



PROTECT

Protection of the Environment from Ionising
Radiation in a Regulatory Context
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Deliverable 5

Numerical benchmarks

for protecting biota from radiation in the environment:
proposed levels, underlying reasoning and recommendations

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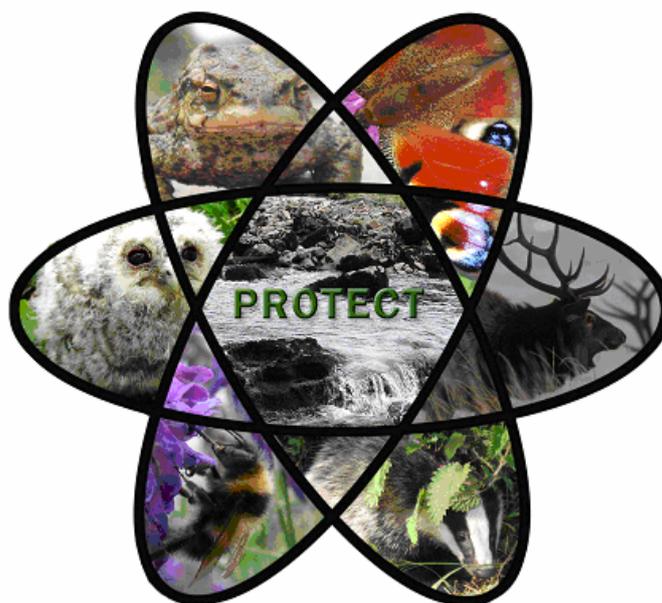
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The EU EURATOM funded **PROTECT** project (FI6R-036425) will evaluate the different approaches to protection of the environment from ionising radiation and will compare these with the approaches used for non-radioactive contaminants. This will provide a scientific justification on which to propose numerical targets or standards for protection of the environment from ionising radiation.



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Executive Summary

The need for a system able to demonstrate that the environment is adequately protected from the effects of radioactive substances has been recognised by international organisations, a number of regulators and many scientists. As a consequence, a number of approaches/tools to estimate dose rates to non-human biota have been developed and some of these are now being used in a regulatory context. Estimated dose rates need to be compared with some form of criteria to judge the level of risk. There is, therefore, a need for predefined dose rate values, or benchmarks, to be proposed and agreed. The transparent derivation of benchmark values, together with the underpinning scientific assumptions is the focus of this report.

The benchmark values derived within the report are screening values. The use of such values (which would typically be used within a tiered assessment framework) is to screen out situations of no regulatory concern. For consistency with chemical risk assessment, PROTECT has adopted the assessment factor and statistical extrapolation techniques as recommended by the EC in the technical guidance document (TGD) on risk assessment. PROTECT has, wherever possible, decided to use the statistical extrapolation techniques (Species Sensitivity Distribution, SSD) to derive our benchmarks. Within this report, we have derived both generic and organism group specific screening values as a basis for further development of the protection of the environment. The FREDERICA database was used to identify references of suitable quality from which EDR₁₀ values (i.e. the dose rate giving rise to a 10% effect in the exposed group in comparison to the control group) could be estimated.

For the estimation of the generic screening value, data for all organism types were used within an SSD. A number of different data treatments were considered, but all of the options we investigated gave a reasonably similar result (giving some confidence in the numbers generated). The methodology thus seems robust when applied to the available data to generate a generic screening value. Although some of the EDR₁₀ values have large statistical errors in themselves the derived HDR₅ value did not change substantially if values with lower associated uncertainty were used or if data were weighted for uncertainty when fitting the distribution. Consequently, we have used the TGD methodology, with simple rules for data selection and without arbitrary weighting, and have some confidence in the robustness of the derived HDR₅ value. As the TGD does not give guidance (other than specifying a range of 1-5) on the assessment factor to be applied to the derived HDR₅ value in order to estimate a predicted no-effects dose rate (PNEDR) value, we used our own selection criteria. However, we acknowledge that there is considerable statistical uncertainty associated with the estimated HDR₅ value, and that the derived PNEDR should therefore be considered an indicative guidance value rather than an exact estimate.

The resultant proposed generic screening value is 10 $\mu\text{Gy h}^{-1}$.

In many cases the most exposed organism type may not necessarily be the most sensitive. Because a generic screening value is applied to all species, its use may result in either: (i) overly conservative assessments which lead to more detailed site-specific assessments which may not be scientifically justified; or (ii) assessments which do not identify the need for more detailed consideration of the more radiosensitive organism groups. Organism group specific screening values may, therefore, be more appropriate than a single generic value. Ultimately, it would be desirable to have screening values for as many relevant groups as justifiable



(probably taxonomically at the family or class level), however, currently we do not have enough data to achieve this. Consideration was therefore given to deriving values for three broad groups, namely plants, vertebrates and invertebrates recognising that these groupings each contain organisms which are likely to have a range of radiosensitivities. Whilst it would be preferable to derive these using the same SSD methodology as applied for the generic screening assessment, the lack of data led us to also consider alternative approaches. The estimated screening values were: (i) vertebrates $2 \mu\text{Gy h}^{-1}$; (ii) plants $70 \mu\text{Gy h}^{-1}$; (iii) invertebrates $200 \mu\text{Gy h}^{-1}$. The vertebrate and invertebrate values were generated using the SSD methodology whereas, because of the fewer available data, the plant value was generated using the assessment factor approach. Taking into account the limited data and uncertainty associated with these estimates, they should be considered as illustrative and indicative of the order of magnitude of values only. However, the organism group values are broadly compatible with the lower end of the derived consideration level (DCL) band for comparable organisms as proposed in the draft ICRP report. Whilst the ICRP values were derived by expert judgement, it is encouraging for both works that similar values have been derived using different approaches.

The conceptual difference between the types of screening value is that the generic value should *protect 95 % of all species* whereas the organism specific values should *protect 95 % of species within each organism group*. Application of a generic screening value may therefore not protect all groups to a 95% level.

An advantage of the SSD methodology is that it can be easily refined as more data become available, and targeted studies could be designed to provide data to enable SSDs to be constructed for organism groupings.

Whilst using a screening value is helpful in identifying when further work is required (or not), an assessor can face a problem when a refined exposure assessment has been completed but the calculated dose rates remain above the screening value. In these circumstances, an assessor cannot easily state with confidence that there will be negligible, or no, impact on biota. Currently there is limited advice on what an assessor should do if the screening value is exceeded. A possible solution is a second, higher, benchmark which identifies, for example, when the risk of impact is 'significant' or 'severe'. This could aid decision making by highlighting where, on the scale of no effect to significant effect, the calculated dose rate is. During the PROTECT consultation it was not possible to reach consensus on the need for this second benchmark with arguments both supporting and objecting to this proposal. The PROTECT consortium recognises that further discussion about the need for this second higher level could be useful. However, it is outside of the scope of the PROTECT project to define such a level as this introduces value judgements and is predominantly a social and ethical decision. The PROTECT consortium suggests that there is a need for a wider discussion on the potential usefulness and application of a second higher benchmark value and this report provides PROTECT's contribution to this debate. We also explore potential approaches which could be used to provide the scientific input to help determine such a level.

The concepts of the screening value proposed by PROTECT and the potential second higher benchmark value (if adopted in the future) can be seen to be broadly consistent with the framework for protection of humans. These concepts could be used within a framework for the protection of the environment which could be applied in parallel to that existing for human protection.



In summary PROTECT recommends the following:

- The use of SSD methodology to derive, or inform the derivation of, numeric benchmarks values where sufficient data are available and that the derivation of any such numbers is clearly documented.
- The scientific community should perform targeted studies to enable SSD to be generated for required organism groups.
- The application of a generic screening value of $10 \mu\text{Gy h}^{-1}$ until sufficiently robust organism group values can be generated.
- The screening value should be applied to total incremental exposure (i.e. it is not a single source benchmark).
- That the concept, use and meaning of a potential second higher level benchmark value is discussed further by the wider community.
- There is a need for co-ordination of the studies required to further develop this area.



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Preface – PROTECT overview

The primary objective of the PROTECT co-ordinated action (CA) is to evaluate the practicability and relative merits of different approaches to protection of the environment from ionising radiation. The project also aims to compare these with methods used for non-radioactive contaminants, particularly with respect to European frameworks for chemicals. This will provide a basis on which the EC could develop protection policies and revise its Basic Safety Standards, and ensure a fruitful collaboration with, and constructive input into, current ICRP and IAEA task groups.

The specific objectives of the PROTECT project are to:

- evaluate current regulatory approaches in different countries to the protection of the environment from both radioactive substances and chemicals and to determine how end points of protection are currently applied within the different regimes
- identify differences and similarities between the approaches used for protection of the environment from chemicals and radiation
- recommend common approaches to the protection of the environment, bearing in mind any broader environmental protection objectives
- evaluate the practicability of existing and developing approaches to explicitly protect non-human biota
- consider the acceptability and relevance of current approaches with respect to the needs of industry and regulators, and the different scenarios any such approach may need to address
- test available approaches against any relevant ICRP recommendation or outputs from PROTECT
- assess the availability, usability and transparency of available approaches to groups other than those involved in their development
- derive an extended set of numerical target values and explain their derivation methods, designed to assure compliance to environmental protection goals that are consistent with protection goals for releases of hazardous substances in general, and to assess the implications for society at large

1. Introduction

The need for a system able to demonstrate that the environment is adequately protected from the effects of radioactive substances has been recognised by international organisations (e.g. IAEA (2006), ICRP (2007a), OECD-NEA (2007)), a number of regulators (e.g. Environment Canada, 2003; USDOE, 2002; Copplestone et al., 2001) and many scientists (IUR, 2000;2002). In part, this has been in response to new regulatory drivers, such as those associated with conservation (e.g. Copplestone et al., 2003). As a result, the last decade has seen considerable international and national effort on this issue with environmental protection now being referred to in the International Atomic Energy Agency's (IAEA, 2006) Fundamental Safety Principles as well as in the Recommendations of The International Commission on Radiological Protection (ICRP, 2007a). In addition, the forthcoming revision of both the International and EURATOM Basic Safety Standards intend to address radiological protection of the environment. To date, the focus has been on collating relevant information and developing, and more latterly comparing, approaches to enable regulatory assessments (e.g. Vives i Batlle et al., 2007; Beresford et al., 2008d). The approaches need to be practicable, credible to stakeholders and fit for purpose in any regulatory context and a comparison of the relevance and usefulness of these approaches is addressed in a further PROTECT report (Beresford et al., 2008c).

Clearly, estimated dose rates need to be compared with some form of criteria to judge the level of risk. There is thus a need for predefined dose rate values, or benchmarks, to be proposed and agreed. The PROTECT project has already reviewed national and international regulatory methods and criteria being used for protection of the environment (from radiation and chemical stressors). PROTECT has also consulted widely with industry and regulators within Europe and the broader international community about their views, and what they see as potential future developments, on this issue (Hingston et al., 2007a). The recommendations of relevance to this report arising from this consultation were as follows:

- In a regulatory context, environmental protection goals aim to protect populations of wild organisms and should be translated into measurable targets with advice on what the tolerable risks associated with these endpoints should be. Forbes et al. (2001) suggest that endpoints that relate stressor levels to measurement endpoints such as mortality, morbidity and reproduction should be targeted because ecological theory shows that these traits determine population sustainability. A caveat regarding protection at the population level is that individuals may need to be considered specifically when it comes to rare or endangered species.
- There is a strong advocacy for linking radiological protection to the processes used for chemicals assessment. Although there are some technical differences, the underlying protection goals are similar and broadly the same risk assessment approaches may be used. For example, the use of Species Sensitivity Distribution and Assessment Factor approaches to extrapolate from data using single species as a basis for benchmark dose rates should be encouraged, and the use of purely expert judgement should be avoided where possible because it lacks transparency.
- The use of the numeric (dose rate) values currently being applied, or suggested, should be assessed and the need for screening values and 'standards' considered. Where possible, harmonisation of future international guidelines and recommendations should



be attempted (for example, IAEA and EC Basic Safety Standards and ICRP Recommendations).

- PROTECT should produce a clearly understandable document outlining the derivation of any numeric benchmark values, including an explanation of where there are limitations in the application because of poor data quality and the level of conservatism in the benchmark values. This document should be developed in consultation with stakeholders.
- The justification and optimisation of discharges should remain central to environmental and human radiological protection. Radiological benchmarks effectively supplement these principles so that attention can be focused where it is needed.
- The positive benefits of regulation for the nuclear and non-nuclear sectors should be identified as they are likely to demonstrate that users of radioactive substances are behaving in an appropriate and environmentally responsible manner. Emphasising and highlighting this could be beneficial in terms of large scale environmental issues such as comparison of energy technologies.

Numerical values that, in various ways, are indicative of effects on non-human biota have been published by, for example, the IAEA (1992) and UNSCEAR (1996). ICRP (2007b) has also recently circulated a draft report for consultation suggesting an approach based on Reference Animals and Plants (RAPs), including “derived consideration levels”. The ICRP further suggest that applied and specific numerical approaches be developed by national and other bodies. Similarly, the Nuclear Energy Agency (NEA, 2007) has recognised the importance of identifying pertinent endpoints defining environmental protection and development of tools that can link data to protection of the environment.

The derivation of benchmark values, together with the underpinning scientific assumptions and transparent justification is the focus of this report, the aim being to suggest:

- a coherent approach encompassing relevant protection goals - matching measurement and assessment endpoints
- meaningful and usable conceptual benchmarks derived by transparent and scientifically justifiable methodologies.

Earlier drafts of this report were made available for consultation, including discussions at a PROTECT workshop involving independent experts (Andersson et al., 2008). Where possible this final report takes into account comments received during these consultations and Deliverable 5 Annex documents the comments received and our responses.



2. Protection goals

The goals of environmental protection, for instance as laid out in the Rio declaration, can be defined on a number of different levels, and reflect a variety of philosophical, political and pragmatic views. A questionnaire survey of stakeholders carried out within earlier work of PROTECT suggested that current aims within legislation regarding environmental radiation are generally of an aspirational and unspecific nature such as “protect the environment” (Hingston et al., 2007a). To make such aims practicable and achievable, within a regulatory context, there is a need for more precise and concrete measurable protection goals. Protection goals could be set at different levels, ranging from structural goals (e.g. to protect all individuals of all species) through to functional goals (e.g. to ensure ecosystem function). The fulfilment of a structural goal would imply fulfilment of functional goals, whereas the opposite may not be true. Even within structural goals there are different levels of protection in practice. For example, the 2003 radioactive substances strategy adopted by the OSPAR Commission seeks to achieve a high level of environmental protection by: *"preventing pollution of the maritime area from ionising radiation through progressive and substantial reductions of discharges, emissions and losses of radioactive substances, with the ultimate aim of concentrations in the environment near background values for naturally occurring radioactive substances and close to zero for artificial radioactive substances"*.

In the OSPAR context, the environmental protection objective was set without reference to a specific evaluation of the radiological impact on biota. However, to achieve this objective, evaluation of the impacts of ionising radiation on organisms is to be taken into account alongside several other considerations.

Theoretically, protection at the level of individuals implies that no severe effects would be accepted even to the most exposed and most sensitive individual. This approach raises questions regarding, for example, defining unacceptable types of effects on the individual, individual variability in radiosensitivity, localised pollution, and, indeed, the costs to society of setting such a stringent goal. For example, adopting such a goal would mean that even individuals with, for any reason, unusually high radiosensitivity that reside as close as possible to a discharge point should not be allowed to show any effect that could be regarded as unacceptable. Such a goal, if employed to all environmental effects caused by human activities (e.g. the actual building of a NPP or operation of a water power plant which resulted in reduced river flow downstream), would clearly not be feasible. This level of protection is only applicable for rare and endangered species and is not used to set the framework for regulation of environmental stressors such as chemicals. Therefore, it is the opinion of the PROTECT consortium that a protection goal for environmental radiation should not be aimed at individuals of non-human biota which are not endangered. However, as discussed below, a protection goal aiming at populations may well imply that regulation would ensure that individuals of certain (e.g. endangered) species are not severely affected.

The most commonly used approach for environmental regulation is to protect at the level of all populations. In this case, it could be acceptable that individuals are severely affected as long as this does not threaten the viability of the population.

Protection of a population requires that increased stress does not significantly affect those statistics or life traits on which the population depends for its maintenance within the dynamic



range of variation resulting from interactions of physical, chemical and biological factors. These life traits are amalgamations of properties that relate to individuals.

There are different ways in which individuals could be severely affected without populations being threatened, namely:

- (i) Only the most sensitive individuals are affected and a sufficient number of more radiation-tolerant individuals are fit enough to sustain population dynamics. In this case, concern could possibly be raised (at least from an ethical point of view) about genetic selection and decreased ability to adapt to a further changing environment.
- (ii) Only part of the population is exposed and affected. This could mean that the area inhabited by stationary organisms, such as plants, is decreased, or that the most exposed individuals of mobile organisms, such as those with a home range in the exposed area, become less fit/reproductive, although the population as a whole is not at risk if the remaining part of the population's habitat is sufficient to sustain the population.

There is no need to introduce a new protection (individual level) goal for rare species as in the assessment process it may be concluded that, to protect a rare species, no individuals could be severely affected without also putting the population at risk. In cases where rare or protected species are exposed, regulatory action could thus be taken to ensure protection of individuals although the protection goal remains at the level of populations. There may be situations where a particularly sensitive species is present at a site, which is not considered to be a foundation¹ or keystone species² and is also present at other sites. In this case, it might be judged to be acceptable to violate the goal to protect all populations if a certain activity is judged to be allowable based on other socio-economic considerations. Alternatively it might be deemed that the benefits of the proposed activity were not sufficient to offset the risk to a particular population, even if exposures were below the protection levels.

If the aim is to protect ecosystem function, then arguably only foundation or keystone species need to be considered; this may only need to be the least radiosensitive species capable of performing critical ecosystem functions. However, this approach would raise questions about our ability to identify foundation and keystone species, their dependency on other species, and the ability for the environment to respond to future challenge. Furthermore, this level of impact is unlikely to be acceptable to most stakeholders, not least because those species which we 'care' most about may be among the most affected.

A more realistic use of the combined approaches of protection of ecosystem function and protection of all populations, is to state that to achieve the goal of sustained ecosystem functioning, the exposure from radiation should not impose a severe risk to the populations of the vast majority of species. So, it could be acceptable to put populations of the most sensitive species at risk, if ecosystem function is still thought to be protected. In this case, special attention is needed in the assessment to make sure that foundation species, keystone species,

¹A foundation species is defined here as: highly interactive species that are often extremely abundant or ecologically dominant

²A keystone species is defined here as: a species that plays a critical role in maintaining the structure of an ecological community and whose impact on the community is greater than would be expected based on its relative abundance or total biomass



threatened or protected species, or species of special symbolic or commercial value are not amongst those species that are assumed to be put at risk. This principle underlies most environmental legislation (and associated technical guidance) concerning chemical regulation.

Following consultation, PROTECT suggests the following general protection goal:

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

Tools developed for assessing the impact of radioactivity on the environment often use some form of ‘reference organism’ concept (Beresford et al., 2008c). It has been suggested that: ‘A *reference organism approach may help with assessments and may also have a role to play as part of a system of radiological protection of the environment. However it does not constitute such a system on its own. A comprehensive approach is needed in order to provide a sufficient basis for developing an effective system for protection of the environment and a framework for decision-making concerning future nuclear activities. At the core of such a system would be an ecosystem-based and precautionary approach, drawing on developments and experience in environmental protection across a range of disciplines, industrial sectors and human activities. A reference organism approach could form a complementary part of such a system.*’ Carroll (in-press³).

PROTECT recognises that, in a specific case, its suggested protection goal might be further governed by legislation or guidelines, such as conservation orientated protection goals. However, the protection goal is consistent with those used in the assessment of other environmental stressors, such as chemicals. The reference organism approach coupled with such a protection goal represents, in our view, a pragmatic approach to assessing the exposure and risk to biota.

2.1 A measurable protection goal?

As stated in the section on protection goals above, regulators need goals at which to aim their regulatory action, and these goals need to be measurable to be able to evaluate whether regulation has succeeded in reaching the goals or not.

Conformity with the goal suggested by PROTECT could be demonstrated in a number of ways if required for example:

- Media and/or biota concentrations or environmental dose rates could be determined to ensure that numeric dose rate benchmarks are not being exceeded; the measured activity concentrations would be compared to predefined concentrations calculated to result in a dose rate equal to the screening dose rate (see Brown et al., 2008 and USDOE, 2002 for examples of this). Such a programme could utilise on-going monitoring conducted in relation to human radiological protection.
- Sensitive, keystone, foundation, rare or protected species could be monitored for changes in population relevant parameters (such as population density). Such information gives a direct indication of the health of a population. However, alone it does not identify the cause of any change in the parameter measured.

