative uncertainty analysis may be performed while selecting a given likelihood of effect for a given assessment endpoint.

To be able to practically apply the ERICA tiered approach we need risk assessment screening values for risk characterisation within Tiers 1 and 2. The derivation of these values needs to be based on methods that ensure generic freshwater, marine and terrestrial ecosystems are protected from detrimental effects (on structure or function) under accidental (acute) or chronic releases of radionuclides. Such screening values are used to guide risk assessors at various decision points in the tiered approach. More precisely, they are:

- In Tier 1, screening values that correspond to limiting activity concentrations in media (Predicted No-Effect Concentration (PNEC, in Bq/L or Bq/kg) obtained by back-calculation from the dose(rate) screening values used in Tier 2;
- In Tier 2, screening values that correspond to Predicted No-Effect Dose (PNED, in Gy) and Predicted No-Effect Dose-Rate (PNEDR, in µGy/h) for acute and chronic scenarios respectively.
- In Tier 3, no predefined values are proposed. Instead, methods to derive refined PNED(R) for a specific ecosystem, community, endpoints, etc, are proposed including a probabilistic approach.

[1] Within Ecological Risk Assessment methodology, the term “benchmark” designates any value that is used for a comparison purpose. More precisely, a benchmark value becomes a screening value when it is used for screening purpose.

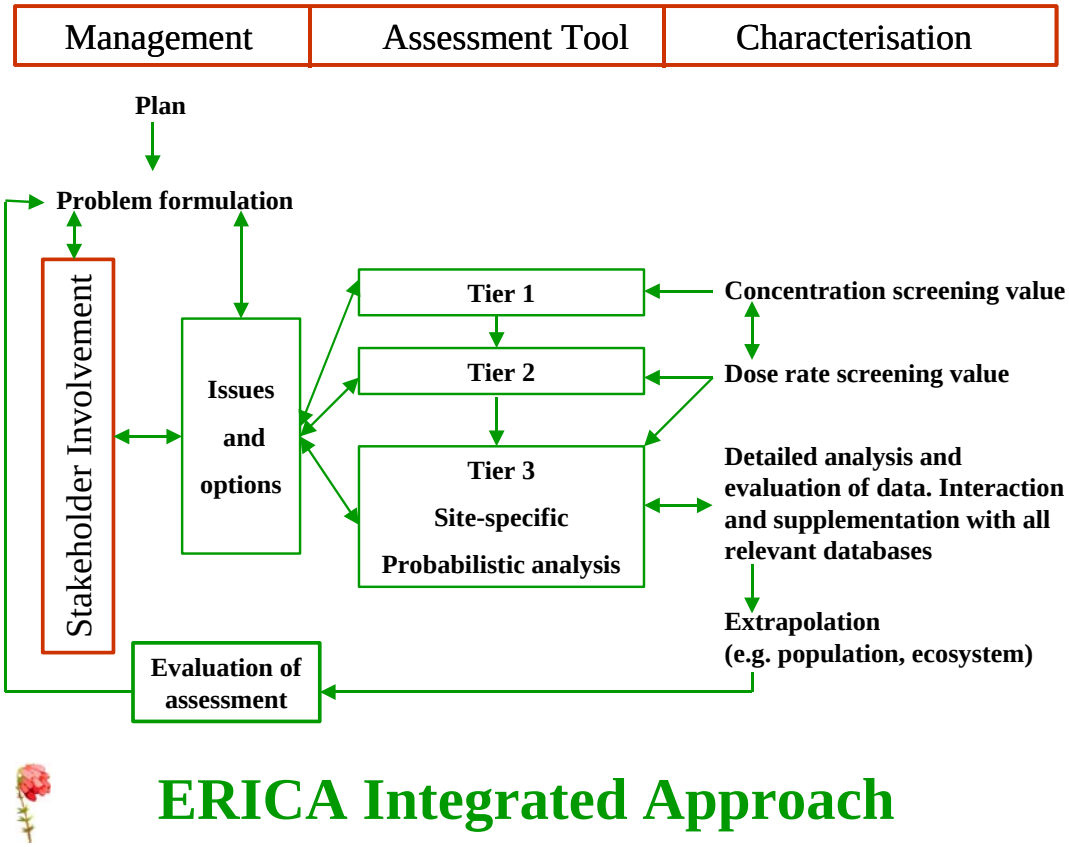

Figure 1. Working model of the ERICA Integrated Approach, depicting its three main integrated features: An assessment tool, methodology for risk characterisation and guidance for stakeholder involvement and decision-making (management).

Starting from the problem formulation and scoping, ***Tier 1*** *corresponds to a risk screening exercise.* ***Tier 2*** *is refined in terms of exposure analysis and corresponds to a generic assessment. Tiers 1 and 2 use as screening value the Predicted-No-Effect-Dose-(Rate) (PNED(R)) that is derived from knowledge on radionuclide effects on non-human species. Tier 1 proposes a back-calculation of corresponding screening values – the environment media limiting concentrations expressed in Bq/L or Bq/kg- for the main media (i.e. water, sediment, soil, air) and for each radionuclide. For a given radionuclide, these screening values (one per medium) correspond to the minimum value among all back calculations from the PNED(R) basis for all reference organisms. At Tier 2, the PNED(R) is used directly and is compared to the calculated dose rate for the set of reference organisms.* ***Tier 3*** *proposes the use of site-specific data and probabilistic methods to calculate the risk (no benchmark values are proposed a priori).*

1.1.2 Uncertainties and extrapolation issues

The common method to deal with uncertainty in ERA is to propose extrapolation rules. Extrapolation may be defined as the process of relating observations of the behaviour of one system to behaviour of another system or of the same system in different conditions (Suter, 1993). Extrapolations over time, space, taxa, stressors,

level of biological organisation are common practice when producing ERAs. This can apply for exposure and effects analyses, and for risk characterisation.

As the effect analysis constitutes an important component within any tier of a tiered approach, and requires various degrees of confidence each corresponding to the selected protection level, the ERICA Consortium decided to focus this report primarily on effects. The work covers an evaluation of the methods used to derive "no-effect levels", namely the PNED(R), and also covers quantification of the main sources of uncertainties associated with these criteria. The key extrapolation issues that are known to influence the proposed values are listed in Table 1. The method applied to address the various issues, and to quantify the remaining uncertainty is also briefly reported. Since screening values used for Tiers 1 and 2 are conservative, a number of key issues will only be treated when Tier 3 is needed. This includes refined problem formulation-driven effects analysis and associated benchmarks based on particular criteria of importance within the assessment being conducted.

Extrapolation issues related to the exposure analysis, reflecting the variability of the DCCs (Dose Conversion Coefficients), the Kds and Concentration Ratios among species and to the lack of values for a number of combinations (radionuclide, exposure pathway, species) are integrated within WP1.

Table 1. Key extrapolation issues and applied methodology to address each issue at each tier and to quantify the remaining uncertainty. The last column indicates the section in this report where the results are presented.

Key issue	Effect analysis	Section
Acute-high dose *vs.* chronic-low dose rate	**Tiers 1 and 2** Ecotoxicity data exists for acute effects and for chronic effects; they can be used separately to derive benchmarks providing protection at the ecosystem level for acute and chronic exposure scenarios.	4
	Tier 3 Use of existing chronic effect data for representative species; Derivation of Acute to Chronic Ratio (ACR) on the basis of effect data for a given wildlife group (*e.g.* vertebrates, invertebrates, plants) and refining benchmarks according to the problem formulation. Experimental refinement can also be performed by additional chronic studies.	5.3 5.4
External (γ) *vs.* Internal (α, β)	**Tiers 1 and 2** Derived benchmarks deal with ecotoxicity data describing effects caused by external γ irradiation only. A safety factor is applied to account for differences relating to internal emitters and thereby ensure conservative estimates.	4
	Tier 3 Experimental refinement also combined with statistical analysis of existing Relative Biological Effectiveness for various effects will help to refine benchmarks as required by the problem formulation.	5.5
Individual *vs.* population	**Tiers 1 and 2** Derived benchmarks deal with ecotoxicity data describing effects observed at the individual level. A safety factor is applied to account for this issue and thereby ensure conservative estimates.	4
	Tier 3 Experimental refinement combined with population dynamic modelling will help to refine benchmarks as required by the problem formulation.	5.5
One species to another	**Tiers 1 and 2** Derived benchmarks deal with ecotoxicity data describing effects observed at the individual level for a set of species. These data are analysed in terms of Species Sensitivity Distribution among generic ecosystems.	4

Key issue	Effect analysis	Section
	Tier 3 Species Sensitivity Distribution appropriately stratified for key-trophic level or wildlife community (*e.g.* fish) will help to refine benchmarks as required by the problem formulation.	5.2 5.3
Population vs. higher organisational levels	**Tiers 1 and 2** Derived benchmarks deal with ecotoxicity data describing effects observed at the individual level. A safety factor is applied to account for board this issue and thereby ensure conservative estimates.	4
	Tier 3 Predator-prey interaction modelling and/or safety factors will help to refine benchmarks as required by the problem formulation. This will be treated while applying an ecologically relevant weight to each trophic level to improve the ecological realism of a well-known ecosystem.	5.2
Single RN *vs.* multi-contaminants	**Tiers 1, 2 and 3** Whatever the tier, risk will be considered separately for each stressor but will allow addition (Added risk approach). For radioactive substances with low specific activity (*e.g.* U), data will be provided to assess risk for both chemical toxicity and radiological toxicity.	in D-ERICA

1.2 Why do we need to derive "no-effect" values and how?

Within any ERA, environmental "no-effect" levels used to characterize the risk have to be derived in a transparent way, and need to be based scientifically on well-defined assumptions and rational ecotoxicity data treatment. Expert judgment does not itself constitute a robust argument. For chemicals, the Technical Guidance Document (EC, 2003) suggests that Predicted No-Effect Concentrations (PNEC) are derived by using fixed safety (or assessment) factors varying from 10 to 1000 when few ecotoxicity data are available, or variable safety factor from 1 to 5 when the data set is more adequate. In the later case, PNEC values are calculated on the basis of Species Sensitivity Distribution (SSD) associated with a cut-off value set at a protection level of 95% of the species. In other words, the Hazardous Concentration is defined as that which affected 5% of the species. At present, for radioactive substances, existing expected "no-effect" levels of exposure for non-human species come from expert judgement based on critical literature reviews in the field of radiobiology performed by several organizations: NCRP, IAEA or UNSCEAR (IAEA, 1992; NationalCouncilonRadiationProtection, 1991; UNSCEAR, 1996). The FASSET critical review of effects of ionising radiation on flora and fauna concluded for chronic exposure conditions that "*the reviewed effects data give few indications for readily observable effects at chronic dose rates below 100 µGy/h*". However, it was advised that "*using this information for establishing environmentally "safe levels" of radiation should be done with caution, considering that the database contains large information gaps for environmentally relevant dose rates and ecologically important wildlife groups"* (FASSET, 2003). In any case, to date, no method to derive these so-called safe levels has been proposed. The lack of scientifically supported "no-effect" levels may constitute a strong limitation to our capability to conceive and apply a robust methodology for ERA within the field of environmental radioprotection, and to make a defensible risk estimate. This point has been largely discussed and agreed upon during the EUG event devoted to standards and criteria in Freising, Germany (ERICA, 2005c).

1.3 Structure of the report

Firstly, a brief overview is presented of the methodological framework promoted by the EC for risk assessment of new and existing hazardous chemicals (EC, 2003). The adaptations needed to enable derivation of ecotoxicity benchmarks for the case of radioactive substances are then developed. This is used as a basis to derive the benchmark values for the ERICA Integrated Approach (Section 2). Section 3 gives an overview of the available effects data in the FRED database and explains how this knowledge was critically analysed for its relevancy. Once the identification and collection of relevant effect data was carried out, the selected data sets were used to (re)construct dose(rate)-effect relationships in a systematic approach to provide estimates of critical ecotoxicity values for both acute and chronic external γ irradiation exposure conditions. In Section 4, issues and practices related to factors which may influence the derived benchmark values are discussed (*e.g.* domain of application, extrapolation issues and proposed methods, background concentrations etc) before applying methods for deriving the PNED(R) and evaluating the relevancy of these values as screening dose (rate) values in Tiers 1 and 2. Section 5 is devoted to cases where refined effects analysis is needed with regard to the problem formulation and/or to the options highlighted by results of Tiers 1 and 2, for instance asking the assessor to move to Tier 3. The problem formulation-driven effect analysis could deal with: (i) a particular target of protection such as well-known ecosystems, a specific wildlife community or keystone species; (ii) effects such as those affecting reproduction, (iii) extrapolation issues such as from individual to population, or external to internal irradiation effects. The discussion of these issues has been supported both by theoretical developments (modelling) and by experiments under controlled conditions to simulate how effects observed at the individual level propagate at the population level and how effects observed during external irradiation exposure modulate when the dose is delivered by internal irradiation exposure. Guidelines for the design and statistical analysis of experiments carried out within WP2 are given in D5-Annex Part A and experimental results are presented in detail in D5-Annex Part B.

Finally, the conclusion (Section 6) reiterates the derived screening dose (rate) values for Tiers 1 and 2, their associated uncertainties and the various possible operational uses of such “no-effect” level values within any prospective or retrospective ERA, for radioactive substances. It also summarizes various methods and options for refining the effect analysis at Tier 3.

2 The EC method proposed to derive "no-effect" values for chemical substances. Adaptations needed for radioactive substances.

A number of regulatory bodies have proposed methodologies for the development of screening or benchmark values applicable within ERA (CCME, 1996; EC, 2003; RIVM, 2001; USEPA, 1998). Since 1996, the European Commission has promoted a pragmatic way to develop an assessment of effect and to characterize risk to ecosystems with the minimum amount of empirical information (EC, 2003). Within this context, an extrapolation methodology and the rationale behind it are of major importance (Forbes and Calow, 2002a). Two techniques are proposed: the safety factor method or the statistical extrapolation method (Species Sensitivity Distributions). In the context of EU risk assessment, both these techniques have been applied for a number of chemical substances but never for radionuclides and/or ionising radiations. Applying the same methodology for all contaminants, including radioactive substances, should ensure the consistency of any prospective or retrospective ERA with regard to the protection of ecosystems against adverse effects whatever the contaminant under consideration.

Note also that, at the European level, all approaches for risk assessment or setting environmental quality standards are very similar since the application of safety factors depending on the quality and quantity of available toxicity data is a common core element (Lepper, 2002). The reasons for selecting the European approach for deriving screening values for radioactive substances is two-fold:

(1) it will keep the ecological effects assessment methodology within the EU as consistent as possible whatever the stressor;

(2) the application of a similar methodology for deriving quality standards will aid any future potential regulatory purpose in the field of radioprotection of the environment, as this derivation methodology has already been accepted and agreed at the European level.

In the latest version of the TGD (EC, 2003), the proposed methodology is said to address the concern of the potential impact of individual substances on the environment by examining both exposures resulting from discharges and/or releases of chemicals as well as the effects of such emissions on the structure and function of ecosystem. With the aim of protecting aquatic, terrestrial and air compartments, the methodology has been developed for: (1) inland risk assessment with associated methods designed for aquatic ecosystems (including sediment), terrestrial ecosystems, top predators, micro-organisms in sewage treatment systems and atmosphere; and (2) marine risk assessment with associated methods designed for aquatic ecosystems (including sediment), top predators. Risk of chemicals through food-chain accumulation is also addressed (through the "top predator" compartment) as well as risk to the proper functioning of sewage treatment plants which is generally considered to be important for the protection of the aquatic environment.

The terminology employed in the EC TGD emphasizes that a number of extrapolation issues are considered in the risk assessment methodology, since the primary objects of protection are the structure and function of ecosystem. These are then simplified into a limited set of primary compartments (aquatic, terrestrial and atmosphere) to be considered, and also combined with a simplified ecosystem function through trophic pathway.

The PNECs are toxicity-based criteria combined with extrapolation rules that correspond to a "no-effect" or threshold values. These values are defined as the concentration below which unacceptable effects on organisms will most likely not occur. The TGD proposes methods for the derivation of PNECs for short-term exposure conditions (corresponding to acute and/or intermittent releases) and for long-term exposure conditions (chronic and/or continuous releases).

2.1 Description of the method: from the data sources to the proposed predicted no-effect value

This part will be very brief as the method recommended by the European Union for existing chemicals is described in detail in the Technical Guidance Document (EC, 2003).

All existing approaches are based on available ecotoxicity data arising from ecotoxicity tests, typically EC_{50} for acute exposure conditions (short-term) and EC_{10} for chronic exposure conditions (long-term). EC_{10} is preferred toNo Observed Effect Concentration (*NOEC)* as this typical value depends on the experimental design.

For practical reasons, the TGD acknowledges that the effects of chemicals on a given ecological receptor must be predicted from a limited set of test data as it is impossible to test all potentially exposed species prior to any chemical releases. This statement means that predictive assessment inevitably involves extrapolations while also retaining an awareness of the associated uncertainties.

Common to all international approaches and all environmental media is the basic step-wise approach of gathering data, selecting a subset of suitable data, estimating effects-based criteria and determining final threshold values and their domain of application (EnvironmentAgency, 2003; ERICA, 2005a).

2.1.1 Gathering and selecting relevant data

Within the TGD, the PNEC derivation is based on the basis of data from ecotoxicity tests. These data need to be evaluated with regard to their adequacy (*i.e.* reliability of the available data and relevance for environmental risk assessment) and completeness. For the latter, the base-set for aquatic ecosystems, requires that short-term effects data are available for the standard test species: fish, daphnia and algae. Non-standard test species can also be taken into account. Data reliability is based on an examination of the adequacy of the ecotoxicity test to the standard European methods or internationally recognised guidelines (OECD) and to good laboratory practice. The method used to estimate the critical toxicity endpoint (*e.g.* $L(E)C_{50}$ for short-term studies and *NOEC*, *LOEC*, EC_x for long-term studies) needs also to be critically examined.To apply the SSD method to derive the PNEC, the fulfilment of a number of additional requirements is needed: for example assignation of ecotoxicity data (*NOEC*s) to a minimum number of taxonomic groups (at least eight “pseudo” groups), and a minimal sample size (at least 10 *NOEC*s). In all cases, the idea is to keep the data set as representative as possible of the biodiversity existing in European ecosystems.

Typically, the measurement endpoints tested in the laboratory are survival, growth and reproduction of species whilst in the field the assessment endpoints include ecosystem structure and function attributes. An extrapolation rule is therefore needed to link the two endpoints (laboratory and field). There is an inherent assumption that the laboratory data can be applied to protect populations of single species and that the use of an appropriate level of individual species protection confers protection on populations, communities and ecosystem even though many of the species that will be potentially exposed have not been tested (Versteeg *et al.* , 1999).

2.1.2 Data extrapolation and risk assessment benchmark derivation

It is becoming widely recognised that the extrapolation problem could be addressed most fruitfully if once the assessment endpoint is defined, assessors consider how the risk might be estimated given the array of possible tests and extrapolations. The TGD proposes that the problem should address the generic ecosystems to be protected and under conservative assumptions that correspond to the screening tiers of a tiered approach.

Safety/Assessment Factor method

According to the review and critical evaluation of this concept by Chapman *et al.* (1998), the term safety factor covers any means by which known data are extrapolated to deal with situations for which there are no data (Chapman *et al.* , 1998). A brief review of this has been produced in D4b (ERICA, 2005a). Overall, the selection of the magnitude of the safety factor to be applied is more a policy decision than one based on a scientific approach. These factors are often in powers of 10. The most common method is to multiply or divide by a factor that accounts for the necessary extrapolation. If several extrapolations are required several safety factors are usually combined in series. The method is highly conservative as it implies the multiplication of several worst cases. Within the TGD, the PNEC is calculated by dividing the lowest short-term $L(E)C_{50}$ or long-term *NOEC* values by an appropriate safety factor. The extrapolations are grounded in two main underlying assumptions of this conceptual approach: (1) the ecosystem response depends on the most sensitive species and (2) protecting ecosystem structure protects community function. Subsequently, many extrapolations are made from: (i) acute to chronic, (ii) one life stage to the entire life-cycle, (iii) individual effects to effects at the population level, (iv) one species to many species, (v) one exposure route to an other, (vi) direct to indirect effects; (vii) one ecosystem to another and (viii) in time and place. When a limited set of toxicity data is available, a constant safety factor is often used to extrapolate from the effect concentration to the PNECs for ecosystems according to a number of well-defined rules as shown in Table 2.

Table 2. Safety factors and SSD (species sensitivity distribution) applied to derive PNEC (Predicted No-Effect Concentration), depending on the quantity and quality of the available toxicity data. Illustration for freshwaters adapted from the TGD (EC, 2003). For information on other ecosystems, see the TGD.

Available toxicity data	Safety factor	Extrapolation
At least one short-term $L(E)C_{50}$[1] from each of three trophic levels of the base-set (fish, Daphnia and algae)	1000	Acute to Chronic and single species to ecosystem
One long-term *NOEC*[2] (either fish or Daphnia)	100	Single species to ecosystem
Two long-term *NOEC*s from species representing two trophic levels (fish and/or Daphnia and/or algae)	50	
Long-term *NOEC*s from at least three species (normally fish, Daphnia, algae) representing three trophic levels	10	
Species Sensitivity Distribution[3] method	5 - 1 (case by case)	

1 -$L(E)C_{50}$ 50% Lethal or Effect Concentration is defined as the concentration associated with 50% change in the (average) level of the endpoint considered.
2 - The No Observed Effect -Concentration is the tested concentration just below the *LOEC*. The Lowest Observed Effect-Concentration is the lowest Concentration out of the tested Concentration at which a statistically significant difference from the control group is observed. They are both obtained by experimental observations and hypothesis testing.
3- Species Sensitivity Distribution is a statistical extrapolation method that can be used to derive a PNEC if data are sufficient in quality and quantity for its application.

Species Sensitivity Distributions and cut-off value

The most recent version of the TGD proposes that PNECs can also be calculated with statistical extrapolation models under the assumption that the variability in the sensitivity of the test species is representative of the variability of all species in the ecosystem. In this case, the extrapolation is from a standard test endpoint (or a mixture of ecologically relevant endpoints) for a set of tested species to the same endpoint (or mixture of endpoints) in the full set of potentially exposed species. This includes the assumptions that: (1) the variability in the sensitivity of the laboratory-tested species is similar to the variability among the species in the field; and (2) the endpoint measured in laboratory tests is indicative of effects on populations in the field. A concentration is derived which is hazardous for only a small fraction of the species in the ecosystem. The Hazardous Concentration 5 % (HC_5) is recommended by the TGD as an intermediate value in the determination of the PNEC, which is then obtained by applying a safety factor ranging from 1 to 5. A 50 % confidence interval associated with this HC_5 is also derived. A number of points are considered to determine the size of the safety factor applied (*e.g.* quality of the database, diversity of the taxonomic groups, statistical uncertainties around the 5th percentile estimate).

One of the advantages of this approach is that it makes use of the whole range of selected toxicity data and not of only the lowest value. It also allows identification of the most sensitive groups of species. However, the quality of the derived HC_5 depends strongly on the quality of the selected data set. This highlights the importance of the approach used to acquire the ecotoxicity data through appropriate laboratory testing. It stresses also the importance of applying adequate statistical data treatment to estimate the critical toxicity

endpoints (*i.e.*, the *NOEC*, and/or the EC_{10} for chronic exposure conditions) that constitute the primary information for the establishment of any SSD (see D5-Annex part A).

The SSD method requires the selection of an appropriate level of protection and the confidence limits around the protection threshold. Thus a third assumption of the method is that the structure and function of the ecosystem will not be adversely impacted by the effects on the 5 % of species lying below the cut-off value. Three extrapolation models from single-species individual-level endpoints to structure and process of ecosystems can be proposed in support of this assumption (Table 3). Note that the first and the second theory are very similar. However, whichever of these three models is applied, the aim of the cut-off value selection is to indirectly protect ecosystem structure and processes by protecting the most sensitive species. The more functional redundancy that there is in a system, the more overprotective such an assumption will be (Forbes and Calow, 2002a). In the difficult case of keystone species, the only way to deal with a cut-off value for the protection level is to identify those species that would be "unprotected" and to examine whether they correspond to one of the keystone species of interest within the assessment.

Table 3. Different theories of the relationship between structure and processes in a given ecosystem, and their main implications in their use for risk assessment. Adapted from Forbes and Calow (2002a).

Ecological Theory	Reference	Implications for ERA
Each time one species is removed, the structure of the ecosystem is weakened gradually resulting in functional failure	"the rivet popper hypothesis" (Ehrlich and Ehrlich, 1981)	Changes in ecosystems structure and processes are closely connected each other. Either one provides relevant endpoints for risk assessment
Several species in an ecosystem perform the same process	"the redundant species hypothesis" (Walker, 1991)	As certain species are removed, others take over their function. Changes in structure are more sensitive than changes in process
Certain species play much larger functional role than others	"the ecosystem engineers hypothesis" (Copplestone *et al.* , 2001)	Many non-keystone species could be lost without any observed changes in function. If a single keystone species were to be removed, dramatic changes could occur in the structure and functioning.

