

NATIONAL DOSE ASSESSMENT WORKING GROUP

PAPER 15-05: UPDATE ON EC FUNDED PROJECT: PROTECT (PROTECTION OF THE ENVIRONMENT IN A REGULATORY CONTEXT)

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1. Introduction

The need for a system capable of demonstrating that the environment is adequately protected from the effects of radioactive substances has been recognised by international organisations (e.g. IAEA, 2006; ICRP, 2007a; OECD-NEA, 2007a), a number of regulators (e.g. Environment Canada, 2003; USDOE, 2002; Copplestone et al., 2001) and many scientists (IUR, 2000; 2002). As a result, the last decade has seen considerable international and national effort on this issue with environmental protection now being referred to in the International Atomic Energy Agency's Fundamental Safety Principles (IAEA, 2006) as well as in the Recommendations of the International Commission on Radiological Protection (ICRP, 2007a). In addition, the forthcoming revisions of both the International and Euratom Basic Safety Standards intend to address radiation protection of the environment.

As a consequence, a number of approaches/tools have been developed to estimate dose rates to non-human biota and initial model intercomparison exercises have been conducted recently (e.g. Vives i Batlle et al., 2007; Beresford et al., 2008a). However, estimated dose rates need to be compared with some form of criteria to judge the level of risk. There is, therefore, a need for predefined dose rate values, or benchmarks, to be proposed and agreed upon. Important steps on the way to suggesting benchmark values are decisions on appropriate protection goals and the method of deriving dose rate values corresponding to these protection goals. Similarly, the Nuclear Energy Agency (OECD-NEA, 2007b) has recognised the importance of identifying pertinent endpoints defining environmental protection and development of tools that can link data to protection of the environment. Numerical values that are indicative of "no effects" on non-human biota have been published, for example by the IAEA (1992) and UNSCEAR (1996). ICRP (2007b) recently circulated a draft report for consultation (subsequently approved by the main commission of the ICRP) suggesting an approach based on Reference Animals and Plants (RAPs), including "derived consideration levels" which are defined by the ICRP as being 'one order of magnitude broad bands of dose rates covering the level where the dose rates warrant a more considered level of evaluation of the situation'. Whereas these approaches to derive numerical values tend to be based solely on expert judgement, the work described in section 4 aims to derive benchmark values by using formalised and transparent methodologies, which are as consistent as appropriate with those used within chemical risk assessment whilst avoiding expert judgement as far as possible.

1.1 The PROTECT Project objectives

The EC EURATOM Framework 6 funded PROTECT project (Contract No. FI6R-036425) set out to develop dose rate thresholds for wildlife to help to determine the risk of exposure to ionising radiation. The project had the following objectives:

- Evaluate current regulatory approaches in different countries to the protection of the environment from both radioactive substances and chemicals and to determine how end points of protection are currently applied within the different regimes;
- Identify differences and similarities between the approaches used for protection of the environment from chemicals and radiation;
- Make recommendations for generating common approaches to the protection of the environment bearing in mind any broader environmental protection objectives;
- Evaluate the practicability of existing and developing approaches;

- Consider the acceptability and relevance of current approaches compared to the needs of industry and regulators and the different situations it may need to address;
- Test available approaches against any relevant ICRP recommendation or outputs from PROTECT;
- Assess the availability, usability and transparency of available approaches to groups other than those involved in their development;
- Derive an extended set of numerical target values and their derivation methods, designed to assure compliance to environmental protection goals that resonate with protective goals for releases of hazardous substances in general, and to assess the implications for society at large.

1.2 The PROTECT Consortium

The PROTECT consortium consisted of five organisations: Centre for Ecology and Hydrology (UK), Environment Agency (England and Wales), IRSN (France), Norwegian Radiation Protection Authority (Norway) and the Swedish Radiation Safety Authority (Sweden). CEH were the project lead.

A key aspect of the PROTECT project was our interaction with other experts and organisations. For example, we worked with the International Commission on Radiological Protection (ICRP), the International Atomic Energy Agency (IAEA), the European Commission, regulators, industry, non-government organisations and experts in chemical risk assessment.

The project consisted of three interlinked work packages (WP):

- WP1: Environmental protection concepts
- WP2: Assessment approaches: practicality, relevance and merits
- WP3: Requirements for protection of the environment from ionising radiation

During the course of the project we ran four workshops with interested parties who helped us with the direction of the project and who provided comments on the draft outputs. Workshop discussions and comments received on draft PROTECT reports can be found on the project website together with our responses to these comments.

All the outputs from the project are available at <http://www.ceh.ac.uk/protect>.

2. WP1: Environmental Protection Concepts

Drawing on the experiences of key stakeholders from regulatory organisations, Non Governmental Organisations (NGOs) and industry (nuclear and chemical) in different member states, this work package:

- Gathered information on the regulatory approaches currently applied to both chemicals and radioactive substances in member states;
- Critically reviewed the biological and ecological endpoints of protection currently in use and the similarities and differences between approaches for chemicals and radioactive substances;
- Made recommendations for generating common approaches to protection of the environment which directly influenced our subsequent work plan.

