Executive Summary

PROTECT: Protection of the Environment from Ionising Radiation in a Regulatory Context

Whilst there is a well developed system of radiological protection for humans, it is only in the last decade that a similar system for wildlife has begun to evolve. Such a system is required to address emerging legislation, particularly, in some countries, from a conservation perspective. Furthermore, the International Commission on Radiological Protection are now developing a framework for undertaking environmental radiological assessments.

There has been a considerable amount of work, funded in part by the EC, to develop tools that can be used to calculate doses and provide information on the biological effects of ionising radiation on wildlife. The key requirements for these tools are methods to:

- Estimate transfer of radioactivity to wildlife;
- Calculate dose rates to wildlife;
- Characterise risk.

The EC EURATOM Framework 6 funded **PROTECT** project (FI6R-036425) set out to develop dose rate thresholds for wildlife to help to determine the risk of exposure to ionising radiation. Without such criteria any radiological protection framework for the environment cannot be applied usefully in a regulatory context. 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).

To develop appropriate criteria, we have evaluated different approaches to protecting the environment from ionising radiation. We have compared these approaches with those used for chemical contaminants, allowing us to suggest numerical target values and develop thresholds for protecting the environment from ionising radiation. We have 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. All the outputs from the project are available at http://www.ceh.ac.uk/protect. These outputs will help to inform a future revision of the EC Basic Safety Standards. 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.

Work Package 1: Environmental Protection Concepts

Drawing on the experiences of key stakeholders from regulatory 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.

Our work showed that the same basic generic assessment framework is applicable to both radioactive and chemical substances consisting 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 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.

Our 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;
- We should use internationally agreed approaches for setting environmental thresholds for chemicals (namely the Species Sensitivity Distribution and Assessment Factor 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.

Work Package 2: 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-BIOTA (implementing the US DOE graded approach), Environment Agency R&D128 (developed for use in England and Wales for assessment of Natura 2000[1] sites) and the ERICA Tool (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 have to conduct assessments of doses to non-human species in the future. We also worked with ICRP Committee 4[2] to conduct an initial evaluation of the draft ICRP draft report on the use of Reference Animals and Plants[3] which forms part of their planned framework for assessing the impact of ionising radiation on non-human species.

Our main findings were:

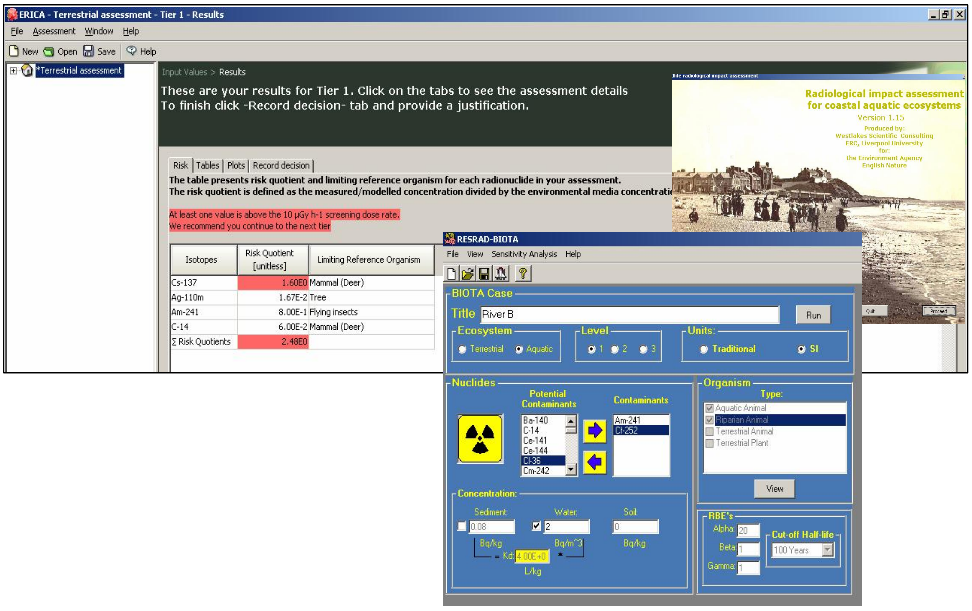
- Currently none of the available approaches are comprehensive and, as a consequence, they are often used in combination (e.g. whilst the R&D128 methodology is the most basic it is the only approach to consider noble gases which contribute a major component of the total activity released from many nuclear sites);

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

[2] ICRP Committee 4 provides advice on the application of the recommended system of protection.

[3] 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.

- 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;



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 group[4] and others, our evaluation showed that the transfer components 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 below). Reasons for this need to be better understood and any deficiencies addressed.

We recommended that the ERICA Tool be used by European Member States on the assumption that it continues to be maintained and improved[5]. We also suggested that training courses on ERICA Tool be provided.