PNECs derived by the proposed methodological framework in the TGD do not explicitly account for a possible combined action of pollutant mixtures. Nonetheless, it is assumed that the safety factors applied in the effects assessment do cover the possible occurrence of combined action of pollutants in most instances to a great extent. For the time being, there is apparently no consolidated and validated approach to account for the combined action of pollutants available.

2.2 Adaptations needed for radioactive substances

D4b (ERICA, 2005a) reviewed the similarities and differences in assessing radioactive substances and other hazardous substances. In general, generic frameworks for chemical and for radionuclide risk assessments have much in common and in any case the overall goals of protection need to be compatible.

There are, however, some differences between radionuclides and chemicals that need to be addressed. with a consideration of radionuclides involves the use of a specific unit to calculate the absorbed dose. Radiation dosimetry is therefore essential to convert exposure concentration in a given medium or biota into the quantity

of energy absorbed by an organism from both internal and external sources. A variety of factors need to be considered including the size of the organism, its location (*e.g.* soil or surface dwelling) and the extent to which the radioactive substances transfers from environmental media to biota. The pathways for internal exposure are similar for both radioactive and non-radioactive substances including the common key problem of speciation and bioavailability. Unlike chemicals, however, the presence of radioactive substances in environmental media can bring about an increase in external radiation dose (rate) without the need for absorption of the radioactive substance. It is therefore necessary to establish a relationship between exposure and dose by means of dosimetric calculation to estimate the absorbed dose(rate). For the effect analysis and the derivation of predicted no-effect dose(rate), a common feature between radioactive and non-radioactive substances, is that the dose-effect relationships are mainly based on adverse effects at individual level with preferred consideration of demographic endpoints (*e.g.* reproduction, growth, survival). However, all effects data existing for radionuclides are expressed in terms of absorbed dose (rate) to which the organism has been exposed rather than the exposure concentration. In other words, for chemicals, dosimetry is generally not applied. This implies that risk is characterised in a one-step analysis (exposure –effect) for chemicals, whilst for radionuclides a two-step calculation is needed (exposure-dose followed by dose-effect). One consequence of this is that the scientific credibility of the suggested back-calculation from PNED(R) to PNEC for the purpose of Tier 1 is strongly linked to the robustness of dosimetric estimation and to the ecological relevancy of the exposure scenario associated with the reference organisms.

In ERICA, the PNED(R) used for Tiers 1 and 2 are derived on the basis of data from FRED. Since dose-effect relationships have not been mathematically structured, a mathematical treatment is needed to obtain robust critical ecotoxicity data, namely the ED_{50} or EDR_{10} for acute and chronic exposure conditions respectively. To conclude, whichever method is used, the robustness and the scientific credibility of the derived screening dose (rate) for radionuclides will be strongly linked to the relevance and quality of the critical ecotoxicity data set selected.

3 Evaluation of ecotoxicity data sets and application to FRED

3.1 Overall presentation of the effects data from FRED

The primary source of information to derive a radionuclide effect benchmark is the FREDERICA database. This includes data from FRED covering the period 1934-2002 (FASSET, 2003) plus data from 2003-2004 added into FREDERICA. At the present time, data from the EC-funded EPIC project have not been included in the data treatment. The extension of the application of the method to the whole database will be considered in 2006.

Over 26,000 data entries in FRED were analysed from more than a thousand literature references. These data correspond to pairs of points (exposure level, biological effect) along with information on the conditions in which these data were experimentally obtained (*e.g.* the tested species and its life stage, the exposure regime defined by the exposure duration and the irradiation pathway, the effect endpoint etc.). As for chemicals, experimental studies of the effects of ionising radiation on living organisms are broadly divisible into those that employ either acute[2] exposures, or chronic[3] exposures. The FRED data are also organized into pseudo-taxonomic groups as follows: amphibians, reptiles, aquatic invertebrates, aquatic plants, bacteria, birds, crustaceans, fish, fungi, insects, mammals, mosses/lichens, soil fauna, terrestrial plants and zooplankton), which are themselves allocated to an ecosystem type (aquatic ecosystems – generic, freshwater, marine and brackish – and terrestrial ecosystems – generic, agricultural, forest, semi-natural grassland). As these wildlife groups are not mutually exclusive in terms of taxonomy, they were also grouped for the ERICA analysis into the "trophic level" (*i.e.* primary producers or plants, invertebrates and vertebrates).

In terms of biological effects the vast majority of the data comes from effects observed on an individual level followed by a sub-individual level. The biological effects were grouped into 4 categories of effects, which may have more or less relevance for use on a population-wide level:

(1) morbidity including growth rate, effects on the immune system, effects on behaviour linked to central system damage;

(2) mortality including the stochastic effects of mutation at the somatic cell level and the consequences for cancer formation, and the deterministic effects which alter mortality rates and life expectancy;

(3) the reproductive capacity including fertility, fecundity, embryo development; and

(4) mutations of somatic and reproductive cells.

Table 4 gives an overview of the quality and quantity of available data within FRED, adopting a simplified categorization (ecosystem type, exposure duration and irradiation pathway). Allocation of effects data is strongly weighted in favour of terrestrial ecosystems (73 % of all data) and for each ecosystem, the available data appears to be biased roughly 2:1 in favour of acute data and an external γ irradiation exposure situation. As a consequence, chronic effect data information is limited and largely dominated by external γ irradiation exposure conditions. This brief examination of the available knowledge on effects of radioactive substances on non-human species demonstrated that only data devoted to effects induced by external γ irradiation pathway are quantitatively adequate to be mathematically processed in terms of dose-effect relationships. These exposure irradiation pathways have been experimentally obtained using γ sources (frequently either Cs-137 or Co-60).

[2] periods of time that are short, usually minutes but less than an hour, in comparison with the time taken for an effect to become apparent, and usually at a high dose rate.
[3] over all, or a large part, of the life stage of interest, and usually at relatively low dose rates.

Table 4. Allocation of effects data within the FRED database to freshwater, terrestrial and marine ecosystems, and to the radiation exposure regimes (duration and irradiation pathways).

			Data per exposure duration			Data per exposure irradiation pathway		
Ecosystem (number of references)	Total number of data	(%)		Total number	%	External	Internal	Other[a]
Terrestrial (579)	19983	(72.6)	acute	12273	61.4	11564	288	421
			chronic	6795	34.0	3449	344	3002
			transitory[b]	913	4.57	670	40	203
			not stated	2	0.03	0	0	2
Freshwater (195)	6067	(22.0)	acute	4526	74.6	4058	97	371
			chronic	1484	24.5	970	20	494
			transitory	54	0.89	12	2	40
			not stated	3	0.01	0	0	3
Marine (45)	1470	(5.4)	acute	1116	75.9	995	58	63
			chronic	353	24.1	286	0	67
			transitory	0	0	0	0	0
			not stated	1	0	0	0	1

[a] "Other" means that the experiment reported in the literature was devoted to the study of effects involved by mixed irradiation pathways, and/or not well characterized to be used for the present analysis.
[b] "Transitory" means in between "acute" and "chronic" in terms of exposure duration.

3.2 Completeness and adequacy (reliability and relevance) of toxicity testing data used for the derivation of screening values. Methodology applied to FRED data

3.2.1 Overview of the approach

The application of any method to derive robust effect benchmarks obviously depends on its relevance with regard to the problem formulation, and the quality and the quantity of the available critical ecotoxicity data. No standardized ecotoxicity tests exist for radioactive substances and therefore there is a wide range of heterogeneity at several levels *e.g.* test species, exposure conditions, observed effects, range of dose or dose rate, *etc*.

It is possible, however, to extract a coherent data sub-set from each experiment in FRED (Figure 2-step 1) and to apply a systematic mathematical treatment to (re)construct dose(rates)-effect relationships (Figure 2-step 2) and thereby derive critical toxicity endpoints. For acute exposure, the critical data are the estimated ED_{50} (in Gy) or Effect Dose giving 50 % change in observed effect – this corresponds to the classic EC_{50}. For chronic exposure, the critical data are the estimated EDR_{10} (in µGy/h) or Effect Dose Rate giving 10 % change in

observed effect –corresponding to the EC_{10} preferred to the *NOEC* (Crane and Newman, 2000; Scholze *et al.* , 2001). The third step of the methodology uses these critical toxicity data to derive a Predicted No-Effect Dose (*PNED*) or Predicted No-Effect Dose Rate (*PNEDR*), corresponding to the PNEC as defined in the TGD (EC, 2003).

Depending on the available data set in terms of number of data and biodiversity, the Safety Factor method or the Species Sensitivity Distribution method (SSDs) was applied to estimate the screening values. With SSD, doses (or dose rates) were estimated below which 95 % of these species in the aquatic/terrestrial ecosystem should be protected. These are defined as the HD_5 – Hazardous Dose giving 50% effect to 5% of species—or HDR_5—Hazardous Dose Rate giving 10 % effect to 5 % of species. The final screening dose (rate) values for application in tiers 1 and 2 (*PNED* or *PNEDR*) are then obtained by applying a safety factor (*SF*) to take on board remaining extrapolation uncertainties (*e.g.* an irradiation pathway dominated by internal dose from α or β emitters, those emitters being more biologically efficient (FASSET, 2004; UNSCEAR, 1996)).

The calculation can be summarised as:

$$PNED = \frac{LowestED_{50}}{SF} \text{ and } PNEDR = \frac{LowestEDR_{10}}{SF}$$ when the Safety Factor method is applied.

Or

$$PNED(R) = \frac{HD(R)_5}{SF}$$ when the SSD method is applied.

Note that for chemicals, when SSD is applied, the *SF* may vary from 1 to 5. In situations where the safety factor method is used *(i.e.* on small data sets where the PNEC is calculated by dividing the lowest short-term $L(E)C_{50}$ or long-term *NOEC* values by an appropriate safety factor), this factor varies from 10 to 1000 depending on the quality and quantity of the primary data (see Table 2).

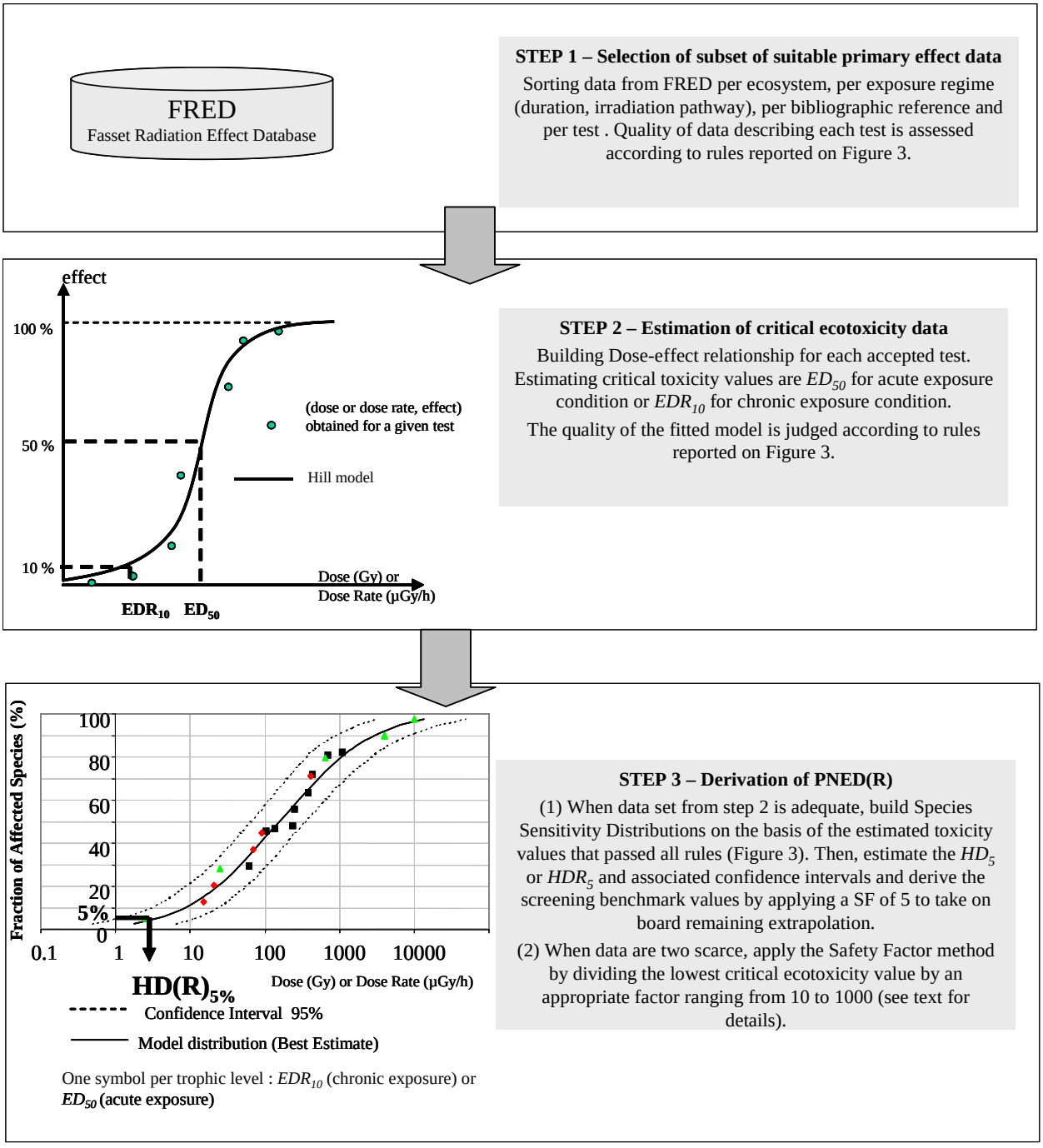

Figure 2. The three-step methodology followed to assess the relevancy of FRED data to obtain consistent toxicity values for acute and chronic exposure conditions (Steps 1 and 2) and to derive screening dose (rate) values (Step 3). *ED_{50}* is the dose giving 50 % effects in comparison with the control group and *EDR_{10}* the dose rate giving 10 % effects in comparison with the control group. *$HD(R)_5$* is the estimated Hazardous Dose(Rate) affecting 5 % of the species in a given ecosystem according to a SSD-type analysis.

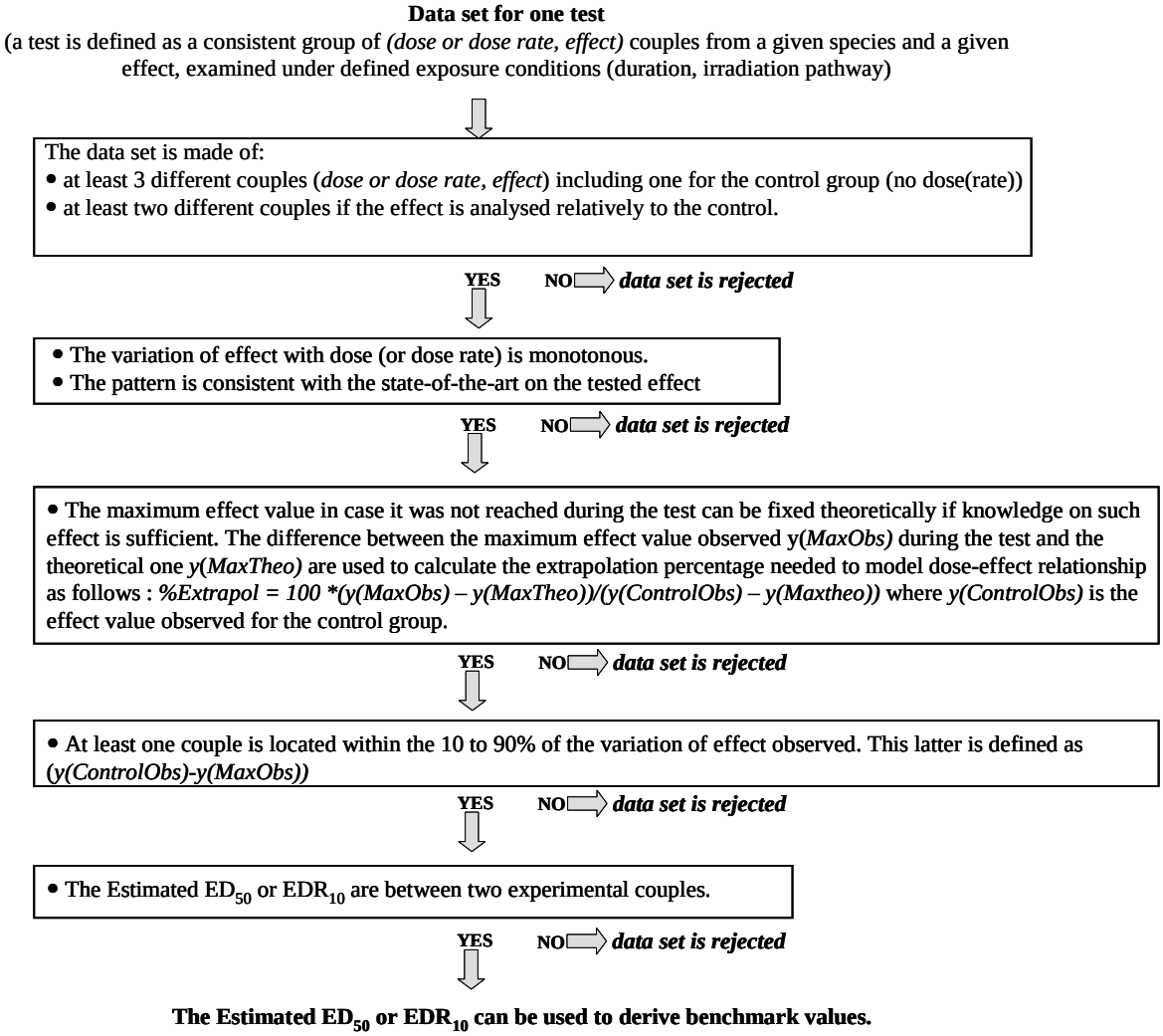

Figure 3. Rules applied on each data set from FRED to estimate and then select consistent, relevant and reliable toxicity values for the derivation of screening dose (rate) values.

3.2.2 Statistical process for Dose-effects modelling

A number of assumptions were needed concerning the quality of the data submitted to the mathematical treatment. Each data point from FRED was considered to be representative of the mean of a statistically correct number of replicates as this information is missing in the database. A number of rules were applied to test the data for acceptance or rejection of a consistent sub-set of data as described on Figure 3. Here a sub-set of data or a test is defined as the number of couples of dose(rate), observed effect endpoint from the same literature reference, a given tested species and a given effect examined under defined experimental conditions combining exposure duration and irradiation pathway. At first, monotonous dose(rate)-response curves were

modelled using the commonly used model based on the Hill equation. The common form of the dose (or x) – response (or y) curve is as follows:

$$y(x) = (y(\infty) - y(0)) \times f(x) + y(0) \qquad \text{(Eq.1)}$$

where $y(0)$ and $y(\infty)$ are the boundaries of the effect zone: *i.e.* the known response at zero dose (the control group) and the effect expected for a dose tending towards infinity respectively; and *f(x)* is a probability function of the dose varying from 0 to 1 with the dose. Two parameters: the Hill number *nH* and the Dose(Rate) giving 50% effect $ED(R)_{50}$ are characteristics of the probability function in a Hill model as follows:

$$f(x) = \frac{x^{nH}}{x^{nH} + ED(R)_{50}^{nH}} \quad \text{(Eq.2)}$$

The curve fitting is based on the Levenberg-Marquardt algorithm and enables the $ED(R)_x$ to be calculated. The $ED(R)_x$ is defined as the dose (or dose rate) that corresponds to x% of the effect with respect to the control. More precisely, the $ED(R)_x$ is the concentration for which x% of the maximum possible variation in response is observed. The extreme effect values, *i.e.* those obtained for the control group exposed only to the dose (or dose rate) corresponding to the natural background - *y(0)*, and the group subject to the maximum dose (or dose rate) in the experiment – $y(\infty)$ - need to be determined in a systematic and robust way as their values greatly influence the resulting curve fit. A rule to initiate the fitting process was defined as follows: if the control effect value *y(0)* is 0 (continuous data), 0% or 100% (percentage data), this value was imposed on the model. Otherwise, the control value could be adjusted. The value for the maximum effect $y(\infty)$ used was always imposed on the model to avoid erroneous estimation (>100% or <0% or < 0). The rules to determine whether a sub-set of data was accepted or rejected were then as follows:

Rule 1. The data sub-set contained, as a minimum, the measured effects for a control group and two additional different treatment groups. Two different dose (dose rate)-effect data pairs were accepted if the effect was measured relative to a control. In such cases, the control point was "reconstituted": 0 for the dose and 0 or 1 for the effect (according to the effect pattern). This rule results from a compromise between the fact that numerous data sub-groups contain only 3 points, and the need for at least a minimum level of accuracy to fit the dose-response curve.

Rule 2. The variation of effect with dose (or dose rate) was monotonous. If not, the sub-set of data was rejected.

Rule 3. When the maximum effect value could not be determined theoretically, the sub-set of data was rejected due to the lack of knowledge on the general characteristics on such effect. When the observed maximum effect value *y(MaxObs)* did not correspond to the theoretical one *y(MaxTheo)*, as, for example, in the case of a 100% mortality rate or 0% survival rate, the theoretical value was imposed on the Hill model. In general, an $ED(R)_x$ determined in this way was not a conservative value but had a real biological meaning. The extrapolation percentage needed to model dose(rate)-effect relationship was calculated as follows:

$$\%Extrapol = \frac{(y(MaxTheo) - y(MaxObs))}{(y(MaxTheo) - y(ControlObs))} x100 \qquad \text{(Eq.3)}$$

where *y(ControlObs)* was the effect value observed for the control group. The more important this percentage was, the less robust the dose(rate)-effect relationship was.

Rule 4. At least one point must fall in the [10%; 90%] interval of the "control value effect to the maximum effect value used" range *i.e. (y(MaxTheo)-y(ControlObs))*. This restriction ensured that the points were

relatively highly spaced so that the curve could be determined more accurately, particularly at the inflexion point, where the $ED(R)_{50}$ was located.

Rule 5. These estimates must be surrounded on either side by at least one point representing experimental data to be valid for use in building SSDs.

3.2.3 Building Species Sensitivity Distributions

The SSD method for deriving PNECs can approximate a community-Species Sensitivity Distribution (*e.g.* (Aldenberg and Slob, 1993; Van Straalen and Denneman, 1989)) based on the hypothesis that the species for which results of ecotoxicological tests are known are representative, in terms of sensitivity, of the totality of the species constituting a specific taxon, a selected species assemblage and/or a natural community. A likely distribution of species sensitivity is estimated from these results, which enables the calculation of a concentration that is assumed to protect a given percentage of the species in the ecosystem. According to the Technical Guidance Document (EC, 2003), it has been agreed that this should be the hazardous concentration affecting 5 % of species with 50% confidence (HC_5); equally, 95% of the species are thus protected with a confidence limit of 50%. This statistical approach raises a number of questions that are not discussed further (see Section 2.1.2) but which should be borne in mind when implementing the SSD approach (*e.g.* (Forbes and Forbes, 1993; Forbes and Calow, 2002a)).

The ED_{50} or EDR_{10} estimated using data sub-sets that passed the 5 rules described above were accepted as critical radiotoxicity values with which to build Species Sensitivity Distributions for acute or chronic exposure conditions respectively. The $ED(R)_x$ from data sub-sets for which the maximum theoretical effect value was reached during the experiment (*%Extrapol*=0), were preferred for building the SSDs. In cases where the number of these critical toxicity values were too small to establish reliable statistics (fewer than 10 data), the set of critical radiotoxicity $ED(R)_x$ data was widened by accepting an extrapolation range for the maximum effect value as defined above.

The SSDs were constructed using an Excel macro "Species Sensitivity Weighted Distribution" (SSWD) (Duboudin *et al.* , 2003). The various critical toxicity values that exist for the same species and the same category of effects were geometrically averaged according to the rule advised in the TGD. As a result, for a given species, a single value per category of effect was used to determine the SSD. Intra-species variation for the same effect category was therefore ignored *a priori* by calculating a geometric mean beforehand. For a given species, each piece of data for different effect categories was weighted to give each species the same weight. In other words, intra-species differences in effects are taken into account but no effect for a given species was given more importance than any other. All tested species were broken down into three taxonomic groups: plants or algae, invertebrates and vertebrates, which were assumed to be representative of the three trophic levels, primary producers, herbivores and predators.

For Tiers 1 and 2, SSDs were constructed without weighting for trophic level *i.e.* without considering the proportion of data in each trophic group within the dataset. The log-normal distribution was fitted to the dose(rate) data. The method used to build the SSD and their confidence intervals, considering the weights previously defined for each data point was that of the Direct Weighted Bootstrap method (DWB). The DWB method was used to construct samples in which the proportions of data among species (and among taxonomic groups if needed) corresponded to those desired. A non-equiprobable resampling of the data with replacement from the raw data (weighted and unweighted) or from species mean values was then conducted such that the probability of drawing each data point corresponded to the weighting coefficient previously defined. The number of samples used was 1000 and the number of data drawn for each one corresponded to that of the initial dataset (bootstrap *n* out of *n*). The $HD(R)_5$ of each sample was then calculated using a parametric approach (that assumed the distribution followed a log-normal form). Using the 1000 bootstrap samples, the median value, as well as the values corresponding to the 5 % and 95 % percentiles of the distribution, were

then obtained from the determined $HD(R)_5$ distribution. The goodness of fit was tested by a Kolmogorov-Smirnov test with a Dallal-Wilkinson approach and by the multiple R-square coefficient (R^2) between theoretical and empirical distributions.

