BIOPROTA

Key Issues in Biosphere Aspects of Assessment of the Long-term Impact of Contaminant Releases Associated with Radioactive Waste Management

Demonstrating Compliance with Protection Objectives for Non-Human Biota within Post-closure Safety Cases for Radioactive Waste Repositories

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PREFACE

BIOPROTA is an international collaboration forum which seeks to address key uncertainties in the assessment of radiation doses in the long term arising from releases of radionuclides as a result of radioactive waste management practices. It is understood that there are radio-ecological and other data and information issues that are common to specific assessments required in many countries. The mutual support within a commonly focused project is intended to make more efficient use of skills and resources, and to provide a transparent and traceable basis for the choices of parameter values, as well as for the wider interpretation of information used in assessments. A list of sponsors of BIOPROTA and other information are available at www.bioprota.org.

The general objectives of BIOPROTA are to make available the best sources of information to justify modelling assumptions made within radiological assessments of radioactive waste management. Particular emphasis is to be placed on key data required for the assessment of long-lived radionuclide migration and accumulation in the biosphere, and the associated radiological impact, following discharge to the environment or release from solid waste disposal facilities. The programme of activities is driven by assessment needs identified from previous and on-going assessment projects. Where common needs are identified within different assessment projects in different countries, a common effort can be applied to finding solutions.

This report is the final report for the BIOPROTA project 'Demonstrating Compliance with Protection Objectives for Non-Human Biota within Post-closure Safety Cases for Radioactive Waste Repositories'. The report provides an outline concept which forms one possible approach to the demonstration of compliance with environmental protection objectives for radioactivity in the environment where available screening values are exceeded. Advice is also provided on how non-human biota assessments may be undertaken within performance assessments for disposal facilities for long-lived radioactive waste.

The report builds upon an interim report which was distributed to BIOPROTA members in March 2011, and which was used as the basis for discussions during an initial project workshop held in Herrankukkaro in Finland, 30-31 March 2011. This initial project workshop informed the development of a second interim report, which was distributed to BIOPROTA members and formed the basis for a further workshop held in Glasgow, 6-7 July 2011.

Both the interim reports and the workshop discussions included review of background information, an overview of available methods applied to evaluate risks from radioactivity released to the environment, and review of methods currently used to demonstrate compliance with environmental protection objectives, both within the nuclear and non-nuclear industry. Where relevant to establishing key arguments presented here, background information continues to be included within this report. Additional relevant and supporting information is appended.

The requirements for demonstrating protection of the environment during the post-closure period following disposal of wastes to deep geological facilities form the primary focus of attention. The principles advanced may also be of relevance to intermediate depth and shallow or 'near-surface' disposal of wastes. A distinction is also made between the long-term (i.e. post-closure), and short-term (i.e. operational) requirements for demonstrating protection although, again, the principles established may be of relevance to the radioactive waste management community within the operational and institutional control phases of a facility as well as in the longer term.

Information is presented as working material to promote discussion and is offered, in the absence of fully formulated and accepted international recommendations, as interim material to assist in establishing the principles whereby an effective post-closure safety case may be established for the protection of the environment. The content of this report does not represent the official position of the participating organisations involved. All material is made available entirely at the user's risk.

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A number of individuals have contributed to the overall concept presented in this document through contribution to workshop discussions and/or provision of comments on working material produced to date. The authors of this report, consisting of staff from Eden Nuclear and Environment and the School of Environment and Life Sciences, University of Salford, would like to thank the following project participants for their valuable contributions within workshops and the broader consultation.

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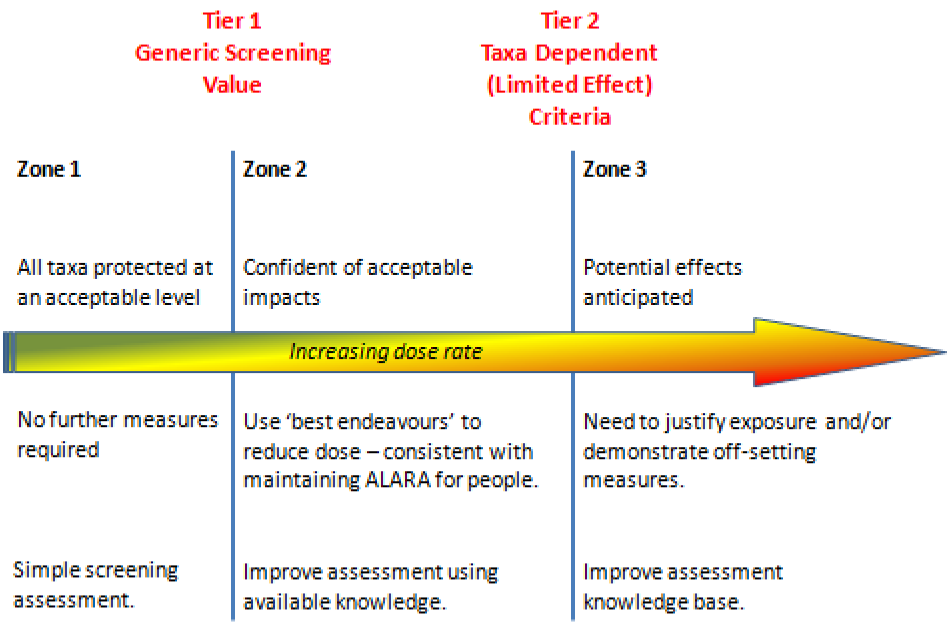
Contribution to the development of this report does not imply that it reflects the opinions of the above named individuals or of the organisations which they represent.

EXECUTIVE SUMMARY

Over recent years, a number of methodologies have been developed that enable assessments to be made of the potential environmental impact of releases of radioactivity through the calculation of dose rates to animals and plants (non-human biota or NHB). The objective has largely been to provide assessment methods that can be applied to evaluate whether activities that may result in the release of radioactivity to the environment will have an adverse impact. However, the applicability of these methods internationally is complicated by the array of protection objectives which may be adopted.

A number of internationally funded studies, and national programmes, have identified screening criteria to indicate those assessment results above which additional consideration is required. However no internationally agreed criteria are currently available and consistency in criteria between countries has not been achieved. Furthermore, since screening criteria are not intended to be applied as limits, but only to indicate a threshold below which adequate protection of non-human biota does not require further demonstration, it is clear that screening criteria cannot always form a sufficient basis for assessing the adequacy of protection afforded. Typically, exceeding a screening value leads to a regulatory requirement to undertake a further, more detailed assessment. It does not, *per se*, imply that there is inadequate protection of the organism types at the specific site, or within the specific assessment. Since this is the case, even where a more detailed assessment can be undertaken, and where it results in an apparent dose which exceeds the screening criteria, this need not imply that there is inadequate protection. It is therefore recognised that there is a need to develop a more structured approach to dealing with situations in which current screening criteria for non-human biota dose assessments are exceeded.

As a contribution to the developing international discussions, and as an interim measure for application where assessments are required currently, a two-tier, three zone framework has been proposed here, relevant to the long term assessment of potential impacts from the deep disposal of radioactive wastes. The purpose of the assessment framework, and associated material, is to promote a proportionate and risk-based approach to the level of effort required in undertaking and interpreting an assessment.



Assessments which fall within Zone 1, where all relevant types of organism are calculated to receive dose rates lower than the Tier 1 generic screening value, are considered to require no further measures to demonstrate that non-human biota are adequately protected at a population level. It is suggested, furthermore, that protection of all populations at this level is sufficient to imply adequate protection based on other measures such as biodiversity or habitat.

Assessments which fall within Zone 2, that is, some or all assessed organisms are exposed to dose rates in excess of the Tier 1 generic screening level, but below a defined Tier 2 taxa-dependent 'limited effect' value, are considered to be consistent with effects which are sustainable at a population level. As the level of exposure moves further from the Tier 1 screening value, it is considered that the assessment should be refined (making best use of available information) and measures to reduce the dose where practicable (and where consistent with maintaining ALARA for people) should be demonstrated.

Neither Zone 1 nor Zone 2 represent 'no effect' assessments. Rather they are to be interpreted as zones which afford protection at a defined level to a defined proportion of all species considered. This is consistent with a Species Sensitivity Distribution approach which specifies a statistically derived effects level for a given proportion of all species for which effects data are available. There are thus some circumstances, for instance where an assessment is driven solely by consideration of currently rare or radiosensitive species, where a more detailed assessment and/or extensive acquisition of new information may be required. However, such circumstances will be limited and the derivation of Tier 1 and 2 values weighted to (but not wholly driven by) the more radiosensitive species should provide reassurance that any impacts at the ecosystem level, and almost certainly at the individual population level for the large majority of species, are sustainable.

Assessments which fall into Zone 3, where there is an increasing likelihood of effects at the population level as the dose rates increase beyond the relevant Tier 2 values, are not automatically unacceptable (i.e. the Tier 2 value is not to be interpreted as a limit). In the first instance, increasing effort will be required to present a refined assessment based, for example, on the acquisition of new knowledge. This could involve additional site characterisation or fundamental radioecology research to derive radioecology parameters. Alternatively, some facility re-design, such as the incorporation of additional engineered barriers, could be considered that would serve to reduce the release of radionuclides to the biosphere.

In situations where it is not feasible to further refine an assessment, the assessor would be required to consider whether there are reasons of overriding public interest on which suitable justification arguments may be based for the continued development of the facility.

A number of alternative approaches to deriving Tier 1 and Tier 2 values are discussed. In each case, the purpose is to maximise transparency of meaning and derivation, and to make best use of information available.

As an interim measure, it is proposed that the Tier 1 generic screening value be set at 10 µGy per hour. This is consistent with guidance from the ERICA / PROTECT programmes and is already familiar to many assessors in a European context.

Likewise as an interim measure it is proposed that a single Tier 2 benchmark value of 100 µGy per hour be adopted. This is consistent with the more restrictive guidance from UNSCEAR for application to terrestrial ecosystems. It is suggested that when ICRP have concluded their review of the values and interpretation of DCRLs, the upper DCRL values may be appropriate for application as taxa-related Tier 2 values.

A simple illustration of the application of the framework concept is presented.

CONTENTS

1 INTRODUCTION

Over recent years, a number of methodologies have been developed that enable assessments to be made of the potential environmental impact of releases of radioactivity through the calculation of dose rates to animals and plants (non-human biota or NHB). The objective has largely been to provide assessment methods that can be applied to evaluate whether activities that may result in the release of radioactivity to the environment will have an adverse impact. However, the applicability of these methods internationally is complicated by the array of protection objectives applied, as acknowledged by the ICRP [2008] that '*no simple or single universal definition of environmental protection is applied internationally and that the concept of environmental protection differs from country to country and from one circumstance to another*'. Nonetheless, the range of environmental protection goals are largely encompassed by the protection goal offered by the ICRP [2003] to '*safeguard the environment by preventing or reducing the frequency of effects likely to cause early mortality or reduced reproductive success in individual fauna and flora to a level where they would have a negligible impact on conservation of species, maintenance of biodiversity, or the health and status of natural habitats or communities*'.

The forthcoming IAEA Basic Safety Standards (BSS) also introduce protection goals for non-human species: the following wording is taken from the Draft EU BSS, dated February 2010*.

Article 102

"*Member States shall include, in the legal framework for radiation protection, provision for the radiation protection of non-human species in the environment; this legal framework shall introduce environmental criteria aiming at the protection of populations of vulnerable or representative non-human species with regard to their significance as part of the ecosystem. Where appropriate, practices shall be identified for which regulatory control is warranted in order to implement the requirements in this legal framework and take account of appropriate environmental assessment criteria*."

Article 103

"*Member States' competent authorities, when establishing authorised limits on discharges of radioactive effluents, in accordance with Article 91 paragraph 2, shall also ensure adequate protection of non-human species; for this purpose a generic screening assessment may be conducted to provide reliance that the environmental criteria are met*."

As indicated by the draft BSS, some form of criteria are required as a means of evaluating the level of risk posed to the environment. However, currently no environmental criteria or generic screening values are recommended or appended to the BSS for guidance and appropriate actions to be taken in the event of exceeding a screening value are not indicated.

In order to define screening (or other) criteria, appropriate protection goals need to be defined and dose rate values (or benchmarks) representative of these protection goals defined and agreed upon [Howard et al, 2010].

A number of internationally funded studies, and national programmes, have identified screening criteria to indicate those assessment results above which additional consideration is required (see Appendix A). However no internationally agreed criteria are currently available and consistency in criteria between countries has not been achieved [Copplestone et al, 2010]. Since screening criteria are not intended to be applied as limits, but only to indicate a threshold below which adequate protection of non-human biota does not require further demonstration, it is clear that screening criteria cannot always form a sufficient basis for assessing the adequacy of protection afforded. Typically, exceeding a screening value leads to a regulatory requirement to undertake a further, more detailed assessment. It does not, *per se*, imply that there is inadequate protection of the organism types at the

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specific site, or within the specific assessment. Since this is the case, even where a more detailed assessment can be undertaken, and where it results in an apparent dose which exceeds the screening criteria, this need not imply that there is inadequate protection. Consequently, there is a need to consider the issue of what to do in practice should a screening value be exceeded.

The use of generic screening values is also acknowledged as being potentially problematic [Copplestone et al, 2010; Howard et al, 2010; Beresford et al, 2010] since the rate-limiting organism in assessments is seldom the most radiosensitive. Agüero et al [2006] reviewed available biota effects data for both acute and chronic exposure conditions and concluded that the radiosensitivity of different taxonomic groups is consistent with the commonly held belief that vertebrates, which are seldom the rate-limiting organisms in assessments, are among the most radiosensitive organisms. For example, the geometric mean per effect (50% mortality) following acute exposure to amphibians was 3.8 Gy as opposed to 430 Gy for algae. Under chronic exposure conditions and taking into account reproductive endpoints, fish were the most radiosensitive taxa in the freshwater environment; in the terrestrial environment, mammals were the most radiosensitive. There is therefore the potential that, following a release of radioactivity to the environment, assessments will indicate a risk of impact based on the *least* radiosensitive organisms, triggering further, more refined assessment.

The extent to which it is possible to derive a more realistic basis for assessment will depend upon the type and scope of the assessment. Even if information is available to undertake a more detailed series of calculations, there remains the issue of what to do in practice, should a breach of a screening value occur since there are currently no standards for environmental protection that can be applied in situations where screening criteria are exceeded. Accordingly, interpretation of results from dose assessments can be difficult in terms of compliance with protection objectives.

It is therefore recognised that there is a need to develop a more structured approach to dealing with situations in which current screening criteria for non-human biota dose assessments are exceeded. This is particularly the case for safety assessments for radioactive waste disposal facilities. Such assessments are complicated by a number of issues.

- Radionuclides will largely be transported from the near-field, through the geosphere, to the biosphere in association with groundwater over prolonged time periods (whereas many assessment methods are derived for releases predominantly to the atmosphere and/or surface waters).

- Repository integrity, hydrogeochemical properties of each individual radionuclide and environmental conditions will determine the period over which release and subsequent transport to the biosphere occurs. Peak activity concentrations in the accessible environment for individual radionuclides may be encountered over a time period stretching many tens of thousands of years.

- The long-time periods over which releases of radioactivity to the environment may occur are consistent with evolutionary adaptation, such that species present at the time of waste disposal are likely to differ from those to which exposure occurs.

- Climatic changes (natural and/or driven by human actions) over very long timescales will also affect both the nature and structure of ecosystems and the species present (since different species vary in their tolerance to different environmental conditions).

- The prospective and long-term nature of the assessments means that there is limited scope for refinement of assessment input data and parameter values through site-specific measurements and no verification activities (such as environmental monitoring) are available to corroborate projections of exposure or of effect.

1.1 BIOPROTA WORK PROGRAMME

In response to the acknowledged difficulties in undertaking, and interpreting, NHB assessments for geological disposal facilities for long-lived radioactive waste, the project 'Demonstrating compliance with protection objectives for non-human biota within post-closure safety cases for radioactive waste repositories' was developed within the framework of the International collaborative forum BIOPROTA, www.bioprota.org. The scope of the project was developed in response to discussions during the 2010 BIOPROTA forum* and in light of conclusions arising from the previous BIOPROTA work programme on uncertainties and knowledge gaps associated with non-human biota assessments for radioactive waste management facilities [Smith et al, 2010].

The overall objectives of the project were to provide input to international discussion of the issues and to propose a structured approach that could be employed to demonstrate compliance with protection objectives for those undertaking assessments relating to radioactive waste disposal facilities.

This report is the final report for the project. The report follows on from two workshops, held at Herrankukkaro in Finland (30-31 March 2011) and at Glasgow in the UK (6-7 July 2011).

The first workshop reviewed a number of alternative models and established an overall framework concept aimed at providing a structured approach to support compliance demonstration in situations where available assessment screening criteria may be exceeded. The concept was based around the derivation of two sets of screening criteria. The first, similar to that developed within the ERICA and PROTECT programmes, would be a generic screening value applied to screen from further assessment those release scenarios that are of no environmental concern. The second set of criteria would be taxa-specific and relate to dose rates at which there could be confidence that only limited (acceptable) effects would occur. The latter criteria would be applied in instances where initial screening values were exceeded. The effort expended in improving assessments would vary according to the degree to which exceedence of tier 1 and tier 2 criteria occurred.

The second workshop explored in further detail the proposed broad framework concept and established detailed interim measures to take forward, as well as identifying aspirational positions to work towards in the longer term.

Workshop notes, detailing the presentations, discussions and agreements reached during the Herrankukkaro and Glasgow workshops, are made available on the BIOPROTA website (www.bioprota.org)†. Additional information used in the development of the overall framework concept includes comments received from project sponsors and other interested persons on information circulated as part of the information pack for workshop participants and on the distributed workshop notes.

The approach is intended to explore issues of relevance to the developing international discussion around arguments that may be advanced to demonstrate adequate protection of non-human biota where initial screening criteria have been exceeded.

Whilst taxa-dependent limited effect criteria are recommended within the concept framework, it is recognised that information upon which these benchmarks could be derived are limited. It is also acknowledged that, whilst the concept and benchmark values can be discussed within the BIOPROTA framework, it is outside of the forum remit to make international recommendations. Ideas and concepts presented herein are therefore intended to promote international discussion and as an

* Report of the forum available from www.bioprota.org

† The framework concept presented following the Herrankukkaro workshop was amended during the Glasgow workshop. No changes have been made to the workshop notes as a result of these changes in order to provide transparency in the development of the framework concept presented in this report. As such, some inconsistencies may be evident between the main report (which focuses on the final agreed framework concept) and the two workshop notes.

aid to those currently undertaking assessments in support of applications for radioactive waste facilities, pending the provision of international guidance.

1.2 REPORT STRUCTURE

The remainder of this document is structured as follows.

- Section 2 defines protection goals, such as rare species and biodiversity, in the context of disposal facilities for long-lived radioactive waste.
- The development of the compliance demonstration framework concept is summarised in Section 3 and the resultant framework concept is presented in Section 4.
- Approaches to deriving assessment criteria that could be applied within the framework concept are discussed in Section 5.
- Section 6 presents the proposed interim framework approach that could be applied for long-term NHB assessments for geological radioactive waste disposal facilities, based around the framework concept detailed in Section 4 and the assessment criteria discussed in Section 5.
- Discussion and conclusions are presented in Section 7.

Throughout, terms which have acquired specific regulatory meaning are avoided where possible. Where terms with specific regulatory meanings have been introduced unintentionally these should be interpreted only in their common, and not their specialist, application.

2 DEFINING PROTECTION GOALS IN THE CONTEXT OF DISPOSAL FACILITIES FOR LONG-LIVED RADIOACTIVE WASTE

A number of environmental protection goals have been set both nationally and internationally (see Appendix A). Whilst differences are evident, there are also a number of recurring themes such as protection of rare or endangered species or the protection of communities of organisms or biodiversity. Whilst these protection objectives may pose limited issues for the majority of assessments whereby species or communities of organisms that may be impacted can be identified and risks therefore evaluated, difficulties arise in relation to identifying targets that would meet such protection objectives under the timeframes relevant to geological disposal facilities for radioactive waste. The problem with assessments which are applicable over very long periods is that environmental changes may occur, unrelated to the source of exposure, which dominate any population changes.

This section provides some discussion around the relevant issues with regard to long-term assessments and proposes approaches that could be taken that may enable such protection objectives to be considered within an assessment framework. In all instances early engagement with the relevant regulatory bodies is recommended such that interpretation of protection objectives and identification of relevant target organisms can be agreed. The information provided below is intended as a means of support for such discussions.

2.1 PROTECTION OF RARE OR ENDANGERED SPECIES

There is a general requirement within environmental protection objectives to pay particular attention to the protection of locally rare or endangered species, or species that are considered to be locally or regionally important. Where preservation of current diversity is valued, this approach makes common sense. However, projecting protection of currently rare species to future environmental conditions makes less sense – the local distribution of rare or currently protected species cannot be known and, indeed, the range inhabited by any species (or the degree of population isolation) cannot be known. Even on a scale of hundreds of years, environmental change may be significant and substantially influence populations. Climate change and sea level rise is currently projected to have significant impacts over timescales of a few hundred years in low lying and coastal regions. Historically the past three hundred years has seen continuing deforestation in many areas, and a significant number of alien species have been transplanted accidentally as a result of shipping and other commerce.

Over longer timescales of thousands and tens of thousands of years, continuing climate related change is predicted to occur. Such predictions are hard to determine with any certainty, particularly given the high levels of prevailing atmospheric CO_2 linked to anthropogenic activities. Entry into the next glaciation is not predicted to occur before 50,000-60,000 years from present, and the next major glacial advance for northern Europe may not occur until >100,000 years from present [Berger et al, 2003]. Direct human impacts over similarly long timescales are harder to predict, but will doubtless be significant.

Over these sorts of timescales, indeed over much shorter timescales, evolutionary change may become a dominant factor. For example, industrial melanism in the peppered moth *Biston betularia* is well attested in the UK, Europe and North America (see e.g. Cook [2003]), indicating that evolutionary change can occur within species in response to changing environments within timescales of one hundred years or so.

Essentially, beyond a few hundred years at most, basing protection of NHB on preservation of currently rare species seems to become a futile exercise. Either current actions will allow population recovery, consistent with environmental conditions, or the species will become locally extinct as a result of continuing environmental change. Nonetheless, it is reasonable to assume that, in the future, some rare or endangered species will be present although the type of species and habitat which they occupy cannot be predicted. As such, a pragmatic approach would be to assume that the same types of rare and/or endangered species that are currently present in the environs of interest to the assessment are present in the future. Such an approach is consistent with regulatory requirements in Finland [STUK, 2001; 2010].

Where populations are demonstrated to be adequately protected such that no affects are likely to occur based on current considerations of species present, it may be reasonable to assume that the degree of protection afforded to future populations would also be sufficient. In demonstrating protection, greater focus upon impacts on individuals rather than populations may be warranted and suitable conservatism in the choice of assessment parameters (e.g. concentration ratios, occupancy factors etc.) may be sufficient to demonstrate protection at the level of the most exposed individual.

