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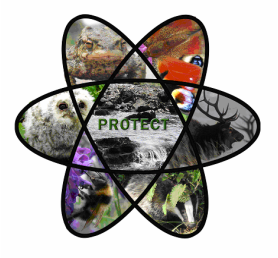
PROTECT

Protection of the Environment from Ionising Radiation in a Regulatory Context

(Contract Number: 036425 (FI6R))



Workshop: Numerical benchmarks - proposed levels and underlying reasoning (14th-16th May 2008, Aix-en-Provence, France)

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Lead contractor for this deliverable: **Centre for Ecology & Hydrology**

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Distribution List

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EC, Henning von Maravic	1	pdf
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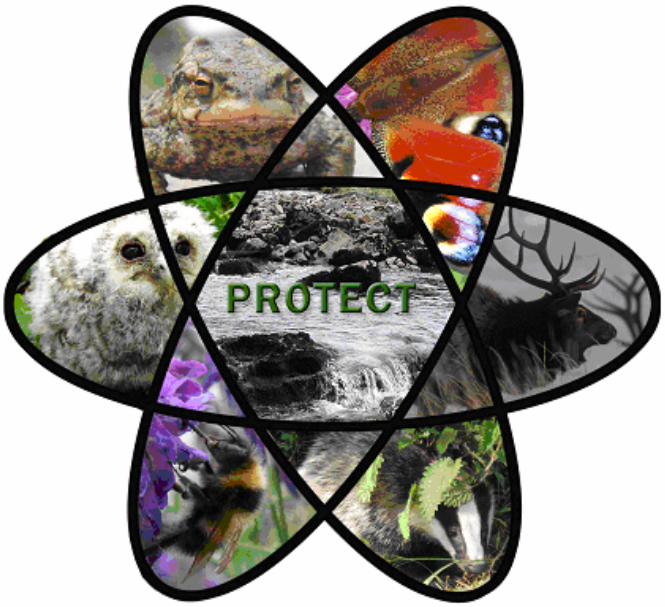
Workshop participants	1	pdf
PROTECT website	1	pdf on Outputs page with links to presentations

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.



Project Co-ordinator: Natural Environment Research Council, Centre for Ecology & Hydrology

Contractors:

Natural Environment Research Council, Centre for Ecology & Hydrology	(CEH)
Swedish Radiation Protection Authority	(SSI)
Environment Agency	(EA)
Norwegian Radiation Protection Agency	(NRPA)
Institute for Radiological Protection and Nuclear Safety	(IRSN)

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Background

The workshop was held to discuss the numeric benchmark values (their derivation and use) as presented within the draft PROTECT Deliverable 5b. This had been made available to all participants and the wider PROTECT emailing list (>170 recipients) approximately one week before the workshop.

Various key organisations had been asked to present their current position with regard to radiological protection of the environment and also their view on the content of the PROTECT deliverable.

The following report documents discussion during the workshop. Discussion sessions are reported anonymously. A draft of the report was made available to all participants (and other respondents to the draft deliverable) and, whilst we have tried to make amendments on the basis of these comments where possible, we obviously have not altered the nature of the discussion or added additional points. However, where additional comments have been made we have included these in Appendix B with the respondents' permission.

Agenda

On-line presentations can be accessed by clicking the links in the agenda below and within the appropriate sections of the report.

Wednesday 14/05/08	
Welcome	Brenda Howard/Jacqueline Garnier-Laplace
PROTECT – introduction and progress	Brenda Howard
Numerical benchmarks: proposed levels and underlying reasoning	Pal Andersson
Assessment approaches	Nick Beresford
Numerical benchmarks: methodology used in PROTECT and results	Jacqueline Garnier-Laplace
Relative radiosensitivity of different organisms	Carmel Mothersill
'Chemicals' view	Paul Howe
International context and response to draft D5b	
UNSCEAR	Doug Chambers
NEA	Ted Lazo
ICRP Committee 5	Ted Lazo (for C5)
ICRP Committee 4	Kirsti-Liisa Sjöblom
EC DG-TREN	Stefan Mundigl
IAEA	Diego Telleria
Natural England - a conservation agency view	Jennifer Best
Comments received on draft deliverable	Deborah Oughton
Complete feedback form	All attending experts
Thursday 15/05/08	
Presentation of feedback & introduction to breakout groups	Deborah Oughton
Breakout session 1	
Plenary - report back of breakout groups (session 1)	
PROTECT recommendations: application in practice	Nick Beresford
Taxonomic screening values	David Copplestone
Application of optimisation within PROTECT	David Copplestone
Breakout session 2	
Friday 16/05/08	
Plenary - report back of breakout groups (session 2)	
Open discussion: *PROTECT recommendations and the international and national context*	

PROTECT: Introduction and Progress (Brenda Howard)

A short overview of the objectives and progress of the PROTECT CA to-date, including objectives of the report being discussed, was presented (link to presentation).

Discussion

There was a question over how and where any identified research should be conducted. In response it was suggested that identifying data gaps is likely to be easy but who does the work and how it is funded is an unknown quantity. It was acknowledged that although there is work being conducted (e.g. a number of studies will be reported at Bergen) it is perhaps not in a co-ordinated manner.

It was asked 'are they data gaps or knowledge gaps?' This can be important in deriving environmental studies, is it the effects we need or is measurements in the environment? In the context of the remit of PROTECT then it was explained that: in work package 2 it is about the tools and how they work and what the problems are; in work package 3 it is about how to gather effects data for the inclusion into the SSD etc.. However, it was also noted that there needs to be a focus on the knowledge/data gaps for the overall system (e.g. what do you actually measure around a power plant not just knowledge gaps on endpoints etc.).

One expert suggested that RBE needed to be addressed to judge its relative importance.

Numerical benchmarks: proposed levels and underlying reasoning (Pål Anderson)

An explanation of the protection goal as defined by PROTECT, justification for the benchmark values derived by PROTECT and an overview of previously proposed benchmark values were given (link to presentation).

Discussion

It was asked if anybody knew where the base data used to derive the relative acute mortality figure presented in UNSCEAR (1996) and IAEA (1992) came from with a question to how much confidence could be place in it. It was suggested that it had been taken from Wicker & Schultz (1982) although nobody attending the workshop had investigated the source data. It was also questioned as to if differences between organism groups in acute mortality would be mirrored for chronic effects.

It was asked if anybody was using the dose rates suggested within IAEA, UNSCEAR and NCRP (1991) as protective of populations. In response it was noted that these values are used by, for example, USDOE.

It was commented that PROTECT was not relying on the UNSCEAR/IAEA figure other than to support the requirement for 'taxonomic' screening levels.

In discussion of 'expert judgement' it was commented that this has to be used and cannot be avoided (*radiation protection is expert judgement*). In response it was noted that PROTECT was avoiding the use of expert judgement alone (as has previously been used) to derive benchmark values. Whilst, it was acknowledged that the species sensitivity (SSD) and assessment factor (AF) methodologies being adopted by PROTECT involved a considerable amount of expert judgement it was noted that these follow accepted methodologies and that the expert judgement used (e.g. in selecting input data or the value of AF) can be documented

The issue of comparative uncertainty within the transfer components of approaches being used compared to uncertainty in effects was raised. It was noted that this would be addressed in a subsequent presentation (see *PROTECT recommendations: application in practice* below).

It was acknowledged that there may be uncertainties in applying laboratory effects data to the field.

It was suggested that for practical reasons, it might be possible to use a less valued ecosystem component to help do the analysis but then use this as an analogue to the valued ecosystem

Assessment approaches (Nick Beresford)

There has been a number of assessment approaches/tools proposed to conduct environmental impact assessments. The more developed of these, in common with assessment of other stressors, used tiered assessment approaches. An overview of the tiered approaches being used (illustrated by reference to RESRAD-Biota and the ERICA Tool (see http://wiki.ceh.ac.uk/x/roHJBg) and how the PROTECT benchmarks values could be used within these was presented (link to presentation).

Discussion

It was questioned as to if adopting the 'taxonomic' screening level in the middle assessment tier(s) made sense as this amounts to changing the decision criteria being applied. This lead to a discussion of when the taxonomic screening level should be employed. It was suggested that if there was confidence in the taxonomic values they should be used from the outset. It was noted that (i) after three years of discussion this was the approach which had been adopted in Canada; (ii) the US DoE Graded Approach uses different screening values throughout.

There was a suggestion that what was included in the 'middle box' in terms of optimisation should be explained (especially as threshold effects may be being dealt with).

Numerical benchmarks: methodology used in PROTECT and results (Jacqueline Garnier-Laplace)

The process used to derive the benchmark values proposed by PROTECT in the draft deliverable was explained (link to presentation).

Discussion

It was commented by one expert that (i) the EDR_{10} values were highly influenced by the shape of the curve fitted to the data and that this was worrying; (ii) the hormetic curves were highly reliant on the value of the control treatment. In response it was stated that statistical goodness of fit etc. had been determined and that the approach was more relevant than using lowest or no observed effect dose rates (LOEDRs or NOEDRs). However, it was acknowledged that whilst the EDR_{10} values are comparable between studies, they are not 'definitive' values.

It was suggested that the uncertainty on each estimate EDR_{10} could be estimated, but pointed out that these were not presented in the draft report. It was questioned as to if underlying data were suitable for the treatment required and suggested that this need to be better justified.