4 Issues and practices in the derivation of screening values by using SFs or SSDs. Application to FRED selected data

As the data in FRED were sufficient in quantity and quality, it was possible to use the SSD methodology to derive benchmarks for radioecological risk assessment. Since the benchmarks are intended for use as screening values in Tiers 1 and 2, they need to be demonstrably protective of the structure and function of generic freshwater, marine and terrestrial ecosystems. In this respect, the approach selected is goal orientated. A comparison of the outcome of results from both the AF and SSD methods was made (see Section 4.2.5).

4.1 Application to generic ecosystems and ERICA screening values

4.1.1 Sets of acute and chronic ecotoxicity data.

Data quality control. At the time of input, all publications were screened by clearly defined selection criteria before data was accepted into the FRED database. Although selection criteria were clearly defined to accept or reject sets of data from a given publication at the time it was input into FRED (Daniel *et al.* , 2003). Despite their passing this set of criteria, , numerous data remained unsuitable usable for establishing the dose(rate)–effect relationships and thus for estimating the critical radiotoxicity values that could be used in an SSD-type analysis.. The reasons for this were varied but included, for example, erroneous input data, trend in relationship could not be described mathematically, too few pairs of exposure and effect, *etc.* Tables 5 to 10 list the percentage of usable data given per trophic level for each ecosystem and exposure regime. The maximum value obtained was 37% for terrestrial invertebrates and acute external γ irradiation exposure following application of steps 1 and 2 of the three-step methodology (Figure 2). No sub-set of data related to internal exposure conditions or chronic external γ irradiation exposure for freshwater plants passed the two first steps in Figure 2. As the same method was applied under a defined list of selection criteria/rules (see the five rules in Section 3.2.2), each piece of data was characterized by the same robustness as it had been subject to quality control, grouped by exposure duration (acute and chronic) and irradiation pathway (external, internal, mixed), and averaged within the effect category. Only the external γ irradiation pathway was sufficiently populated to implement the statistical data process as described.

Table 5. Set of ED_{50} geometric means per effect category (expressed in Gy) obtained from building dose-effect relationships using acute external γ irradiation data for freshwater ecosystems. The percentage of usable data from FRED to build dose-effect relationship is given per trophic level. No extrapolation was needed to build any of these regression models. The number (n) of data refers to the number of ED_{50} used to calculate the geometric mean.

Trophic level (% data usable)	Taxonomic group	Species	Effect category	n of data	Geometric mean (Gy)
Algae (15 %)	Algae	*Closterium moniliferum*	Mortality	1	430
Invertebrates (27 %)	Crustaceans	*Diaptomus clavipes*	Mortality	2	36.9
		Diaptomus clavipes	Reproduction	3	7.67
	Molluscs	*Physa acuta*	Reproduction	4	38.8
Vertebrates (20 %)	Fish	*Oryzias latipes*	Mortality	2	58.5
		Oncorhynchus tshawytscha	Mortality	2	9.3
		Carassius auratus	Mortality	5	35.2
		Oryzias latipes	Reproduction	5	14.6
		Carassius auratus	Reproduction	3	66.3
		Cyprinus carpio	Reproduction	3	5.63
		Salmo gairdnerii	Reproduction	4	3.43
	Amphibians	*Bufo fowleri*	Mortality	3	3.82
		Necturus maculosus	Mortality	1	5.38

Table 6. Set of EDR_{10} geometric mean per effect category (expressed in µGy/h) obtained from building dose-effect relationships using chronic external γ irradiation data for freshwater ecosystems. The percentage of usable data from FRED to build dose-effect relationship is given per trophic level. The range of the percentage of extrapolation needed to fit the regression model is indicated. The number (n) of data refers to the number of EDR_{10} used to calculate the geometric mean.

Trophic level (% data usable)	Taxonomic group	Species	Effect category	Range *% Extrapol.* (%)	n of data	Geometric mean (µGy/h)
Invertebrates (15 %)	Crustaceans	*Daphnia pulex*	Mortality	5-90	3	441815
			Reproduction	90-97	2	461491
		Daphnia pulex	Morbidity	15	1	27763
	Molluscs	*Physa heterostropha*	Reproduction	0	3	66578
Vertebrates (5 %)	Fish	*Poecilia reticulata*	Reproduction	1	1	516
		Oryzias latipes	Reproduction	0-2	2	54672

Table 7. Set of ED_{50} geometric means per effect category (expressed in Gy) obtained from building dose-effect relationships using acute external γ irradiation data for terrestrial ecosystems. The percentage of usable data from FRED to build dose-effect relationship is given per trophic level. No extrapolation was needed to build any of these regression models. The number (n) of data refers to the number of ED_{50} used to calculate the geometric mean.

Trophic level (% data usable)	Taxonomic group	Species	Effect category	n of data	Geometric mean (Gy)
Plants	Plants	*Pinus elliottii*	Morbidity	1	77.2
(10 %)		*Perennial ryegrass*	Morbidity	1	23.0
		Triticum aestivum	Morbidity	1	66.6
		Pinus sylvestris	Morbidity	1	35.6
		Festuca pratensis	Morbidity	2	32.0
		Maize-tripsacum hybrid	Reproduction	2	124
		Gossipium hirsutum	Reproduction	2	153
		Cucumis sativus	Reproduction	2	214
		Pinus sylvestris	Reproduction	5	9.1
Invertebrates	Soil Fauna	*Eisenia foetida*	Mortality	3	506
(37 %)		*Lumbricus terrestris*	Mortality	1	760
		Armadillidium vulgare	Mortality	4	225
		Eisenia foetida	Reproduction	1	2.71
		Sinella curviseta	Reproduction	1	33.6
	Insects	*Neoparasitidae*	Mortality	1	80.3
		Acheta domesticus	Mortality	5	23.3
		Tenebrio molitor	Mortality	2	60.2
		Dermestes ater	Mortality	2	1066
		Lasioderma serricorne	Mortality	1	2061
		Rhyzopertha dominica	Mortality	2	428
		Sitophilus oryzae	Mortality	1	802
		Tribolium confusum	Mortality	2	659
		Rhizopertha dominica	Mortality	1	576
		Melanolus sanguinipes	Mortality	6	7.83
		Blatta orientalis	Mortality	1	76.1
		Blattella germanica	Mortality	1	30.3
		Harpalus pennsylvanicus	Mortality	1	10.8
		Oncopeltus fasciatus	Mortality	1	57.0
		Thermobia domestica	Mortality	1	24.1
		Caloglyphus mycophagus,	Reproduction	5	42.4
		Blattella germanica	Reproduction	2	8.20
Vertebrates	Mammals	*Mus musculus*	Mortality	3	6.24
(9 %)		*Sus scrofa*	Morbidity	1	13.1
		Rattus norvegicus	Reproduction	1	1.22
	Birds	*Gallus gallus*	Mortality	3	5.35

Trophic level (% data usable)	Taxonomic group	Species	Effect category	n of data	Geometric mean (Gy)
		Sturnus vulgaris vugaris	Mortality	1	6.16
		Gallus domesticus	Mortality	1	13.6
		Gallus gallus	Morbidity	1	10.5
		Sialia sialis	Morbidity	2	18.0
		Gallus domesticus	Reproduction	2	11.0
		Black-headed gulls	Reproduction	1	8.48
		Anas platyrhynchos	Reproduction	1	8.47
		Gallus gallus	Reproduction	2	6.91
		Coturnix coturnix	Reproduction	2	12.7
	Reptiles	*Uta stansburiana*	Mortality	1	10.6
		Elaphe obsoleta	Mortality	1	3.15

Table 8. Set of EDR_{10} geometric means per effect category (expressed in µGy/h) obtained from building dose-effect relationships using chronic external γ irradiation data for terrestrial ecosystems. The percentage of usable data from FRED to build dose-effect relationship is given per trophic level. The range of the percentage of extrapolation needed to fit the regression model is indicated. The number (n) of data refers to the number of EDR_{10} used to calculate the geometric mean.

Trophic level (% data usable)	Taxonomic group	Species	Effect category	Range *%Extrapol* (%)	n of data	Geometric mean (µGy/h)
Plants	Plants	Canopy cover numerous species	Morbidity	2-55	3	17540
(5 %)		*Pinus rigida*	Morbidity	10	1	710
		Triticum monococcum	Reproduction	24-80	15	10881
			Morbidity	44-87	2	12868
	Moss/lichen	Moss/lichen	Morbidity	9	1	166553
Invertebrates	Soil Fauna	*Porcellio scaber*	Reproduction	52	1	1030
(2 %)			Morbidity	57	1	7931
Vertebrates	Birds	*Gallus gallus*	Reproduction	42-80	2	13316
(13 %)	Mammals	*Mus musculus*	Mortality	1-87	8	12746
			Reproduction	5-43	6	512
		Rattus norvegicus	Reproduction	20-49	6	349
		Capra hircus	Reproduction	10-50	3	303
		Sus scrofa	Morbidity	85	1	1667
			Reproduction	0-20	4	31.3

Table 9. Set of ED_{50} geometric means per effect category (expressed in Gy) obtained from building dose-effect relationships using acute external γ irradiation data for marine ecosystems. The percentage of usable data from FRED to build dose-effect relationship is given per trophic level. No extrapolation was needed to build any of these regression models. The number (n) of data refers to the number of ED_{50} used to calculate the geometric mean.

Trophic level (% data usable)	Taxonomic group	Species	Effect category	n of data	Geometric mean (Gy)
Algae (4 %)	Algae	*Acetabularia mediterranea*	Morbidity	3	939
Invertebrates (27 %)	Crustaceans	*Artemia salina*	Mortality	1	1337
			Mortality	7	1658
			Morbidity	6	0.837
			Reproduction	5	5206
		Diaptomus clavipes	Mortality	3	46.2
		Callinectes sapidus	Mortality	3	168
	Molluscs	*Crassostrea gigas*	Morbidity	3	39.0
		Crepidula fornicata	Morbidity	1	70.9
			Mortality	1	58.7
	Annelids	*Neanthes arenaceodentata*	Mortality	6	42.6
			Reproduction	7	18.2
Vertebrates (23 %)	Fish	*Fundulus heteroclitus*	Reproduction	7	88.0

Table 10. Set of EDR_{10} geometric means per effect category (expressed in µGy/h) obtained from building dose-effect relationships using chronic external γ irradiation data for marine ecosystems. The percentage of usable data from FRED to build dose-effect relationship is given per trophic level. The range of the percentage of extrapolation needed to fit the regression model is indicated. The number (n) of data refers to the number of EDR_{10} used to calculate the geometric mean.

Trophic level (% data usable)	Taxonomic group	Species	Effect category	Range *%Extrapol* (%)	n of data	Geometric mean (µGy/h)
Invertebrates (11 %)	Annelids	*Neanthes arenaceodentata*	Reproduction	0-23	4	444
		Ophryotrocha diadema	Mortality	0-90	3	5157
	Molluscs	*Mercenaria mercenaria*	Mortality	11-13	2	114973
Vertebrates (32 %)	Fish	*Pleuronectes platessa*	Reproduction	22-89	5	217

Ecological relevancy of the selected effect categories. The aim of producing a protection threshold for the structure of ecosystems gives preference to effects that can be interpreted at the population level. The endpoints that are directly linked to phenotypic effects were therefore carefully selected with mortality, reproduction and morbidity being preferred. Mutation was not used as there were very few such data sets within FRED. Moreover, even though the primary mechanisms governing the mode of action of ionizing radiation are well known at the sub-cellular and cellular levels especially for acute exposure conditions, there are still significant gaps in our understanding of the ecological relevance of low-level exposure irradiation and there are still .gaps in the understanding of mechanisms in the domain of low-level exposure irradiation.

Taxonomic diversity and number of ecotoxicity values. Several authors have made recommendations on the quality and quantity of input data used for deriving generic protection thresholds (*e.g.* (EC, 2003); (Posthuma *et al.* , 2002)). For instance, the TGD states that at least ten critical toxicity data for different species covering at least eight taxonomic groups are suggested as the minimum taxonomic diversity of several genera or families and the minimum sample size (EC, 2003). The following list of trophic levels has been recommended for freshwater ecosystems: "a fish, a second family in the phylum Chordata, a crustacean, an insect, a family in any order of insect, an algae and a higher plant". However, there was insufficient data in this study to cover these requirements. For example, the acute toxicity data related to freshwaters (number of geometric means or n_{gm}=13) only covered five taxonomic groups (*e.g.* no higher plant or insect) as shown in Table 5, and for the chronic toxicity data set (n_{gm}=6) only three taxonomic groups (crustaceans, molluscs and fish) representative of four species were found (Table 6). For terrestrial ecosystems, the taxonomic diversity was quite high for acute external exposure conditions (n_{gm}=46, 6 taxonomic groups, 40 species, see Table 7) but again was much lower for the chronic toxicity data set (n_{gm}=14, 5 taxonomic groups, 10 species, see Table 8). For marine ecosystems, there was sufficient data for acute exposure conditions (n_{gm}=13, 5 taxonomic groups, 8 species, see Table 9) but very little for chronic exposure conditions (n_{gm}=4, 3 taxa, 4 species, see Table 10). For chronic exposure conditions therefore an extrapolation technique was used to build dose-effects relationships from the available data to obtain a sufficient number of data for the SSD-type analysis.

Radiosensitivity amongst trophic levels. For acute exposure conditions in freshwaters, the geometric mean per effect of estimated ED_{50}s varied from 3.4 Gy for reproduction in salmonids and 3.8 Gy for mortality of amphibians, to 430 Gy for mortality of a representative species in a less radiosensitive taxonomic group such as algae. A similar radiosensitivity scale among taxonomic diversity was observed for terrestrial ecosystems, ranging from 1.2 Gy for reproduction capacity in mammals to 2061 Gy for mortality in insects. These results are consistent with those described elsewhere (Copplestone *et al.* , 2001; UNSCEAR, 1996) and thus emphasizes two key points from the data:

(1) vertebrates are among the most radiosensitive organisms; and

(2) reproductive capacity is likely to be a more sensitive endpoint than adult mortality.

For chronic exposure conditions, the estimated EDR_{10}s followed the same trend, even though the dataset was less robust with regard to the taxonomic diversity and extrapolation techniques were used to obtain sufficiently large data set for evaluation. The study showed that the most radiosensitive taxonomic groups in freshwaters were fish (minimum EDR_{10} geometric mean of 516 µGy/h for reproduction) and mammals were the most sensitive in terrestrial ecosystems (minimum EDR_{10} geometric mean of 31.3 µGy/h for reproduction). For marine ecosystems, the minimum values obtained were 18.2 Gy for reproduction in annelids and 271 µGy/h for reproduction in fish, for acute and chronic exposure respectively.

Number of data points to generate robust SSD. This point has been discussed extensively elsewhere ((Newman *et al.* , 2000);(Wheeler *et al.* , 2002). The data sets used in this study met the basic requirement of $n>10$ for the data as argued by various authors (Vega *et al.* , 1999; Wheeler *et al.* , 2002) with the number of geometric means available for the SSD ranging from 13 to 47 with the exception of freshwaters (and marine ecosystems) under chronic exposure conditions where only 6 (4) EDR_{10} geometric means were available. Adding new species representing a new taxonomic group for marine and/or freshwaters (*e.g.* primary producers) would probably increase the spread of the resulting SSD, but would also reduce the uncertainty of the derived $HD(R)_5$. Additional data from the literature could be added providing the data meets the quality assessment by following the rules outlined above in the methodology, as the literature becomes available. This will be done with the use of FREDERICA.

4.1.2 Acute and chronic SSDs

Testing for the difference in species sensitivity per ecosystem. Ecotoxicity data have been grouped according to ecosystem: freshwaters (FW), marine (SW), and terrestrial (TER), and exposure regime (acute or chronic). The statistical difference in radiosensitivity of the species/umbrella effects between ecosystems (terrestrial, marine and freshwaters) was tested with a bilateral Wilcoxon test ($\alpha=0.05$). These results are reported in Table 11.

For the acute exposure situation, a statistical difference appeared between species from marine ecosystems and species from freshwaters. Thus aquatic ecosystems could not be grouped to build a single SSD. In contrast, there was no statistical difference between the sensitivity of freshwater and terrestrial species and this allowed the construction of a common SSD for continental ecosystems.
For the chronic exposure situation, no statistical difference was observed between the radiosensitivity of species from marine and freshwater ecosystems. Thus the two data sets were grouped into a single aquatic ecosystem for the SSD. The difference between aquatic species and terrestrial species sensitivity was also tested and this also was not different, allowing the construction of a unique SSD for the generic ecosystems chronically exposed to external γ irradiation.

Robustness of fitted distributions. Estimates of the $HD(R)_5$ values and their associated confidence intervals were calculated. These are reported in Table 12. Table 12 also shows the statistical characteristics of each fitted distribution. The goodness-of-fit values demonstrated how well the distributions fitted the observed data for all cases. The number of species and their taxonomic diversity for generic ecosystems (FW+TER and FW+SW+TER) were sufficient to estimate properly the $HD(R)_5$. These generic SSDs reflecting the taxonomic composition of the ecotoxicity data sets were constructed as identified in Table 12. However, real ecosystems are usually very different from those that are based on the species for which effects data exist in the literature. It is therefore important to consider this when assessing the impact of radioactive substances and other stressors on ecosystems. For an accurate comparison, SSDs would ideally be based on identical sets of taxa. A refinement that might be applied in a Tier 3 assessment would be to weight the trophic levels according to the taxonomic groupings found in real ecosystems to make the SSD more realistic. However, this requires knowledge on the ecosystems under examination and should only be attempted with the assistance of a relevant expert.

Table 11. Comparison of species sensitivity (based on geometric means of ED_{50} and EDR_{10} for acute and chronic exposure respectively) among ecosystems. Distribution parameters and p value given for α=0.05 and a bilateral Wilcoxon test.

Exposure regime	Ecosystem	Nb geom.mean	Median	Mean	SD	Comparison	p value
Acute			**Gy**	**Gy**	**Gy**		
external γ	Marine (SW)	13	70.9	744	1454		
	Freshwater (FW)	13	14.6	55.0	115	SW vs. FW	0.00724 FW species more sensitive than SW species
	Terrestrial (TER)	46	24.1	179	375	TER vs. FW	0.240 No difference
Chronic			**µGy/h**	**µGy/h**	**µGy/h**		
External γ	Marine (SW)	4	2800	30198	56563		
	Freshwater (FW)	6	172106	217118	204859	SW vs. FW	0.114 No difference
	Generic Aquatic (SW+FW)	10	60625	142350	183572		
	Terrestrial (TER)	14	4798	17603	43324	AQ vs. TER	0.1375 No difference

Table 12. Probabilistic effects thresholds for radioactive substances from SSDs. HD_5 (in Gy) and HDR_5 (in µGy/h) and their associated 95% confidence intervals when the distribution fitted was log-normal. Grouping of ecosystems is carried out only when the statistical difference between the radiosensitivity of species from different ecosystems was not significant (Wilcoxon test, Table 11).

Exposure regime	Ecosystem	Nb data Nb sp[a]	Distribution	Taxonomic Weight[b]	Weighted mean[c] (weighed SD)	R^2 (KS p)[d]	$HD(R)_5$ [95%CI]
Acute,							**Gy**
external γ	Generic (TE+FW)	n=123 n_{gm}=60 n_s=50	Log-normal	Literature based (0.2; 0.4; 0.4)	1.47 (0.75)	0.953 (0.04)	1.86 [1.16; 2.98]
	Marine	n=53 n_{gm}=13 n_s=8	Log-normal	Literature based (0.13; 0.74;0.13)	2.00 (0.80)	0.889 (0.5)	4.84 [0.64; 12.7]
Chronic							**µGy/h**
external γ	Generic (TE+FW+SW)	n=82 n_{gm}=24 ns=18	Log-normal	Literature based (0.22; 0.33; 0.44)	3.71 (1.09)	0.951 (0.5)	81.8 [23.8; 336]

[a] n is the total number of data, n_{gm} is the number of geometric means when data are averaged per umbrella effects for each species; n_s the number of different species.
[b] given as follows (plants weight; invertebrates weight; vertebrates weight) based on the data set composition (Literature based).
[c] Weighted mean of the log-normal distribution of the data (log 10) and weighted Standard Deviation of the log-normal distribution of the data (log 10).
[d] multiple R-square and p value of the Kolmogorov-Smirnov goodness of fit test (with Dallal-Wilkinson approximation)

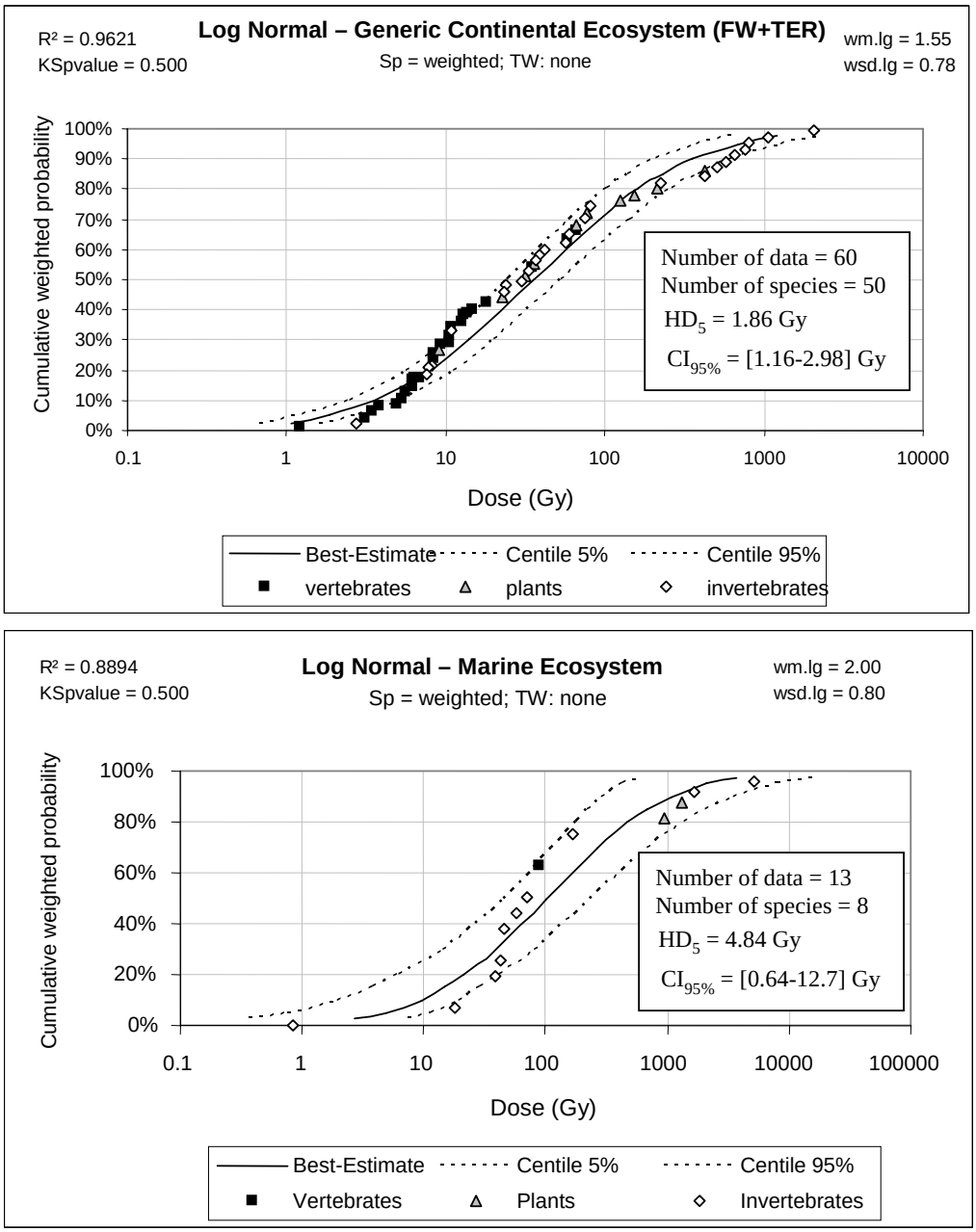

Figure 4. SSDs for generic continental ecosystems (FW+TER - top) and marine ecosystem (bottom) and acute external γ irradiation exposure conditions. The log-normal distribution with its associated 95% confidence interval is fitted to geometric means per effect category for each species calculated on critical ecotoxicity data (ED_{50}). Species are weighted. The trophic-level weight reflects the trophic diversity of the primary data sets (see Table 12).