The information was gathered through the completion of a questionnaire. Slightly different versions of the questionnaire were used depending upon whether the discussions were with industry or regulators. The questionnaires were, for the most part, completed using telephone based interviews and the resulting responses were reviewed at an open workshop. 130 organisations were contacted and 50 responded. 36% of the respondents were from regulators and 36% from industry, 10% from NGOs and international organisations and 18% from advisory bodies. Although the bulk of the respondents were from Europe, some also came from Australia and Canada. Full details are given in PROTECT Deliverable 3 (Hingston et al., 2007).

The work showed that the same basic generic assessment framework is applicable to both radioactive and chemical substances and consists of: problem formulation, exposure and effects assessment, and risk characterisation and management. The more developed radiological assessment tools are based on this framework as they had previously evaluated and adopted parts of the approaches used in chemicals risk assessment. However, whilst there are various numeric criteria being used by some national regulatory bodies, there are no internationally agreed numeric criteria or methodologies to derive thresholds for radiological purposes.

The key recommendations were:

- Protection should focus on the population level and that protection goals should be translated into measurable targets with advice provided on tolerable risks associated with these endpoints;
- There is a strong advocacy for linking radiological protection to the processes used for chemicals assessment as far as practicable, note that some technical differences in the approaches were identified but essentially the underlying protection goals are similar (see Table 1);
- To use internationally agreed approaches for setting environmental thresholds for chemicals (namely the Species Sensitivity Distribution (SSD) and Assessment Factor (AF) approaches) to determine numeric criteria (as dose rates) and that the use of purely expert judgement should be avoided where possible;
- The use and purpose of the numeric criteria (e.g. screening value, 'regulatory action level') currently being applied, or suggested, should be evaluated and PROTECT should then recommend criteria that can be used within a tiered assessment process. Any criteria that we recommend should be supported with a clear understandable document explaining clearly how they were derived.

Table 2 highlights the relative merits and weaknesses between the AF and SSD approaches. Appropriate techniques were then discussed and applied to derive benchmarks for radiological protection of the environment in Work Package 3 (see section 4).

Table 1. Similarities and differences between chemical and radiological risk assessments

<i>Problem Formulation</i>	<i>Scoping and protection goals common to both approaches. A priori definition of ecosystems and reference organisms in radionuclide risk assessment</i>
Exposure Assessment	Environmental transfer of contaminants is a common feature but attention to interactions between ambient environment and biological receptors different (chemical approaches consider factors that affect availability e.g. pH)
Dosimetry	Major differences: this is a significant feature of radionuclide risk assessment but not chemical assessments where the focus is just on ambient concentrations. Possible internal and external exposure from radionuclides but only internal residues are relevant to chemicals
Effects Assessment	Significant differences: assessment of chemicals is based on assessment of empirical ecotoxicological data relating concentrations to effects, whilst assessment of radionuclides uses data that relate effects to dose. Separate assessments are needed for each new chemical but radionuclide assessments need only consider a limited range of radiation types and qualities
Risk characterisation	Similar approaches for characterising risk are now being used for both chemicals and radioactive substances. For example, approaches for radiological protection of the environment have applied the SSD and assessment factor approaches to derive values to compare with predicted dose rates to determine the magnitude of any risks (Garnier- Laplace and Gilbin, 2006)

Table 2. The relative merits and weaknesses of the AF and SSD approaches

	Merits	Weaknesses
AF	Process is simple and transparent	Uses only small part of available data
	Aims to protect all species	Can discourage generation of data
	Available data may permit no other approach	Provides no information on possible impact of a particular concentration or dose
	Permits expert judgement	Can be influenced by external factors e.g. political expediency, obscuring transparency
SSD	Uses all available data	'Data hungry'
	Uncertainty is quantified	Only deals with interspecies differences
	Resultant standard is less influenced by any particular dataset	Assumes that: a) Fitted models are valid; b) 95 th percentile provides adequate protection; c) Toxicity tests data are random, independent trials
	Consequences of a particular environmental concentration can be predicted	

3. WP2: Assessment approaches – practicality, relevance and merits

This WP brought together organisations using, or developing, approaches to demonstrate protection of the environment from ionising radiation to:

- Evaluate whether existing and developing approaches are practical;
- Consider how acceptable and relevant the approaches are to regulators and industry;
- Apply numerical target values recommended by work package 3 and others;
- Assess the user friendliness of the approaches to potential users.

In part, available approaches were applied to case studies to help achieve these objectives. Whilst all known approaches were considered, the work package concentrated on the three which are freely available to any users: RESRAD-BIOTA¹ (implementing the US DOE graded approach (USDoE, 2002)), Environment Agency R&D128² (developed for use in England and Wales for assessment of Natura 2000³ sites) and the ERICA Approach (Larsson, 2008) and Tool⁴ (developed under a previous EURATOM funded project). Links to software and documentation on each of these approaches can be found on the PROTECT website. The existence of such tools should reduce the cost to industry and regulators who may have to conduct assessments of doses to non-human species in the future. We also worked with ICRP Committee 4⁵ to conduct an initial evaluation of the draft ICRP report on the use of Reference Animals and Plants⁶ which forms part of their planned framework for assessing the impact of ionising radiation on non-human species.