It was noted that unfortunately many of the underlying studies do not provide the information required to estimate uncertainty.

However, it was suggested that the output of the SSD was generally not susceptible to one datum. There was comment that although 'chemicals' had the advantage of having data from standardised tests the no observed effect concentration was often used and that the EDR_{10} approach was preferable to this. Following this it was noted that work in the UK and the EURATOM project ERICA had proposed experimental protocols for radiological effects studies. It was agreed that PROTECT should make reference to these when discussing data gaps/requirements.

It was suggested that this uncertainty should be reflected in the assessment factor used.

The quality scoring applied to studies included within the FREDERICA database (Copplestone et al. 2008) was described. An expert familiar with approaches used for chemicals assessor commented that the quality scoring appeared similar. An expert who had previously been involved in scoring papers for the FREDERICA database noted that some papers (often from field studies) which were attributed low scores contained data which could be used to support the benchmark values used (i.e. as weight of evidence).

It was asked if studies available for the assessment of chemical effects generally considered large numbers of animals. In response the example of Daphnia was given for which there would generally be 10 individuals per treatment and 9-10 treatment concentrations. The number of organisms and treatments for the radiological data varies by study.

It was commented that although too few data were available to conduct SSD for vertebrates (the more radiosensitive organisms) it would be expected that an HDR_5 specific for these organisms would be lower than the generic screening value. It was acknowledged that these issues need to be more clearly brought out in the deliverable report. It was also suggested that the current 'non-vertebrate taxonomic' screening level (450 µGy h^{-1}) should be rounded to one significant place.

The suggestion was made that the analyses conducted could be used to target future studies (to enable a more refined set of taxonomic screening values to be derived) and that from the work presented it did not appear that this would be a great deal of work.

Relative radiosensitivity of different organisms (Carmel Mothersill)

An overview of radiosensitivity of biota including mechanism, biomarkers (for potential use in 'multi-stressor effects based regulation') and comments on the approach taken by PROTECT was presented (link to presentation).

Discussion

One workshop attendee stated that 'from a regulators perspective there is a need to understand complexity and use a straightforward and practical, reductionist approach' and requested clarification on what had been meant by effects based regulation. In response it was explained that the speaker had meant the use of biomarkers to enable total (multi) stressor impact for use in regulation, but whilst biomarkers were available we currently do not have the confidence to be able to use them.

There was discussion around the potential use of biomarkers: for use in practical regulation it would be necessary to understand the link between biomarker response and protection endpoint; how regulate to reduce impact if do not know what stressor is causing biomarker response. Furthermore, it was commented that when assessing biota incremental dose rates are usually considered. The speaker accepted that there was a need to acknowledge these uncertainties and that we were not at the stage of answering all the questions.

'Chemicals' view (Paul Howe)

An overview of benchmark setting from the field of chemicals was presented to put the work of PROTECT into context (link to presentation).

Discussion

The speaker was asked how data rich do we need to be to be able to use SSD and what else should inform the selection of benchmark values. In response it was suggested that (i) data need to be evaluated to determine if sufficient to run SSD, but obviously more data equals more information; (ii) the type and quality of data need to be evaluated, the point was made that a considerable amount of radiological effects studies were not performed for the purpose of setting environmental benchmarks.

A member of the PROTECT consortium suggested that the TGD guidance and confidence intervals around estimated HDR_5 values could be used to aid decision making.

UNSCEAR (Doug Chambers)

A summary of the on-going review by UNSCEAR review with respect to effects of radiation on non-human biota was presented (link to presentation).

Discussion

The speaker was asked what the meaning of the 100 µGy h^{-1} chronic exposure value below which UNSCEAR will suggest non-human population level effects are unlikely compares to the proposed PROTECT screening value of 10 µGy h^{-1}? In reply it was stated that the UNSCEAR suggestion is not a screening level and assessment factors were not used in derivation of this number. The speaker suggested that from their own perspective conservatism should be placed in the exposure assessment.

NEA (Ted Lazo)

A summary of NEA's Committee on Radiation Protection and Public Health recent activities in the area of radiological protection of the environment was given (link to presentation). This included views on the ICRP Committee 5 draft report.

Discussion

It was questioned as to if it was too early to define numeric values (as implied in the presentation) what should be done in the meantime? The speaker responded that most countries have defined environmental protections statements and that the question is how to demonstrate compliance with these. There was discussion that radiation protection (of the environment) needs to be put into context with the broader issues of protection of the environment as a whole (e.g. from fishing, chemical stressors etc.).

There was discussion of putting protection of biota into context with the concept of optimisation.

It was suggested that there was an expectation that ICRP would define what is to be protected. The speaker responded that if ICRP propose tools they need to clearly say what they are to be used for. The opinion was expressed that the work of ICRP Committee 5 was at an early stage and represented a consideration of science but not a regulatory framework. Countering this it was suggested that ICRP Publication 103 (2007) states that ICRP will provide a framework. Hence one of the ICRP committees

has to do this, otherwise the community is left in limbo. It was further suggested that the ICRP need to establish a framework, including principles (such as optimisation) and need to go beyond the development of tools.

ICRP Committee 5 (Ted Lazo)

Unfortunately ICRP Committee 5 could not attend the workshop as they had a meeting at the same time to, amongst other things, discuss the consultation inputs to their draft report. Ted Lazo had attended the first day of the Committee 5 meeting as an observer and agreed to present an overview of the Committee's intentions with regard to redrafting their report (link to presentation).

Discussion

One member of the workshop suggested that ICRP needed to provide a broader overarching framework suggesting this could be an additional document to the current (concept focussed) draft report.

It was questioned as to if the ICRP approach was based on that used for chemicals – the workshop were in general agreement that this was not obviously the case. The presentation reported that Committee 5 members were of the opinion that Reference Animals and Plants (as proposed in their draft report) were the same as Reference Organisms (as proposed by a number of projects). A number of comments were given that this appeared to be a big change from what had been generally understood and required further clarification from Committee 5.

Brenda Howard summarised verbal comments received from Carl-Magnus Larsson (vice-chair of Committee 5) on the draft PROTECT report:

- Committee 5 do not disagree in principle with the principle of the taxonomic screening levels but do not like the grouping of plants and invertebrates as it is in disagreement with the DCLs suggested by Committee 5 for 'pine trees' which are the same as those for vertebrate species.
- The PROTECT report had made Committee 5 realise the problems associated with deriving benchmark values.

One expert attending the workshop stated that they could not understand the objection to the taxonomic grouping as there is evidence that (young) invertebrates are more radiosensitive than pine species.

It was also suggested that 'problems in using SSD' should not be used as an excuse for using purely expert judgement (as used to select the DCL values in the ICRP report). The SSD methodology is more transparent and enables the problems to be identified so that issues can be identified and efforts focussed.

EC DG-TREN (Stefan Mundigl)

An overview of the development of new European Basic Safety Standards (BSS) Directive consolidating European radiological protection legislation and updating the European Basic Safety Standards was presented (link to presentation). The BSS will include protection of the environment and is expected to be available for discussion with the EURATOM Treaty Article 31 Group of Experts June-November 2009.

Discussion

It was commented that whilst the presentation considered potential impact of the Drinking Water Directive, there are other relevant directives, Birds and Habitats being an obvious one also about Environmental Crime, this specifically mentions damage to animals?

It was queried as to who would write the BSS section on Environmental Protection? In response it was stated the outputs of the IAEA, PROTECT etc. were being waited upon. Once available the EC may require the assistance of invited experts.

ICRP Committee 4 (Kirsti-Liisa Sjöblom)

The role of ICRP Committee 4 was explained and personal comments of the speaker on the PROTECT draft report presented (link to presentation).

Discussion

There was support for the speakers observation that optimisation should not only occur between PROTECTs proposed Regulatory Action and Screening levels.

IAEA (Diego Telleria)

An overview of the IAEAs activities relevant to radiological protection of the environment was presented and comments from the IAEA on the draft PROTECT report given (link to presentation).

Discussion

It was agreed that PROTECT needed to be clearer in what it was addressing in the deliverable. It was also noted by the consortium that work package 2 would address some of the assessment process queries raised.

Natural England – a conservation agency view (Jennifer Best)

Views on the methodology used by and proposals of PROTECT were given from the context of experience of regulation of chemicals in the environment from the perspectives of Natural England (link to presentation).

Discussion

A member of the consortium with experience of the regulation of chemicals in the environment expanded upon some of the approaches available to use small datasets to derive benchmark values, also expressing the opinion that these could be a communication nightmare.

The speaker suggested that the approaches were of value if used in weight of evidence approach – benchmarks derived from ‘small datasets’ could be validated against field data.

Comments received on the draft deliverable (Deborah Oughton)

Comments had been received on the draft deliverable from five individuals not in attendance. These represented two regulators, two scientists associated with Greenpeace and a recent former member of staff of NEA. These comments were presented to the workshop. The comments from the scientists

associated with Greenpeace and the former member of staff of NEA can be found in Appendix A; other comments received have been amalgamated with those received from workshop attendees (see next section).

