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Protection of the Environment from Ionising Radiation in a Regulatory Context

(Contract Number: 036425 (FI6R))

Deliverable 5 Annex

Numerical benchmarks for protecting biota from radiation in the environment: record of the consultation process and views of independent experts

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

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

Contractors:

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

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Background

A key input to the PROTECT Deliverable 5 (D5): *Numerical benchmarks for protecting biota from radiation in the environment: proposed levels, underlying reasoning and recommendations* (Andersson et al., 2008a) has been the consultation with experts throughout the PROTECT coordinated action. Open workshops which have had a direct influence on D5 were held in March 2007 (Hingston et al., 2007a), January 2008 (Beresford et al., 2008) and May 2008 (Andersson et al., 2008b). Draft versions of D5 were made available for comment (in May, September and October 2008) and were the focus for discussion during the May 2008workshop and during a consultation meeting with international bodies (IAEA, EC Directorate-General for Energy and Transport (DG TREN), ICRP Committee 5) in September 2008. All presentations given during these workshops can be accessed from the workshop reports if reading on line (see http://www.ceh.ac.uk/protect/outputs/).

This annex summarises the main conclusions of the consultation workshops, comments received on the September and October 2008 draft versions of D5 and the PROTECT consortiums responses to these comments.

Input from Workpackage 1 Workshop in Chester March 2007

Workpackage (WP) 3 (the WP responsible for D5) did not start its work on benchmark values until the second year of the PROTECT project. This was because the results from WP1 were to be fed into WP3 as the views and recommendations from experts on how to proceed on deciding protection goals and methods for the derivation of any numerical benchmarks. An open workshop, attended by 16 independent experts, was held during March 2007, as part of WP1s activities. Prior to the workshop, WP1 had sent out questionnaires to a broad group of experts including regulators, industry and NGOs within the areas of both radioprotection and chemicals (Hingston et al., 2007b), the results of which were discussed during the workshop. The main points, in form of take home messages, from this workshop (Hingston et al., 2007a) with direct relevance for WP3 and D5 were:

- In terms of the numbers that are currently being used in the context of protection of the environment it is not clear how the NCRP (1991), IAEA (1992) or UNSCEAR (1996) numbers of 40 and 400 μGyh^{-1} were derived and this should be documented if possible
- There may be a tension between the desire to align chemical and radioactive substances regulation and to align the protection of non-human species and humans in radiological protection. It is however clear that the overarching principles of environmental protection should be aligned as the protection goals should be the same whether we are considering chemicals or radioactive substances.
- PROTECT should consider the role of optimisation in terms of environmental protection and how this should be incorporated into the process.
- PROTECT should consider the use of standards/limits versus the use of trigger/screening values, which are what organisations/nations are tending to develop.
- When deriving standards/trigger values etc. the quality of the effects data is important. For example, when small quantities of data are used in the derivation of

the lowest observed effects value then this may be questionable. It is key that PROTECT clearly documents the derivation of any numbers and in particularly highlights where there are limitations in the application of a number because of poor data quality.

- The use of methods such as SSD and AF to derive trigger/screening values were generally seen as appropriate and fit for purpose, and there is a good degree of consistency with approaches adopted in chemicals regulation. The fact that the methods have been used in chemicals to derive standards since the 1970s was viewed as a form of peer review.
- If, and when, any numbers are proposed as screening values and/or standards there needs to be transparent, traceable and clearly understood document detailing their derivation.

Further input from WP1

Apart from the workshop recommendations to WP3, the further evaluation of the discussion of the workshop and of the questionnaire responses resulted in more detailed recommendations from WP1 as reported in Hingston et al. (2007b):

- Protection should focus on the population level (which is in agreement with current suggestions by the IAEA (1992) and the ICRP (2003)) although it should be noted that individuals may need to be considered e.g. those that are rare or endangered species
- PROTECT should consider the need for a standard[1] number (i.e. an equivalent to the 1 mSv for public)
    - What are the advantages and disadvantages of having a screening level and a standard?
    - Advice will be needed if either a screening level or a standard is exceeded
    - What criteria should be used to define a standard value? (examples might include the Dutch approach where a 'Ecotoxicological Serious Risk Concentration' (SRC_{ECO}) is derived using AF and SSD methodologies and the Canadian approach to sediment quality guidelines, where a higher threshold, entitled a 'Probable Effects Level'

All inputs from WP1 and the Chester workshop have subsequently been considered in the preparation of D5.

Input from WP2 Workshop in Oslo January 2008

Part of the WP2 workshop in Oslo (attended by 16 independent experts) was devoted to WP3 and the derivation of numerical benchmarks. WP3 presented a suggested protection goal and a preliminary approach to derive screening values as well as upper values

The main points, in form of take home messages, from this workshop (Beresford et al., 2008) with direct relevance for WP3 and D5 were:

[1] This evolved into the 'second higher benchmark value' in the final version of D5 which also puts PROTECT into context with ICRP Recommendations for human radiological protections.

- General agreement on need for/use of a screening level dose rate for use in assessments.
- General agreement on use of SSD for the derivation of a screening level (consistent with chemicals and allows updating as new data become available).
- General agreement that there is a need for an 'action level(s)[2]'.
- Lack of agreement on how an action level is derived or what it actually is although it was recognised that the procedures used to set it should be scientifically defensible and it should be easy to defend legally (but this relies on knowing what a level of significant harm actually is).
- PROTECT needs to consider the implications of including in environmental management the precautionary principle, optimisation etc. In particular it was felt that the differences between the screening and action levels could be related to how optimisation might be applied to environmental protection although it was noted that any action that is taken must be proportional to the risk and should do more good than harm.

Input from WP3 Workshop in Aix en Provence May 2008

Before the workshop a draft version of the D5 was made available to workshop participants (including 24 independent experts) and the wider PROTECT e-mailing list (>160 recipients). Various key organisations were 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. All participants were asked to complete a questionnaire on D5 which was summarised and reported back to the workshop for discussion. A thorough discussion of the report and the approaches suggested therein was therefore possible during the workshop. A few people not able to attend the workshop provided written comments instead. The outcomes of the discussions, the written comments and resulting take home messages for the PROTECT consortium was reported by Andersson et al. (2008b). The take home messages were:

- 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[2] - further develop the concept and clearly explain the potential intended use.
- It is important for PROTECT to demonstrate the robustness of the values derived.

The deliverable was subsequently revised to try to accommodate comments received during the Aix workshop.