The main findings were:

- Currently none of the available approaches are comprehensive and, as a consequence, they are often used in combination (e.g. whilst the R&D128 methodology is the most basic it is the only approach to consider noble gases which contribute a major component of the total activity released from many nuclear sites);
- The ERICA Tool has the most developed databases, arguably giving it a better basis for conducting prospective assessments when site specific data will not be available (above its initial screening tier, RESRAD-BIOTA is more reliant on site-specific data);
- The ERICA Tool represents the most appropriate platform for implementing the ICRP framework once it becomes available as it already includes adult life stages of the ICRP Reference Animal and Plants, and uses the same method for the dosimetry;

¹ <http://web.ead.anl.gov/resrad/home2/>

² <http://www.environment-agency.gov.uk/> and <http://www.coger.org.uk/R&D128index.html>

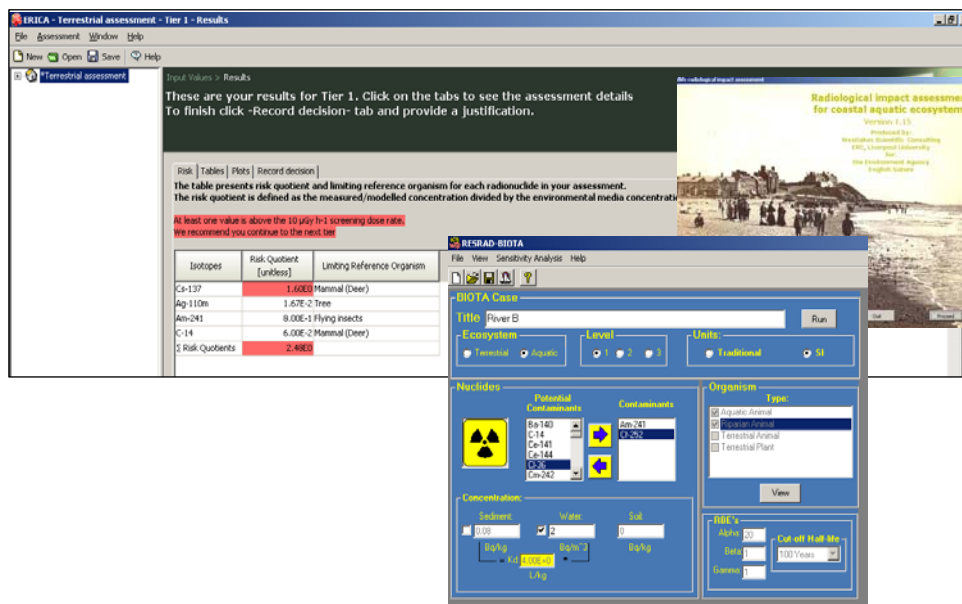
³ A Natura 2000 site is a protected ecological area within the EU containing threatened habitats and/or species.

⁴ <http://www.ceh.ac.uk/protect/ERICAdeliverables.html>

⁵ ICRP Committee 4 provides advice on the application of the recommended system of protection.

⁶ ICRP (in-press). The concept and use of reference animals and plants for the purposes of environmental protection. International Commission on Radiological Protection, Annals of the ICRP.

A number of assessment tools are available including some freely available for any interested user:



- RESRAD-BIOTA has greater functionality in terms of being able to define simple food chains and using dynamic modelling approaches for predicting radionuclide transfer rather than relying on an assumed equilibrium ratio approach;
- In support of the conclusions of the IAEA Biota working group⁷ and others, our evaluation showed that the transfer component of the tools contributes most to the overall uncertainty of the dose rate predictions;
- When used to conduct screening tier assessments, which are designed to identify situations where no further assessment is required to a high degree of confidence, we found that in some circumstances the three available tools gave widely different results (see figure 1 below). Reasons for this need to be better understood and any deficiencies addressed.

Of the three most developed approaches that are freely available to any user, the EA R&D128 could be described as this most basic and the developers state an intention to adopt parameters from the ERICA Tool. The RESRAD-BIOTA package is designed as a screening tool with, in effect, a requirement for site specific data at anything above the initial screening levels. However as mentioned above the tool does contain allometric models enabling the user to define transfer to terrestrial/riparian mammal and bird species of interested (including the ability to create simple food chains). The ERICA tool has the most developed concentration ratio based transfer databases for a wide range of reference organisms arguably giving it a better basis for prospective assessments. It also considers the largest number of radionuclides and has the ability to estimate dose conversion coefficients for most radionuclides included within ICRP Publication 38 (ICRP, 1983). The ERICA Tool can also be used to create new reference organism geometries. The ERICA Tool may also provide the most appropriate platform to implement the ICRP framework when it becomes available, as the ERICA Tool already includes the adult life stages of the ICRP proposed Reference Animals and Plants, and the ICRP have adopted the same dosimetric methodology as used in the ERICA Tool. However the ERICA Tool

⁷ The Biota working group was part of the IAEA's international programme called Environmental Modelling for Radiation Safety. Full details of the programme are available from: <http://www-ns.iaea.org/projects/emras>

lacks the functionality of the allometric approaches present in RESRAD-BIOTA. It should also be noted that if organisms are to be assessed at an individual or species level (e.g. as in the Canadian 'valued ecosystem component' approach) then robust generic approaches to deriving transfer will need to be further developed.