Draft Deliverable 5b feedback form

At the end of the first day of the workshop the expert attendees were asked to complete a feedback form on the draft deliverable. The responses were collated by a small group of consortium members and presented to the workshop the following day. The summarised responses are presented within the template of the feedback form in Table 1. The table also contains comments from two US contributors received subsequent to the workshop.

Note the feedback form and summary presented in Table 1 were used as an input for the subsequent breakout discussion sessions and do not, necessarily, represent views of the participants by the end of the workshop.

Table 1. Feedback form soliciting views on draft Deliverable 5b with summarised responses from expert attendees.

1. What are the likely impacts of the PROTECT recommendations for regulators and industry?
• None: 1 • Maybe/moderate: 17 • High: 5 • Don't know: 3 In practice will depend on other factors: e.g. what legislators or regulators do, what comes out of ICRP, IAEA etc. Depends on how the screening level is applied and at what level the regulatory action level is set. If it could be used to justify eliminating monitoring, then it would be good. However, if it is used as an action level it would be bad.
2. Does the suggested approach strike the correct balance between the objects of being similar to chemical assessments and human radiological protection? If not why not?
• Consistent: 16 • Inconsistent: 4 • Don't know: 5 Caveat: Some differences can never be resolved / should not be resolved
3. Are the derived PROTECT screening levels "fit for purpose"
• Fit-for-purpose: 17 • Not fit: 3 • Don't know/no opinion: 6 Many expressed concerns about the taxonomic and action levels… Specific comments:

- Approach to optimisation needs clarification
- '450' μGy/hr is too precise
- 10 μGy/hr is low compared to existing numerical values and to natural background.
- Concerns about taxonomic screening level of 450 μGy/h being used for a diverse set of organisms (plants and invertebrates), with invertebrates defined as "crustaceans, annelids and molluscs".
- Single screening value of 10 μGy/h is OK, but leave it up to the risk assessor to interpret site-specific effects
- The method and principles are OK; the robustness of derived levels needs to be demonstrated

  ...alternatively…
- Can live with the number for the screening value, but would like more information on the limitations and assumptions behind the methods used to derive it…

4. Are the quality and the number of data points sufficient to derive the PROTECT screening level or are more data required?
If you feel more data are required – what is needed and how will this be achieved?

- Data sufficient: Yes 7; Maybe 10; No 6; No opinion 3
  - More data would be nice, but for the time being, can live with what we have
  - Not enough for taxonomic screening
  - Possibly not enough for generic screening level, particularly with an AF=1

- What is needed?
  - Targeted, funded research that addresses the data gaps and prioritises research needs.
  - A clear message to regulators and industry as to the <u>implications</u> of inadequate data.
  - Specific tests at appropriate dose rates
  - Research is needed for other types of radiation emitters, for internal contamination, and for contaminant mixtures.
  - Data on birds
  - Unified approaches and methods for experimental testing

5. Do you have any reservations regarding: (i) appropriate data selection and treatment for input into the SSD; (ii) assumptions and limitations (or advantages) of the SSD approach

All respondents had some concerns and reservations, although some were also supporting of SSD in principle. The main concerns were:

- Not enough data
- The actual assessment factor chosen and/or the lack of reasoning behind the choice, particularly the large differences in 1 for taxonomic and reproduction set, and 5 for ecological
- The derivation of EDR_{10}
- That biodiversity may not be protected (the '5%' being affected to 10% or more)
- That it can be done for taxonomic levels?
- The rationale behind the "Repro" and "Ecol" datasets
- That the method is not suitable for the protection of individuals
- The approach is a community-level analysis. Not convinced that we have sufficient data to predict the effects to populations of organisms exposed to radiation under field conditions, much less, how a community of organisms might respond.
- Over conservative

Advantages pointed out:

- Better than expert judgement (best we can do)
- Robust/systematic/logical use of data
- Reasonable for generic screening level

6. Do you think your organisation will make use of the PROTECT output? If yes please detail how will you use it and if no please say why not.

- Yes: 11
- No: 4
- No opinion/not applicable/indirectly: 11

Specified uses for some none regulatory or industry experts included teaching and experimental design
The need to include background radiation was expressed
'If legislation forces us…'
Greater freedom in assessment methods is allowed by USDOE

7. Is the suggestion for a way forward with the *regulatory action level* appropriate (i.e. to provide a scientific analysis of the available data but not to recommend a value)? If not why not?

- Yes: 6
- Yes, but… 6
- Maybe: 8
- No: 6

Too premature
Should be decided by stakeholders

Needs to be site/case specific
Will be impossible to give a precise number
Give us a single value
Need to address socio-economic factors
…

8. Are the definitions and suggested application of the *generic screening, taxonomic screening* and *regulatory action* levels clear? If not what needs to be improved?

- Description OK:
  - Yes 7; No 7; Partly/Don't know 12
  - In general, for both description and application, there was a more positive response for screening vs taxonomic and action levels. For those that specified:
    - Screening: ✓ ✓ ✓ ✓
    - Taxonomic: ? x ? x ✓ ✓ x
    - Action: x ? ✓ x x
- More positive response to description than application, most problems with application of action level and taxonomic screening levels

- Main concerns
  - Terminology for action level – 'Constraint'; 'intervention', …
  - The description of optimisation
  - Pay more attention to site and case specific
  - Problems in communicating different screening levels

9. Are there any of the responses to the PROTECT recommendations from international or national organisations presented at the workshop which you think we must consider in your opinion?

- All
- Limitations and uncertainties in SSD
- Do not lump together plants and invertebrates
- 'Action' level
- Multiple stressors
- Validation
- Problems with AF
- Optimisation
- Interaction with ICRP/IAEA
- Other extrapolation methods
- Flexibility
- Precaution
- …

10. Which of these organisation types do you represent:

a) Industry
b) Regulator
c) Research
d) International
e) Other

11. Any other comments:

- Glossary and definitions[1]. Readers could quickly refer back to the section to refresh their understanding of the various concepts presented (e.g. L(E)C-50; NOEC; HDR-5, etc).
- Include biological survey within decision-making
- Most important to agree on an approach – do not worry about numbers
- Address stimulus to improve environmental condition
- If it is possible to derive taxonomic levels soundly, then these should be included at the beginning
- Need to improve understanding of mechanisms, thresholds and RBE
- Not possible to use screening and action level in the same scheme
- More clarification is needed on how one would "demonstrate compliance" to the benchmark values
- A dose rate that is more integrated over the spatial heterogeneity found in nature would be more appropriate. A screening level "per day" dose rate seems more appropriate

Breakout Session 1

The attendees were divided into three groups for the break out sessions; the groups having as far as possible a balance of invited experts and PROTECT consortium members. The groups were asked to discuss the following topics:

1) Data input: quality and quantity
   - Appropriate endpoints?
   - Data availability
   - How to address protected species?
2) Data treatment and manipulation
   - How to derive EDR_{10}?
   - How to deal with uncertainty?
   - How to validate screening levels?
3) Practical Application and Implementation of Screening Level
   - How to deal with background in the application of a screening level?
   - Consider total versus incremental application
   - How to estimate background?

A chairperson (attending expert from outside the PROTECT consortium) and secretary (PROTECT participant) were allocated to each discussion topic. The groups circulated around the topics in turn, the chair and secretary giving a brief overview of preceding group discussions to each new group.

The chair or secretary presented a summary of the discussions in plenary. Below is a summary of the breakout discussions of each topic and discussion following the plenary presentation where appropriate.

[1] Note: a draft glossary can be found on the PROTECT website: http://wiki.ceh.ac.uk/x/KADnBg

Data input: quality and quantity

Appropriate endpoints

The majority of participants accepted that reproduction effects were likely to be the most sensitive with biological meaning, and therefore most appropriate for inclusion in the SSD analyses. However, this should be backed up by consideration of other endpoints (e.g. compare mortality – reproduction effects levels and use the lowest EDR_{10} value for a given species). There was some comment that participants were aware of studies where reproductive effects were seen at higher dose rates than other effects (e.g. root regeneration). What was meant by reproductive stress for an organism such as a pine tree was questioned. The revised deliverable should be clear with regard to what is meant by 'reproduction effects'.

With respect to data treatment it was mostly accepted that only data for the same species-endpoint should be averaged for inclusion into the SSD.

Throughout the discussions the point was made that PROTECT should make better use of additional data (including studies from which EDR_{10} values could not be generated, field irradiator studies, areas affected by accidental releases, high background areas etc.) as a 'weight of evidence' to support the values it derives.

It was noted that PROTECT had provided all the EDR_{10} values it had been possible to calculate and that if required people could generate their own PNEDR using SSD software available on the internet (http://www.rivm.nl/bibliotheek/rapporten/601501028.html).

The comment was also made that the fact that the available EDR_{10} data had been analysed in a number of ways by ERICA and PROTECT with the screening value being estimated to be similar gave some confidence in the value.

Data availability

There was some concern that the number of EDR_{10} values available to PROTECT and their taxonomic spread was insufficient. However, the counter view was posed that we need something (i.e. a numeric benchmark) and that the PROTECT value may be the 'best' we currently have. Acknowledging the data gaps and limitations of any values derived on what data are available may force an increased effort into addressing the data gaps/limitations. The loss of those studies which EDR_{10} values cannot be generated from was stated to be the disadvantage of the manner in which PROTECT was using SSD analysis. Overall it was considered that we could move forward with what data are available, but, that PROTECT must be very clear about the uncertainties and limitations of the available data and numeric benchmark values derived from them.