Input from consultation meeting in Manchester September 2008.

A second draft of D5, amended following comments received on the first draft during the Aix workshop, was made available for consultation to the PROTECT e-mailing list in

[2] Subsequently termed 'second higher benchmark value' in the final version of D5.

September 2008. In addition, representatives of three international bodies, IAEA, EC DG TREN, and ICRP committee 5 were invited to a consultation meeting held in Manchester. The main outcomes from the discussion on the draft D5 could be summarised as:

- Whilst the principle of the usefulness of the upper level was agreed, the participants also agreed that it was premature to specify any value(s) and that the decision of the criteria for selection of a value and how it should be derived is outwith the remit of PROTECT. It was recommended that this was made clearer in the deliverable (and the accompanying figure revised). It was agreed that the derivation of examples of potential values using the SDD approach should be retained in D5 as an example of an approach to include scientific input into the debate.
- A discussion of the relative merits of the generic screening value and the organism screening values concluded with agreement that the preferred option under current circumstances is the generic screening value as the output appears to be robust and conforms to European guidance (EC 2003). The organism values were considered conceptually preferable, but currently not suitable for use due to the lack of adequate data. It was agreed to amend D5 accordingly.
- It was agreed that D5 needed to better discuss what the organism values represent with their advantages and disadvantages compared to the generic value
- It was suggested that PROTECT try to put its suggested benchmark values into context with ICRP values for human radiological protection.

The final version of the deliverable incorporates all of these recommendations.

Comments received on the second draft September 2008

All written comments received on the second draft made available to the e-mailing list in September 2008 are collated in Table 1 together with the PROTECT consortiums responses.

Comments received on the third draft October 2008

Deliverable 5 was amended in October 2008 taking into account as far as possible those comments received on the earlier drafts (see above and Table 1). The revised deliverable was made available to the PROTECT e-mailing list together with an invitation to contribute any final comments on the deliverable. There were some comments stressing previous comments to which the response from the PROTECT consortium was felt insufficient. These are presented in Table 2. New comments to the revised draft are presented in Table 3. In both tables a description of the response from the PROTECT consortium is also given. Additional minor comments (e.g. editorial corrections) received in response to the October draft are not documented.

Table 1. Collation of received comments and responses on PROTECT Deliverable 5 draft version 22nd September 2008

	Section in September 2008 draft	Page in September 2008 draft	Content/location	Comment received	PROTECT Response
1	Executive summary	5	Generic 10µGy/h……	It is not clear at this stage why there is a generic screening level that is higher than e.g. vertebrates. There must be more explanation at this stage to understand the logics of this	Splitting the overall dataset into organism groups will, if the data show differences in sensitivity between groups, generate some values which are higher than the generic screen and some which are lower. This is now discussed within section 4.4.2.
2	Executive summary	5	Whilst ultimately it would be desirable to derive screening values for as many relevant groups as justifiable, currently there are insufficient data to achieve this.	It is not clear why is should be desirable	The revised Executive Summary now addresses this point. It is also discussed within Section 4.
3	1.Introduction First bullet	8	Endpoints that relate stressor levels to measurement endpoints such as mortality, morbidity and reproduction should be targeted because ecological theory shows that these traits determine population sustainability (Forbes et al., 2001).	A very strong statement that ecological theory shows this. There are several ideas about this and Forbes et al are just one opinion. Reformulate that Forbes et al suggest that mortality…	Edited as suggested.
4	1.Introduction First bullet	8	(Forbes et al., 2001).	Not in the reference list	The reference is now included.
5	2. Protection goals	10	The most commonly used approach for environmental regulation is to protect at the level of (all) populations	It is not clear why of the word (all) it reoccurs at several places, explain or take away brackets.	Edited as suggested.
6	2.	10	Bakker (1971): "A population is a biological unit for study, with a number	This is not a very helpful definition and it seem generally not the definition used in ecology, from where the concept is derived from e.g Pianka (1978, Evolutionary ecology. Harper &Row)) describes a	On reflection, a detailed definition of the word population adds little to the report. The definition has therefore been removed.

			of varying statistics (e.g. number, density, birth rate, death rate, sex ratio, age distribution), and which derives a biological meaning from the fact that some direct or indirect interactions among its members are more important than those between its members and members of other populations."	biological population as a group of organisms with a substantial amount of genetic exchange. That means that it focus on the genetic relationship, not a collection of individuals with some arbitrary characteristics as in the statistical sense of population. The Bakker definition seems to mix up these very important distinctions.	
7	2	11	*Keystone species* occurs at several places in text	This term needs to be explained and defined correctly. There are several interpretations and misuses of the word. Define clearly how it is used here or still better avoid the term to minimize misunderstanding.	See next comment/response.
8	2	12	'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'.	Here keystone species is used in a strange way, seems to be translated from the Swedish "nyckelarter" which is another concept (usually dominant or characteristic indicators for an habitat) than the original concept of keystone species (a species which has that has a disproportionate effect on its environment relative to its abundance). *Species of particular value* is vague and can include all rare species which are very nicely put in the right perspective in the previous two paragraphs and here put back again as a very special case. Suggest that you at least clarify what particular value species are.	The criticism was correct – keystone species now defined and foundation species added (and defined). Replaced with: 'Special attention should be given to keystone, foundation, rare, protected or culturally significant species'
9	Table	17	ERICA The default screening criterion in the ERICA Integrated Approach is an incremental dose rate of 10 µGy h-1, to be used for all ecosystems and organisms. This value was derived from a species sensitivity distribution analysis performed on chronic exposure data in the	There is no reference supporting the last part of sentence …. "by other methods…." which ?	An appropriate reference added.