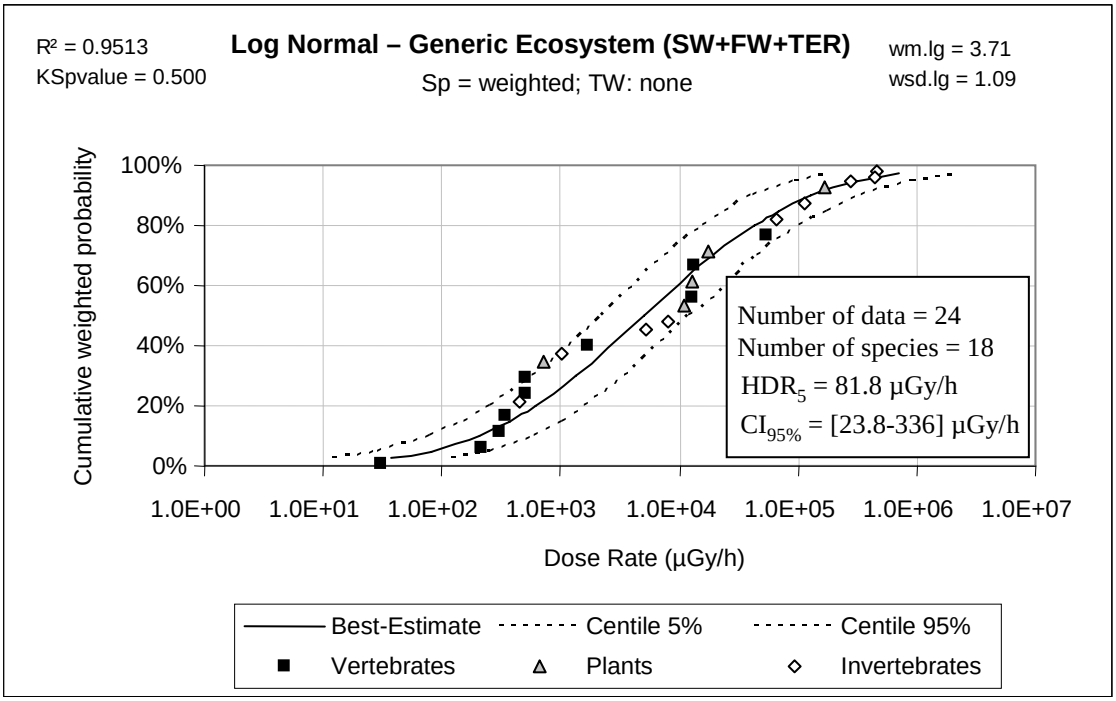

Figure 5. SSDs for generic ecosystems (FW+SW+TER) and chronic external γ irradiation exposure conditions. The log normal distribution with its associated 95 % confidence interval is fitted to geometric means per effect category for each species calculated on critical ecotoxicity data (EDR_{10}). Species are weighted. The trophic-level weight reflects the trophic diversity of the primary data sets (see Table 12).

Comparison of the estimated safe levels with guidelines from literature. A number of dose rates at which no significant effects were expected at the level of the population have been proposed on the basis of literature reviews by the IAEA (IAEA, 1992) or UNSCEAR (UNSCEAR, 1996) as follows: less than 400 µGy/h for aquatic animals and terrestrial plants, and less than 40 µGy/h for terrestrial animals. In this study, the HDR_5 values estimated for chronic external γ irradiation were close to these values, when they were derived statistically using an ecosystem-based approach. For example, the SSD results indicate that 95% of species in a generic ecosystem would be protected at a dose rate of between 23.8 to 336 µGy/h (95%CI of the best estimate, covering one order of magnitude). No recommended value exists in the literature for acute exposure conditions (or accidental scenarios), consequently the values derived here that would be protective of 95% of species from a 50% effect under acute external gamma irradiation are the first ones to be suggested. In this case, the HD_5 is *ca*.1.8 to 4.8 Gy, with the marine ecosystems being less sensitive than the continental ones. The associated 95% confidence intervals also covered one order of magnitude (Table 12).

The selected level of protection of 95 % of the species. Selection of the 95 % cut-off level is consistent with the approach used for chemicals assessments in the TGD (EC, 2003). Use of a 95 % level of protection has been discussed elsewhere. For example, Van Straalen *et al.* (Van Straalen and Denneman, 1989) and (Van Straalen, 2002) argued that ecosystems possess a certain degree of resilience. They also indicated that any risk assessment philosophy should acknowledge that environmental protection cannot eliminate all possible risks but should reduce them to an acceptable level. A number of authors have noted that there may be keystone

species among the 5 % that are “unprotected” (Forbes and Forbes, 1993; Hopkin, 1993). Accordingly, it is recommended that an assessor should identify the trophic level and taxonomic group(s) and the effect endpoint(s) present in the lowest quartile of the distribution and consider whether this is significant within their assessment. For example, during this study, species found in the 5% of “unprotected” species included vertebrates, particularly those situated at the top of food webs (Table 13). This may be significant in the context of protection of the higher trophic levels and therefore the relevance of this in an assessment would need to be determined.

SSDs do enable all critical toxicity data used to be displayed and used to identify the most sensitive species located to the left-hand side of the distribution. This information needs to be kept in mind when using the protection goals and screening levels for a given ecosystem. Moreover, cautious interpretation is needed when the aim of the assessment is to protect an object other than the structure of the ecosystem (*i.e.* an endangered species). In this case further guidance is given in Section 5 but it is unlikely that a proposed screening dose (rate) value derived from a SSD type approach using a generic ecosystem is unlikely to be valid.

Table 13. Identification of the taxonomic group, species and effect endpoint falling in the 5 % species unprotected (ED_{50} or EDR_{10} lower than the upper limit of the 95 %CI of the $HD(R)_5$ estimated by fitting a log-normal distribution without applying any trophic weight to the SSD. ED_{50}s are expressed in Gy and EDR_{10}s in µGy/h. The values presented in this table reflect individual data points and not the geometric means used to construct the SSD.

Ecosystem Exposure regime	Taxonomic group (TL)[a]	*Latin name* (common name)	Effect category	Description of the effect endpoint	Critical toxicity values
Acute external γ					**ED_{50} (Gy)**
Generic (FW)	Amphibian (V)	*Bufo fowleri* (fowlers toad)	Mortality	Mortality in 50 days of juvenile toads after exposure to whole body gamma irradiation.	0.11
	Fish (V)	*Salmo gairdnerii* (rainbow trout)	Reproduction	% of abnormalities resulting in incomplete development	1.49
				Egg mortalities (%) from eggs obtained from irradiated parents	1.66
Generic (TER)	Mammals (V)	*Rattus norvegicus* (rat)	Reproduction	Mean number of germ cells per foetus following irradiation on day 14 (oogonia)	1.22
	Soil Fauna (I)	*Eisenia foetida* (earthworm)	Reproduction	Rosette number of spermatogonia after 5 and 40 days post irradiation	2.71
Marine (SW)	Arthropods Crustaceans (I)	*Artemia salina*	Morbidity	Percentages of pro, meta, and ana telophases in newly hatched nauplius derived from dry egg irradiated.	0.098
		Diaptomus clavipes	Mortality	Survival (%) of irradiated adults at different time points	2.83
	Molluscs (I)	*Crassostrea gigas*	Morbidity	No. of mitotic figures - in oyster gut 30 day after irradiation.	0.614
			Morbidity	Frequency of abnormal larvae at 48 h post fertilisation (%), X-ray exposure at different rearing temperatures	2.12
	Annelids (I)	*Neanthes arenaceodentata*	Mortality	Survival (as fraction) of juveniles.	0.012

Ecosystem Exposure regime	Taxonomic group (TL)[a]	*Latin name* (common name)	Effect category	Description of the effect endpoint	Critical toxicity values
			Mutation	Radiation effects, percentage abnormal metaphases.	1.32
			Reproduction	Brood size (fecundity) of irradiated adults	2.69
			Reproduction	The effect of radiation of adults on time to spawning (as % that spawned). No differences in spawning times of worms irradiated as juveniles	12.6
			Reproduction	Brood size (fecundity) - % of broods with > 150 embryos	3.13
			Reproduction	Mean survival of embryos (as % of survival fraction of the controls) against dose	0.586
			Reproduction	Abnormal broods - % of abnormal embryos in the > 75 brood category.	1.17
Chronic external γ					***EDR*$_{10}$ (µGy/h)**
Generic (FW)	Fish (V)	*Oryzias latipes* (medaka)	Reproduction	Ovary weight at 70 days of age	24.9
				Testis weight at 70 days of age	6.7
Generic (TER)	Mammals (V)	*Mus musculus* (mouse)	Reproduction	Germ cells per ovary at 56 days of age.	195.6
				Nº of litters per fertile female during 245 days (mean; SE).	26.2
		Rattus norvegicus (rat)	Reproduction	A1 spermatogonia (% of control)	23.8
		Capra hircus (goat)	Reproduction	Total sperm production (% of control)	11.6
Generic (SW)	Annelids (I)	*Neanthes arenaceodentata*	Reproduction	% Abnormal embryos % of broods with <25% abnormal embryos	1.44
			Reproduction	% live embryos % of broods with >75% embryos	134
	Fish (V)	*Pleuronectes platessa*	Reproduction	Mean proportion of plaice testes occupied by different cell types irradiated for 197 days - sperm	53.4
			Reproduction	Mean proportion of plaice testes occupied by different cell types irradiated for 73 days - non germal cells	193
			Reproduction	Mean proportion of plaice testes occupied by different cell types irradiated for 73 days - spermatogonia	193

[a] Trophic Level: I invertebrates; V vertebrates and P plants

4.2 Summary: screening values recommended for Tiers 1 and 2

On the basis of the previous derivation of HD_5 or HDR_5 values for generic ecosystems under acute or chronic external exposure conditions, ERICA has determined screening dose (rate) values to be applied in the first two tiers of the tiered approach for ecological risk assessment based on the following points:

4.2.1 Object of protection

Generic ecosystems (freshwater, marine and terrestrial ones) should be protected from effects on structure and function under accidental (acute exposure) or chronic releases of radionuclides.

4.2.2 Methods

Species Sensitivity Distributions were built on ecotoxicity data derived from mathematical processing of FRED effects data. These ecotoxicity data were averaged per umbrella effect for each species (geometric mean per umbrella effect for each species). Each species was weighted in the distribution, and no weight was allocated per taxonomic group. A cut-off value was fixed at 95 % of species to be protected (as recommended in the TGD) and the likely distribution is used for the derivation of the $HD(R)_5$ with the associated confidence intervals (95 %).

4.2.3 Rules to select ecotoxicity data sets

Ecotoxicity data were gathered per ecosystem: freshwaters (FW), marine (SW), and terrestrial (TER), and per exposure regime (acute or chronic).

For the acute exposure situation, a statistical difference between species from marine ecosystems and species from freshwaters was observed so species from aquatic ecosystems were not grouped to construct the SSD. In contrast, there was no difference observed between species sensitivity in freshwater and terrestrial ecosystems and this allowed the construction of a common SSD which is reported here as a generic continental ecosystem (FW+TER).

For the chronic exposure situation, no difference was observed in the radiosensitivity of species from marine and freshwater ecosystems. The two sets were therefore grouped into a unique aquatic ecosystem. The difference between aquatic species and terrestrial species sensitivity was then tested and also shown to be insignificant. This finding allowed the construction of a unique SSD for generic ecosystems (SW+FW+TER) chronically exposed to external γ irradiation.

4.2.4 Results of SSDs and screening values for Tiers 1 and 2

For the acute exposure situation, the HD_5 and associated 95 % confidence interval were as follows:

- Marine ecosystems: 4.84 Gy [0.64; 12.7]
- Terrestrial and freshwater ecosystems: 1.86 Gy [1.16; 2.98].

To derive the screening dose(rate) values for application in Tiers 1 and 2, a SF of 5 was applied to take account of the need to extrapolate the data set to consider the internal irradiation pathway (*e.g.* the higher biological effectiveness of internal bound alpha and low level beta emitters when compared with the external γ irradiation). Once rounded down and expressed with one digit significant, this gave values of **900 mGy for marine ecosystems; and 300 mGy for terrestrial and freshwater ecosystems.**

For the chronic exposure situation, the HDR_5 and associated 95% confidence interval were as follows:

- Generic ecosystems (terrestrial, freshwater and marine): 81.8 µGy/h [23.8; 336]

To derive the screening dose(rate) values for application in Tiers 1 and 2, a SF of 5 was applied. , Once rounded down and expressed with one digit significant, this gave a value of **10 µGy/h for all ecosystems**.

4.2.5 Comparison of screening benchmark values for Tiers 1 and 2 obtained with SSD methodology or while applying the Safety Factor methods:

The SF method appeared to be more stringent than the SSD analysis as the Predicted no-effect values are obtained by dividing the lowest critical ecotoxicity data by an appropriate SF ranging from 10 to 1000 as shown in Table 14. It is generally recognised that, with suitable ecotoxicity data sets, the SSD-type analysis is more ecologically relevant than the SF method becaus it:

(1) uses all available information that satisfy a series of applicability rules;

(2) captures the inter- and intra-species variability in response to a radioactive substance;

(3) quantifies uncertainties; and

(4) encourages new data generation to reduce uncertainty by identifying knowledge gaps.

Table 14. Comparison of the benchmark values obtained while applying the safety factor method (SF from the TGD, 2003) or applying the method of SSD method combined with a SF of 5. All bnechmark values are rounded down and expressed with one significant digit.

Exposure regime	Ecosystem	Lowest toxicity value	Case described in the TGD (2003) and corresponding SF	SF	Benchmarks from SF method	Benchmarks from SSD method
		ED_{50}				
Acute external γ	Terrestrial	1.22 Gy	Lowest value among at least 3 short-term tests from 3 trophic levels	100	10 mGy	900 mGy
	Freshwaters	0.11 Gy	Lowest value among at least 3 short-term tests from 3 trophic levels	100	1 mGy	900 mGy
	Marine	0.60 Gy	Lowest value among at least 3 short-term tests from 3 trophic levels	100	6 mGy	300 mGy
		EDR_{10}				
Chronic external γ	Terrestrial	6.7 µGy/h	3 NOECs (equivalent to EDR10) for 3 trophic levels	10	0.6 µGy/h	10 µGy/h
	Freshwaters	516 µGy/h	2 NOECs (equivalent to EDR10) for 2 trophic levels	50	10 µGy/h	10 µGy/h
	Marine	185 µGy/h	2 NOECs (equivalent to EDR10) from FW or SW species representing 2 trophic levels + 1 NOEC from an additional marine taxonomic group	50	3.7 µGy/h	10 µGy/h

4.2.6 Comparison of the estimated predicted no-effect values with background levels and dose-rates triggering ecological effects.

Only the predicted no-effect values for chronic exposure were submitted to this comparison. Generally, the situations for which ecological and human risk assessments are to be carried out either retrospectively or

prospectively for any facility or man-made practices which lead to a significant increase in the level of exposure to radionuclides in comparison to the background level (*e.g.* nuclear plants under normal operating conditions, storage sites for radioactive wastes, uranium-bearing ore mining sites, post-accident situations such as Chernobyl). Background radiation exposure obviously varies with geochemical characteristics of the each area. UNSCEAR (1996) and Copplestone *et al.* (2001) in their review estimated that the background dose rates to terrestrial plants were between 0.02 and 0.7 µGy/h with aquatic plants being at the lower end of this range. For animals/mammals, ranges are typically between 0.01 and 0.44 µGy/h. For freshwater organisms, ranges of background were between 0.022 and 0.18 µGy/h with the minimum corresponding to fish and the maximum to benthic organisms. Obviously all the upper limits of these ranges may vary by a factor up to 1000 in areas of particular geochemistry. UNSCEAR (1996) estimated that typical absorbed dose rates in environments continuously contaminated by authorized waste management practices were generally less than 0.1 mGy/h and only very exceptionally in the order of several thousand µGy/h.

Examination of available data within the FASSET project led to similar conclusions. For a number of naturally occurring radionuclides, absorbed dose rates for various groups of marine organisms (bacteria, phytoplankton, zooplankton, microalgae, molluscs, crustaceans, fish, and mammals) vary roughly over the range 0.03 – 1 µGy/h, without weighting for the radiation type, and in some cases without any consideration of internal dose rates. For freshwater organisms, the range (unweighted) was somewhat wider (0.02 – 6 µGy/h), which reflect the larger variability in radionuclide concentrations within freshwater ecosystems (Brown *et al.* , 2004). The FASSET review of data for terrestrial organisms indicated values roughly in the range 0.01 – 0.1 µGy/h for external radiation, and in the same order, or higher, for internal radiation (Gómez-Ros *et al.* , 2004). Again, weighting may change this range substantially, and inclusion of radon doses for burrowing organisms would constitute a major additional contribution to the absorbed dose rates.

Data are generally scarce at the ecosystem level on observed ecological effects in contaminated sites. The EPIC research program has however provided a global overview of graduated radiation effects observed on representative organisms of wildlife in northern-temperate climatic zone, on the basis of a critical review of field observations in the former Soviet Union (Table 15) (Sazykina, 2005). The no-effect values at the ecosystem level determined in this study generally lie within the categories of subtle effects on vertebrates which may be described as minor cytogenetic effects or minor effects on morbidity. These effects are not directly relevant at higher organizational levels, such as the structure and functioning of ecosystems. Moreover, the effects data from contaminated sites often result from mixtures of external and internal irradiation pathways, and for post accidental situations from acute exposure conditions followed by chronic exposure. For example, the absorbed dose for coniferous trees from external γ-radiation at the time of the accident of the Chernobyl NPP varied from more 100 Gy in the 4 km^2 area worst affected area down to 1 Gy in the 120 km^2 area while the corresponding dose rate on the 1st of October, 1986 was more 5mGy/h to 0.5 mGy/h respectively (Smith and Beresford, 2005).

Table 15. Global overview of dose rate-effects relationships for wildlife and chronic exposure to low-LET radiation observed in field studies from former Soviet Union sites (adapted from (Sazykina, 2005)).

Dose rates (µGy/h)	Radiation effects on representative organisms
<0.04	Natural background
0.04 – 4	No data
4 – 20	Minor cytogenetic effects in sensitive vertebrate species
20 – 80	Threshold for minor effects on morbidity in sensitive vertebrate species
80 – 200	Threshold for effects on reproductive organs of vertebrates, decrease of embryo's survival
200 – 400	Threshold for life shortening of vertebrates. Threshold for effects in invertebrates. Threshold for effects on growth in coniferous trees
400 – 4000	Symptoms of "chronic radiation sickness" for vertebrates. Considerable damage to coniferous trees
4000 – 40000	Symptoms of acute radiation sickness in vertebrates. Death of coniferous trees. Considerable damage in eggs and larva of invertebrates
>40000	Lethal dose received within several days for vertebrates. Increased mortality of eggs and larva of invertebrates. Death of coniferous trees, damage to deciduous plants

4.2.7 Conclusion and summary of guideline and recommended predicted no effect dose rates used for biota and chronic exposure conditions

As summarised in Table 16 and for comparison purpose, a number of dose rates, given by different organisations/authors, at which no significant effects were expected at various levels (population, wildlife group, ecosystem) has been collated. Sources justifications were mainly narrative based on effects observations and on expert judgement. The approach outlined in this report provides an improvement in the methodology for assessing risks from radioactive substances by deriving, for the first time for radioactive substances, protection thresholds using a rational and transparent process based on the approach adopted for chemicals in Europe. These values were urgently needed to demonstrate radioprotection of the ecosystems as radioactive substances are used in a variety of industries, hospitals or research laboratories, and very widely in terms of geographical distribution.

Table 16. Dose rate values (in µGy/h) proposed by various organisations/programmes to support effect analysis for chronic exposure to radioactive substances.

Targeted protected level as described in the source	Method/justification of the value	Dose rate (µGy/h)	Source (complete list below)
Terrestrial ecosystems			
Generic ecosystems	SSD-95% species protected plus SF of 5	10	This report
Generic ecosystems	SF method	0.6	This report
Plants	Background	0.02-0.7	UNSCEAR 1996
Plants	Review, SF on the lowest critical radiotoxicity value	110	Environment Canada 1997 Bird *et al.* 2002
Plants	Review based on NCRP 1991; IAEA 1992; UNSCEAR 1996	400	ORNL 1998 US DOE 2002
Plants	Critical review for screening purpose from IAEA 1992	400	Environment agency UK 2002
Organisms	Background –external irradiation and non weighted	0.01-0.1	Gomez-Ros *et al*, 2004
Animals	Background	0.01-0.44	UNSCEAR 1996
Animals	Review based on NCRP 1991; IAEA 1992; UNSCEAR 1996	40	ORNL 1998 US DOE 2002
Animals	Critical review for screening purpose from IAEA 1992	40	Environment agency UK 2003
Small mammals	Review, SF on the lowest critical radiotoxicity value	110	Environment Canada 1997 Bird *et al.* 2002
Invertebrates	Review, SF on the lowest critical radiotoxicity value	220	Environment Canada 1997 Bird *et al.* 2002
Vertebrates and cytogenetic effects	Review Contaminated environments	4 – 20	Sazykina et al. 2005
Vertebrates and effects on morbidity	Review Contaminated environments	20 – 80	Sazykina et al. 2005
Vertebrates and effects on reproduction	Review Contaminated environments	80 – 200	Sazykina et al. 2005
Aquatic ecosystems			
Generic freshwater ecosystems	SSD-95% species protected plus SF of 5	10	This report
Generic freshwater ecosystems	SF method	10	This report
Generic marine ecosystems	SSD-95% species protected plus SF of 5	10	This report
Generic marine ecosystems	SF method	3.7	This report
Freshwater organisms	Background	0.022-0.18	UNSCEAR 1996
Freshwater organisms	Background–external irradiation and non weighted	0.02-6	Brown *et al.* 2004
Aquatic algae/macrophytes	Review, SF on the lowest critical radiotoxicity value	110	Environment Canada 1997 Bird *et al.* 2002
Aquatic animals	Review based on NCRP 1991; IAEA 1992; UNSCEAR 1996	400	ORNL 1998 US DOE 2002

Targeted protected level as described in the source	Method/justification of the value	Dose rate (µGy/h)	Source (complete list below)
Freshwater and coastal marine organisms	Critical review for screening purpose from IAEA 1992	400	Environment agency UK 2002
Amphibians/Reptiles	Review, SF on the lowest critical radiotoxicity value	110	Environment Canada 1997 Bird *et al.* 2002
Benthic invertebrates	Review, SF on the lowest critical radiotoxicity value	220	Environment Canada 1997 Bird *et al.* 2002
Fish	Review, SF on the lowest critical radiotoxicity value	20	Environment Canada 1997 Bird *et al.* 2002
Marine organisms	Background–external irradiation and non weighted	0.03-1	Brown *et al.* 2004
Marine mammals	Critical review for screening purpose from IAEA 1992	40	Environment agency UK 2003
Deep ocean organisms	Critical review for screening purpose from IAEA 1992	1000	Environment agency UK 2003
Aquatic and terrestrial flora and fauna	*Review concluded that few indications for readily observable effects at chronic dose rates below*	<100	FASSET 2003

Bird, G., Thompson, P., MacDonald, C. and Sheppard, S. (2002) Assessment of the impact of radionuclide releases from Canadian nuclear facilities on non-human biota. In: *SPEIR 3* (Ed, AIEA) Darwin, Australia, pp. 241-247.

Brown J, Jones S, Saxén R, Thørring H, Vives I Batlle J. (2004). Radiation doses to aquatic organisms from natural radionuclides. *J Radiol. Prot.*, **24**:63-78.

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Environment Canada (1997). Environmental assessments of the priority substances under the Canadian environmental protection act. Guidance manual, version 1.0. EPS 2/CC/3E., Chemicals Evaluation Division, Commercial Chemicals Evaluation Branch, Environment Canada.

FASSET, Framework for Assessment of Environmental Impact (2003). Radiation effects on plants and animals Deliverable 4, FASSET Project Contract FIGE-CT-2000-00102, Woodhead and Zinger (Eds)

Gómez-Ros J, Pröhl G, Taranenko V. (2004). Estimation of internal and external exposures of terrestrial reference organisms to natural radionuclides in the environment. *J Radiol. Prot.*, **24**:79-88.

IAEA (1992) *Effects of ionizing radiation on plants and animals at levels implied by current radiation protection standards. IAEA-TECDOC-332*, IAEA, Vienna, Austria.

NCRP (1991) Effects of Ionising Radiation on Aquatic Organisms: Recommendations of the National Council on Radiation Protection and Measurements. NCRP rep. 109, Bethesda, MD, USA, 109, pp. 1-115.

ORNL (1998) Radiological benchmarks for screening contaminants of potential concern for effects on aquatic biota at Oak Ridge National Laboratory, Oak Ridge, Tennessee. Oak Ridge National Laboratory, Report to USDOE, Office of Environmental Management, ORNL, BJC/OR-80.

Sazykina TG. (2005). A system of dose-effects relationships for the northern wildlife: radiation protection criteria. *Radioprotection*, **Suppl.1 (40)**:S889-S892.

UNSCEAR (1996) *Sources and effects of ionizing radiation.A/AC.82/R.549*, Report to the general assembly with scientific annex, United Nations, Vienna.

US DOE (2002) *A graded approach for evaluating radiation doses to aquatic and terrestrial biota. U.S. Department of Energy. Technical Standard DOE-STD-1153-2002*, Washington, DC. USA.

5 Methods and examples for Tier 3

5.1 Background

When a lower tier assessment indicates a potential risk, then a risk management decision is made to warrant an additional Tier 3 assessment. Given that the Tier 3 assessment is so much more resource and time consuming than previous tiers the first question to ask is whether a refinement; for example a quantitative analysis of uncertainty and variability, specific analysis of available effects data or incorporating new effects data, will improve the risk assessment. Furthermore, stakeholders, such as the regulatory agency, those applying for the application, other interested parties, may also be involved in making a decision on what is an appropriate action to take for Tier 3.