With regard to providing new data it was suggested that we need to: (i) prioritise based on uncertainty analyses; (ii) be clear about what endpoints need to be measured; (iii) have defined experimental protocols to ensure the resultant data are useful; (iv) consider how field validation of SSD outputs could be conducted. It was noted that there is increasing pressure to reduce animal experimentation, hence we need to make best use of what can be done. Following on from this it was suggested that research into understanding mechanisms would allow extrapolation.

It was also acknowledged that there needs to be a balance of resources in the future (e.g. do not focus solely on effects studies when it is clear that the transfer element of current approaches add considerable uncertainty to assessments). The need not to consider radiation in isolation but as part of a multi-stressor environment was also raised.

Protect species

In describing how protected species should be considered within radiological environmental impact assessments it was agreed that PROTECT did not go far enough.

In general it was considered that if the screening level was suitably conservative then it should be sufficient for consideration of protected species. The comment was made that AF=1 would not be suitably conservative. There may be a greater requirement to look for evidence that the application of screening values are being protective of PROTECT species.

It was acknowledged that there is legislation with regard to conservation which would come into consideration. This may mean that more detailed/site specific assessments are required from the start when considering protected species. It was noted that the issues being address were the same (with the same limitations) as for assessment of chemicals in the environment.

Screening level

There was some discussion of what a screening level appropriate for? It was felt to be very useful for assessment of 'small sites'. With regard to new build of large sites (e.g. power plants, repositories) there was comment that a detailed ERA would be required and that the screening level may not be appropriate. This highlighted the need for PROTECT to be clear with regard to what it proposes the screening value to represent and be used for (and remove any confusion with 'screening level tiers' of (exposure) assessment approaches).

Plenary discussion

With regard to suggestion for the need of defined experimental protocols it was noted that work within the UK and also the ERICA project had gone some way to defining these (Wood et al. 2003; Garnier-Laplace & Gilbin 2006a).

It was reiterated that PROTECT needs to be very clear (and clearer than it had been in draft D5b) in its definition of 'reproduction endpoints'.

Data treatment and manipulation

The discussions took their departure in the various choices, assumptions and data limitations that are associated with each stage of the derivation of a species sensitivity distribution. The main conclusions were:

- the uncertainties and limitations in the data used in the SSD, and their implications, need to be made much more explicit;
- the assumptions and alternatives should be addressed more transparently;
- even if data was not considered robust enough or relevant for construction of the SSD, it could be used for validation and as supporting lines of evidence.

A summary of the main issues discussed during the breakout group, together with some supporting information on alternatives, assumptions and conservatism at the various stages of the process, is given below.

SSD: Alternatives, Assumptions and Conservatism

Alternatives were identified as: Deterministic assessment factor or safety factor methods, combination of SSD and AF, field studies, ecosystem approach.

SSD is not necessarily the most conservative, but has significant advantages in that it uses all relevant data and is open to revision. It was proposed that it is more "scientific" compared to the pure assessment factor, since it uses all available evidence in order to reduce the potentially "arbitrary" choice of an assessment factor. But it was also argued that the SSD is more difficult to communicate, and could be interpreted as a way of avoiding precaution. If there are lots of data on effects, then the deterministic approach may be over-conservative. Some combination of AF and SSD could be a "halfway house", but there will be similar issues regarding the choice of assessment of safety factors for all three methods (see below).

Assumptions: The main assumptions identified were that: data generated from laboratory reflect field conditions; the few species for which we have data are representative of their groups; and ecosystems are resilient enough to cope with up to 5% of species being affected to a 10% effect level or more. But it was also noted that there are assumptions with the other methods (e.g., the most sensitive species may not be the most exposed or representative of the whole ecosystem, etc.).

Another assumption is that a 10% effect on various reproduction endpoints for various species can be compared in terms of eventual effects on populations and ecosystems. Population modelling indicates that this is not necessarily the case, since lifestyle history (e.g. number and rate of offspring, etc.) can have a variable impact on the relevance of the endpoint for populations. For example, effects on some "higher" species could be multiplied by effects on lower species. Whereas populations of earthworms are not likely to be impacted by 10% change in offspring, due to high fecundity, there could be a period of time where there will be 10% less food for other organisms, which could add additional stress.

Conservatism: SSD is not likely to be the most conservative approach, the AF approach is likely to be more conservative.

Selection of data – EDR_{10} for reproduction endpoints derived from experimental studies using chronic exposures

The data used to derive $EDR_{10\ values}$ was selected from FREDERICA papers that scored greater than 35 out of 80, and only included data where it was possible to fit a logistic or hormetic model to the data. Additional caveats were placed on statistical significance, number of points, etc. The restriction of endpoints to those impacting on reproduction was grounded in the assumption that these had the greatest impact on effects at a population and ecological level. Only external gamma irradiation studies gave sufficient values for the SSD for chronic exposures.[2]

Alternatives include use of: HNEDR, LOEDR, EDR_{20} rather than EDR_{10}; other endpoints (cytogenetic, mortality, etc); and use of alternative models for data fitting. This could include an estimate of the confidence interval on the EDR_{10} number.

Assumptions and conservatism: Compared to EDR_{10}, HNEDR and LOEDR are heavily dependant on experimental set-up, but there are more data. It was noted that EDR_{10} is conservative in the sense that many of the points are unlikely to be different to doses giving "no effect" or "no observable effect" (as is apparent from some of the figures in D5s appendix). However, "not observable" on a laboratory

[2]SSD for acute exposures have been derived previously as part of the in ERICA project – all endpoints (Garnier-Laplace & Gilbin, 2006b).

population does not necessarily equate to no effect on a field population. In certain cases, the use of HNEDR could increase conservatism, while LOEDR would tend to decrease it compared to EDR_{10}. Clearly, EDR_5 would be more conservative and EDR_{20} less so. While it is probable that EDR_{20} would give more robust data (i.e., with less uncertainty on the derived number), EDR_{10} is more common in chemical SSD.

The figures in the D5 appendix illustrate the large variability in the robustness of the data for derivation of EDR_{10}. For example, if all the data were like *Daphnia pulex* there would be no problem, but not all data are of this quality. Since the acquisition of experimental data is not as easy for all species, particularly for the higher organisms, it was proposed that the quality of data needs to be balanced by availability. Nevertheless, the figures indicate that a more rigorous selection of model may improve the data fitting for some of the EDR_{10}'s. Alternatively, there may be other data that give a better "fit and shape" for a particular endpoint and species, even if it were not the most sensitive. In this case the selection of a higher value for EDR_{10} number could be outweighed by less "uncertainty" regarding the curve shapes.

It was noted that the ecological dataset ("Ecol") is less conservative than the reproduction dataset ("Repro") since it excludes endpoints that are indirectly linked to effects on offspring (e.g., sperm and seed production are excluded, while the number of offspring and bud production are included). For the other endpoints, cytogenetic effects are likely to be more sensitive, but more tenacious with regard to the evidence of effects at population and ecosystem level. Compared to reproduction, mortality and morbidity are usually less sensitive as endpoints for radiation exposure for individual species, but can also have effects on populations (species dependent). For species where data on reproduction effects were lacking, it was suggested that data on these endpoints could be used in combination with a weighting factor.[3]

Conclusion: Make better use of the data available. Data that is not used in the derivation of the EDR_{10} for input to an SSD, can still be used as lines of evidence to validate the eventual selection of benchmarks, or in refining data used in assessments where the exposure was greater than the screening level. This includes field data, data on NOEL and LOEL, and data on endpoints other than reproduction.

Input to model – for each species, the lowest available EDR_{10} for reproduction

Alternatives: geometric mean of all available data; weighted EDR_{10} (i.e., confidence intervals) reflecting the robustness of the underlying data; other endpoints weighted for sensitivity compared to reproduction.

Assumptions and Conservatism: The selection of the lowest available reproduction endpoint acknowledges the large variability in species sensitivity within groups and with life history stage. While it is clear that this is more conservative than a geometric or weighted mean, it may still not reflect the most sensitive species, endpoint of life-stage.

Data treatment in SSD

Alternatives: The assessment factor is crucial for the treatment of the data in SSD, and perhaps the choice where expert judgement is most prevalent. Compared to the clear rules for selection of assessment and safety factors in the deterministic approach, the reasons for the selection in SSD are

[3] In the ERICA project, SSD were constructed for all endpoints (mortality, morbidity and reproduction), leading to an HDR_5 of 10 (Garnier Laplace & Gilbin 2006b).

variable and unclear, and this limitation is recognised in chemical assessments. Other alternatives include the choice of HDR_5 (over, for example $HDR_{1,10,50,..}$) and the options available for data assessment and treatment such as jack-knifing, weighting for trophic level, and construction of SSD for different species groups.

Assumptions and Conservatism: Whatever the choice of assessment factor, this needs to be supported by a transparent analysis of the reasoning behind the selection. In addition to points already discussed above, other lines of evidence identified included the understanding of the biological effects and interactions of radiation, factors influencing the variability in sensitivity of species to radiation, evidence of hormesis and adaptation at low doses, and comparison with background exposures. While there are still large data and knowledge gaps for radiation, it was suggested that the level of understanding is greater, and the quality and quantity of data no worse than for many other chemical pollutants. Nevertheless, the selection of an assessment factor of 1 may be difficult to communicate, since it implies very low uncertainties and high confidence in the data.