			FREDERICA database and is supported by other methods for determining predicted no effect values.		
10	4.4.2	38/63	Specific screening level estimates	Should it be "The resultant PNEDR for **in**vertebrates is then 200 µGy h^{-1}"?	The text has been corrected.
11	4.4.2	39/63	Specific screening level for vertebrates	How was the screening value of 2 µGy h^{-1} for vertebrates decided? It seems as though there was expert judgement involved to find an appropriate value because the PNEDR calculations provided a value that was too low?	The derived PNEDR of 0.7 µGy h^{-1} was judged not to be fit for purpose as it is in the background range. Therefore pragmatically we propose that the actual HDR5 value of 2 µGy h-1 is currently our best estimate as the vertebrate screening value There is a little additional discussion around this in the revised report and the focus on recommending the organism group values removed following discussions on the draft.
12	4.4.2	39	Specific screening level for vertebrates	Vertebrates are a very wide group from fish, birds to mammals, which seem to have very different EDR10 according to appendix 2. Mammals (at least the pigs) are main vertebrates discussed and compared in text and seem to be more sensitive than others, eg fish and birds.	This is now acknowledged in the text.
13	General	General	If screening values are exceeded	More guidance on what to do when a screening value is exceeded could be useful	The report has been restructured with a new section on "protection in a regulatory context".
14	Appendix 2	59	Fish Pleuronectes platessa 197 days sperm EDR10 = 47 and all rows with ID 207	Very strange that sperm production has this large impact on radiation limits. This fish is a batch spawner, and has a type III survivorship, that means enormous amounts of spawn are released by the entire population (milky water) extremely few sperms have success to fertlise eggs. The fertilised eggs and hatchling have an enormous death rate. Thus the few indivduals surviving to adults are recruited from years with favourable weather, plenty of food. That means that reductions in sperm and egg production has very little impact on the size of the population.	The report recognises that a 10% effect regarding different endpoints might be of very different importance for the population (referencing Stark et al 2004). However the EDR_{10} value should be interpreted as a more robust no-effect value than NOEDR or HNEDR values. The SSD uses no-effect values for endpoints of relevance for the population. In addition the impact of an individual EDR_{10} value is normally not that large.
15	Title Page	1	Not applicable	It is suggested that the document title be changed from '…for protecting biota against radiation…' to '…for protecting biota from radiation…'.	Title has been amended slightly
16	General	General	General	It would be useful to add a glossary to the document, especially to define acronyms and their meanings all in one place.	There is an existing draft glossary on the PROTECT website and we are currently looking at updating this to reflect the contents of D5 and D4
17	Executive	4/63	Para 5	In the Executive Summary, a level of effect of 10% is recommended;	See response below

	Summary			however, a value of 20% is often used (e.g., EC20 for the protection of fish populations).	
18	Executive Summary	5/63	Para 3	The Executive Summary discusses the request by some regulators for an 'upper' value, which would be more conservative than a 'screening' benchmark value, and above which the risk to the environment would be considered 'unacceptable'. This 'upper' value would allow regulators to quickly determine whether the risk is considered 'unacceptable' in cases where the conservative screening-level benchmarks are exceeded. Due to the lack of consensus regarding the need for 'upper' values and the difficulty in determining what would be considered an 'acceptable' risk to the environment, the concept of their establishment is discussed in the draft D5b document, but numerical 'upper' values are not being recommended at this time by the PROTECT Consortium. That said, it is important to note that in some cases, other factors (such as socioeconomic considerations) may result in acceptance even when 'upper' values are exceeded. From our perspective, the establishment of such 'upper' values is considered premature at this time due to the lack of clarity in terms of what could be considered an 'unacceptable' risk. For example, the acceptability of risk would likely be influenced by what is being protected, in addition to site-specific conditions, which might lead to 'acceptable' risk at some locations, but 'unacceptable' risk at others when the same level of stress is being applied. In addition, deeming a risk as 'unacceptable' prior to consideration of other, non-scientific factors (such as socioeconomic factors) could lead to the passing of a 'point of no-return' from a public perspective without consideration of all the information. At least in ……, the weighing out of risk and its acceptability (from a balanced perspective that considers technical, as well as non-scientific factors) typically falls outside of the realm of risk assessment. Instead, such decisions are typically made through an iterative process between the regulatory bodies and industry in a transparent manner (often with public input) as part of the risk management phase. The risk management phase (which is meant to consider all factors, scientific and non) is kept at arm's length from the risk assessment phase. It might be worthwhile to distinguish risk assessment from risk management in this document	We consider that the comments received generally reflect discussion in the report. We recognise all the factors contributing to the selection of such a value and recommend no more than the issue be discussed by the wider community. The text around the 'upper value' (or 'second higher benchmark') has been substantially rewritten.

19	1	8/63	1st bullet	Note that measurement of endpoints to reflect population stability would likely be an extremely onerous and costly process in many cases. Interpretation of such results is difficult, particularly in the field, which can make such information difficult to communicate in a transparent manner.	Section 2.1 revised in acknowledgement of this comment.
20	1	8/63	2nd bullet	Bullet 2 suggests that assessment of the potential effects for radiological and non-radiological contaminants should be harmonized. Although it is clearly a reasonable approach to make use of existing well-defined and transparent approaches for non-radiological contaminants with respect to radionuclides, it might be useful to note that future harmonization of protection for radiological versus non-radiological contaminants may be difficult for a number of reasons, as follows: • There is a lack of consensus on 'acceptable' risk levels for regulated radionuclides versus genotoxic chemical hazards; • Doses from radionuclides are typically additive and include all radioisotopes and pathways, whereas for most chemicals, dose is typically assessed for individual contaminants; There is a limited number of radionuclides, all of which may cause damage by relatively well-known mechanisms, whereas there is an unlimited number of anthropogenic chemicals (and more all the time), possibly resulting in harm from several different mechanisms which are generally less well understood.	Whilst most of these comments are valid we do not think that they do not detract from a desire to have the two systems has harmonised as possible.
21	1	8/63	3rd bullet	Bullet 3 discusses the need to harmonize future international guidelines and recommendations. It should be noted that harmonization between radiological and non-radiological contaminants may be difficult, for example, because in the case of radionuclides, the sum of the dose to organisms is considered, whereas in most cases, non-radiological contaminants are considered on a contaminant-by-contaminant basis and for the reasons listed in Comment 6 above.	Again, this does not mean that the systems cannot be as harmonised as possible
22	1	9/63	2nd bullet on page	Bullet 2 on Page 9/63 discusses the development of regulatory limits. It should be noted that such limits are typically developed and implemented by the regulatory bodies in-country (with the possible	Text has been amended.