³ See also comments submitted in response to the first consultation on this report (Andersson et al. 2008).



These two approaches could be used in combination to help identify the causative agent(s) giving rise to an observed response. Having identified the causative agent(s) appropriate risk reduction measures could be targeted.

The remainder of this report reviews previously published numerical values and proposes how the recommended protection goal could be implemented by applying one or several benchmark values that could be used as indicators of compliance with the goal.



3. Overview of previously 'proposed' numeric benchmark values

A number of publications have reviewed and compiled data from the available literature on the effects on biota of ionising radiation or radionuclides in the environment (NCRP, 1991; IAEA, 1992; UNSCEAR, 1996; Environment Canada, 2003; Thompson et al., 2005; Garnier-Laplace and Gilbin, 2006; ICRP, 2007b). The methodology of derivation, the proposed interpretation, and the level of protection (individuals, populations, ecosystems) targeted varies between the studies. Generally, these publications refer to incremental exposure (i.e. above background) when the effects at different exposures are discussed, although the derived numerical values are not always specifically stated as referring to incremental dose rates. These existing numerical values are briefly discussed and compared below.

3.1 Level of targeted protection

Most existing numerical values are intended to protect populations, thus in one way or another they are intended to relate to effects at the level of populations (see Tables 1 and 2). However, this does not mean that the values are necessarily derived from observed effects on populations or even that the whole population is assumed to be exposed at the given dose rate. Whereas the protection goal is set at the level of population, experiments evaluating effects on populations at varying dose rates are scarce. Instead, most data address measurement endpoints at the individual level. To derive numbers that are relevant at the population level, only data for measurement endpoints that are directly relevant to population dynamics should be used in approaches to derive numerical values. However, the relevance of different endpoints is debatable and will inevitably be open to varying interpretation (see discussion later).

IAEA (1992) included mortality, fertility, fecundity, growth rate, vigour and mutation rate in their consideration of the data available by the early 1990s. NCRP (1991) also published a literature review on effects of ionising radiation on aquatic organisms, also considering all these endpoints. Subsequently, UNSCEAR (1996) considered all of these endpoints except growth rate.

Garnier-Laplace and Gilbin (2006) considered morbidity (including growth rate, effects on the immune system, effects on behaviour linked to central nervous system damage), mortality (including stochastic effects such as cancer formation, and deterministic effects which alter mortality rates and life expectancy) and reproductive capacity (including fertility, fecundity, embryo development) as relevant for use on the population level. Mutation effects were not used in the derivation of numerical values because these were considered to be generally low level effects with no direct relevance to ecological effects.

In the Canadian approach (Environment Canada, 2003), reproduction (processes from gametogenesis to embryonic development) was considered to be the most likely limiting endpoint. Genetic damage *per se* was not considered because of the difficulty in interpreting its significance at the population level, instead relevant genetic effects were assumed to be incorporated in measurements of reproductive effects.

ICRP (2007b) considers mortality, morbidity, reproduction impairment (fertility and fecundity) as well as DNA damage (chromosome aberrations and mutations).



All of the above reviews have predominantly looked at effects that are measured at the individual level but which are of relevance for the population. The level of effect, when specified, is taken as the effect on individuals and few attempts have been made to extrapolate from individual to population effects. Dynamic population models have been used to rank the sensitivity of the population growth rate to individual endpoints, and it has been demonstrated that equal levels of effect on different individual endpoints might have different impacts on population dynamics depending on life history strategies of the species (Stark et al., 2004). This was corroborated in studies using ionising radiation by Alonzo et al. (2008) who demonstrated that population effects depended on the life-cycle traits of the considered species. Thus, while individual effects data can form the basis of assessing ecological risk, these effects should preferably be supported by integrating impacts on key-cycle variables via population growth rate analysis (Forbes and Calow, 2002)

A different approach was adopted by Thompson et al. (2005) who derived numerical values for radionuclides in sediments looking directly at the population level by assessing the occurrence/absence of sediment dwelling species within the benthic invertebrate community at different radionuclide activity concentrations in the environment. To our knowledge, this is the only approach taken to propose radiological benchmark values which explicitly evaluated population effects.

3.2 Deriving a benchmark - expert judgement or formalised methods?

The numerical values resulting from the above publications (compared in Table 1) all originated from a literature review and were derived using varying degrees of expert judgement and are reported with different levels of transparency. The earlier reviews tend to rely on expert judgement whereas later approaches use more formalised methods consistent with those used for chemicals.

The numbers derived by IAEA (1992) and UNSCEAR (1996) involved expert judgement based on reviews of the available data on effects. There is no information on factors such as (i) whether key studies were given greater weight; (ii) if specific criteria were used to include a study for consideration; (iii) how the derived value is set relative to results from the studies; or (iv) the degree of conservatism in the method used.

One important issue, further decreasing the transparency of how some of the values should be applied, is that they do not explicitly refer to a dose rate applied to the whole population, but rather use statements such as “maximally exposed individual”, “most exposed individual” or “a small proportion of individuals” (see Table 2). Furthermore, these statements are not used consistently across the different biota categories within a single document. It is, presumably, assumed that the dose rate to the population in general is less than to the specified more highly exposed individuals. However, it is unclear how much less the typical dose rate in the population should be to conclude that the population is protected. NCRP (1991) stated that such guidelines must be used with care if substantial proportions of the population are exposed.

Benchmark values which are being used in assessments by USDOE (2002) and the England and Wales Environment Agency (Coppstone et al., 2001) were derived from a consideration of the UNSCEAR, NCRP and IAEA outputs.



ICRPs draft report (2007b) has recently developed “derived consideration levels” (DCLs) for each of their proposed Reference Animals and Plants⁴. These are one order of magnitude broad bands of dose rates (Table 1) covering the level where the dose rates warrant a more considered level of evaluation of the situation. The derivation of DCLs used expert judgement to define the values. The draft ICRP report recognises that this was based on “*informed opinion and not on any statistically derived, or rigorously reviewed and defensible, analysis of all the available data*”. The draft ICRP report stated that ‘It intended that this framework should therefore serve as a basis from which national and other bodies could develop, as necessary, more applied and specific numerical approaches to the assessment and management of risks to non-human species under different circumstances, and different exposure situations’.

In the Canadian approach (Environment Canada, 2003) a clearer framework for the expert judgement is specified based on the methodology used in assessments of other chemicals. Literature searches have been used to identify a critical toxicity value from the lowest discernible dose where there is an effect. To derive an estimated no effect value an assessment factor of one was applied. The expert judgement used in this approach therefore included selecting appropriate studies and the value of the assessment factor (AF) (which in this case gives no additional conservatism). However, the derivation of the benchmark value is more transparent than the expert reviews discussed above. In contrast to the numbers derived by IAEA and UNSCEAR, the Canadian numbers are defined as referring to dose rates experienced by the population in general.

The numerical values derived within the EURATOM funded ERICA project (Garnier-Laplace and Gilbin, 2006; Garnier-Laplace et al., 2006; 2008) were derived using methodologies used for chemicals as described in the European Union Technical Guidance Document (EC, 2003; hereafter referred to as the TGD). Several stages of the derivation involved expert judgement, but these decisions were documented throughout so the process was relatively transparent compared to many of the other documents. There was one generic value derived within the ERICA project, which was considered protective of the structure and function of generic ecosystems (including all organism groups), whereas in the other approaches different dose rate values are assigned to different organism groups. The ERICA value was defined to be used only as a screening dose rate (for use in lower assessment tiers) applicable to incremental (i.e. above background) exposures.

In the study by Thompson et al. (2005), activity concentrations of different radionuclides (²²⁶Ra, ²¹⁰Pb and ²¹⁰Po) and metals in sediments were evaluated in a similar way to that previously used for other hazardous substances. In this approach, using a formalised methodology, no dosimetry was needed as the occurrence or absence of species in the sediment invertebrate community was compared directly with individual radionuclide activity concentrations. The rationale behind the derivation involves a species specific concentration (the 90th percentile of sediment activity concentrations where the species is still present) and a type of species sensitivity distribution where the ‘lowest effect level’ was set at the 5th percentile of the species specific activity concentrations. Separate numerical values, expressed as Bq g⁻¹ rather than μGy h⁻¹, were derived for each radionuclide independent of the activity concentration of other radionuclides or metals which may have been present.

⁴ A revised draft of the ICRP has subsequently been approved by the ICRP main Commission.



Table 1. Numerical values (dose rates or sediment concentrations) proposed by various authors relevant for protection of populations. Note that the meaning and intended use of the values differ (Table 2).

	NCRP (1991)	IAEA (1992)	UNSCEAR (1996)	Environment Canada, 2003	ERICA ¹	ICRP (2007b)	Thompson et al., 2005 ²	ERICA Tool ³
	$\mu\text{Gy h}^{-1}$						Bq g^{-1}	
Terrestrial								
<i>Plants</i>								
Reference Pine tree ⁴		400	400	100	10		4-40	
Reference Wild grass							40-400	
<i>Animals</i>								
Invertebrates		40	40-100		10			
Reference Bee				200			400-4000	
Reference Earthworm							400-4000	
<i>Birds</i>								
Reference Duck							4-40	
<i>Mammals</i>								
Reference Deer				100			4-40	
Reference Rat							4-40	
Aquatic								
<i>Freshwater organisms</i>								
Algae	400	400	400		10			
Macrophytes				100				
Benthic invertebrates				100				
Ra-226				200				0.1-0.6
Pb-210								0.5-0.9
Po-210								0.6-0.8
Reference Frog							4-40	
<i>Fish</i>								
Reference Trout				20			40-400	
<i>Marine organisms</i>								
Reference Crab	400		400		10		400-4000	
Reference Flatfish							40-400	
Reference Brown seaweed							40-400	
<i>Deep ocean organisms</i>		1000			10			

¹Garnier Laplace and Gilbin, 2006

²Two Lowest Effect Level (LEL) values were derived with different statistical approaches to estimate the 5th percentile from the available data.

³The estimated sediment concentrations corresponding to dose rates of $10\mu\text{Gy h}^{-1}$, derived, for comparison with Thompson et al., using default parameters for insect larvae and Tier 3 of the ERICA Tool.

⁴Reference 'organism type' refers to the ICRPs proposed Reference Animals and Plants.

3.3 Comparison of existing numerical values

The numerical values resulting from the above reviews and analyses are compared in Table 1. The numbers are difficult to compare as they are stated to be indicative of different broad organism groups. For example, the ERICA screening value is intended to protect all organism groups (entire generic ecosystems) whereas the Environment Canada approach suggests values for smaller groups such as benthic invertebrates. Furthermore, some of the values suggested by IAEA and UNSCEAR refer to the most exposed individual rather than the population as a whole, which appear to be in contrast with the other approaches. As can be seen from Table 2 the explanation of the values quoted by UNSCEAR and IAEA differs between organism groups. However, a few comments can be made.



Table 2. The wording from source reviews regarding the numerical values presented in Table 1.

	Terrestrial plants	Terrestrial animals	Aquatic organisms
NCRP			It appears that a chronic dose rate of no greater than 0.4 mGy h ⁻¹ to the maximally exposed individual in a population of aquatic organisms would ensure protection for the population. If modelling and/or dosimetric measurements indicate a level of 0.1 mGy h ⁻¹ , then a more detailed evaluation of the potential ecological consequences to the endemic population should be conducted
IAEA	It would appear that there are unlikely to be any detrimental long term effects on plant communities in which the maximum dose rate is on the order of 10 mGy d ⁻¹ or less	Irradiation at chronic dose rates of 1mGy d ⁻¹ or less does not appear likely to cause observable changes in terrestrial animal populations	It appears that limitation of the dose rate to the maximally exposed individuals in the population to <10 mGy d ⁻¹ would provide adequate protection for the population
UNSCEAR	Chronic dose rates less than 400 µGy h ⁻¹ (10 mGy d ⁻¹) would have effects, although slight, in sensitive plants but would be unlikely to have significant deleterious effects in the wider range of plants present in natural plant communities	For the most sensitive animal species, mammals, there is little indication that dose rates of 400 µGy h ⁻¹ to the most exposed individual would seriously affect mortality in the population. For dose rates up to an order of magnitude less (40-100 µGy h ⁻¹), the same statement could be made with respect to reproductive effects.	For aquatic organisms, the general conclusion was that maximum dose rates of 400µGy h ⁻¹ to a small proportion of the individuals and, therefore, a lower average dose rate to the remaining organisms would not have any detrimental effects at the population level.
Environment Canada	An assumption is made that a radiation dose level can be defined, an environmental no effects value (ENEV), where the probability of an effect is so low that the population of organisms will not be affected. The ENEV is thus intended to represent effect thresholds for sensitive endpoints that clearly have ecological relevance. In this assessment the ENEV was set with as much rigor as possible (i.e., small application factors; minimal conservatism).		
ERICA	The default screening criterion in the ERICA Integrated Approach is an incremental dose rate of 10 µGy h ⁻¹ , to be used for all ecosystems and organisms. This value was derived from a species sensitivity distribution analysis performed on chronic exposure data in the FREDERICA database and was supported by other methods for determining predicted no effect values (as described in Garnier-Laplace and Gilbin, 2006).		
ICRP (draft)	The Derived Consideration Levels are NOT intended to be regarded as dose limits, or ‘substitute’ values for them. They are zones of dose rates at which, with respect to the Reference Animals or Plants, or types similar to them, a more considered level of evaluation of the situation would be warranted. It does not imply that higher dose rates would be environmentally damaging, nor that lower dose rates were in some way ‘safe’ or non-damaging. But they are dose rates that could be used in any management action or decision-making process, in terms of being starting points from which further, auditable, information could be appended in order to justify or optimise any subsequent action that was taken.		
Thompson et al.	The LEL [Lowest Effect Level] represent the contaminant concentration below which harmful effects on benthic invertebrates are not expected. Benthic communities were considered to be not adversely affected if there was less than a 20% reduction in abundance and species richness relative to the reference. Each radionuclide was considered separately even if other radionuclides (or non-radioactive contaminants) were present.		



The lowest dose rates quoted by each approach (i.e. a dose rate which could be inferred to be relevant for the protection of *all* organism groups) are broadly comparable and all within an order of magnitude: 4-40, 10, 20, and 40 $\mu\text{Gy h}^{-1}$ as suggested by ICRP, ERICA, Environment Canada and IAEA/UNSCEAR respectively. However, there is no general agreement on which organism group is the most sensitive, and none of the approaches seems to consistently yield the highest or lowest dose rates for different organism groups. IAEA and UNSCEAR identify terrestrial animals as being more sensitive, whereas, by deriving their benchmark values on the basis of the lowest observed effect level, Environment Canada identifies the most sensitive as freshwater fish. The IAEA documents considered plants relatively insensitive compared to terrestrial animals, whereas the ICRP DCLs are comparable for pine trees and mammals.

Most approaches have derived numerical values with respect to dose rates, which is a particular characteristic (and advantage) of radionuclides compared to other hazardous substances. This is because (i) there are external doses to account for in addition to internal dose and (ii) the doses from all different radionuclides can be summed directly as the dose-response relation is assumed to be the same for all types of radiation exposure (with the use of an appropriate weighting factor for different radiation types). The exception is the lowest effect level (LEL) values for sediment radionuclide concentrations derived in Canada (Thompson et al., 2005), which are radionuclide specific and expressed in Bq g^{-1} . To compare these to the other dose rate values, we have used the default transfer parameters and dose conversion coefficients for aquatic insect larvae provided within the ERICA Tool (Brown et al., 2008) to estimate the sediment activity concentrations (presented in Table 1) which would give rise to a dose rate for each radionuclide of 10 $\mu\text{Gy h}^{-1}$. Whilst the predicted sediment concentrations are similar to the Canadian LELs for ^{226}Ra , they are considerably higher for the other two radionuclides. However, an important difference is that in the approach of Thompson et al. the effect of a single radionuclide is evaluated under varying exposures to other contaminants, including chemical stressors, which may or may not correlate with the radionuclide evaluated. The relatively low LEL for ^{210}Pb and ^{210}Po may therefore be explained by correlated sediment concentrations of ^{226}Ra , ^{210}Pb , ^{210}Po and metals. Using the ERICA Tool calculated dose rates from ^{210}Pb and ^{210}Po at the suggested LEL-values are 0.1 and 0.01 $\mu\text{Gy h}^{-1}$ respectively. This highlights the benefit of using dose rates, which combine all radionuclides as all approaches other than that of Thompson et al. have adopted, and also the need to further develop our understanding of synergistic effects of radionuclides and other contaminants and how to address this issue during risk assessment.



4. Numerical values proposed by PROTECT for risk assessment

4.1 Introduction

Numeric criteria may be used in a variety of ways as part of a regulatory scheme and this diversity must be considered when deriving them. Two contrasting uses are when a numeric criterion is set as: (i) a legally binding condition (a standard) or (ii) a 'trigger' in a decision-making framework.

In chemicals regulation, examples of legally binding standards include Air Quality Guidelines and EQSs (environmental quality standards) for the protection of aquatic biota under the EC Dangerous Substances Directive. These would typically apply in the ambient environment, but are translated into emission limits on discharges to air or water to take account of local factors such as the amount of dilution and dispersion provided by the water flow in the receiving river etc. In this type of direct regulation, compliance must be demonstrated, usually by sampling of the environment or of the undiluted discharge. The consequences of failing the standard can be serious, possibly resulting in legal action and/or an obligation to take steps to reduce emissions to a level where they will comply with the standard. It follows that there must be a high degree of confidence that a breach corresponds to an 'unacceptable risk' for the environment, i.e. is fairly likely to result in unacceptable effects.

Numeric values may also be used as screening (or trigger) values where exceeding the value in itself carries no serious consequences. Instead, exceeding the value requires further work to better understand the risks at the site of interest. Such screening values are typically used within a tiered assessment scheme meaning that "failure" at an early (simple) tier might change to "pass" at a later tier after more work have been done on either the site specific dose-effects or refining the exposure assessment. It might also be concluded that exposures above the screening value might be permissible due to site-specific risk factors or socio-economic considerations.

It is sensible for the screening value to be precautionary to try to ensure a low incidence of false negatives. The associated risk of false positives is reasonable because failure to comply with the screening value initially prompts only a modest response (i.e. a refined and more realistic assessment).

Consultations with experts during PROTECT workshops have resulted in recommendations regarding requirements of any proposed numerical values. These were that values should:

- have a clearly intended meaning and use
- be related to the protection goal
- be fit for purpose
- be derived using a formalised transparent methodology consistent with those used to set numeric values for chemicals.

There was also general acceptance that a 'screening value' should be derived for use in risk-based regulation. This is intended to screen out benign scenarios so that attention can focus on those where there is a potential risk.



4.2 Screening value(s) – meaning and intended use

The screening value is the most central benchmark value discussed within PROTECT, its purpose is to screen out situations of no regulatory concern (Figure 4).

The assessment process would typically go through a tiered approach. The inputs and parameters used within the initial tier of assessment models are, in themselves, conservative (e.g. using maximum or 95th percentile values) (Brown et al., 2008; USDOE, 2002) and enables sites potentially at risk to be identified whilst excluding from further assessment those which present no risk, thereby making best use of resources. This represents a proportionate risk based approach to regulation (Hutter, 2005; Oughton et al., 2008).

If the dose rate to populations of any species estimated from the simple conservative assessment exceeds the screening value, this only tells the assessor that a more realistic assessment of the site is warranted. The greater degree of realism would be achieved by a more refined exposure assessment (e.g. potentially using site specific measurements of biota activity concentrations) which still should use the same benchmark (i.e. the screening level).

Within the assessment process, exceeding the screening level after a more refined exposure assessment would highlight a need to consider the level of potential impact in more detail. Some form of additional assessment or management action may be undertaken (e.g. site specific effect assessment, increased monitoring, biological surveillance, optimise processes to reduce discharges). However, there may be reasons why exceeding the screening level can be justified (e.g. for social and economic benefits); the screening level **is not** proposed as a prescriptive limit which must not be exceeded.