Overall the many options available for data treatment provide a good illustration of the sensitivity of the SSD to the different variables, and help to identify the ways in which the robustness of data and confidence in the selected number can be improved. The choice of HDR_5 is always going to be open to criticism, particularly since the 5% of species affected could include keystone or endangered species. This could also reflect the limited applicability of SSD (and/or the screening level) in certain cases. Hence SSD should be seen as one of a number of tools that can inform environmental risk assessment and management, rather than the only approach available.

Plenary discussion

One expert expressed the view that they were not comfortable with adding conservatism in a way that was difficult to justify (i.e. application of an AF to the derived HDR_5 value).

The question was posed as to what effect uncertainty in the EDR_{10} values had on the estimated HDR_5 value and if a weighted (for uncertainty) SSD could be conducted?

It was request that PROTECT is transparent with regard to the description of where conservatism appears in the derivation of suggested numeric benchmark values. Limitations of the database, data gaps and uncertainties should also be clearly described.

Practical Application and Implementation of Screening Level

Background exposure

During discussions it was noted that organisms are adapted to natural background and that, as a consequence, we are interested in the man made component of ionising radiation that we are ‘adding’ to the environment through the release of radioactive substances. This will vary on a site by site basis in relation to the sources of radioactive substances that may be present in the vicinity. It was also noted that levels of natural background radiation vary (and that in general information on levels of natural background is very patchy) and therefore it is important, wherever possible, to have knowledge of the natural background radiation levels prior to a new practice starting which will release radioactivity into the environment. Another aspect that would need to be considered during any assessment against a screening level is the geographic extent of the additional man made radioactive substances burden and the scale of any high natural background areas. Particular aspects that might be important include considering migratory species, the chemical form of the radioactivity, what radionuclides are

contributing to the natural background and the percentage of site and/or foodstuffs for species of particular interest that might be affected by the background radiation levels.

Another aspect that came up was consideration of the ICRP exposure situations – planned, existing and accident. A suggestion was made that for planned situations (especially those that are prospective i.e. before a practice has started) it may be appropriate that background is not explicitly considered (i.e. only incremental dose rates are assessed). However, there was not agreement on this distinction and it was acknowledged that if the assessment is being conducted prior to a practice starting then some measurement of the natural background in the environment likely to be contaminated by releases of man made radioactivity is required for future reference. However for existing situations it is probable that some estimate of background is required to assist in the assessment. It was noted that whatever approach is taken (e.g. whether to include natural background in an assessment or not), the problem formulation stage should acknowledge the issue and describe what is to be done clearly within a particular assessment and the consequences of including natural background or not should be documented. It was also acknowledged that a screening level is to help identify and prioritise those sites at which an impact might be possible, again its application within the assessment process should be documented in the problem formulation.

Following on from the general discussion about background and its use within the ICRP exposure situations, the question of how to estimate background was discussed. Here it was noted that there are potentially very complex sites that may require assessment (e.g. uranium mines) where a good understanding of the natural background may be required in order to be able to estimate the incremental component from the authorised practice which is releasing additional radioactivity to the environment. How this should be achieved was discussed and it was agreed that this should be clearly documented in each specific case within the problem formulation which should describe the measurement procedures etc..

When considering the derivation of the screening level and its application, it was noted that we are often interested in deterministic effects for wildlife and in these cases it would be the total dose rate that would be of interest as we are looking a thresholds. On a scientific basis then the derivation of the screening level should consider total exposure (i.e. the natural background and any anthropogenic releases). However it was also recognised that the only ‘controllable’ source of the radiation that we can control in order to prevent deterministic effects from occurring is the incremental contribution from the anthropogenic sources. Regulation must therefore be targeted at this controllable component. How this is implemented needs to be discussed further and PROTECT should document how this aspect can be addressed and explain why the screening level is incremental more clearly.

Another aspect that came up is the source or type of natural background. For example exposure of burying organisms to radon gas in the soil, external exposure to gamma and some beta emitting radionuclides, food intake of naturally occurring radionuclides etc. Should natural background be just those radionuclides present in the environment naturally (i.e. primordial in origin) or should it now also include the component of anthropogenic radionuclides from global fallout (i.e. a long term background) from weapons testing – a non controllable source of additional radioactivity. It was also noted that it is possible to distinguish the contribution of naturally occurring radionuclides to the internal dose but that this might be more difficult to do for external dose.

In summary:

- It was recognised that dealing with background requires an understanding of how organisms may be adapted to natural levels of radiation. Often the assessment will need to consider site specific issues (prior knowledge etc.) and will need to account for any scale issues in terms of

geographical extent of any high natural background levels and the extent of any anthropogenic contamination. Special consideration may need to be given to migratory species that might live in high natural background areas for some of their life.

- There is a need to consider how background is taken into account for planned and existing situations and when considering prospective or retrospective assessments. From a regulatory point of view, it was recognised that the incremental anthropogenic component of the radiation present at a site was all that was controllable and could be regulated to reduce the potential impact but this may then require an understanding of the natural background levels specifically as many of the biological effects we are interested in for non human species are deterministic in nature. This leads to an interesting scientific question of whether all sources of naturally occurring radioactivity (e.g. cosmic, radon, external sources of radiation) are equal in their potential effect. Finally it was noted that in general information on natural background levels is patchy and may need to be considered further.

Tolerable risk: is 95% protection level OK?

There was some discussion over the application of the 95% value (i.e. HDR_5) and what it actually means in terms of a protective value – e.g. does this ensure biodiversity is adequately protected if biodiversity is your protection goal? What if you visit a site and demonstrate that it is protected to 95% but then when you come back to the site is there a problem because the second time you are protective of 95% of the original species diversity, but have lost 5%. Does this mean that there is a slow loss of species over time? Why should 95% be the chosen value, why not 99% etc. (although it was noted that using 99% the level of uncertainty would be much greater). The relevance of the endpoints being used in the test was also discussed and considered (for example we are not usually looking at lethal endpoints etc). What happens if the species that have been selected for inclusion in the SSD are examples of the average sensitivity for the wildlife group and not representative of those that might be more radiosensitive? Could this have long term consequences for the application of the SSD and possible reduction in biodiversity over time? As a consequence of these questions, is it appropriate to apply an assessment factor of 1 or should the AF be larger to try to account for some of these issues? Linking to the question of multistressors, is the effect additive or synergistic with other contaminants?

It was pointed out that the approach of using 95% to derive the screening level(s) is not necessarily to say that everything is protected but to identify sites where further resource and effort should be focused. It was also noted that using an alternative approach to the SSD (such as the deterministic AF) does not allow you to chose the level of protection applied because there is no information to say what the % protection of using an AF of 1, 100 or 1000 is. The key is that whilst there are recognised doubts and potential problems with the application of 95% it is statistically relevant, can be applied and has been previously accepted for use in chemicals risk assessment (accepting the same arguments apply for chemicals as for radioactive substances).

One point that was stressed following these discussions is that the 95% protection level actually means that it is acceptable (using these criteria) that 5% of the species can be affected to a 10%, or more, level of effect. This is not the same as saying that 5% of the species could be affected and potentially eliminated from the environment (although we do not know how effects on these 5 % of species will manifest themselves at the population and ecosystem level). The question here then is, are we confident that the effect on given endpoints is not critical to the maintenance of the population. In addition we need to consider the level of recovery and redundancy that is inherent in population dynamics (the point was made about how a very large reduction in a population can occur as a result of a hard winter for bee populations but the population can then readily recover within a short time

although there is the long term question over whether there may be a genetic bottleneck caused by such changes).

Can we deal with multiple stressors?

The question here, already mentioned in the previous discussion, was about whether the use of SSDs and the 95% protection level was additive or synergistic when looking at different chemicals and radioactive substances. In other words should we not be challenging the approach of regulating individual chemicals and radioactive substances against numeric criteria defined for that chemical or those radioactive substances? What is the degree of precaution built into this approach? It was noted that, whilst a more ecosystem based measure and/or the use of effect based measures to assess total impact on a individual/population level is perhaps needed, for regulation it is essential to know where and what to target to reduce the potential or actual impact and this by default then requires knowledge of the impact of individual chemicals and/or radioactive substances. It was also noted that multistressors might include stressors such as UV exposure, over-fishing, etc. and not just be limited to chemicals and/or radioactive substances.

A particular example where there is a pressing need to be able to evaluate the impact of multistressors in the environment is that of Uranium mining sites where the uranium itself has both chemical and radioactive properties. In these cases it was thought that a radiological screening criteria was probably not applicable. It was agreed that there is a need to conduct multiple stressor type experiments to evaluate these questions scientifically. Some work on pesticides in aquatic ecosystems and some unpublished to date studies on mice might help answer some of these questions. Any experiments that are conducted need to be carried out under well controlled conditions to reduce the impact of any confounding factors and the focus should be on identifying and understanding response mechanisms. Field based experiments were also highlighted as this should provide a suitable reality check. When it comes to the application of a screening level it was felt that there is a need to clearly define how it has been derived and whether it would be protective when applied in circumstances where there are likely to be multiple stressors present.