				exception of the EC and trans-boundary agreements, etc.) through a well-defined, transparent process. That said, national regulatory limits are often informed by international guidelines or recommendations.	
23	2	10/63	Last paragraph	The last paragraph on Page 10/63 states that the stress contributed by the stressor of interest should not be significantly higher than the stress from other, unrelated conditions (or stressors) that are present. It might be useful to mention the use of reference versus control areas here, since as written, it is unclear how the contribution of the stressor of interest (e.g., ionizing radiation) is being distinguished.	This was not actually said – but have removed reference to ionising radiation in this paragraph to remove any ambiguity
24	2	11/63	Bullet (i)	Bullet (i) states that there may be concern about 'genetic selection' and the decreased ability to adapt to a further-changing environment. It should be noted that 'genetic selection' is the basis for evolution following exposure to the complement of stressors that exist in natural ecosystems, and this is not necessarily a bad thing. In fact, hormesis may appropriately be mentioned here to add balance to this statement.	Not appropriate here to begin a discussion of hormesis etc.. Have edited to note that concern may be raised from an ethical viewpoint at least (even if the effect could be considered 'beneficial').
25	2	11/63	3	The last sentence of Paragraph 3 states that *'…those species which we 'care' most about are likely to be among the most affected'*. It is unclear how this conclusion has been drawn. It is suggested that this statement be softened to say that such species 'could be' among the most affected.	The text has been edited.
26	2	12/63	1	Paragraph 1 recommends the general protection goal: *'To protect the sustainability of populations of the vast majority of all species and thus ensure ecosystem function now and in the future. Special attention should be given to keystone species and other species of particular value.'* It should be noted, again, that it is unclear how changes in ecosystem function that occur due to the stressor of interest (e.g., ionizing radiation) are to be distinguished from the impacts of other, unrelated stressors. This is an important point that merits consideration, since the establishment of routine monitoring programs at the ecosystem level would likely be exceptionally onerous, difficult to interpret and difficult to communicate to regulatory bodies, members of the public and other stakeholders. In general, it is important to select practical measurement endpoints for routine monitoring purposes and a clear distinction should be made between special/one-time follow-up studies that are meant to investigate whether significant impacts are occurring	Section 2.1 has been edited in acknowledgement of this comment.

				at a given site or to confirm exposure conditions versus routine monitoring. In addition, the second sentence in the above protection goal seems to contradict the first sentence to some extent.	We disagree
27	2.1	12/63	1st Bullet	Bullet 1 discusses monitoring of sensitive, keystone, rare or protected species to look for changes in relevant parameters (such as population density). First, it should be noted that for many species, it can be extremely difficult to design a feasible monitoring program to accomplish this and for most types of organisms, the interpretation of such information in natural ecosystems is exceedingly difficult and costly (and would be difficult to demonstrate and to regulate in a transparent manner). Secondly, it is not always clear which species represent keystone species until after an effect can be seen, and when such effects are observed, it is important to determine whether or not the cause is, in fact, related to the stressor of interest. Finally, sampling (and possible stress/disruption, which could occur during monitoring) of rare or protected species is often illegal and therefore, not likely feasible as part of a routine monitoring program. Therefore, such sampling/monitoring may cause more harm that good, if it causes stress to such species. It may be possible to instead protect the ecosystem attributes upon which such species rely (e.g., habitat).	Section 2.1 has been edited in acknowledgement of this comment.
28	2.1	12/63	2nd Bullet	It should be noted that monitoring of media and/or biota concentrations or environmental dose rates are much more straight-forward and align with current practices in existing monitoring approaches for human protection, which could facilitate harmonization between human and environmental protection	The text has been amended.
29	3.1	13/63	3	The 3rd paragraph in Section 3.1 lists the measurement endpoints that were considered to reflect mortality, including stochastic effects of mutation at the somatic cell level and consequences for cancer. It is unclear how mutation at the cellular level can be related to the potential for higher level (e.g., population-level or ecosystem-level) effects at this time	The text referring to this earlier work has been clarified
30	4.1	19/63	3	Paragraph 3 of Section 4.1 discusses the application of screening (or trigger) values. It might be worth mentioning Administrative or	These are not terms which are used in all countries. However, we have now tried to put benchmarks

				Investigative Levels here (which are lower than those that would result in a reportable event, but that would trigger an internal investigation at a facility).	into context with ICRP terminology
31	4.1	19/63	4	Paragraph 4 discusses the manageability of false positives and false negatives from a regulatory compliance perspective. It might be noted that such decisions (e.g., with respect to emissions that would result in reportable events) are typically set through discussions between the regulator and the facility-manager in the form of 'Administrative Levels' or 'Investigative Levels' with balance in mind (to ensure protection, while avoiding a high frequency of reportable events that can detract from higher-priority issues). It might be reasonable to mention that such decisions typically fall under the realm of Risk Management, as opposed to Risk Assessment. In general, there does not seem to be any mention of the distinction between Risk Management and Risk Assessment in this draft document. In some ways, decisions that are made during Risk Management can help to inform the 'acceptability' of impacts under a given set of conditions or for a specific site, in the context of other, non-scientific considerations.	This paragraph has been edited
32	4.2.2	21/63	Bulleted List	Section 4.2.2 asks a number of questions regarding which the PROTECT Consortium is seeking guidance, as follows *[with COG comments, in blue italics beside each]*: • Would the development of 'upper values' (as defined in Comment 4 above) be useful/desired? *[Currently, there is not consensus on the need for such values. In addition, establishment of upper values are linked to regulatory compliance, which would be set by regulatory agencies in a given country, often during the Risk Management phase, as opposed to the Risk Assessment phase. It should also be noted that at higher assessment tiers, more realistic estimates of exposure levels are typically undertaken. Therefore, if upper values are established for effects, this would mean that both the numerator (exposure level) and denominator (effects level) of the Risk or Hazard Quotient would be changing simultaneously at the higher assessment tiers. In addition, in cases where exceedances of the screening level occur, effort would likely be required to conduct a site-specific*	In general we regard the comments as input to the wider discussion we are suggesting is needed and not issues which require any comments or changes in the report.