2.2 PROTECTION OF BIODIVERSITY

As noted in Section 1, the ICRP [2003] include within their environmental protection goal a requirement to safeguard the environment to a sufficient degree such that there would be a *negligible impact* on *maintenance of biodiversity*. Increasingly, biodiversity is also being included explicitly as a protection objective at the national level. For example, draft regulatory guidance for non-human biota dose assessments in Finland includes biodiversity as a target for protection such that there is a requirement to demonstrate that exposures remain "*clearly below the levels which, on the basis of the best available scientific knowledge, would cause decline in biodiversity or other significant detriment to any living population*" [STUK, 2010]. Whilst this is a laudable goal, there is no clear definition of what is meant by protection of biodiversity in this context, which leaves the requirement open to interpretation. This presents difficulties for regulators and industry alike, so a baseline or protection target needs to be identified against which 'no decline' in biodiversity can be demonstrated. This section explores what is meant by biodiversity and possible targets of protection.

2.2.1 What is biodiversity?

The term biodiversity is ubiquitous within environmental regulations and policies that have been developed over the last three decades. Biodiversity, a contraction of biological diversity, is a measure of the various life forms within a specified environment and is often taken to represent environmental health. It can be defined as "*the variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part. Biodiversity includes all diversity within species, between species and between ecosystems*" [MA, 2005]. Therefore, biodiversity in its broadest sense covers all levels of biological and ecological complexity: genes, individuals, populations, species, communities, ecosystems and biomes [TEEB, 2010]. Biodiversity depends on the inter-action between many species and the complex inter-relationship of many stressors. Habitat diversity will contribute to biodiversity, and habitats will continue to evolve over time. Current grazed grassland areas may revert to scrubland or forests (possibly even cropped for timber) in future regimes, or may become inundated if field drains are not maintained or sea levels rise.

2.2.2 Protecting 'biodiversity'

If biodiversity covers everything from genes to biomes, the draft regulatory guidance from Finland could be interpreted as requiring demonstration that no individual (and hence genetic diversity) within a population will be impacted. If a qualifier was added to this interpretation, specifying a 'no impact' level for individuals with a defined probability, then this interpretation would be consistent with the radiation protection goal adopted for humans, namely protection of the individual at a specified level of risk of harm. This may be viewed as the ideal option from a conservation perspective, but the available data on radiation effects in non-human biota are unlikely to be sufficient for establishing a 'no individual impact' target across all organism types and, even if this target could be established, this would be a stricter regulatory requirement than that used in other areas of environmental protection (e.g. chemical contaminants).

An alternative way to categorise the biodiversity protection goal may be to consider how biodiversity is measured. Indicators are often used to describe biodiversity in quantitative terms, such as richness, rarity and uniqueness [TEEB, 2010]. The target of most indicators of biological diversity and programmes to conserve biodiversity is the *species* (e.g. Kadoya et al [2011]). Mayr [1942] defined species as "*groups of actually or potentially interbreeding natural populations, which are reproductively isolated from other such groups*". Although this definition has its limitations [de Queiroz, 2005], it is broadly applicable and widely adopted within the international literature. Focussing the protection goal at the species level enables the use of standard diversity indices to establish baselines and to assess deviations from these baselines. However, two provisos must be noted. First, indices of diversity do not ensure that the current species are maintained, only that relative species richness and abundance is maintained (i.e. one species may substitute for another without any impact on the overall diversity measure). Second, for the long time horizons associated with repository assessments, it is only practicable to *imply* protection of biodiversity based on protection of individual populations – since relative abundance of species may change.

If focussing protection at the species level, an alternative to the use of indicators would be to establish whether the zone of predicted impact from a repository would encompass a given percentage of the range of a species (this would have to be defined on the basis of the carrying capacity of the species over the extent of its geographical range). Although it is recognised that a specific species carrying capacity may be difficult to define, expert judgement could be used to identify a percentage of a species that could be impacted whilst allowing the species to remain viable. For example, it may be decided that 10% of the individuals within a species could be lost in any year without risking loss of the entire species. Therefore, as long as the zone of impact from a repository does not extend through more than 10% of the range of the species, it could be concluded that 'biodiversity' is protected. Taking this approach may be a pragmatic option from the perspective of repository assessments. However, it would mean that local populations would be seen as 'expendable', which is at odds with the last part of the statement from the Finnish regulatory guidance, stating that there should be no "…..*significant detriment to any living population*".

Focussing protection at the genetic, individual or species level also conflicts with conventional international interpretations of the target for radiation protection when considering non-human biota (e.g. ICRP, ERICA). The broadly accepted target of protection is the population, and the above analysis suggests that the population is also the most suitable target for demonstrating protection of biodiversity. Although it is possible that some rare genes may be lost from the gene pool due to the loss of individuals within a population, focussing on populations will protect genetic diversity to a greater extent than focussing at the species level. This is because local populations may be physically isolated from other populations of that species. Whilst there may be no genetic barriers preventing breeding between geographically dispersed populations, the barrier of physical distance often prevents such breeding occurring in practice. As a result, organisms generally breed within their local population and genetic diversity between populations may result.

Continued biodiversity can only be demonstrated against an assumption that other factors will not change. As such, an appropriate starting point in the protection of biodiversity may be to evaluate available national and/or regional biodiversity action plans, particularly where these encompass species, habitat and/or local biodiversity actions plans, representative of the sites of interest to an assessment. Such plans will aid in the identification of protection targets to be included within an assessment.

2.3 PROTECTION OF NATURAL HABITATS OR COMMUNITIES

The ICRP [2003] protection goal presented in Section 1, includes a specific goal to ensure "*negligible impacts"* to the "*health and status of natural habitats or communities*". Protection of communities, as discussed further below, may be addressed through consideration of population interactions, whereas habitats may be valued as a type (for example the Drigg Dunes in the north west of England which are designated as a protected site on the basis of their nature as a habitat (Wood et al [2008])), beyond the specific community of organisms.

2.3.1 Protection of Communities

A biological community is an assemblage of interdependent organism populations that live and interact with each other in the same habitat. The structure of a community is a function of the properties of the habitat and interactions between species and between species and their habitat. Biological communities, together with the habitat they occupy, essentially form ecosystems that can be defined on different scales.

The species present within communities can vary over time – the key component to the continued functioning of a community is that the role (or niche) of a particular organism or species within that community continues such that, if one species is removed from a community, its role is replaced by an alternative species.

Keystone species, those that have a disproportionate effect on their environment relative to their abundance, are particularly important considerations for communities. Such species play a critical role in maintaining community structure, determining the type and number of other species in the community. Removal of keystone species may result in a large shift in community structure, even though that species was itself a small part of the ecosystem in terms of abundance. For example, where a predatory animal acts as a keystone species, removal of that species may result in a large increase in the population of prey organisms which has commensurate effects on other species that may share that niche within a community. By altering the relative proportions of different species that occupy this niche, other species lower in the food web will also be affected, potentially resulting in large changes to plant species within the community. The inclusion of keystone species within radiological assessments may therefore be warranted – ensuring that keystone species are protected would, in principle, ensure that community structure and function will not be adversely affected.

Focusing upon organism roles within a community may also warrant consideration. This could be achieved by considering ecosystem food webs and selecting species indicative of each trophic level with the aim of demonstrating that organisms representative of each trophic level are not at risk and, as such, species interactions should not be adversely affected. In addition, organisms with particularly important functional roles within a community/ecosystem should be considered. This would encompass pollinators, detritivores and seed dispersers, for example. As noted previously, reference to regional or national biodiversity action plans, specifically species action plans, may be of benefit in identifying key organisms (and in defining the range, habitat and behaviour of species, as well as interactions with other species).

2.3.2 Protection of Habitats

As indicated above, habitats may be the subject of protection rather than any specific biota present within the habitat. This represents a potential difficulty in establishing the focus of an assessment. One possible approach may be to draw upon information presented within relevant habitat action plans developed, for example, in response to the 1992 Convention on Biological Diversity or the 1992 EU Habitats Directive[*]. Such information is likely to identify which features contribute to a site being nominated for 'favourable conservation status', allowing the protection target to be focused on one or a few species. Alternatively, it may be appropriate to assess the collective impact upon a range of generic organisms representative of the habitat type to establish whether anticipated releases of radioactivity to the habitat or its immediate environs would impair ecological function.

2.4 ADDITIONAL CONSIDERATIONS

2.4.1 Selection of Representative Organisms

Whereas operational releases of radioactivity to the environment are typically to air or surface waters, releases from waste repositories in the geosphere are generally mediated via the groundwater pathway, which presents the potential for alternative routes of maximal exposure of biota [Smith et al,

[*] Council Directive 92/43/EEC on the Conservation of natural habitats and of wild fauna and flora.

2010; Robinson et al, 2010]. As a consequence, performance assessments for geological disposal facilities often focus on the use of contaminated irrigation water as a source of contamination of environmental media. This route is identified as potentially important for human dose considerations (i.e. as a source of contamination of agricultural crops) and will lead to the contamination of surface soils. For non-human biota, other than those that may occupy agricultural land, upwelling of groundwater may be the greatest route of exposure within terrestrial ecosystems. Discharge to surface waters may also be a significant exposure pathway for many organisms where exposure may be direct (e.g. occupancy within the water body, consumption of drinking water by terrestrial biota or root penetration into freshwater bodies) or indirect (e.g. seepage into soils / sediments, transition of water bodies to mires and terrestrial land as a result of land uplift).

For freshwater and marine biota, exposure pathways are likely to be similar to those considered for conventional releases, although diffuse rather than point source discharges may take a greater precedent. For terrestrial biota, however, organisms living within, or penetrating into soil are likely to receive a greater exposure than those living on the soil due to the greater potential for accumulation of radionuclides within the soil column. Exceptions to this may occur, particularly where the release of radionuclides in the gaseous phase is anticipated. Nonetheless, a greater focus on soil-dwelling organisms may be warranted in assessments. This would particularly be the case for earthworms which not only provide a vital role in maintaining healthy soil structure, but are also key prey items for many organisms.

Trees are also of potential importance with regards to exposure pathways. Trees have been included in the majority of biota dose assessment tools and are included as a reference plant within the ICRP developing protection framework [ICRP, 2008]. However, the conventional exposure route considered within such assessment tools is exposure (internal and external) of the trunk of the tree and/or the tree canopy; roots are effectively excluded from consideration in the dose calculations. Roots of trees have the potential to penetrate through soils, potentially accessing contaminated groundwater directly, depending upon the height of the local water table. Although considerations of internal exposure of roots are likely to be similar for all tissues of the tree[*], external exposure will be maximised for roots compared with other tissues of a tree for a subterranean source term. It is therefore recommended that specific consideration is given to the exposure of tree roots within such assessments.

Were tree roots to directly contact contaminated groundwater, a preferential route of uptake of radionuclides may arise that could result in the cycling of radionuclides from groundwater to soil through leaf senescence and litter fall. Organisms present within the soil litter layer, particularly detritivores that play an important role in element cycling within ecosystems, may be subject to relatively increased exposure. Selection of representative organisms from this specific habitat may therefore be appropriate. However, the cycling of radionuclides by trees would require specific consideration to enable leaf litter activity concentrations to be evaluated. Exposure of detritivores relative to leaf litter activity concentrations rather than the standard approach of exposure relative to soil should then be determined.

2.4.2 Selection of Reference Biospheres

Over long time periods, ecosystems will evolve due to natural or man-made processes, reflecting climatic conditions, land rise, sea level, agricultural practices, industrial development etc. With respect to ensuring adequate protection of NHB within a region, a range of ecosystems may require assessment on the grounds that they may (realistically) be expected to develop. For example, currently coastal areas may be inundated (if sea level rises) or succeed through dunes to coarse pasture to scrubland and eventually climax forest (if sea level falls or land rise occurs).

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[*] Dose assessment methods largely apply a single concentration ratio for the entire organism in relation to its environment (e.g. soil). Translocation and accumulation in different tissues is therefore excluded at this time although it is recognised that some concentration ratios that are used as 'whole-organisms CRs' may actually be derived from measurements of particular tissues rather than the whole organism.

Even at a very broad level of grouping, ecosystems embrace many distinct types including marine systems and brackish water, freshwater (ponds, lakes and rivers), transitional systems such as coastal areas, estuaries, mires or heaths, as well as veldt, scrubland, climax forest and agricultural systems. These types are by no means complete and, for instance, omit hyper saline lakes, or ecosystems characterised by climatic conditions (e.g. desert, tundra, boreal etc.). Within each of these very broad ecosystem types, there are many communities or assemblages which may be distinguished.

Marine systems may be classified by depth of water (coastal shelf to deep ocean and abyssal trenches), with quite distinct fauna and flora. Freshwater systems contain both emergent and submergent communities, they may be characterised by nutrient status (oligotrophic, eutrophic etc.), they include fringe communities such as reed beds and differ according to size, turnover and degree of isolation. Similar identifications may be made for each of the transitional and terrestrial systems identified above.

For assessments relevant to very long timescales, as applies in the case of deep geological disposal facilities, identifying and characterising ecosystems of relevance to a particular assessment needs to reflect both current and reasonably foreseeable conditions. Only when the ecosystems to be assessed have been characterised adequately can representative and keystone species be identified.

It is generally accepted that identification of species relevant to each ecosystem should reflect current, similar systems, particularly where these are proximal to the region of interest.

2.5 SUMMARY

In considering assessments for geological disposal facilities for radioactive waste, difficulties arise in relation to the assumptions of what plants and animals will be present in distant time frames. One approach to addressing this (which is consistent with the approach for human assessments) is to assume the same species as now are present in the future. Although unrealistic, since genetic drift and evolutionary change continues to occur, this appears the most pragmatic approach and is consistent with some national regulatory guidance (see for example STUK [2010]). Where ecosystem change is predicted to occur (for example due to sea level or land rise or climate variations), species relevant to current systems, representative of those likely to develop over time, should be identified. This latter approach is consistent with the Canadian approach to selecting representative organisms for long-term assessments [Garisto et al, 2008].

Notwithstanding that, some additional difficulties arise in relation to specific protection goals, especially where these are expressed in terms of protection of biodiversity or of habitat or community. In order to address these, the following suggestions on approach are provided.

- In practice, protection of populations provides the most accessible target. Nonetheless, this in turn is based on dose-effect relationships expressed at the individual level and therefore requires care in identifying ‘typical’ exposures.

- Since it is not possible to assess all species which are, or which might foreseeably be, present in the region of interest, some selection of species must be made. The selection should draw on representative species, keystone species, community niches, food webs and trophic level, and species likely to be most exposed (e.g. for sub-surface releases this may include soil/sediment dwelling species or soil/groundwater penetrating organisms).

- Regional or national biodiversity action plans (species and habitat action plans plus local biodiversity action plans) may help to identify key biological features of communities etc.

- In modelling routes of uptake, there may be a need to develop models to represent recycling of radionuclides (e.g. from groundwater, via trees, to soil litter layer).

It may be a reasonable assumption that, where all selected species from all relevant ecosystems are demonstrated to be protected adequately at the population level, then habitats, communities and biodiversity are also protected adequately.

3 APPROACH TO THE DEVELOPMENT OF A COMPLIANCE DEMONSTRATION FRAMEWORK CONCEPT

This section describes the development of an overall framework concept, intended as a means of demonstrating whether the environment is protected from releases of radioactivity to the biosphere that may occur as a result of radioactive waste disposal within the geosphere. The approach outlined builds on discussions during project workshops held 30-31 March 2011 at Herrankukkaro, Finland and 6-7 July 2011 at Glasgow, Scotland*.

The approach is intended to explore issues of relevance to the developing international discussion around arguments that may be advanced to demonstrate adequate protection of non-human biota where initial screening criteria have been exceeded. In developing the concept, the specific focus has been the need for demonstrating compliance with environmental protection objectives for radioactive waste disposal facilities for which long-term releases of long-lived radionuclides are a particular issue. The information presented should therefore be considered in this light, but may be relevant to other assessment contexts; for example intermediate/shallow disposal systems.

3.1 STARTING POINT

As noted in Section 1, numerical benchmarks currently adopted to demonstrate protection of NHB generally represent screening levels to segregate low effect activities from further regulatory consideration. Values that are currently applied by different countries, and their derivation, are detailed in Appendix A.

The dose rate may be expressed relative to all or some of the potentially exposed NHB (e.g. separate dose rates may be expressed for terrestrial or aquatic organisms or be generic to all ecosystems), may be based on different effects considerations, presented in units of Gy or Gy-derivatives (e.g. including weighting factors for different types of radiation), and is generally expressed nett of natural background. The unifying concept is that below a set dose rate, it is accepted that no further argument is required to demonstrate that NHB have been protected adequately.

In no cases have upper dose rates been identified which would automatically be regarded as unacceptable (i.e. no dose limits are imposed).

This is the inverse of the radiological protection philosophy advanced for people. Generally, for people, some variant on the ICRP concepts of justification, optimisation and limitation are accepted. In effect, this means that:

- all doses should be justified (i.e. the practice being introduced should offer a nett benefit to society);
- all doses should be maintained As Low As Reasonably Achievable (ALARA), subject to economic, social and other factors, which include equitability of distribution between groups of people and across generations; and,
- no individual should be exposed above the relevant limit.

In general, for protection of people, there is no lower limit below which the optimisation argument does not apply. Some regulatory regimes (such as adopted in the UK) do recognise a lower dose level below which further reduction is not required; however, this remains subject to demonstrating that Best Available Techniques (BAT) or Best Practicable Means (BPM) are being implemented. Since both BAT and BPM are tools used to demonstrate optimisation of approaches, this effectively

* Workshop notes are made available at www.bioprota.org.

does little more than recognise the changing balance of any cost-benefit argument as the benefits to be gained progressively decrease. The application of the upper and lower bands has been formalised by the UK Health & Safety Executive [HSE 1992] as a Tolerability of Risk (see Figure 1).

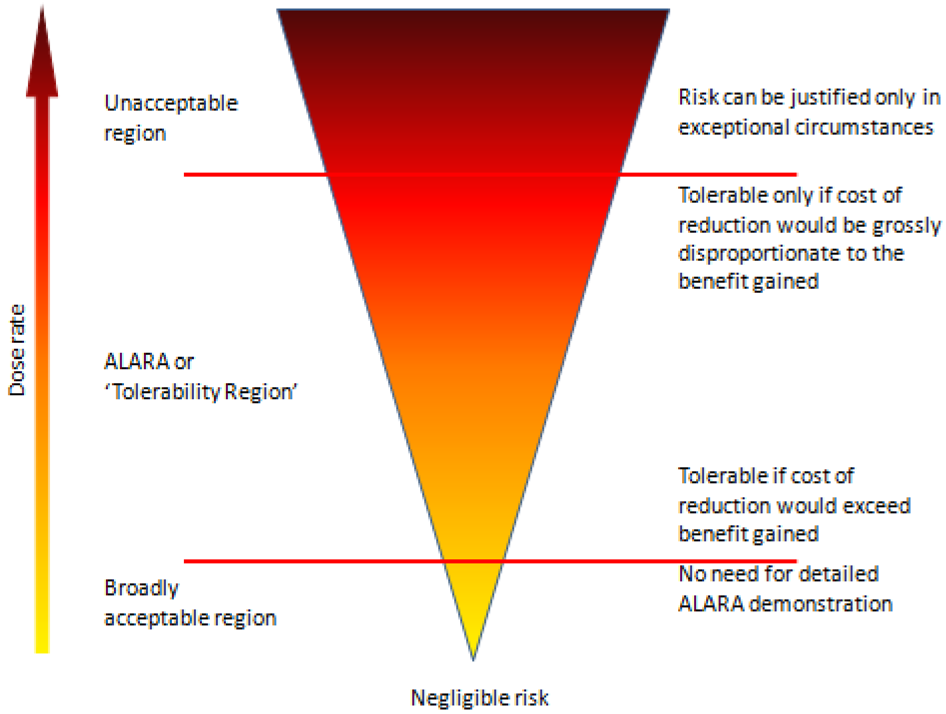

Figure 1. Tolerability of Risk (*Redrawn from HSE [1992], with minor modifications)*

With respect to NHB, a lower screening value is established below which no further action is required. Above this value it is necessary to demonstrate that NHB are protected (see Figure 2), generally at a species or population level (although other measures such as biodiversity or ecosystem function may also be introduced). Such protection does not require demonstration of optimisation of exposure.

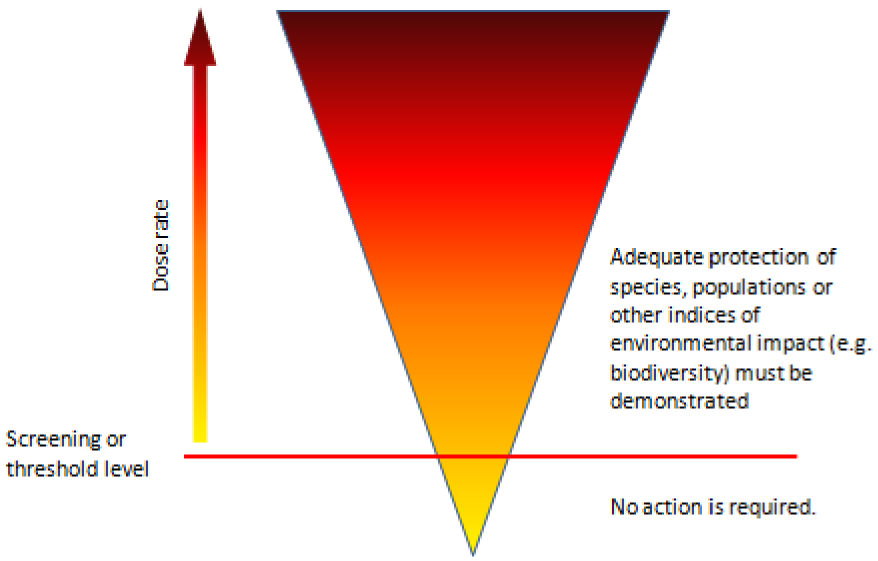

Figure 2. Schematic approach to demonstrating protection of non-human biota

Where adequate protection cannot be demonstrated, an argument may be advanced which identifies Imperative Reasons of Overriding Public Importance (IROPI) as described in Article 6(4) of the European Habitats Directive 92/43/EEC*. In such a case any damage to, or loss of, part of a European protected site *must* be compensated by creation in the same country of new habitat of the same type, quality and extent as that lost to ensure the integrity of the Natura 2000 suite of protected sites. The requirement for off-setting compensation measures applies only in the case of an internationally protected site (e.g. Special Protection Areas, SPAs; or Special Areas of Conservation, SACs), although by extension a justification argument based on compensating measures may be advanced in the context of damage to, or loss of, other habitats – whether or not such sites are designated as sites of national or international importance.

The general approach represented by Figure 2 is considered to be inadequate as a framework to assist in the demonstration of the protection of NHB where screening thresholds are exceeded. This forms the basis for advancing an initial framework concept as a starting point for discussion (Figure 3). The framework concept promotes tiered numerical benchmarks in combination with increasing effort to reduce uncertainty in derived dose estimates. Starting with a highly conservative, simple to use, screening level, the assessment process continues, if needed, with progressively more refined, user-driven assessments and with more targeted effects based benchmark values.

The application of a tiered framework is intended to represent a proportionate risk based approach such that sites potentially at risk can be identified whilst those judged to be adequately protected are excluded from further assessment.

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* The European Commission has issued guidance on the interpretation of IROPI and the Habitats Directive [European Commission 2000, 2007]. This guidance is not binding, but does offer clarification of interpretation of the requirements and exemptions granted under the Habitats Directive. It is likely that similar provisions exist within other regulatory frameworks, establishing the primacy of protecting people and allowing, on occasion, for overriding public need to permit higher levels of environmental detriment that would typically be regarded as 'reasonable'.