There may also be requirements to conduct spatial and/or temporal assessments; capabilities which the three models considered in most detail in this report do not have. Some dynamic models have however been developed. For spatial assessments, the USEPA SADA⁸ model enables screening tier assessments to be conducted spatially (utilising parameters from RESRAD-BIOTA), and parameters from both the FASSET⁹ and ERICA Tool have been implemented in geographical information systems. Similarly, if packages such as RESRAD-BIOTA and the ERICA Tool do not have the required flexibility in the dosimetric assessment components there are other bespoke dosimetry tools available which may have the required flexibility, although these may not have been as independently assessed to date as the more generic tools.

Perhaps the most important criteria for the assessment tools, such as RESRAD-BIOTA or the ERICA Tool, are that they can be used with confidence in screening tier assessments. However, a comparison of screening tier predictions conducted during the PROTECT project does not promote the level of confidence required as there were large differences in output between the three approaches evaluated. If these models are to be (increasingly) used for regulatory assessment the reasons for such large variation in basic screening tier outputs needs to be more fully understood and any deficiencies addressed. This emphasises the importance of continuing the work of groups such as the IAEA EMRAS BWG¹⁰ and further funding for this still developing area of radiological protection.

The PROTECT project has recommended that the ERICA Tool be used by European Member States on the assumption that it continues to be maintained and improved¹¹. The provision of training courses on the ERICA Tool and approach was also recommended. The RESRAD-BIOTA tool is also being maintained and developed further.

The full report on the activities of Work Package 2 is given in Beresford et al. (2008b) (Deliverable 4) available from the PROTECT project website.

⁸ <http://www.tiem.utk.edu/~sada/index.shtml>

⁹ FASSET, Framework for Assessment of Environmental Impact (FASSET) Contract No. FIGE-CT-2000-00102

¹⁰ IAEA EMRAS programme – Environmental Modelling for Radiation Assessment and Safety. The Biota Working Group started in 2004 and in January 2009, the follow on project, EMRAS2, started.

¹¹This is currently (until 2011) being conducted by a core group of the ERICA consortium with no additional EC funding.

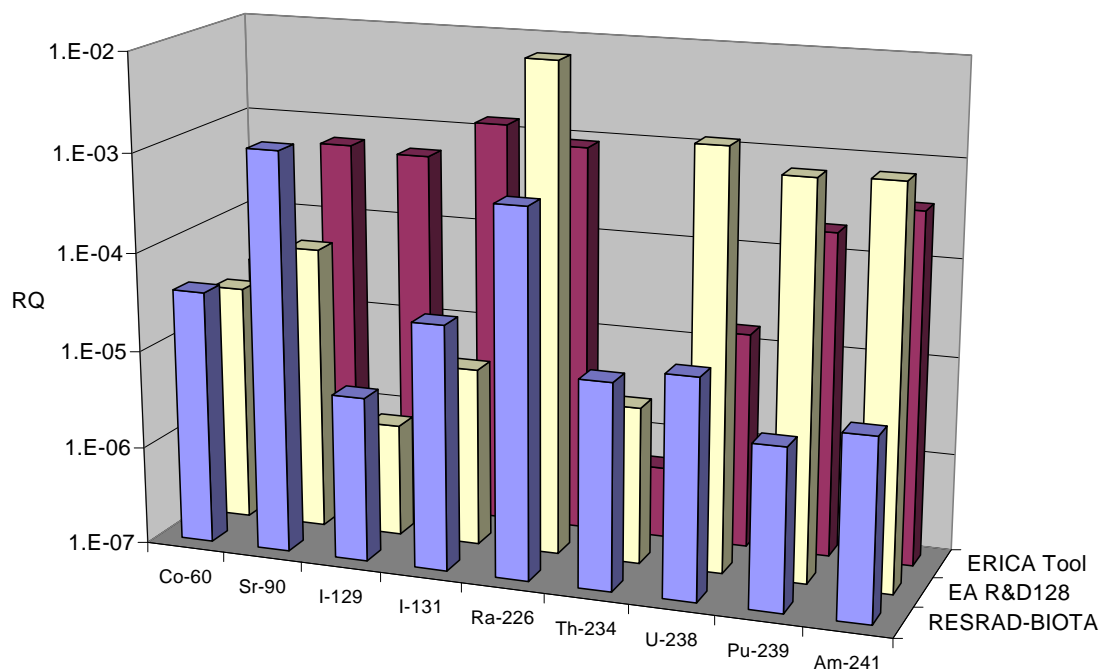


Figure 1. A comparison of risk quotient (RQ) values predicted by the ERICA Tool, EA R&D 128 and RESRAD-BIOTA for selected radionuclides in terrestrial ecosystems assuming 1 Bq kg⁻¹ in soil. Note for this comparison screening values of 40 µGy h⁻¹ for terrestrial animals and 400 µGy h⁻¹ for terrestrial plants were used as these are the default values within the RESRAD-BIOTA package

4. WP3: Requirements for protection of the environment from ionising radiation

WP1 identified a need for predefined numeric criteria to be applied when conducting environmental impact assessments to allow the risk associated with any exposure to ionising radiation to be determined. WP1 also noted that a wide range of numeric criteria are currently in use in different countries often which have been derived using different methods.