				investigation (or a 'special study') of exposure and possibly effects to determine whether or not significantly impacts are occurring. The establishment of somewhat generic 'upper' values without site-specific validation or 'ground-truthing' could be questionable.] • What is meant by an 'unacceptable' level of effect? (acknowledging that there is no agreed precedent from chemicals regulation). *[It should be noted that the acceptability of effect is likely dependent upon what is being protected – i.e., the protection goal – in addition to site-specific factors.]* • How could these be derived? *[Again, this is likely dependent upon the protection goal to some extent. In addition, the level at which 'unacceptable' effects could occur would likely be site-specific and situation specific. A much greater understanding would be required in order to develop widely-applicable 'upper' values that account for site-specific factors and their influence on potential impacts in natural ecosystems.]* • Should it be a prescriptive limit or only a benchmark aiding decision makers? *[In Canada, prescriptive limits are set and implemented by Canadian Regulatory bodies, although, the setting of such limits is often informed by the recommendations of independent International Bodies (such as ICRP, UNSCEAR, IAEA, ICRP, etc.).]*	The second benchmark value would not replace the screening value in higher level tiers. This is now stated in the text.
33	4.2.4	23/63	2	Note that compensation (such as has been applied for fish habitat in Canada) is an example of a 'transfer of risk'.	We do not agree. By risk transfer we mean when a certain management action reduces the risk for on group by the cost of a simultaneous increase of the risk for another group. Compensation is defined in the Policy for the Management of Fish Habitat (Fisheries and Oceans Canada) as: "The replacement of natural habitat, increase in the productivity of existing habitat, or maintenance of fish production by artificial means in circumstances dictated by social and economic conditions, where mitigation techniques and other measures are not

					adequate to maintain habitats for Canada's fisheries"
34	4.2.4	24/63	Middle	The second last sentence of the middle paragraph on Page 24/63 states that: *'A question that could be raised is whether a screening value regarding environmental protection could also be the level above which the optimization process should explicitly include consideration of doses to biota, whereas below the screening level, the optimization should only consider human protection.'* It should be noted that later in the document (in Section 4.2.2, top of Page 39/63), it is noted that screening levels are sometimes set at or near background radioactivity levels. Therefore, in cases where there is no significant difference between the area of concern and the surrounding background values, the justification for additional work is unclear.	The potential to optimise below the screening level reflect the majority view expressed by independent experts during PROTECT workshops.
35	4.2.4	25/63	1	When looking at remediation of contaminated lands, it should be noted that the idea of scale is a key concept (e.g., at what scale could an effect be considered significant, both spatially and temporally, as well as from the perspective of what we are trying to protect.).	No change required
36	4.3.1	25/63	2	Paragraph 2 in Section 4.3.1 discusses EC_{10} values as appropriate from an environmental protection perspective; however, it should be noted that there is a great deal of literature that recommends an EC_{20} for the protection of fish populations.	Reference to some guidance documentation recommending EC_{20} was already given on the next page – USEPA guidance to this effect is also now acknowledged
37	4.3.2	26/63	1	The first paragraph under the 'Deterministic method' section of 4.3.2 states that one underlying assumption of the deterministic assessment is that *'the ecosystem response depends on the most sensitive species.'*. The likelihood of this is unclear (it may be more probable that this is not the case). In addition, changes in ecosystem response may not be related to radiological stressors (in fact, with the exception of accidental releases, radiological stressors will not likely significantly influence ecosystem structure and function).	This text is a description of the TGD – we have included reference to EC 2003 to ensure this is clear to reader.
38	4.3.2	27/63	1	Overall, it is useful that the PROTECT Consortium selected a transparent, well-defined method to develop probabilistically-derived benchmarks; that said, however, it is important to note that it remains unclear how the effects levels were arrived at (for example, Suter et al., 2002) states that the HC_5 value is 'arbitrary and the result of political	

				compromise'. In the same section, but in Paragraph 2 of Page 28/63, it is stated that there is some precedence for the application of this value. If the underlying basis for the use of the HC_5 is unclear, even though it has been used before, precedence may not be a strong argument. On a similar note, again on Page 27/63 (Section 4.3.2), it is unclear how the assessment factor (which is equivalent to a safety factor) should be consistently selected between situations, etc. In general, it is likely difficult to update parameter values that have been set in a relatively arbitrary way as more information becomes available in the future. It is likely better to include traceable uncertainties in the assessment (where possible) that can be refined in a transparent manner as more information becomes available.	We agree – but unfortunately the TGD does not provide guidance on this. We have now made reference here to PROTECTs documentation of selection of the AF used within the derivation of PNEDR (and also a TGD which is in preparation).
39	4.3.3	28/63	1	The last paragraph of Section 4.3.3 states that *'the method is dependent upon having an appropriate standard deviation which is applicable to the data under assessment'*; however, it is unclear how one decides whether an appropriate standard deviation has been achieved. In addition, site-specific factors would likely influence the standard deviation inconsistently between sites and conditions.	Again this is a description of an existing method and reference is made to how this is achieved for some chemicals.
40	4.3.4	29/63	2nd last on page	Under the *'Estimation of critical ecotoxicity values (step 2)'* section, it is stated that the mean of a suitable number of replicates was considered representative. Does this mean that the data were normally-distributed in all cases (or that the data distribution could not be discerned due to the small sample sizes), or would a different measure of central tendency (e.g., geometric mean or median) produce a more representative measure of ecotoxicity?	Text edited to clarify.
41	4.3.4	35/63	3 (last sentence)	The document states that *'the same weight was given to each taxonomic group, meaning that species in under-represented groups (i.e. less species than the average number of species per group) were allocated a higher weight and species from over-represented groups were allocated a lower weight'*. The reasoning behind this approach is a bit unclear. Would these be equal in nature?	No, the organism groups are unlikely to be 'equal' in nature. This is one example of how data can be weighted – we make reference to a paper evaluating of other approaches.
42	4.3.4	36/63	Table 5	Table 5 sets the assessment factor to a value of unity for field data; however, this does not seem to account for the complexity in interpretation and the variability for field data	Table amended to clarify
43		29	'Below, we document the data selection and application of SDD as used by	Important remark: there is a lot of important and useful info on NOEL which is not used. e.g. doses/conc causing no effect.	It is now noted in section 4.3.4 that the FREDERICA data base was searched for suitable data on HNEDR or LOEDR, but that no additional

