

Protection of the environment from ionising radiation in a regulatory context (PROTECT): proposed numerical benchmark values

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INTRODUCTION

Tools for assessing whether the environment is protected from the effects of ionising radiation need benchmark numerical values (dose rates, doses or activity concentrations) against which the assessment results can be compared. However, the issue of benchmark values has not been rigorously addressed during the development of radiological environmental protection tools over the last decade. Whilst, most approaches (e.g. those used in the UK and USA) make reference to IAEA (1992) and UNSCEAR (1996), the derivation of guideline dose rate values in these publications is not transparent. The EURATOM project ERICA (see <http://www.ceh.ac.uk/protect/ERICAdeliverables.html>) established a radiation effects database (FREDERICA) (Copplestone *et al.*, in press) which can be used as a source of information to derive predicted no effect or effect levels (Garnier-Laplace *et al.*, 1996).

This paper describes the interim outputs from the EURATOM funded project PROTECT (<http://www.ceh.ac.uk/protect>) which will propose benchmark values that can be used for guidance in regulatory processes. Important steps on the way to suggesting benchmark values are decisions on appropriate protection goals (e.g. the level and target of protection) and the method of deriving values corresponding to these protection goals. Furthermore, environmental protection goals and methods for deriving corresponding benchmark values concerning ionising radiation should be consistent with those for other hazardous substances if appropriate and feasible.

PROTECTION GOALS

Current quoted aims regarding environmental radiation are generally of an aspirational and unspecific nature such as “protect the environment” (Hingston *et al.*, 2007). To make them practicable and achievable, and thus useful to guide regulation, the aims need to be more precise and expressed as measurable protection goals. Protection goals could be set at different levels the two extremes being: 1) to protect all individuals of all species and 2) to simply ensure ecosystem function.

Protection at the level of individuals is only commonly used in environmental legislation for rare and endangered species and is not used to set the framework for regulation of environmental stressors such as chemicals. If the aim is to protect ecosystem function, then arguably only keystone species need to be considered; this may only need to be the least (radio)sensitive species capable of performing critical ecosystem functions. However this approach would raise questions about our ability to identify 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’ about are likely to be among the most affected.

The most commonly used approach for environmental regulation is to protect at the level of the population. In this case it could be acceptable if individuals are severely affected as long as this does not threaten the viability of the population. Protection of populations will by definition ensure sustainable ecosystem function. Using this approach, special attention may be needed to ensure that the exposure assessment for keystone, rare or endangered species, or species of symbolic value is as realistic as possible.

Following consultation, PROTECT recommends that the protection goal should be: *To protect the sustainability of populations of the vast majority of species and thus ensure ecosystem function now and in the future. Special attention should be given to keystone species and other species of particular value.*

IMPLEMENTATION OF THE RECOMMENDED PROTECTION GOAL

The available frameworks for radiological assessments of the environment use a tiered approach where the result of the exposure assessment at each tier is compared with a 'benchmark' in order to quantify the likely risk. Starting with a highly conservative, simple to use, screening level, the assessment process continues, if needed, with progressively more refined, user-driven assessments.

The application of a screening tier enables sites potentially at risk to be identified whilst excluding from further assessment those which present no risk with a high degree of confidence whilst using minimal resources. This represents a proportionate risk based approach to regulation. To achieve this, we need a simple, ideally generic, conservative benchmark which can be applied across species and preferably ecosystems. This benchmark value is hereafter referred to as the *generic screening level*.

In some circumstances when the available frameworks have been applied using provisional generic screening levels expressed as a dose rate(s), the most limiting organisms (i.e. the most exposed organisms) are those which are generally considered to be the least radiosensitive (e.g. phytoplankton/lichen). This is a consequence of using dose rate, in contrast to environmental concentration, as the benchmark. At a given environmental concentration, the exposure differs between organism groups depending on differing uptake rates and behaviours. This contrasts to the use of concentration based benchmarks for chemicals which intrinsically incorporate differences in uptake. Put simply, if in a chemical assessment a given benchmark is exceeded then some species will be at risk whereas in a radiological assessment, the most exposed species will be identified and these may not necessarily be at risk. On the basis of this, we recommend 'taxonomically' derived benchmarks for use in more refined assessments if the generic screening level has been exceeded. Within the assessment process, exceeding these values would highlight concern over the level of potential impact and *trigger* management action (e.g. optimise processes to reduce discharges). There may be reasons why exceeding the *trigger levels* can be justified (e.g. for social and economic benefits). They are not prescriptive limits which must not be exceeded.

During consultation by PROTECT, the need for a prescriptive limit which must not be exceeded was suggested by a number of regulators. A number of reasons to justify this were discussed and include: the need to be consistent with the approach for human radiological protection; a requirement to have a robust, defensible regulatory action level above which it is likely that significant harm would be caused to the environment; and a value which can act as an upper threshold below which the regulatory action would be to encourage optimisation of

operational practices to drive environmental dose rates to a level close to or below that of the trigger level. This value is hereafter referred to as the *management action level*.