To efficiently achieve this screening capability, we need a simple, ideally generic, conservative benchmark which can be applied across species and preferably ecosystems. However, as the exposure as well as sensitivity might differ widely between organism groups living within the same ecosystem, a generic value might not be fit for purpose (as also recently recognised by Brownless (2007)). In many cases the highest exposure is likely to be estimated for a comparatively radioinsensitive organism (e.g. for 59 of the 63 radionuclides considered within the ERICA Tool invertebrate organisms, plants or phytoplankton are the limiting freshwater organism) (Beresford et al. submitted). Conversely, vertebrates which are generally considered to be the most radiosensitive organisms are comparatively rarely identified as the limiting organism because they are less exposed. A generic screening value may therefore result in either: (i) overly conservative assessments which lead to more detailed site-specific assessments which may not be scientifically justified; or (ii) assessments which do not identify the need for more detailed consideration of the more radiosensitive organism groups. Organism group specific screening values may, therefore, be more appropriate than a single generic value.

Although the complexity of the screening process possibly increases with multiple screening values based on organism groups, the derivation was broadly supported by participants at a PROTECT workshop, with the caveat that data would need to be sufficient (Andersson et al., 2008). Multiple values are already in use in Canada and, in a more simplistic way, in the USA (Table 1); they have also been suggested by the ICRP (2007b). However, the scarcity of data makes the derivation of organism group specific screening values challenging and consequently both generic as well as organism group specific screening values are subsequently derived and discussed within this report.



4.3 Methodology to derive the screening value(s)

4.3.1 Overview of methods

Within chemical risk assessment, three main methodologies are commonly used for deriving environmental benchmarks:

- Deterministic, based on the application of Assessment (or Safety) Factors to a single species sensitivity value (the most sensitive species observed).
- Probabilistic, based on Species Sensitivity Distribution (SSD) modelling.
- A weight of evidence approach, typically using data from field exposures.

The two first approaches are currently used for chemicals under the European recommendations from the Technical Guidance Document (TGD) (EC, 2003). The aim of these two methods is to derive the Predicted No-Effect Concentration (PNEC). Within the TGD this is based on critical ecotoxicity values (e.g. stressor level in a given medium representing the no observed effect concentration (NOEC) or a 10% effect in the exposed group in comparison to the control group (EC₁₀) for chronic exposure, or 50% effect (EC₅₀) for acute exposure conditions). Such ecotoxicity values are derived from individual experiments for as many species as possible for the contaminant under concern (for chemical assessments a common set of test species and experimental methodologies are often used, see e.g. requirements in EC regulation 1907/2006 (EC, 2006)). The difference between the methods is in the extrapolation from the results for single species in individual experiments to a PNEC for an ecosystem. Whereas the deterministic method simply takes the lowest significant ecotoxicity value found for any species and divides it by a predefined (depending on availability of data) assessment factor, the probabilistic method uses the distribution of all available ecotoxicity data and applies a cut-off value for this distribution, normally the 5th percentile (HC₅), in the derivation of the PNEC. Both of these extrapolation methods seek to account for uncertainties arising from the available data by applying an assessment factor (AF).

These two approaches were critically reviewed and compared with respect to deriving predicted no-effect dose rates (PNEDR) for radioactive substances within the ERICA project (Garnier-Laplace et al., 2006; Garnier-Laplace and Gilbin, 2006). The assessment factor approach has also been used within Canada to derive radiological benchmark values (Environment Canada, 2003). Detailed discussions on advantages and disadvantages of applying these methods can be found in Garnier-Laplace and Gilbin (2006). Further critical discussion of the SSD methodology can be found in Forbes and Carlow (2002) and Posthuma et al. (2002). Within the PROTECT project, we have tried to be as consistent as possible with current European chemicals regulation and the TGD methodologies are further described in the next section as they have formed the basis of much of our work.

Alternative approaches to estimating risk include field observations and population or ecosystem modelling all of which have associated assumptions and uncertainties. The weight of evidence approach evaluates each separate line of evidence and organises these coherently to assess risk according to: relevance to the exposure scenario of interest; relevance to the assessment endpoint; and degree of confidence in the evidence (Environment Canada, 1997). The weight of evidence approach has been used for radioactive substances by Thompson et al. (2005). However, a consideration of the available evidence is also used as part of the process of deriving benchmarks by deterministic and probabilistic methods. For example, if the derived



benchmark was below the range of typical background (e.g. metal) concentrations then weight of evidence would suggest that it is not fit for purpose.

4.3.2 Brief description of the EC guidance to derive “no-effect” values for chemical substances

Deterministic method

According to the TGD (EC, 2003), the PNEC can be calculated using the **deterministic assessment factor method** by dividing the lowest short-term (acute) EC₅₀ or long-term (chronic) EC₁₀ or No Observed Effect Concentration (NOEC) values by an appropriate assessment factor. The extrapolations include two underlying assumptions: (i) the ecosystem response depends on the most sensitive species and (ii) protecting ecosystem structure protects community function (EC, 2003). In reality, when a limited set of toxicity data are available, a constant assessment factor is used to extrapolate from the NOEC, EC₅₀ or EC₁₀ concentration to the PNEC for an ecosystem according to a number of well-defined rules as shown in Table 3. Because of the limited data usually available, this is the most commonly used approach to derive chemical PNECs.

Probabilistic method

Providing sufficient data points are available, PNECs can also be calculated using a **probabilistic statistical extrapolation model** in the form of a species sensitivity distribution (SSD). The SSD model is based on the assumptions (EC, 2003) that: (i) the variability in the sensitivity of the laboratory-tested species is similar to the variability among the species in the field; (ii) the endpoint measured in laboratory tests is indicative of effects on populations in the field (e.g. Van Straalen and Denneman, 1989; Aldenberg and Slob, 1993); and (iii) input data are drawn at random from the distribution of possible species sensitivities. Thus, an extrapolation is made from a standard test endpoint (or a mixture of ecologically relevant endpoints) for a set of test species to the same endpoint (or mixture of endpoints) in the full set of potentially exposed species. The input to the SSD can include the NOEC, EC₅₀ or EC₁₀ (see below) depending upon the protection goal. The output is the concentration which is hazardous for only a small fraction of the species in the ecosystem. For chemicals, the TGD recommends that the *Hazardous Concentration 5%* (HC₅) is estimated, where HC₅ is the predicted concentration at which 95% of species will be affected by less than, for instance, the 10% level if EC₁₀ values are used as the input (i.e. 5% of species may demonstrate a 10% or higher effect - see Figure 1). Whilst the selection of HC₅ has been described as ‘arbitrary and the result of political compromise’ (Suter et al., 2002) it has been independently adopted by regulators in a number of countries world-wide and is that recommended in the TGD (EC, 2003).

The TGD also recommends the application of an assessment factor ranging from 1-5 to the estimated HC₅ value to determine the PNEC. The magnitude of the assessment factor should be assessed on a case by case basis depending upon a number of factors including quality of the database, diversity of the taxonomic groups and statistical uncertainties in the HC₅ estimate.



Table 3. Assessment factors applied to derive PNECs depending on the quantity and quality of the available toxicity data and the extrapolation method used. Illustration for freshwaters adapted from the TGD (EC, 2003). For information on other ecosystems, see the TGD.

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

1 - $L(E)C_{50}$ 50% Lethal or Effect Concentration is defined as the concentration associated with 50% change in the (average) level of the endpoint considered.

2 - The No Observed Effect Concentration is the tested concentration just below the $LOEC$. The Lowest Observed Effect-Concentration is the lowest Concentration out of the tested concentration at which a statistically significant difference from the control group is observed. They are both obtained by experimental observations and hypothesis testing.

However, the TGD presents no defined rules on how to select the assessment factor. In section 4.3.4 PROTECT has outlined rules for determining an appropriate assessment factor to apply with the decisions recorded in a transparent manner⁵. Whilst a $NOEC$ or lowest observed effect concentration ($LOEC$) may be reported for a given study, this endpoint can be influenced by the test design for instance, the level of replication and choice of test concentrations. The reported $NOEC$ or $LOEC$ may be well below or above the true no effects concentration depending upon the number and range of experimental concentrations used. An accepted alternative is to estimate the no effects concentration by determining the concentration corresponding to the 10% effect compared with a control group (i.e. the EC_{10}) by statistical extrapolation of the response data for an individual study. Whilst the TGD recommends the use of the EC_{10} for this purpose, it has been suggested that this will not always be significantly different to the control treatment and some alternative guidance documentation suggest the use of EC_{20} as a compromise (USEPA, 2001; MERAG, 2005).

The main advantage of the SSD method over the deterministic AF method is that it uses all the appropriate available data, whereas the deterministic method uses only the lowest relevant value. The SSD method is, therefore, also more likely to result in a revised value as additional data become available; the deterministic approach is only influenced if the new data are lower than existing toxicity values, unless the additional data triggers the use of a different AF value (e.g. see Table 3). The main criticisms of the SSD methodology have been on the implicit assumption of equal relevance for all endpoints for all species (Stark, 2004), and concerns that there may be foundation or keystone species among the 5% that are “unprotected” (Forbes and Forbes, 1993; Hopkin, 1993). However, it has also been stressed that ecosystems possess a varying degree of resilience, and that any risk assessment philosophy should acknowledge that environmental protection cannot eliminate all possible risks but should reduce them to an acceptable level (Van Straalen and Denneman, 1989; Van Straalen, 2002). Finally, in practice,

⁵We are aware that a TGD being developed for use with the EC Water Frameworks Directive may contain advice on selection of AF values (European Commission (2009) 'Technical Guidance for deriving Environmental Quality Standards under the Water Framework Directive'. Working Group E, Directorate-General Environment, Env.D.2 - Water and Marine.)



there may be disagreements over which data and endpoints to include, and how to treat those data mathematically. These issues are discussed in more detail in the following sections.

As evident from the above description the SSD approach does require some degree of expert judgment (e.g. in selection of AF and EC_n values). However, there is precedence for some of these judgements from the application of SSD within chemicals (e.g. the use of HC₅ in the derivation of PNEC) and all the judgements which are required can be transparently documented in a stepwise manner.

4.3.3 Methodologies for small datasets

The TGD (EC, 2003) recommends that an SSD is based on at least 10 data points, although deviation from this recommendation could be made on a case by case basis under certain conditions. In many cases this amount of data is not available, and methodologies to utilise smaller datasets (4-10 input values) in a probabilistic approach have been developed (e.g. Aldenberg and Luttik (2002), van Vlaardingen et al. (2004)). The approach utilises a standard deviation from a larger appropriate dataset making the assumption that this standard deviation is representative of that for the smaller dataset. As an example, van Vlaardingen et al. (2004) present standard deviation values estimated from pooled toxicity data for 55 pesticides in birds for application to small toxicity datasets of individual pesticides under assessment. However, the method is dependent upon having an appropriate standard deviation which is applicable to the data under assessment.

4.3.4 PROTECT derivation method for screening values

The SSD methodology has previously been used to successfully derive radiological benchmarks by Garnier-Laplace et al. (2006) and it was selected as the favoured approach for use in the derivation of numeric benchmarks by the PROTECT consortium for the following reasons:

- it provides a framework for transparent derivation
- it is broadly endorsed by consulted experts (Andersson et al., 2008; Beresford et al., 2008a)
- it is consistent with approach used within chemical assessments in the EC
- it imposes a high level of quality control for data selection
- it makes most use of all available data

Below, we document the data selection and application of SDD as used by PROTECT. Where data were insufficient for the application of an SSD, the deterministic method was used instead following the recommendations given in the TGD (although other approaches were considered).



The derivation of benchmark values for ionising radiation consists of three steps as shown in Figure 1.

Compiling quality assessed exposure-effect data (step 1):

The primary source of effects data used was the FREDERICA database (available online at <http://www.frederica-online.org>; Copplestone et al., 2008). The robustness and the scientific credibility of the derived numerical thresholds are strongly linked to the relevance and quality of the critical ecotoxicity data set selected. In contrast to chemical substances, for radioactive substances there are no standardised ecotoxicity test exists. Therefore, we have to make best use of the available data which, especially in the case of data for mammals, may not have been produced for the purposes of environmental protection.

When input into the database, each reference in FREDERICA was assessed against three criteria (dosimetry, experimental design and statistical details) which were then aggregated into a total score with a maximum value of 80 (Copplestone et al., 2008). Only data from papers considering chronic exposures and with medium to high scores (>35) were used in the analysis described below. Moreover, the papers needed to present sufficient data to enable an EDR_{10} to be derived (e.g. data-set includes a dose rate giving rise to at least a 10% effect); the rules to select data suitable for deriving an EDR_{10} value are illustrated in Figure 2. All potential useful source references identified were reviewed by members of the PROTECT consortium with expertise in chemical risk assessment before the data were accepted for subsequent use.

This process is similar to how data were extracted by Garnier-Laplace et al. (2006; 2008) the difference being that more data are now included within the FREDERICA database.

Additionally, dose rate-effect relationships showing a hormetic pattern have now been accepted, providing they met the criteria specified in Table 4.

Having applied the above criteria, data suitable for inclusion in the SSD were available only from chronic, external, gamma-irradiation studies.

Estimation of critical ecotoxicity values (step 2):

The dose rate-effect relationships were then analysed to give the EDR_{10} that has been adopted here, in accordance with European guidance (i.e. the TGD).

A number of assumptions were made concerning the quality of the data submitted to the mathematical treatment. For example, data from FREDERICA were assumed to be representative of the mean of a sufficient number of replicates, although the actual number of replicates was often not presented in the source reference. Depending upon the nature of the data, one of two curve types was fitted (Figure 3) as described below.

Before the calculated EDR_{10} values were accepted for further use in the process of benchmark derivation, they were checked against rules 3-5 in Figure 2 to ensure the spread of experimental dose rates was sufficient to determine a robust EDR_{10} value. The data and the fitted models for all data sets that were accepted for inclusion in the SSD are presented graphically in Appendix 1.



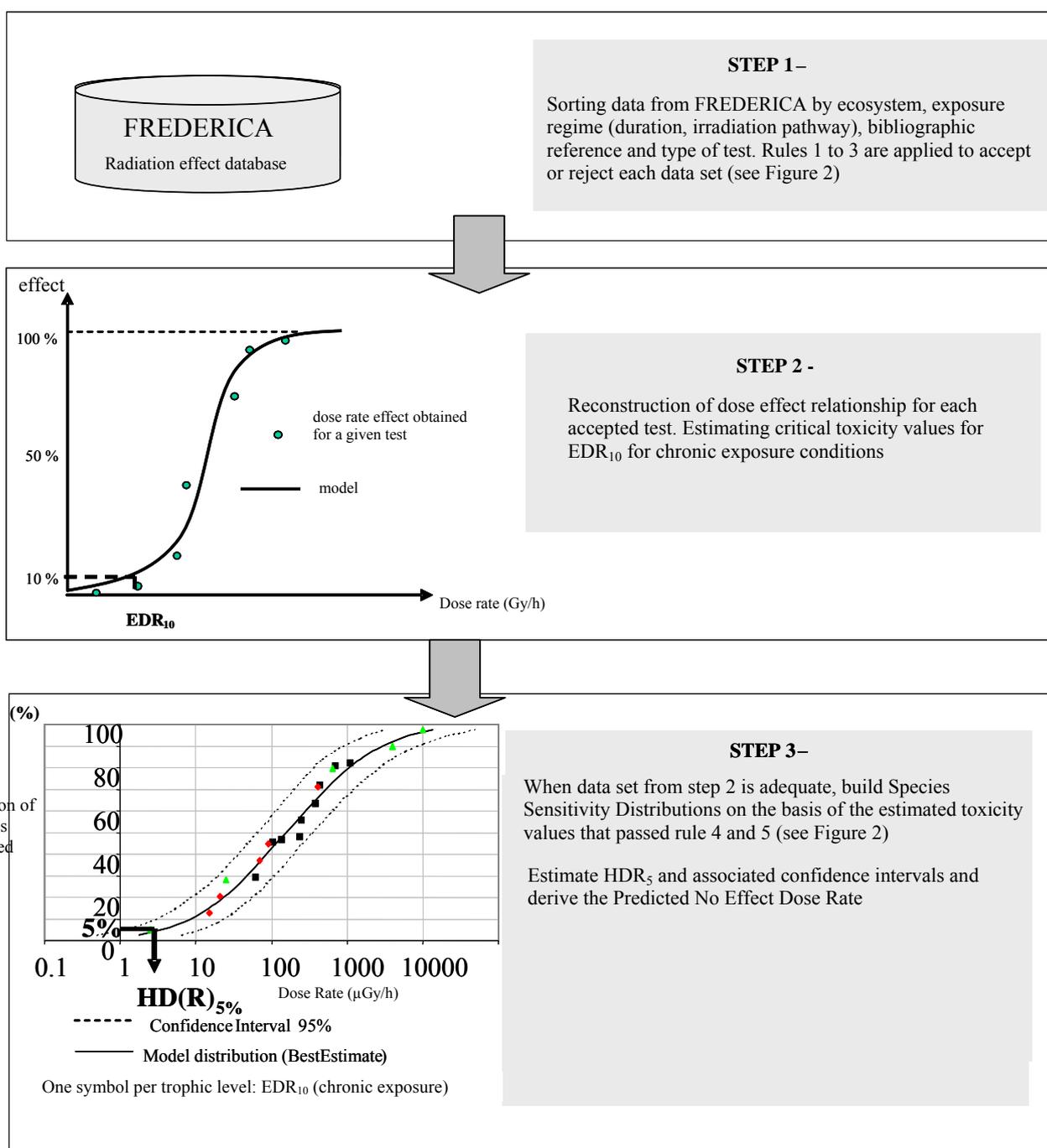


Figure 1. The methodology applied to the FREDERICA database to reconstruct chronic exposure dose-effect relationships and derive benchmark values (see subsequent text for definitions) from SSD.

Logistic dose rate-effects relationships:

Typical dose rate-response curves (Figure 3) were modelled using the commonly used logistic model:

$$y(x) = c + \frac{d - c}{1 + \exp[b(\ln(x) - \ln(e))]}$$

Where d denotes the control response, and c is the response at infinite dose. The parameter e is the dose rate at which the value of $(d - c)$ is reduced by 50% (EDR₅₀), and b is proportional to the slope around EDR₅₀. Depending on whether the response or the effect is being assessed, the logistic functions are either decreasing from a maximal control response at zero dose rate to a lower limit at infinite dose or increasing from no effect at zero dose rate to maximum effect at infinite dose rate.

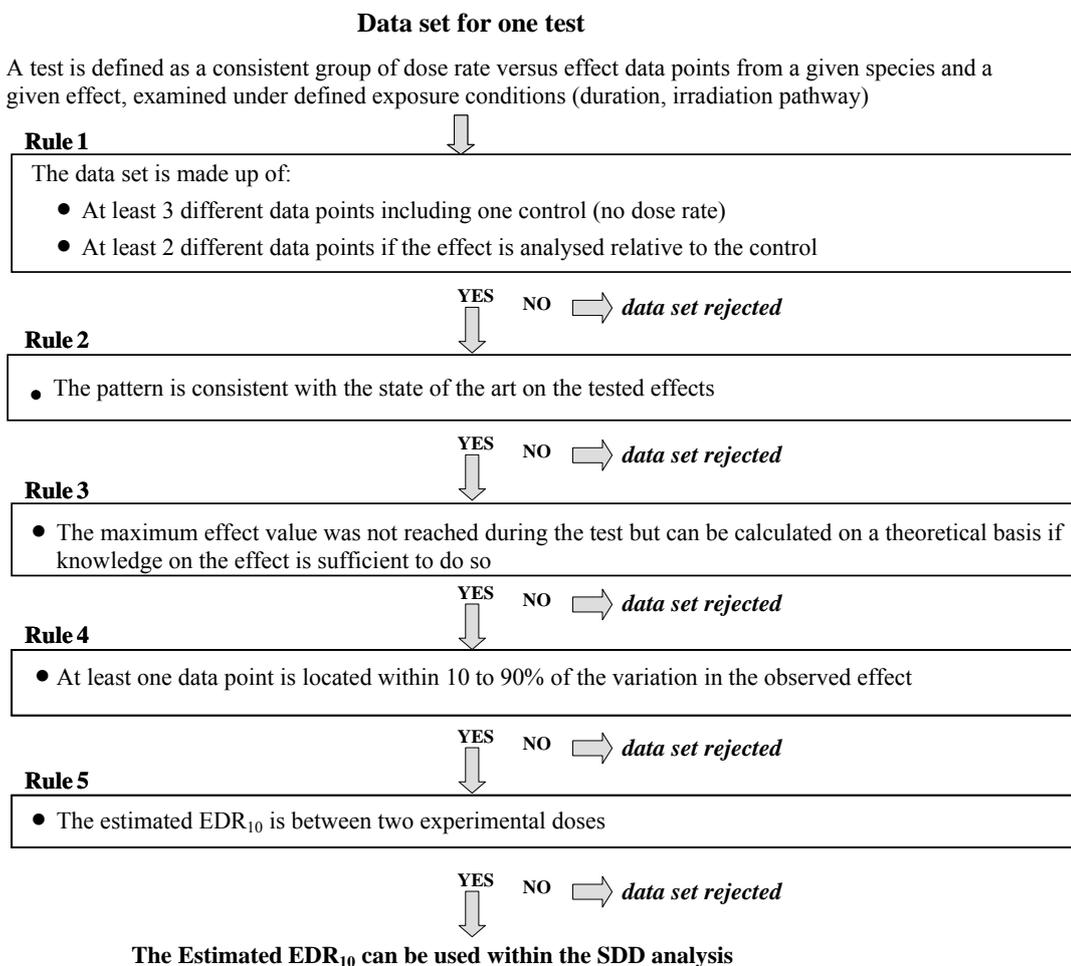


Figure 2. Rules applied on each data set from FREDERICA to reconstruct dose-effect relationships.