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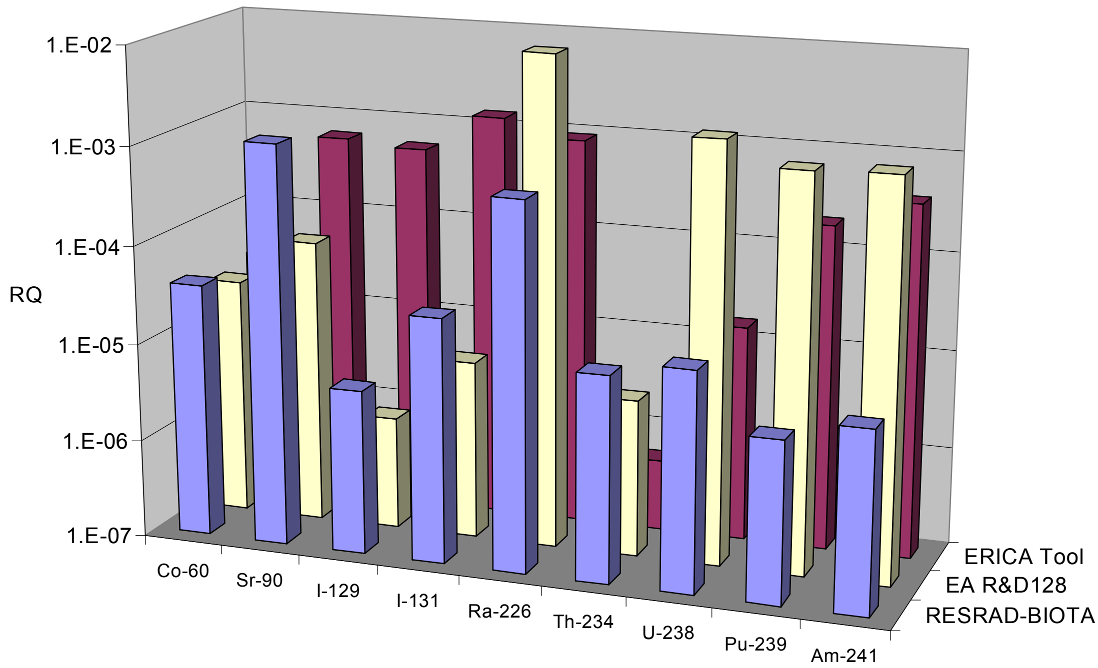
[4] The Biota working group was part of the IAEA's international programme called Environmental Modelling for Radiation Safety. Full details of the programme are available from: http://www-ns.iaea.org/projects/emras

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



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.

Work Package 3: 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 having been derived in different ways.

Within WP3 we set out to propose numerical values for protection of the environment from ionising radiation to 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:

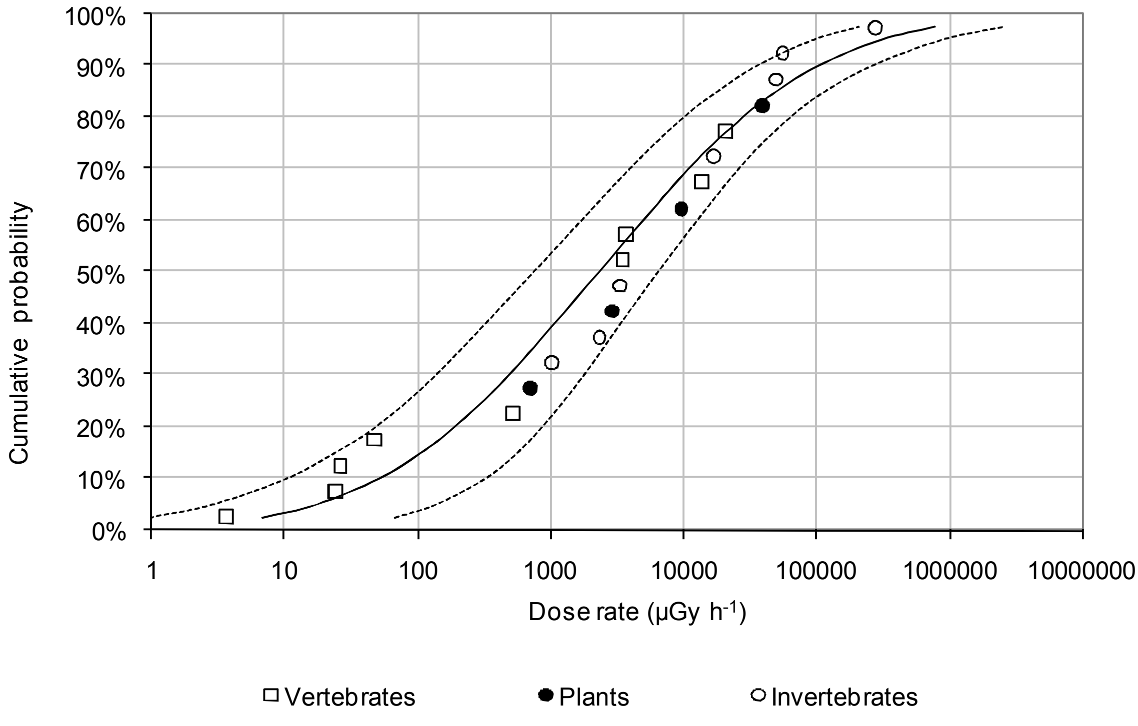
- Define appropriate levels of protection, taking into account European legal requirements and existing practices for other hazardous substances;
- Identify approaches to evaluate the available biological effects data and to determine, in consultation with experts in chemical risk assessment, which data 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, we proposed the following general protection goal:

'*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*'.

The FREDERICA database[6] was then 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 EDR_{10} value). Initially, data for all organism types were used to derive a generic screening value applicable across all taxonomic groups. Screening value 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, we adopted the methodology outlined within the EC Technical Guidance Document on risk assessment for chemical substances[7]. The approach used within PROTECT was to select the most sensitive (lowest EDR_{10}) endpoint for any given species; cytogenetic endpoints were not considered to be relevant to population sustainability, although these may be more sensitive. Reproduction endpoints were most often amongst the more sensitive and these are clearly population relevant. Twenty two values were extracted from the information contained within the FREDERICA database comprising: 4 plants, 2 annelids, 3 crustaceans, 2 molluscs, 2, birds, 4 fish and 3 mammals. The selected EDR_{10} values were used to construct a species sensitivity distribution (SSD, see figure below) to determine the dose rate at which 95 % of species will not experience more than a 10% effect (termed the HDR_5 value). To determine the predicted no effect dose rate (PNEDR) an assessment factor of 2 was applied to the HDR_5 to account for any remaining uncertainties. The resultant PNEDR value was 10 μG h^{-1} and is 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).



Species sensitivity distribution based on all available relevant EDR_{10} values. HDR_5 is estimated to be 17 μGy h^{-1} (dashed lines represent the 95% confidence intervals).

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

[7]EC (2003) Technical guidance document in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances, Luxembourg: Office for Official Publication of the European Communities.

However, 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 µGy 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. The estimated screening values were: (i) vertebrates 2 µGy h^{-1}; (ii) plants 70 µGy h^{-1}; (iii) invertebrates 200 µGy 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.

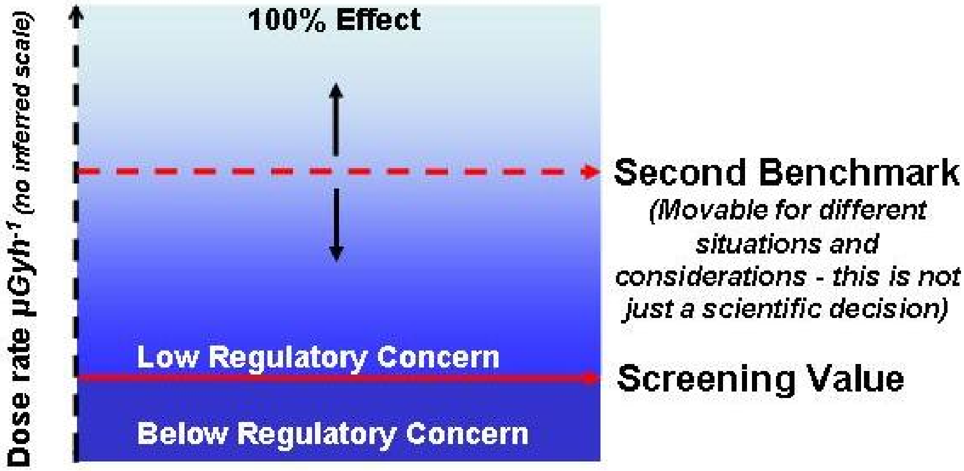
The conceptual difference between the types of screening value is that the generic value aims to *protect 95% of all species* whereas the organism specific values aim to *protect 95% of species within a specific organism group*. Application of a generic screening value may therefore not protect all groups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

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 and 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.



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.

PROTECT Recommendations

In summary our recommendations are:

- International coordination and cooperation in this developing field of radiological protection of the environment should continue.
- To improve consistency in the modelling approaches, 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).
- We need to have some numeric criteria against which the results of environmental impact assessments can be compared. 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 the use of methods based on statistical evaluation of 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 μGyh^{-1} should be used in environmental impact assessments. The 10 μGyh^{-1} should be used to identify situations which are below regulatory concern with a high degree of confidence. Above the 10 μGyh^{-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 μSvh^{-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 an 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.