Within WP3, PROTECT set out to propose numerical values for protection of the environment from ionising radiation that would ensure compliance with a defined protection goal, using a consistent approach with that used in chemicals risk assessment and which utilised the available biological effects data. To achieve this we needed to:

- Define appropriate levels of protection, taking into account European legal requirements and existing practices for other hazardous substances;
- Identify approaches to evaluate the available biological effects data and to determine, in consultation with experts in chemical risk assessment, which data would be the most appropriate to use to calculate criteria for application in environmental impact assessments;
- Consult with regulators, industry, NGOs and other experts to identify areas of consensus and concern.

Following consultation, the following general protection goal was agreed:

'To protect the sustainability of populations of the vast majority of all species and thus ensure ecosystem function now and in the future. Special attention should be given to keystone, sentinel, rare, protected or culturally significant species'.

4.1 Derivation of a generic screening level

The FREDERICA radiation effects database¹² (Coppelstone et al., 2008) was used to identify effects data of suitable quality, from which the dose rate giving rise to a 10% effect in the exposed group in comparison to the control group could be estimated (this is termed the Effective Dose rate (EDR₁₀ value)). Initially, data for all organism types were used to derive a generic screening value applicable across all taxonomic groups. It is important to note that screening values are intended for use within tiered risk assessment frameworks. Their purpose is to determine if a site requires more in-depth assessment. A screening value is not a prescriptive limit which must not be exceeded but simply a trigger to focus on those sites where further work might be needed.

As far as possible within the PROTECT project, the methodology outlined within the EC Technical Guidance Document (TGD) on risk assessment for chemical substances (EC, 2003) was adopted. The approach used within PROTECT was to select the most sensitive (lowest EDR₁₀) endpoint for any given species that was deemed relevant to population sustainability (for example reproduction endpoints); although cytogenetic endpoints may be more sensitive, they were not considered to be relevant to population sustainability.

¹²An online radiation effects database considering non-human species created by the ERICA project (www.frederica-online.org)

Reproduction endpoints were most often amongst the more sensitive and these are clearly population relevant. From a possible 5500 endpoints listed in FREDERICA database, twenty two values were extracted as being the most relevant and appropriate following much discussion. These comprised: 4 plants, 2 annelids, 3 crustaceans, 2 molluscs, 2, birds, 4 fish and 3 mammals. Figure 2 shows the steps used to extract, sort and then process the effects data in the FREDERICA database for use in the PROTECT project.