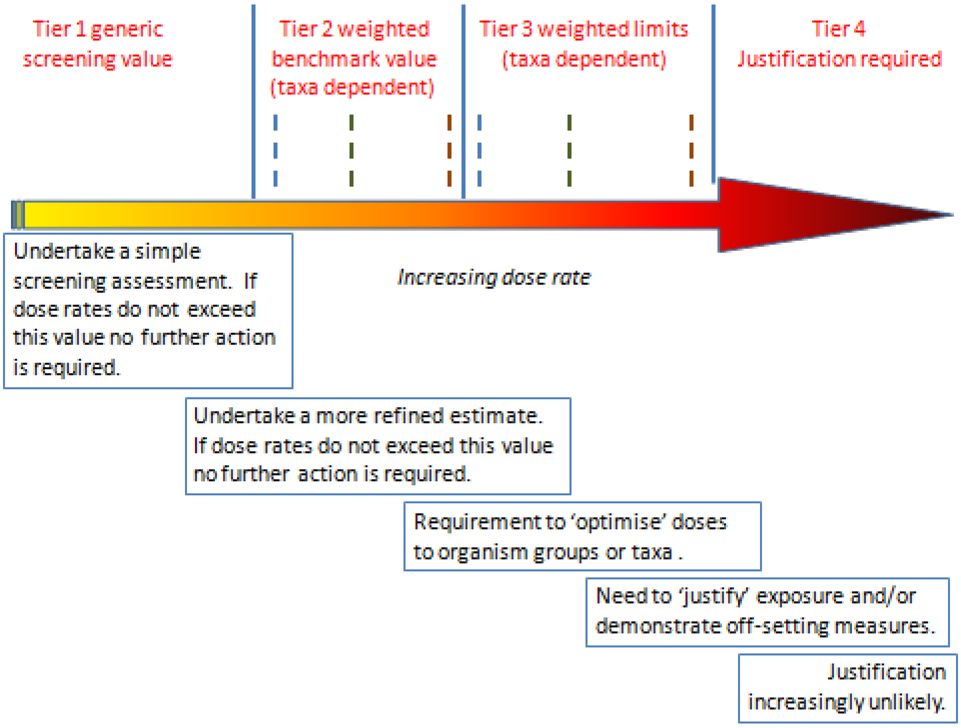

Figure 3. Illustrative approach to demonstrating compliance with environmental protection objectives

3.2 APPROACH TO REFINING THE INITIAL FRAMEWORK CONCEPT

Refinement of the initial framework concept occurred in two stages.

3.2.1 Stage 1 – Herrankukkaro Workshop

Initially, the concept was refined in light of discussions during the first project workshop at Herrankukkaro, Finland, 30-31 March 2011, which largely focused on the number of assessment criteria (i.e. how many tiers should be included within the framework concept), what they should constitute and how they should be derived. The main discussion points and agreements are documented in a workshop note, made available at www.bioprota.org. Key agreements were that:

- The concept should be based around two sets of assessment criteria, the first representing a conservative generic criterion that would be applied across all organisms irrespective of ecosystem, and a second higher tier.

- The tier 2 criteria should be taxa dependent (i.e. focused on vertebrates, invertebrates and plants) with plants being further sub-divided into higher and lower forms to take account of the perceived difference in radiosensitivity between the two extremes (e.g. pine trees versus phytoplankton). This is broadly supported by Figure 4, which is taken from UNSCEAR [1996] and relates to acute lethal doses. The general conclusion is that vertebrates are more radiosensitive than invertebrates, considered as a whole, and similarly higher plants are more radiosensitive than other plant species, again considered as a whole.

- Although narrower organism groupings than those put forward here would be likely to be more readily defensible at Tier 2, ability is constrained by the current dose-effects database which is inadequate, at this time, to support such an approach. This drives the argument in favour of broader groupings, as *an interim measure*.

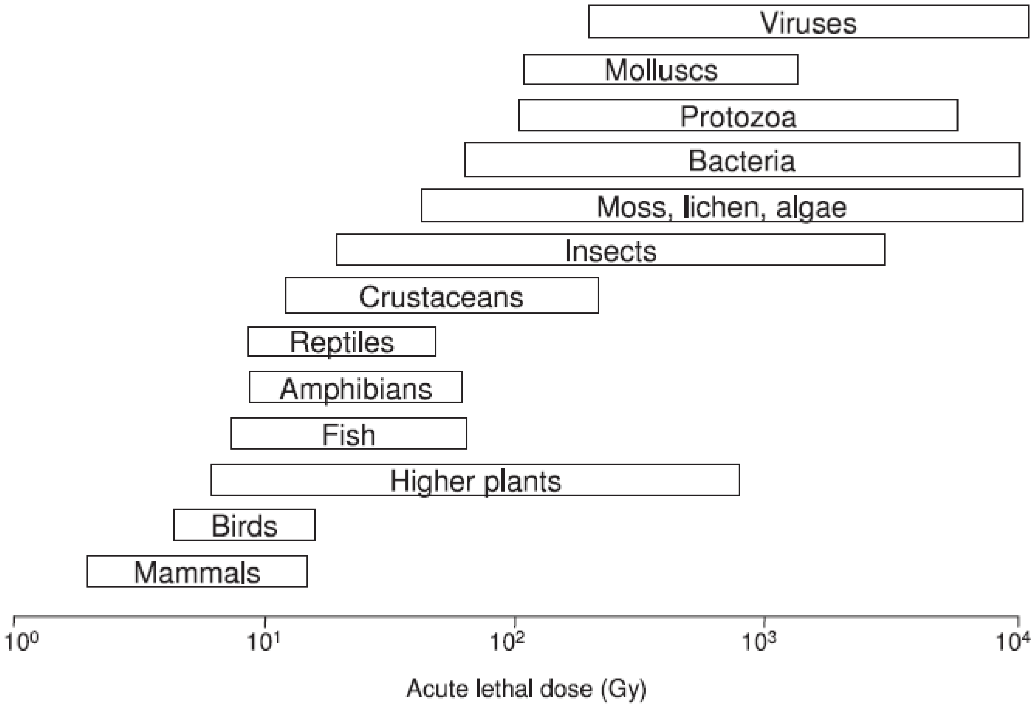

Figure 4. Approximate acute lethal dose ranges for various taxonomic groups (*reproduced from UNSCEAR [1996]; based on Sparrow et al [1967] and Whicker & Schultz [1982]*).

- Tier 2 criteria should represent dose rates at which only limited effects would be evident and that such effects would not be considered harmful to populations such that, at dose rates below the taxa-relevant tier 2 criterion, there could be reasonable confidence that impacts would be acceptable.

- Dose rates within zone 2 (i.e. between the generic tier 1 screening value and the taxa-dependent tier 2 criteria) should trigger refinement of the assessment by drawing upon additional information that is readily available (i.e. use of site-relevant radioecology data, alternative assessment models and/or more realistic assessment input).

- Dose rates within zone 3 (i.e. in excess of tier 2 criteria) would not necessarily indicate that impacts would occur, but rather confidence that they would not occur would be reduced such that additional effort to evaluate impacts or to address the potential issue may be warranted. Such efforts may include, for example, generation of new knowledge such as further site-characterisation work to address assessment uncertainties or may involve further consideration of facility design.

The methods by which protection criteria could be derived was also discussed. These approaches are presented and discussed in Section 4.

3.2.2 Stage 2 – Glasgow Workshop

The refined concept was then presented and discussed at a second workshop held in Glasgow, Scotland, 6-7 July 2011. Discussions and agreements from this workshop are detailed in a note that is made available at www.bioprota.org. Key points arising from this workshop included:

- Although the different approaches discussed by which Tier 1 and Tier 2 criteria could be derived provides a useful input to the international discussion around this issue, the ability to derive such values is outwith the remit of the BIOPROTA forum. Consequently, an interim approach was agreed upon, based on existing authoritative benchmarks.

- The possible merit of having an upper limit (rather than a further ‘benchmark’ which has no absolute definition) was discussed and, although the concept of a strict limit was not considered to be appropriate, the possibility of a higher value criterion (above that intended for Tier 2), which reflects a *significant risk of unacceptable harm* was considered to be of potential use. This is further touched upon in Section 4.

As a consequence of comments received, the concept framework was reduced to a two-tier, three zones approach, corresponding to ‘no environmental effect’, ‘limited (acceptable) effect’ and ‘risk of harm’. These terms and defining characteristics were further refined.

3.3 SUMMARY

Combined feedback from project participants and sponsors on information distributed as input to, and output from, project workshops provided the means by which the initial framework concept has been refined. There are two aspects to this. One pertains to what could be considered the *‘ideal situation’,* i.e. how the assessment framework could be taken forward were appropriate assessment criteria available. The latter aspect relates to what could be considered a workable interim approach, taking into account the extent of assessment criteria currently available, that could be applied in relation to demonstrating compliance with environmental protection objectives for assessments relating to disposal facilities for long-lived radioactive waste.

4 REFINED FRAMEWORK CONCEPT

Building on the initial concept presented in Section 2, the output from the project workshops (see Section 3 and workshop notes at www.bioprota.org) and comments from project participants on this material, the following generalised framework concept (Figure 5) is put forward for discussion.

The approach is intended to optimise resource commitments commensurate with the degree of risk posed to the environment from a proposed radioactive waste geological disposal concept.

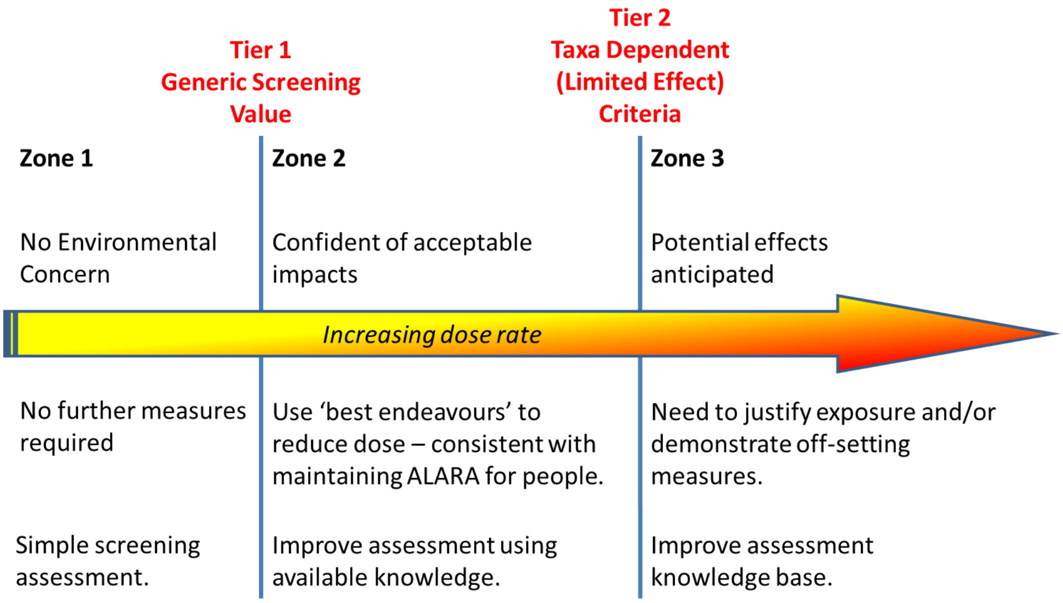

Figure 5. Generalised two-tier compliance demonstration framework concept

The framework concept is based on two tiered benchmark levels and three corresponding zones, which represent levels of confidence that adequate protection of NHB has been demonstrated, and identify further actions that may be required.

4.1 TIER 1 - GENERIC SCREENING VALUE

A lower benchmark value is defined as a screening value, consistent with current regulatory benchmarks adopted in many countries. This Tier 1 value is generic (that is, it is intended to be applied across all organism types or species and across all environmental systems or ecological niches)*.

Deriving the Tier 1 value requires recognition of differing radio-sensitivities between species or organism types and needs to be sufficiently restrictive to ensure that adequate protection can be argued for all reasonable, or reasonably foreseeable, circumstances without being so restrictive that it does not provide a useful discriminator between assessments. In relation to this, workshop discussions acknowledged that measurable effects, potentially relating to reproduction, may be seen at very low dose rates, but that these effects may have no implications for the population (see

* Whether or not an element of taxa-specificity at Tier 1 may potentially be desirable was discussed during both project workshops. It was concluded that this would lose the simplicity and clarity offered by the use of a single generic value when used for screening purposes to identify assessments which fall below further concern; hence the adoption of a single generic screening value approach.

comments in Section 5.2.1). As such it is considered that the Tier 1 value should be weighted toward the more radiosensitive species and/or effects indicators without necessarily being based on the avoidance of all measurable effects for the most sensitive species or indicator.

Consistent with currently defined screening values (see Appendix A), the Tier 1 generic screening value does not imply that there is no environmental impact. Rather, it implies that any environmental impact which may occur is negligible, described here as being of '*no environmental concern'* (see Section 4.3). This is consistent, for example, with the explicit requirement of the Canadian Nuclear Safety and Control Act, 1997, which defines the goal of environmental protection to be "*to prevent unreasonable risk*". It is a key phrasing, implicitly acknowledging that achieving zero risk is not feasible (whilst still requiring a definition of 'reasonable'; see CNSC [2002]).

4.2 TIER 2 - TAXA DEPENDENT PROTECTION CRITERIA

The usefulness of a second tier protection criterion has been broadly acknowledged within the radioecological community. As one example, Howard et al [2010] state that:

"*where [an] environmental impact assessment identifies that a site may potentially be at risk from the impact of ionising radiation, it may be helpful to have a higher numeric value to aid the assessor ..."*

Where a higher protection criterion is to be identified, it is necessary to define clearly its meaning and applicability.

4.2.1 Tier 2 Criteria Categories

Although, in principle, a generic Tier 2 protection criterion could be set, the purpose of such a value is to aid the interpretation of assessments which exceed the Tier 1 value. A greater distinction between the implications of doses which exceed the Tier 1 generic screening value can be achieved by introducing an element of species or taxa based dependency within the Tier 2 higher protection criterion. Taking into account the relative paucity of data for some organism types, the following broad groupings are recommended as an initial stance: vertebrates; invertebrates; higher plants; and, other plants.

No delineation by ecosystem type (e.g. marine, terrestrial etc.) is suggested since it is not clear that aquatic mammals, other vertebrates, invertebrates, higher plants or other plants are, in general, more or less radiosensitive than their terrestrial counterparts. This does not rule out recognition of different ecosystems in the future, should the dose-effects database indicate that such a distinction is useful and sustainable.

4.2.2 Effects Level Implied at Tier 2

The intended meaning and application of Tier 2 values requires careful consideration. If they are set too low they would become simply an alternative screening value to be adopted for more refined assessments whereas if they are set too high they may be interpreted as limits and offer little guidance on the progressive actions to be taken within zone 2 (see Section 4.4 below). It was therefore concluded in discussions at the Glasgow workshop that Tier 2 values, as presented in the framework concept, should be set at a level which recognises 'limited effects' for some species within the relevant broad category, but where the radiological impact *considered in isolation* can be identified as sustainable in most cases. The degree of confidence around this assertion should be quantifiable. It then follows that, at a given confidence level, dose rates to typical individuals at or below the tier 2 values would be sustainable at a population or community level.

The confidence interval and interpretation of sustainable effects are considered further in the approach to derivation of the Tier 2 limited effect criteria in Section 5.2.

4.3 ZONE 1 – NO ENVIRONMENTAL CONCERN (SIMPLE SCREENING)

Assessments which indicate that all organism groups considered receive doses below the Tier 1 Generic Screening Value are considered to be of '*no environmental concern*' and may be excluded from further assessments. This is consistent with current practice (for suitably defined Tier 1 values) and is consistent with the concept of adopting a screening value.

A detailed discussion of the method to determine the Tier 1 generic screening value is presented in Section 5. Nonetheless, given the generic nature of the screening approach put forward for discussion, the range in radiosensitivities exhibited by organisms, the range in robustness of local populations and the uncertainties inherent in the dose-effects database, it is clear that Zone 1 does not represent 'no effect', nor even 'no observable effect'. Rather, care should be taken to define this zone as being of "*no environmental concern*"; that is, any effects which might occur are at a level that could be demonstrated (or reasonably supposed) to be sustainable at a population level, or restricted to a sufficiently small group of organism types, that they do not represent a significant perturbation to the overall ecosystem or habitat under evaluation.

4.4 ZONE 2 – INITIAL ACTION ZONE (IMPROVE ASSESSMENT)

Zone 2 essentially provides a measure of the distance from an assessment of 'no environmental concern' and, accordingly, does not represent a region in which a single response is required, but rather where a set of actions may be considered in a progressive fashion. Assessments which appear to exceed the Tier 1 generic screening value based on a conservative assessment may be demonstrated to fall below the Tier 1 value on the basis of a more refined assessment. Consequently, actions following an initial assessment which falls in Zone 2 will follow a graded process. This can be summarised as follows.

1. Undertake a more realistic assessment based on improved assessment models and/or more realistic input data (e.g. a move from peak activity concentrations irrespective of time to temporal discharge considerations), using the existing information base. If this demonstrates that the likely dose incurred falls within Zone 1 no further action is required, if not proceed to Step 2.

2. Undertake a more realistic assessment based on improved assessment models with additional information relating to the species or ecosystem under consideration. Additional information may include site relevant distribution coefficients to determine partitioning between water and sediments, local habitat occupancy and/or site and biota relevant concentration ratios. If this demonstrates that the likely dose incurred falls within Zone 1 no further action is required, if not, proceed to Step 3.

3. Where the most realistic assessment that can reasonably be undertaken continues to identify doses within Zone 2, determine the dose ranges associated within each of the broad taxonomic groupings adopted (vertebrates, invertebrates, higher plants, other plants) and compare to the Tier 2 taxa relevant criteria. Then proceed to Step 4.

4. Demonstrate use of 'best endeavours' to reduce the assessed dose to the NHB, consistent with maintaining doses to people As Low As Reasonably Achievable (ALARA).

Where dose rates are below the taxa relevant Tier 2 criteria, it could be argued that any effects will be limited. Nonetheless, efforts should be made to demonstrate that a robust assessment has been undertaken and that uncertainties and assessment data gaps have been addressed where possible with all remaining uncertainties and data gaps acknowledged. Tier 2 arguments should be formulated in light of discussions with all relevant stakeholders, particularly statutory consultees.

In practice, Steps 1 and 2 are likely to overlap (as new information may be sought to augment more refined assessment models). Steps 3 and 4 will also proceed in parallel in most instances since the

Tier 2 limited effect criteria have a degree of taxa specificity and is set to reflect a potentially higher effects level than the initial Tier 1 screening benchmark.

When comparing dose values to the Tier 2 criteria, the most refined assessment that can be achieved reasonably should be used as the point of comparison to ensure that realistic judgements can be made with respect to risk.

Since the Tier 2 criteria are associated with environmental impacts which are considered to be sustainable in isolation, but which exceed the generic screening value established to identify impacts of ‘no environmental concern’, it is likely that more detailed regulatory attention will be given to such assessments. Consequently, where a more refined assessment continues to indicate that doses exceed the Tier 1 value, particularly where calculated dose rates are toward the relevant Tier 2 criteria, there is merit in considering whether additional mitigation measures can be introduced to reduce the dose. Such measures must not detract from establishing doses which are ALARA for people, but may form one of the ‘social, economic and other factors’ taken into account when identifying the optimised approach for people.

4.5 ZONE 3 – SECONDARY ACTION ZONE

Within Zone 3, the possibility of notable impacts increases with the margin of dose exceeding the Tier 2 taxa-relevant criteria. Doses within this zone would not automatically be rejected as unacceptable. However, if doses are predicted within Zone 3, further investment may be required to support the case. This could involve improving the knowledge base supporting the assessment such that a more refined assessment may be undertaken, or developing a justification argument that the level of impact may be considered acceptable within its specific context. This could include, for example, demonstration that, for the area and species under consideration, the level of impact is sustainable at a population, species, habitat or ecosystem level; or societal need outweighs concern for the level of environmental impact. In considering sustainability of populations etc. it may be possible to formulate an argument that impacts may be limited spatially or temporally such that re-colonisation of the area is likely (although arguments on a temporal scale relevant to waste disposal facilities, where ‘short term’ may effectively relate to some hundreds of years may be difficult sustain since persistence of the species at an alternative location is required and is uncontrollable). Alternatively, natural ecosystem change may render the original target populations or communities unsustainable (e.g. as a result of coastal erosion) and an alternative point of assessment may be required[*].

Consideration of mitigation measures (i.e. to reduce the dose to the relevant organism group) may also form part of a justification argument. In considering mitigation measures, a balance of benefit and detriment must be considered and actions progressed only where an overall benefit can be demonstrated. In the extreme, commitment to introduce off-setting measures (i.e. to provide an alternative and equivalent habitat to replace the damaged system) may be required (see Section 4.8).

4.6 THE BASIS FOR JUSTIFYING ‘LIMITED EFFECTS’

It has been noted that any assessment which indicates doses to organisms in Zone 2 or Zone 3 will require some discussion of the basis for confidence that the impact is limited in effect, and is sustainable. Such a discussion may be termed ‘justification’. Considerations to be addressed within such a supporting discussion are outlined below.

[*] Such an argument was made in support of the low-level waste disposal facility in the UK for which impacts on seabirds were predicted, but at timescales in excess of the potential duration of the habitat as a consequence of sea level rise and coastal erosion [LLWR Repository Ltd, 2011].

4.6.1 Adopting an Anthropogenic Approach

With respect to non-human biota, both justification and optimisation arguments can rapidly become confused. Brownless [2007] poses the example of a mud bank which has accumulated a high activity concentration of radionuclides. On the basis of a simple cost-benefit argument it is conceivable that the surface layer of the mud could be removed to achieve a dose reduction to the local wading bird population. However, almost by definition, removing the surface layer of mud would be detrimental to the worm communities living in it. Furthermore, although this point is not made by Brownless [2007], reducing the faunal populations by removing the surface mud would reduce or remove the primary food-source for the wading birds being protected, leading to a net detrimental effect even for the target species.

To cut through the complexities of such considerations, it is suggested here that optimisation will almost always be with respect to human exposure, where impacts on non-human biota will form one of the other social and economic factors to be taken into account. Justification arguments will also be anthropocentric. The protection of one or other species relates to value judgements which are imputed to the target species, rather than representing an intrinsic value.

In cases where an assessment is undertaken solely for the purpose of establishing impacts to non-human biota, and where protection of people is not an objective (explicit or implicit), then optimisation with respect to the biota may be established in a fashion analogous to establishing ALARA for man.

4.6.2 Extent of Impact (Spatial Scale)

A discharge which results, for example, in exposure to a widespread and common species within a limited area may be regarded as acceptable, even though locally deleterious impacts are predicted; whereas a lower exposure to a less common species, or across a much larger area, may be deemed unacceptable. Brownless [2007] advances the example that barnacles impacted in the immediate vicinity of a discharge pipeline may be "*regarded as unimportant whereas the same exposure over, say, a 50 km radius might be regarded as totally unacceptable*".

4.6.3 Ecosystem Recovery (Temporal Scale)

When considering the effects of exposure on the environment, another key aspect may be recovery time. Just as an impact limited spatially may be more acceptable than a widespread impact (see above) an impact which is limited temporally may be more acceptable based on ecosystem capacity to recover through re-colonisation of an area.