Table 4. Data selection criteria for datasets exhibiting a hormetic pattern.

Curve shape		
Inverted U shaped curve	NOEC definition	the highest dose with a response $\geq 90\%$ of the control
	Selection criteria	<ul style="list-style-type: none"> - at least 5 dose-response data points (the minimal number to fit a hormesis model with 4 parameters, requires fixing the lower limit to 0) - 1 control data point - at least 2 doses \leq NOEC with a response numerically higher than the control - 1 NOEC - at least 1 dose $>$ NOEC with a response $\leq 90\%$ of control
U shaped curve	NOEC definition	the highest dose with a response $\leq 110\%$ of the control
	Selection criteria	<ul style="list-style-type: none"> - at least 6 dose-response data points (the minimal number to fit a hormesis model with 5 parameters; lower and upper limit are different to 0) - 1 control point - at least 2 doses \leq NOEC with a response numerically lower than the control - 1 NOEC - at least 1 dose $>$ NOEC with a response $\geq 110\%$ of control
Exclusion criteria		<ul style="list-style-type: none"> (1) the absence of a relevant control; (2) the incapacity to achieve responses greater than (or less than, depending on end point) the control response (e.g. studies where the end point was survival and the control response was 100% or where the end point was tumour incidence and the control response was zero); (3) at least two doses below the NOEC; (4) at least one dose showing <i>a priori</i> criteria-based inhibition.

The curve fitting is based on the Levenberg-Marquardt algorithm and enables the EDR₁₀ (or other EDR_n) to be calculated together with corresponding uncertainty. The extreme effect values, i.e. those obtained for the control group exposed only to the dose rate corresponding to the natural background (d), and a hypothetical group exposed to infinite dose rate (c) need to be determined in a systematic and robust way as their values greatly influence the resulting curve fit. A rule to initiate the fitting process was defined as follows: if the control effect value is 0 (continuous data), 0% or 100% (percentage data), this value is imposed on the model. Otherwise, the control value can be adjusted. The value for the maximum effect used is always imposed on the model to avoid irrational estimates (i.e. $>100\%$ or $<0\%$ or <0).

Hormetic dose rate-effects relationships:

The logistic functions previously described cannot be used to model dose responses that exhibit an initial response stimulation or effect minimisation. Some data sets from FREDERICA visually exhibit a hormetic pattern (i.e. a stimulation effect in low dose rates zone, Figure 3). These data were processed through data selection criteria described in Table 4. Non-linear regression was applied to the hormetic data sets using the Brain-Cousens model:

$$y(x) = c + \frac{d - c + fx}{1 + \exp[b(\ln(x) - \ln(e))]}$$



where interpretation of c and d is the same as that for the logistic model, whereas e and b have no specific interpretation except the fit. The statistical test for the presence of hormesis is the test of $f=0$. For more detail, see Cedergreen et al. (2005).

The hormesis effect in the selected data is assessed statistically using the lack of fit test to compare the logistic and Brain-Cousens model fits with the DRC package (Ritz and Streibig, 2005) and R Software (R Development core team, 2006). For the effective hormesis data (for which the lack of fit test would be significant), the hormesis effect is described by means of the shape of the curve (U or inverted U), the size of induction regarding control, the estimation of the dose rate corresponding to the maximal response and to the EDR_{10} . Both data sets showing hormetic response relationships included in the SSD for derivation of benchmarks are presented in Appendix 1.

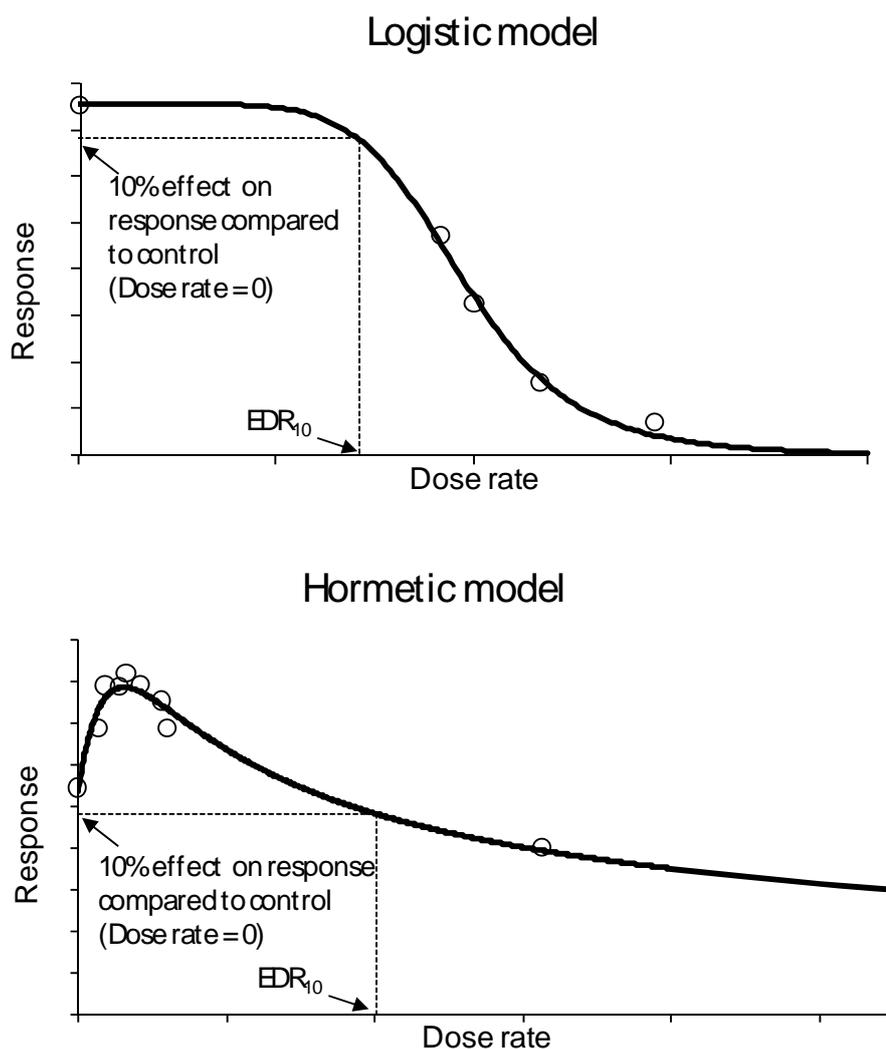


Figure 3. Examples of the two dose rate – effect models used to estimate EDR_{10} values; the y-axis represents a measure of response relative to the control treatment (where the control is shown as the data point marked on the y-axis).

Derivation of screening values (step 3):

The last step of the methodology uses the EDR₁₀ values calculated in step 2 to derive the HDR₅ (i.e. dose rate at which 95 % of species will be effected below a 10 % level) by applying the SSD method. The predicted no effect dose rate (PNEDR) is then obtained by applying a relevant assessment factor to the HDR₅ to account for any residual uncertainties (e.g. lack of data for certain taxa or endpoints). The PNEDR is equivalent to the screening value referred to above.

There are several considerations that need to be addressed during this third step which have a direct and potentially considerable influence on the final benchmark value. These include the selection of data to include in the SSD, the precise methodology of fitting a distribution to these data, and the value of the assessment factor applied to the HDR₅. We discuss these issues in relation to the derivation of the PROTECT benchmark values below.

Selection of data

The work of Garnier-Laplace and Gilbin (2006) suggested that SSD for radiological effects can be created using data across both terrestrial and aquatic ecosystems as resultant HDR₅ estimates were similar for species in both ecosystem types. Consequently, for the purposes of defining screening levels we have considered the available EDR₁₀ values as one combined generic dataset. All 105 of the EDR₁₀ values derived from references meeting the above criteria within the FREDERICA database are presented in Appendix 2.

As our protection goal is to protect populations from ionising radiation, the selection of which EDR₁₀ should be included in the SSD needs to consider each endpoint's relevance for population sustainability. In an earlier approach, Garnier-Laplace et al. (2006; 2008) estimated the geometric mean EDR₁₀ for a given species and a given category of endpoints among reproduction, morbidity and mortality. This approach has been challenged within PROTECT as it may produce an EDR₁₀ which is not the most protective as it mixes endpoints of differing sensitivity within the SSD.

The approach used within PROTECT was to select the most sensitive (lowest EDR₁₀) endpoint for any given species; cytogenetic endpoints were not considered to be relevant to population sustainability, although these may be more sensitive. Reproduction endpoints were most often amongst the more sensitive and these are generally accepted as being population relevant (IAEA, 1992; UNSCEAR, 1996) (see Appendix 2). The approach of Environment Canada (2003) used the most sensitive reproductive endpoint for each wildlife group in a deterministic assessment factor approach. This selection required expert judgement of the ecological relevance of each individual endpoint.

The EDR₁₀ values used in the final derivation of PNEDR values are identified in Appendix 2. The total number of EDR₁₀ values was 20 comprised of 4 plants, 2 annelids, 3 crustaceans, 2 molluscs, 2, birds, 4 fish and 3 mammals. There is considerable statistical uncertainty associated with some of the EDR₁₀ estimates (as may be inferred by consideration of the figures presented in Appendix 1). An alternative dataset comprising EDR₁₀ values with the lowest uncertainty for each species was therefore also compiled (Appendix 2).

To evaluate the robustness of the HDR₅ resulting from this data selection, HDR₅ values were also derived using slightly differing data selection approaches. These include the EDR₁₀ with



the lowest uncertainty rather than the EDR₁₀ with the lowest value, or substituting the EDR₁₀ with an available HNEDR (Highest No Effect Dose Rate) value if this was lower (thus using results from experiments that did not fulfil the requirements to derive an EDR₁₀ value). The database was also investigated to determine whether HNEDR or LOEDR values from studies that did not allow determination of EDR₁₀ values could be used to increase the number of species included in the SSD. However, no suitable data were found.

Methodology of fitting a distribution to the selected data

The SSDs were constructed using a log-normal distribution by the approach of Duboudin et al. (2003). The Direct Weighted Bootstrap method (DWB) was used to build SSDs and their confidence intervals. The bootstrapping was run for a 1000 samples. The goodness of fit was tested by a Kolmogorov-Smirnov test with a Dallal-Wilkinson approach and by the multiple R-square coefficient between theoretical and empirical distributions.

A basic assumption of the SSD approach is that the species tested are representative of all species. Depending upon the proportions of test species from different trophic levels or taxonomic groups the validity of this assumption could be questioned. Duboudin et al. (2004) and Forbes and Calow (2002) investigate an approach to weight data within an SSD for different taxonomic groupings although such data manipulation is not common practice in chemical risk assessments. The DWB method was used to enable the construction of samples in which the effect of different proportions of data among species and among taxonomic groups could be investigated. For instance, the analysis could be weighted to let the influence of species from dominating taxonomic groups (in terms of number of species) reflect this dominance even if they are not prevalent within the test species.

Within PROTECT, results from unweighted SSDs have been compared with those using a weighting based on taxonomic group. For the generic screening value, which is based on values from all species from all types of ecosystems, the weighting was based on proportion of species within three taxonomic groups (the small dataset available precluded further division): plants, invertebrates and vertebrates. As an example, the same weight was given to each taxonomic group, meaning that species in underrepresented groups (i.e. less species than the average number of species per group) were allocated a higher weight and species from over-represented groups were allocated a lower weight. Duboudin et al. (2004) discuss other approaches to taxonomic weighting.

Furthermore, SSDs were also produced for which the data were weighted according to the uncertainty in the individual EDR₁₀ values. The weighting factors for uncertainty were given by dividing the values into three groups based on the coefficient of variance for each estimated EDR₁₀ value where 0-10% was classed as low (L) uncertainty, 10-100 % as medium (M), and >100 % as high (H) uncertainty. Arbitrary weightings of L:M:H of 3:2:1 and 100:10:1 were applied and compared.

Choosing an appropriate assessment factor to apply to the generic HDR₅

As described above, whilst the TGD (EC, 2003) suggests that an assessment factor between 1 and 5 should be applied to the HC₅ value (equivalent to our HDR₅ value), it gives no clear guidance on how these assessment factors should be chosen.

Table 5. Factors contributing to uncertainty of a derived HDR₅

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

Within PROTECT we have applied scores between one and three stars to the factors contributing to uncertainty given in Table 5 (where three *** denotes the least uncertainty). On this basis, the justification for selection of an appropriate AF for the generic screening value is outlined below.

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

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

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

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

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

On the basis of the above, we consider the application of an assessment factor of 2 to be justified. To avoid the application of an assessment factor (thus minimising expert judgements) and still address uncertainty in the data Twining et al. (2005) used the lower end of a confidence interval around the HDR₅. However, as PROTECT has followed the recommendations of the TGD (EC, 2003) we have applied an AF.



Table 6. Derived HDR₅ values ($\mu\text{Gy h}^{-1}$) with 95% confidence interval within brackets using the standard methodology (EDR₁₀; lowest value and no weighting) as well as alternative input data and weighting options. See text for explanation of the different options.

Data used	No weight	Weighting for uncertainty (100:10:1)	Weighting for uncertainty (3:2:1)	Weighting for organism group (1:1:1)
EDR 10; lowest value	17 (2-211)	28 (3.1-304)	21 (2.4-212)	34 (3.7-307)
EDR 10; lowest uncertainty	37 (5.9-323)	24 (4.6-188)	37 (5.6-298)	63 (13-240)

4.4 Resulting benchmark values

4.4.1 Generic Screening level estimates

The resulting generic HDR₅, when all 20 EDR₁₀ values are used to produce a generic SSD as described above, is 17 $\mu\text{Gy h}^{-1}$ (Table 6). Table 6 also shows the resulting HDR₅ values when the alternative derivation methods were used as described above (weighting for organism group or uncertainty in individual EDR₁₀ values, or using alternative data, i.e. the EDR₁₀ value for each species with the lowest uncertainty rather than the lowest value or substituting EDR₁₀ with HNEDR if lower). As can be seen from Table 6, the median values derived by the different approaches to analysing the available data are similar especially when considering the uncertainty around the estimates (as indicated by the 95% confidence limits).

There were three instances when an available HNEDR was lower than the EDR₁₀ for a given species. However, use of these values resulted in a poor fit to the modelled distribution and this option was therefore rejected. Using the other alternative data or weighting options gave similar results as the unweighted approach using the lowest EDR₁₀ value for each species. This suggests that the derivation is robust and that high uncertainty in some of the individual EDR₁₀ values do not influence the results unduly. As weighting makes little difference to estimated HDR₅, and as it is not common practice and requires additional expert judgement, PROTECT has favoured the use of unweighted SSD. The robustness of the methodology is further supported by the similarity to the HDR₅ values previously determined by: (i) Garnier-Laplace et al. (2008) of 82 $\mu\text{Gy h}^{-1}$ based upon a different data input selection which included some less sensitive endpoints in the SSD (see above); (ii) Twining et al. (2005) of 15 $\mu\text{Gy h}^{-1}$ for aquatic organisms using HNEDR and LOEDR values as inputs into an SSD.

Applying the selected assessment factor of 2 results in a **generic screening level of 10 $\mu\text{Gy h}^{-1}$** .

4.4.2 Organism group specific screening level estimates

As discussed above the application of a generic screening value to all organism types raises some problems when used in assessments as the most exposed organism identified may not necessarily be the organism most at risk. Ultimately, it would be desirable to have screening values for as many relevant groups as justifiable (probably taxonomically at the family or class level), however, currently we do not have enough data to achieve this. Consideration was therefore given to deriving values for three broad groups, namely plants, vertebrates and invertebrates recognising that these groupings each contain organism which are likely to have a range of radiosensitivities

Table 7. Proposed organism group screening values ($\mu\text{Gy h}^{-1}$), deterministically derived estimated PNEDR and HDR₅ values estimated using SSD or ‘small dataset’ methodologies (see text for explanations of these alternatives).

	Proposed PNEDR	n	Lowest EDR ₁₀	Deterministically estimated PNEDR*	HDR ₅ generated using SSD**	HDR ₅ estimated using ‘small dataset approach’***
Vertebrates	2	9	3.6	0.4	2.1 (0.3-62)	2.9 (0.6-15)
Invertebrates	200	7	1030	100	505 (55-4447)	106 (17-670)
Plants	70	4	710	70	n/a	40 (3.5-470)

*Estimated assuming AF=10

***95 % confidence limits presented in parenthesis

***Estimated using software of Vlaardingen et al. (2004); 90 % confidence limits presented in parenthesis

The numbers of datapoints for each of these groups were: vertebrates (n=9), invertebrates (n=7) and plants (n=4). Even for vertebrates and invertebrates, the available data were therefore below the ideal requirements to enable a SSD to be generated according to the TGD. To derive organism specific screening levels three approaches were compared: (i) generate an unweighted SSD as above for both vertebrates and invertebrates; (ii) apply the small sample method within the EXT^{2.0} programme (Vlaardingen et al., 2004) to generate HDR₅ values for each group; (iii) estimate a PNEDR for each group deterministically.

No attempt to generate an SSD was made for plants as the available dataset was too small. The EXT^{2.0} programme has a function enabling HDR₅ values to be generated from small datasets (n≤10) implementing the methodology described by Aldenberg and Luttik (2002). The method requires a suitable standard deviation (SD), for assessment of chemicals the assumption is made that a SD derived for similar chemicals/organisms (e.g. the programme contains predefined SD of pesticide toxicity values in birds – pooled across different pesticides) is available and can be applied to the chemical being assessed. However, for radioactivity we do not have alternative datasets from which to derive SD values. Therefore, we assumed that all three groups had the same SD value as the overall dataset of 20 values; an assumption which we acknowledge is unlikely to be valid. To estimate PNEDR values deterministically, an AF of 10 was applied to the lowest EDR₁₀ value within the dataset for each organism group, justified on the basis that for each group data, were available from more than 3 species (see Table 3 for guidance on selection of deterministic AF values from the TGD). Results from each of the three approaches are compared in Table 7; confidence intervals are also shown where appropriate.

The SSD and small dataset methods give broadly comparable results for vertebrates and invertebrates. Given our application of the small dataset method is limited by the lack of suitable SD values, we favour the SSD approach whilst acknowledging that the datasets are sub-optimal according to the TGD (which recommends n≥10). Statistically acceptable fits are achieved for the two SSD and the comparison with the small dataset method implementation (accepting the limitations of this) is encouraging. Therefore, for invertebrates and vertebrates we recommend using the SSD derived HDR₅ values to estimate organism specific PNEDRs. The arguments put forward above for the selection of an AF for calculation of the generic



screening level remain valid for the organism specific screening values with the exception that the datasets are smaller (although coverage within each group is the same as for the generic screening level derivation). Taking into account the smaller dataset, an AF value of 3 is suggested. The resultant PNEDR for invertebrates is then $200 \mu\text{Gy h}^{-1}$ (rounded to one significant number). The resultant PNEDR for vertebrates would be approximately $0.7 \mu\text{Gy h}^{-1}$, which is similar to the value estimated deterministically (Table 7), this value is considerably below any relevant observed effects measured in field studies. For example, Sazykina (2005) reported only minor cytogenetic effects for mammals in the dose rate range $4\text{-}20 \mu\text{Gy h}^{-1}$ from a review of data from contaminated sites in former Soviet Union countries. The value is also similar to background dose rates for many vertebrates (Beresford et al., 2008b; Brown et al., 2004) and considerably lower than some reported values for aquatic organisms and estimates for burrowing animals, both of which are of the order of $10^1 \mu\text{Gy h}^{-1}$. A screening value $<1 \mu\text{Gy h}^{-1}$ for vertebrates would not be fit for purpose and therefore pragmatically we propose that the actual HDR₅ value of $2 \mu\text{Gy h}^{-1}$ is currently our best estimate as the vertebrate screening value. Environment Canada (2003) used an assessment factor of 1 in deriving radiological benchmarks for a similar reason (see also Hingston et al., 2007b).