PROTECT recommendations: application in practice (Nick Beresford)

An overview of the work of the IAEA EMRAS programme Biota Working Group (BWG) was presented to demonstrate the relative importance of the dosimetry and transfer components of the available models to uncertainty/variability in predictions (link to presentation). The numeric benchmark values suggested by PROTECT in deliverable 5b were put into context by looking at available assessment results using the assessment conducted in England & Wales (715 discharge authorisations) of Natura 2000 sites and data presented in SENES (2007) which enable the ERICA Tool to be run for a variety of sites and receiving ecosystems.

Discussion

Some points of clarification with regard to results presented based upon SENES (2007) were made by participants: (i) nuclides contributing most to estimated dose rate at Pickering NNP were based on end of pipeline activity concentrations; it was pointed out that the La Hague assessment is available in full on the internet; it was noted that the areas estimated as giving rise to high dose rates at Chalk River were small and not inhabited by all organisms assessed.

Taxonomic Screening values (David Copplestone)

PROTECTs reasoning for the need for 'taxonomic' screening levels was presented (link to presentation).

Discussion

The need for the generic screening value was questioned if taxonomic values were available. It was acknowledged that the generic screening value was only one option.

It was asked how chemical assessments address this issue. In response it was noted that benchmarks derived for chemical assessments tend to be media based and do not consider transfer; the most at risk organism is identified. Although one expert commented that some chemical assessments use foodchain transfer approaches.

Application of optimisation within PROTECT (David Copplestone)

An outline of optimisation with regard to radiological environmental assessments in general and specifically in the context of PROTECTs recommendations was presented (link to presentation).

Discussion

There was considerable discussion that optimisation should not stop at the screening dose rate but continue below this. It was suggested that the screening value is the point where you move on to more detailed assessments.

Breakout Session 2

The following three topics were put up for discussion:

1) Taxonomic Screening Values
    - Do we need them?
    - When do we use them?
    - Can we derive them?
    - Are we happy with what has been done in PROTECT so far?
    - Are there other ways to derive them?
2) Upper Level
    - Do we need it or are the screening values enough?
    - Is Regulatory Action Level the most appropriate term/description?
    - Do we need to agree on what is unacceptable harm in order to derive defined value(s) or are they defined on a case by case basis?
    - Should there be one single number or multiple numbers
    - Can we define value(s) now, if appropriate?

3) Optimisation
   - Are there any fundamental differences between optimisation for humans and wildlife?
   - Can the IAEA/ICRP definitions be adapted for protection of the environment?

Taxonomic screening values

Terminology

There was consensus that PROTECT should not use the term 'taxonomic' screening level as the groupings are not taxonomic and naming them as such may make it more difficult to explain their purpose.

There was some question as to if the term 'screening' was also misleading as it is used as a trigger.

Do we need them?

Overall there was agreement that 'taxonomic' screening levels were needed as:

- a generic screening level may be overly restrictive
- use of taxonomic screening level would better focus where efforts were warranted
- allows proportionate risk based assessment

There was however, some concern expressed that there are insufficient data on which to base them at the minute.

It was also noted that the value derived for some groups was likely to be lower than the currently suggested generic screening value.

When do we use them?

The majority of participants were of the opinion that if taxonomic values could be derived in which there was sufficient confidence then they should be used in the initial screening tier of assessments (i.e. no need for a generic screening value). This will provide a more realistic/robust assessment.

There were concerns raised that the use of different screening dose rates may be more difficult to communicate. However, it was pointed out that in the initial screening tiers risk quotients are most often calculated based on soil activity concentrations. It was also noted that in Canada multiple screening dose rates for different biota types are used (approximately 6). Whilst there had been lots of discussion of this, it now seems to be working OK in practice.

Can we 'live with' what PROTECT has produced?

There was less consensus on this question. A number of participants were 'uncomfortable' with the PROTECT approach of combining invertebrates and plants (in part simply because 'it looks strange'). However, there was some feeling that this represented the best use of the available data and was a pragmatic starting point.

Reservations were also expressed that the groupings were not consistent with ICRP Committee 5 (who recommend the same DCLs for their mammal and pine tree RAP).

The question was raised as to if the gap between the two current groupings (10 and 450 µGy/h) was too large.

It was suggested that PROTECT investigate other methods of estimating group screening values from smaller datasets (see below) and also used other data (e.g. acute exposure studies) to inform the process.

Are there other ways to derive group level screening values?

It was suggested that PROTECT should investigate other available statistical methods to derive PNEDR values for taxonomic groups – even if after evaluation they were not used.

It was also recommended that better use of the data not used to derive EDR_{10} values should be made.

The potential for a relationship between DNA content and radiosensitivity was suggested – would this allow some mechanistic interpretation?

Interestingly nobody suggested using deterministic methods (i.e. AF approach).

Upper level

The need for an upper level (referred to in the draft deliverable as the regulatory action level) was identified by some of the regulators on the basis that once you are above the screening level(s), it is not clear what kind of threshold you should use or how high above the screening level(s) the dose rate predictions need to be before you do something to control them. Having an upper and screening level(s) would at least allow the assessor to see how important the environmental assessment might be in terms of driving the need for regulatory action. Whilst this approach was generally felt appropriate by some there was not unanimous agreement for the need of an upper threshold. A diverse range of views were expressed including 'it's premature' to 'yes it should be applied' However, it was noted that the science (in terms of known biological effects data) might be insufficient to support the derivation of one or more numbers for use as a regulatory action level. One thing that the majority agreed with though was that the name was inappropriate and should be changed. Suggestions included simply an "upper level" or a descriptive term perhaps based on the derivation of the number so "probable effects level" or "observed effects level".

When it comes to how to define the regulatory action level, there is no equivalent to an upper regulatory action level in chemicals risk assessment so there is no precedent to follow. Suggestions for how to proceed were made based on the information provided in the draft D5 report using a probable effects level based on selecting a different percentile of the distribution of the SSD and a higher effect dose rate (say 50% effect) for deriving the input values into the SSD. Other options suggested in the discussion were on the use of additional effects data based on where observed effects are seen as these could provide an upper value above which biological effects are known to occur. One comment on this approach however is that the observed effects might not be ones that society would consider as unacceptable so there is a need to clearly identify and document how such data may be used and on what basis they have been used to derive an upper level. Note there was some concern of the potential use of biological effects data derived from observations following accidental exposures because of the acute rather than chronic nature of the exposure.

Questions were asked about what happens if you exceed the regulatory action level. Would this behave as a limit (not the current thinking) or something else? The general feeling was that above the regulatory action level there might be a need to do something to reduce the potential impact (especially if the level is based on observed effects data) but it was stressed that this must do more good than harm. The mechanism to achieve this action was generally felt to be through optimisation with the regulatory action level acting more like a constraint. It was noted that if a prospective assessment was being conducted then it would probably not be authorised if the potential impact put you above the

regulatory action level and that steps to limit the discharge might be required. The idea of using a regulatory action level as a constraint was explored with the possibility of site specific constraints being defined based on whether the environment is pristine or 'damaged' already as there may be different levels of tolerable impact that are acceptable. However it was pointed out that many of these judgements on what is acceptable or not is not a question for science to resolve but for society and policy makers. Once the decision on what is acceptable has been made then it would be possible for science to support the derivation of an appropriate value(s) to use as a regulatory action level.

Plenary discussion

Clarification was sought as to if the regulatory action level would be a 'limit'. In response the chair reporting back on these discussions suggested that (in his view) it was a point of reference and constraint, but not a 'limit'.

Optimisation

Main conclusions:

- Broad acceptance that the fundamental principle should apply and be the same for humans and for the environment.
- Caveat that in practice their application may be different (e.g., due to different driving forces, scientific basis, dose constraints).
- Recognition that optimisation of protection will not be done in isolation, but almost always together with optimisation of human exposures.

Discussion summary

The discussions took as a starting point the definitions of optimisation given by ICRP and IAEA:

Principle of Optimisation of Protection (ICRP, 2007) 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"

Fundamental Safety Principles (IAEA 2006): Protection (*of humans and the environment*) must be optimized to provide the highest level of safety that can reasonably be achieved.

There was a broad agreement that, at a fundamental level, the principle of optimisation should apply, and be the same, for humans and for the environment. The existing ICRP and IAEA definitions could be adapted (or are already adapted) to encompass optimisation of protection of the environment.

Differences in the scientific basis

A number of experts noted differences in the scientific basis for optimisation. For humans, the principle of optimisation is based on the linear no-threshold assumption for dose-effect; for the environment the scientific basis is still to be explored. Many of the endpoints associated with environmental effects relate to deterministic effects, and thereby a threshold can be assumed. There is certainly a difference in protection goal, which for humans is individuals, and for the environment is usually set at the level of populations or ecosystem functioning. The importance and implications of this distinction were not always clear, but it was noted that the methods to achieve optimisation may be different in practice.

Level of implementation of optimisation

For both humans and the environment, optimisation is a societal decision based on values defined in a (specific) society. The process depends heavily on resource allocation and value judgements, as illustrated by the definition "economic and social factors taken into account". Thus optimisation of protection of the environment is unlikely to be done in isolation, and will always be combined (or at least part of) the optimisation of protection of humans.