It is likely that ecosystem recovery could form part of a sustainability argument during the construction and operation phase of a facility (e.g. where disturbances are of a short term nature) rather than for sustained releases to the environment over long timescales, such as may be applicable to the post-closure phase of a disposal facility.

4.7 FURTHER CONSIDERATIONS IN THE APPLICATION OF THE FRAMEWORK CONCEPT

Besides comparison with derived tier 1 and tier 2 criteria, a number of additional considerations are likely to be warranted when undertaking an assessment.

4.7.1 Consideration of Competing Environmental Stressors

It is well known that environmental stressors (such as temperature, nutrient status, heavy metals, chemical toxins etc.) may act independently, additively or synergistically. In the same fashion, removing one or more stressors may have little effect in isolation or may have a dramatic compounding effect.

In principle, multiple stressors may be important in determining environmental responses and could form part of the additional information to be acquired within the step-wise process suggested for assessments which fall within Zone 2. With respect to the influence of other stressors on responses to the presence of radionuclides, the effects may be considered in two broad categories: a) modification of the uptake or distribution of radioactive material within the target organism; b) modification of radiosensitivity of the target organism. UNSCEAR included the effects of multiple stressors in their review of impacts [UNSCEAR 2008, Volume II, Annex E] and noted that effects measured at the sub-cellular level typically lack specificity with respect to the inducing agent, which indicates that caution is required in using biomarkers to assess risk to non-human biota.

Since the presence of other stressors cannot be determined generically, consideration would necessarily be largely site-specific and would need to include aspects such as the non-radiological components and properties of disposed wastes and materials used in the construction of facilities.

4.7.2 Consideration of Life-Cycle Stage

All higher organisms exhibit some differentiation between life-cycle stages. This may involve differing life-forms (e.g. polyp-medusa; plankton; larvae-pupae etc.) with complete or incomplete metamorphosis between instar stages, or may represent a gradation associated with sexual maturation. In some species, organisms may survive beyond their reproductive stage, but may still contribute to the reproductive success of a local population (e.g. through shared protection of offspring, notably in species which group within families, or where they may form part of a potential reproductive pool excluded by the presence of dominant individuals).

Different life-cycle stages may be more or less radiosensitive and similar environmental conditions may result in higher or lower exposure due to niche occupancy.

The broad organism groupings identified in the generalised concept presented here do not explicitly take account of life-cycle stages. This represents a weakness in the approach and more explicit reference to life cycle stages may be desirable in a better developed concept, based on a more complete dose-effects database.

It is recommended that, when undertaking an assessment, specific consideration is given to relevant life stages of representative organisms, particularly where large differences are evident between the habits of juvenile and adult forms. Data on life stages of a number of families of organisms is provided in ICRP [2008], which may be a useful resource for data on organisms of general interest.

4.7.3 Protection of Rare, Endangered or Sensitive Species

There is a general requirement to pay particular attention to the protection of locally rare or endangered species, or species that are considered to be locally or regionally important, which can lead to a number of uncertainties with respect to assessments for disposal facilities for long-lived radioactive waste.

In the absence of species specific dose-effects based benchmark values, the adequate protection of rare, endangered or potentially sensitive species must form part of an interpretation or justification argument advanced as part of the overall demonstration of compliance.

This implies that all assessments which fall into Zone 2 or Zone 3 must be supported by discussion of local conditions and the basis for confidence that any radiological impacts will be of limited effect and will not compromise the sustainability of the population.

Further information in support of such considerations for disposal facilities for long-lived radioactive waste is provided in Section 6.

4.7.4 Transient or Migratory Populations

In some cases, juvenile and adult organisms of the same species may occupy not only different ecological niches, but may be spatially removed. In other cases, populations may migrate seasonally.

In principle, this does not address any new limitations on application of the generalised concept but does have implications for site characterisation studies, which need to incorporate seasonal effects. Assessors should consider occupancy of organisms within each relevant habitat / ecosystem within an assessment.

4.8 OFF-SETTING MEASURES FOR NON-SUSTAINABLE IMPACT ASSESSMENTS

Throughout Europe, and as described in Article 6(4) of the European Habitats Directive 92/43/EEC, damage to, or loss of, part of an internationally protected site may be justified where there are Imperative Reasons of Overriding Public Importance (IROPI). In such cases, the habitat loss *must* be compensated by creation in the same country of new habitat of the same type, quality and extent as that lost to ensure the integrity of the Natura 2000 suite of sites.

Article 6(4) states that,

> *"If, in spite of a negative assessment of the implications for the site and in the absence of alternative solutions, a plan or project must nevertheless be carried out for imperative reasons of overriding public interest, including those of a social or economic nature, the Member State shall take all compensatory measures necessary to ensure that the overall coherence of Natura 2000 is protected. It shall inform the Commission of the compensatory measures adopted.*
>
> *Where the site concerned hosts a priority natural habitat type and/or a priority species, the only considerations which may be raised are those relating to human health or public safety, to beneficial consequences of primary importance for the environment or, further to an opinion from the Commission, to other imperative reasons of overriding public interest".*

This allows quite explicitly for arguments based on societal need to outweigh limited environmental protection within defined areas and at the same time restricts the type of arguments which may be advanced.

The European Commission [2000, 2007] has issued guidance on its interpretation of the Habitats Directive. This includes the requirement that IROPI must be preceded by an effects assessment (i.e. it does not replace the need for an adequate impact assessment) and must follow an examination of alternative schemes which would result in less harm to the environment.

The compensatory measures required are intended to ensure the maintenance of the contribution of a site to the conservation, at a favourable status, of natural habitat types and habitats of species "*within the biogeographical region concerned*". It follows that any compensatory measures should be introduced before the project proceeds.

4.9 SUMMARY

A protection framework based on a two-tier concept for reference dose rates is advanced, with explicit recognition of three zones. Tier 1 represents a generic screening value. Tier 2 represents a number of taxa related values which are consistent with limited impact to ensure that populations are sustainable.

Assessments which fall within Zone 1 (i.e. are below the Tier 1 generic screening value for all species considered) can be excluded from further consideration.

Assessments which fall within Zone 2 (i.e. where each species falls below its relevant Tier 2 value) are considered to be acceptable based on limited effects. However, as dose rates increase within Zone 2, a range of progressives measures are outlined to provide a more realistic assessment or to demonstrate that best endeavours are used to minimise the dose to NHB (consistent with maintaining ALARA for people).

Assessments which fall into Zone 3 (i.e. which exceed Tier 2 dose rate values) may nevertheless be justifiable based on a range of considerations, including societal need.

The overall concept forms a proportionate, risk-based, approach to demonstrating protection.

5 APPROACHES TO DERIVE TIER 1 AND TIER 2 PROTECTION CRITERIA

Different approaches are available, and have been employed at one time or other, for deriving numerical values that can be applied as benchmarks for demonstrating compliance with environmental protection objectives, including:

- Use of expert judgement (essentially a qualitative but informed approach to interpolating data);
- Comparison of dose rate calculations against exposure to natural background;
- Use of effects data derived from laboratory or field studies (predicted 'no effects' concentration or dose rate) to which an assessment factor is applied to account for extrapolation uncertainties; and,
- Application of statistical approaches, such as the species sensitivity distribution (SSD) methodology, to laboratory and/or field-derived effects data.

Expert judgement remains the most common approach[*], yet has received criticism, as it is traceable but inherently difficult to reproduce since the outcome can change depending upon the experts consulted [Hingston et al, 2007]. Nonetheless, the approach is evidence-based and auditability can be improved by recording constraints and assumptions adopted in decision making.

Deriving protection criteria by comparison to ranges in natural background offers an apparently straightforward approach. Organisms which exist under identifiable conditions appear to provide clear evidence, at least, of 'no unsustainable impact'. However, such an approach may mask effects. For example, the existence of one species or group of organisms provides no information regarding the absence of other species. Nonetheless, natural background can provide a useful comparator in setting benchmark values and in the interpretation of assessment results in a regional setting.

An assessment factor approach applies a consistent set of rules to available data to derive a predicted no effect level. The approach maximises the use of data, is transparent and reproducible, and can be modified as further data become available. Furthermore, the assessment factor approach is routinely applied to chemical contaminants. Further detail is provided in Section 5.2.

Of the methods available, statistical approaches such as SSD (described in Section 5.2) may be the most robust, but application is often hampered by lack of data relating exposure to effects. Furthermore, an element of expert judgement is required in order to select appropriate input data. This can have a large effect on the resultant criterion, the degree of robustness associated with the derived value and the level of consensus around appropriateness and applicability.

Although each method for deriving benchmark values has its shortcomings there are broad similarities in the protection criteria derived in different national and international programmes. This similarity between statistically derived values and those obtained through expert judgement is supportive of an expert judgement approach in situations where data for more statistical derivation is limiting. Where expert judgement is applied as the sole means of derivation, accurate documentation of the approach and the data upon which judgement is applied is vital to ensure transparency and to increase confidence in the application of derived criteria.

A significant effects database (FREDERICA) has been developed within the EC FASSET and ERICA programmes[†]. In principle, this database (and additions to it) allow for distinctions between species to be made. However, there appears to be a reluctance to use the database to its full extent on the

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[*] Ultimately, it can be argued, all guidance which relates to risk based non-threshold benchmarks is based on value judgement, since there is no single objective measure as to when a risk becomes 'acceptable'.

[†] Available online from www.frederica-online.org . Access to the database requires registration.

grounds that: a) more data are required; and, b) applying the approaches for deriving protection criteria may not protect all species under all circumstances. Nonetheless, different authorities have applied different dose rate values to protect organism groups or taxa (see e.g. the review within Howard et al [2010] and Appendix A) and the FREDERICA database is sufficient to allow the derivation of multiple threshold values applicable to different organism groups or taxa [e.g. Garnier-Laplace et al 2010] even if the data are not actually applied in this way.

The remainder of this section provides discussion on approaches considered appropriate to derive Tier 1 and Tier 2 protection criteria consistent with the framework concept presented. The intention is to provide thoughts on approaches as input to the international debate around this issue. Interim values are also proposed, drawing on international publications with demonstrable provenance.

5.1 OVERALL CONSIDERATIONS IN THE APPLICATION OF APPROACHES TO DERIVE ASSESSMENT CRITERIA

Prior to undertaking an evaluation of effects data as a means of deriving assessment criteria, a number of decisions must be made: notably, relevant end points of concern and the level of protection required must be determined. Discussion points in relation to these issues are provided below.

5.1.1 Relating Assessment Methods and Criteria

A particular aspect of importance in moving toward the development of assessment criteria for use within a framework for evaluating environmental risks is the linkage between the assessment method and the criteria adopted, i.e. consistency must be assured. For instance, units of dose must be equivalent such that weighting for different types of radiation is addressed explicitly; some comparability of conservatism would be desirable to avoid situations in which effects are under- or over-estimated in relation to radiation exposure. For instance, data are often restricted to effects from external gamma exposure and interpretation in relation to effects from internal exposure will require some judgement. Similarly, organism groupings, if used, should be consistent and it would be desirable for methods to specify whether the focus is on the most exposed individual or representative individual, with assessment criteria being appropriately derived, demonstrably conservative in relation to a Tier 1 criterion and correctly applied in relation to the assessment target.

5.1.2 Identifying the End-Point of Concern

There has been much discussion around the goals of environmental protection and the biological end-points to be referenced with respect to demonstrating specified levels of protection (see e.g. [Robinson et al 2010]). Both direct mortality and reproductive success appear to be measures which relate to population integrity in a simple and readily understood fashion. Even with these measures, however, it is necessary to identify the level of impact which is judged to be commensurate with population harm. For instance, an overall population annual mortality of 5% may be negligible[*], unless it relates only to that sub-component of the population which is sexually immature (i.e. the impact on recruitment to the sexually active population may be significantly higher than the overall 5% loss suggests and may become significant).

Likewise, measures of reproductive potential must be treated with caution. Some species, such as many aphids, have complex reproductive adaptations which make any single measure of fertility difficult to interpret. For other obligatory sexually reproducing species, the relative size of external sexual organs (e.g. testes) or rate of gamete production may be a poor indicator of reproductive success, particularly where large numbers of eggs are produced whether with internal or external fertilisation. For viviparous species with extended juvenile development, the health of the nurturing adult may be as important a factor in reproductive success as the number of offspring.

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[*] Note: this is an illustration only. A calculated mortality rate may be incremental to the natural mortality rate or may be indistinguishable under field conditions (for instance, where morbidity precedes mortality individuals will be more susceptible to predation or over-population pressure).

Other measures of impact, such as chromosome aberrations, may have longer term implications, although the physiological end-point is less certain [Ryabokon & Goncharova 2006].

UNSCEAR [1996] reproduces an illustration of a range of end-points for herbaceous plants for acute doses expressed as a percentage of the lethal dose (based on the work of Sparrow et al [1967]). It should be noted that effects do not occur in isolation. Thus, in the illustration below, an acute dose causing 10% mortality is also likely to cause failure of seed set and to reduce yield by 50%.

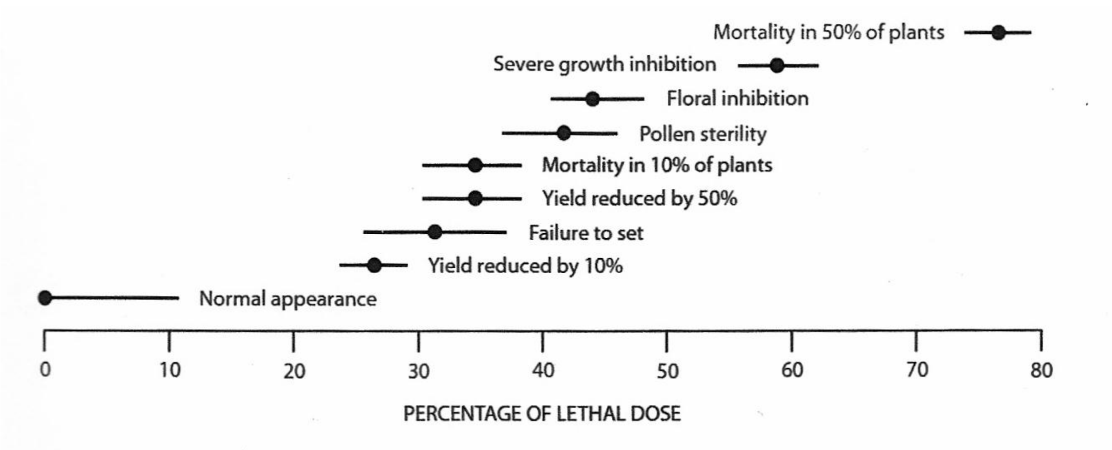

Figure 6. General range of measurable end-points in response to radiation of herbaceous plants in comparison to the lethal dose (LD_{100}). (*Reproduced from UNSCEAR [1996]; based on Sparrow et al [1967]).*

Provided that there is a sufficient effects database for the species or organism grouping of concern, part of the argument for demonstrating adequate protection at the population level may involve defining the end-point which is considered to be the most relevant indicator of harm.

5.1.3 Inclusion of Natural Background

No radiation doses are received in isolation. The environment is radioactive, both as a consequence of naturally occurring radioactive materials and due to the presence of man-made materials. In most cases, natural background is the dominant source term although in some environments (for instance, the ‘Red Forest’ region around Chernobyl in Ukraine) the anthropogenic sources dominate.

Garnier-Laplace et al [2010] argue that, logically, absolute dose rates should be applied within impact assessments (i.e. inclusive of all sources of exposure), since most effects of interest are deterministic in nature. However, only incremental dose rates can be controlled and focusing on the controllable dose is consistent with the principles of radiological protection applied to man.

The EC ERICA programme makes reference to the range of natural background exposure to determine whether the incremental dose under consideration is of ‘negligible concern’ and Hosseini et al [2010] have produced illustrative background dose calculations for a range of organism types or taxa. Median weighted absorbed dose rates to reference plants and animals in aquatic systems ranged from 0.37 µGy h^{-1} (duck) to 1.9 µGy h^{-1} (grass). The fact that a species maintains its competitive position within a given background exposure does not necessarily mean that the background has no deleterious impact. Particular species may be present because they are more resistant to the conditions than another species, not because the conditions are optimal for that species. Nonetheless, it seems reasonable to argue that a minor incremental dose will have limited impact on the overall species composition of a region. Whether this extends to perturbations several times the natural background is less intuitive – but it is known that for humans natural background conditions can span an order of magnitude or so with no observable population health impacts*.

One advantage to an approach based on comparison to background exposure is that large species specific effects databases are not required at low levels of dose, since the argument is not based on no-effects, but is based on no-additional effects.

There are also disadvantages with this approach; for example, i) basing protection on background levels would introduce an inconsistency with human radiological protection, ii) it is unclear how an area with existing high and widespread levels of artificially introduced radioactive materials would be assessed (see e.g. NEA [2007]), iii) currently adopted generic screening values are expressed net of background (but typically making an explicit or implicit allowance for background exposure).

At this time, it is considered clearer to express dose benchmark values in terms only of the controllable fraction of the dose. This is consistent with much of the effects data: although some data are derived from field experiments, the majority are from laboratory experiments that are largely expressed net of natural background. As such, effects data would be inconsistent with dose calculations and assessment criteria derived inclusive of natural background.

5.1.4 Appropriateness of Organism Groupings

It is likely (although not necessarily demonstrable from the available effects database) that the radiosensitivity of individuals, populations, species and broader taxonomic groupings of species will differ. Therefore a single assessment criterion is unlikely to be sufficient for all organism groups; a lower exposure may have a more significant impact for a more radiosensitive species. In the illustration below (Figure 7), species B is more radiosensitive than species A. If an action level is set based on the impact on species B, it is possible for species A to exceed the threshold without harmful effect. An impact based action level thus needs to distinguish between species or organism types.

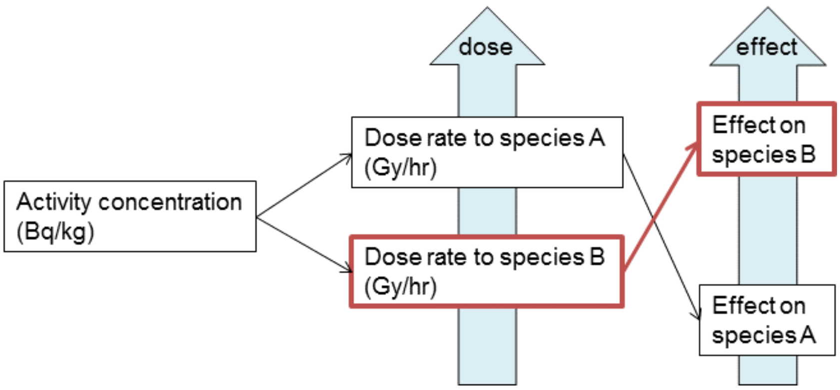

Figure 7. Relationship between activity concentration, dose rate and effect. (*Adapted from Brownless [2007]*).

A taxonomic distinction in radiosensitivity has been postulated over many years. Data collated by UNSCEAR [1996] were introduced in Section 3.2.1 [Figure 4] to illustrate ranges of acute lethal doses for major taxonomic groupings. Whilst this approach is simplistic and open to criticism†, not least in

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* The evidence for causal association between radon levels and lung cancer incidence is complex. Collectively (although generally not within individual studies) the range of radon levels varies across several orders of magnitude and indicate a linear no threshold cause-effect relationship. However, this does not contradict the general statement that modest variability in background has no *observable* (as opposed to calculable) impact. See Darby et al [2005] for a more detailed discussion.

† This illustration may be criticised at a number of levels. For example, the measure of mortality is not specified (e.g. $LD_{50/30}$), the higher plants are not further differentiated into the major groupings (e.g. gymnosperms,

that it ignores potentially important trophic considerations, there nonetheless remains a broad physiologically based recognition that lower taxa are less radiosensitive. This general observation was accepted within the project workshops (see Sections 3.2.1 and 3.2.2, and the workshop notes available at www.bioprota.org), and it is notable that the current ICRP [2008] approach to Reference Animals and Plants (RAPs) explicitly recognises broad distinctions between classes of organisms in setting banded DCRLs.

Assuming that the data presented in Figure 4 have some validity in terms of relative response when applied to effects from much lower chronic exposures, it is evident that there is no *absolute distinction* to be made between the radiosensitivity of vertebrates and invertebrates, or between higher plants and other plants. Nonetheless, there is a *general indication* that vertebrates are more radiosensitive than invertebrates, considered as a whole, and similarly higher plants are more radiosensitive than other plant species, again considered as a whole.

The general conclusion to be drawn may be that narrower organism groupings than those put forward here would be likely to be more readily defensible at Tier 2, but the constraint that the current dose-effects database is inadequate to support such an approach drives the argument in favour of broader groupings, as *an interim measure*.

5.2 CONSIDERATION OF APPROACHES TO DERIVING TIER 2 ASSESSMENT CRITERIA

5.2.1 Species Sensitivity Distribution

As indicated above, statistical approaches such as species sensitivity distribution (SSD) are often preferred by the international community because they provide for a robust and transparent basis for deriving assessment criteria. A standardised approach to undertaking an SSD analysis of effects data is provided in European Commission [2003].

The SSD approach makes use of toxicity data for a particular effect for a number of species. It assumes that effect values such as the LC_{50} (the concentration of a substance killing half the test subjects in a specified time) for all the species in an ecosystem vary according to a distribution, typically represented as log normal. It further assumes that species for which data have been obtained are a random sample of all the species in the ecosystem of interest. Parameters for the distribution can then be estimated by fitting the assumed distribution to the available data. This is shown schematically in Figure 8 for acute toxicity.

angiosperms) which may have different sensitivities, the distribution of responses within each taxa is not clear (e.g. it is not known whether the ranges are truncated to reflect quantified confidence intervals, nor whether responses are normally distributed within the range), and the database is incomplete (being restricted to literature available through to the early 1980s).

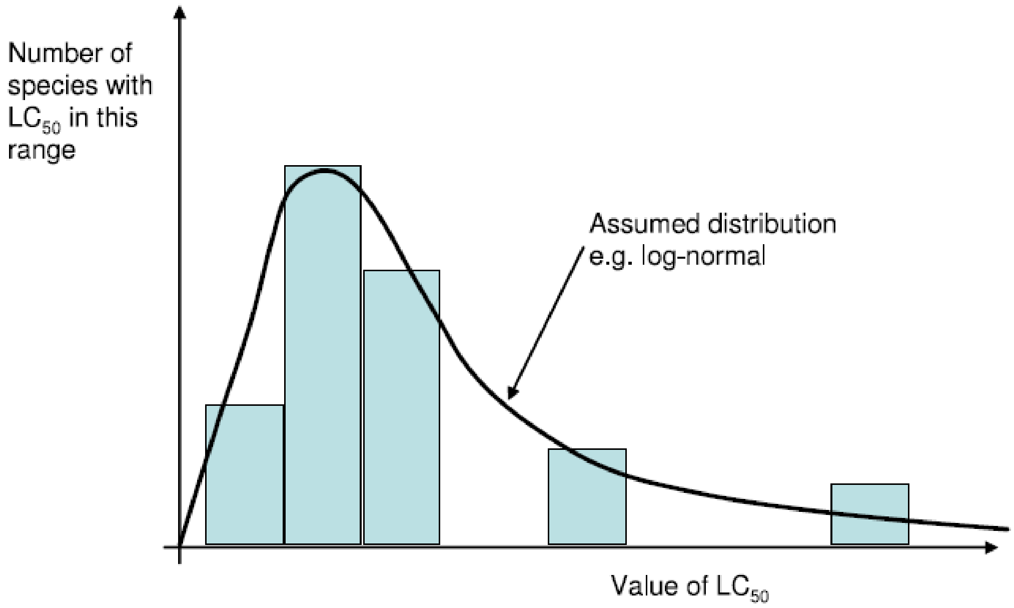

Figure 8. Schematic illustration of frequency distribution of LC_{50} amongst species (*Reproduced from Brownless [2007]*).