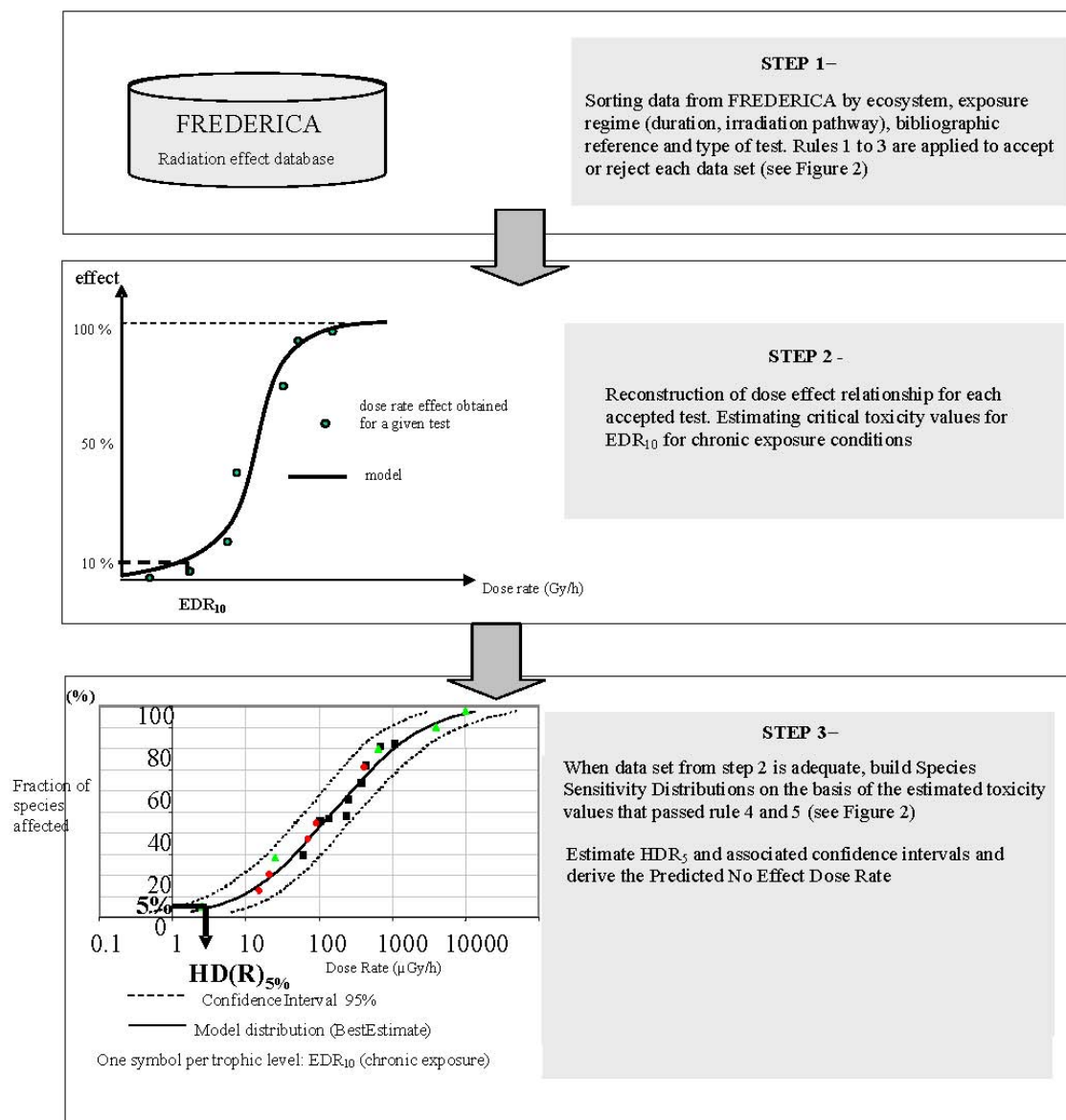


Figure 2. The methodology applied to the FREDERICA database to reconstruct chronic exposure dose-effect relationships and derive benchmark values from SSD

The selected EDR_{10} values were used to construct a species sensitivity distribution (SSD, see figure 3) to determine the dose rate at which 95 % of species will not experience more than a 10% effect (termed the HDR_5 value). The SSDs were constructed using a log-normal distribution by the approach of Duboudin et al. (2003). The Direct Weighted Bootstrap method was used to build the SSDs and their confidence intervals. The bootstrapping was run for a 1000 samples. A basic assumption of the SSD approach is that the species tested are representative of all species.

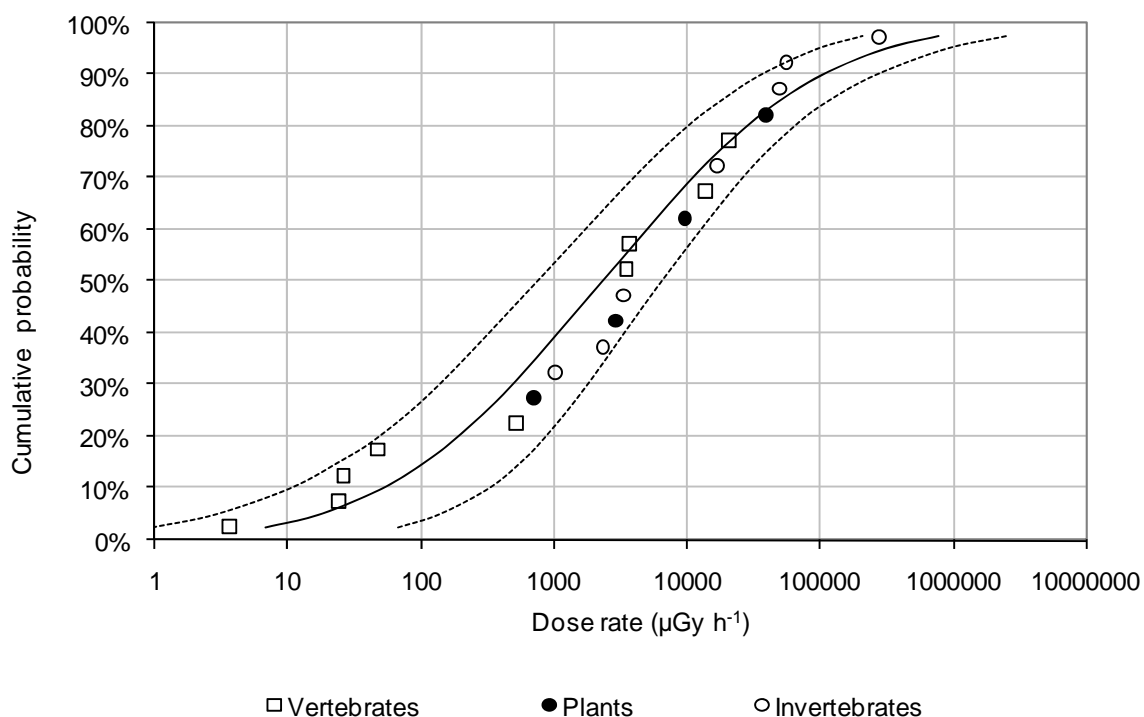


Figure 3. Species Sensitivity Distribution Curve through the data extracted from the FREDERICA database

To determine the predicted no effect dose rate (PNEDR) an assessment factor of 2 was then applied to the HDR_5 to account for any remaining uncertainties. The TGD (EC, 2003) suggests that a factor between 1 and 5 be applied but it does not give any clear guidance how to select the value to use. Within PROTECT, the main factors contributing to the uncertainty of a derived HDR_5 were determined (Figure 4), these were scored using a 1-3 star weighting approach (see Box 1) and then an appropriate AF was selected (in this case a value of 2).