Given the lack of data for plants, the deterministic option has to be used to derive a suggested PNEDR of $70 \mu\text{Gy h}^{-1}$.

Taking into account the uncertainty associated with these estimates they should be considered as indicative of the order of magnitude of values, rather than definitive numbers. These illustrative organism group values were derived because we recognised that there would be differences in radiosensitivity depending upon taxa. As discussed above, it would be desirable to derive screening values for as many relevant groups as justifiable and this should probably be at the taxonomic levels of family or class. The groupings selected for derivation of organism group screening values in this report represent what could be practically achieved with the current data. The PROTECT consortium considers that, whilst currently there may be less confidence in the organism specific values we have derived compared to the generic screening value (which appears to be fairly robust), that the derivation of more robust organism group values should be pursued in the future. Table 8 compares the advantages and disadvantages of the two types of screening value (with some comments being based upon current data availability). The conceptual difference between the two approaches is that the generic value should *protect 95 % of all species* whereas the organism specific values should *protect 95 % of species within each organism group*. However, if organism group screening values are to be derived, then all groups should be considered in an assessment; in the examples presented here, use of just the lowest value, for vertebrates, could result in components of the vertebrate foodchain not being adequately considered possibly resulting in indirect effects on vertebrates. Accepting that there are differences in radiosensitivity between groups, it should be acknowledged that the generic screening value will over protect some groups and under protect others. For instance, on the basis of the currently available data we estimate that 85 % of vertebrate species are protected at $10 \mu\text{Gy h}^{-1}$. Obviously, some organism group screening values will be higher than the generic screening value (plants and invertebrates in the examples presented here) whilst others will be lower (vertebrates in the examples presented here).



Table 8. Comparison of generic and organism specific screening values

Generic	Organism specific
Implementation does not take account of difference in radiosensitivity & exposure between taxa	Implementation does take account of difference in radiosensitivity & exposure between taxa
95% of all species protected	95% of species in each group protected
Over protective of plants & invertebrates	More realistically protects plants & invertebrates
Under protective of vertebrates	Better protects vertebrates – but more stringent
Simple to explain & implement	Slightly less simple to explain & implement
Uses all data	Uses data for a given group
Higher confidence in number (as all appropriate data included)	Lower confidence in numbers (as less data included in the SSD)
Existing guidance on data requirements	No guidance on data requirements

The organism group screening values presented above are generally comparable to the lower end of the range of the DCL values for broadly similar RAPs suggested in the ICRP draft report (see Table 1), which is the other major on-going work considering dose rate benchmarks for wildlife. Whilst the ICRP values were derived by expert judgement it is encouraging for both PROTECT and ICRP that similar values have been derived using different approaches. Together the results of PROTECT and the ICRP evaluations of the available radiation effects data suggest that some of the previous interpretations of the available data have proposed dose rates relevant for protection of populations that may have been too high (see Table 1).

The notable difference between the PROTECT screening values and ICRP DCLs is the ICRP suggested value for reference Pine tree of 4-40 $\mu\text{Gy h}^{-1}$ compared to our value of 70 $\mu\text{Gy h}^{-1}$ for plants. ICRP quotes studies that show reproduction effects (pollen viability) at doses within an order of magnitude greater than this range, i.e. 100 $\mu\text{Gy h}^{-1}$ (Kozubov and Taskaev, 1994) as well as mortality effects at 60 $\mu\text{Gy h}^{-1}$ (Pautov and Il'chukov, 1993). These comparatively low dose rate effects were all observed close to the Chernobyl NPP, and consequently there is considerable uncertainty in dose estimates and also the potential influence of early acute phase higher dose rates on subsequent 'chronic exposure effects'. The justification presented by ICRP for the Pine tree DCL of 4-40 $\mu\text{Gy h}^{-1}$ rather than 40-400 $\mu\text{Gy h}^{-1}$, which they recommend for other plant RAPs, and which might be considered to better reflect the available data, was the potential for long life-time periods of exposure. The suggested PROTECT plant group screening value was based on an EDR_{10} value for *Pinus rigida* (pitch pine) (Sparrow et al., 1965) of 710 $\mu\text{Gy h}^{-1}$ to which an AF of 10 was applied to derive a PNEDR of 70 $\mu\text{Gy h}^{-1}$. This value was the lowest EDR_{10} value derived for any plant type from data within the FREDERICA database that met our data quality requirements; the measurement endpoint was the effect of long-term irradiation on seed development.

4.4.3 Are the derived screening values realistic and fit for purpose?

Within this report we have derived both generic and organism group specific screening values as a basis for further development of the protection of the environment, and before any recommendation of which type of screening values to use, the suggested values also need to be



evaluated regarding comparisons with background levels, observed effects at/close to the suggested levels and whether they are fit for purpose (i.e. what would be the implication of these values if used in assessments already undertaken and published).

When the estimated screening levels are put into context with dose rates to wildlife from natural background radioactivity, in general the screening values seem reasonable. Brown et al. (2004) present estimates of weighted⁶ absorbed doses to a range of marine organisms based on a review of published marine biota, water and sediment activity concentrations. Average estimates of total absorbed dose ranged from 0.1 - 6 $\mu\text{Gy h}^{-1}$, the upper estimate being for bacteria. Individual estimates ranged up to 27 $\mu\text{Gy h}^{-1}$ for crustacean samples. Estimates are also presented for freshwater organisms. However, because of a lack of data these were based upon biota activity concentrations estimated using biota-water concentration ratios. The resultant total weighted mean doses for different organism groups were in the range 0.4 - 4 $\mu\text{Gy h}^{-1}$. Beresford et al. (2008b) reported total weighted absorbed dose rates for terrestrial wildlife in England and Wales due to ^{40}K , ^{232}Th -series radionuclides and ^{238}U -series radionuclides categorised on the basis of the ICRPs suggested (RAPs). Average dose rates ranged from *circa* 0.07 – 0.6 $\mu\text{Gy h}^{-1}$ with a 95th percentile prediction for the RAP predicted to be the most exposed (earthworm) of 1.5 $\mu\text{Gy h}^{-1}$. The authors suggested that the values they had derived should be broadly typical for elsewhere in Europe although extremes of exposure may not be indicated within this work as values were estimated based upon soil concentrations averaged over 25 km^2 areas. A potential route of exposure not considered by Beresford et al. (2008b) was inhalation of ^{222}Rn by burrowing animals. Macdonald and Laverlock (1998) suggested that dose rates to the lung of burrowing animals (in southeastern Manitoba Canada) may be in excess of *circa* 60 $\mu\text{Gy h}^{-1}$ which is above the proposed screening values. However, the potentially high radon background dose for burrowing mammals need further investigation although they may have little impact on population relevant endpoints.

When comparing the derived screening values with observed effects, a first approach is to look at the evaluated data itself as presented in Appendix 2. The lowest reported EDR_{10} values are 710 $\mu\text{Gy h}^{-1}$ for plants (which is the basis for the screening value by applying an AF of 10) around 1000 $\mu\text{Gy h}^{-1}$ for invertebrates (respiration rate and number of offspring in two different crustaceans) and 3.6 for vertebrates (reduced testis relative to body weight in pigs). The very low EDR_{10} values for a species of cyanobacteria living in hot springs was not used as this species is an extremophile. The derived screening levels are below any dose rate of observed relevant effect on the individual level of those studies within FREDERICA database that meet the quality criteria required for use in PROTECT (e.g. possible to derive an EDR_{10} value from) thus suggesting that the approach taken has generally been conservative.

However, the study by Harrison and Anderson (1994) on polychaete worms (*Neanthes arenaceodentata*) includes investigations of several endpoints. The data as presented in the paper, permits the derivation of an EDR_{10} value for only one of these endpoints (number of F2 embryos live and dead) which is *circa* 12 000 $\mu\text{Gy h}^{-1}$ (Appendix 2). The same study is also the basis for the Canadian estimated no effect value for invertebrates (Environment Canada, 2003). The Canadian evaluation of this study led to the conclusion that reproductive effects

⁶ Both the papers of Brown et al.(2004) and that of Beresford et al. (2008b) used radiation weighting factors of 3 for low energy beta and 10 for alpha.

(percentage of live embryos) were seen at $190 \mu\text{Gy h}^{-1}$ as suggested by the authors (thus giving the benchmark value $200 \mu\text{Gy h}^{-1}$). The indications in the paper of a more sensitive endpoint led us to decide to disregard this study rather than include a less sensitive endpoint in the derivation of the HDR_5 . There is, however, the possibility that an EDR_{10} value for the most sensitive endpoint in this study, had the data been available, could have come close to the suggested screening value for invertebrates of $200 \mu\text{Gy h}^{-1}$.

A review of the available data from field studies within the FREDERICA database and a review of data from field studies in the former Soviet Union (Sazykina, 2005) yielded no effects observed below our generic or organism group screening values (see also Appendix 3). Therefore, the weight of evidence from available field studies suggests that the screening values are at a level at which relevant effects have not been observed.

As an example of the application of our proposed screening levels to planned exposure situations (and to help assess if they are fit for purpose), we have reviewed the results of the assessments of Natura 2000 sites conducted by the Environment Agency in England and Wales between 2004 and 2008 (Allott and Coppleson, 2008). The potential impact of 715 authorisations for the discharge of radioactive substances on 433 Natura 2000 sites or candidate sites were evaluated. Sixty-six sites were identified as requiring more detailed assessment by the application of a screening tier with a generic screening level of $5 \mu\text{Gy h}^{-1}$. If we were to apply a generic criteria of $10 \mu\text{Gy h}^{-1}$, then the number of sites exceeding the screening level would drop to 43 primarily because many of the sites exceeding $5 \mu\text{Gy h}^{-1}$ did so on the basis of predicted dose rates to seabirds and aquatic mammals of $>5 \mu\text{Gy h}^{-1}$ but $<10 \mu\text{Gy h}^{-1}$ (Allott *pers. comm.*⁷). If the organism group screening values as derived above were to be used 109 sites would exceed a screening value; the vertebrate screening value is predicted to be exceeded at all 109 of these sites, with the plant and invertebrate values also being exceeded at one coastal (marine) site.

We have also evaluated the suggested screening values by assessing sites described by SENES (2007) which presents information for a number of sites including data suitable for conducting initial screening level (i.e. simple and conservative) assessments. To investigate the use of the proposed screening levels, the following sites were selected to give a number of both freshwater and terrestrial assessments, and a range of radionuclides (see SENES (2007) for more detailed site descriptions):

Freshwater assessments

- Marcoule – nuclear complex located on Rhone river in southern France
- Hanford Area 300 – site of fuel fabrication (USA)
- Pickering – nuclear power plant (Canada)
- McArthur River – uranium mine (Saskatchewan, Canada)

Terrestrial assessments

- Hanford Bear Creek – waste disposal area (USA)
- Pickering – nuclear power plant (Canada)

⁷ R. Allott, England & Wales Environment Agency.



- o McArthur River – uranium mine (Saskatchewan, Canada)

Table 9. Illustrative ‘screening level’ conservative absorbed dose rates predicted for various sites presented in SENES (2007). Shaded cells denote predictions exceeding proposed organism specific screening values; rate limiting organisms are identified by bold text.

Freshwater sites				
Reference organism	Weighted absorbed dose rate ($\mu\text{Gy h}^{-1}$)			
	Marcoule	Hanford 300	Pickering NPP	McArthur River
Amphibian	3.38E+00	9.20E+00	4.42E-01	2.30E+00
Benthic fish	5.24E+00	9.23E+00	2.55E+01	3.25E+00
Bird	3.18E+00	9.23E+00	4.71E-01	2.30E+00
Bivalve mollusc	2.39E+02	5.38E+01	4.81E+01	1.41E+02
Crustacean	6.78E+01	1.49E+02	6.32E+01	7.02E+01
Gastropod	1.52E+02	5.38E+01	5.23E+01	8.79E+01
Insect larvae	8.27E+01	1.49E+02	1.23E+02	8.18E+01
Mammal	3.55E+00	9.23E+00	5.02E-01	2.30E+00
Pelagic fish	3.36E+00	9.23E+00	3.64E-01	2.30E+00
Phytoplankton	1.47E+02	3.57E+01	3.20E-02	9.86E+01
Vascular plant	6.65E+01	8.65E+02	5.57E+01	1.62E+02
Zooplankton	1.31E+02	1.55E+01	1.39E+00	9.54E+01
Terrestrial sites				
Reference organism	Weighted absorbed dose rate $\mu\text{Gy h}^{-1}$			
	Hanford Bear Creek	McArthur River	Pickering NPP	
Amphibian	3.15E+00	5.62E-04	3.23E+00	
Bird	3.43E+00	6.02E-04	3.29E+00	
Bird egg	3.36E+00	8.53E-03	3.21E+00	
Detritivorous invertebrate	5.18E+01	6.02E-04	4.26E+00	
Flying insects	5.15E+01	8.63E-03	3.00E+00	
Gastropod	5.16E+01	8.52E-03	3.16E+00	
Grasses & Herbs	8.51E+01	1.42E-02	3.16E+00	
Lichen & bryophytes	4.12E+02	6.77E-02	2.57E+00	
Mammal (Deer)	1.26E+00	1.43E-04	3.29E+00	
Mammal (Rat)	1.39E+00	3.07E-04	4.27E+00	
Reptile	3.43E+00	5.58E-04	3.30E+00	
Shrub	4.16E+01	6.89E-03	3.23E+00	
Soil Invertebrate (worm)	5.18E+01	8.65E-03	4.26E+00	
Tree	3.96E+01	6.52E-03	3.06E+00	

Tier 2 of the ERICA Tool (Brown et al., 2008) was used to make predictions (see Beresford et al. (2008c) for inputs as used here⁸) assuming default parameters and maximum available media activity concentrations. Note whilst it would have been preferable to use Tier 1 of the ERICA Tool this would not have readily allowed comparison of the organism group screening levels; Tier 2 has been applied in a manner such that outputs are compatible with Tier 1 (see Brown et al. (2008) for a description of the tiers of the ERICA Tool). Table 9 presents results

⁸ Beresford et al. (2008c) use [this sites](#) to compare the initial screening tier prediction of three assessment tools.



indicating organisms which would exceed the organism group screening levels proposed by PROTECT. The absorbed dose rates presented are the 'conservative' values output by Tier 2 of the ERICA Tool which are approximately equal to the 95th percentile prediction and therefore broadly compatible with the conservatism included in initial screening level (Tier 1) of the tool which cannot be used here as it uses predefined screening values. For the majority of these sites some vertebrate organisms are predicted to have dose rates in excess of 2 $\mu\text{Gy h}^{-1}$ (the proposed vertebrate screening value); vertebrates were predicted to be rate limiting in three of the seven assessments (against a screening benchmark of 2 $\mu\text{Gy h}^{-1}$). Plant organisms were predicted to be rate limiting in three of the assessments when compared to an organism screening level of 70 $\mu\text{Gy h}^{-1}$. In these examples the use of organism screening levels led to one more site being identified for further assessment as compared to using the generic value. However, at some sites different organisms would be identified as rate limiting using the generic screening level perhaps resulting in the subsequent more detailed site assessments being wrongly focussed. Although in this exercise the suggested screening values only screened out one site as being of no concern (terrestrial environment at McArthur River), this is not necessary an indication that the screening values are not fit for purpose. Most of the assessed sites have by their nature comparatively high environmental concentrations and a refined assessment is likely to be warranted (N.B. in the case of the Pickering NNP freshwater assessment some end of pipe-line activity concentrations were used in the assessment making it highly conservative).

Note, whilst the evaluations presented above use available data from actual sites they are conducted for illustrative purposes only and should not be interpreted as 'complete' screening assessments. Some of the available data for radionuclides not considered within EA R&D128 were not used and input data have been derived solely from the SENES (2007) report without reference to original sources. Furthermore, the results do not necessarily reflect actual potential risk at the case study sites, as the data sets were used for illustrative purposes only, and detailed knowledge of the sites was not applied; the SENES report outlines the outcomes of more refined assessments where initial conservative assessments identified that this was required.

4.4.4 Risk assessment and risk management

Using screening values is helpful during risk assessment in identifying when further work is required or not. However, there is a problem for an assessor which occurs when a refined exposure assessment has been completed but the calculated dose rates remain above the screening value. In these circumstances, an assessor cannot easily state with confidence that there will be negligible, or no, impact on biota and hence the screening level alone does not help determine whether there is a need for risk management action (Figure 4).

During the PROTECT workshops and consultation exercises (Andersson et al., 2008; Beresford et al., 2008a), some (although not all) of the consulted regulators highlighted the need from their perspective for a benchmark value which could be used to identify where the risk of an impact was significant, the intention being that such a value could aid risk management decision making when a screening value is exceeded. The concept of a second benchmark value is discussed in the next section.



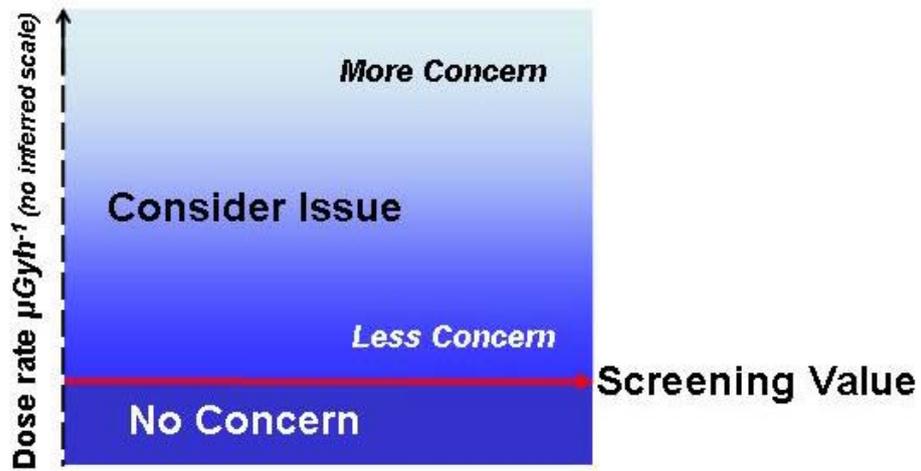


Figure 4. Screening values are used within risk assessment in order to screen out situations of no concern.

5. Protection of the environment from ionising radiation in a regulatory context

As discussed above, if a refined exposure assessment has been completed and if the estimated dose rates remain above the screening level then an assessor cannot state with confidence that there will be negligible impact. Some assessment approaches (e.g. Larsson, 2008) have provided guidance for the situations where a screening value is exceeded following a refined exposure assessment. In these cases, the assessor may be directed to review the available biological effects information for the species affected, but then to determine for themselves how significance the risk is. However, without any further information, the level of risk associated with the calculated dose rate cannot be assessed except by the obvious increase in magnitude of the calculated dose rates above the screening value. For instance, if the dose rate to an organism is predicted to be two-orders of magnitude greater than the screening value it is likely to be more of a risk than a dose rate of one-order of magnitude higher than the screening value (Figure 5). However, there is no information readily available to an assessor to place a refined exposure assessment dose rate which is above a screening value into context. In their draft document ICRP (2007b) also recognised this: “it is difficult, in the absence of any form of ‘sliding scale’ against which to apply some form of ‘risk related’ criteria, to make assessments or judgements at lower dose rates.” Similarly, the OECD-NEA has independently suggested a three tier/two level scheme for environmental protection for similar reasons as PROTECT (Brownless, 2007).

The main intended use of such a second higher level benchmark value, as interpreted by the PROTECT consortium from the workshop discussions, would be to help the assessor to understand where they are on the scale of no effect to a risk of ‘serious’ effect (Figure 5). This would aid in making decisions regarding the need for risk management and in the overall justification and optimisation (of public, worker and environmental risk) process. Any second benchmark value derived to represent a greater risk than the screening value should not be used as a replacement for the screening value in refined exposure assessments.