The purpose of the refinements made in Tier 3 is to obtain more realistic estimates of exposure and effects to reduce the uncertainty in the risk assessment, and to describe, quantify and interpret the magnitude of risk. In earlier tiers, estimates of exposure/effects are made based conservatively on maximum dose rate and/or the most sensitive species and thus reflect worst-case scenarios. Since lower tier assessments should be precautionary to minimise the number of false negatives they also lead to an over estimation of the risk, but it is not possible to determine the degree of overprotection. Hence, the outcome of the refined tier 3 risk assessment is expected to be a decreased estimate of risk with its associated uncertainty.

The assessment at Tier 3 needs to evaluate issues related to temporal and spatial variations through a full site investigation addressing knowledge gaps and uncertainties. Refinement of the Tier 3 risk assessment is expected to be driven primarily through the use of revised exposure estimates (ERICA WP1) owing to a generally larger uncertainty in this estimate. Further refinement of the effects analysis is certainly needed in several cases to increase the relevance with regard to the problem formulation, especially by introducing ecological realism related to the site or the case-study under examination. The assessment endpoints may also include individuals to populations of a given species, the assemblage of species in communities, habitats and ecosystems. The potential refinements and associated methods vary according to the problem formulation, in particular to the object of protection, and could be:

- to use SSD with other (usually more conservative) levels of protection (*i.e*. moving from 95 % to 99 % of species being protected), based on the judgement of the consequences of loss of species, *e.g.* impact on ecosystem stability and function (not illustrated in this section since it is easily implemented);
- to use SSD methodology combined with the application of trophic/taxonomic weightings to derive more ecologically relevant sensitivity distribution curves related to a specific ecosystem (Section 5.2);
- to use SSD methodology restricted to a particular endpoint (for instance reproduction) and/or a particular trophic/taxonomic group (*e.g.* vertebrates or fish) (Section 5.3);
- to refine the effects analysis by focussing on the protection of keystone species and/or endangered species (Section 5.4);
- to refine the effects analysis to address situations when the knowledge of effects is too scarce with regard to the problem formulation, and additional studies may be required. Two examples are given in Sections 5.5.2 and 5.5.3 to illustrate possible ways of addressing extrapolation issues of concern, *i.e.* individual to population and external to internal irradiation effects.

The Tier 3 assessment should make use of, but is not limited by, data evaluated in the earlier tiers. It is assumed that a full and critical re-evaluation of available data as well as a revision of the problem formulation precedes any decision to move to a higher tier. Any data gaps should be clearly identified and described in this

process. Additional effects studies may be required either in response to existing data indicating a potential risk, or to lack of data in potentially important areas. A number of approaches to higher tier effect studies have been used in the past to address concerns identified at lower tier ERAs, including the use of modelling approaches, additional species studies (including sensitive life stages and/or endpoints), population studies, multi-species studies, artificial streams, micro- and mesocosms and field studies *e.g.* (Boxall *et al.* , 2001; Campbell *et al.* , 1999). These approaches have a number of advantages over single species investigations, including the ability to assess endpoints at higher levels of biological organisation, species interactions and indirect ecological effects. The approaches also allow the assessment of population and community recovery.

However, these types of approach of higher tier studies also have limitations. Results from more complex studies can be more difficult to interpret and understand than those from standard single species tests. The studies may also be more time and resource consuming than standard single species studies and, whilst methodologies for lower-tier studies are generally available (*e.g.* in the TGD), there is currently little or no guidance on the incorporation of higher tier studies into the risk assessment process. The exact nature of the studies to be performed will be dependent on a number of factors including the problem formulation and results of lower tiers. However, it seems appropriate to use a stepwise procedure, involving the existing data already assessed, followed by the identification of additional data needs and appropriate methods to address these needs.

Hence, by its nature Tier 3 will be problem formulation driven and requires case specific assessment depending on the areas of potential risk and data gaps identified in the lower tier assessments. As such, it is not appropriate to make specific recommendations for the Tier 3 process, as it needs to be open and flexible. Rather, some guidance on the sorts of approaches that may be applied for refined effect analysis is exemplified in the following sub-sections.

5.2 Case where the object of protection is a particular ecosystem

For the case of particular ecosystems which is well-known in terms of biodiversity and associated structure, the SSD methodology can be used in a refined way attributing an ecologically relevant weighting to each trophic level to better represent the structure of the ecosystem: SSD becomes then SSWD (Species Sensitivity Weighted Distribution). Duboudin *et al.* (Duboudin *et al.* , 2004) together with Forbes and Calow (Forbes and Calow, 2002a) demonstrated the sensitivity of the HC_5 to the weighted approach as these proportions may influence directly the result of the SSWD. Actually, the representativeness of laboratory species is in general small when compared to species in the environment. This method was examined in this study using the ecologically relevant trophic composition of taxa suggested by Forbes and Calow (Forbes and Calow, 2002a) as a general ecological rule for species distributions amongst trophic levels (*i.e.* ecosystem structure). The associated weights are 0.64, 0.26 and 0.1 for primary producers, invertebrates and vertebrates respectively.

Another important use of Species Sensitivity Weighted Distributions (SSWDs) is in comparative risk assessment: for example for comparing the risks of radioactive stressors among different sites or different uses or for comparing risks between different stressors such as chemicals and radionuclides or for a given radionuclide, for comparing risk between it's radiotoxicity and chemotoxicity.

Two sets of data could not be fitted with a log-normal distribution so the log-empirical distribution was used for the calculation of the HDR_5 as defined by linear interpolation on the log of the data (see (Duboudin *et al.* , 2004) for further details).

Table 17. Probabilistic effects thresholds for radioactive substances from SSDs taxonomically weighted (weight from (Forbes and Calow, 2002a) *i.e.* 0.64; 0.26 and 0.1 as taxonomic weight for plants, invertebrates and vertebrates respectively. HD_5 (in Gy) and HDR_5 (in µGy/h) and their associated 95 % confidence intervals when the distribution fitted was log-normal.

Ecosystem	Exposure regime	Number of data and species[a]	Distribution	Weighted mean[b] (weighed SD)	R^2 (KS p)[c]	$HD(R)_5$ [95 %CI]
Terrestrial	Acute, external γ	n=85 n_{gm}=47 n_s=40	Log-normal	1.74 (0.61)	0.979 (0.5)	5.51 [2.88; 10.2]
	Chronic external γ	n=54 n_{gm}=12 n_s=10	Log-normal	3.82 (0.89)	0.932 (0.5)	229 [55.6; 1105]
Freshwaters	Acute, external γ	n=38 n_{gm}=13 n_s=10	Log-Emp.[d]	-	-	3.74 [3.43; 58.7]
	Chronic external γ	n=12 n_{gm}=6 n_s=4	Log-Emp.	-	-	516 [516; 66578]
Marine	Acute, external γ	n=53 n_{gm}=13 n_s=8	Log-Emp.			
	Chronic external γ	n=16 n_{gm}=4 n_s=4	Log-normal[e]	3.40 (1.41)	0.925 (0.5)	11.9 [0.67; 252]

[a] n is the total number of toxicity data, n_{gm} is the number of geometric mean per umbrella effect; n_s the number of different species.
[b] Weighted mean of the log-normal distribution of the data (log 10) and weighted Standard Deviation of the log-normal distribution of the data (log 10)
[c] multiple R-square and p value of the Kolmogorov-Smirnov goodness of fit test (with Dallal-Wilkinson approximation)
[d] Log-Empirical distribution
[e] based on raw data, as the set of geometric mean values was too small.

The following paragraphs provide an example of how to state a problem formulation where the assessment endpoint is defined as follows.

- Problem formulation: the ecological value to be protected is the structure and functioning of the freshwater ecosystem under examination. The exposure scenario corresponds to chronic and external exposure dominant situation.
- Assessment endpoint: a particular freshwater ecosystem viewed as a valuable resource to be protected.
- Corresponding qualitative statement: significant loss of biodiversity at the ecosystem level.
- Refined Effect analysis: the ecosystem under examination is well-known, and ecological realism is given whilst weighting trophic levels to build a SSWD for freshwater ecosystems.
- Case-specific:*PNEDR* determined using the SSWD approach: 516 µGy/h. In the case of probabilistic risk characterisation, select the corresponding SSWD as a whole and then compare it to the exposure profile.

5.3 Case where the object of protection is a specific community or/and a specific endpoint

For the case of a particular object of protection such as a specific wildlife community and/or a specific effect endpoint, the SSD methodology can be used in a refined way by restricting the ecotoxicity data set in relation to the assessment endpoint (given that appropriate data is available). As a wide number of combinations are possible, a few examples are described below: HDR_5 for fish community and reproduction endpoints, HD_5 and HDR_5 for terrestrial vertebrates and several effect endpoints, and finally for plants (Table 18).

Table 18. Probabilistic effects thresholds for radioactive substances from SSDs restricted to a specific taxonomic or wildlife group and/or to a specific umbrella endpoints. HD_5 (in Gy) or HDR_5 (in µGy/h) is given with its associated 95 % confidence interval when the distribution fitted was log-normal.

Taxonomic level	Wildlife group	Exposure regime	Effect category	Nb data n Nb sp n_s	Distribution	R^2	$HD(R)_5$ [95%CI]
Vertebrates	Fish	Chronic external γ	Reproduction	n=7 n_s=3	Log-normal	0.65	4.6 [22; 170]
Terrestrial Vertebrates	Mammals Birds	Chronic external γ	Reproduction	n=51 n_s=5	Log-normal	0.96	7.8 [2.2; 44]
Terrestrial Vertebrates	Mammals Birds Reptiles	Acute external γ	Reproduction Mortality Morbidity	n=13 n_s=23	Log-normal	0.87	2.1 [1.2; 4.3]
Terrestrial Plants	Higher Plants Moss	Chronic external γ	Reproduction Mortality Morbidity	n=22 n_s=4	Log-normal	0.87	598 [229; 2095]
Terrestrial Plants	Higher Plants Moss	Acute external γ	Reproduction Morbidity	n=17 n_s=8	Log-normal	0.98	11 [4.9; 23]

The following paragraphs provide an example of how to state a problem formulation where the assessment endpoint is defined as follows.

- Problem formulation: the ecological value to be protected is the fish community of a given aquatic ecosystem under examination. The exposure scenario corresponds to chronic and external exposure dominant situation.
- Assessment endpoint: a specific wildlife community and/or a specific effect endpoint.
- Corresponding qualitative statement: significant loss of diversity in species within the fish community.
- Refined Effect analysis: A SSWD is built on fish species and all effect endpoints to estimate the HDR5.

5.4 Case where the object of protection is a keystone species

For the case of particular object of protection such as a specific species (*e.g.* keystone species – *i.e.* a species that influences the ecological composition, structure, or functioning of its community far more than its abundance would suggest -, species from the red list), the protection will be put at the individual level against adverse effects on various functions such as growth, reproduction and survival. The SSD methodology cannot be used in this case and a specific search should be undertaken within the FREDERICA database. One

important point would be the selection of the best surrogate species if the actual species is not represented in the database.

The FREDERICA database may be searched either directly through the ERICA assessment tool or as a stand alone package available on line. There are a number of ways to search the data contained within the FREDERICA database and to output the results (by selecting which information the assessor would like to view). The list of searches are as follows:

- Search by:
  - Author;
  - Keywords;
  - Source of radiation (internal, external etc);
  - Specific type of radiation (alpha, beta and gamma);
  - For specific radionuclides as the source of radiation;
  - Specific endpoints;
  - By particular species (or all) from within a particular wildlife group.
  - By wildlife group
  - By dose or dose rate steps
  - By umbrella endpoints.

Indirect protection of the species may also be defined within the problem formulation for example by ensuring that the food supply of a keystone or identified feature species is protected, for instance benthic community for a benthic fish. In this case, the effect analysis can be directed to the protection of species that are representative of the food supply.

5.5 Case where effect testing in laboratory is needed: focus on two extrapolation issues (from individual-level endpoint to population level endpoint and from external irradiation to internal irradiation)

5.5.1 Background

Another example of a question that may need to be addressed in Tier 3 is the issue of extrapolation of stressor responses from the individual organisms to the population level, *i.e.* to estimate stress effects on demographic characteristics.

Another important issue for radioactive substances is to extrapolate effects observed after external irradiation to internal exposure pathways, as the vast majority of the available effects data are related to external γ irradiation exposure.

Within ERICA, it was decided to perform specific experiments under controlled conditions with the objective of demonstrating the types of methodology and modelling that can be applied to these two fundamental extrapolation issues. The experiments addressed both issues for two organisms (an earthworm and a daphnid), with particular emphasis on chronic irradiation and a number of vital rates such as survival, growth and reproduction (which are basic parameters in modelling from individual to population). Detailed results from these studies are presented separately in a stand alone report (D5-Annex Part B). These studies demonstrate

how experimental testing and mathematical modelling can be applied in combination with adequate statistical analysis. They also provide a better estimate of the scientific uncertainty associated with data extrapolation. Good practice guidance for performing experiments to acquire properly new data on effects of chronic exposure to radioactive substances is given in D5-Annex Part A. The following sections only reports the main results obtained and the associated modelling to answer the two specified extrapolation issues. In addition, the raw experimental data constitute new knowledge input to the FREDERICA database and the results will be entered accordingly. The three-step process (see Section 3.2) will then be applied during 2006 on these new data generating critical ecotoxicity data (EDR_{10}) for two invertebrate species and updating the chronic SSDs.

5.5.2 Individual-to-population extrapolation

General background

For Tier 3, it is necessary to introduce more ecological realism without making too many demands in terms of quantity of data and/or underlying assumptions of the extrapolation methods used. One of the main disadvantages of SS(W)Ds is that interactions between species are not taken into account (Duboudin *et al.* , 2004; Forbes and Calow, 2002a; Pennington, 2003). Actually SSD techniques deal with the assumption that only physiological variability leads to the variation in individual endpoints in response to a given stressor. In other words, they ignore the interspecies variability due to variability in life-cycle characteristics. A better approach has been proposed and applied for chemical stressors by a number of authors which integrates the effects on survival, reproduction and timing in terms of population growth rate. This can be done using population models to extrapolate toxic effects on various combinations of individual life-cycle variables to effects on population dynamics. More refined approaches also include consideration of density-dependent factors to understand whether they are likely to amplify toxic effects at the population level. Among others, Calow *et al.* (1997) developed an approach that catalogues a series of plausible simplified life-history scenarios to demonstrate, on the basis of results from ecotoxicological tests, how effects at the individual level propagate to influence the population dynamics. This approach helps to answer the following questions:

- How sensitive is the population growth rate to changes in each of the life-history traits?
- To what extent do effects on life-history traits influence population growth rate?
- How do effects observed on a given phase of the life-cycle influence population growth rate? (Calow et al. , 1997)

A literature review carried out by Forbes and Calow (Forbes and Calow, 1999) found no evidence to support the concern that small, statistically undetectable effects on several individual life-cycle traits might be magnified into large effects at the population level. In other words, the population growth rate was less or as sensitive as the most sensitive individual life-cycle traits. Given this, Forbes and Calow (Forbes and Calow, 2002b) suggested that, due to the fact that the most sensitive variables being measured at the individual level under laboratory testing vary across species and toxicants, it was not feasible to identify the best predictors of population growth rate *a priori*. This underlines the necessity for adequate experimental development to address the three previous questions for radioactive substances.

Delay-in-population-growth index. Evaluating effects of radionuclides or of any stressor at population level is complex because population dynamics depend on many additional environmental factors (trophic conditions, predation pressure, density-dependence, exposure to toxicants, etc.). The problem can be simplified using the Wennergreen and Stark approach known as delay-in-population-growth index (Wennergren and Stark, 2000). In this study, this method was used to predict how long population recovery might take under stressful radiological exposure. Such predictions are based on life table parameters. Considering that exposure to

sublethal dose(rate)s does not kill all individuals, surviving organisms may reproduce and their reproductive rates may or may not be affected by radiation. This has potential critical consequences for population growth. In this situation the delay for a stressed population to recover to the same number of individuals as the control provides a measure of the extent of effect on its population dynamics is.

The delay-in-population-growth index may be modulated to fit the studied species, depending on their specific features. Wennergren and Stark (Wennergren and Stark, 2000) defined the delay as the time for a population exposed to contaminants to recover to the same number of individuals as a control population. This model was modified by Stark *et al.* (Stark *et al.* , 2004) who examined the predicted time taken by a population to grow from 10 to 100,000 individuals. The choice of a 10,000-fold increase was made to ensure stable population growth rates (stable age distribution). In this study, simulations were run from 1 to 50,000 individuals, to ensure that stable growth rates and age distributions were reached.

Population models and Leslie Matrix (Leslie 1945). The population was structured per age classes (=cohorts) where $N_i(t)$ is the number of individuals of age i at time t (Figure 6). A simple differential equation prescribes exponential decay of abundance for each cohort over time:

$$\frac{dN_i}{dt} = -\mu N_i$$

where μ is the instantaneous background mortality rate.

All cohorts of age ranging from 1 to I_{max}-Δ advance one age class at discrete, equidistant time intervals Δ. The cohort of age ≥ I_{max} is removed under the assumption that any remaining individuals die of old age. Over Δ, a new cohort (N_1) is produced from the cumulative reproduction of individuals in all cohorts N_i, following their fecundity rates $F_i(t)$.

$$\frac{dN_1}{dt} = \sum_i N_i \cdot F_i(t)$$

Eggs hatch upon reaching age I_H (representing the embryonic development in cocoons for earthworms and in brood pouch for daphnids). Individuals subsequently enter a juvenile stage. Juveniles contribute no reproductive effort until age of reproduction I_R that may be affected by radiation or not.

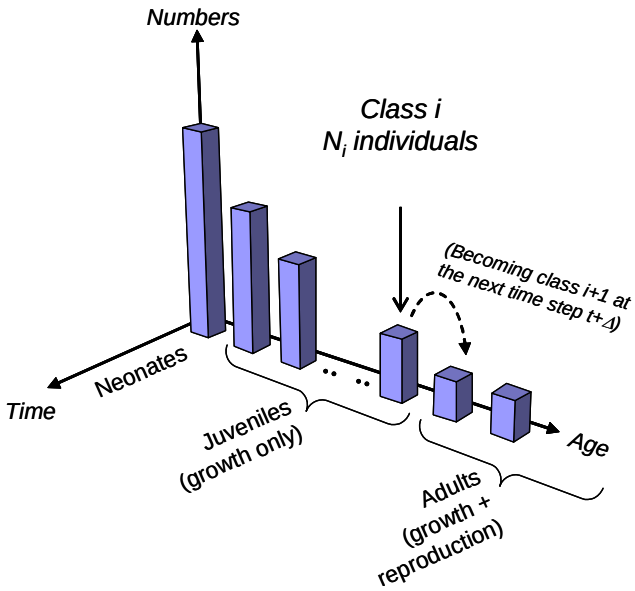

Figure 6. Age-structured representation of a population in matrix models

Description of life-cycles. The two studied invertebrate species, daphnids and earthworms, were selected partly because of their contrasted life-cycles: daphnids are parthenogenetic freshwater crustaceans whereas earthworms are terrestrial Annelids with sexual reproduction (Figure 7).

Earthworms are hermaphrodites and during mating they cross-fertilise. *Eisenia fetida* is a very prolific species producing from 2 to 5 cocoons per worm per week. The number of fertilized ova in each cocoon varies and gives from 1 to 6 hatchlings per cocoon (Edwards and Bohlen, 1996). Most of the cocoons hatch 3 to 4 weeks after production, and it takes approximately 8 to 12 weeks before the hatchlings reach sexual maturity.

Individual life history traits involved in the daphnid population model are illustrated in Figure 8. Briefly, **mortality** is a combination of daily probability of survival observed in experiments (red line: 50 % mortality after 70 days) and an exponential decay (blue line: 98 % survival every day). Daphnids release neonates every 3 days at a **fecundity** rate, which depends on age, starting at **age of first brood** (10 days). Table 19 shows values of life history traits used in the two models.

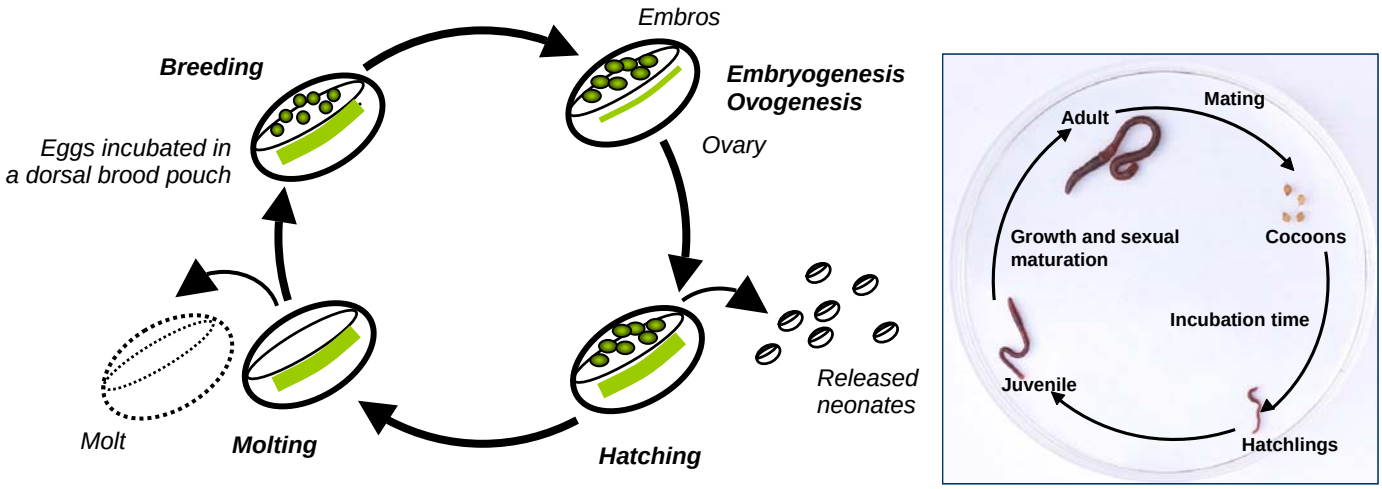

Figure 7. Schematic representation of the life-cycle of the two invertebrate models used. Left side: Parthenogenetic life-cycle of *Daphnia magna* – Right side: life-cycle of *Eisenia foetida.*

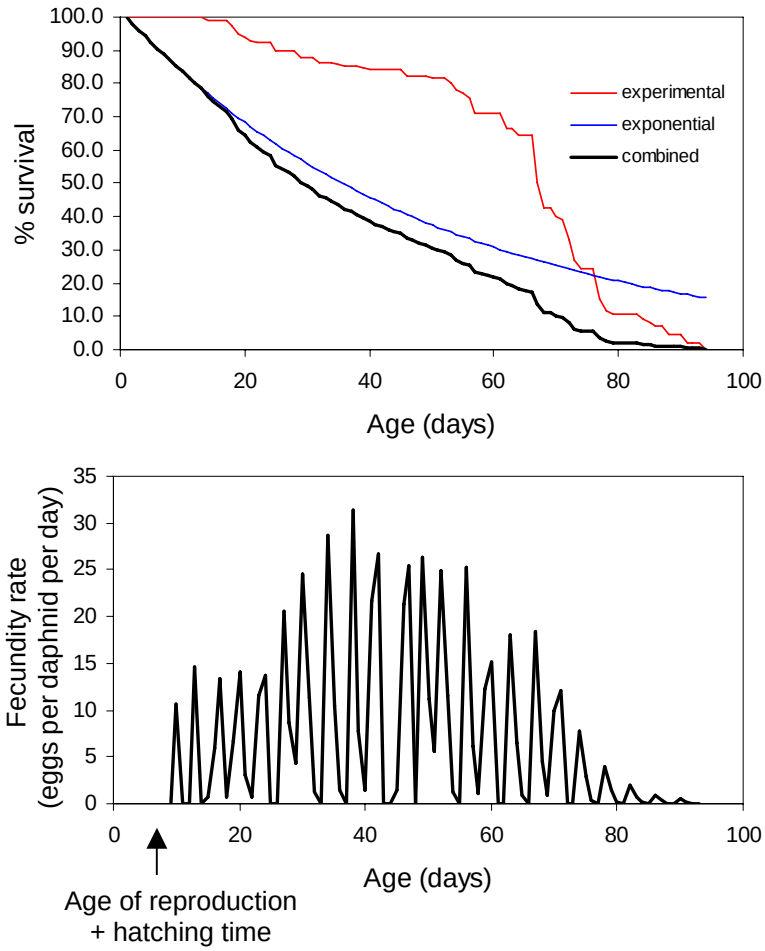

Figure 8. Individual life history traits used for the population model of *Daphnia magna*

Table 19. Typical values for life history traits of Daphnid and Earthworm models.