Differences in application may depend on whether optimisation is applied to planned or existing exposure situations. For planned exposures, such as new build or an existing plant, the optimisation will relate largely to discharges to the environment ("numbers in pipes"), and the optimisation goals and methods would be the same for human populations and the environment. There were some concerns that optimisation may involve "risk transfer" (i.e., between workers and the public, or the public and the environment), but other participants suggested that experience to date shows that this has rarely been a problem in real scenarios. For planned exposures, optimisation is in line with protection of humans and the environment from chemicals (e.g., BAT, BPM). The role of the screening level for protection of the environment was thought to be rather minor, since the main driving force for optimisation would be human exposures.

For existing exposure situations, such as rehabilitation or 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. 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 have to be considered at the same time.

Plenary discussion

Concern was expressed that optimisation for protection of the environment may increase risk to man. In response it was stated that if conducted in an appropriate manner optimisation will take into account both the environment and human population at the same time (i.e. it is not an independent process).

Final open discussion session

It was suggested that the revised EC BSS would contain only a general statement requiring member states to assess the environment. It is unlikely that numeric values will be advised as they are not robust enough. There needs to be room for regulators to make the final decision. The PROTECT output will be useful as a regulator decision aid to show where a site is on the scale and how much it has to do. It was commented that new regulation preparation within the EC is difficult even for things which have been consider for many years (e.g. indoor radon) and the opinion given that we are 'too far from applying any regulation' with respect to the environment.

There was comment that perhaps PROTECT would not provide absolute numeric values which can be put into regulation. But rather provide the regulator with tools (numeric values). PROTECT should be providing informed guidance (at current state of art) – not 'limits'.

It was commented that there could be some scientific confidence that there are unlikely to be any effects below the screening level (as suggested in draft Deliverable D5b). This should be

complemented with a higher level where we are fairly sure there will be effects. Thereafter leave the regulator to make a decision.

It was suggested that an expansion of the EDR_n-HDR_n table, put into context, would be useful. Although one regulator expressed the view that one number is required.

Countering this there was an opinion that '….not sure can give value which could be used at all facilities. Concerned that make nuclear look worse than other industries'.

It was suggested that only a single 'pass/fail' value was required. This was criticised as lacking the ability to put a 'fail' value into context with requirements for optimisation.

Others acknowledged they understood the regulators need for an upper value but that they were uncomfortable since flexibility us needed to take account of sensitivity.

It was also suggested that as there were more high dose rate experimental data than low dose data it may not 'technically' be so difficult – but it was acknowledged that there were social issues in defining an upper value.

There was considerable discussion as to what the upper value should be referred to as: constraint, upper threshold, consideration level, probable effect level, observed effect level. There was agreement that "action level" was not appropriate.

It was suggested that there were field population studies (for other stressors) which PROTECT could make use of.

It was questioned as to what the purpose of the ICRP DCL numbers were. It was generally felt that these needed clear explanation. Although it was acknowledged that the ICRP were at an early stage of their work and that there was on-going interaction between ICRP and PROTECT.

Take home messages for PROTECT

The following lists issues raised in the final session of the workshop. Whilst it may not be possible for PROTECT to address all of these it will prioritise and address those it can and discuss others as further requirements in deliverables/reports.

- Clear guidance is needed on how to apply and NOT apply the concepts.
- PROTECT should highlight and discuss differences/commonalities between PROTECT values and those of others, e.g. ICRP.
- Make better use of other data as 'weight of evidence' to support values derived or provide additional data.
- Better consider optimisation.
- Develop 'taxonomic' grouping values.
- Upper level - further develop the concept and clearly explain the potential intended use.
- It is important for PROTECT to demonstrate the robustness of the values derived.

Acknowledgements

The PROTECT consortium would like to thank all experts who attended the workshop and provided valuable inputs. Similarly we are grateful to those who sent comments on the deliverable for discussion at the workshop.

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Appendix A: Collation of comments on draft PROTECT Deliverable 5b

David Santillo (Greenpeace Research Laboratories, Exeter University, UK)

After so many years of recognising that protection of the environment from radiation was a justifiable goal but that the tools were not available to do so, I'm very pleased that these discussions are being carried forward on a more practical level. Nonetheless, have read through the draft report, I'm left unconvinced that this is really the right way in which goals and assessment tools should develop.

It comes across rather as an approach based on trying to making use of what we have rather than evaluating whether this provides what we need and, if not, then what more may be required. After a fairly general introduction and a statement of the protection goal, it then seems to slip too readily into established toxicological principles and methods, and implies that what is happening already in regulatory and control terms is providing all the protection we need.

In short, there is a danger that the tools available might ultimately justify the level of protection to which we aspire, which was not what I understood the project to be aimed at.

The stated protection goal itself still seems rather generic and open to interpretation, and I'm not sure it helps greatly in moving us forwards. With all due respect, it does not seem to be something which has developed from a fundamental assessment of what might be desirable and justifiable

I was a little surprised by the implication in the introduction that regulatory processes which may develop from this work could be used to show the benefits of nuclear power within the climate change debate - I see this as going well beyond the purpose of the project and see a danger that the outcome itself might in some way be influenced by this 'higher' policy agenda. I can understand that this statement is included as it came from the conclusions of a previous study, but I think it is important to qualify the manner in which this conclusion has subsequently been taken into account, if at all, in order to avoid any misunderstandings and bias.

I saw no mention of precaution which i would assume, given the limits to knowledge of effects and appropriate endpoints, would be a central part of any future regulatory system to ensure environmental protection.

Application of the precautionary approach was explicitly recognised in the guidance for de minimis adopted by the London Convention, in recognition of the current absence of measures aimed specifically at environmental protection:

"Until complementary international radiological criteria for the protection of flora and fauna are developed, permitting authorities should use appropriate scientific information and a precautionary approach (as provided for in resolution LDC.44(14)) in conducting assessments of the potential impacts on the marine environment".

Although it could be argued that the results of this project provide something of the basis for such criteria and measures, the need for precaution very much remains.

I was also surprised that the environmental protection goals of international agreements such as the London Convention and, more regionally, the OSPAR Convention, both of which address the protection of the environment from radiation in some way, were not more clearly reflected in the proposed approach. OSPAR has as its goal:-

"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".

This seems to be a very valid protection objective, focused on the sources of radiation, and remains as an objective to be implemented by all Parties. It may not be applicable to the assessment of sites which are already contaminated, but sets a clear goal for environmental protection in relation to ongoing discharges from all sectors.

The term 'justification' is used in several places, but only in the context that any measures taken should be justified as not causing more harm than good. That's fine as far as it goes, of course, but what is missing is the concept of justification as I understand it under ICRP:-

"Justification: No practice involving exposures to radiation should be adopted unless it produces enough benefit to the exposed individuals or to society to offset the radiation detriment it causes".

In other words, it is not simply the scale of any protection measures that should be justified, but releases of and exposure to radioactive substances in the first place. This must also be part of any responsible goal for environmental protection. The fact that this aspect does not appear to receive sufficient emphasis reinforces the concern that I have from the document as a whole that this starts from the point of accepting current practice with regard to radioactive discharges from both nuclear and non-nuclear sector, rather than attempting to set a level of protection which is desirable and justifiable and then reviewing whether current practice is consistent with this or not. The assumption that it is consistent rather pervades the approach.

Simon Carroll (formerly Greenpeace International, currently Swedish Centre for Biological Diversity)

My main concern is perhaps most easily expressed in relation to the recommended general protection goal (* see also note below *). The general protection goal in PROTECT is stated 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 species and other species of particular value’. [Protection goals, p. 10 of D5b]

I do not think the report adequately explores whether the PROTECT general protection goal is a fully sufficient environmental protection goal (i.e. will realising the goal be deemed fully equivalent to ensuring protection of the environment), or whether it is a protection goal of a somewhat more limited character (i.e. realising the goal may be considered as a partial contribution towards protection of the environment, but it is not in itself sufficient). I consider that what is being proposed in PROTECT is more akin to the latter. With this in mind, the approach outlined in PROTECT should be seen as a subset of a more comprehensive system of environmental protection, and should be evaluated in that context.

To enlarge briefly on the above paragraph: what is presented at the start of the PROTECT report is a very truncated explanation of the reasoning behind the approach taken in PROTECT. In the "preface", the objective is stated as to explore practicability and relative merits of different approaches to the protection of the environment; in the, "introduction" this becomes more the need to "demonstrate" the adequacy of protection, and the "protection of the environment", which in turn rapidly becomes equated to the protection of organisms, or groups of organisms; and the measurable targets to be associated with this. This approach is reinforced in the "protection goals" section that follows. It seems

to me that what is lacking is consideration of where such an approach fits into an overall system of environmental protection, of which the PROTECT approach may only play a part. Also lacking is a serious examination of the question of whether and to what extent the system being proposed is more of a system of assessment, or a true framework for ensuring protection.
A second consideration is whether and to what extent the PROTECT approach as described can realise this more limited goal - for this too I have some concerns.

The approach taken in PROTECT can play a part, but it needs to be located within an environmental protection framework (i.e. it could be part of, but does not in itself constitute, an environmental protection framework). I consider that the approach taken in PROTECT plays a part more in assessments and decision-making in the context of assessments, but it does not establish a framework for environmental protection within which activities may occur.