Replotting this in a cumulative fashion gives a ‘species sensitivity distribution’ which shows how many species in an ecosystem would be affected by a given concentration. A point on this curve, say the 95th percentile, can be chosen as the value for a standard. This is shown schematically in Figure 9. In this case, choosing the 95th percentile as a standard would mean that, at the level of the standard, 5% of the species in the environment would be exposed to a concentration greater than or equal to their LC_{50}, whilst the other 95% of species would be exposed at a level below their LC_{50}.

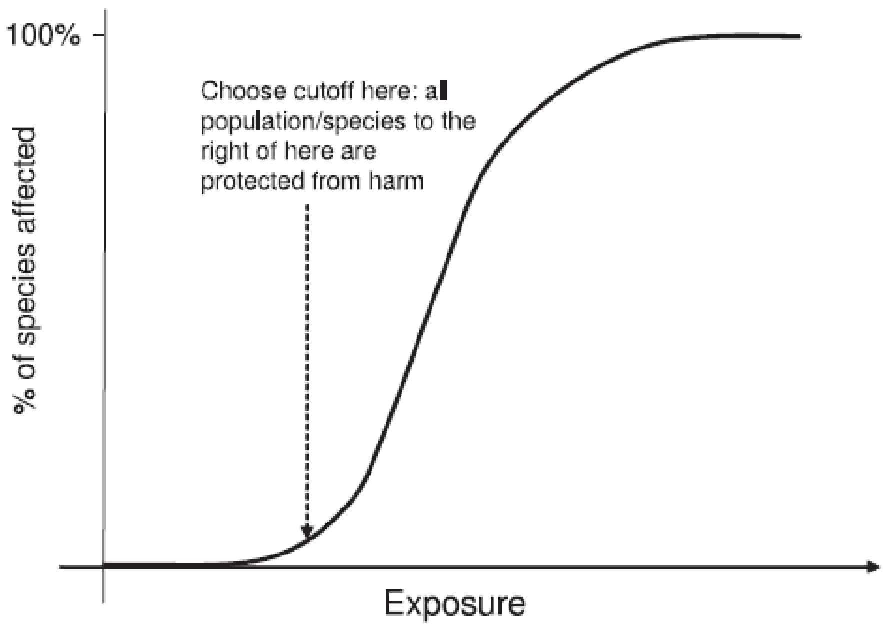

Figure 9. Schematic illustration of cumulative frequency of LC_{50} amongst species: a ‘species sensitivity distribution’. (*Reproduced from Brownless [2007]*).

The approach assumes that adequate protection of an ecosystem is commensurate with protection of the majority of species. Even if this surmise is considered appropriate, problems with the approach are: first, how to choose a ‘cut-off’; second, that some of the most sensitive species are, by definition, affected; and, third that the available database is incomplete.

To address the uncertainties arising from an incomplete database, additional factors may be applied (i.e. to reduce the benchmark level of ‘acceptable’ exposure) to take account of the extrapolation from those species for which effects data are available to the entirety of species within an ecosystem of concern[*]. Finally, the illustrations in Figures 8 and 9 are based on hypothetical LC_{50} data. Even if the benchmark criterion were based on NOEC data, and a benchmark value set based on no observable effects for 95% of species, and an ‘uncertainty factor’ were applied to reduce the benchmark further, the resultant value would still not reflect a ‘no effect’ concentration (or dose rate) but would instead represent a level at or below which unacceptable effects will most likely not occur.

The ERICA and PROTECT EC project both applied the SSD approach to derive a generic (all species, all ecosystems) screening level on the basis of available radiation effects data. The approach followed the guidance provided in European Commission [2003]. Although there were differences of note in the selection criteria for effects data, both projects employed EDR_{10}[†] values (equivalent to an EC_{10} for chemicals) derived from the FREDERICA radiation effects database and derived a generic screening value of 10 µGy/h, which has been routinely applied within the ERICA tiered assessment approach as a Tier 1 screening threshold value. In principle, this approach can be applied consistently as new data become available to redefine both the derived benchmark value and the ‘uncertainty factor’ applied (i.e. this should be less significant with increasing completeness and certainty in the database).

The same approach could also be applied, using alternative values of EDR_x to derive higher protection criteria such as Tier 2 values such that consistency is maintained between tiers. Since the Tier 2 values are intended to represent limited effects, the argument could be made for selection of data at a higher effect level than the EDR_{10}. In ecotoxicity tests, the lowest observable effect concentration (LOEC) is often reported in addition to the NOEC and is largely considered equivalent to an EC_{20}. Taking into account that the Tier 2 values are intended not as limits, but as secondary benchmarks against which risk of impact can be evaluated on a taxa (or similar) level, it could be argued that the EDR_{20} be used as the basis for their derivation, using an SSD approach consistent with ERICA and PROTECT. At such a level, and assuming data were available for the range of taxa or other groupings of interest, there would be a reasonable level of confidence of only limited effects in the environment.

It should be noted, however, that the SSD approach adopted in the PROTECT programme has been criticised; for example, questions have arisen as to whether data were included primarily because they were open to statistical manipulation rather than being appropriate indicators of reproductive success[‡]. Careful consideration would be required in selecting appropriate input data (e.g. representative of reproductive effects that can be related to population effects) for any further protection criteria derivation to avoid such criticisms.

[*] A structured and traceable basis for selecting the appropriate factor is required to increase confidence in the resultant criterion.

[†] The dose rate at which a 10% effect is observed. It is important to note that this endpoint is very much dependent upon experimental design.

[‡] An example was cited in discussions in Glasgow (see workshop note at www.bioprota.org) relating to mouse testes weight relative to whole body weight following exposure to radiation. Whilst a good data set is available (consistent with the requirements for a SSD analysis), no simple relation between testes weight to reproductive success is evident.

5.2.2 Assessment Factor Approach

Due to the general paucity of effects data for any given chemical, the assessment factor approach is applied more routinely than the SSD approach, and is the conventional approach for deriving environmental protection criteria for chemicals.

The assessment factor approach makes use of available toxicity data, largely derived from laboratory studies. The most sensitive species and endpoint are determined and an assessment factor applied to derive predicted no effect concentrations (PNEC), defined as the concentration below which *an unacceptable effect will most likely not occur*. A standardised approach has been developed for application throughout European member states [European Commission, 2003].

In deriving effects data, a common suite of organisms is often considered (e.g. a fish, invertebrate and plant species representative or fresh or saline waters) with resultant effects data generally being presented in one of two forms:

- EC_x - the concentration of a substance causing a measured effect to x% of the test population; or,
- NOEC - the highest test concentration at which no effects are observable relative to controls.

A rather extreme measure, 'LC_{50}' (the concentration of a substance killing half the test subjects in a specified time) is frequently used as there are usually more data available for this endpoint. However, longer-term (chronic) effects data can be employed where available.

The assessment factor applied to the effects data for the most sensitive species reflects the degree of uncertainty associated with extrapolation of effects data from e.g., laboratory tests for a limited number of species to the 'real' environment and acute to chronic exposure conditions. Guidance is provided in European Commission [2003] as to the appropriate assessment factor to apply based on the range of data available. Different assessment factors are proposed for freshwater (Table 1) and marine (Table 2) ecosystems. Due to the greater species diversity in the marine environment, a greater assessment factor may be recommended than that for freshwater to take account of the potentially increased species sensitivity distribution when data are limited.

Throughout chemicals assessments, it is acknowledged there is a general paucity of data, yet the assessment factor approach is routinely applied. In the field of radioecology, there has been a reluctance to apply such an approach to derive assessment criteria to evaluate the risk of impacts from ionising radiation in the environment. This appears inconsistent with the approach taken for chemicals and may therefore merit further consideration whilst acknowledging that the SSD approach would provide a more robust outcome should adequate data become available.

Table 1 Assessment factors for the derivation of a PNEC for freshwater

Available toxicity data	Assessment factor
At least one short-term EC_{50} from each of three trophic levels (fish, *Daphnia* and algae)	1000
One long-term NOEC (either fish or *Daphnia*)	100
Two long-term NOECs from species representing two trophic levels (fish and/or *Daphnia* and/or algae)	50
Long-term NOECs from at least three species representing three trophic levels (normally fish, *Daphnia* and algae)	10
Species sensitivity distribution (SSD) method. It is recommended that the SSD approach is applied where an effects database contains, as a minimum, 10 robust NOEC values for species covering at least 8 taxonomic groups.	1-5

Source: European Commission [2003]

Table 2 Assessment factors proposed for deriving a PNEC for saltwater

Available toxicity data	Assessment factor
Lowest short-term LC_{50} from freshwater or saltwater representatives of three taxonomic groups (e.g. algae, crustaceans and fish) of three trophic levels	10,000
Lowest short-term LC_{50} from freshwater or saltwater representatives of three taxonomic groups (e.g. algae, crustaceans and fish) of three trophic levels plus two additional marine taxonomic groups (e.g. echinoderms, molluscs)	1000
One long-term NOEC (from freshwater or saltwater crustacean reproduction or fish growth studies)	1000
Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish)	500
Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels	100
Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish) plus one long-term NOEC from an additional marine taxonomic group (e.g. echinoderms, molluscs)	50
Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels plus two long-term NOECs from additional marine taxonomic groups (e.g. echinoderms, molluscs)	10

Source: European Commission [2003]

The assessment factor approach was applied within the EC PROTECT programme as a means of deriving taxa-specific screening values where data were insufficient to apply the SSD approach. The resultant screening values are shown in Table 3.

Table 3 PROTECT organism group screening values

Organism group	Screening Value (µGy/h)
Vertebrates	2
Plants	70
Invertebrates	200

From Andersson et al, 2008

The PROTECT consortium did not recommend use of the values presented in Table 3, but rather cautioned their application as 'indicative order of magnitude values only' [Garnier-Laplace et al, 2010].

These taxa-specific values could be applied within the framework concept, but would be representative of Tier 1 values, having been derived on the basis of available EDR_{10} data, and would therefore be inconsistent with the objective for Tier 1 to represent a generic screening value. Nonetheless, further analysis of input data may enable criteria consistent with the objectives for Tier 2 to be derived, accepting that a combination of approaches for the derivation of the Tier 2 values may be required.

It should be noted that the assessment factor approach has received some criticism, not least that it inherently adopts a formula whereby fewer data (i.e. irrespective of the quality of the data) will always lead to a greater safety margin, and hence the adoption of a lower protection criterion. It is also worth noting that, should the approach be taken forward with regards to the derivation of protection criteria for radionuclides, some considered amendments to the structured assessment factor approach outlined in European Commission [2003] may be required. This would largely need to focus on defining appropriate assessment factors for given quantities of effects data to account for the lack of standardised test guidelines for deriving effects data for radioactive substances.

5.2.3 Radiosensitivity Multipliers

As noted previously (Section 5.1.4), sensitivity of organisms to radiation is highly variable. UNSCEAR [1996] cite data indicating that for chronic exposures, dose rates of 10,000 to 30,000 µGy h^{-1} had no effect on mortality for aquatic snails, marine scallops, clams and blue crabs. The same report indicates that fish (especially the developing fish embryo) are generally the most sensitive of the aquatic organisms.

With respect to terrestrial organisms, much of the available data relates to mammals (some of it derived experimentally as a contribution to human radiological protection studies). UNSCEAR [1996] note that mammals and birds are generally the most radiosensitive taxa, while adult invertebrates are generally less radiosensitive to mortality impacts. Again, for most species, eggs and juvenile stages tend to be more sensitive.

The concept of applying knowledge in relation to the relative radiosensitivity of different organism groups was discussed during both project workshops as a supplementary approach to deriving Tier 2 values. The concept involves deriving criterion multipliers – to be used in association with a Tier 1 generic screening value – that would allow for differences in radiosensitivity of different organisms to be taken into account. The overall concept was considered to provide a potentially favourable interim approach. Nonetheless, further discussion would be required, particularly in relation to the basis for defining relative radiosensitivity of different organism groupings (and which groupings would be appropriate) and on what point in the range of radiosensitivity for each organism group should the criterion multipliers be derived?

The benefit of such an approach would be to enable a broad range of criterion multipliers to be derived such that Tier 2 values could be calculated for a larger number of organism types than possible based on currently available data suitable for SSD or assessment factor approaches. The approach would also allow flexibility such that alternative multipliers could be employed where justifiable (for example where the presence of a particularly sensitive species is known and/or to take account of the reliance of one species upon the presence of another within a different organism group).

Ideally, ranges in effects representative of radiosensitivity under chronic exposure conditions would be used as the basis, with reproductive endpoints being preferred to ensure consistency with data consistently used to derive the Tier 1 generic screening values.

Were such an approach considered acceptable, effort could be made to interrogate the FREDERICA database with the objective of formulating a chronic-reproductive endpoint radiosensitivity figure upon which criterion multipliers could be derived. An example of how such an approach could be applied is detailed in Appendix B.

5.3 INTERIM NUMBERS TO REPRESENT TIER 1 AND TIER 2 BENCHMARK VALUES

Information presented above is intended to promote discussion on the means to derive criteria to be applied to assessments of long-lived radionuclides in the environment emanating from geological disposal facilities. Further work will be required before this is resolved fully. Nonetheless, there is a need for assessments to be undertaken *here and now* such that some interim means of evaluating the relative risk of environmental impacts is required in support of licence applications for construction and operation. The remainder of this section therefore focuses on determining an appropriate *interim* stance in relation to protection criteria against which biota dose assessments may be evaluated.

5.3.1 Tier 1 Generic Screening Value

As a starting point, it is suggested that the Tier 1 screening value to be adopted should be the ERICA and PROTECT derived 10 µGy/h. Although concerns have been raised as to whether this value is sufficiently conservative or well founded*, it does have a demonstrable provenance and definition, and it is already widely applied throughout Europe.

5.3.2 Tier 2 Values

There is a pragmatic distinction to be made between the ideal approach to deriving Tier 2 taxa-specific values and the use of currently available data sets from reference sources with demonstrable provenance as an *interim* measure. As such, consideration is given to two sources: UNSCEAR [2008] and ICRP [2008]. Whilst it is acknowledged that the data presented in this latter source may be subject to change with the ongoing work of ICRP Committee 5, the broad bands of DCRLs nonetheless present a useful point of reference against which assessment results may be compared.

UNSCEAR [2008]

Following review of available effects data, UNSCEAR [2008] concluded that:

"*chronic dose rates of less than 0.1 mGy/h to the most exposed individuals would be unlikely to have significant effects on most terrestrial communities and chronic dose rates of less than 0.4 mGy/h to any individual in aquatic populations would be unlikely to have any detrimental effect at the population level*".

These values could be applied as interim Tier 2 values. As they are not fully consistent with the framework concept outlined (particularly with respect to taxa-specificity), either this difference between terrestrial and freshwater could be maintained or the more conservative value (100 µGy/h) applied across all ecosystems and taxa.

The advantage of adopting such an approach would be that the protection criterion is of known provenance, having also been considered previously by UNSCEAR [1996] and IAEA [1992]. The use of these values would also be consistent with some national environmental protection programmes (see Appendix A) and, even where not adopted within a national programme, the values are widely recognised. Notwithstanding that, some disadvantages could also be postulated:

- The criteria are intended to protect populations based on consideration of the *most exposed individual* for terrestrial organism and *any individual* for aquatic systems, whereas protection based on *representative* exposure may be a better focus for population effects;
- The definition requires interpretation of specific terms used to describe effect (e.g. 'unlikely', 'significant effects') and distinctions introduced between 'communities' for terrestrial systems and 'populations' for aquatic systems; and,
- The distinction based on aquatic / terrestrial ecosystems is not biologically relevant, but may be intended as a surrogate representation of dominant organism types (although this would be in contrast to the greater level of conservatism applied for marine environments in the chemicals assessment factor approach, reflecting the diversity of marine organisms).

Nonetheless, adoption of these values would provide a workable system that could be used in the interim and could be used in combination with current ICRP DCRLs to support interpretation at a more organism-specific level.

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* Additional concerns have been raised (see Glasgow workshop note at www.bioprota.org) that the ERICA / PROTECT value is below natural background for many areas and may be too restrictive for broad application. Doubt was also expressed in relation to the selection of input data to the SSD analysis and the use of different 'uncertainty factors' and rounding of data such that, even on the basis of differing input data, the end result was the same under both EC programmes. Nonetheless, at the present time, the ERICA / PROTECT devised screening value is one of the most widely applied screening criteria in an international context.

Appendix C presents a further examination of the UNSCEAR [2008] underpinning data to determine whether more specific (e.g. species specific) benchmark values may be derived and to evaluate the level of protection implied by the threshold values proposed.

ICRP DCRLs [ICRP, 2008]

The ICRP are developing a framework for the evaluation of impacts from radioactivity on the environment, which is broadly parallel to that for humans. The framework is intended to provide guidance and advice upon which both operators and regulators can draw as a means of demonstrating compliance with national and international environmental legislation.

The framework is based around the concept of ‘reference animals and plants’ (RAPs), consistent with the concept of a ‘reference person’, where a RAP is defined as:

‘a hypothetical entity, with the assumed basic biological characteristics of a particular type of animal or plant, as described to the generality of the taxonomic level of family, with defined anatomical, physiological, and life-history properties, that can be used for the purposes of relating exposure to dose, and dose to effects, for that type of living organism’ [ICRP, 2008].

Dose conversion coefficients have been derived to enable both internal and external dose rates to each RAP to be calculated. In order to evaluate the potential for environmental impacts, calculated dose rates are compared against derived consideration reference levels (DCRLs) for each RAP. The DCRLs are defined as:

‘a band of dose rate within which there is likely to be some chance of deleterious effects of ionising radiation occurring to individuals of that type of reference animal or plant…that, when considered together with other relevant information, can be used as a point of reference to optimise the level of effort expended on environmental protection, dependent upon the overall management objectives and the relevant exposure situation’ [ICRP, 2008].

The bands – derived in consideration of a review of dose effects for early mortality, morbidity and reduced reproductive success endpoints – represent broad ‘order of magnitude’ zones where it may be considered that the risks of impact will increase as one moves from the lower to the upper range. The DCRL bands are reproduced in Table 4 below.

Table 4 ICRP DCRL bands for reference animals and plants

Reference Animal / Plant		DCRL (µGy/h)*	
		Lower range	Upper range
Higher vertebrates	Deer Rat Duck	4	40
Poikilothermic vertebrates	Frog Trout Flatfish	40	400
Invertebrates	Bee Crab Worm	400	4000
Plants	Pine tree	4	40
	Grass	40	400
	Seaweed	400	4000**

From ICRP [2008]

* All values are rounded to one significant figure (ICRP express the DCRLs as mGy per day).

** Paragraph 203 of ICRP [2008] states that the DCRL for seaweed is the same as grass, but this is inconsistent with data presented in the DCRL tables. Data from the tables has been presented above.

The definition of the dose rate band represented by the DCRLs is similar to the interpretation of Zone 2 (see Section 4.4) and hence the upper range DCRL value may be considered broadly consistent with the Tier 2 screening criteria (see Section 4.2). However, there are some points of note with regard to the DCRLs.

- The lower end of the range for higher vertebrates (represented as deer, rat and duck) is somewhat lower than the value proposed within the ERICA / PROTECT programmes as generic screening values (10 µGy/h) but in the context of 'order of magnitude estimates' the discrepancy is not large – and there is a broad consistency with the organism group screening level of 2 µGy/h identified (but not used) within PROTECT for vertebrates – see Appendix A.

- The lower end of the range for higher plants (represented by the pine tree) is somewhat lower than the ERICA / PROTECT generic screening values but, as identified for vertebrates (see point above) in the context of 'order of magnitude estimates' the discrepancy is not large. In this case, however, there is an expanded inconsistency with the organism group screening level of 70 µGy/h identified (but not used) within PROTECT for plants (see Appendix A). The lack of additional specificity within PROTECT (e.g. for higher plants, grasses and algae) may explain this apparent anomaly.

- The lower end of the range for poikilothermic vertebrates (represented as frog, trout and flatfish), for invertebrates (represented as bee, crab and worms) and for grass and seaweed is somewhat higher than the ERICA / PROTECT generic screening values. The inconsistency with respect to invertebrates is very much reduced by comparison to the organism group screening level of 200 µGy/h identified (but not used) within PROTECT for invertebrates.

- The DCRL data themselves contain an inconsistency with respect to seaweed, and the interpretation in Table 4 above (which attempts to resolve the anomaly) is subject to confirmation.

- At the upper end of the range for higher vertebrates and higher plants (40 µGy/h), poikilothermic vertebrates and grass (400 µGy/h) and for invertebrates and lower plants (4000 µGy/h) there is some consistency with the UNSCEAR values of 100 & 400 µGy/h although, since the interpretation of these values differs somewhat, this apparent consistency should not be over-emphasised.

Finally, it should be noted that the ICRP framework is still developing. It is considered likely that the broad DCRL approach will remain constant, but the upper and lower range values, the definition of the implied effects and the interpretation of the values for regulatory guidance may be subject to modification. Further details are presented in the notes for the Workshop held in June 2011, in Glasgow (see www.bioprota.org). It is anticipated that ICRP Committee 5 will complete its consultation and deliberations in Autumn 2011.

IAEA EMRAS

The general aim of the IAEA sponsored EMRAS (Environmental Modelling for Radiation Safety) II Programme is to improve capabilities in the field of environmental radiation dose assessment by means of acquisition of improved data for model testing, comparison, reaching consensus on modelling philosophies, approaches and parameter values, development of improved methods and exchange of information.

Working Group 6 ('Biota Dose Effects Modelling') under EMRAS II has established a number of sub-groups, one of which is focussing on the relationships between exposures to ionising radiation and effects on flora and fauna. Within this context, existing dose-effects databases will be updated, dose-response relationships will be analysed, models for the impact of exposures to populations will be attempted, the exposure to multiple stressors will be investigated and statistical methods for analysing dose-effects relationships will be further developed. The group are also looking to revisit group-specific screening values as was attempted by PROTECT [Copplestone et al, 2010].

At present, Minutes of meetings held early-2009 to early-2011 are available from the EMRAS II website*, but no announcements regarding interpretation of dose-effect data have been made. The group do not plan an interim meeting during 2011.

5.4 SUMMARY

Two aspects have been considered in this section: first, the approaches which may be adopted to derive Tier 1 and Tier 2 benchmark values; second, interim (existing) guidance which may be adopted to define Tier 1 and Tier 2 benchmark values.

There appears to be a general preference for the SSD approach to identifying benchmark dose rate values linked to specified effects levels, but data are currently lacking to enable Tier 2 values to be developed for a range of organism groups. Should data become available, it is suggested that an EDR_{20} may be applicable upon which to derive confidence-based limited effect levels.