Life history trait	Daphnid	Earthworm
Age of reproduction	7 days	9 weeks
Hatching time	3 days	3-4 weeks
Brood per individual	1 every 3 days	1.6 cocoons per week (progressively increasing from 0.4 to 1.6 from week 9 to week 12)
Offspring per brood	10-30 neonates per brood (depending on age, see Figure 8)	2.8 hatchlings per cocoon
Offspring viability	100%	98%
Survival	μ = 98% per day *Pi* depending on age, see Figure 8	*μ = 98% per week* *Pi = 1*

Results from ERICA experiments and modelling

General assumptions for modelling. For the two species, simulations were run assuming:

1) a closed system with no immigration or emigration of individuals. Changes in population numbers were only the result of birth and mortality; and

2) no density dependence *i.e.* the abundance of individuals has no consequence for their vital rates.

Assumptions 1 and 2 above imply that population models simulate the spread of populations in an unlimited environment in terms of space and resource.

3) If no multi-generation data are available, fecundity and viability rates are constant over generations, *i.e.* what is observed in the experiments for a generation is also true for any offspring generations.

Thus, vital rates measured in the F0 generation were used for every generation in simulated daphnid populations. Simulations of earthworm populations were based on F0 parameters for the first generation, then on F1 parameters for every subsequent generation.

Earthworms exposed to chronic gamma external radiation. Table 20 and Table 21 report on results obtained on the individual effect endpoint previously listed. *Eisenia fetida* was continuously exposed during different stages of the life cycle, in 2 generations (F0 and F1). Adult F0 reproduction capacity (i.e., number of cocoons produced, hatchability and number of F1 hatchlings) was measured over a 13-week exposure period, at 5 dose rates (0.18, 1.7, 4, 11 and 43 mGy/h). Survival, growth and sexual maturation of F1 hatchlings (from cocoons produced during the last 9-13 week period of adult F0 exposure), were examined for 11 weeks, at 4 dose rates (0.18, 1.7, 4, 11 mGy/h). This was followed by 13 weeks exposure of the F1 as adults, for registration of their reproduction capacity. Results showed no radiation-induced mortality or maturation delay. The most sensitive endpoints were the hatchability and the number of hatchlings per hatched cocoons; main results are shown in Table 20 and Table 21. For details, see D5 Annex – part B. No significant effects on the individual endpoints were observed at dose rates up to 4 mGy/h, and hence the population growth was not delayed compared to the control (Figure 9). At 4 mGy/h there was a slight (but not significant) reduction in hatchability of cocoons produced by F0 worms (92-94% versus 98% in the controls) and in the number of hatchlings per hatched cocoon (2.53 versus 2.81 in the controls). No effects on the reproduction capacity in the next generation (F1)

at this dose rate was observed, and overall this resulted in a minor delay-in-population-growth to 5,000 individuals of 0.8 week (< model time step Δ = 1 week, Figure 9). At 11 mGy/h, the hatchability in F0 was mildly impaired (~89 %) for cocoons produced during weeks 1-8, dropping to ~25% for those produced after week 9. Hatchability in F1 was also reduced and the number of hatchlings per hatched cocoon was significantly reduced for both F0 and F1 (Table 21). This resulted in delayed population growth after 13 weeks and the delay-in-population-growth to 5,000 at this dose rate was 5.8 weeks. The strong reduction observed in cocoon hatchability from 60 % (weeks 1-4) to 0 % (after week 4) at the dose rate of 43 mGy/h showed dramatic consequences for simulated population growth after 9 weeks. At this dose rate, earthworm population never recovered, slowly decaying in number of individuals down to 0.

*Daphnids exposed to chronic internal alpha contamination.*Table 22 and Table 24 report on results obtained on the individual effect endpoint previously listed. There was no effect of alpha internal radiation on daphnid fecundity (expressed as the number of eggs produced per female) and mortality rates and therefore no significant delay in population growth (Figure 9). However, reduced resistance of larvae under starvation with increasing alpha dose rate may have strong consequences for recruitment. Note that the same trend was observed for gamma exposure but only at the highest dose rate of 40 mGy/h; see Table 23 and Table 25.

A conditional larval mortality rate dependent on the parameter « duration of larval starvation » was introduced to simulate the population effect of temporary food shortage. This represented a first step towards development of more complex models taking combined effects of exposure to alpha radiation and fluctuating food resource into account. This model predicted increasing delay in population growth with increasing duration of starvation in larvae. For example, delay-in-population-growth up to 5,000 individuals reached 2 days and 10 days in the control, after starvation of 4 days and 5 days respectively. Contaminated populations showed much greater sensitivity to larval starvation, with probable extinction after 4 days of starvation at 0.07 mGy/h as alpha dose rate. Model outcomes showed that alpha contamination possibly reduces the ability of population to cope with the variability in natural environmental conditions.

Table 20. Reproductive rates of Earthworms with increasing gamma dose rate and time in the F0 generation. At the start of experiments (week 1) worms were 21 weeks old. Means ± SD of replicate boxes are shown. Control: n=12; 0.19 –11.4 mGy/h, n=4; 43 mGy/h, n=1. Significant difference from controls is indicated (n.s.=non significant ; *=p<0.05; **=p<0.01; ***=p<0.001).

		Dose[a]		Cocoons/worm/week			Hatchability (%)[b]			Hatchlings/hatched cocoon[b]			Total number of F1 hatchlings/ Adult F0[b]		
		Gy	SD	mean	SD	p	mean	SD	p	mean	SD	p			
Control	week 1-4			**1.68**	0.13		**97.8**	2.1							
	week 5-8			**1.89**	0.13		**98.3**	2.2							
	week 9-13			**1.46**	0.12		**97.7**	2.6		**2.81**	0.25		**59**	6	
0.19 mGy/h	week 1-4	**0.11**	0.02	**1.58**	0.13	*n.s.*	**93.7**	5.7	*n.s.*						
	week 5-8	**0.23**	0.03	**1.81**	0.16	*n.s.*	**93.7**	5.8	*n.s.*						
	week 9-13	**0.37**	0.05	**1.44**	0.17	*n.s.*	**91.2**	3.2	*n.s.*	**2.82**	0.15	*n.s.*	**54**	4	*n.s.*
1.8 mGy/h	week 1-4	**1.1**	0.2	**1.74**	0.06	*n.s.*	**95.3**	2.4	*n.s.*						
	week 5-8	**2.2**	0.3	**1.84**	0.16	*n.s.*	**97.9**	2.0	*n.s.*						
	week 9-13	**3.6**	0.5	**1.55**	0.18	*n.s.*	**96.4**	4.0	*n.s.*	**2.88**	0.03	*n.s.*	**61**	5	*n.s.*
4.2 mGy/h	week 1-4	**2.7**	0.4	**1.63**	0.10	*n.s.*	**93.9**	6.6	*n.s.*						
	week 5-8	**5.4**	0.8	**1.79**	0.09	*n.s.*	**93.4**	3.0	*n.s.*						
	week 9-13	**8.6**	1.3	**1.42**	0.14	*n.s.*	**91.9**	9.6	*n.s.*	**2.53**	0.10	*n.s.*	**49**	4	*
11 mGy/h	week 1-4	**7.1**	0.9	**1.68**	0.10	*n.s.*	**88.9**	10.4	*n.s.*						
	week 5-8	**14**	2	**1.81**	0.25	*n.s.*	**90.2**	5.6	*						
	week 9-13	**23**	3	**1.15**	0.36	*n.s.*	**24.5**	8.7	***	**2.43**	0.23	*	**34**	6	***
43 mGy/h	week 1-4	**26**	4	**1.83**	-	*n.s.*	**60.3**	-	***						
	week 5-8	**53**	8	**1.75**	-	*n.s.*	**0.0**	-	***						
	week 9-13	**85**	13	**1.26**	-	*n.s*	**0.0**	-	***	**2.27**	-	*n.s.*	**10**	-	***

a – Dose accumulated at the end of the F0 exposure period; b – Percentage hatchability after 9 weeks; c – Results shown are calculated for the whole 1-13 week period

Table 21. Reproductive rates of Earthworms with increasing gamma dose rate and time in the F1 generation.. Means ± SD of replicate boxes are shown. Control: n=12; 0.18 –11 mGy/h. Significant difference from controls is indicated (n.s.=non significant ; *=p<0.05; **=p<0.01; ***=p<0.001).

	Condition	Dose[a]		Cocoons/worm/week			Hatchability (%)[b]			Hatchlings/hatched cocoon[c]			Total number of F2 hatchlings/ Adult F1[c]		
		Gy	SD	mean	SD	*p*	mean	SD	*p*	mean	SD	*p*	mean	SD	*p*
Control	week 12-16			**3.15**	0.25		**97.8**	3.8							
	week 17-20			**3.10**	0.21		**97.4**	3.9							
	week 21-24			**1.90**	0.21		**96.3**	2.8		**3.53**	0.38		**123**	19	
0.18 mGy/h	week 12-16	0.44	0.06	**2.92**	0.33	*n.s.*	**98.5**	2.9	*n.s.*						
	week 17-20	0.54	0.08	**2.80**	0.56	*n.s.*	**97.5**	4.0	*n.s.*						
	week 21-24	0.64	0.09	**1.72**	0.39	*n.s.*	**96.7**	4.2	*n.s.*	**3.64**	0.61	*n.s.*	**116**	28	*n.s.*
1.7 mGy/h	week 12-16	4.2	0.6	**3.26**	0.53	*n.s.*	**97.0**	3.4	*n.s.*						
	week 17-20	5.2	0.8	**3.11**	0.66	*n.s.*	**96.9**	2.0	*n.s.*						
	week 21-24	6.1	0.9	**1.84**	0.37	*n.s.*	**94.5**	2.9	*n.s.*	**3.54**	0.39	*n.s.*	**124**	34	*n.s.*
4.0 mGy/h	week 12-16	10	2	**3.35**	0.30	*n.s.*	**96.0**	4.3	*n.s.*						
	week 17-20	13	2	**3.19**	0.15	*n.s.*	**98.0**	1.8	*n.s.*						
	week 21-24	15	2	**1.91**	0.14	*n.s.*	**94.9**	5.0	*n.s.*	**3.78**	0.55	*n.s.*	**135**	17	*n.s.*
11 mGy/h	week 12-16	27	4	**3.35**	0.15	*n.s.*	**45.5**	12.9	***						
	week 17-20	34	5	**3.30**	0.29	*n.s.*	**55.6**	13.0	***						
	week 21-24	40	6	**1.98**	0.10	*n.s*	**69.2**	9.0	***	**2.24**	0.46	***	**46**	13[a]	***

a – Dose accumulated at the end of the F1 exposure period; b – Percentage hatchability after 9 weeks; c – Results shown are calculated for the whole exposure period, week 12-24.

Table 22. Reproductive rates of Daphnids with increasing alpha dose rate and duration of larval starvation. Mean and standard deviation with n=3. *p* is the level of significance of the mean compared to the control (*t* test): n.s.=non significant ; *=*p*<0.05; **=*p*<0.01; *=*p*<0.001.**

Condition	Dose (mGy)	Days of deposition			Neonates/daphnid			Duration of larval starvation for 50% survival (in days)			
		mean	SD (1)	*p*	mean	SD (1)	*p*	mean (2)	min	max	*p*
Control											
Brood 1		**6.9**	0.7		**10.2**	1.8		**6.4**	5.3	7.4	
Brood 2		**10.2**	0.9		**14.0**	3.9					
Brood 3		**12.9**	1.3		**25.9**	2.8		**4.0**	3.5	4.7	
Brood 4		**17.0**	1.1		**15.5**	9.5					
Brood 5		**19.6**	1.1		**18.2**	6.0		**6.3**	5.5	7.0	
0.01 mGy/h											
Brood 1	1.8	**6.8**	0.5	*n.s.*	**10.0**	2.0	*n.s.*	**3.5**	3.0	4.0	**
Brood 2	2.4	**9.6**	0.8	*	**13.4**	2.4	*n.s.*				
Brood 3	3.2	**12.5**	0.9	*n.s.*	**24.5**	4.0	*n.s.*	**3.8**	3.6	3.9	*n.s.*
Brood 4	4.3	**16.4**	0.8	*n.s.*	**13.0**	7.8	*n.s.*				
Brood 5	5.2	**19.4**	0.9	*n.s.*	**18.5**	4.4	*n.s.*	**4.6**	4.1	5.1	**
0.07 mGy/h											
Brood 1	8.2	**6.9**	0.8	*n.s.*	**9.3**	1.9	*n.s.*	**3.0**	2.4	3.5	**
Brood 2	10.4	**10.0**	0.6	*n.s.*	**12.2**	2.9	*n.s.*				
Brood 3	15.3	**12.8**	0.9	*n.s.*	**24.1**	5.1	*n.s.*	**3.3**	3.2	3.6	**
Brood 4	23.6	**16.5**	1.0	*n.s.*	**15.1**	8.1	*n.s.*				
Brood 5	30.7	**19.2**	0.4	*n.s.*	**22.2**	1.7	*	**4.8**	4.6	5.0	**
0.8 mGy/h											
Brood 1	157.3	**7.0**	0.8	*n.s.*	**10.0**	2.4	*n.s.*	**4.6**	3.8	5.5	**
Brood 2	182.2	**9.9**	0.9	*n.s.*	**13.9**	4.6	*n.s.*				
Brood 3	226.4	**12.9**	1.0	*n.s.*	**25.6**	3.9	*n.s.*	**3.5**	3.2	3.8	*n.s.*
Brood 4	295.1	**16.7**	0.9	*n.s.*	**16.8**	7.0	*n.s.*				
Brood 5	360.8	**20.2**	1.0	*n.s.*	**16.0**	6.1	*n.s.*	**4.5**	4.4	4.0	**

(1) n=20 individual replicates (2) n=3 replicates of 5 daphnids each.

Table 23. Reproductive rates of Daphnids with increasing gamma dose rate and duration of larval starvation. Mean and standard deviation with n=3. *p* is the level of significance of the mean compared to the control (*t* test): n.s.=non significant ; *=*p*<0.05; **=*p*<0.01; *=*p*<0.001.**

Condition	Dose (mGy)	Days of deposition			Neonates/daphnid			Duration of larval starvation for 50% survival (in days)			
		mean	SD (1)	*p*	mean	SD (1)	*p*	mean (2)	min	max	*p*
Control											
Brood 1		**7.8**	1.5		**13.1**	2.7		**4.5**	4.4	4.6	
Brood 2		**9.2**	0.5		**23.0**	4.1					
Brood 3		**12.5**	0.6		**23.1**	3.8		**4.6**	4.6	4.6	
Brood 4		**16.3**	2.6		**33.8**	4.1					
Brood 5		**19.0**	0.6		**24.9**	4.8		**5.6**	5.4	5.7	
0.4 mGy/h											
Brood 1	67.2	**6.0**	0.0	***	**14.4**	1.8	*n.s.*	**4.3**	4.1	4.5	**
Brood 2	96.0	**9.0**	0.0	*n.s.*	**23.9**	3.1	*n.s.*				
Brood 3	124.8	**12.0**	0.0	***	**19.0**	2.3	***	**4.1**	3.8	4.1	**
Brood 4	153.6	**14.9**	0.3	*	**27.6**	8.7	*				
Brood 5	182.4	**18.1**	0.3	***	**22.7**	2.5	*n.s.*	**3.5**	3.3	3.7	**
4.0 mGy/h											
Brood 1	672.0	**6.6**	0.7	***	**15.7**	3.7	*	**4.6**	4.4	4.7	*n.s.*
Brood 2	960.0	**9.2**	0.6	*n.s.*	**24.9**	3.5	*n.s.*				
Brood 3	1248.0	**12.2**	0.6	*n.s.*	**22.1**	2.9	*n.s.*	**4.6**	4.6	4.7	**
Brood 4	1536.0	**15.4**	0.7	*n.s.*	**32.3**	8.7	*n.s.*				
Brood 5	1824.0	**18.6**	0.5	*n.s.*	**28.8**	2.9	*	**4.2**	4.1	4.6	**
40 mGy/h	6720.0										
Brood 1	6720.0	**6.1**	0.5	***	**15.6**	3.2	***	**3.2**	2.9	3.6	**
Brood 2	9600.0	**8.6**	0.5	***	**24.3**	3.6	*n.s.*				
Brood 3	12480.0	**11.4**	0.5	***	**19.5**	3.6	***	**3.2**	3.2	3.2	**
Brood 4	15360.0	**14.3**	0.5	*	**30.4**	2.5	***				
Brood 5	18240.0	**17.3**	0.5	***	**21.8**	2.3	*	**3.4**	3.3	3.6	**

(1) n=20 individuals replicates (2) n=3 replicates of 5 daphnids

Table 24. Individual dry mass of daphnids, eggs and neonates and mass specific respiration rates in relation to alpha dose rate. Mean and standard deviation with n=3. *p* is the level of significance of the mean compared to the control (*t* test): n.s.=non significant ; *=*p*<0.05; **=*p*<0.01; *=*p*<0.001.**

Condition	Day	Dose (mGy)	µg per daphnid			µg per egg			µg per neonate			µmol O_2 per mg per h		
			mean	SD	*p*	mean	SD	*p*	mean	SD	*p*	mean	SD	*p*
Control														
Brood 1	7		**124.2**	6.8		**5.0**	0.1		**7.8**	0.9				
Brood 2	10		**238.2**	44.5		**5.8**	0.7		**8.2**	0.9		**56.4**	7.5	
Brood 3	13								**13.1**	2.9				
Brood 4	16		**374.1**	10.0		**11.6**	1.0		**13.8**	0.8		**43.5**	4.4	
Brood 5	19								**15.7**	1.0				
Brood 6	23		**431.6**	21.3		**13.5**	1.7					**41.3**	5.1	
0.01 mGy/h														
Brood 1	7	1.8	**155.6**	10.1	***	**4.8**	0	*						
Brood 2	10	2.4	**225.6**	6.3	*n.s.*	**6.3**	0.6	*n.s.*	**8.6**	0.2	*n.s.*	**65.7**	2.4	*n.s.*
Brood 3	13	3.2							**8.2**	0.1	*n.s.*			
Brood 4	16	4.3	**314.8**	26.9	*	**10.2**	0.7	*n.s.*	**12.8**	1.6	*n.s.*	**47.2**	3.8	*n.s.*
Brood 5	19	5.2							**13.6**	1.7	*n.s.*			
Brood 6	23	6.1	**424.8**	41.0	*n.s.*	**11.6**	1.3	*n.s.*	**15.8**	1.8	*n.s.*	**43.5**	0.5	*n.s.*
0.07 mGy/h														
Brood 1	7	8.2	**121.8**	21.6	*n.s.*	**4.5**	0.2	*						
Brood 2	10	10.4	**241.6**	40.9	*n.s.*	**6.3**	0.4	*n.s.*	**8.4**	1.3	*n.s.*	**65.0**	9.9	*n.s.*
Brood 3	13	15.3							**8.3**	1.4	*n.s.*			
Brood 4	16	23.6	**319.9**	42.7	*n.s.*	**9.2**	0.8	*	**10.0**	1.0	*n.s.*	**52.2**	6.6	*n.s.*
Brood 5	19	30.7							**12.5**	1.4	*n.s.*			
Brood 6	23	37.8	**364.9**	66.2	*n.s.*	**11.3**	0.2	*n.s.*	**12.2**	2.2	*	**46.2**	6.2	*n.s.*
0.8 mGy/h														
Brood 1	7	157.3	**127.5**	6.7	*n.s.*	**4.4**	0.0	***						
Brood 2	10	182.2	**267.8**	15.2	*n.s.*	**6.2**	0.3	*n.s.*	**7.6**	0.7	*n.s.*	**57.4**	5.3	*n.s.*
Brood 3	13	226.4							**8.4**	2.0	*n.s.*			
Brood 4	16	295.1	**332.2**	7.0	***	**10.2**	1.8	*n.s.*	**10.3**	3.7	*n.s.*	**49.0**	4.3	*n.s.*
Brood 5	19	360.8							**11.9**	1.7	*n.s.*			
Brood 6	23	441.1	**376.4**	15.4	***	**10.5**	0.9	*	**12.1**	1.8	*	**53.0**	3.7	*

Table 25. Individual dry mass of daphnids, eggs and neonates and mass specific respiration rates in relation to gamma dose rate. Mean and standard deviation with n = 3. *p* is the level of significance of the mean compared to the control (*t* test): n.s.=non significant ; *=*p*<0.05; **=*p*<0.01; *=*p*<0.001.**

Condition	Day	Dose (mGy)	µg per daphnid			µg per egg			µg per neonate			µmol O_2 per mg per h		
			mean	SD	*p*	mean	SD	*p*	mean	SD	*p*	mean	SD	*p*
Control														
Brood 1	7								**4.6**	0.8				
Brood 2	10		**227.7**	52.9		**7.1**	0.4		**9.2**	2.4		**43.5**	5.3	
Brood 3	13								**11.3**	0.3				
Brood 4	16		**291.8**	16.0		**7.9**	0.9		**12.4**	1.9		**31.7**	9.0	
Brood 5	19								**11.3**	0.7				
Brood 5	23		**395.1**	35.3		**9.9**	0.7					**44.3**	7.3	
0.4 mGy/h														
Brood 1	7	67.2							**6.3**	0.1	*			
Brood 2	10	96.0							**10.9**	0.9	*n.s.*			
Brood 3	13	124.8							**12.0**	0.1	*			
Brood 4	16	153.6							**12.0**	0.6	*n.s.*			
Brood 5	19	182.4							**14.4**	0.7	***			
Brood 5	23	220.8	**488.3**	62.2	*	**11.5**	0.6	*				**39.5**	1.6	*n.s.*
4.0 mGy/h														
Brood 1	7	672.0							**5.7**	1.2	*n.s.*			
Brood 2	10	960.0							**9.6**	1.7	*n.s.*			
Brood 3	13	1248.0							**8.8**	2.2	*n.s.*			
Brood 4	16	1536.0							**11.5**	0.7	*n.s.*			
Brood 5	19	1824.0							**11.5**	2.9	*n.s.*			
Brood 5	23	2208.0	**455.1**	40.9	*n.s.*	**10.0**	0.7	*n.s.*				**37.2**	5.1	*n.s.*
40 mGy/h														
Brood 1	7	6720.0							**6.7**	0.3	*			
Brood 2	10	9600.0	**256.5**	28.3	*n.s.*	**6.8**	0.8	*n.s.*	**8.8**	0.9	*n.s.*	**42.0**	1.6	*n.s.*
Brood 3	13	12480.0							**12.1**	0.9	*n.s.*			
Brood 4	16	15360.0	**312.9**	35.2	*n.s.*	**8.5**	0.4	*n.s.*	**9.4**	1.1	*	**35.6**	3.5	*n.s.*
Brood 5	19	18240.0							**15.9**	4.3	*n.s.*			
Brood 5	23	22080.0	**535.6**	100.1	*n.s.*	**8.9**	4.4	*n.s.*				**33.8**	5.3	*n.s.*

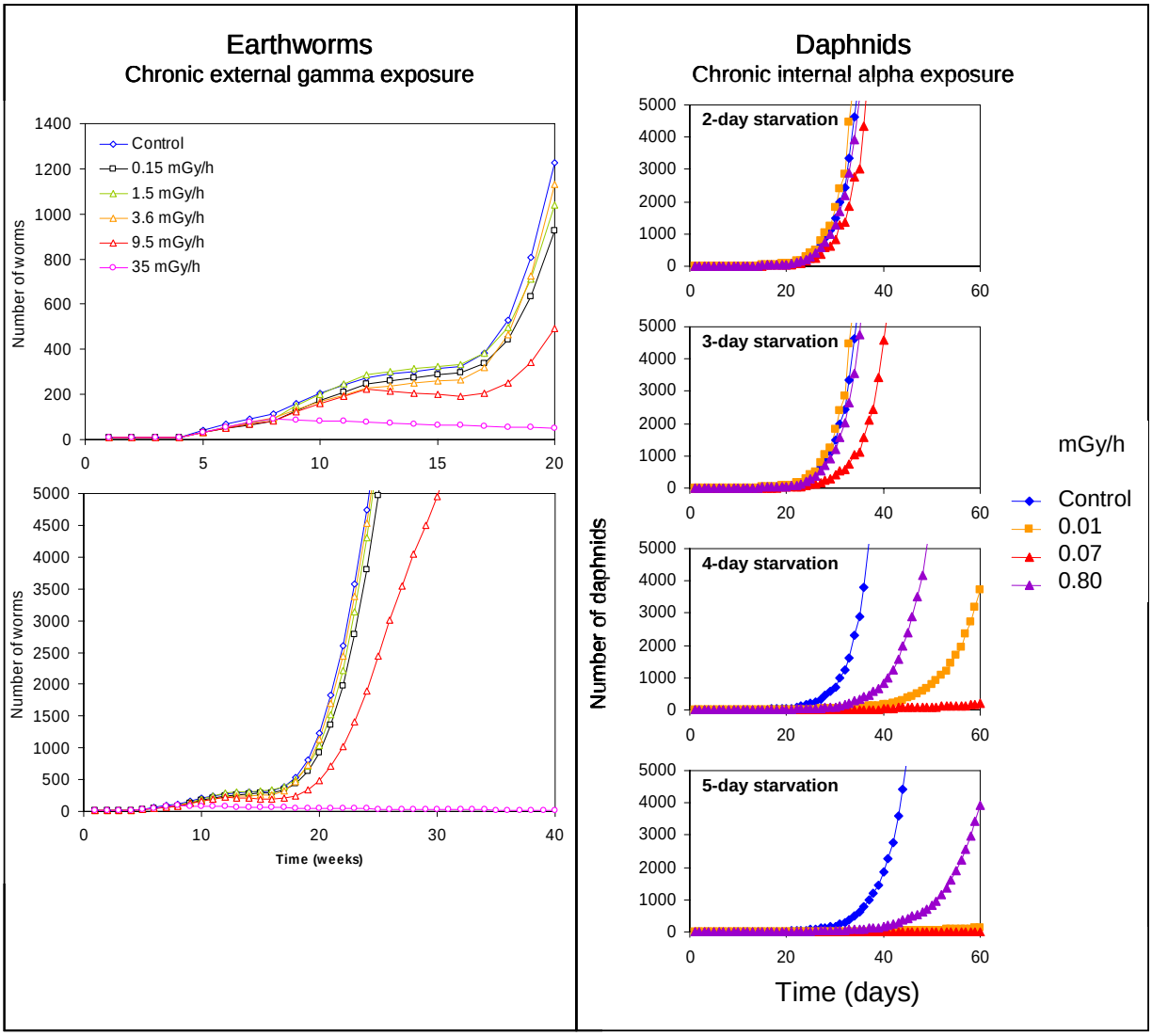

Figure 9. Simulation of the changes in earthworm population in relation to gamma dose rate -*left side*- and Changes in daphnid population in relation to alpha dose rate and duration of larval starvation –*right side*-. Y-axis was limited to 1,400 or 5,000 individuals for better visualisation.