AF = 1	→	AF = 5
Many data	→	Few data
Predominantly field data	→	Predominantly laboratory data
Sensitive endpoints	→	Non-sensitive endpoints
Supporting evidence	→	Lack of evidence
Wide data spread	→	Poor data spread

Figure 4. Factors contributing to uncertainty of a derived HDR_5

Box 1. Determination of Assessment Factor to apply to the derived HDR₅ to determine a Predicted No Effect Dose Rate (PNEDR) (* = poor, ** = good, * = very good)**

Amount and quality of data***: The data have been through a rigorous selection process from being quality controlled when first entered into FREDERICA through to the consideration of endpoint relevance. Quality and robustness of the data are further strengthened by the evaluation of the effects of weighting data according to taxonomic groups or EDR₁₀ uncertainty and effect of using different input data (i.e. HNEDR if lower than EDR₁₀). The amount of data was above the minimum required according to the TGD.

Field-lab data***: Although most of the data are from laboratory studies, the vast majority of available field observations (not included as not suitable for input to SSD) suggest that population relevant effects would not be observed at dose rates below the derived HDR₅ (17 $\mu\text{Gy h}^{-1}$).

Sensitivity of end-points***: We have selected the lowest EDR₁₀ value for each species for observations of ecologically relevant endpoints.

Data spread**: The overall data spread of the 20 data entries is fairly good covering plants, crustaceans, molluscs, annelids, fish, birds and mammals.

Supporting indications**: The derived HDR₅ is comparable to, or lower than, the recommendations of ICRP, UNSCEAR, NCRP and IAEA (see Table 1). It is also comparable to the upper range of estimated background dose rates (1-30 $\mu\text{Gy h}^{-1}$) as given in the ERICA Tool (Brown et al., 2008). Available laboratory and field effects data for appropriate endpoints, as discussed below, are above the HDR₅ value.

For the generic screening level the SSD was based on all available relevant EDR₁₀ values and the HDR₅ was estimated as 17 $\mu\text{Gy h}^{-1}$ (dashed lines represent the 95% confidence intervals). Applying an AF of 2, the resultant PNEDR value was 10 $\mu\text{G h}^{-1}$ and is thus proposed as the generic screening dose rate by the PROTECT consortium. The generic screening dose rate should be used within assessments as an additional dose above that received from natural radiation (called an incremental dose rate).

For the estimation of the generic screening value, data for all organism types were used within the SSD. However a number of different data treatments were also applied but all the options investigated gave a reasonably similar result (thus giving confidence in the numbers generated).

4.2 Wildlife or Organism specific screening levels

There is a key problem with the use of a single generic screening value in radiological risk assessments for non-human species. In many cases, the most exposed taxon may not necessarily be the most sensitive. Because a generic screening value is applied to all species, it may result in either (i) overly conservative assessments which lead to more detailed site-specific assessments which are unwarranted (false positive) or (ii) assessments which do not identify the need for more detailed consideration of the more radiosensitive organism groups (on the basis of the currently available data we estimate that only 85% of vertebrate species are protected using a screening dose rate of 10 $\mu\text{Gy h}^{-1}$) even though they may be warranted (false negative). Consequently, screening values that are specific to a particular organism group (probably taxonomically at the family or class level) may be more appropriate than a single generic value.

We considered deriving values for three broad groups, namely plants, vertebrates and invertebrates, recognising that these each contain organisms which are likely to have a range of radiosensitivities. These groups were however appropriate given the available effects data. The estimated screening values were: (i) vertebrates $2 \mu\text{Gy h}^{-1}$; (ii) plants $70 \mu\text{Gy h}^{-1}$; (iii) invertebrates $200 \mu\text{Gy h}^{-1}$.

The vertebrate and invertebrate values were generated using the SSD methodology whereas, because of the fewer available data, the plant value was generated using the assessment factor approach. However, to derive values for invertebrates and vertebrates the SSD methodology was applied to fewer data than recommended in the European guidance. Taking into account the limited data and uncertainty associated with these estimates, they should be considered as only illustrative, giving the probable order of magnitude of such values. Nevertheless, they are broadly compatible with the lower end of the derived consideration level (DCL) band for comparable organisms as recently proposed by the ICRP. Whilst the ICRP values were derived by expert judgement, it is encouraging that similar values have been derived using different approaches.

The conceptual difference between the types of screening value is that the generic value aims to protect 95% of all species whereas the organism specific values aim to protect 95% of species within a specific organism group. Application of a generic screening value may therefore not protect all groups to a 95% level unless an additional margin of safety is applied to the value.

4.3 Second, higher benchmark value

Whilst a screening value is helpful in identifying sites where non-human species are potentially at risk from exposure to ionising radiation and thus when further work is required, an assessor can still encounter a situation where a refined exposure assessment has been completed but the calculated dose rates remain above the screening value. Currently there is limited advice on what an assessor should do if the screening value is exceeded which makes it difficult to conclude if there is an unacceptable risk or not. A possible option is a second, higher, benchmark which identifies, for example, when the risk of impact is more likely to be 'significant' or 'severe'. This could aid decision making by highlighting where the calculated dose rate is on the scale of no effect to significant effect.