			PROTECT. Where data were insufficient for the application of an SSD, the deterministic method was used instead following the recommendations given in the TGD (although other approaches were considered'		data to increase the number of species covered was found in the database.
44		34	Para 4	Is HNEDR defined? - highest no effect dose rate – Hypothetical?	The acronym is now explained.
45		38	Para 2	Taking into account the smaller dataset an AF value of 3 is suggested The resultant PNEDR for invertebrates (505/3 =200?).	Text is now clarified that 200 is a rounded value.
46				Nice report I have one major remark: at the Protect workshop it was mentioned that there was a lot of unused useful or at least meaningful information out there. Not using this information may have an impact on the Screening Value. This should be clearly mentioned in the report.I assume you approached this to some extent with the HNEDR. It is somewhat hard to believe tot e.g. for the whole plant kingdom there is not HNEDR I think it will be hard to take this comment in a final draft report but it would be nice if you could give your opinion on this	Have added text noting that database was investigated for additional HNEDR/LOEDR data to supplement EDR_{10}'s and increase species coverage. However, no data were identified.
47	4.2		Discussion and Fig 1	The discussion in section 4.2 covers very similar ground to Brownless (2007) and Figure 1 is really rather similar to what appeared in that paper, to the point where I feel that some discussion of this, including reference to the paper, is warranted (which should not be a problem given the common ground), especially since the report authors are clearly aware of this work, as it is in the list of references – the citation in section 5, 'Discussion' is on a different aspect of the paper.	The paper of Brownless (2007) is now better referenced in relevant sections of the report.
48			The last paragraphs of the Executive Summary and the Discussion	The last paragraphs of the Executive Summary and the Discussion mention 'the major international organisations' involved in this field – the OECD's Nuclear Energy Agency is omitted. The Nuclear Energy Agency is a major international organisation that is actively involved in radiological protection of the environment and has been for many years. Therefore, it should not be omitted from a list of 'the major international organisations'. Incidentally, the original source for much of the Agency material which is referenced as NEA, 2007 'Scientific issues…' is 'Environmental Radiological Protection in the Law—A	Have mentioned and used reference in the introduction

				Baseline Survey' (NEA#06172, ISBN: 92-64-99000-5) I think both of these should be referred to as they are directly relevant.	
49			Exec summary, 2nd para	: a screening value is not necessarily meant to confidently represent a no effect dose rate – rather it is to screen out those situations that do not require further attention	Executive summary has been extensively rewritten.
50			Exec. Summary, 6th para:	worth pointing out that consistency in approach between chemicals/radioactivity is generally a good thing?	Executive summary has been extensively rewritten.
51	4.1		2nd para	Such limits apply to radioactive discharges as well, e.g. RSA 93 discharge authorisations in the UK, making identification of a breach similarly clear. Is the point that effects are/can be directly correlated to concentration for chemicals, that they are standards explicitly set for protection of non-human biota, or that a somewhat similar situation applies for chemicals as for radioactive substances	Included 'biota' to clarify. The limits for chemicals referred to are specifically for protection of the environment
52	Sec 4.2.4	24	Para 1	'…goal. For humans,…' Is there another point that could be made here: even if, at the individual level, effects are stochastic, the corresponding, population level effect we are looking may be deterministic (e.g. a threshold where there are enough [stochastic] fatalities to compromise the population).	The main point is that there are probably thresholds to consider within the protection of non-human biota, whereas this is not the case regarding humans. We did not feel it was necessary to further complicate the argument here.
53	Sec 4.3.2		end of first para	Also worth saying that in most cases there is no background for chemicals, so it's [more] meaningful to set very low/cautious values?	Text here is a discussion of TGD. The point made would be appropriate for some chemicals but not other (e.g. metals).
54			Fig 4:	Y-axes – the current label 'effect' is a little confusing – would something like '% not effected' be clearer?	Information added to figure legend.
55		40	Para 2	para starting 'when comparing the derived screening values…', end of para: would it be possible to elaborate on the last sentence which notes that the derived values are lower than the lowest observed effects? i.e. is this/why is this significant (or not)?	Text amended Relevance is that infers that the approach taken has been conservative
56				One generic issue I have is with the use of the Application Factor method. Whilst I appreciate that it is a widely used approach and perhaps the only appropriate method in cases of limited data, it still suffers from the 'expert opinion' affect. That is inasmuch as that the factor eventually applied is arbitrarily chosen to reflect the degree to which the group of experts asserts that the criterion derived is based on sound knowledge. There will always be some degree of subjectivity in what factor is eventually applied. Selecting an AF from a table based on some pre-determined criteria on the number of tests used to derive an effect value does not remove the subjectivity applied in setting the table. I would always recommend a SSD approach in preference to an	The report acknowledges that there are expert judgments involved in the methodologies used.

				AF by itself	
57				Similarly, the SSD approach is recommended to be applied with a final AF (1 or greater) in this document. I would prefer that the uncertainties in the data be better applied. That is, use the available data from any individual study to derive an EDR10 (as described in your Executive Summary) and then use the range of available EDR10s to produce a SSD. However, instead of applying an AF to the resultant 95% species protection criterion (for example), use the uncertainty in the SSD to extrapolate to a 95% species protection criterion with a prescribed level of confidence. Currently the best estimate is chosen, this is the HDR5;50 of the SSD. However, if you select the 95% lower CI for that criterion (the HDR5;95 as shown by the dotted line in your Figure 2) then you will derive a more conservative and precautionary criterion without the need for as much subjectivity. I have applied a similar process in the AQUARISK software for aquatic toxicant assessments and I am currently in the process of using that code together with the EA R&D128 model to undertake radioecological risk analysis and criterion setting. I appreciate that there will always be some subjectivity, for example in deciding which form of distribution to fit the species sensitivity data to; or in selecting what is deemed as acceptable or sufficiently confident. This is true for any probabilistic analysis. Irrespective of those problems, the overall approach has the big advantage of allowing as much information and inherent variability on the biological affects of radiological dose as possible to be used in coming up with an appropriate set of criteria. To that end, I would also like to suggest that some studies be undertaken to compare the modelling outcomes of including some data on radiological effects that might be excluded on the basis that, say, it was inadequate for the purposes of deriving an ED10, with the more conservative and 'correct' approaches applied to date. This would introduce more data given that many of the early studies were not designed to produce the sort of information necessary for a toxicological approach to analysis. It would be interesting to see if the increased robustness derived from using additional data gives rise to any significant shift in the degree of conservativeness of the final outcomes.	PROTECT has tried to be as consistent as possible with the European approach for chemicals, and therefore we have used HDR_5 together with an AF in this report. The alternative approach of using the CI is now acknowledged. PROTECT did search the FREDERICA database for more data (HNEDR/LOEDR) but did not find suitable (e.g. relevant endpoint) data for any new species.
58				I am also aware of recent work by Alonzo et al (2008) looking at the cumulative effects of chronic irradiation across generations. They	Taking into account transgenerational effects of ionizing radiation is a challenge relevant for