Consequences of effects observed at the individual level for the population

Methods used. The sensitivity of population growth rate to chronic exposure to radionuclides depends on how sensitive individual life history traits of organisms are to radiation and how changes in individual life history traits may affect population growth. This second aspect is strongly determined by the life-cycles of the studied species. Daphnids and earthworms are clearly very different both in how organisms respond to chronic exposure to radionuclides and how these effects extrapolate through life-cycles. This offers the opportunity of a contrasted analysis of the propagation of effects from the individual level to the population level.

The sensitivity of the delay-in-population-growth index was analysed in relation to changes in each individual life history traits using the daphnid and earthworm population models (Figure 10). Change in individual and population endpoints were expressed as follows.

- **Fecundity**: total number of offspring produced over 21 days (daphnids) and 21 weeks (earthworms).

- **Mortality:** proportion of survival after 21 days (daphnids) and 21 weeks (earthworms).

- **Age of reproduction:** the delayed time when individuals start reproducing is calculated considering the control age I_R(control) at first brood of 10 days (daphnids) and 9 weeks (earthworms). A delayed age of reproduction I_R(X) for the treatment *X* is equivalent to a relative change of $I_R(\text{control})/I_R(\text{X})$, *i.e.* a relative change of 0.5 means that it takes organisms twice as much time to start reproducing as the control.

-**Relative delay in population growth**: at the population level, consequences for population growth are expressed as $\Delta T/T(\text{control})$ where *T* is the time it takes the population to grow from 1 to 50,000 individuals and *ΔT=T(X)-T(control)* for the treatment *X*. A value of 0 means that population growth is unchanged compared to the control; a value of 1 means that population takes twice as much time to grow as the control. This index depends on how fast the control population grows, *i.e. T*(control) may vary from ~70 days (daphnids) to ~48 months (earthworms).

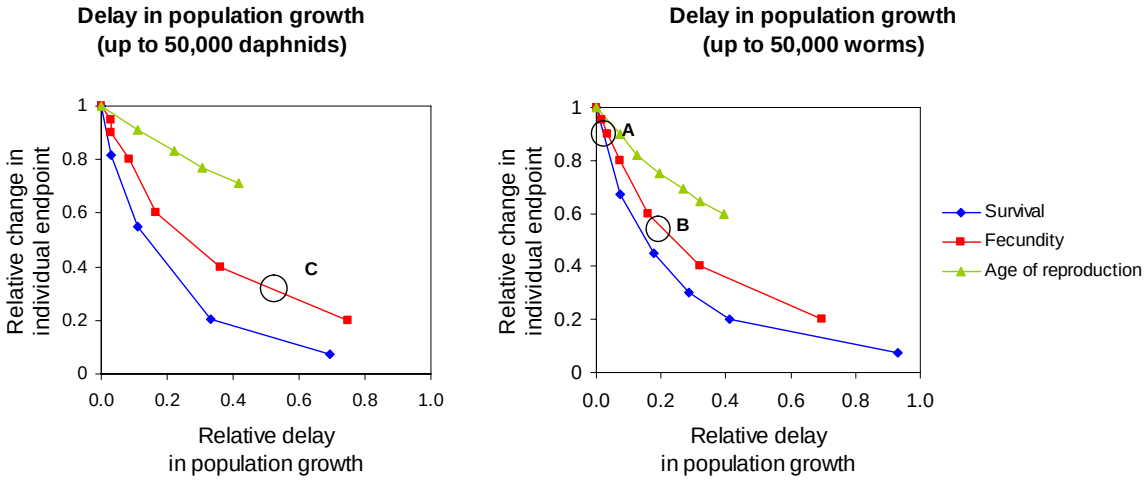

Figure 10. Relationship between effects at individual level and their relative consequence at the population level. Earthworms. A - 10 % reduction in fecundity at 3.3-3.6 mGy/h; B - 55 % reduction in fecundity at the dose rate of 9-9.5 mGy/h. **Daphnids.** C - 70% reduction in starved control and up to 100% reduction (i.e. extinction) independent of the dose rate.

Main lessons learnt from experiments and modellings

Different individual endpoints show equivalent consequences at the population level

Observed impact of chronic exposure to radionuclides at the population level is mediated through individual effect endpoints as follows: 1) effects on the hatchability of cocoons and number of hatchlings per hatched cocoon for earthworms and 2) effects on larval resistance to starvation for daphnids. Ultimately, effects increase early mortality of larvae in both species (offspring are produced but they never reach reproduction age), which are, with regard to population dynamics, equivalent to not producing those offspring. In other terms, observed effects can be assimilated to a reduction in fecundity in every case:

- 10 % reduction in fecundity in earthworms at 4 mGy/h (point A on Figure 10),
- 55 % reduction in fecundity in earthworms at the dose rate of 11 mGy/h (point B on Figure 10),
- 70% reduction in starved control daphnids and up to 100% reduction (i.e. extinction) in starved contaminated daphnids independent of the dose rate (point C on Figure 10).

One main difference is that in the case of daphnids, the exposure to radionuclide led to an increased sensitivity of the population growth rate to environmental changes at the juvenile stage. In natural habitats, population growth rates are driven by food availability, among others. The species became more vulnerable to food depletion for radionuclide contaminated environment than in non-contaminated habitats.

Consequences at the population level depend on the considered life history trait

Small effects on a critical individual endpoint for population dynamics may impair population growth rate to a greater extent than large effects on neutral individual endpoint. In other words, the impact of chronic exposure to radionuclides at population level depends on which history trait is impaired. The data on daphnids can be used to illustrate this point. Figure 10 shows that a relative delay in population growth of 0.3 is reached for individual effects of 0.75 on age of reproduction, 0.50 on fecundity or 0.25 on survival. Thus, individual endpoints do not show the same importance at the population level, population growth being by far more sensitive to changes in age of reproduction than to changes in fecundity or survival.

Consequences at the population level depend on the considered species

The other main lesson learnt is that the propagation of effects from individuals to population depends greatly on the characteristics of the specific life history. For example, a value of 0.8 in age of reproduction induces respective delays in population growth of 0.25 in daphnids and 0.15 in earthworms. This shows that changes in an individual endpoint such as age of reproduction (= generation time) has much stronger consequence in the fast growing daphnids (with short generation time and high fecundity rate) than in the slow growing earthworms. Conversely in the slow growing species, duration of the reproductive period was a key parameter, with a high sensitivity of population growth to adult mortality: a value of 0.2 yields a greater delay in population growth in earthworms (0.47) than in daphnids (0.33).

Finally, the experimental results on the two invertebrate species emphasised that in any species, consequence for population dynamics differ between life history traits, with the highest sensitivity of population growth to age of reproduction, intermediate sensitivity to fecundity and lowest sensitivity to adult mortality. However, the relative importance of each life history trait also varies between species, depending on the type of reproductive strategy (short time generation *versus* long time generation, iteroparous *versus* semelparous, sexual *versus* asexual reproductive strategy, etc.).

Recommendations for taking individual-to-population extrapolations into account in a refined effect analysis

Finally, the recommendations for taking this extrapolation issue into account in a refined effect analysis implemented in Tier 3 are as follows.

- Since the propagation of effects from individuals to population depends greatly on the life-cycle characteristics, the first stage is to collect the data describing the life history traits of the species under investigation.
- The second stage is to implement theoretical population dynamics models to rank the sensitivity of the population growth rate to individual vital rates or endpoints; this modelling should be run under a well-defined scenario that will produce a relative ranking of each individual vital rate that is specific to the life-cycle.
- The third stage is to search in the literature or to implement adequate effects testing in case of knowledge gaps to obtain dose(rate)-effect relationship for those individual effect endpoints inducing a substantial reduction in the growth rate of the population.
- In case the assessor needs to apply the results in a particular ecosystem characterised by other environmental changes (e.g. food depletion, high temperature period, dryness period), effect testing could be completed with dose(rate)-effect relationship for individual endpoints other than vital rates, helping to quantify the energy budget and the way that resource allocation is disturbed in response to the chronic exposure to the radioactive substances.

5.5.3 External-to-internal extrapolation

Background

The issue of using the concept of Relative Biological Effectiveness (RBE) and derived Radiation Weighting Factors (RWF) in assessing risk to non-human biota is still under debate. The question is whether it is relevant to modify the absorbed dose (rate) expressed as a physical quantity by the application of a properly derived RWF for each radiation type to estimate a biologically equivalent dose (rate). Even though it is widely accepted that a number of factors affects RBE values, *e.g.* the dose distribution in the targeted cells, organs or organisms, the dose-effect relationship, the LET, no consensus has been reached on the way to derive robust RWF at the individual level. Furthermore understanding how its value could change for upper organisational level such as population for instance is still limited.

Statistical approach

Recently a compilation and systemic review of currently available literature has been conducted on the alpha radiation RBEs for non-human species(Chambers *et al.* , 2005; Chambers *et al.* , 2006). Some of the data were extracted from FRED, but the set included other relevant papers. In total, 145 RBE values were extracted from 66 papers; among which 84 were considered sufficiently robust (see Chambers *et al.*(2005) for detailed selection criteria) to be applied to non-human species. For the present statistical approach, since deterministic effects are of major importance in terms of demographic implication, only RBE values experimentally determined for survival, fecundity and reproduction were considered (61 values). This set was completed by other papers and by those relevant to enlarge the review to other beta particles. The criteria as defined by Chambers *et al.* (2005) were kept for this addition. Table 26 lists the resulting set of RBE values. It is well accepted that RBE depends on many factors, *e.g.* the endpoint, the species/tissue/cell, the type of particles and its LET

distribution, the exposure pathway, the dose, the type of radiation used as reference. Only the main factors were reported as supporting information in the table, with the aim to analyse their influence on the RBE values statistical distribution.

Table 26. RBE values from the literature compilation performed by Chambers *et al.* (2005) (reference without prefix), or from this study (reference with A as prefix) or from FREDERICA (F prefix). For the complete reference, see Chambers *et al.* (2005, 2006) or see the Table footnote or consult FREDERICA database.

Radiation type isotope	Reference radiation	RBE	Species	Taxonomic group	Umbrella effect	Effect endpoint	Exposure condition	Authors	Ref.
Po-210	Cs-137	35.00	*Danio rerio*	Fish	Reproduction	egg production	in vivo	Knowles, 2001	6
Po-210	Cs-137	20.00	*Danio rerio*	Fish	Reproduction	egg production	in vivo	Knowles, 2001	6
Po-210	Cs-137	7.10	*Danio rerio*	Fish	Reproduction	egg production	in vivo	Knowles, 2001	6
Pu-239	Co-60	2.50	Mouse	Mammals	Reproduction	oocyte killing	in vivo	Searle *et al.*, 1980	7
Pu-238	X	3.40	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	3.00	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	1.40	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	1.30	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	3.80	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	3.20	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	2.90	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	2.20	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	2.80	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	2.10	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*, 2001	8
Pu-238	X	1.40	Hamster	Mammals	Mortality	cell survival	in vitro	Zyuzikov *et al.*,	8

Radiation type isotope	Reference radiation	RBE	Species	Taxonomic group	Umbrella effect	Effect endpoint	Exposure condition	Authors	Ref.
								2001	
Po-210	Co-60	2.50	Mouse	Mammals	reproduction	oocyte survival	in vivo	Samuels, 1966	9
alpha	X	1.39	Mouse	Mammals	Mortality	oocyte survival	in vivo	Feola *et al.*, 1969	10
alpha	X	1.13	Mouse	Mammals	Mortality	oocyte survival	in vivo	Feola *et al.*, 1969	10
Pu-239	Co-60	3.50	Yeast	Micro-organisms	Mortality	cell repair ability	in vivo	Petin *andand* Kabakova, 1981	11
Pu-239	Co-60	2.15	Yeast	Micro-organisms	Mortality	cell repair ability	in vivo	Petin *andand* Kabakova, 1981	11
Pu-238	Co-60	5.30	Hamster	Mammals	Mortality	cell survival	in vitro	Jenner *et al.*, 1993	12
Pu-238	Co-60	4.00	Hamster	Mammals	Mortality	cell survival	in vitro	Jenner *et al.*, 1993	12
Pu-238	Co-60	11.80	Hamster	Mammals	Mortality	cell survival	in vitro	Jenner *et al.*, 1993	12
Pu-238	X	2.20	Hamster	Mammals	Mortality	cell survival	in vitro	Schwartz *et al.*, 1992	18
Pu-238	X	2.40	Hamster	Mammals	Mortality	cell survival	in vitro	Schwartz *et al.*, 1992	18
Pu-238	X	3.00	Hamster	Mammals	Mortality	cell killing	in vitro	Schwartz *et al.*, 1992	18
Pu-239	Co-60	2.45	Hamster	Mammals	Mortality	cell survival	in vitro	Fisher *et al.*, 1985	20
He-4	X	4.81	Hamster	Mammals	Mortality	cell survival /embryos	in vitro	Martin *et al.*, 1995	22
Pu-238	Co-60	7.90	Mouse	Mammals	Mortality	cell survival	in vitro	Roberts *andand* Goodhead, 1987	25
Pu238	Co-60	6.20	Mouse	Mammals	Mortality	cell survival	in vitro	Roberts *andand* Goodhead, 1987	25
Pu-238	Co-60	4.60	Mouse	Mammals	Mortality	cell survival	in vitro	Roberts *andand* Goodhead, 1987	25
Pu-238	X	4.00	Hamster	Mammals	Mortality	cell survival	in vitro	Manti *et al.*, 1997	32
Pu-238	X	3.70	Hamster	Mammals	Mortality	cell survival	in vitro	Manti *et al.*, 1997	32
He-4	Co-60	1.49	E.Coli	Bacteria	Mortality	Cell survival	in vivo	Nikjoo *et al.*, 1999	34

Radiation type isotope	Reference radiation	RBE	Species	Taxonomic group	Umbrella effect	Effect endpoint	Exposure condition	Authors	Ref.
He-4	Co-60	1.70	E.Coli	Bacteria	Mortality	Cell survival	in vivo	Nikjoo *et al.*, 1999	34
alpha	X	1.22	Rat	Mammals	Morbidiy	Damage to spinal cord	in vivo	Baredsen, 1992	39
Po-210	X	6.30	Rat	Mammals	Mortality	Cell survival	in vitro	Ford and Terzaghi, 1993	41
Pb-212	X	4.70	Mouse	Mammals	Mortality	Cell survival	in vivo	Howell *et al.*, 1994	42
Pb-212	X	4.10	Mouse	Mammals	Mortality	Cell survival	in vivo	Howell *et al.*, 1994	42
Bi-212	X	6.00	Mouse	Mammals	Mortality	Cell survival	in vivo	Howell *et al.*, 1994	42
Po-212	X	4.60	Mouse	Mammals	Mortality	Cell survival	in vivo	Howell *et al.*, 1994	42
Gd-148	X	7.40	Mouse	Mammals	Mortality	Cell survival	in vivo	Howell *et al.*, 1997	48
Ra-223	X	5.40	Mouse	Mammals	Mortality	Cell survival	in vivo	Howell *et al.*, 1997	48
Pu-238	X	2.60	Hamster	Mammals	Mortality	Cell survival	in vitro	Prise *et al.*, 1987	49
Pu-238	X	5.80	Hamster	Mammals	Mortality	Cell survival	in vitro	Tjacker et a., 1982	50
Pu-238	X	4.80	Hamster	Mammals	Mortality	Cell survival	in vitro	Tjacker et a., 1982	50
Pu-238	X	3.50	Hamster	Mammals	Mortality	Cell survival	in vitro	Tjacker et a., 1982	50
Po-210	X	6.70	Mouse	Mammals	Reproduction	Cell survival / spermatogonies	in vivo	Rao *et al.* 1989	52
Am-241	Co-60	4.20	Hamster	Mammals	Mortality	Cell survival /embryos	in vitro	Lücke-Huhle *et al.*, 1986	54
Po-210	X	13.10	Bovine	Mammals	Mortality	Cell survival	in vitro	Thomas *et al.*, 2003	62
Po-210	X	10.20	Bovine	Mammals	Mortality	Cell survival	in vitro	Thomas *et al.*, 2003	62
Po-210	X	11.10	Bovine	Mammals	Mortality	Cell survival	in vitro	Thomas *et al.*, 2003	62
Po-210	X	7.70	Bovine	Mammals	Mortality	Cell survival	in vitro	Thomas *et al.*, 2003	62
Po-210	X	9.90	Bovine	Mammals	Mortality	Cell survival	in vitro	Thomas *et al.*, 2003	62

Radiation type isotope	Reference radiation	RBE	Species	Taxonomic group	Umbrella effect	Effect endpoint	Exposure condition	Authors	Ref.
Po-210	X	13.10	Bovine	Mammals	Mortality	Cell survival	in vitro	Thomas *et al.*, 2003	62
Po-210	X	14.00	Bovine	Mammals	Mortality	Cell survival	in vitro	Thomas *et al.*, 2003	62
He-4	Co-60	2.30	Hamster	Mammals	Mortality	Cell surviva l/embryos	in vitro	Suzuki *et al.*, 1989	64
He-4	Co-60	2.50	Hamster	Mammals	Mortality	Cell survival /embryos	in vitro	Suzuki *et al.*, 1989	64
H-3	Cs-137	1.50	Mouse	Mammals	Reproduction	Cell mutagens in male reproduction cells	in vivo	Balonow *et al.*, 1992	A1
H-3	Cs-137	1.77	Mouse	Mammals	reproduction	Cell mutagens in male reproduction cells	in vivo	Balonow *et al.*, 1992	A2
H-3	Cs-137	2.50	Mouse	Mammals	reproduction	Cell lethal mutation in male germ cells	in vivo	Balonow *et al.*, 1984	A3
Sr-90	Cs-137 or Co-60	0.10	Rat	Mammals	Mortality	Life span shortening	in vivo	Korytny *et al.*, 1995	A4
Pu-239	?	1.50	Rat	Mammals	Mortality	LD50 acute	in vivo	Buldakov *et al.*, 1969	A5
Pu-239	?	2.00	Rat	Mammals	Mortality	LD50 acute	in vivo	Buldakov *et al.*, 1969	A5
He-4	X	2.00	*Chlamydomonas*	Algae	Mortality	LD50	in vivo	?	F
H-3	Cs-137	1.00	Medaka	Fish	Reproduction	Embrio malformations, hatching	in vivo	Hyodo-Taguchi and Etoh, 1993 FRED ID 76	F
H-3	Cs-137	3.50	Mice	Mammals	Reproduction	Cell survival /oocytes	in vivo	Satow *et al.*, 1989 FRED ID 545	F
Sr-90	Co-60	0.49	*Sinella*	Soil invertebrat	Mortality	Survival /adult	in vivo	Styron, 1971	F

Radiation type isotope	Reference radiation	RBE	Species	Taxonomic group	Umbrella effect	Effect endpoint	Exposure condition	Authors	Ref.
			curviseta	es				FRED ID 761	
Sr-90	Co-60	0.56	*Sinella curviseta*	Soil invertebrates	Mortality	Juveniles	in vivo	Styron, 1971 FRED ID 761	F
Sr-90	Co-60	0.93	*Sinella curviseta*	Soil invertebrates	Reproduction	eggs	in vivo	Styron, 1971 FRED ID 761	F
H-3	Co-60	1.60	Mouse	Mammals	Reproduction	Cell survival /oocytes	in vivo	Dobson and Kwan, 1977 FRED ID 1031	F
H-3	Co-60	2.80	Mouse	Mammals	Reproduction	Cell survival /oocytes	in vivo	Dobson and Kwan, 1977 FRED ID 1031	F

A1. Balonov MI, Chetchueva ME, Pomerantseva MD and Ramaja LK (1992) The mutagenic effect of ^{3}H-thymidine on germ cells of male mice. *Genetika (Genetics*), 28 (3), pp.147-154 (in Russian).
A2. Balonov MI, Chetchueva ME, Pomerantseva MD and Ramaja LK (1992) The mutagenic effect of ^{3}H-deoxycytidine on germ cells of male mice. *Genetika (Genetics*), 28 (3), pp.155-162 (in Russian).
A3. Balonov MI and Kudritskaya OY (1984) The mutagenic effect of tritium on germ cells of male mice. Report 1. Induction of dominant lethal mutations by tritium oxide and the estimation of RBE. *Genetika (Genetics*), v.XX, N.2, pp.224-231 (in Russian).
A4. Korytny VS, Shvedov VL and Pryahin YeA (1996) Some quantitative relationships between major long-term effects and certain dosimetric parameters of exposure to Sr-90 in rats. In: Proceedings of 1st Int. Symp. "Chronic radiation exposure: risk of long-term effects" (Chelyabinsk, Russia, 9-13 January, 1995). Vol 1. Moscow, Izdat, pp.76-89 (in Russian).
A5. Buldakov LA, Lubchansky ER, Moskalev YuI and Nifatov A.P. (1969) Problems of plutonium toxicology**.** Moscow, Atomizdat (in Russian).

A log-normal distribution was fitted to RBE values attributed to alpha particles (Figure 11) and to beta particles (Figure 12). For alpha articles, the taxonomic group and endpoint are dominated by mammals (*e.g.* 54 data for mammals represented by 4 species) and mortality (cell survival, with 53 data). For beta particles, the RBE set is smaller: 11 data, 4 species, 3 taxonomic groups. Full details are given in Table 27. As data appeared to be grouped per particle type, statistical distributions were fitted to subset of the data for Pu, Po and tritium for which the sample size was large enough to obtain 95% Confidence Interval (CI). Finally, Table 27 recommends the median and associated 95 % CI together with a brief description of the biodiversity represented in each of the sub-set. Note that neither the reference radiation type nor the methodological approach for exposure *i.e.* in vitro or in vivo, play a major role in the RBE value sensitivity.

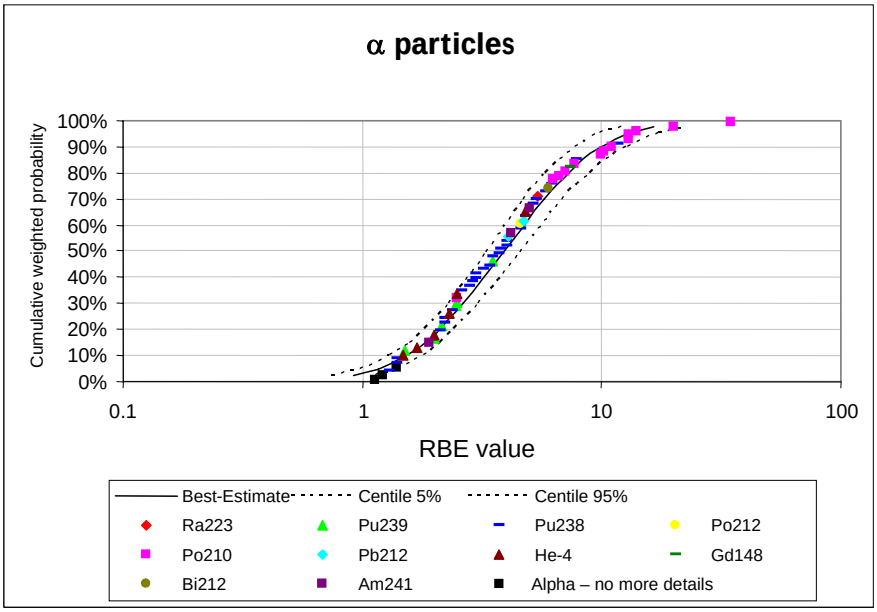

Figure 11. Statistical distribution of RBE values for all alpha particles from the literature. A log-normal distribution with its associated 95 % confidence interval was fitted successfully (see Table 27 for statistics).