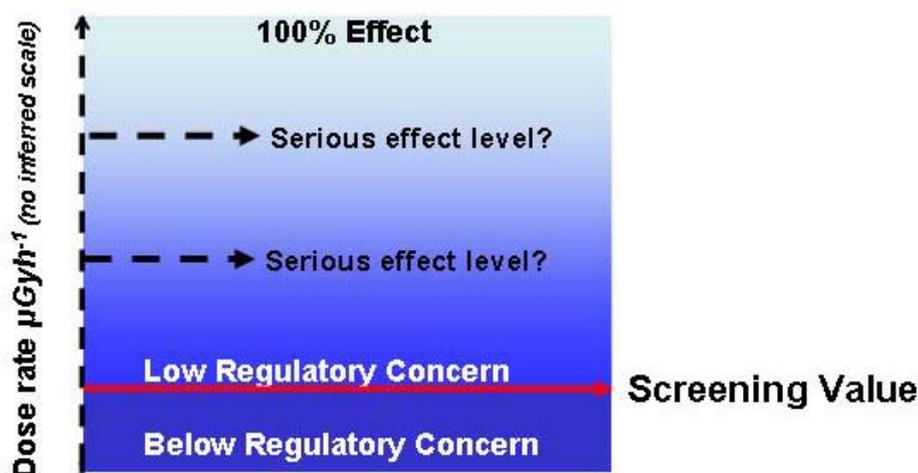


Figure 5. In a regulatory context, the use of single screening value provides no guidance to judge the level of risk if the screening value is exceeded.

Whilst recognising the desire of some regulators for such an additional second higher level benchmark, the PROTECT consortium considers that there are many questions to be discussed outwith the PROTECT project before any firm recommendations could be made:

- Is there a need for a second higher level benchmark? There was not unanimous agreement of the need for such a value within the PROTECT workshops (Andersson et al., 2008).
- What is meant by a 'significant' level of effect? Acknowledging that there is no agreed precedence from chemicals regulation.
- How could a second higher level benchmark be derived?
- How would it be used in risk management and regulation under different exposure situations?

Given these questions the view of the PROTECT consortium is that it is not currently possible (until there is agreement on what the second higher benchmark actually represents) to give any definitive recommendations regarding a second higher benchmark. Furthermore, the area of environmental radioprotection will be subject to a number of international developments over the next few years, including the ICRP developing framework for the protection of the environment, developments within the IAEA in accordance with their Action Plan on Environmental Protection and the revised International and EC Basic Safety Standards. The PROTECT consortium suggests that there is a need for a wider discussion on the potential usefulness and application of a second higher benchmark value and the rest of this section is PROTECT's contribution to this debate. We also explore potential approaches which could be used to help determine such a level (Appendix 3).

5.1 Putting PROTECT into context with ICRP Recommendations

There is desire to produce a system for environmental radiological protection that is as similar as possible to that existing for humans. To that end in this sub-section we attempt to put into context the two potential benchmarks discussed above (and their use) with the framework for human protection. During the course of the PROTECT project a similar approach has also been proposed by Brownless (2007).

The ICRP consider three generic exposure situations as follows:

- Planned exposure situations - everyday situations involving planned operations, including decommissioning of nuclear facilities, disposal of radioactive waste and rehabilitation of radioactively contaminated land.
- Existing exposure situations - exposure situations that already exist where a decision on control has to be taken, including residues from past practices.
- Emergency exposure situations - unexpected situations that occur during the operation of a practice, requiring urgent action.

Assessments can also be prospective or retrospective, where the prospective assessment typically deals with question of authorisation of new planned exposure situations, but also assessments of future releases from existing sites perhaps under different management. This type of assessment would naturally need to use a great deal of modelled rather than measured



data. Retrospective assessments could be based on actual discharges and measurements in the environment and typically deal with effects of on-going planned situations and evaluation of any earlier prospective assessment for the site. There is, however, also often a need for modelling in retrospective assessments to account for deficiencies in monitoring and other data.

In comparison to human radiological protection this second higher value could be put into context with: (i) the ‘reference level’ for existing (and emergency) exposures and (ii) the ‘dose constraint’ for planned exposures (ICRP, 2007a). Where these are defined by the ICRP (for human protection) as follows:

Reference level - “In emergency or existing controllable exposure situations, this represents the level of dose or risk, above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimisation of protection should be implemented. The chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration.”

Dose constraint - “A prospective and source-related restriction on the individual dose from a source, which provides a basic level of protection for the most highly exposed individuals from a source, and serves as an upper bound on the dose in optimisation of protection for that source. For occupational exposures, the dose constraint is a value of individual dose used to limit the range of options considered in the process of optimisation. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source.”

As for the derivation of numeric values used in human radiological protection, science would be only one input into the determination of a second benchmark for use in environmental protection with wider societal, economic and political judgements incorporated into the derivation process. This implies that the second higher benchmark value may vary depending on these value judgements, which may themselves differ between exposure situations. The derivation of such a benchmark value would also need to consider the size of area and percentage of population affected, and the status of the affected population(s) and/or habitat. Therefore, there is the potential for different benchmark values to be set for different exposure situations and by different national competent authorities (as indicated on Figure 6).

The screening level could be considered to be broadly consistent with an exemption level. ICRP (2007a) define exemption as: “The determination by a regulatory body that a source or practice activity involving radiation need not be subject to some or all aspects of regulatory control.” and for which regulation on any reasonable scale will produce little or no improvement (ICRP, 2007c).

Whilst the ICRP reference levels and constraints are intended to be applied to a single source it is likely that environmental assessments may consider sites receiving discharges from a number of sources. Furthermore, the screening level has been derived as a PNEDR for total incremental exposure and is not therefore specifically a single source benchmark.

The screening value proposed by PROTECT and the potential second higher benchmark value (if adopted in the future) can therefore be seen to be broadly consistent with the framework for protection of humans. Both the screening and second higher benchmark value(s) will be applicable to planned and existing exposure situations although we do not envisage that they are relevant to emergency exposure situations (Table 10).



Table 10. Illustrative application of screening and second benchmark values in different exposure situations

	Prospective	Retrospective
Planned	An activity or process is very unlikely to be permitted if the predicted exposure to biota exceeds the second benchmark (i.e. as a dose constraint may be applied in human protection).	Depending where the predicted dose rates fall (below screening value, above screening value but below the second benchmark, or above the second benchmark), management may be considered/required to reduce the risk of impact. This would be considered in the context of optimisation of radiological protection as a whole.
Existing	The screening and second benchmark values would assist an assessor in determining risks of not undertaking remedial action. This would form part of the overall review (i.e. environmental and human radiological protection considered together) and be balanced against the likelihood of doing more good than harm.	
Emergency	Not applicable, although it is possible that assessments could be undertaken for ‘what if’ scenarios and the screening and second benchmark values could be helpful in highlighting where potential problems may occur – although screening and second benchmark values derived from chronic exposure data may not be appropriate to acute exposure scenarios	Not applicable, although data derived from this situation could be used to refine benchmark values

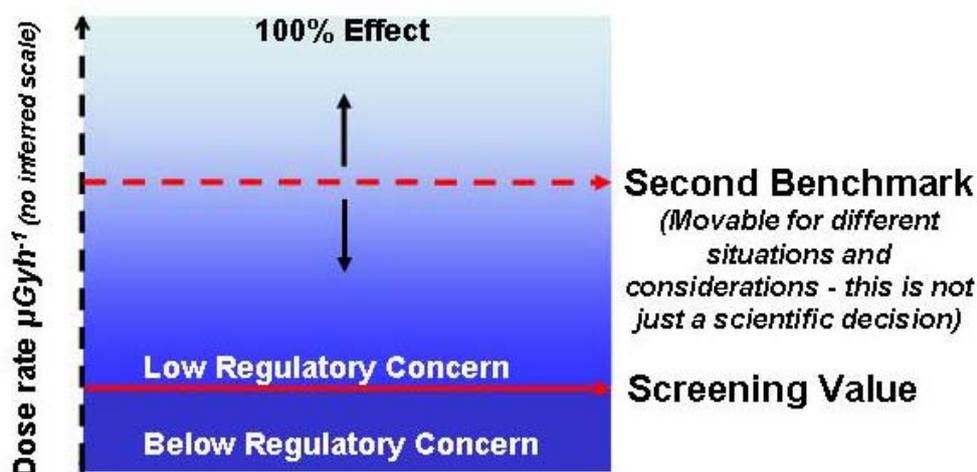


Figure 6. A second higher benchmark could help assessors place their results into context if dose rates were estimated to exceed the screening level. However, the selection of the numeric value of a second benchmark needs to take account of wider societal, economic and political judgements and may vary between situations.

5.2 The role of optimisation in relation to these numeric values and environmental radioprotection

At a fundamental level, the principle of optimisation could be applied to both humans and the environment. The definitions currently in use by ICRP and IAEA are as follows:

Principle of Optimisation of Protection (ICRP, 2007a) states that: “the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses, should be kept as low as reasonably achievable, taking into account economic and societal factors”.

IAEA: Protection (*of humans and environment*) must be optimised to provide the highest level of safety that can reasonably be achieved.

Optimisation could be viewed as a process that should be always gone through (Figure 7). It is unlikely that optimisation of protection of the environment would be done in isolation; it would almost certainly be combined with the optimisation of protection of humans.

There are many similarities between optimisation for humans and the environment. In both cases, optimisation is a societal decision based on values and tradeoffs as defined by a specific society. The process depends heavily on resource allocation and value judgements, as illustrated by the inclusion of the phrase: “economic and social factors taken into account” in the (ICRP) definition of the principle. There may be concerns over the possibilities for transfer of risk from one population to another (or from one species to another), as well as disagreements on the best course of action, or the exposure level at which optimisation may become irrelevant, if ever.

Despite these similarities, there are some important differences between human and environmental optimisation, specifically in the scientific basis for protection and the protection goal. For humans, the principle of optimisation is based on the linear no-threshold assumption for dose-effect. Many of the endpoints associated with environmental effects relate to deterministic effects, and thereby a threshold can be assumed. The protection goal for humans is individuals, and for the environment is usually set at the level of populations. Thus the methods used to achieve optimisation may be different in practice.

Differences in application may also depend on whether optimisation is applied to planned or existing exposure situations. For planned exposures, such as new build or an existing plant, one focus for optimisation would relate largely to discharges to the environment, and the desired consequences of optimisation are likely to be broadly similar for the public and the environment. Optimisation will thus probably result in benefit for both the public and the environment. It is possible however, that optimisation could lead to “risk transfer” (i.e. between workers and the public, or the public and the environment).

Brownless (2007) suggested that a screening (or threshold) value regarding environmental protection could also be the level above which the optimisation process should explicitly include consideration of doses to biota, whereas below the screening level, optimisation should only consider human protection. This could be justified in most cases because steps taken to optimise human protection would also improve the situation for biota.



In cases where this is not true (i.e. exposure transfer from humans to non-human biota), the differences between the assumed linear response and stochastic effects for humans, and threshold response and deterministic effects for other biota, means that, if doses to biota are below these threshold values, it could be argued that risk transfer from humans to biota would be inconsequential.

For existing exposure situations, such as remediation of contaminated land, the problem may be more complex. For example, cleaning up contaminated land to reduce exposures to humans (or non-human species) would be likely to result in environmental damage, thus the problem of risk transfer may be more prominent, and multi-criteria analysis may be more complex than for the planned situation (see, for example, Oughton et al., 2004). On the other hand the application of the screening level for environmental protection may be more straightforward, since if the site is below this level it would indicate that: i) that there was no issue, and ii) that no action is needed, at least with respect to environmental protection. But, again, reduction in exposures to humans, if present, and the environment would be considered together.

Figure 7 summarises the approach described above. If an assessment shows that measured/modelled dose rates are below the screening level, there should be no need for further concern about environmental effects (although it may be decided to optimise to below the screening level). If the dose rate is above the screening level, something needs to be done. A more refined assessment could show that dose rates are less than the screening values. Alternatively, site specific considerations could lead to the conclusion that risks associated with predicted dose rates are acceptable at levels greater than screening levels. Dose rates predicted to be higher than the second benchmark level may require some form of risk mitigation. However, as always, any action taken must be justified to do more good than harm⁹; Brownless (2007) has independently made the same suggestion.

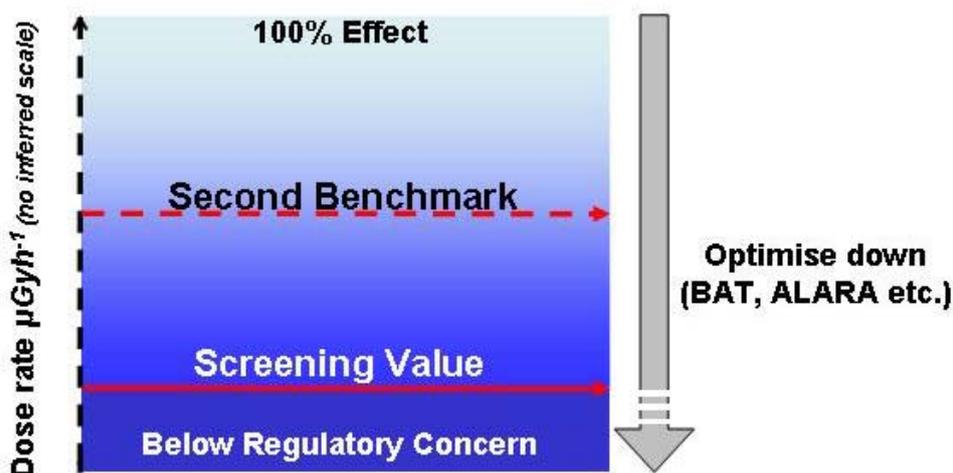


Figure 7. A potential system for protection of the environment in a regulatory context (see text for discussion).

⁹ Adhering to the principle of justification as defined by the ICRP (2007a).

5.3 Potential approaches to derive a second benchmark value

The TGD for chemical risk assessments does not give any guidance on setting a second benchmark value as the concept is not considered (EC, 2003). The approach taken in the TGD for situations where the risk quotient is estimated to be greater than 1 is to refine the exposure assessment and/or improve the effects database to determine whether the initially derived risk quotient is too conservative. If the risk quotient cannot be reduced to below 1 then the guidance is to implement risk reduction measures. However, there is an allowance for judgement depending upon the size of the quotient with factors listed (such as bioaccumulation and reference to results for analogous substances) that should be taken into account. There is also the suggestion that if the risk quotient is above but close to 1, then initiation of long-term monitoring may be a justifiable conclusion. For assessment of new chemicals there is some guidance based upon order of magnitude bands of estimated risk quotient.

Since there is no commonly agreed approach to define a second benchmark value which may be chosen to represent, for example 'serious' risk (for which there is no acknowledged definition), Appendix 3 explores approaches which may be used to provide the scientific input to help derive a value. It also discusses cases where a second higher benchmark(s) has previously been suggested for chemicals and also a limited number of radionuclides.



6. Discussion

The objectives of the work described in this report were to:

- derive numerical benchmarks for use in assessing the impact of ionising radiation on non-human species;
- use transparent methods adopted from those applied to derive benchmarks for chemical risk assessment; and
- suggest an approach which is broadly compatible with that used for human radiological protection.

PROTECT has met these objectives through:

- consultation with appropriate experts during a series of open workshops and external review of PROTECT outputs;
- applying those methods used in chemicals risk assessment to derive numeric benchmarks and documenting all the steps in this process in a clear and transparent manner;
- evaluating whether the resultant numeric values are ‘fit for purpose’; and
- putting PROTECT outputs into context with the ICRP Recommendations.

Before deriving any numeric values, PROTECT defined its protection goal as:

‘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, foundation, rare, protected or culturally significant species’.

Such a protection goal is consistent with those used for other environmental stressors such as chemicals. Whilst there is a desire to align any system for protection of non-human biota with the existing ICRP system for human protection (ICRP, 2007b), there are obvious differences between the ICRP system of human protection and proposals for the protection of non-human biota. These include: protection goals (individuals versus populations); relevant endpoints (stochastic versus deterministic effects); and the complexity of what needs be protected (one versus many contrasting species).

The focus of this report has been on the derivation of screening values and describing this process in a clear and transparent manner. The report has highlighted the need for careful review of the effects data that is used as an input into any method for deriving numeric benchmarks. We have described our process for selecting data.

For consistency with chemical risk assessment, PROTECT has adopted the assessment factor and statistical extrapolation techniques as recommended by the EC (2003) (i.e. the technical guidance document). PROTECT has, wherever possible, decided to use the statistical extrapolation techniques (SSD) for deriving our benchmarks. Within this report we have derived both generic and organism group specific screening values as a basis for further development of the protection of the environment. The FREDERICA database was used to identify references of suitable quality from which EDR₁₀ values (i.e. the dose rate giving rise to a 10% effect in the exposed group in comparison to the control group) could be estimated.



Several major international organisations (i.e. ICRP, EC, IAEA and UNSCEAR) have draft documents in progress on the topic of environmental protection. The results of the PROTECT project should make a valuable input into the overall consideration by the wider community of the outputs of these various groups.

6.1 Derivation of the generic screening value

For the estimation of the generic screening value, data for all organism types were used within an SSD. A number of different data treatments were considered, but all of the options we investigated gave a reasonably similar result (giving some confidence in the numbers generated). The methodology thus seems robust when applied to the available data for generate a generic screening value. Even if some of the EDR₁₀ values are uncertain in themselves (Appendix 1) the derived HDR₅ value did not changed substantially if values with lower associated uncertainty are used or if data were weighted for uncertainty. Consequently, we have used the TGD methodology, with simple rules for data selection and without arbitrary weighting, and have some confidence in the derived HDR₅ value. As the TGD does not give detailed guidance on the selection of an assessment factor, from the recommended range of 1 to 5, to apply to a derived HDR₅ value to estimate a PNEDR value we have used our own selection criteria. However, we acknowledge that there is considerable statistical uncertainty associated with the estimated HDR₅ value and the derived PNEDR should therefore be considered an indicative guidance value rather than an exact estimate.

The resultant proposed generic screening value is 10 $\mu\text{Gy h}^{-1}$.

6.2 Organism group screening values

In many cases the most exposed organism types may not necessarily be the most sensitive. Because a generic screening value is applied to all species its use may result in either: (i) overly conservative assessments which lead to more detailed site-specific assessments which may not be scientifically justified; or (ii) assessments which do not identify the need for more detailed consideration of the more radiosensitive organism groups. Organism group specific screening values may, therefore, be more appropriate than a single generic value. Ultimately, it would be desirable to have screening values for as many relevant groups as justifiable (probably taxonomically at the family or class level), however, currently we do not have enough data to achieve this. Consideration was therefore given to deriving values for three broad groups, namely plants, vertebrates and invertebrates recognising that these groupings each contain organisms which are likely to have a range of radiosensitivities. Whilst it would be preferable to derive these using the same SSD methodology as applied for the generic screening assessment, the lack of data led us to also consider alternative approaches. The estimated screening values were: (i) vertebrates 2 $\mu\text{Gy h}^{-1}$; (ii) plants 70 $\mu\text{Gy h}^{-1}$; (iii) invertebrates 200 $\mu\text{Gy h}^{-1}$. Taking into account the limited data and uncertainty associated with these estimates they should be considered as illustrative and indicative of the order of magnitude of values only. However, the organism group values are broadly compatible with the lower end of the DCL bands for comparable organisms as proposed in the draft ICRP report (ICRP, 2007b). Whilst the ICRP values were derived by expert judgement it is encouraging for both works that similar values have been derived using different approaches.

The conceptual difference between the types of screening value is that the generic value should *protect 95% of all species* whereas the organism specific values should *protect 95% of species*



within each organism group. Application of a generic screening value may therefore not protect all groups to a 95% level.

An advantage of the SSD methodology is that it can be easily refined as more data become available, and targeted studies could be designed to provide data to enable SSDs to be constructed for organism groupings.

6.3 Application of screening values

The resulting values of both types of screening values seem to be realistic and are generally within the lower range of values suggested as being appropriate for population level protection by other organisations using purely ‘expert judgement’. The generic screening value is consistent with other studies that used different data treatments (Twining et al., 2005; Garnier-Laplace et al., 2008). Furthermore, whilst there are still large data and knowledge gaps for radiation, the level of understanding is greater, and the quality and quantity of data certainly no worse than for many other chemical pollutants for which benchmarks often have to be derived using deterministic approaches.

All screening values derived within PROTECT should be applied within assessments as incremental dose rates. A potential criticism of the use of incremental dose rate as a basis for effects on the environment is that most relevant endpoints are considered as deterministic and showing a threshold, thus making the use of total dose more relevant from this point of view. However, only the incremental dose can be regulated. Consideration of incremental dose is also consistent with the protection of humans regarding radiation. A similar “added-risk approach” is also sometimes used within chemicals regulation.

6.4 Second higher level benchmark

The PROTECT consortium recognises the potential usefulness of a second higher level benchmark value as requested by some regulators and recommends that this is discussed further by the wider community. However, currently there is no widespread acceptance that such a value is required (see Andersson et al., 2008) nor is there consensus (or a precedent which can be adopted from chemicals regulation) with regard to what this value should represent (i.e. what is a ‘significant effect’). The view of the PROTECT consortium is that it is not currently possible (until there is agreement on the need for and potential application of a second benchmark) to give a prescriptive value. As a scientific input into this debate, we have explored approaches which could be used to help determine a second higher benchmark value.