An “assessment factor” approach is widely used to derive environmental criteria for chemicals yet has been ruled-out previously with respect to deriving similar criteria for radioactivity. This “ruling out” may be overly restrictive in the sense that the assessment factor approach maximises use of such data as are available and would be consistent with the derivation of environmental protection standards employed for chemicals.

Other approaches, including radiosensitivity multipliers and ‘expert judgement’ have been considered. These offer valid methods to maximise use of available data and may be used in conjunction with an assessment factor (or indeed a SSD) approach.

In the absence of an agreed method to derive Tier 1 and 2 values, or of an adequate database for detailed statistical evaluation, interim guidance based on existing recommendations may be adopted.

With respect to deriving a Tier 1 generic screening value, it is suggested that the ERICA / PROTECT screening value of 10 µGy/h is appropriate. The value is of known provenance, it is based on an SSD approach (with reduction factor) and is currently used widely across Europe. Comparison with the ICRP DCRL lower range values is not conclusive, but suggests that for many organism groups, adoption of a 10 µGy/h screening level will be conservative.

Identification of a Tier 2 value, or series of values, is more complex. A single value of 100 µGy/h may be applied generically, based on UNSCEAR guidance for terrestrial ecosystems. Alternatively values may be derived from the upper end of the range of DCRLs proposed by ICRP as 40 µGy/h for vertebrates and higher plants (represented by trees), 400 µGy/h for invertebrates and plants which may be represented by ‘grasses’ and 4000 µGy/h for plants which may be represented by ‘seaweed’.

Given that the DCRL values are currently known to be under consideration and may be subject to change in the short term, it is suggested that for now a single Tier 2 value of 100 µGy/h be adopted, but for this to be reviewed when ICRP Committee 5 publish their revised guidance.

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* http://www-ns.iaea.org/projects/emras/emras2/working-groups/working-group-six.asp?s=8

6 PROPOSED FRAMEWORK FOR COMPLIANCE DEMONSTRATION FOR LONG-TERM RADIOLOGICAL ASSESSMENTS

As stated in Section 1, the objectives of the current project are two-fold:

- to provide thoughts and discussions on approaches that could be employed to demonstrate compliance with environmental protection objectives to feed into international discussion on this issue; and,
- to develop an assessment framework that could be applied to address the particular issues associated with evaluating the potential impact of releases from geological disposal facilities in the long-term.

This section aims to address the latter objective by setting out the proposed three-zoned framework in the particular context of geological disposal facility assessments. In setting out the proposed framework, examples are given assuming that a site-specific assessment is being undertaken such that information is available on the types of plant and animal requiring consideration on the basis of species currently present.

The framework is summarised in Figure 10.

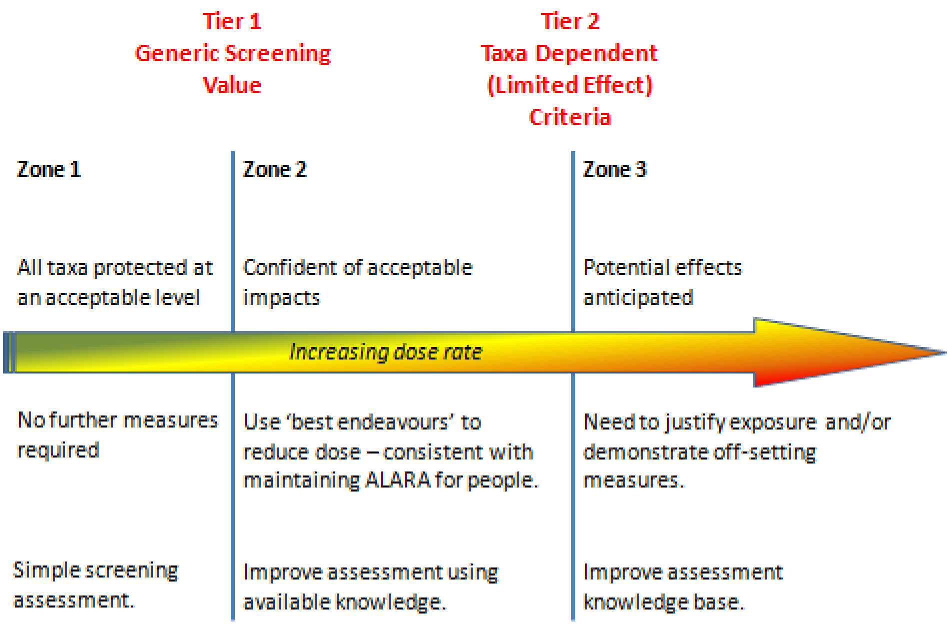

Figure 10. Tiered compliance demonstration concept

6.1 UNDERSTANDING THE EFFECTS ZONES

6.1.1 Zone 1

It is suggested that the starting point for assessments at Tier 1 is peak predicted activity concentrations, irrespective of time, for the range of radionuclides that could be released from a facility. The assessment could be based on a generic range of organisms (for example, those included as default within the ERICA assessment tool[*]). Alternatively, an assessor may include additional site-relevant organisms.

Resultant dose rates would be compared against the Tier 1 generic screening value for which a value of 10 µGy/h, consistent with that derived in the ERICA and PROTECT projects, is recommended.

Below this screening value, no further biosphere based assessment would be required. The use of peak activity concentrations, irrespective of time, is considered to be sufficiently conservative that, when compared with the generic screening value, there can be confidence that impacts will be below levels which could be unsustainable at the population level.

Whilst the specific does-rate value which may be applied as a Tier 1 screening threshold may be open to discussion (and refinement as additional dose-effects data become available) the concept and purpose of a Tier 1 screening threshold, to define a zone of 'no further action' was widely accepted within the BIOPROTA workshop.

In situations where predicted biota dose rates are greater than the generic screening value, a more refined Tier 2 assessment is warranted.

6.1.2 Zone 2

A zone 2 assessment should be refined in the light of available knowledge. For example, input data should represent the realistic release from the geosphere to the biosphere rather than use of peak activity concentrations irrespective of time. Use should also be made of available site-relevant data (such as soil-type, Kd and concentration ratios for the plants and animals of interest). Consideration should be given to those organisms that may be at greater risk of enhanced exposure; it is proposed that relevant soil-dwelling organisms be incorporated within an assessment.

Results of the assessment should be compared against the organism-relevant Tier 2 value. Where dose rates are below, it can be concluded that there is confidence that effects will be limited such that ecosystem impacts will not occur. Nonetheless, an assessor should ensure that exposure is reduced as far as practicable. Dose rates above a relevant Tier 2 criterion would indicate that there is no longer confidence that impact will be at an acceptable level such that further assessment effort may be warranted. This could be through further refinement of the zone 2 assessment (for example, by gathering further supporting data that are relevant to the site of interest) or a zone 3 assessment may be warranted.

In the interpretation of assessment output within zone 2, assessors should give due consideration to the interaction of species, i.e. food web interactions and interdependence between species for population recruitment.

6.1.3 Zone 3

Greater effort is required within zone 3 to further refine the assessment, to demonstrate that under the specific conditions prevailing locally that the impact is sustainable, or to make justification arguments where there is an overriding public interest for the development of the facility in its current design / location.

Refinement of an assessment within zone 3 is anticipated to require the generation of new knowledge. This could, for example, involve additional site characterisation or fundamental radioecology research to derive radioecology parameters. Alternatively, some facility re-design, such as the incorporation of additional engineered barriers, could be considered that would serve to reduce the release of radionuclides to the biosphere. Such a consideration would likely be driven by human dose considerations as a priority.

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[*] Due to the restricted range of radionuclides included within Tier 1 of the ERICA assessment tool, it may be necessary for an assessor to perform an initial (zone 1) assessment using ERICA Tier 2 to enable use of the 'add radionuclide' functionality.

In situations where it is no longer feasible to further refine an assessment, the assessor would be required to consider whether there are reasons of overriding public interest and to set out suitable justification arguments as to why the development should continue. The types of arguments that may be relevant include:

- Dose rates in excess of a relevant Tier 2 criterion are predicted for a species with a high reproductive output with wide geographical dispersion such that localised impacts are unlikely to affect the population as a whole and/or repopulation is anticipated.
- Organisms are wide-ranging in relation to the spatial extent of the impacted area.
- A Tier 2 criterion is considered too cautious for application to the organism of interest; for example, phytoplankton may be maximally exposed and use of a Tier 2 criterion based on 'all plants' may be too restrictive.
- Similar habitats are present in areas out-with the predicted spatial impact zone.
- The chemical form of radionuclide release may indicate that bioavailability would be reduced from that incorporated into the assessment in the form of Kd and concentration ratios. Assessments are often conducted on the basis of elements rather than chemical form, although chemical form may be implied through the selection of parameter values or distributions used. The potential for chemical form of a radionuclide to influence environmental transfers should be addressed in an assessment and uncertainties around this noted.
- Population dynamics may support a higher level of exposure before population impacts would occur for a given species.
- The timescale of release may be immediately prior to or following the next anticipated climatic glaciations period such that climate-induced impacts on plants and animals may be substantial when compared against those resulting from radiation; potentially preventing those organisms for which high exposure has been calculated from occupying the region. Alternatively, the ability of a habitat to endure over time may be restricted (e.g. as a result of sea level rise or coastal erosion) such that species populations will not be sustainable at the location at which impacts are predicted to occur.
- Data gaps in environmental transfer parameters have resulted in a number of conservatisms that, whilst acknowledged, give dose rates in excess of what would reasonably be expected. Judgement may suggest that actual impacts would be unlikely to be of such a magnitude.

The list of justification arguments provided above is not intended to be exhaustive. An assessor would be required to consider the results of an assessment in the context of the ecosystem of concern.

Finally, there is a need to recognise that all ecosystems will be subject to stresses from a number of sources, both natural and man-made and this must be acknowledged when interpreting assessments.

6.2 ILLUSTRATIVE APPLICATION TO AN ASSESSMENT CONTEXT

The means by which the framework concept could be applied in an assessment context is illustrated in Figure 11.

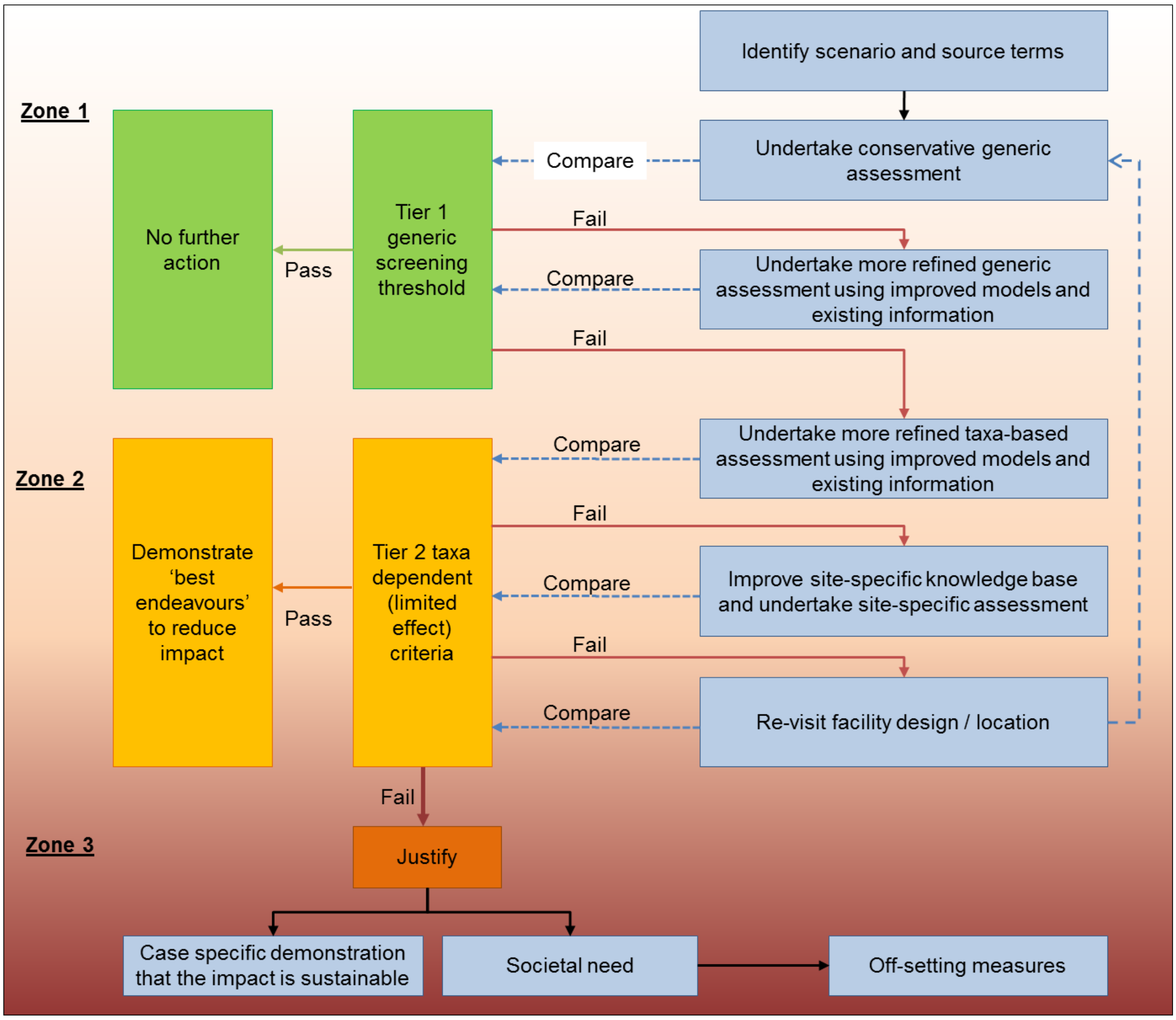

Figure 11. Example application of the framework concept to an assessment context

Although presented as a three-zone assessment, it is not intended that an assessor be tied to one assessment within each zone; rather decisions should be made on the appropriateness of each zone-assessment level to the scenario being considered and the availability of supporting assessment data. For example, additional data may be sourced that would help refine a previously conducted assessment such that this may warrant a second assessment run at any given tier. As such, the framework is intended to be applied in a way that allocates efficient and effective use of resources.

6.3 SUMMARY

The purpose of the assessment framework, and associated material, is to promote a proportionate and risk-based approach to the level of effort required in undertaking and interpreting an assessment. The zoned structure is not intended to present hard and fast rules for the nature and detail of an assessment to be undertaken, but provides direction on the approach and the amount of site-specific information which may be required.

7 DISCUSSION AND CONCLUSIONS

A two-tier, three zone framework has been proposed, relevant to the long-term assessment of potential impacts from the geological disposal of radioactive wastes. The purpose of the assessment framework, and associated material, is to promote a proportionate and risk-based approach to the level of effort required in undertaking and interpreting an assessment.

Assessments which fall within Zone 1, where all organisms are calculated to receive dose rates lower than the Tier 1 generic screening value, are considered to require no further measures to demonstrate that non-human biota are adequately protected at a population level, for all relevant types of organism. It is suggested, furthermore, that protection of all populations at this level is sufficient to imply adequate protection based on other measures such as biodiversity, habitat or community structure.

Assessments which fall within Zone 2, that is some or all species are exposed to dose rates in excess of the Tier 1 generic screening level, but below a defined Tier 2 taxa-dependent criterion, are considered to be consistent with limited effects which are sustainable at a population level. As the level of exposure moves further from the Tier 1 screening value, it is considered that the assessment should be refined (making best use of available information) and measures to reduce the dose where practicable (and where consistent with maintaining ALARA for people) should be demonstrated.

Neither Zone 1 nor Zone 2 represent 'no effect' assessments. Rather they are defined in a quantitative fashion (where data are available) as zones which afford protection at a defined level to a defined proportion of all species considered. There are thus some circumstances, for instance where an assessment is driven solely by consideration of currently rare or radiosensitive species, where a more detailed assessment and/or extensive acquisition of new information may be required. However, such circumstances will be limited and the derivation of Tier 1 and 2 values weighted to (but not wholly driven by) the more radiosensitive species should provide reassurance that any impacts at the ecosystem level, and almost certainly at the individual population level for the large majority of species, are sustainable.

Assessments which fall into Zone 3, where there is an increasing likelihood of effects at the population level as the dose rates increase beyond the relevant Tier 2 values, are not automatically unacceptable (i.e. the Tier 2 value is not to be interpreted as a limit). In the first instance, increasing effort will be required to present a refined assessment based, for example, on the acquisition of new knowledge. This could involve additional site characterisation or fundamental radioecology research to derive radioecology parameters. Alternatively, some facility re-design, such as the incorporation of additional engineered barriers, could be considered that would serve to reduce the release of radionuclides to the biosphere.

In situations where it is not feasible to further refine an assessment, the assessor would be required to consider whether there are reasons of overriding public interest and to set out suitable justification arguments for the continued development of the facility.

As an interim measure, it is proposed that the Tier 1 generic screening value be set at 10 µGy/h. This is consistent with guidance from the ERICA / PROTECT programmes and is already familiar to many assessors in a European context.

Likewise as an interim measure it is proposed that a single Tier 2 benchmark value of 100 µGy/h be adopted. This is consistent with the more restrictive guidance from UNSCEAR for application to terrestrial ecosystems. It is suggested that when ICRP have concluded their review of the values and interpretation of DCRLs, the upper DCRL value may be appropriate for application as taxa- related Tier 2 values.

8 REFERENCES

Agüero A, Alonzo F, Björk M, Ciffroy P, Copplestone D, Garnier-Laplace J, Gilbin R, Gilek M, Hertel-Aas T, Jaworska A, Larsson C-M, Oughton D, Zinger I (2006). Derivation of predicted-no-effect-dose-rate values for ecosystems (and their sub-organisational levels) exposed to radioactive substances. ERICA Deliverable 5.

Andersson, P, Beaugelin-Seiller, K, Beresford, NA, Copplestone, D, Della Vedova, C, Garnier-Laplace, J, Howard, BJ, Howe, P, Oughton, DH, Wells, C, Whitehouse, P (2008). Numerical benchmarks for protecting biota from radiation in the environment: proposed levels, underlying reasoning and recommendations. PROTECT Deliverable 5.

Andersson P, Garnier-Laplace J, Beresford NA, Copplestone D, Howard BJ, Howe P, Oughton D, Whitehouse P (2009). Protection of the environment from ionising radiation in a regulatory context (PROTECT): proposed numerical benchmark values. J Environ Radioact 100: 1100-1108.

Baker RJ & Chesser RK (2000) The Chernobyl nuclear disaster and subsequent creation of a wildlife preserve. Letter to the Editor. Environ Toxicol Chem 19 (5):1231-1232.

Barnthouse LW (1995). Effects of ionising radiation on terrestrial plants and animals: A workshop report. Oak Ridge National Laboratory report ORNL/TM-13141.

Beresford NA, Bron J, Copplestone D, Garnier-Laplace J, Howard BJ, Larsson C-M, Oughton D, Pröhl G and Zinger I (2007a). D-ERICA: an integrated approach to the assessment and management of environmental risks from ionising radiations. ERICA Deliverable D-ERICA.

Beresford NA, Hosseini A, Brown JE, Cailes C, Copplestone D, Barnett CL, Beaugelin-Seiller K (2007b). Evaluation of approaches for protecting the environment from ionising radiation in a regulatory context. PROTECT Deliverable 4.

Beresford NA, Hosseini A, Brown JE, Cailes C, Beaugelin-Seiller K, Barnett CL, Copplestone D (2010). Assessment of risk to wildlife from ionising radiation: can initial screening tiers be used with a high level of confidence? J Radiol Prot 30: 265-282.

Berger A, Loutre MF and Crucifix M (2003) The earth's climate iin the next hundred thousand years (100 KYR). Surveys in Geophysics 24: 117–138.

Brownless GP (2007). Issues around radiological protection of the environment and its integration with protection of humans: promoting debate on the way forward. J Radiol Prot 27: 391–404.

CNSC (2002). Protection of Non-Human Biota From Ionizing Radiation. INFO-0730. Canadian Nuclear Safety Committee, Canada.

Cook LM (2003). The rise and fall of the *Carbonaria* form of the Peppered Moth. Quart Rev Biol 78(4): 399-417.

Copplestone D, Bielby S, Jones SR, Patton D, Daniel P and Gize I (2001). Impact assessment of ionising radiation on wildlife. R&D publication 128. Environment Agency, Bristol.

Copplestone D, Wood MD, Bielby S, Jones SR, Vives J and Beresford NA (2003a). Habitats regulations for Stage 3 assessments: radioactive substances authorisations. R&D Technical Report P3-101/SP1a Environment Agency, Bristol.

Copplestone D, Zinger I and Jackson D (2003b) The challenge of protecting non-human biota from exposure to ionising radiation. In the Sociey for Radiological Protection 40th Anniversary Meeting: ALARP: principles and practices. St Catherine's College, Oxford

Copplestone D, Brown JE and Beresford NA (2010). Considerations for the integration of human and wildlife radiological assessments. J Radiol Prot 30: 283-297.

Darby S, D Hill, A Auvinen, JM Barros-Dios, H Baysson, F Bochicchio, H Deo, R Falk, F Forastiere, M Hakama, I Heid, L Kreienbrock, M Kreuzer, F Lagarde, I Mäkeläinen, C Muirhead, W Oberaigner, G Pershagen, A Ruano-Ravina, E Ruosteenoja, A Schaffrath Rosario, M Tirmarche, L Tomášek, E Whitley, H-E Wichmann & R Doll (2005). Radon in homes and risk of lung cancer: collaborative analysis of individual data from 13 European case-control studies. Br Med J 330: 223-227.

de Queiroz K (2005) Ernst Mayr and the modern concept of species. Proc Nat Acad Sci 102(Suppl. 1): 6600-6607.

Environment Canada. 2003. Priority Substances List 2 Assessment Report, Releases of radionuclides from nuclear facilities (impact on non-human biota). Priority Substances List Report. Ottawa (CA): Environment Canada.

European Commission (2000). Managing Natura 2000 SITES. The provisions of Article 6 of the 'Habitats' Directive 92/43/CEE. Luxembourg: Office for Official Publications of the European Communities, 2000, Article 6.

European Commission (2003). Technical Guidance Document on Risk Assessment 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, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part II. Luxembourg': Office for Official Publication of the European Communities. Report EUR 20418 EN/2.

European Commission (2007). Guidance document on Article 6(4) of the 'Habitats Directive' 92/43/EEC. Clarification of the Concepts of: Alternative Solutions, Imperative Reasons of Overriding Public Interest, Compensatory Measures, Overall Coherence, Opinion of the Commission. January 2007, Article 6 Guidance.

Fesenko SV, Alexakhin RM, Geras'kin SA, Sanzharova NI, Spirin YV, Spiridonov SI, Gontarenko IA, Strand P (2005) Comparative radiation impact on biota and man in the area affected by the accident at the Chernobyl nuclear power plant. J Environ Radioact 80: 1-25.

Garisto NC, Cooper F, Fernandes SL (2008). No-Effect Concentrations For Screening Assessment of Radiological Impacts on Non-Human Biota. NWMO Report TR-2008-02. Available from: www.nwmo.ca/uploads_managed/MediaFiles/20_NWMOTR-2008-02_No-Effect-Concentrations-for-Non-Human-Biota.pdf.