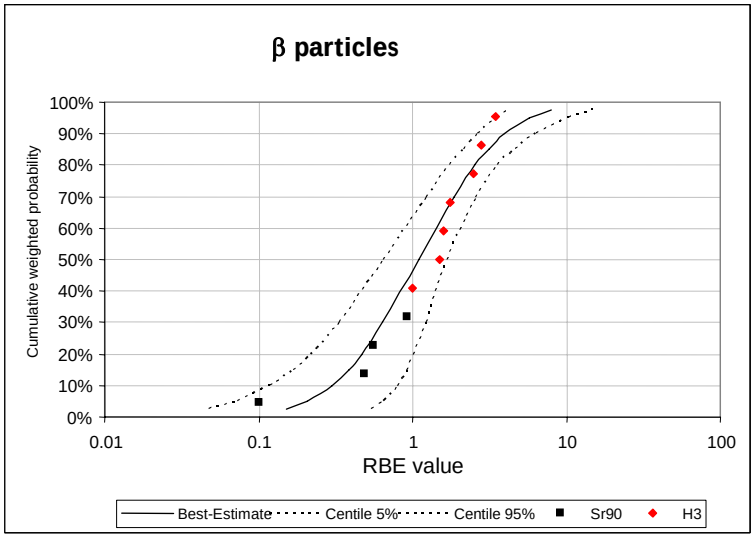

Figure 12. Statistical distribution of RBE values for all beta particles from the literature. A log normal distribution with its associated 95 % confidence interval was fitted successfully (see Table 27 for statistics).

Table 27. RBE values allocation per radiation type or radionuclides and per wildlife group and effect category and their statistical distribution.

Radiation type/ Radionuclide	Number of data	Wildlife group (Number of species - Number of data)	Effect category (Number of data)	Distribution	R^2	RBEmedian and [95 %CI]
All Alpha particles	62	Algae (1 - 1) Micro-organisms (2 - 4) Fish (1 - 3) Mammals (4 - 54)	Mortality (55) Reproduction (6) Morbidity (1)	Log-normal	0.97	3.9 [3.2; 4.7]
Pu-238 and Pu-239	33	Microorganisms (1 - 4) Mammals (3 - 33)	Mortality (32) Reproduction (1)	Log-normal	0.98	3.15 [2.7; 3.7]
Po-210	14	Fish (1 – 3) Mammals (3 – 11)	Mortality (9) Reproduction (5)	Log-normal	0.97	9.5 [6.8; 13.2]
All beta particles	11	Soil invertebrates (1 – 3) Fish (1 – 1) Mammals (2 – 7)	Mortality (3) Reproduction (8)	Log-normal	0.89	1.1 [0.60; 1.8]
H-3	7	Fish (1 – 1) Mammals (2 – 6)	Reproduction (7)	Log-normal	0.97	1.1 [0.60; 1.8]

Recommendations to take this extrapolation issue into account in a refined effect analysis

In conclusion, this study supports the conclusions and recommendations from Chambers *et al.* (2005; 2006) on the median value or best estimate for alpha particles of 3.9, with a 95 % CI from 3.2 to 4.7 which upper bound justifies the safety factor value of 5 applied to derive the PNEDR. We offer a refinement with respect to particle types, also with the range of a 95 % CI to be applied when using this best estimate for a probabilistic approach. Such recommendations are mainly valid for mammals and mortality and do not account for the influence of the life-cycle.There is an important gap on other umbrella effects, mainly reproduction and on how the life traits of a given species may modulate the response at the population level as the sensitivity to ionising radiation and the RBE value depend on both the life stage and the endpoint.

Any of those RBE data take account of the life-cycle of the species under examination. As a first start, the ERICA experiments with daphnids were carried out both with alpha (Am-241) and gamma (Cs-137) exposure. Results were only obtained for a restricted range of dose rates, especially for alpha exposure. For the most sensitive endpoint *i.e.* larvae resistance to starvation (shown to have a strong effect at the population level), the available results allowed a RBE value of 40 and 36 to be determined, for the effect measured at brood 1 and 5 respectively. For the endpoint “day of deposition”, no significant effect was observed with alpha exposure (LOEDR > 0.8 mGy/h) whereas an effect was observed with gamma at 0.4 and 40 mGy/h for brood 1 and 2 respectively. This resulted in a RBE value of <50. The calculation of RBE on the basis of LOEDR is highly dependent on the experimental design (*i.e.* on the range of tested dose rates). A more robust estimation needs a well-established dose-effect relationship, covering the whole range of effect from NOEDR to dose rate at maximal effect. Moreover, RBE calculation would depend on the level of observed effect chosen to calculate the exposure dose ratio. Finally, RBE could be regarded much more as a function of the effect value than as a single value. This function (RBE=f(effect value)) would then be determined by the shapes of the dose-effect curves obtained for the reference radiation type and for the tested radiation type respectively (*e.g.* linear or exponential relationships, Hill model).

6 Conclusions

The ERICA consortium has adopted an Ecological Risk Assessment tiered approach that requires risk assessment screening dose (rate) values for the risk characterisation within tiers 1 and 2 and for an understanding of the effects of ionising radiation on reproduction, mortality and morbidity within tier 3. Recommendations for how to address this within tier 3 are provided here.

This document describes the methodology used to derive ERICA risk assessment predicted no effect dose (rate) values that correspond to screening levels for use in Tiers 1 and 2. The method used was based on the mathematical processing of data from FRED and on the construction of Species Sensitivity Distributions. The PNED(R)s or dose(rate screening values for Tiers 1 and 2) were determined by the SSDs as:

- For acute exposure situations, the PNED was equal to 900 mGy for marine ecosystems and 300 mGy for terrestrial ecosystems and freshwaters;
- For chronic exposure situations, the PNEDR was equal to 10 µGy/h for all ecosystems.

In Tier 3 the effects analysis must be driven by the problem formulation and may involve discussions with stakeholders in order to determine what is considered acceptable or not. Thus this is highly case specific. As such, the ERICA consortium has decided that it would not be appropriate to make specific recommendations on numeric values for application in tier 3. Rather, guidance on the sorts of approaches that may be applied for refined effect analysis has been provided and will be further developed within the D-ERICA deliverable. The following questions and corresponding suggestions have been addressed in this report:

- To apply the SSD methodology to introduce more ecological realism by (1) using 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);
- To refine the effects analysis by focussing on the protection of keystone species and/or endangered species (unlikely to be achieved through mathematical and statistical approaches such as the SSD);
- To refine the effects analysis to address situations when knowledge of effects is too scarce with regard to the problem formulation and thus identify where additional experimental studies may be required. Two examples are given to illustrate possible ways of addressing extrapolation issues of concern, *i.e.* individual to population and external to internal irradiation effects (annexes A and B).

The last bullet point was supported both by experimental results on two invertebrate species with contrasted life cycle and theoretical development.

The experiments and the modelling work performed clearly support the following recommendations that should therefore be applied when assessors need to address individual-to-population extrapolation on board:

(1) collect the data describing the life history traits of the species under investigation;

(2) implement theoretical population dynamics models to rank the sensitivity of the population growth rate to individual vital rates or endpoints;

(3) search in the literature or undertake experimental work to obtain data on effects where knowledge gaps exist in order to obtain relevant dose(rate)-effect relationships for those individual effect endpoints inducing a substantial reduction in the growth rate of the population.

Concerning the extrapolation from gamma external irradiation to internal irradiation effect (alpha or beta emitters), the data evaluated within this project support the main conclusions and recommendations of Chambers *et al.* (2005; 2006). The statistical analysis performed gave a best estimate of 3.9 for RBE of alpha particles and deterministic endpoints, with a 95 % confidence interval from 3.2 to 4.7. Note that the upper bound to the confidence interval is in line with the safety factor value of 5 applied to derive the PNEDR. However, these values are mainly valid for mammals and mortality and do not take account of the influence of the life-cycle. Furthermore, the data presented here indicate a radiation weighting factor of up to 1.8 (upper bound of the 95% confidence interval) would be appropriate for low energy beta particles.

The ERICA experiments on daphnids provided a set of additional RBE values for Am-241. The main lesson learnt was that a robust estimation of RBE needs a well-established dose-effect relationship, covering the whole range of effect from NOEDR to a dose rate where maximal effects can be observed. RBE needs to be regarded as a function of the effect value rather than as a single value. This function (RBE=f(effect value)) could then be determined by the shapes of the dose-effect curves obtained for the reference radiation type and for the tested radiation type respectively (e.g., linear or exponential relationships, Hill model).

The assessment tool being developed within the ERICA work package 1 integrates the derived screening values for Tier 1 and Tier 2. The guidance illustrated herein for Tier 3 will be developed within the D-ERICA Furthermore, the management options at the different Tiers are now being taken forward by interactions between work package 3 and work package 2.

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Appendix - Acronyms and Glossary

Absorbed dose	Quantity of energy imparted by ionising radiation to unit mass of matter such as tissue. Unit gray, symbol Gy. 1 Gy = 1 joule per kilogram.
Activity concentration	the activity per unit mass or volume in which the radionuclides are essentially uniformly distributed, *e.g.* Bq kg^{-1}, Bq l^{-1}
Air kerma	The kerma value for air. Under charged particle equilibrium conditions, the air kerma (in gray) is numerically approximately equal to the absorbed dose in air (in gray). See also kerma.
ALARA	"As low as reasonably achievable", refers to actions directed to limiting doses to individuals, the number of exposed individuals, and the probability of receiving a dose.
Allometric	Correlation of changes in any organism part (*i.e.* contaminant concentration) to organism size and metabolic needs.
Assessment endpoint	The biological effect inferred from the measurements or predictions and which the assessment framework is designed to study.
Assessment factor	See safety factor.
Assessment framework	Identification and demarcation of the assessment boundaries. In FASSET, the framework contains the process from problem formulation through to characterisation of the effects of radiation on individuals. The overall assessment system describes the tools, methods and information flow used to carry out the impact assessment.
Authorisation	The granting by a regulatory body or other governmental body of written permission for an operator to perform specified activities.
Background	The dose or dose rate (or an observed measure related to the dose dose rate), attributable to all sources other than the one(s) specified. Strictly, this applies to measurements of dose rate or count rate from a sample where the background dose rate or count rate must be subtracted from measurements. However, background is used more generally, in any situation which a particular source (or group of sources) is under consideration, to the effects of other sources. It is also applied to quantities other than doses dose rates, such as activity concentrations in environmental media. **natural background:** The doses, dose rates or activity concentrations associated with natural sources or any other sources in the environment which are not amenable to control. This is normally considered to include doses, dose rates or concentrations due to natural sources, global fallout (but not local fallout) from atmospheric nuclear weapon tests and the Chernobyl accident.
Benchmark	Risk assessment benchmarks are Concentration, dose or dose rate that are assumed to be safe based on exposure–response information (*e.g.* ecotoxicity

	test endpoints). Those values are used to guide risk assessors in the tiered approach. For Tiers 1 and 2, they correspond to screening values. Generally speaking, a measurable variable used as a baseline or reference in evaluating the performance of an organisation/a methodology.
Bioaccumulation	The process whereby an organism accumulates substances in living tissues to concentrations higher than those existing in the surrounding media (*e.g.* soil, water and water).
Bioassay	A test to determine the relative strength of a substance by comparing its effect on a test organism with that of a standard preparation.
Bioavailability	defined as the fraction of the contaminant that can be taken up by living organisms, dependant both on the chemical speciation of the exposure source(s) and on the physiological status of the organism.
Biodiversity	The number and abundance of species found within a common environment. This includes the variety of genes, species, ecosystems, and the ecological processes that connect everything in a common environment
Biological half-life	The time required for a biological system (e.g., animal) to eliminate, by natural processes, half the amount of a substance that has been absorbed into that system.
Biomagnification	Situations where the concentration of certain substances increases as one moves higher up the food chain.
Biomass	The total weight of all living organisms in a biological community.
Biosphere	That part of the environment normally inhabited by living organisms. In practice, the biosphere is not usually defined with great precision, but is generally taken to include the atmosphere and the Earth's surface, including the soil, surface water bodies, seas and oceans and their sediments. There is no generally accepted definition of the depth below the surface at which soil or sediment ceases to be part of the biosphere, but this might typically be taken to be the depth affected by basic human actions, particularly farming. In waste safety in particular, the biosphere is normally distinguished from the geosphere.
Biota	The animal and plant life of a given region.
BPEO	Best Practicable Environmental Option.
Conceptual model	Representation of the environmental system and of the physico-chemical and biological processes that determine the transport/transfer of contaminants from sources through environmental media to ecological receptors within the system.
Contaminant	Any physical, chemical, biological, or radiological substance or matter that has a potentially adverse effect on air, water, or soil, with the implication that the amount is measurable.
CR	Concentration Ratios used to quantify the equilibrium between an environmental medium and a living organism (*e.g.*, water to fish CR)
Cytogenetic effect	An observed effect in chromosomes that can be correlated with adverse

	hereditary effects or genetic effects (effects that are inheritable and appear in the descendants of those exposed).
DCC	Dose Conversion Coefficient expressed as Gy per kg of the target organism per Bq per unit of mass or volume of the source. The DCC is specific to each radionuclide and organism and was calculated for external and internal exposure.
Dispersion model	Model for the representation of the spreading of radionuclides in air (aerodynamic dispersion) or water (hydrodynamic dispersion) resulting mainly from physical processes affecting the velocity of different molecules in the medium.
Dose	See absorbed dose
Dose rate	Dose (normally absorbed dose) received over a specified unit of time.
Dose-effect	The relationship between dose (usually an estimate of dose) and the gradation of the effect in an exposed population, that is a biological change measured on a graded scale of severity.
Dose-response	A correlation between a quantified exposure (dose) and the proportion of an exposed population that demonstrates a specific effect (response).
Ecological impact	The total effect of an environmental change, natural or man-made, on the community of living organisms.
Ecological receptor	Living organisms at various organisation level (*i.e.* ecosystems, communities, populations, individual organisms (except humans – note that humans are included when the term "environmental receptors" is used) potentially exposed to and adversely affected by stressors because they are present in the source(s) and/or along stressor migration pathways.
Ecosystem	The interacting system of a biological community and its nonliving surroundings.
EC_x, ED_x, EDR_x	The concentration of a substance that is estimated to cause an effect *x* on the test organisms under specified conditions. The duration of the exposure must be specified. *x* is defined as the percent change in the (average) level of the endpoint considered $x\% = 100\left(\frac{y(EC_x)}{y(0)} - 1\right)\%$. The same definition can apply for the Dose (ED_x) or the dose rate (EDR_x). Currently, these parameters are estimated by modelling (concentration-effects, dose-effects or dose rate-effect modelling).
Effect	A biological change caused by an exposure. Strictly speaking, an effect is the change in an endpoint under consideration when it is compared to a control.
EIA	Environmental Impact Assessment
Endpoint	In toxicity testing and evaluation it is the biological response that is measured. Endpoints vary with the level of biological organization being examined and include responses at the subcellular level to the community level such as biomarkers (subcellular level), survival, growth, reproduction (individual level), primary production, and structure (and abundance) and function in a

	community (population or community level). Endpoints are used in toxicity tests as criteria for effects.
Environment	Water, air, land, plants and man and all other organisms living therein, and the interrelationships which exist among them.
EIS	Environmental Impact Statement is a document providing information for decision makers on the positive and negative effects of an action, practice or policy, which identifies and evaluates the environmental impacts of the hazard source and feasible alternatives, including taking no action.
Environmental justice	Often used interchangeably with the term environmental equity, refers to the distribution and effects of environmental problems and the policies and processes to reduce differences in who bears environmental risks. In a general sense, it includes concern for disproportionate risk burden placed upon any population group, as defined by gender, age, income, race, nationality or generation.
Environmental quality criteria	The levels of pollution and lengths of exposure, above which adverse effects may occur on health and welfare.
Environmental quality standards	The level of contaminants prescribed by law or regulation that cannot be exceeded during a specified time in a defined area.
ERA	Ecological Risk Assessment
ERICA	Environmental Risk from Ionising Contaminants: Assessment and Management
EUG	End-Users Group, formed under ERICA to provide advice to the ERICA Consortium from the perspective of being users of ERICA outputs.
Exposure	The co-occurrence or contact between the endpoint organism and the stressor (*e.g.*, radiation or radionuclide).
Exposure assessment	The process of measuring or estimating the intensity, frequency, and duration of exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment.
Exposure pathway	A route by which radiation or radionuclides can reach humans and cause exposure – an exposure pathway may be very simple, *e.g.* external exposure from airborne radionuclides, or a more complex chain.
Fecundity	The survival of offspring.
Fertility	The ability to produce offspring.
FRED	FASSET Radiation Effects Database, see www.erica-project.org
FREDERICA	The FASSET Radiation Effects Database which has been updated through the addition of a quality scoring exercise of each literature source to evaluate how useable the data is in the context of defining dose (rate) effect relationships for incorporation into the SSD and other approaches. In addition new literature sources have been added to the database and it has been updated to make it available on the internet. It has been renamed as the FREDERICA database in

	recognition of these changes.
Hazard	A condition or physical situation with a potential for an undesirable consequence, such as harm to health or environment.
Hazard analysis	Procedure used to (1) identify potential sources of release of hazardous materials from fixed facilities or transportation accidents; (2) determine the vulnerability of a geographical area to a release of hazardous materials; and (3) compare hazards to determine which present greater or lesser risks to a community.
Hazard identification	Recognizing that a hazard exists and trying to define its characteristics. The process of determining whether exposure to an agent can cause an increase in the incidence of an adverse health or environmental effect.
$HD(R)_5$	Hazardous Dose (rate) affecting 5% of the species of a given ecosystem. This value is estimated from the Species Sensitivity Distribution.
Iteroparous	Producing offspring in successive, e.g., annual or seasonal batches, as is the case in most fishes. Iteroparous animals must, by definition, survive over multiple seasons (or periodic condition changes).Opposite of semelparous.
Kd	Distribution Coefficient used to quantify the equilibrium between solid and liquid phases (soil or sediment-interstitial water), usually expressed in$L.kg^{-1}$. It is the ratio of the mass of the solute species adsorbed (or precipitated) on the solid particles per unit of dry mass of the soil or sediment to the solute concentration in the liquid phase. It represents the partition of the solute in the soil or sediment matrix and soil or sediment water, assuming that equilibrium conditions exist between the solid and liquid phases. The Kd values are dependent on the soil or sediment physical and chemical characteristics.
Kerma	The quantity K, defined as: $K = \frac{dE_{TR}}{dm}$ where, dE_{TR} is the sum of the initial kinetic energies of all charged ionising particles liberated by uncharged ionizing particles in a material of mass dm. Unit: gray (Gy).
Keystone species	A species that influences the ecological composition, structure, or functioning of its community far more than its abundance would suggest.
Indicator organisms	A species, whose presence or absence may be characteristic of environmental conditions in a particular area of habitat; however, species composition and relative abundance of individual components of the population or community are usually considered to be a more reliable index of water quality.
Licence	1) A legal document issued by the regulatory body granting authorisation to perform specified activities related to a facility or activity. 2) Any authorisation granted by the regulatory body to the applicant to have the responsibility for the siting, design, construction, commissioning, operation or decommissioning of a nuclear installation. 3) Any authorisation, permission or certification granted by a regulatory body

	to carry out any activity related to management of spent fuel or of radioactive waste.
LOEC, LOED(R)	The lowest observed effect concentration in a toxicity test that causes a statistically significant effect in comparison to the control. The same deifinition applies for Dose or Dose Rate (in place of Concentration)
Measurement endpoint	Measured or predicted value that an assessment produces.
Morbidity	A loss of functional capacities generally manifested as reduced fitness, which may render organisms less competitive and more susceptible to other stressors, thus reducing the life span.
Morbidity	A loss of functional capacities generally manifested as reduced .fitness., which may render organisms less competitive and more susceptible to other stressors, thus reducing the life span.
Mortality	Death; the death rate; ratio of number of deaths to a given population.
Mortality	Death; the death rate; ratio of number of deaths to a given population.
NOEC, NOED(R)	No observed effect concentration is the highest concentration in a toxicity test not causing a statistically significant effect compared with the control. The same definition applies for Dose or Dose Rate (in place of Concentration)
Permission	See licence
Permit	See licence
PNED(R)	Predicted No-Effect Dose (Rate) expressed in Gy or Gy per unit of time.
Pollution	The presence of matter or energy (*e.g.* smoke, gas, hazardous or noxious substances, light, heat, litter or a combination thereof) in sufficient quantities and of such characteristics and duration as to produce, or likely to produce, undesired environmental effects.
Precautionary principle	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. (UNCED, Rio principle 15, 1992.)
Radiation weighting factors	Its value represent the relative biological effectiveness of the different radiation types, relative to X- or gamma-rays, in producing endpoints of ecological significance.

Radioactive material	1) Material designated in national law or by a regulatory body as being subject to regulatory control because of its radioactivity. Some States use the term radioactive substance for this regulatory purpose. However, the term radioactive substance is also sometimes used to indicate that the scientific use of radioactive (see radioactive (1)) is intended, rather than the regulatory meaning of radioactive (see radioactive (2)) suggested by the term radioactive material. It is therefore essential that any such distinctions in meaning are clarified. 2) Any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in paras 401–406 of "Regulations for the Safe Transport of Radioactive Material, 1996 Edition (As Amended 2003) Requirements Details". IAEA Safety Standards Series No. TS-R-1 2004
Radioactive substance	See radioactive material (1). It should be noted that radioactive substance is sometimes used to indicate that the scientific use of radioactive is intended, rather than the regulatory meaning of radioactive.
Radioecological sensitivity	A combination of features which include the exposure situation and biology of an organism, that contribute to the sensitivity of the organism to presence of radioactive substances in its environment
Radionuclide	An unstable nuclide that undergoes spontaneous transformation, emitting ionising radiation.
RBE	For a given type of radiation, the Relative Biological Effectiveness (RBE) is defined as: $RBE = \frac{\text{Dose of the reference radiation needed to produce the same effect}}{\text{Dose of the given radiation needed to produce a given biological effect}}$
Receptor	See ecological receptor.
Reference organisms	A series of entities that provide a basis for the estimation of radiation dose rate to a range of organisms that are typical, or representative, of a contaminated environment. These estimates, in turn, would provide a basis for assessing the likelihood and degree of radiation effects.
Response	The proportion or absolute size of an exposed population that demonstrates a specific effect. May also refer to the nature of the effect.
Risk	A statistical concept describing the expected frequency or probability of undesirable effects arising from exposure to a contaminant. A measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard. A technical estimation of risk is usually based on the expected value of the conditional probability of the event occurring times the consequence or magnitude of the event given that it has occurred.
Risk assessment	A qualitative or quantitative evaluation of the risk posed to human health and/or the environment by the actual and/or potential presence of contaminants. It includes problem formulation, exposure and dose-response assessment and

	risk characterisation.
Risk characterisation	The synthesis of information obtained during risk assessment for use in management decisions. This should include an estimation of the probability (or incidence) and magnitude (or severity) of the adverse effects likely to occur in a population or environmental compartment, together with identification of uncertainties.
Risk communication	The exchange of information about health or environmental risks among risk assessors and managers, the general public, news media, interest groups, etc.
Risk evaluation	A component of risk assessment in which judgments are made about the significance and acceptability of risk.
Risk management	The selection and practical implementation of regulatory and non-regulatory responses to risk. Practical implementation of procedures, actions or policies to mitigate, reduce, remove or monitor health or environmental risks.
Safety factors	Measure of degree of uncertainty, caused by lack of effects data. For example, an estimated lowest observed effect concentration may, as a precautionary approach, be divided by a safety factor (normally within the range 10 to 10 000) to safeguard against harmful effects, where the magnitude of the safety factor reflects the degree and type of uncertainty (*e.g.* lack of chronic exposure data, lack of data for different taxonomic groups or trophic levels, etc.). Also known as assessment factor
Screening value	Or screening benchmark represent values that are used in the lower tiers of ERA for screening purpose. For the ERICA method, the screening value is equivalent to the PNED(R).
Semelparous	Producing all offspring at one time, in a single group (litter, clutch, etc.), after which the parent usually dies. Reproduction occurs as a single investment of energy in offspring, with no future chance for investment in reproduction.
Source	Anything that may cause radiation exposure — such as by emitting ionising radiation or by releasing radioactive substances or materials — and can be treated as a single entity for protection and safety purposes.
SS(W)D	Species Sensitivity Distribution or Species Sensitivity Weighted Distribution whether or not a taxonomic weight is applied while establishing the statistical distribution of the species radiosensitivity
Sustainability	The ability of an ecosystem to maintain ecological processes and functions, biological diversity, and productivity over time.
Synergism	An interaction between two substances that results in a greater effect than both of the substances could have had acting independently.
Threshold	A contaminant concentration (or dose), below which no deleterious effect occurs.
TLD	Thermo-luminescent Dosimeter
Toxicant	A substance that kills or injures an organism through chemical or physical action or by altering the organism's environment; for example, cyanides,

	phenols, pesticides, or heavy metals; especially used for insect control.
Uncertainty	Statistical term that is used to represent the degree of accuracy and precision of data. It often expresses the range of possible values of a parameter or a measurement around a mean or preferred value.

From:

ERICA D4b (2005)

FASSET, Framework for Assessment of Environmental Impact (2002b). Overview of programmes for the assessment of risks to the environment from ionising radiation and hazardous chemicals. Deliverable 2, Part 2, A project within the EC 5th Framework

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