The concepts of the screening value proposed by PROTECT and the potential second higher benchmark value (if adopted in the future) can be seen to be broadly consistent with the framework for protection of humans. These concepts could be used within a framework for the protection of the environment which could be applied in parallel to that existing for human protection. Brownless (2007) has also suggested a two benchmark scheme and similarly proposed that it could be readily integrated into the current system of human radiological protection. It is encouraging that different groups working on this issue are proposing similar recommendations.



7. Recommendations

PROTECT recommends the following:

- The use of SSD methodology to derive, or inform the derivation of, numeric benchmarks where sufficient data are available and that the derivation of any numbers is clearly documented.
- The scientific community should perform targeted studies to enable SSD to be generated for required organism groups.
- The application of a generic screening value of $10 \mu\text{Gy h}^{-1}$ until sufficiently robust organism group values can be generated.
- The screening value should be applied for total incremental exposure (i.e. it is not a single source benchmark).
- That the concept, use and meaning of a potential second higher level benchmark value are discussed further by the wider community.
- There is a need for co-ordination of the studies required to further develop this area.



Acknowledgements

The PROTECT consortium would like to thank all those experts who attended the two workshops associated with this work package (Andersson et al., 2008; Beresford et al., 2008a). We are also grateful to those who submitted comments in response to draft versions of this report.

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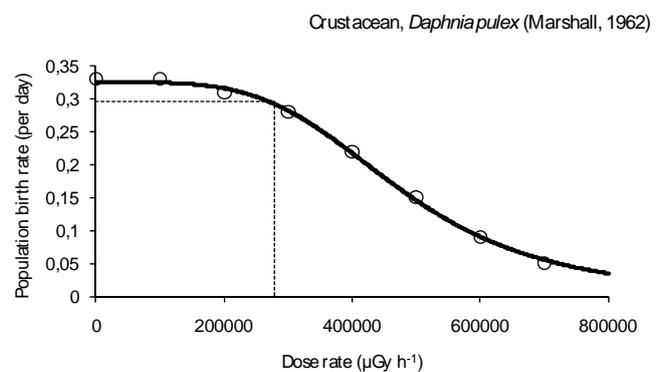
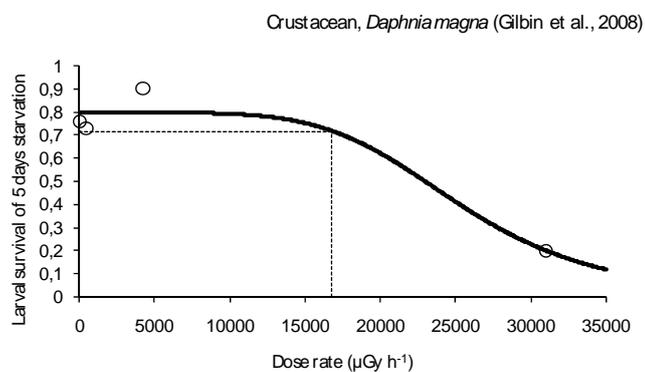
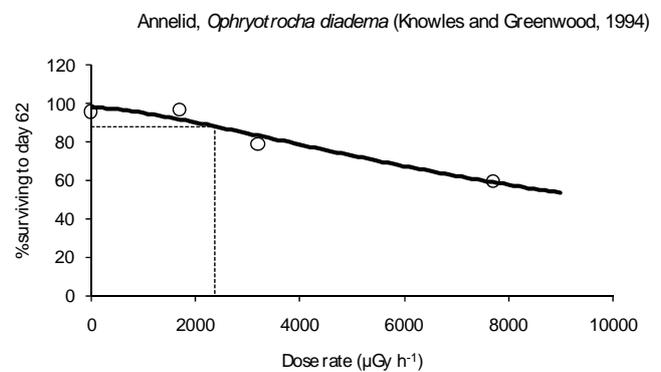
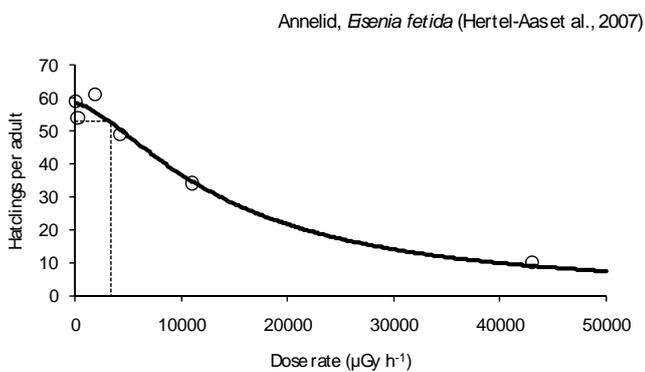
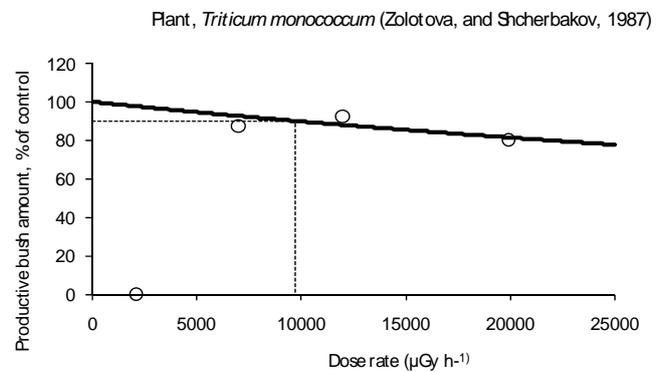
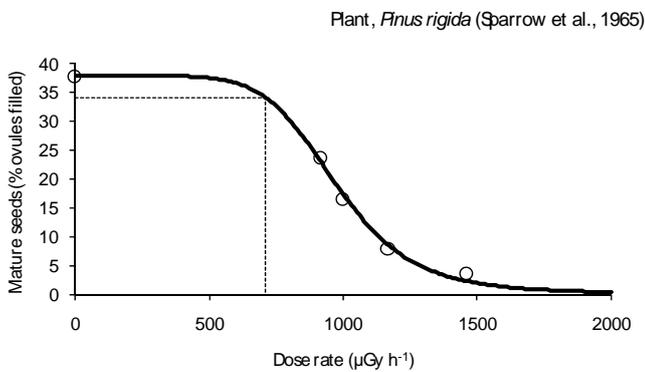
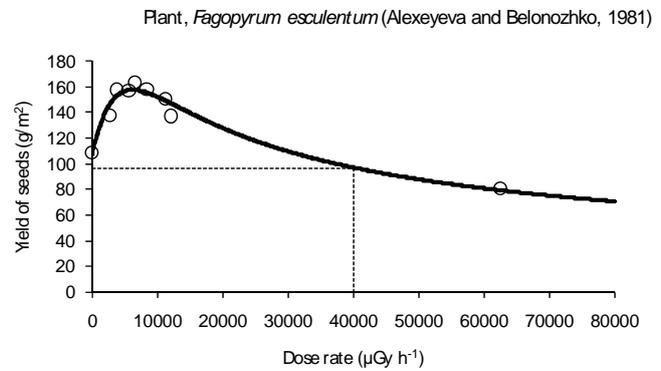
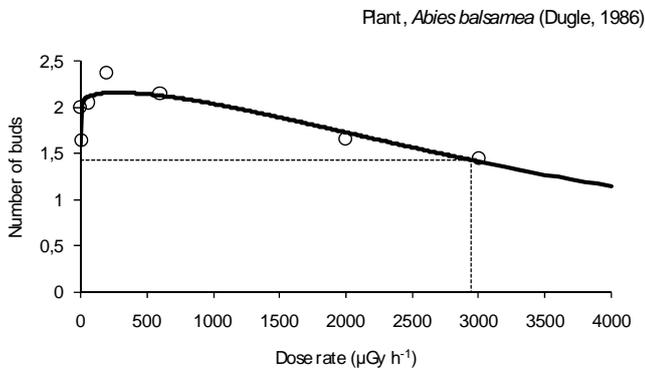
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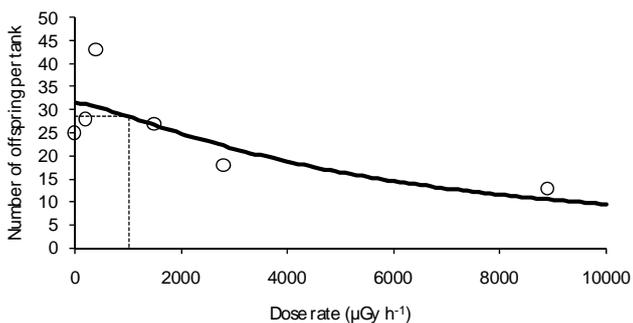
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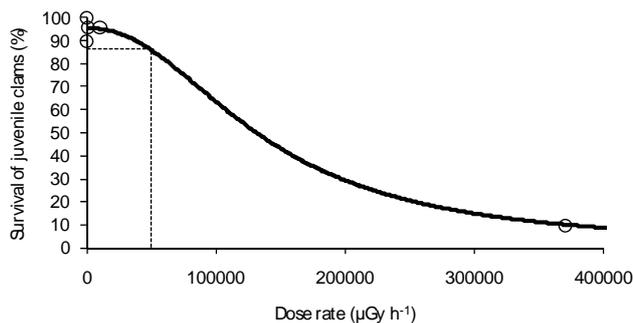
Appendix 1. Graphs showing the fitted distributions and the derived EDR₁₀ values for the 20 datasets showing the lowest EDR₁₀ value for each species which have been used for derivation of the screening values presented within the report.



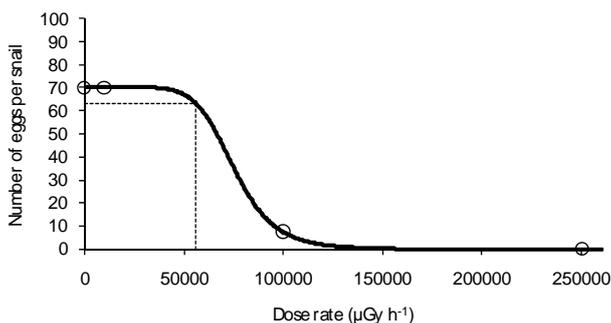
Crustacean, *Porcellio scaber* (Hingston et al., 2004)



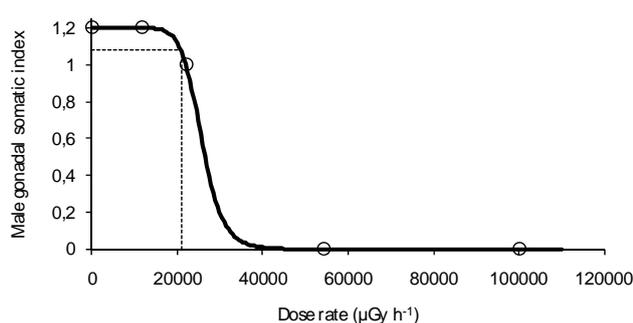
Mollusc, *Mercenaria mercenaria* (Baptist et al., 1976)



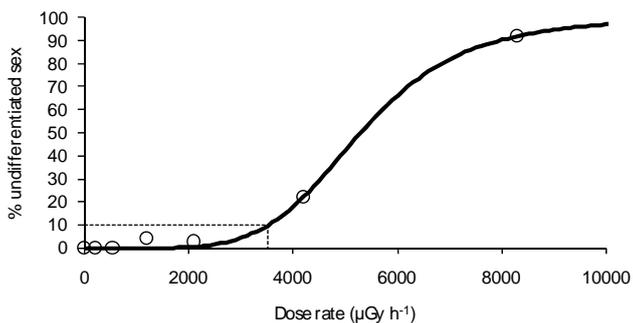
Mollusc, *Physa heterostropha* (Cooley and Nelson, 1970)



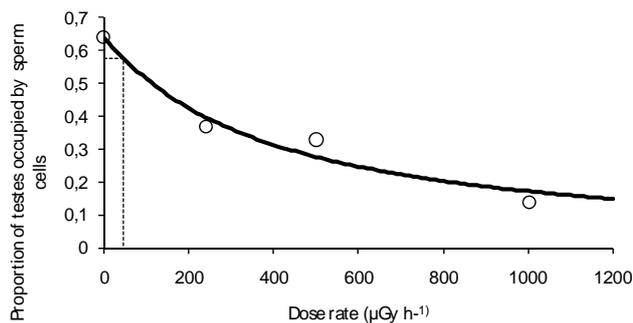
Fish, *Oryzias latipes* (Egami and Hama-Furukawa, 1981)



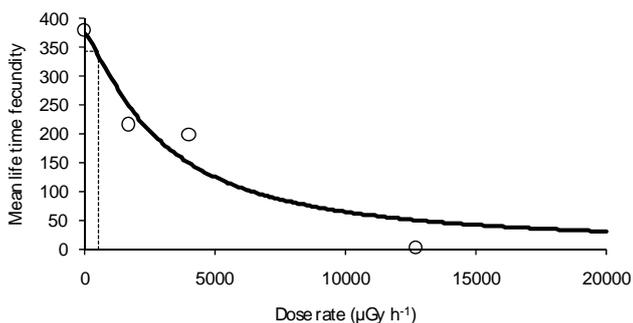
Fish, *Oncorhynchus tshawytscha* (Bonham and Donaldson, 1972)



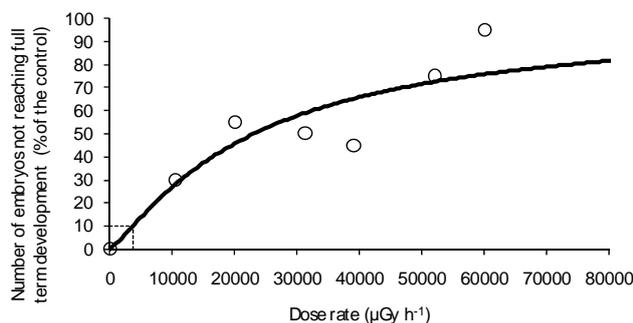
Fish, *Pleuronectes platessa* (Knowles, 1999)



Fish, *Poecilia reticulata* (Woodhead, 1977)



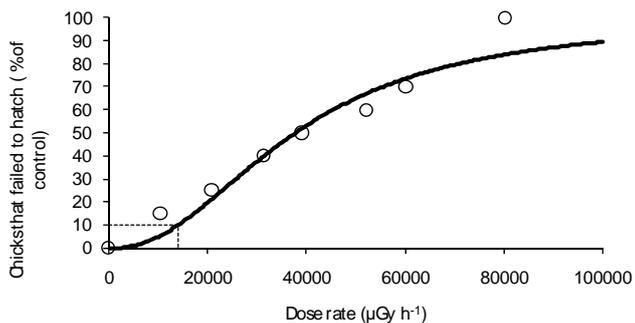
Bird, *Larus ridibundus* (Phillips and Coggle, 1988)



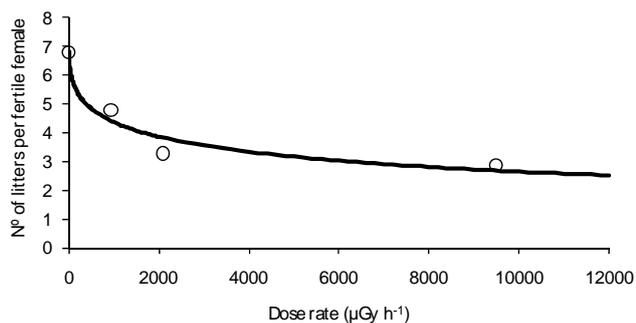
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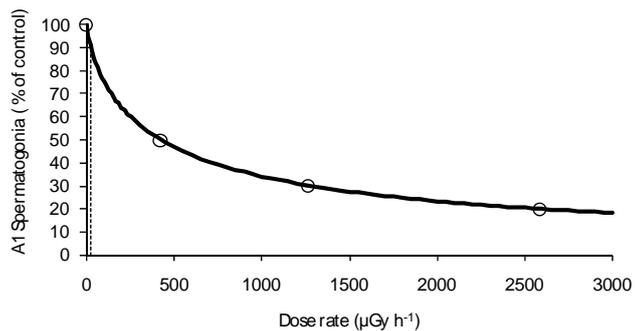
Bird, *Gallus gallus* (Phillips and Coggle, 1988)



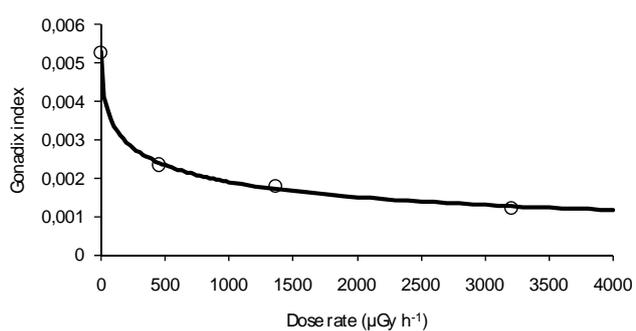
Mammal, *Mus musculus* (Rönnbäck, 1983)



Mammal, *Rattus norvegicus* (Erickson, 1978)



Mammal, *Sus crofa* (Erickson, 1976)



Appendix 2. Datasets in the Frederica database that passed all criteria set up to ensure that EDR₁₀ values were derived only from suitable datasets. The lowest of these for each species were used as input to SSDs and are marked in yellow. Alternative input to SSD as described in the text are marked in green (lowest uncertainty) or blue (available HNEDR lower than EDR₁₀). Reference ID refers to the ID number used in the FREDERICA database. The most recent studies considered within PROTECT have not yet been added to the Frederica database.