Garnier-Laplace J, Della-Vedova C, Anderrson P, Copplestone D, Cailes C, Beresford NA, Howard BJ, Howe P & Whitehouse P (2010). A multi-criteria weight of evidence approach for deriving ecological benchmarks for radioactive substances. J Radiol Prot 30: 215-233.

Hingston JL, Andersson P, Beresford NA, Brown J, Copplestone D, Garnier-Laplace J, Howard BJ and Whitehouse P (2007). A review of approaches to protection of the environment from chemicals and ionising radiation: Requirements and recommendations for a common framework. PROTECT Deliverable 3.

Hoessini A, Beresford NA, Brown JE, Jones DG, Phaneuf M, Thrring H & Yankovich T (2010). Background dose-rates to reference animals and plants arising from exposure to naturally occurring radionuclides in aquatic ecosystems. J Radiol Prot 30: 235-264.

Howard BJ, Beresford NA, Andersson P, Brown JE, Copplestone D, Beaugelin-Seiller K, Garnier-Laplace J, Howe P, Oughton D and Whitehouse P (2010). Protection of the environment from ionising radiation in a regulatory context – an overview of the PROTECT coordinated action project. J Radiol Prot 30:195-214.

HSE (1992). The Tolerability of Risk from Nuclear Power Stations (revised edition). London: HMSO, 34 pp plus Appendices.

IAEA (1992). Effects of Ionizing Radiation on Plants and Animals at Levels Implied by Current Radiation Protection Standards. Technical Reports Series No. 332. IAEA, Vienna.

ICRP (2003). A framework for assessing the impact of ionising radiation on non-human species. ICRP Publication 91.

ICRP (2007). Recommendations of the International Commission on Radiological Protection. ICRP Publication 103

ICRP (2008). Environmental Protection: the Concept and Use of Reference Animals and Plants. ICRP Publication 108.

Kadoya T, Akasaka M, Aoki T and Takamura N (2011) A proposal of framework to obtain an integrated biodiversity indicator for agricultural ponds incorporating the simultaneous effects of multiple pressures. Ecological Indicators 1: 1396–1402.Kozubov GM and Taskaev AI (eds) the Radiation Influence on the Coniferous Forests in the Region of the Catastrophe at the Chernobyl Atomic Power Station. Siktivkar, USSR, 1990

Larsson C-M (2009). Waste disposal and the recommendations of the International Commission on Radiological Protection – Challenges for radioecology and environmental radiation protection. J Environ Radio 100: 1053–1057.

LLW Repository Ltd (2011). The 2011 Environmental Safety Case: Assessment of Impacts on Non-human Biota, LLWR/ESC/R(11)10030, May 2011.

MA, 2005. Millenium Ecosystem Assessment: findings of the condition and trend working group. Island Press, Washington D.C.

Mayr E (1942) Systematics and the Origin of Species. Columbia Univ. Press, New York.

NEA (2007). Environmental Radiological Protection in the Law - A Baseline Survey. NEA Report 06172. ISBN: 92-64-99000-5.

Real A, Sundell-Bergman S, Knowles JF, Woodhead DS, Zinger I (2004) Effects of ionising radiation exposure on plants, fish and mammals: relevant data for environmental radiation protection. J Radiol Prot 24: A123-A137.

Robinson CA, Smith KL and Norris S (2010). Impacts on non-human biota from a generic geological disposal facility for radioactive waste: some key assessment issues. J Radiol Prot 30: 161-173.

Ryabokon NI & Goncharova RI (2006). Transgenerational accumulation of radiation damage in small mammals chronically exposed to Chernobyl fallout. Radiat Environ Biophys 45:167-77.

Sparrow AH, Underbrink AG & Sparrow RC (1967). Chromosomes and cellular radiosensitivity. I. The relationship of D_0 to chromosome volume and complexity in seventy-nine different organisms. Radiat Res 32: 915-945.

Sparrow AH & Woodwell GM (1963). Prediction of the sensitivity of plants to chronic gamma irradiation, pp 257-270 in: Proc First National Symposium on Radioecology (eds Schultz V & Klement AW). Reinhold Publishing Corp, New York, and American Institute of Biological Sciences, Washington.

Smith K, Robinson C, Jackson D, De La Cruz I, Zinger I and Avila R (2010). Non-human biota dose assessment: sensitivity analysis and knowledge quality assessment. POSIVA Working Report 2010-69.

STUK (2001). Long-term safety of disposal of spent nuclear fuel. STUK Guide YVL 8.4, May 2001. Finnish Radiation and Nuclear Safety Authority.

STUK (2010). GUIDE YVL D.5 – Disposal of nuclear waste, draft 3, 10.5.2010.

TEEB (2010) The Economics of Ecosystems and Biodiversity (TEEB): Ecological and economic foundations. Earthscan, London.UNSCEAR (1996). Sources and Effects of Ionizing Radiation. Report to the General Assembly with Scientific Annexes. New York: United Nations.

UNSCEAR (2008). Sources and Effects of Ionizing Radiation. Report to the General Assembly with Scientific Annexes. New York: United Nations (published 2011).

US DoE (2002). A graded approach for evaluating radiation doses to aquatic and terrestrial biota, DOE-STD-1153-2002.

Whicker FW & Schultz V (1982). Radioecology: Nuclear Energy and the Environment, Vol II. CRC Press, Boca Raton, Florida, USA.

Wood MD, Marshall WA, Beresford NA, Jones SR, Howard BJ, Copplestone D & Leah RT (2008) Application of the ERICA integrated approach at the Drigg coastal sand dunes. J Environ Radioact 99(9): 1484-1495.

GLOSSARY OF TERMS AND ACRONYMS USED IN THIS REPORT

This list is not intended to be exhaustive but provides an introduction to main terms and acronyms used throughout this report.

BAT	Best Available Techniques
BPM	Best Practicable Means
DCRL	Derived Consideration Reference Level
EC_x	Effect Concentration at which change of x% in the observed effect occurs relative to the control group
EDR_x	The dose rate at which change of x% in the observed effect occurs relative to the control group
EMRAS	Environmental Modelling for Radiation Safety
ENEV	Environmental No Effect Values
HDR	Hazardous Dose Rate (HDR_5; the dose rate at which 5% of all exposed species will be affected to a maximum 10% level)
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IROPI	Imperative Reasons of Overriding Public Importance
LC_{50}	Lethal Concentration at which 50% of individuals or species die (generally within a specified time, which may be expressed as $LC_{50/x}$ where x is the time, generally in days, for the effect to be realised)
LD_{50}	Lethal Dose (or dose rate) at which 50% of individuals or species die (generally within a specified time, which may be expressed as $LD_{50/x}$ where x is the time, generally in days, for the effect to be realised)
LOEC	Lowest Observable Effect Concentration
NEC	No Effect Concentrations
NOEC	No Observable Effect Concentration
NHB	Non-human biota
PNER	Predicted No Effect Dose Rate
RAPs	Reference Animals and Plants
SAC	Special Area of Conservation
SPA	Special Protection Area
SSD	Species Sensitivity Distribution

APPENDIX A: NATIONAL AND INTERNATIONAL PROTECTION GOALS AND CRITERIA

As indicated in Section 1, screening criteria must be developed in line with appropriate protection goals. As such, international and national protection goals and associated criteria, relevant to non-human biota assessments for radioactive waste disposal facilities that have been developed as a result of various national and international programmes have been reviewed and are presented below. The method by which criteria have been derived is also outlined.

International Protection Goals and Criteria

Protection goals that have been considered in the development of assessment approaches to evaluate the impacts of radiation on the environment at an international level are presented in this section. Assessment criteria developed in line with these protection goals are also presented. Consideration is given to protection goals set by international organisations and research programmes.

International Commission on Radiological Protection

Historically, recommendations of the ICRP have considered that, by providing an adequate level of protection for humans the environment would also be protected. However, ICRP Publication 91 [ICRP, 2003] specifically addressed the issue of protection of the environment from radioactivity and acknowledged that there were a number of drivers for the development of a framework that would enable radiation impacts on the environment to be explicitly assessed. In part this arose from an acceptance of the difficulties associated with demonstrating that the environment is protected in situations where humans are not present, but also developments in environmental protection criteria arising from international agreements and regulations that specifically require that environmental protection is demonstrated. Demonstrating adequate environmental protection would be hindered by the lack of both a policy and a technical basis for assessment, criteria, or standards, endorsed at an international level; hence the Commission established Committee 5 which had the objective to develop a clear framework for evaluating the effects of radiation on non-human species. The stated protection goal for a developing framework was to '*safeguard the environment by preventing or reducing the frequency of effects likely to cause early mortality or reduced reproductive success in individual fauna and flora to a level where they would have a negligible impact on conservation of species, maintenance of biodiversity, or the health and status of natural habitats or communities*' [ICRP, 2003].

In 2007 the Commission published revised recommendations [ICRP, 2007] which served to broaden the scope of radiological protection to explicitly include the environment and adopted the protection goal given in their 2003 report. This goal is likely to form the basis for the future development of national and international protection standards. The 2007 recommendations also stated that any approach should be commensurate with the overall level of risk and should therefore be optimised. The approach should also be compatible with other approaches for environmental protection.

<u>*Protection Criteria*</u>

A Reference Animal and Plant (RAP) approach has been developed by ICRP Committee 5, the objective of which was 'to provide '*high-level guidance and advice upon which regulators and operators may draw in order to demonstrate compliance, where necessary, with the wide range of international and national environmental legislation that already exists, or is likely to emerge in the near future*' [ICRP, 2008]. As a means of achieving this, Committee 5 developed taxonomic-group specific dose rate criteria (Derived Consideration Reference Levels, DCRL) for each of the 12 RAPs. These DCRLs are defined as '*a band of dose rate within which there is likely to be some chance of deleterious effects of ionising radiation occurring to individuals of that type of reference animal or plant (derived from a knowledge of defined expected biological effects for that type of organism) that, when considered together with other relevant information, can be used as a point of reference to optimise the level of effort expended on environmental protection, dependent upon the overall* *management objectives and the relevant exposure situation*' [ICRP, 2008]. DCRL bands (Table A1) were set on the basis of current informed judgement following review of available effects data. The objective of DCRLs is to assist in optimising the level of effort that might be expended on environmental protection, which will largely depend on the overall management objectives and exposure situation.

It is intended that the bands will be reviewed as more data become available.

Table A2 Derived Consideration Reference Levels

RAP	DCRL (mGy/d)	Comment
Higher vertebrates		
Deer Rat	0.1 - 1	Low probability of effects occurring that could result in reduced reproductive success or morbidity. No observed effects at lower band (0.01-0.1 mGy/d).
Duck		No direct data, but some form of 'harm' could be expected at such dose rates when considering bird metabolism, longevity and reproductive behaviour.
Poikilothermic vertebrates		
Frog Trout Flatfish	1 - 10	Minimal effects data available at dose rates below 1 mGy/d and interpolation therefore required.
Invertebrates		
Bee Crab Worm	10 - 100	Minimal data available, with exception of annelids, within or below the DCRL band. Broadly equivalent effects to those observed in vertebrates appear to require another order of magnitude of dose rate to appear in invertebrates.
Plants		
Pine tree	0.1 - 1	Prolonged exposure to 1-10 mGy/d can lead to reduced reproductive success.
Grass	1 - 10	Degree of reduced reproductive success could occur at dose rates in band higher than for pine trees.
Seaweed	10 - 100*	

* Paragraph 203 of ICRP [2008] states that the DCRL for seaweed is the same as grass, but is inconsistent with data presented in DCRL tables. Data from the tables has been presented above.

IAEA Protection Criteria

In the early 1990s, the International Atomic Energy Agency (IAEA) undertook a review of available data on the effects of radiation on non-human species. On this basis, it was suggested for discussion that chronic exposures below the following rates-rates would be unlikely to lead to observable changes to populations [IAEA, 1992]:

- 10 mGy/d (400 µGy/h) – terrestrial plants and aquatic organisms
- 1 mGy/d (40 µGy/h) – terrestrial animals

The dose rates were expressed as order of magnitude indicators, derived on the basis of expert judgement. Although they were not intended as such, these values have been applied subsequently in a number of instances as benchmarks for comparison within assessments of the impacts of radioactivity on the environment.

UNSCEAR Protection Criteria

In 1996, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) published a report detailing the results of an evaluation of dose rates below which effects on populations of non-human biota were considered unlikely following review of available radiation effects data. The evaluation resulted in the following recommendations that are consistent with the findings from the IAEA review [UNSCEAR, 1996]:

- Terrestrial plants – dose rates of 400 µGy/h may induce slight deleterious effects in sensitive plants, but no significant effects for plant communities;
- Aquatic organisms – exposure of a small proportion of a population to dose rates of 400 µGy/h will not give rise to detrimental effects on the population; and,
- Terrestrial animals – dose rates of 400 µGy/h would be unlikely to affect mortality rates in the population of the most sensitive animal species (i.e. mammals), whereas at dose rates of 40-100 µGy/h the same statement applies to reproduction.

As with the IAEA dose rates, these values were derived on the basis of expert judgement following review of available effects data. As far as possible, account has been taken of the most radiosensitive organisms for which information was available in arriving at these limiting values and it is considered that they become more robust if they are applied to the most highly exposed members of the populations [UNSCEAR, 1996]. This condition recognises that it will usually be simpler to provide an estimate of the maximum dose rate likely to be experienced by any specific organism of concern (in view of habits or radionuclide accumulation potential which render them likely to receive the highest dose rates, and/or are likely to be the most radiosensitive), rather than the mean dose rate across the whole population. Such an approach takes account of the fact that the majority of radioactive contamination will lead to point releases to the biosphere with consequent gradients in both the contaminant radionuclide concentrations and the resulting increments of radiation exposure.

Being consistent with the dose rate values derived by the IAEA, these values have also been widely applied as benchmarks for comparison within assessments of the impacts of radioactivity on the environment.

In 2008, UNSCEAR published a further report which detailed findings of a subsequent review of chronic data [UNSCEAR, 2011]. The result of this subsequent review was that there was no evidence to support changing the conclusions from the 1996 report, such that:

- chronic dose rates to the most highly exposed individuals below 100 µGy/h would be unlikely to have significant effects on most terrestrial communities; and,
- chronic dose rates below 400 µGy/h to the most exposed individuals within the aquatic environment would be unlikely to induce significant effects on the population.

Expert judgement was again the basis for the judgements made.

ERICA

ERICA (Environmental Risks from Ionising Contaminants: Assessment and Management) was a further EC EURATOM Framework 6 funded project. The objective of the project was to develop an integrated approach to evaluating environmental risks associated with radioactivity in the environment and to EC EURATOM Framework 6 funded project. Since the project was aimed at providing an approach that could be applied throughout the European Community, no specific protection goals were cited other than to ensure that decisions on environmental issues gave '*appropriate weight to the environmental exposure, effects and risks from ionising radiation with emphasis on ensuring the structure and function of ecosystems'* [Beresford et al, 2007a].

Protection Criteria

ERICA [Beresford et al, 2007a] provides for a tiered assessment approach by with the level of detail and assessment requirements increase through the different tiers. Within the project, an incremental (i.e. dose rates above natural background) screening value of 10 µGy/h was derived. The incremental screening value is intended as a means by which it can be determined whether a site requires more in-depth assessment. It is considered protective of the structure and function of generic ecosystems, inclusive of all organism groups and is intended to be applied to incremental exposures (i.e. those above background) in lower tier assessments (tiers 1 and 2 of the ERICA assessment framework). It is not intended to be applied as a limit that must not be exceeded. No upper benchmark is available for application at higher tiers of assessment.

To derive the incremental screening value a species sensitivity distribution (SSD) approach was applied to available radiation effects data derived from the FREDERICA database. Expert judgement was involved (both in the selection of appropriate data and in the selection of an appropriate assessment factor), but in all cases this has been documented to allow for traceability.

The screening value was derived using the EC statistical Species Sensitivity Distribution (SSD) approach for deriving benchmarks for chemical stressors [European Commission, 2003]. Data relating to reproductive, morbidity and mortality effects arising as a result of chronic radiation exposure were identified from the FREDERICA radiation effects database*. A number of strict criteria were applied in selecting appropriate data, which related to:

- The number of observations (including control);
- The trend in effect response with dose; and,
- Availability of experimental data on either side of the calculated EDR_{10}/ED_{50} value for each data set.

Selected data were used to reconstruct dose rate-effect relationships and, from these, EDR_{10} values (the dose rate at which a 10% change in the observed effect occurs relative to the control group) were derived.

Statistical analysis of the data did not identify any significant difference between reproduction, mortality and morbidity effects in species within different ecosystems and, as such, data were collated to enable a single, ecosystem generic, SSD analysis to be performed.

The derived EDR_{10} data for all species were plotted to give a probability distribution from which a Hazardous Dose Rate, HDR_5, (the dose rate at which 5% of all exposed species will be affected to a maximum 10% level) was derived. It is assumed that the ecosystem will not be affected by the 5% of species that fall below the cut-off value of the HDR_5. A safety factor of 5 was then applied to derive the predicted no effect dose rate (PNEDR), which was rounded to one significant figure to give the derived screening value of 10 µGy/h.

PROTECT

The EU EURATOM funded PROTECT project was primarily aimed at evaluating the practicability and relative merits of different approaches to protection of the environment from ionising radiation and comparing these with the approaches used for non-radioactive contaminants. This provided the basis on which numerical targets (dose rate thresholds) for the exposure of wildlife, compliant with environmental protection goals, could be proposed such that biota assessment frameworks could be applied usefully in a regulatory context.

* Available online from www.frederica-online.org. Access to the database requires registration.

In achieving its objectives, the project undertook an international consultation with environmental regulators, nuclear and non-nuclear industries and non-government organisations to elicit information and views on:

- the various national regulatory instruments and procedures plus the underlying principles and criteria applied in relation to environmental protection; and

- industry views on how environmental regulations are applied at a national level.

Responses to the questionnaire [Hingston et al, 2007] indicated that it is generally accepted that the level of protection for individual people must be greater than for non-human species with respondents indicating in many instances that the sustainability of populations of non-human species should be a key protection goal, i.e. there is an acceptance that individuals may be at risk of impact, but the population as a whole should be sustainable. Protection requirements may differ however for rare or endangered species, particularly those with low reproductive output where impacts at the individual level may have a greater impact upon the survival of the population.

In developing numerical targets, the PROTECT consortium thus provided the following protection goal [Andersson et al, 2008]: '*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, foundation, rare, protected or culturally significant species*'.

Protection Criteria

The PROTECT Consortium used SSD analysis as the preferred means of deriving screening values, which is similar to that applied in the ERICA programme. The primary focus was on the derivation of a generic screening value (i.e. for all non-human species, irrespective of ecosystem). Data on radiation effects in plant and animal species derived from the FREDERICA effects database was the basis for the analysis.

Differences in the approach applied within the PROTECT programme and that of ERICA were:

- The application of stricter selection criteria for effects data within the FREDERICA database.

- Inclusion of only reproductive endpoints, which are largely considered to be the most sensitive and ecologically relevant endpoint within the FREDERICA database for the majority of species [Larsson, 2009].

- Hormetic data were included whereas such data were excluded within the ERICA data selection procedure. However, the 'positive' hormetic effect itself was not included, rather the subsequent decline in effect to the 10% level was calculated.

The generic screening value was derived on the basis of the most sensitive endpoint (i.e. the lowest EDR_{10}) for any given species (plant or animal within aquatic or terrestrial ecosystems) and was selected (i.e. the lowest EDR_{10}). Following the selection procedure, 20 EDR_{10} values were included. These comprised 4 plant, 2 annelid, 3 crustacean, 2 mollusc, 2 bird, 4 fish and 3 mammalian data sets [Andersson et al, 2008]. The subsequent calculation mirrored that described for the ERICA programme. The resultant HDR_5 calculated was 17 µGy/h (range 2- 211 µGy/h) and a safety factor of 2 applied to take account of extrapolation uncertainties, giving a generic screening value of 10 µGy/h.

A sensitivity analysis was also performed test the robustness of the calculated screening value. This was performed by varying data selection criteria such as selecting EDR_{10} values with the lowest uncertainty rather than the lowest value or use of the highest no effect dose rate (HNEDR). Little difference in the calculated screening value was observed with the variable data sets selected with the resultant PNEDR always being a few tens of µGy/h.

It is recommended that the derived generic screening value be used to identify situations that are below regulatory concern with a high degree of confidence [Howard et al, 2010]. For assessments with results that exceed this generic screening value, further assessment work is required to identify the potential for significant risks to populations. However, in recommending the generic screening value, PROTECT recognised the potential for assessments to be overly conservative since the most exposed organism in an assessment is often one of the least radiosensitive [Andersson et al, 2008a]. For example, the lichen and bryophyte reference organism is acknowledged to often be the most limiting in terrestrial assessments using the ERICA approach, yet is perhaps the least radiosensitive [Beresford et al, 2010]. Similarly, phytoplankton is one of the least radiosensitive organisms in the marine environment and yet is often the most exposed reference organism in ERICA assessments [Copplestone et al, 2010].

Thus, derivation of screening values for as many organism groups as possible would be more desirable, and certainly conceptually preferable, than a single generic value to take account of the relative radio-sensitivity of different organism groups. The PROTECT consortium therefore made some progress towards the derivation of more organism group screening values although effects data were considered limiting. The resultant screening values are shown in Table A1.

Table A2 PROTECT organism group screening values

Organism group	Screening Value (µGy/h)
Vertebrates	2
Plants	70
Invertebrates	200

from Andersson et al, 2009

In the case of both vertebrates and invertebrates, screening values were derived on the basis of the SSD approach. However, the lack of effects data for plants meant that an assessment factor approach had to be applied.

Although the PROTECT consortium were able to derive organism group screening values, they do not recommend their use, but rather caution their application as ‘indicative order of magnitude values only’ [Garnier-Laplace et al, 2010].

Protection Goals at a National Level

Methods for assessing radiation impacts on the environment have been developed by a number of countries in order to address national protection goals. The protection goals and associated criteria are presented below. Where available, the protection goals and criteria relevant to the geological disposal of radioactive waste are presented.

Canada

In Canada, a ‘valued ecosystem component’ approach is typically applied when considering the potential for environmental impacts arising from radioactive waste disposal practices [Garisto et al, 2008] whereby the protection goal is to prevent impacts on individual species of interest locally. However, in selecting these, consideration is given to ensuring a cross-section of exposure pathways, trophic position, radionuclides etc. are included.

Screening values have been derived by Environment Canada, and further applied by the Canadian Nuclear Waste Management Organisation (NWMO).

<u>Environment Canada Protection Criteria</u>

Environment Canada [2003] derived taxa-based dose-rate criteria representative of benchmarks for population-level impacts. These are presented in Table A3.

Table A3 Environment Canada Estimated No Effect Values

Wildlife group	ENEV (µGy/h)
Fish	20
Terrestrial invertebrates Benthic invertebrates	220
Algae Macrophytes Mammals Terrestrial plants	110

The inclusion of birds is not apparent within these broad taxa groupings. An ENEV of 200 µGy/h (in round terms) can be derived from the text [Environment Canada, 2003].

Values were derived on the basis of predicted no effect dose rates identified following review of available effects data. A safety factor of 1 was then applied to obtain Estimated No Effect Values (ENEV) that incorporate a minimum of conservatism [Environment Canada, 2003].