				found that shorter lived organisms (Daphnia in their case) were more at risk from sublethal effects that longer lived species. This is a crucial finding as many of the real-world situations involving human-influenced radiological dose will fall into the chronic low-dose category. It is also very pertinent to the setting of screening values as it would seem that using a range of EDR10s may not derive criteria that result in a no effect dose rate, as required. Given my short time to read your document and the date of the recent work, I am unsure if this type of effect has been adequately considered, although the fact that you have Dr Garnier-Laplace on your authorship gives me some confidence in that regard.	chronic exposure situations. Currently we have few data regarding this (e.g. from the results obtained on daphnids and earthworms during the ERICA project). The knowledge within this area will hopefully increase in the future.
59				Conclusion of deliverable 5 that an upper screening level cannot currently be agreed further suggests the science in this area does not yet support regulatory assessments.	It is already possible to give some scientific input to the derivation of an upper level. The main questions are currently non-scientific, i.e. does the community want a second benchmark, what should it represent, how should it be used etc? When these questions are answered science could give some matching input.
60				Deliverable 5 would benefit from the inclusion of a comparison of species type specific screening criteria with RD128 outcomes to allow comparison of approaches	This is now included.
61				The deliverables taken together indicate a need to coordinated action to address gaps in current information on this topic.	This is addressed in the new section on recommendations
62				One thing you should correct in the draft is the reference to "rats" in French (1974) on Page 45. The kangaroo "rats" in that study are about as different from a lab rat as a cat is from dog. Their main data came from "pocket mice", which are also nothing like lab mice. Use the word small rodent if you want to keep it simple	Text corrected.
63				I won't dwell on this, but there are major problems of interpretation in French's study. This was discussed in Mihok (2004). I am not sure why this has not yet sunk into the minds of the scientific community, but population-level radiation effects were not detected in meadow voles up to about 4,000 uGy/hr. This result held for several other species of small rodent as well. These rodents are all short-lived, but that's where most of our truly chronic radiation effects data come from.	The Mihok reference is now considered.
64				Life-shortening effects are hard to detect because they appear to involve simply advancing the age of first onset of cancer occurrence, and this occurs at much, much lower dose rates. We are still a long way	We agree with the comment. However, we do not see how we can make use of

68		18	Para 2	This is misleading, as the dose-response relationships for protection on the LNT for the radiation effects similar values. I hope that the draft UNSCEAR document might do a good job of discussing these issues, but it has not. You have to go to the original scientific literature to find out what might happen in the long-term. A good example is the recent paper by Tanaka et al. (2007) in Radiation Research 167:417-427 on causes of death in mice exposed to chronic gamma radiation. This study did a really nice study, but even they blew it by not irradiating the animals in utero. I am still waiting for someone to do the perfect experiment.	Text amended to acknowledge this
69		20	Para 1	This is a very simplistic statement and one which much more careful consideration given might happen in the long-term.	Text amended
70		20	Para 6	This arises, in part, because most radionuclides are preferentially excluded at higher trophic levels. This is in contrast with many organic chemicals that are preferentially bioaccumulated.	Not entirely true with regard to bioavailability.
71	4.2.3	22	Para 4	"existing exposure situations" - I would say that existing situations are also of high significance, given that non-human biota are likely to be present even if human access is limited or prevented.	Text amended
65				My only comment relates to whether the screening value is intended to be used for the combined impact from a number of sources (perhaps as controlled by a discharge authorisation) or a single source. The paragraph highlighted in green in the discussion section certainly implies that the screening criteria are being used on a single source basis. As indicated in this highlighted text, not many sources/authorisations by themselves would exceed the vertebrate screening level of 2 microgray/h. There is clearly no issue with the screening levels for plants and invertebrates as they are higher than 40 microgray/h threshold we have used in our assessments.	Section 5.1 acknowledges that environmental assessments may have to consider multiple sources. See above.
72		23	Table 3 - existing	This seems an appropriate statement - noting that such situations may be of equal relevance to planned situations - see previous note.	Furthermore the recommendation state: 'The screening value should be applied to total incremental exposure (i.e. it is not a single source benchmark).'
73		24	Para 2	numbers in pipes – This colloquial phrase adds nothing to the text.	Deleted
74		40	para 1	However, effects on fertility and fecundity are unlikely from lung doses and I would not expect deterministic effects such as fibrosis to occur at these dose rates.	Text amended
75				Looking at the draft of deliverable 5B, I am concerned that some of the comments and strong concerns raised relating directly to the substance of section 2 (protection goals) are not reflected at all. However, I cannot see how the screening levels can apply to single sources or should apply to single sources. The total dose from all controllable sources should be taken into account to determine whether there are unlikely to be any health effects. The equivalent threshold for human protection is probably 10 microsievert/y and this relates to total 'added risk' exposures. I would suggest that it is for regulators/Government Agencies to decide (on a risk basis) whether to compare doses from single sources against such a screening level when deciding whether to perform more detailed assessments. Having completed habitat assessments for England and Wales we are in a position to decide whether the risk of using such a screening level for single sources is acceptable. It is not clear whether this same conclusion can be drawn for other countries.	While it may be the intention that these are addressed in the Aix-meeting report, I do think it would be appropriate to at least refer to them also in this 5B document. I hope you will be able to address this concern.
76	General	General	Overall	The request of this review has a very short deadline. It is not reasonable to expect that reviewers can be available without notice for this. It can be questioned that there is a willingness from the consortium to receive comments on this short time horizon. The following is very quick review of the document. To obtain feedback on the points we comment on and reassurance that the comments are taken care of, we wish that revision section is filled in and sent back. If the review time is extended a more thorough review can be made of both documents	We acknowledge the short deadline – but as explained the PROTECT project finished at the end of September. The EC have been flexible with regard to when the report is submitted and as a consequence we have been able to make the revision available for comment (with advance notification of the timetable). However, we strongly reject any inference that the PROTECT consortium is unwilling to receive comments. An earlier version of this deliverable was made available for comment in May 2008 and was the focus of an open workshop held in Aix. Furthermore, the consortium ran two earlier open
66		14	Para 1	This is rather damning of ICRP.	A more direct quote from the DRAFT ICRP report is now used.
67		16	Table 1	This naming of specific types of organism is likely to sound rather silly to the outsider.	The table presents organism as listed in the different publications.