ID	Group	Species	Effect description	EDR10	HNEDR	Comments
PLANTS						
804	Cyanobacteria	<i>Synechococcus lividus</i>	Cell numbers in cultures irradiated at various doses in media inoculated with early stationary cells	5,5		Extremophile
804	Cyanobacteria	<i>Synechococcus lividus</i>	Cell numbers in cultures irradiated at various doses in media inoculated with early stationary cells	7,4		Extremophile
349	Moss/lichen	Numerous species	Number of lichen species per 10m2 (mean density of thalli/m2)	166553		Numerous species
523	Plants	<i>Abies balsamea</i>	Summary of mean fir characteristics for seven dose-rate categories, Number of buds (1975).	2945		
841	Plants	<i>Fagopyrum esculentum</i>	Productivity in M3 generation (1979), Yield of seeds (g/sq.m)	40151		
336	Plants	Numerous species	Percentage canopy deaths	22341		Numerous species
485	Plants	Numerous species	Percentage canopy cover after 10 years.	4453		Numerous species
347	Plants	Numerous species	Species diversity.	54247		Numerous species
416	Plants	<i>Pinus rigida</i>	Effect of long term irradiation on seed development. Dose rate provided as average per day	710		
998	Plants	<i>Triticum monococcum</i>	Productive bush amount, % of the control value. N 3, K-29602 T. monococcum var. Atriaristatum	9760		
998	Plants	<i>Triticum monococcum</i>	Fertility, % of the control value. N 15, K-23653 T. monococcum var. Hornemanni	9819		
998	Plants	<i>Triticum monococcum</i>	Fertility, % of the control value. N 17, K-39756 T. monococcum var. Flavescens	10149		
998	Plants	<i>Triticum monococcum</i>	Fertility, % of the control value. N 12, K-35915 T. monococcum var. Vulgare	10222		
998	Plants	<i>Triticum monococcum</i>	Productive bush amount, % of the control value. N 15, K-23653 T. monococcum var. Hornemanni	10710		
998	Plants	<i>Triticum monococcum</i>	Fertility, % of the control value. N 18, K-39722 T. monococcum var. Atriaristatum	11095		
998	Plants	<i>Triticum monococcum</i>	Fertility, % of the control value. N 21, K-1990/7 T. monococcum	11943		
998	Plants	<i>Triticum monococcum</i>	Fertility, % of the control value. N 2, K-6532 T. monococcum var. Hornemanni	12269		
998	Plants	<i>Triticum monococcum</i>	Fertility, % of the control value. N 23, K-1509/2, 3, 5, 6, 1 T. monococcum var. Niricultum	12471		
998	Plants	<i>Triticum monococcum</i>	Productive bush amount, % of the control value. N 17, K-39756 T. monococcum var. Flavescens	13081		
998	Plants	<i>Triticum monococcum</i>	Productive bush amount, % of the control value. N 18, K-39722 T. monococcum var. Atriaristatum	13911		
998	Plants	<i>Triticum monococcum</i>	Productive bush amount, % of the control value. N 23, K-1509/2, 3, 5, 6, 1 T. monococcum var. Niricultum	13953		
998	Plants	<i>Triticum monococcum</i>	Height of plant, % of the control value. N 21, K-1990/7 T. Monococcum	15461		
998	Plants	<i>Triticum sinskajae</i>	Productive bush amount, % of the control value. N 13, K-48993 T. sinskajae var. Sinskajae	6434		
INVERTEBRATES						
Hertel-Aas et al., 2007	Annelid	<i>Eisenia fetida</i>	Hatchlings per adult during the whole 13 weeks reproduction exposure period (F1/ Adult F0)	3369		
Hertel-Aas et al., 2007	Annelid	<i>Eisenia fetida</i>	F0 Hatchability (%) during the ninth and the thirteenth week of exposure	5424		
Hertel-Aas et al., 2007	Annelid	<i>Eisenia fetida</i>	F1 Hatchability (%) between the 12h and 16th weeks of exposure	6351		
Hertel-Aas et al., 2007	Annelid	<i>Eisenia fetida</i>	F1 Hatchability (%) between the 21h and 24th weeks of exposure	7795		
1282	Annelid	<i>Eisenia fetida</i>	Average mutation frequency (x 10 ⁻⁵)	7906		Mutations not considered
Hertel-Aas et al., 2007	Annelid	<i>Eisenia fetida</i>	F1 Hatchability (%) between the 17h and 20th weeks of exposure	9093		
Hertel-Aas et al., 2007	Annelid	<i>Eisenia fetida</i>	Hatchlings per adult during the whole 13 weeks reproduction exposure period (F2/ Adult F1)	9098		
358	Annelid	<i>Neanthes arenaceodentata</i>	Mean number of embryos (F2) produced.	12290		1
361	Annelid	<i>Ophryotrocha diadema</i>	The percentage of worms in generation 3 surviving to day 62.	2360		
361	Annelid	<i>Ophryotrocha diadema</i>	The percentage of worms in generation 7 surviving to day 62.	7368		
361	Annelid	<i>Ophryotrocha diadema</i>	The percentage of worms in generation 3 surviving to day 50.	7891		
361	Annelid	<i>Ophryotrocha diadema</i>	Number of sacs per worm - generation 1, Data extracted from a figure	10852		
361	Annelid	<i>Ophryotrocha diadema</i>	Number of eggs per worm - generation 1, Data extracted from a figure	10935		
Gilbin et al., 2008	Crustaceans	<i>Daphnia magna</i>	change in daphnid mass-specific respiration rates at 21 days of age	1018		Endpoint not consider relevant
Gilbin et al., 2008	Crustaceans	<i>Daphnia magna</i>	Larval survival to starvation during 5 days, brood 1 (% survival when food lacks)	16797		2
490	Crustaceans	<i>Daphnia pulex</i>	Number of aborted eggs		45000	

ID	Group	Species	Effect description	EDR10	HNEDR	Comments
1065	Crustaceans	<i>Daphnia pulex</i>	Population birth rate (per day) Data read from graph	277634		
1065	Crustaceans	<i>Daphnia pulex</i>	Life expectancy (in day) Data read from graph	287667		
1065	Crustaceans	<i>Daphnia pulex</i>	Survival (fraction) Data read from graph/DAY 20	410744		
1065	Crustaceans	<i>Daphnia pulex</i>	Survival (fraction) Data read from graph/DAY 10	729897		
247	Crustaceans	<i>Porcellio scaber</i>	Mean number of offspring per tank per dose rate group	1030		
Hingston et al., 2005	Crustaceans	<i>Porcellio scaber</i>	cumulative number of mortalities per dose rate group	5915		
247	Crustaceans	<i>Porcellio scaber</i>	Cumulative number of mortalities per dose rate group	6274		
296	Molluscs	<i>Mercenaria mercenaria</i>	Survival of juvenile clams (%) on day 426. Dose = max. cumulative dose	49520		3
296	Molluscs	<i>Mercenaria mercenaria</i>	Survival of juvenile clams (%) on day 214. Dose = max. cumulative dose	110974		3
326	Molluscs	<i>Physa heterostropha</i>	Several endpoints, including those below			10000
326	Molluscs	<i>Physa heterostropha</i>	No of eggs/snail	55831		
326	Molluscs	<i>Physa heterostropha</i>	Percentage of eggs that hatched	61229		
326	Molluscs	<i>Physa heterostropha</i>	Average number of eggs/capsules	66271		
VERTEBRATES						
384	Birds	<i>Gallus gallus</i>	Male body weights of 2 week old birds that were irradiated at different periods during incubation:	6948		4
448	Birds	<i>Gallus gallus</i>	Hatchability as a % of the control	13932		
384	Birds	<i>Gallus gallus</i>	Male gonadal weights of 2 week old birds that were irradiated at different periods during incubation.	25519		4
448	Birds	<i>Larus ridibundus</i>	Number embryos reaching full term development as a % of the control	3696		
170	Fish	<i>Oncorhynchus tshawytscha</i>	% (of irradiated fish) undifferentiated sex	3518		
46	Fish	<i>Oryzias latipes</i>	Median survival time (d)			4167
Egami and Furukawa, 1981	Fish	<i>Oryzias latipes</i>	Male mean gonad weight (mg)	19730		5
Egami and Furukawa, 1981	Fish	<i>Oryzias latipes</i>	Male gonadal somatic index (mean gonad weight (mg) / mean body weight (mg) *100)	20881		
204	Fish	<i>Oryzias latipes</i>	Female gonadal somatic index ((mean gonad weight/mean body weight) x 100)	32897		
Egami and Furukawa, 1981	Fish	<i>Oryzias latipes</i>	Female mean body weight (mg)	85008		
204	Fish	<i>Oryzias latipes</i>	Number of surviving fish	90861		
207	Fish	<i>Pleuronectes platessa</i>	Mean proportion of plaice testes occupied by different cell types irradiated for 197 days - sperm	47		
207	Fish	<i>Pleuronectes platessa</i>	Mean proportion of plaice testes occupied by different cell types irradiated for 73 days - spermatogonia	193		
207	Fish	<i>Pleuronectes platessa</i>	Mean proportion of plaice testes occupied by different cell types irradiated for 73 days - non germinal cells	193		
207	Fish	<i>Pleuronectes platessa</i>	Mean proportion of plaice testes occupied by different cell types irradiated for 197 days - non germinal cells	487		
207	Fish	<i>Pleuronectes platessa</i>	Mean proportion of plaice testes occupied by different cell types irradiated for 197 days - spermatogonia	499		
74	Fish	<i>Poecilia reticulata</i>	Mean life time fecundity	516		
3	Fish	<i>Poecilia reticulata</i>	% steril pairs of fish	1958		
616	Mammals	<i>Mus musculus</i>	N° of litters per fertile female during 245 days (mean; SE).	26		
616	Mammals	<i>Mus musculus</i>	Germ cells per ovarie (mean; SE). Analysis at 56 days of age.	196		
Tanaka et al., 2007	Mammals	<i>Mus musculus</i>	female mean survival of all causes of death	523		
Tanaka et al., 2007	Mammals	<i>Mus musculus</i>	female mean survival of soft tissue neoplasms	528		
Tanaka et al., 2007	Mammals	<i>Mus musculus</i>	female mean survival of all fatal neoplasms	630		

[PROTECT]

ID	Group	Species	Effect description	EDR10	HNEDR	Comments
Tanaka et al., 2007	Mammals	<i>Mus musculus</i>	female mean survival of non-neoplastic lesions	685		
Tanaka et al., 2007	Mammals	<i>Mus musculus</i>	male mean survival of all fatal neoplasms	727		
Tanaka et al., 2007	Mammals	<i>Mus musculus</i>	male mean survival of all causes of death	767		
Tanaka et al., 2007	Mammals	<i>Mus musculus</i>	male mean survival of lymphoma,malignant	795		
Tanaka et al., 2007	Mammals	<i>Mus musculus</i>	female mean survival of lymphoma malignant	797		
Tanaka et al., 2007	Mammals	<i>Mus musculus</i>	female incidence of all fatal neoplasms	862		
624	Mammals	<i>Mus musculus</i>	Litter size (mean number of living foetus; SE) : treatment on the 2nd week after birth	888		
619	Mammals	<i>Mus musculus</i>	Life span reduction (% from control)	896		
624	Mammals	<i>Mus musculus</i>	Litter size (mean number of living foetus; SE): treatment on the 1st week after birth	1068		
624	Mammals	<i>Mus musculus</i>	Fertility (% among the tested females): treatment on the 2nd week after birth	1525		
624	Mammals	<i>Mus musculus</i>	Fertility (% among the tested females f): treatment on the 1st week after birth	2436		
1021	Mammals	<i>Mus musculus</i>	Percentage of pulmonary adenomas in female mice	5364		Tumors not considered
615	Mammals	<i>Mus musculus</i>	Mortality ratio (BALB/c mice)	10483		
615	Mammals	<i>Mus musculus</i>	Mortality ratio (B6CF1 mice)	17750		
615	Mammals	<i>Mus musculus</i>	Specific mortality rate on age k for all causes of death (x10-3/d) (BALB/c mice)	18032		
615	Mammals	<i>Mus musculus</i>	Specific mortality rate on age k for all causes of death (x10-3/d) (B6CF1 mice)	18429		
1021	Mammals	<i>Mus musculus</i>	Number of lymphoid tumors in male mice exposed to low dose daily gamma irradiation,	19754		Tumors not considered
615	Mammals	<i>Mus musculus</i>	Specific mortality rate on age k for all causes of death (x10-3/d) (C57BL/6 mice)	20299		
615	Mammals	<i>Mus musculus</i>	Specific mortality rate on age k for all causes of death (x10-3/d) (A/J mice)	24041		
615	Mammals	<i>Mus musculus</i>	Mortality ratio (C57BL/6 mice)	25768		
593	Mammals	<i>Rattus norvegicus</i>	A1 Spermatogonia (% of control)	24		
593	Mammals	<i>Rattus norvegicus</i>	As Spermatogonia (stem cells) % of control	452		
629	Mammals	<i>Rattus norvegicus</i>	Germ cells in Female rats (% of control)	473		
593	Mammals	<i>Rattus norvegicus</i>	A4 Spermatogonia (% of control)	547		
593	Mammals	<i>Rattus norvegicus</i>	Testis weight (% of control)	631		
629	Mammals	<i>Rattus norvegicus</i>	Germ cells in Male rats (% of control)	1026		
629	Mammals	<i>Sus crofa</i>	Gonadic index : Testis weight (g) at 150 days of age (+- SE)/Body weight (g) at 150 days of age	3,6		
629	Mammals	<i>Sus crofa</i>	Testis weight (g) at 70 days of age (+- SE)	6,7		
629	Mammals	<i>Sus crofa</i>	Gonadic Index : Ovary weight (g) at 70 days of age (+- SE)/Body weight (g) at 70d	16		
629	Mammals	<i>Sus crofa</i>	Ovary weight (g) at 70 days of age (+- SE)	25		
629	Mammals	<i>Sus crofa</i>	Germ cells in Male pigs (% of control)	47		
629	Mammals	<i>Sus crofa</i>	Germ cells in Female pigs (% of control)	123		
629	Mammals	<i>Sus crofa</i>	Brain weight (g) at 70 days of age (+- SE)	1667		

1 Data regarding the most sensitive endpoint (% live embryos) was not reported in a form possible to use in a derivation of an EDR₁₀ value - the study was therefore not included.

2 Stress on stress test of indirect effect on energy allocation to juveniles production

3 Survival at a later date is more relevant than at an earlier date

4 Judged to be acute exposure rather than chronic exposure

5 Gonadal index considered a more valid endpoint than gonad weight alone

[PROTECT]

69/72

Dissemination level: PU

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Appendix 3. Potential approaches which could aid in the selection of a second benchmark value

We are aware of a few different approaches to derive a higher level benchmark that have been used within chemicals regulation. In the Netherlands a ‘Serious Risk Concentration for the ecosystem’ (SRC_{eco}) value is used for deriving intervention levels (Traas, 2001; Verbruggen et al., 2001). If there are sufficient data, the SRC_{eco} is derived as the 50th percentile of an SSD based on no observed effect concentration values. Therefore, as a first approach to illustrating how this could be derived, PROTECT has used the same SSD methodology as used for the screening level. However, different levels of potential impact have been predicted by using different values of EDR_n and outputting various HDR_n values.

Table 11 presents HDR_n values for the EDR₁₀, EDR₂₅ and EDR₅₀ estimates for the data described above and presented in Appendix 1. This analysis has included data across all organism groups, however, there are less data for EDR₂₅ and EDR₅₀ estimates than for EDR₁₀, as not all datasets were sufficient to enable determination of these values (i.e. the reported effects were all less than 25 or 50% respectively). Thus, if the Dutch SRC_{eco} was adopted for radioactivity the second higher benchmark value would be set at 2000 µGy h⁻¹ (based on EDR₁₀ values) which would be in the dose rate range of considerable impact for some organisms, especially vertebrates, as discussed below regarding field observations. If few data are available the Dutch approach also proposes that the SRC_{eco} can be derived based on the lowest value from the geometric mean of the chronic toxicity data or acute toxicity data (estimated as LC₅₀/10).

The other approaches we are aware of which have suggested a set of higher level benchmark values are sediment quality guidelines derived in Canada. In one approach (CCME, 1995) a *probable effect level* (PEL) was estimated for each chemical as the geometric mean of the 50th percentile concentration of the effect data set and the 85th percentile concentration of the no-effect data set. The PEL is stated to represent the lower limit of the range of chemical concentrations that is usually or always associated with adverse biological effects. In the second approach (Fletcher et al., 2008) occurrence or absence of species in the sediment invertebrate community is compared directly with concentrations of contaminants in the sediment. The rationale behind the derivation involves a species specific concentration (the 90th percentile of sediment concentrations where the species is still present) and a type of species sensitivity distribution where the ‘severe effect level’ (SEL) was set at the 95th percentile of the species specific concentrations. The SEL is stated to represent the concentration above which severe effects are expected. This approach has also been used for some radionuclides in Canada (Thompson et al., 2005). In this case the upper level was

Table 11. Different HDR_n of an unweighted SSD derived using EDR₁₀, EDR₂₅ or EDR₅₀ values as inputs and following the same derivation methodology as used for the generic screening value (µGy h⁻¹).

Input data	EDR ₁₀	EDR ₂₅	EDR ₅₀
Number of data	20	18	16
R ²	0.95	0.98	0.97
HDR₅	17	65	233
HDR₁₀	51	166	514
HDR₂₀	189	514	1340
HDR₅₀	2304	4499	8368



Table 12. Global overview of dose rate – effects relationships for wildlife and chronic exposure to low-LET radiation observed in field studies at former Soviet Union sites. Adapted from Sazykina, 2005.

Dose rate ($\mu\text{Gy h}^{-1}$)	Radiation effects
0.04-4	No data
4-20	Minor cytogenetic effects in sensitive vertebrate species
20-80	Threshold for minor effects on morbidity in sensitive vertebrate species
80-200	Threshold for effects on reproductive organs of vertebrates, decrease of embryo's survival.
200-400	Threshold for life shortening of vertebrates. Threshold for effects in invertebrates. Threshold for effects on growth in coniferous trees.
400-4000	Symptoms of "chronic radiation sickness" for vertebrates. Considerable damage to coniferous trees
4000-40000	Symptoms of acute radiation sickness in vertebrates. Death of coniferous trees. Considerable damage in eggs and larva of invertebrates.
>40000	Lethal dose received within several days for vertebrates. Induced mortality of eggs and larva of invertebrates. Death of coniferous trees, damage to deciduous plants.

derived individually for each radionuclide based on concentration rather than total dose rate for all radionuclides combined. The SEL was in most cases about twenty times higher than the LEL (Lowest Effect Level) values presented in Tables 1 and 2.

PROTECT has also reviewed the available literature (concentrating on review publications) and the FREDERICA database to investigate if field observations could be used to help in the process of finding the appropriate level for a higher level benchmark representing 'serious risk of harm'. Only a few published results/reviews that could be used as a basis to aid expert judgement on this issue were identified. However, most studies report effects on individuals rather than populations, so additional expert judgment is needed to consider if the described effects would be manifested at the population level. Regarding vertebrates, the lowest dose rate giving observed effects, a significantly higher percentage of dead embryos in Mosquitofish (*Gambusia affinis*), was $25 \mu\text{Gy h}^{-1}$ (Trabalka and Allen, 1977). The lowest dose rate for observed effects in plants was $120 \mu\text{Gy h}^{-1}$ which resulted in reduced germination of seeds from *Pinus rigida* (Mergen and Johansen, 1964). Neither of these effects are mentioned by the originating authors as representing significant harm to the population, and hence they do not aid the discussion of derivation of a second higher benchmark value.

Sazykina (2005) reviewed data from studies conducted at contaminated sites within the former Soviet Union. Table 12 presents the summary of these data as reported by Sazykina (2005). These summarised results illustrate an issue with regard to selecting a second higher benchmark which we have not yet discussed. As we do not yet have a definition of 'serious risk' it is possible to suggest on the basis of the summarised data that this may be in the range $80\text{-}200 \mu\text{Gy h}^{-1}$ for vertebrates. This is similar to the proposed screening value of $200 \mu\text{Gy h}^{-1}$ for invertebrates perhaps leading to the suggestion that higher benchmarks would be required for different organism groups. Much of the field data reviewed by Sazykina is derived from studies close to the Chernobyl NNP (post 1986), areas impacted by the Mayak plant and areas of high or enhanced natural radionuclides. Therefore, whilst this represents one of the more comprehensive reviews, there are issues with data interpretation including: if 'chronic' exposure effects are really being observed rather than 'acute phase' responses followed by long-term exposure; confounding factors such as the removal of human populations; and the chemical toxicity of elements present at some sites (including U toxicity). Geras'kin et al.



(2008) have also recently summarised observed doses (and some dose rates) and corresponding observed effects after the Chernobyl NPP accident. These authors acknowledge that observed effects after an accident such as the one in Chernobyl are very much influenced by the acute doses from short-lived radio nuclides received just after the accident, and that it is difficult to judge the effects caused by chronic exposure from the long-lived nuclides.

The FREDERICA database yielded few studies of direct relevance. Leonard et al. (1985) investigated mice enclosed in buildings on a site with high levels on natural radioactivity and found reduced number of offspring at dose rates of 60-100 $\mu\text{Gy h}^{-1}$. The mean number of offspring decreased from 7.7 to 5.0 per female and mean weaned offspring decreased from 3.9 to 2.9. However, the authors make no comment on whether their results have any significance at the population level. A field irradiation study in Nevada (USA) analysed the effects of chronic gamma irradiation on desert small rodent populations (French et al., 1974). Animals received a gamma irradiation rate of 241-411 $\mu\text{Gy h}^{-1}$ from April-May 1963 to May-June 1968. The irradiated population showed reduced survival rates one month after the irradiation started although a higher birth rate was seen in the irradiated population which also showed increased rate of death. Effects on fertility were not measured in the study, but from the data of birth and death rate, a 40% reduction in the multiplication rate per generation was estimated. The authors concluded that chronic exposure to dose rates of 241- 411 $\mu\text{Gy h}^{-1}$ gamma radiation was ‘clearly detrimental for a population of desert rodents’. However, commenting upon this study Mihok (2004) notes that rodent densities in the irradiated enclosure remained considerably higher than in the control enclosures throughout many years of exposure. Mihok (2004) also notes that exposure rates of burrowing rodents in the study of French et al. (1974) may have varied between 0 $\mu\text{Gy h}^{-1}$ (when underground) and $>4000 \mu\text{Gy h}^{-1}$. The paper of Mihok also considers two field irradiation studies in Manitoba (Canada). In the first of these studies¹⁰, which spanned over 10 years with dose rates ranging from $<1 \text{ mGy d}^{-1}$ to $>1000 \text{ mGy d}^{-1}$ (close to the irradiator), “there was no clear evidence for any effect on *Clethrionomys gapperi* (red-backed vole) populations”. For the second study¹¹ Mihok (2004) concludes that no effects on populations of *Microtus pennsylvanicus* (meadow vole) were detected over irradiation periods of 1-1.5 years up to the highest dose rate of 81 mGy d^{-1} .

In deriving any second higher benchmark value it may also be useful to consider variability around the HDR₅ value as additional weight of evidence with regard to the numeric values being considered.

The on-going reviews of both the UNSCEAR and the ICRP will, hopefully, significantly improve our understanding of ‘population significant’ effects observed in field studies.

¹⁰Referred to as the FIG forest study (see Mihok (2004) for original references)

¹¹Referred to as the ZEUS study, the original data being presented in Mihok (2004)