DERIVATION OF 'BENCHMARK' VALUES

The existing benchmark values suggested for radiological environmental protection (IAEA, 1992; UNSCEAR, 1996) appear to have all been derived using expert judgement and not a scientifically justifiable and transparent approach. Following consultation, PROTECT has decided to make use of quantitative approaches described within the EC Technical Guidance Document (TGD¹) for chemical assessments. The TGD outlines deterministic and probabilistic methods which can be used to obtain a predicted no effect dose rate (PNEDR) for use in a radiological environmental assessment. The deterministic approach could be applied where we have small data sets and involves the application of assessment factors (AF) to the no observed effect dose rate (NOEDR) taken from experiments described in the scientific literature. The TGD provides advice on the AFs to be applied depending upon the available information.

The probabilistic approach is a statistical extrapolation method referred to as a species sensitivity distribution (SSD) and can be used if a sufficiently large data set of NOEDRs, or its equivalent, are available (at least 10 values from suitable range of taxa). The main assumptions underlying the statistical extrapolation approach are that: the distribution of species sensitivities follows a theoretical distribution function; and the group of species tested is a random sample of this distribution. An advantage of this method is that it uses the whole sensitivity distribution of species in an ecosystem to derive the PNEDR instead of always taking the lowest NOEDR as used within the assessment factor approach.

The FREDERICA database has been shown to contain sufficient radiation effects data to enable the use of the SSD approach to determine PNEDR (Garnier-Laplace *et al.*, 2006). Whilst a NOEDR may be reported for a given study, it is possible that this may be well below the true NOEDR depending upon the number of experimental dose rates used. An accepted alternative is to approximate the true NOEDR by determining the dose rate corresponding to the 10% effect compared with a control group (EDR₁₀) by statistical extrapolation of the dose response data for an individual study. We have adopted the EDR₁₀ approach.

Generic screening level: The TGD recommends that the PNEDR should be set using the 5th percentile (or HDR₅²) of the distribution of the EDR₁₀ values divided by an AF ranging from 1-5 to be justified on a case by case basis. Within chemical assessments, a larger AF has been applied in cases where the taxonomic spread within the data set has been limited. Within PROTECT, we have adopted the TGD approach using all available data for aquatic and terrestrial ecosystems in order to produce an ecosystem generic PNEDR. Despite this wide range of taxonomic groups included in the generic SSD we have applied an AF of 5 in order to ensure that we have addressed: 1) overall quality of the database (including coverage of all sensitive lifestages); 2) diversity of the taxonomic groups covered; 3) statistical uncertainty around the 5th percentile estimate; 4) that the data used are for external gamma irradiation only. Applying an AF of 5 also maintains a high degree of conservatism as required for this stage of the assessment.

¹ See http://ecb.jrc.it/home.php?CONTENU=/DOCUMENTS/TECHNICAL_GUIDANCE_DOCUMENT/

² The HDR₅ is the hazardous dose rate effecting 5% of the species

Trigger levels: As described above, species vary in the radiosensitivity and consequently when undertaking a more refined assessment using a single screening value for all species is inappropriate. Based on the relative radiosensitivities of different wildlife taxa to acute radiation exposure (UNSCEAR, 1996) the following groups are proposed for deriving the trigger levels: vertebrates, invertebrates, higher plants, 'lower plants' (e.g. phytoplankton).

Where possible the same statistical approach as that used to derive the generic screening level should be applied (i.e. inputting EDR₁₀ values to derive the HDR₅) for the dose response data from the wildlife groups to derive specific PNEDRs. However depending upon the quality (representativeness) and quantity of this data, an AF of between 1 and 5 should be applied to the HDR₅ with the value of the AF being determined on a case by case basis to produce the trigger values for use in the radiological assessments.

Currently there are too few data to determine a PNEDR for each wildlife group using the statistical extrapolation approach. Therefore, in the interim, we recommend that either: 1) the deterministic approach as outlined in the TGD should be used to derive the wildlife group specific trigger values; or 2) a trigger value based on the PNEDR for the next most radiosensitive wildlife group should be used. It is probable that acute radiation effects data will have to be used for this (e.g. UNSCEAR, 1996). It is likely that the lowest taxonomic trigger value will be lower than the generic screening value derived as described above; if this is the case then the lowest taxonomic trigger will be suggested as the generic screening value.

Management action level: Whilst the generic screening and trigger levels can be proposed in a scientifically justified and defensible manner, the use of a value to determine when regulatory action should be taken is reliant on the determination of what is an unacceptable and equates to 'significant harm'. This relies on stakeholders determining what is (un)acceptable and cannot be prejudged scientifically. There appears to be no widespread use of this type of action level within chemical assessments an exception being sediment quality guidelines. It is possible to suggest how the statistical extrapolation approach could be used to help in the management decision making process by generating different levels of potential impact (e.g. by taking the 50th percentile of the EDR₁₀ distribution or 20th percentile of the EDR₂₅ distribution etc). PROTECT will provide a range of tabulated effect levels and percentiles which may prove to be useful to decision-makers.

Note the work described here is an on-going process with wide consultation and hence the terminology used etc. may change as the rationale is further developed.

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