Nuclear Waste Management Organisation Protection Criteria

The Canadian Nuclear Waste Management Organisation has developed a screening methodology for assessing post-closure radiological impacts of a deep geological repository on non-human biota for hypothetical sites that are representative of Canadian conditions [Garisto et al, 2008]. An important component of the method was the estimation of reference No Effect Concentrations (NECs) for radionuclides in environmental media. So long as predicted environmental concentrations are below the relevant NEC there can be confidence that, despite model uncertainties, there will be no significant ecological effects.

The NECs were based on the Environment Canada [2003] dose-rate criteria presented in Table A3 or on more conservative lower dose-rate guidance values from other sources. Dose pathways based on the characteristics of representative species were then used to derive No Effect Concentrations in key media that would ensure that, at lower concentrations, the resulting species dose rates would be below the dose rate criteria.

England and Wales

The Environment Agency is the regulatory body responsible for authorising discharges of radioactive waste to the environment in England and Wales and will also be responsible for authorising the disposal of radioactive waste to the proposed geological disposal facility. There is a regulatory requirement for the Environment Agency to ensure that any activities it authorises do not cause an adverse effect on sites designated under the EC Habitats and Birds Directives. In evaluating risk, the protection objective is thus to prevent deleterious impacts on protected species and communities occupying protected habitats.

Guidance on requirements for authorisation has also been produced specifically in respect to the disposal of radioactive waste in a deep geological facility [Environment Agency and Northern Ireland Environment Agency, 2009]. This requires an operator to '*carry out an assessment to investigate the radiological effects of a disposal facility on the accessible environment, both during the period of authorisation and afterwards, with a view to showing that all aspects of the accessible environment are adequately protected*'. In evaluating radiological effects it is acknowledged that there are no currently available internationally agreed protection criteria; as such an assessor is required to draw conclusions about the effects of a disposal facility on the accessible environment using the best available information at the time of the assessment. The same guidance has also been given which applied to near surface disposal which applies across the whole United Kingdom [Environment Agency, Northern Ireland Environment Agency and Scottish Environment Protection Agency, 2009].

Protection Criteria

In 2001, the Environment Agency published an assessment approach to enable impacts on species of non-human biota to be determined for discharges of radioactivity to freshwater, terrestrial and marine ecosystems [Copplestone et al, 2001]. The approach included a range of screening values to evaluate risk of impact to populations of animal and plant. The screening values were based on environmental benchmarks (40 µGy/h for terrestrial biota and 400 µGy/h for freshwater and marine biota) proposed by UNSCEAR [1996] and IAEA [2002]. For assessments employing largely site generic data, screening values of 5% of the environmental benchmarks are applied. However, where site-specific data are available (e.g. concentration ratios between environmental media and reference organisms), this is increased to 30%.

This method was further developed [Copplestone et al, 2003a] to enable the Environment Agency to meet its regulatory commitment to ensure that authorised discharges of radioactivity to the environment do not have deleterious impacts upon Natura 2000 conservation sites[*]. The resultant method provided a staged approach to evaluating impacts for which different screening values are applied. For authorised discharges that have the potential to affect designated sites, maximum permissible radionuclide discharges are compared against a screening dose rate of 5 µGy h^{-1}. This screening value was derived in consultation with the statutory consultee on nature conservation issues in England – English Nature. Where results indicate that this screening value may be exceeded, an assessment is undertaken that takes account of all permissions to discharge that may affect a designated site. Results of this combined assessment are compared against an upper action level of 40 µGy h^{-1}.

The upper action level was defined on the basis of the FASSET biological effects work that concluded that no adverse effects would be expected on populations at dose rates below 100 µGy h^{-1}. This was used in combination with a generic background dose rate for European ecosystems of 50 µGy h^{-1}, with a safety margin of 10 µGy h^{-1} to account for the background dose rate not being specific to the UK. Below this dose rate, the Environment Agency considers that adverse impact is unlikely. Regulatory action is likely to be required where this action level is exceeded.

Finland

The Finnish Radiation and Nuclear Safety Authority (STUK) in 2001 issued Guide YVL 8.4 [STUK, 2001] that specifies the regulatory requirements relating to the safe disposal of spent nuclear fuel. The guide provides specific protection goals in relation to the environment such that no detrimental effects to species of fauna and flora should occur as a result of spent fuel disposal. In demonstrating protection, typical radiation exposures are required to be assessed for both terrestrial and aquatic populations and should '*remain clearly below levels which, on the basis of the best available scientific knowledge, could cause a decline in biodiversity or other significant detriment to any living population*'.

A further stipulation is made that '*rare animals and plants as well as domestic animals shall not be exposed detrimentally as individuals*'.

Guide YVL 8.4 will be replaced by Guide YVL D.5, currently in draft form [STUK, 2010]. The revised guidance is largely consistent with its predecessor, however the stipulation relating to protection of rare animals and plants and domestic animals has not been incorporated in the revised draft guidance. It is anticipated that Guide YVL D.5 will come into force in 2011.

No national protection criteria are stipulated in either YVL 8.4 or the draft YVL D.5.

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[*] Natura 2000 sites are a series of conservation sites throughout Europe that comprise Special Protection Areas (SPA) and Special Areas of Conservation (SAC) designated under the EC Birds and Habitats Directives respectively. In the UK, Natura 2000 sites are awarded protection under the Habitats Regulations, 1994.

Russia

Currently, there are no specific protection goals for the environment in relation to radioactivity in Russia. Rather, the focus of protection from ionising radiation is on people at this time although concepts are being developed for the protection of non-human biota (see discussion in the Herrankukkaro workshop note at www.bioprota.org). These concepts are focused on communities of organisms in natural ecosystems.

No national protection criteria are stipulated.

Sweden

The Swedish Radiation Protection Institute Act of 1988 sets the protection objective that '*man and the environment shall be protected against harmful radiation effects*' and that '*the final management of spent nuclear fuel shall be implemented so that biodiversity and the sustainable use of biological resources…shall be protected*'.

No national protection criteria are stipulated for non-human biota.

USA

The United States has developed a graded approach for evaluating compliance with limits on radiation dose to populations of aquatic animal and terrestrial plants and animals for which biota dose limits have been specified. The protection objective for these dose limits are to ensure that populations of plants and animals are adequately protected from the effects of ionising radiation through the avoidance of measurable impairment of reproductive capability [US DoE, 2002].

Protection Criteria

The US DoE apply 'dose-rate guidelines' (or constraints) that are consistent with the guidance values proposed by IAEA [1992] for discussion and adopted by UNSCEAR [1996, 2011]. The constraints were set following a US DoE sponsored workshop in 1994, which concluded [Barnthouse, 1995] that:

- The guidance values originally recommended by the IAEA [1992] for discussion were adequately supported by the available scientific literature; and

- Available data supported the application of these values as constraints for representative, rather than maximally exposed, individuals in the population.

The dose-rate values adopted are considered to represent expected safe levels of exposure and are consensus No Adverse Effects Levels (NOAELs) for effects on population-relevant endpoints in natural populations of biota [US DoE, 2002]. They are intended to be applied as guidelines or constraints. Prolonged exposure at dose-rates above these values to populations of plants and animals could lead to adverse effects and further investigation or action may be necessary. It is also noted that the dose-rate guidance is intended to apply as a constraint to representative rather than maximally exposed individuals within populations (i.e. exposure at or below the dose-rate guidance values to a *representative individual* within a population could result in some *maximally exposed individuals* within the same population being exposed at a higher rate, with potential adverse affects to that individual, but not causing unsustainable effects within the population as a whole).

APPENDIX B: POTENTIAL APPLICATION OF THE CRITERION MULTIPLIER APPROACH

As discussed in Section 5.2.3, the possibility of using criterion multipliers as a means to derive Tier 2 values for use within the framework concept was discussed during the project workshops and was, on the whole, met favourably. The concept involves deriving one or more benchmark value(s) against which the relative sensitivities of different organisms or organism types can be compared.

The ideal characteristics of a benchmark value are that it should be based on a well-founded data set, applicable to a clear organism type (or modest range of organism types), with identifiable effects expressed as end points of relevance to the desired level of protection, and with a clear and traceable method to define the value derived. If, in an ideal world, such a benchmark could be set it would have the additional benefit that it would be unlikely to be subject to significant change as new datasets become available.

As a consequence of having even a single benchmark as outlined above, any data giving an indication of radiosensitivity of the organism type (or types) relative to the benchmark can be used to fix an approximate exposure value giving a similar effect.

In extrapolating information a number of assumptions may be required, depending on the data available which contribute to the comparative radiosensitivity. For instance:

- extrapolation between species may be required, and the degree of taxonomic or physiological similarity between species may be somewhat variable;
- extrapolation based on differing effects end points may be required;
- comparative data may become further removed from the original benchmark(s), such that data for end point X is available for groups ‘a’ and ‘b’, and data for end point Y is available for groups ‘a’ and ‘c’, where the comparison is required for groups ‘b’ and ‘c’.

The key point is that, provided the general rule holds that radiosensitivity can be linked to biologically recognisable organism groupings, approximations based on relative radiosensitivity can be drawn from incomplete, even poor quality, datasets and refined as new data become available to augment or replace previous information. Ultimately, if data for a particular organism group improves sufficiently, a new benchmark value may be added, giving even greater confidence in remaining approximations.

Differences in radiosensitivity are well attested, as discussed in Sections 3 and 5 of the main report.

UNSCEAR [1996] collated data, first presented in the 1960s and 1980s, to construct a figure that indicates the relative sensitivity of a range of organism groups to acute radiation exposure. This was presented in Figure 4 of the main report. A number of concerns associated with this figure were raised in project workshops and reflected in the main body of this report. For example, the groupings are based on very broad taxonomic associations, but important distinctions relating to trophic levels are not considered. Perhaps more significantly, the end point of concern is identified as ‘lethal dose’ but the measure of mortality is not specified (e.g. it is not stated whether this is based on the $LD_{50/30}$ or some other index of mortality). The higher plants are not further differentiated into the major groupings (e.g. gymnosperms, angiosperms) which may evidence different sensitivities and the distribution of responses within each group is not clear (e.g. it is not stated whether the ranges indicated are truncated to reflect quantified confidence intervals, nor what statistical distribution of dose-effect relationships is observed within the range – that is, whether dose-effects are normally distributed, log-normally distributed or asymmetrically distributed around a mean value). Finally, the database is clearly incomplete by comparison to all relevant effects data currently available (being restricted to literature available in the 1960s through to the very early 1980s).

Notwithstanding the above criticisms, the illustration is sufficiently well accepted to allow the general conclusion to be reached that a similar figure *could* be derived which would allow a more or less directly relevant comparison of radiosensitivities to be presented. A hypothetical example is provided, as a means of illustrating such an approach, in Figure B1. Construction of such a figure for practical application would require agreement on an appropriate endpoint of concern (e.g. mortality expressed against a specified index, reproductive success based on an agreed measure of intergenerational cohort recruitment, etc.) and the protection objective to be achieved within the range of the organism-group represented (e.g. 'no effect' or 'limited effect' levels, protective of all or of a specified percentage of species within the group, etc.).

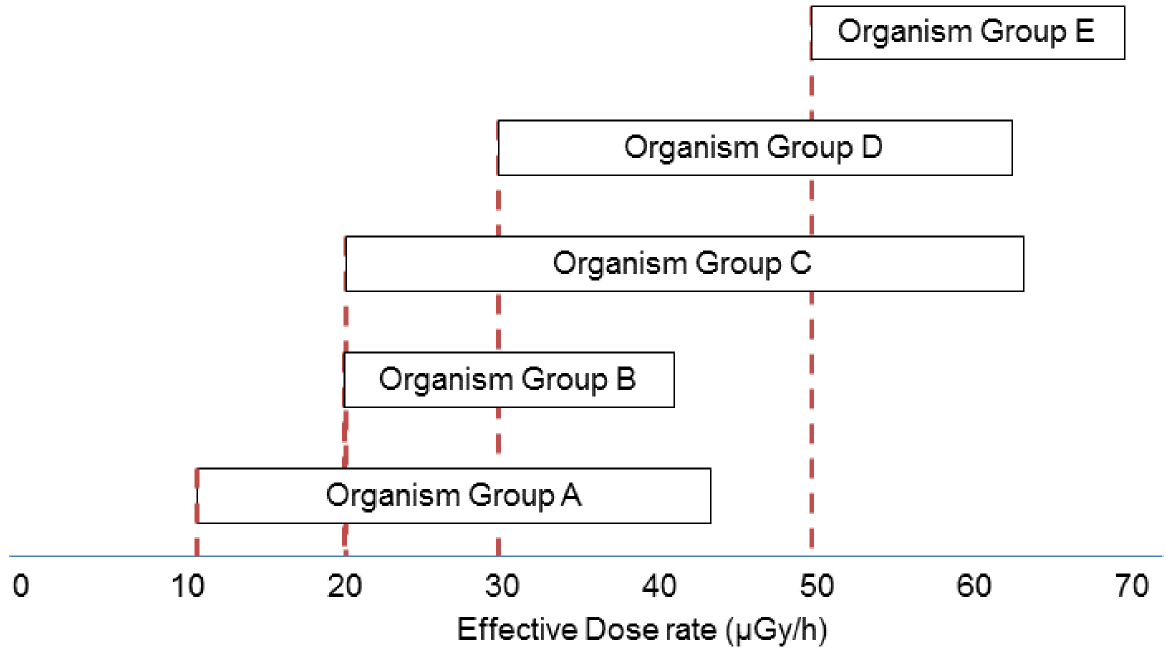

Figure B1 Hypothetical illustration of relative radiosensitivities of different organism groups for a defined effect end-point

Let us suppose that data for organism group A in Figure B1 are considered to be well founded and that the spread of effects data presented for groups B to E all relate to the same endpoint, or which can be extrapolated to provide reasonably similar measures of effect, and that the objective is to avoid any observable effect (i.e. the dose rate is to be restricted to the level at which an effect is observed for the most sensitive species within the group). The relative radiosensitivity of groups B, C, D and E (compared to group A) can be expressed as criterion multipliers of 2, 2, 3 and 5 respectively.

It should be clear from the discussion above that there are four areas for consideration before a 'criterion multiplier' can be derived and applied in a fashion which is likely to achieve some level of broad based support from within the scientific community.

1. Identification of an organism, or related group of organisms, which are well studied and for which dose-effects relationships can be derived with some confidence.

2. Identification of the endpoint(s) of concern.

3. Agreement on the level of protection to be afforded against measures of the agreed endpoint.

4. Selection of the initial benchmark value(s) against which relative radiosensitivites can be expressed.

In order to provide a more practical illustration of the use of criterion multipliers, it may be valid to make some assumptions relating to existing datasets and guidance in order to satisfy the requirements above.

Let us suppose, to satisfy the first requirement noted above, that mammals are a reasonably well studied group against a range of endpoints. This is not unrealistic since much data used to derive human radiological protection criteria are based on observation of other mammalian responses to radiation exposure.

The PROTECT programme identified that if a mammalian-only reference screening level were to be derived based on protection of 95% of all species at a 5% effects level for measures of reproductive impact (see Appendix A for details of the approach adopted), a value of 2 µGy/h could be identified (see Table 3 in the main report and the accompanying discussion in Section 5.2.1 that adoption of this value for screening purposes was *not* recommended). This appears to satisfy the requirements to identify an endpoint of concern (reproduction), a defined level of protection and a corresponding benchmark value.

In theory, it should prove possible to derive an EDR_{20} for mammals by reinvestigating the FREDERICA database in the same way as undertaken within the PROTECT programme (see the discussion in Section 5.2.1 with respect to the relevance of using EDR_{20} as the basis for deriving an illustrative Tier 2 value). Purely for illustrative purposes, let us suppose that a value of 20 µGy/h could be derived as an EDR_{20} based on the FREDERICA database. Again solely for illustrative purposes, the current upper range of the DCRL adopted by ICRP for reference higher vertebrates (40 µGy/h) could be adopted as an alternative Tier 2 benchmark value.

Finally, notwithstanding the reservations expressed above, suppose that the relative radiosensitivities of the major taxonomic groupings illustrated by UNSCEAR [1996] held true when considering chronic exposures for reproductive endpoints. Based on comparison of the most sensitive end of the range indicated for each organism group, hypothetical criterion multipliers (relative to mammals) would be approximately 2 for birds, 3 for higher plants, 4 for fish, etc.

Putting these various suppositions together, illustrative Tier 2 values would be derived as presented in Table B1.

Table B1 Example of derivation of Tier 2 values on the basis of illustrative criterion multipliers

Organism group	Criterion multiplier	Tier 2 value (µGy/h)
Mammals	1	20 - 40
Birds	2	40 - 80
Higher Plants	3	60 - 120
Fish	4	80 - 160
Amphibians	5	100 - 200
Reptiles	5	100 - 200
Crustaceans	8	160 - 320
Insects	10	200 - 400
Moss, lichen, algae	20	400 - 800
Molluscs	80	1600 - 3200

No validity is implied for the values presented, beyond demonstration of the concept.

The conclusion which *is* drawn is that an approach similar to that identified above has the benefit that the derivation of the Tier 2 values would be transparent and alternative values could be derived where this is considered helpful (for example to address organisms with life-stages significantly different from the adult) or as new information becomes available. The most significant advantage of this approach may be that it allows maximum use of data to be made, without implying a level of confidence which cannot be supported on the basis of the extent or quality of information available.

APPENDIX C: EVALUATION OF DATA PRESENTED BY UNSCEAR TO DERIVE TIER 1 OR TIER 2 BENCHMARK VALUES

The project Technical Support Team were tasked at the BIOPROTA workshop held in Glasgow, 6-7 July 2011, to undertake a preliminary examination of the UNSCEAR [2008] underpinning data to determine whether species (or taxa) specific benchmark values may be derived and to evaluate the level of protection implied by the threshold values proposed.

The following presents a brief summary of data available from UNSCEAR [2008]. It is not intended to challenge the benchmark values derived by UNSCEAR but to determine whether supplementary benchmark values may be derived.

UNSCEAR [2008, Volume II, Annex E] reviewed the basis for assessing the effects of radiation exposure to non-human biota, including the choice of reference organisms (see Table C1), radioecological models to be employed, equilibrium transfer factors between components of the environment, evaluation of doses to biota and a summary of dose-effects data (including dose-effects from the Chernobyl accident). They also reviewed their own conclusions presented in UNSCEAR [1996] in the light of more recent evaluations undertaken by the United States Department of Energy, Canada, and the EU FASSET and ERICA programmes.

Table C1 Reference organisms and types considered in UNSCEAR [2008]

Representative organism	Type of organism represented
Earthworm	soil invertebrate
Rat	burrowing mammal
Bee	above ground invertebrate
Wild grass	grasses, herbs and crops
Pine tree	tree
Deer	herbivorous mammal
Duck	bird
Frog	amphibian
Brown seaweed	macroalgae
Trout	pelagic fish
Flatfish	benthic fish
Crab	crustaceans

UNSCEAR [2008] concluded that their previous recommendations remained valid and restated that "*chronic dose rates of less than 100 µGy/h to the most highly exposed individuals would be unlikely to have significant effects on most terrestrial communities and that maximum dose rates of 400 µGy/h to any individual in aquatic populations of organisms would be unlikely to have any detrimental effect at the population level*." This conclusion was supported by a table (Table 39 in UNSCEAR [2008, Volume II, Annex E]) summarising underpinning dose-effects data, indicating 'no detrimental endpoints' to mammals exposed at less than 100 µGy/h and a re-evaluation of data to produce a species sensitivity distribution indicating that 95% of species in both terrestrial and aquatic ecosystems (considered generically) are protected at dose rates of 'about 80' µGy/h.

Independent evaluation of the dose-effects is complicated by the fact that only selective data are tabulated in UNSCEAR [2008], presenting a range of endpoints for different species exposed at different dose levels or at different dose rates (generally without stating the follow-up period for observation of effects and, in the case of exposures expressed as dose rates, often not defining the duration of the exposure). Nonetheless, it is apparent that the datasets reproduced or summarised within UNSCEAR [2008] are generally supportive of higher screening values representing no significant detrimental impact than the 10 µGy/h adopted within the ERICA/PROTECT programmes.

Data presented in Table 23 of UNSCEAR [2008, Volume II, Annex E], reproduced from Kozubov and Taskaev [1990], indicate that below 200 µGy/h only 'minor damage' was observed within coniferous forest in the area around the Chernobyl nuclear power plant within the first few years following the accident in 1986. However, the term minor damage was defined as inclusive of some disturbance to growth, reproduction and morphology, so the evidence is inconclusive with respect to setting a threshold consistent with 'no significant effects' for either coniferous forest or a broader grouping of trees and higher plants.

Data presented in Table 25 of UNSCEAR [2008, Volume II, Annex E], reproduced from Copplestone et al [2003b] (itself derived from the FASSET database), indicate effects of chronic radiation exposure on reproduction in fish. Fish exposed to dose rates in the range 0 to 99 µGy/h were described as the 'background dose group' with 'normal' damage and mortality rates. No data were available in the dose rate range 100 to 199 µGy/h, but at 200 to 499 µGy/h reduced spermatogonia and sperm in tissues was observed. At 500 to 999 µGy/h delayed spawning and reduction in testis mass were observed. Only above 1000 µGy/h was mean lifetime fecundity observed to be decreased, with associated early onset of infertility. The significance of reduced sperm formation is debateable since the high gamete production generally associated with external fertilisation such as exhibited by many fish species suggests this may be of limited consequence unless the decline is dramatic. Nonetheless, it appears that a threshold value for 'no significant effect' would not be lower than 200 µGy/h and could be considerably higher.

UNSCEAR [2008, Volume II, Annex E] also cite a review of data arising from the Chernobyl accident undertaken by Fesenko et al [2005] to produce a table (Table 26) of dose rates below which an effect would not be expected (which they refer to as 'critical exposure doses or CDV_b). For a range of species in both terrestrial and aquatic ecosystems, Fesenko et al [2005] present CDV_b values ranging from 46 µGy/h (for pine and cattle) to 342 µGy/h (for grass and phytoplankton).

Data from the FASSET programme (the FRED database) were also reproduced in part within Tables 30 to 33 of UNSCEAR [2008, Volume II, Annex E]. However, almost all of the data presented relate to observed effects associated with chronic exposure above 100 µGy/h dose rates and, in many cases, relate to dose rates in excess of 1000 µGy/h. UNSCEAR [2008] cite the evaluation of the FRED database for plants, fish and mammals by Real et al [2004] to note that "*the reviewed effects data give few indications for readily observable effects at chronic dose rates below 100 µGy/h*". Indeed below 1000 µGy/h there appears to be little evidence for irreversible impairment, although the general paucity of the database led Real et al [2004] to give a cautionary note when seeking to establish environmentally 'safe levels' of radiation exposure.

Conclusions

Based on this preliminary review of information presented within UNSCEAR [2008], project Technical Support Team conclude that the data are not sufficient in their own right to derive species specific, or even more generic, threshold values below which no significant harm is likely to be observable in the environment. This is not a criticism of UNSCEAR, since the limited database is a restriction on all studies. Nonetheless, the data presented do indicate that use of the generic threshold of 10 µGy/h proposed from the ERICA and PROTECT programmes, and adopted in many studies, as the Tier 1 benchmark is likely to be conservative under most circumstances and a higher, but currently undefined, value could be appropriate.

Adoption of the UNSCEAR values as a Tier 2 benchmark is likely to be equally conservative (since they represent values consistent with no significant effect, rather than a defined but limited effect) but the database presented does not allow alternative values to be derived with confidence.