"Protection" of biota as described in the report does NOT in my opinion equate to "protection of the environment".

Lastly, while the goals of the LC and OSPARCOM with respect to radioactive substances might be described as "aspirational goals" as mentioned in the PROTECT report, they have also being operationalised with specific decisions following from them and frameworks for regulatory decisions established, etc..

Note subsequently at the *International Conference on Radioecology & Environmental Radioactivity* Simon Carroll presented a paper expanding on issues raised above with regard to radiological protection from an environmental NGOs perspective (click here to access his presentation).

George Brownless (UKAEA, formerly of NEA)

The following are personal comments made by the respondent

Reference in draft	**Comment**
General	A good report with sensible conclusions
P7, 2nd para	'Clearly, estimated dose rates need to be compared with some form of criteria to judge whether there is an unacceptable risk.' – rather, *if* harm is to be judged using estimated dose rates (cf humans) then criteria are needed. This point is recognised in the 3rd bullet point on the page.
P7, 2nd bullet	Says underlying protection goals similar – it is perhaps also worth pointing out that for industrial sources of chemicals, there are also broad similarities in sources (point discharges to air and water) and how they are regulated.
P8, 1st bullet on page	Says derive numerical values then evaluate methods for demonstrating compliance. Isn't the process more like: decide what needs to be protected, decide whether/what measurable standard should be used, set values for the standard? As phrased, this point under-sells PROTECT, which seems to be in a position of suggesting quantitative values for compliance, given an apparent demand for a standards based approach (thus implicitly covering what needs to be protected), but also, implicitly, whether quantitative values are practical; in effect, a feasibility study.
P8, 3rd bullet	A good point. Particularly for anyone supporting/promoting the nuclear power industry.

P10, 1st para, starting 'There is…'	It should also be noted here that, in any case, protected species will (by definition) already be protected by legislation. In my study (http://www.nea.fr/html/rp/reports/2007/nea6172-law.pdf), I observed that either protection was stipulated more specifically for rare/threatened/valued species than for the environment in general, or where only general phrases were used, they applied to specific species/populations/localities; in either case this seemed to give a much clearer steer than for the environment in general.
P10, 2nd para, starting 'If the aim…'	What is/are the ecosystem function(s) to be protected? Discussion may be beyond the scope of this report but would it be possible to give some examples? E.g. provision of [drinking] water, maintenance of biodiversity, characteristic appearance OR primary producer, decomposer. Examples would either focus the meaning of 'ecosystem function', if intended, or alternatively serve to demonstrate difficulty of doing so!
P14, 2nd para	Suggest reconsidering assessment of ICRP C5 work. My understanding is that the meaning of the DCLs is quite clear (to flag up situations where attention/action may be warranted) and an explicit intended use is deliberately not given, in recognition that environmental protection goals vary greatly; rather DCLs are intended as a tool to assist somebody in deciding whether particular goals have been met. For instance, an environmental protection goal might be to protect fish stocks (for fishermen to catch) rather than the environment *per se*. Incidentally, the role of DCLs as a 'flag' for where attention may be needed is similar to what is proposed by PROTECT, if one interprets the bottom of the DCL band as the screening level and the top of the band as the 'regulatory action level'.
P17, last para	Good discussion of use of dose and raising issue of combined effect.
P18, 'Generic screening level'	Review of screening levels is important to make sure they are correctly 'tuned' (reviewed?) – too high a level means that potentially harmful situations are not identified, too low and resources are deployed unnecessarily. Suggest referring forward to good coverage of this point in 'Discussion' (2nd para, p35).
P18, last para	How far is exceeding the screening level after more refined assessment a problem? A screening level is just that. Surely a more refined assessment means a more refined consideration of the (potential) level of harm, rather than a more detailed calculation to see whether the screening level is exceeded?
P18/p19, last/first line	See last point: perhaps better to rephrase from 'There may be reasons why exceeding the screening level can be justified…' to something like 'Nevertheless, consideration on a case-by-case basis may result in acceptance of estimated dose rates above the screening level, based on the more refined evaluation of effects and the implications of action to reduce the estimated dose rates (e.g. more refined assessment shows no effect, impacts of remediation, social and economic importance of the activity responsible for the radioactivity).'
P22, 2nd to last para ('As evident…')	This point is important and needs to be kept. There is expert judgement in using SSDs – this is not (necessarily) a problem, nor does it mean that SSDs aren't more transparent than other approaches – but it does need to be stated.
P24, 1st para	The 'cleanliness' of the data in the appendix used in the following selection is impressive – worth pointing out the wide range of scatter usually seen to make crystal clear the 'value-added' of the methodology/work done?
P30, 3rd para, last sentence	Notwithstanding the lack of clear guidance in the Technical Guidance Document, how does this rationale for selection of an assessment factor compare with practice for chemicals?
P30, 3rd para	Would it be better to consider the discussion of Repro vs Ecol and applied assessment

and Table 6	factors the other way round? i.e. Repro clearly gives values around 10 µGy h^{-1}, precaution implies taking the lowest of Repro and Ecol, and that applying an assessment factor of 5 – as permitted in the Technical Guidance Document – to Ecol gives more or less the same values as Repro. Would an assessment factor of 5 have been chosen if Ecol had given answers around 10 µGy h^{-1}? Based on the current reasoning given it would (which would have implied a screening dose of 2 µGy h^{-1}) since the reasoning given is not dependent on the screening rates derived. I do not think re-phrasing the discussion in the way suggested invalidates the choice of 10 µGy h^{-1} but it would make clear that expert judgement has been applied here (which I had understood was the case). As an alternative, why make the argument? Couldn't the Repro figures alone be used as a basis for what is, after all, an initial recommendation of a screening level? This fits with a precautionary approach and, given that it is a screening level, doesn't preclude 'tuning' it at a later date if appropriate, although pragmatically, it is generally easier to start high then reduce a level rather than start with a low level and increase it.
P31, sentence beginning 'In such cases it becomes clear…'	A very good point – this reinforces earlier comments on P18-19 regarding more refined assessments/exceeding the screening level.
P32, 'Derivation of taxonomic screening levels'	Should some discussion be included on the dose rate level ICRP Committee 5 are proposing for the reference pine?
P35 2nd para	Good discussion of the effectiveness of the proposed screening level.

Appendix B: Comments received on workshop report

Note the following comments were not available for comment by all attendees and do not, necessarily, reflect the views of the consortium members.

IAEA

The IAEA made a number of comments of the draft deliverable and these can be found in the presentation made by their representative at the workshop (link to presentation).

In their comments on the workshop report the IAEA reiterated some of these points with regard to discussions of the need for an upper benchmark (termed regulatory action level in the draft deliverable) as follows[4]:

'Not all the regulators adhered to this view (*that the regulatory action level is required*) and this is not reflected in the report. Particularly it was stressed by the IAEA participant during the workshop that any confusion on the uses of a screening level should be avoided. This is not a regulatory constraint and therefore, regulators should not apply it as a decision making tool at this stage. There are many reasons for this which were discussed in the meeting. Starting from the high degree of uncertainty and including the parallel work being done by ICRP in order to define a system for non-human protection which still cannot define any type of action level, and by the IAEA within the Plan of Activities for the Protection of the Environment to study "the need for" and "the form" of any regulatory proposal.'

The IAEA also wished a clarification regarding optimisation to be added:

'Optimisation is not only based on scientific considerations on radiological protection. Optimisation serves as an input to a wider decision making process which may include other societal concerns and ethical aspects. The IAEA participant mentioned during the meeting that optimisation has been demonstrated to be a useful tool to increase the protection and that is a useful tool for regulators.'

Anonymous (regulator)

The following are personal remarks received from an attending invited expert:

Protected species

'There is too few data to proclaim benchmarks which would definitely secure protected species, i.e. no data for birds and their feed. No screening value could really guarantee the protection of protected species and it would be inappropriate to conduct experiments with these species to address data gaps. I am opposed to further animal experimentations in order to back up the screening value with additional evidence.'

Benchmark values

'The benchmark should be treated as one of a number of tools that can inform environmental risk assessment and management, rather than the only approach available. Especially because there is so much political stress on proposing numeric benchmarks, it is our responsibility to be very explicit on the limitation of the data base, its data gaps and uncertainties etc..'

[4]Note italicised text added by the editors for the reader clarification.

Background dose rates

'While it is clear that only the anthropogenic increment can be regulated, background irradiation has to be monitored and the total dose has to be assessed in any case, since there is no knowledge whether biota adapted to high background irradiation will react to a further increment just in the same way as biota scarcely affected by natural background irradiation. Biota used to a certain level of stress might react more severely on further stress than previously unaffected biota.'

Optimisation - Differences in the scientific basis

'I do not agree with the discussion above: "For humans, the principle of optimisation is based on the linear no-threshold assumption for dose-effect; for the environment the scientific basis is still to be explored." The linear no threshold assumption for humans is more an agreed approach than a scientifically verified reality; if this assumption should not be applied to optimisation of the protection of the environment then it is due to societal or financial motives and not to a differing scientific basis.

Suggested additional take home messages for PROTECT

Clear guidance should also be given regarding: protected species; site specific issues; and natural background irradiation.

As to optimisation: risk transfer and the necessity of harmonising human and environment protection issues should be acknowledged.