During the PROTECT consultation it was not possible to reach consensus on the need for this second benchmark with arguments both supporting and objecting to this proposal. We recognise that further discussion about the need for this second higher level would be useful. However, it was outside of the scope of the PROTECT project to define such a level as this introduces value judgements and will be influenced by social and ethical factors ("how much damage is society prepared to tolerate?"). We suggest there is a need for a wider discussion on the potential benefit of a second higher benchmark value. Such discussions need to consider:

- Is there a need for a second higher level benchmark?
- What is meant by a 'significant' level of effect (acknowledging that there is no agreed precedent from chemicals regulation)
- How could a second higher level benchmark be derived?
- How would it be used in risk management and regulation under different exposure situations?

Our remit was to produce a system for environmental radiological protection that is as similar as possible to that existing for humans. We have put our recommendations for

environmental protection into context with that in place for human protection. In comparison to human radiological protection the second higher value could be consistent with: (i) the 'reference level' for existing (and emergency) exposures and (ii) the 'dose constraint' for planned exposures as defined by the ICRP. In this case, the screening level could be considered to be broadly consistent with an exemption level. The screening value proposed by PROTECT and the potential second higher benchmark value (if adopted in the future) can therefore be seen to be broadly consistent with the framework for protection of humans. Both the screening and second higher benchmark value(s) will be applicable to planned and existing exposure situations although we do not envisage that they are relevant to emergency exposure situations. Figure 5 illustrates how this might be applied in practice.

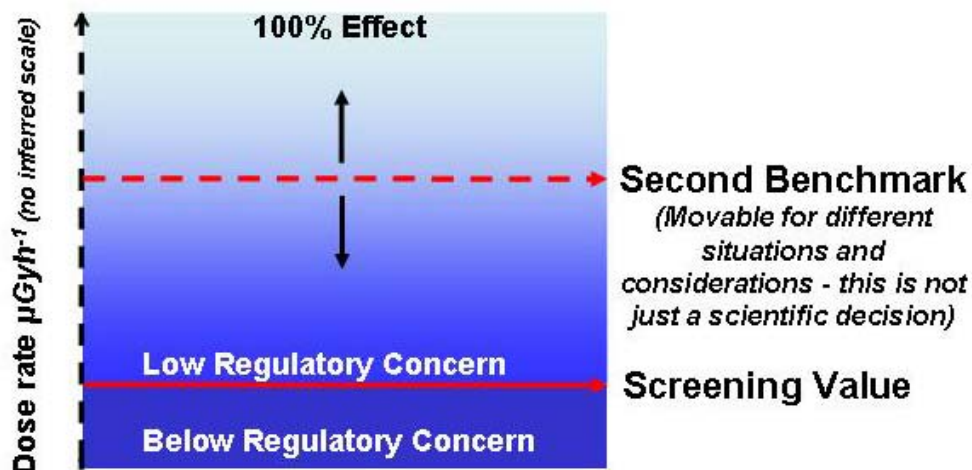


Figure 5. Potential application of two numeric values within radiological environmental assessments

A second higher benchmark could help assessors place their results into context if dose rates were estimated to exceed the screening level. However, the selection of the numeric value of a second benchmark needs to take account of wider societal, economic and political judgements and may vary between situations. A full discussion on the issues around the second benchmark is provided in PROTECT Deliverable 5 and the Annex of Deliverable 5 (Andersson et al., 2008a, b).

5. Recommendations from the PROTECT project

In summary the recommendations of PROTECT are:

- International coordination and cooperation in this developing field of radiological protection of the environment should continue;
- Consistency in the modelling approaches should be improved, there is a need to review and agree on internationally accepted data to model the transfer of radionuclides to biota;
- Research effort should be directed at better understanding the variation and uncertainty between the available assessment models and that this should be kept under review (for example when a standard set of transfer parameters becomes available);
- Numeric criteria against which the results of environmental impact assessments can be compared are required. There are a range of approaches that can be applied to generate such numeric criteria, but we caution against those relying mostly on expert judgement. We recommend methods which use statistical techniques to evaluate the available biological effects data such as the Species Sensitivity Distribution approach, where the data permit. This is also the approach recommended for chemicals assessment;
- More biological effects data on key wildlife groups need to be either extracted from the available scientific literature or obtained through experimentation to fill data gaps thus allowing more robust wildlife group specific screening levels to be determined;
- Where possible, the available effects data should be summarised by wildlife group (e.g. fish, plants, mammals etc.) that may be relevant when undertaking environmental impact assessments. Numeric screening values should be determined for each of these wildlife groups, where the amount of data allows it;
- In the interim, following a rigorous review of the available biological effects data and consideration of the relevance of the endpoints being measured in terms of maintaining populations, a numeric screening value of $10 \mu\text{Gy h}^{-1}$ should be used in environmental impact assessments. The $10 \mu\text{Gy h}^{-1}$ should be used to identify situations which are below regulatory concern with a high degree of confidence. Above the $10 \mu\text{Gy h}^{-1}$ further assessment work will be required to identify if there is a potentially significant risk to a population. The use of a numeric screening value in this way is consistent with the use of an exemption value (such as the 10 or $20 \mu\text{Sv h}^{-1}$) applied in human radiological protection;
- In some circumstances, where a refined environmental impact assessment continues to identify that a site may be potentially at risk from the impact of ionising radiation, it may be helpful to have a higher numeric value to aid an assessor and so we recommend that the concept and use of a second, higher numeric value be explored by the wider radiological protection community.

5. References

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