					workshops (Chester and Oslo) the discussions of which directly contributed to Deliverable 5. The consortium also presented three oral papers at the Bergen conference in June 2008.
			Comments which did not require a response from the PROTECT consortium		
77		General	Overall	The document is good overview of the available options and a good discussion on different alternatives. It looks generally transparent	
78	4.2.4	23-24	Despite these similarities, there are some important differences between human and environmental optimisation, specifically in the scientific basis for protection and the protection…….	Very positive that the differences are acknowledged between human individuals and population in the environment. This has very important implications on the interpretation of effects.	
79	4.2.4	25	For existing exposure situations…..	Very good to point on that remediation can cause more harm than help for the environment	
80	General	General	Overall	Good with a more transparent method for a screening value than to only rely on expert judgement. Good also to use a method that is used for other contaminants in environmental protection	
81	4.2.4	25/63	1 and 2	It is good that the document states that reductions in human exposure will likely result in reductions in environmental exposure and that these should be considered together. Also, the concept of deciding on mitigation only in cases where we do more good than harm is logical.	
82	4.3.2	26/63	1	The assumptions underlying the 'Probabilistic method' are not likely to be the case (i.e., it is unlikely that the variability in sensitivity under laboratory conditions will be similar to the variability among species in the field, and it is unlikely that the endpoint measured in lab tests are necessarily indicative of effects on populations in the field due to the influence of multiple stressors and other factors). That said, it is recognized that we must start somewhere and by clearly stating the	

				assumptions as done in the draft PROTECT document, it is possible to fine-tune and update the approach as more information becomes available.	
83			General	Overall, I think this is a good report. I liked the approach of developing both a single screening value and deriving organism-group values (e.g. vertebrate, invertebrate). I also think the description of how the values have been derived using SSDs is much better than previous descriptions – it makes clear where expert judgement has been used and also explains why the 'judgements' are what they are (e.g. assessment factor of 2 selected). For me, this greatly strengthens the approach used. The expanded discussion, to my mind, has also reinforced (and explained) the purpose of the screening levels. I think not recommending 'hard' upper values is wise, though at some point I suspect some sort of upper level, possibly rather fluid, will be helpful to give a sense of scale to the screening values (e.g. is 12 µGy h^{-1} a problem, or 100 µGy h^{-1}?).	
84				Whoever "holds the pen" should be congratulated. I enjoy reading your deliverables as the logic is always clear, and whoever "holds the pen" has a good grasp of how to use the English language. I only wish we could do the same for what we write here.	
85				I don't have much new to add from what you have heard in person in the past. I'm still on the opposite side of the fence when it comes to stretching the data to come up with group-specific recommendations; otherwise I agree with your approach. You've given all the facts one needs to use the information wisely, so there is no point in nit-picking at this stage	
86				I very much agree with the observation that any radioecological risk assessment can be further refined to focus down on keystone &/or economically or ecologically sensitive subsets of any exposed community.	
87				As to the availability of data, the best response is that if the data do not exist; set the criteria more conservatively as a precautionary measure. If the assessors find that they are approaching or exceeding the criterion, then there is a need to acquire more data. Any fresh site-specific data can then be included into the global databases. I appreciate that practical, ethical & economic factors come into play when deciding on whether or not to undertake studies but that can be better evaluated if you can compare the economics of the process in question against the	

				potential for adverse environmental outcomes.	
88				This raises an issue that I will only comment on briefly but it is crucial to the current developments; that of data availability and quality. My comments here should in no way suggest that I do not sincerely appreciate the effort that has gone into developing the FRED as a wonderful resource. However, in my recent attempts to use the FRED I found some inconsistencies such as that the LOEDR values were in some cases lower that the NOEDRs. This is counter intuitive and I have communicated my observations to Dr Copplestone who responded that a review of the database is underway. As a further consequence of my observations, I went into the data in more detail and obtained examples of the most critical data for my study. Some very low values, particularly from work by Brown & / or Templeton, seemed to be having excess influence so I got hold of the original Nature paper to look at the data first hand. The paper was assessing effects of chronic radiation exposure on egg development and hatching for a couple of fish species. Whilst there are some significant differences from controls across the range of exposures studied, the differences are inconsistent (i.e. sometimes occurring at low doses but not at higher ones) and mixed (i.e. sometimes improving hatching or reduced larval abnormalities, sometimes making things worse). The authors summarise their findings as follows "It is concluded that irradiation of fish eggs by either Sr-90 contamination or external radiation source at levels used in these experiments... does not cause significant differences in the proportion hatching or in the number of abnormal larvae produced". That being the case, it seems to me that if the data were to be retained in the database (a moot point) then the highest doses used in each of their studies should be the only ones recorded in the database and they should all be HNEDR values. As an independent user of the database I can, of course, make the decision to exclude that data on my own behest. However, the implications are fairly intimidating. I have been trusting the QA applied when compiling the database to have adequately addressed these issues and was hoping to be able to safely use the data as is. If I now need to go to each and every paper from which data has been included in FASSET to make an assessment of it for myself, then that becomes a major task and the database becomes much less useful. I presume this has implications for the ERICA tool as well and for the overall discussion on setting	This is predominantly a comment on the FREDERICA database. For this report, PROTECT has reviewed the original papers of those datasets considered for use in the derivation of benchmark values.

				internationally acceptable numerical benchmarks.	
89				Once again, thank you for giving me the opportunity to comment on the draft. I hope my comments do not reflect too poorly on my limited opportunity to critically evaluate the document and that I have not unnecessarily covered issues that have received due comment at some point in the draft. I would also like to reiterate my appreciation to everyone concerned with the development of this review and set of recommendations.	
90				Overall, I think that this is an extremely useful report. The only thing that is a bit disappointing is the Executive Summary that does not quite convey the understanding of the authors and the sophistication of the approach adopted. In particular, the report is extremely good at recognising the distinction between protection at the organism, population, community and ecosystem levels. Also, the reliance on objective analyses of information from the FREDERICA database is commendable. I think that this is by far the best approach that we have yet seen to defining threshold dose rates for screening purposes.	
91	Exec summ	4	Para 2	I think that what is really represented is no significant degree of detrimental effects. Subtle biochemical and behavioural effects may be observed at extremely low dose rates, and there is no threshold for stochastic effects in non-human biota just as is the case for humans.	
92		5	Para 4	I agree that the selection of an upper value is very difficult. It also reopens the debate on whether we are concerned with effects at the individual organism level or at the population/community or ecosystem level	
93		8	Para 2	There also needs to be agreement on the environmental media or organisms for which dose rate values should be calculated. Although dose rate is generally regarded as an appropriate measure for evaluating impacts, this is not a self-evident truth for all of the wide range of effects of interest.	
94		8	Para 3	A caveat is that individuals (e.g. those that are rare or endangered species) may need to be considered specifically…. agreed	
95		12	Para 2	I think that this is a very good well-balanced account that I would strongly endorse. It is a pity that the flavour of these remarks is not brought out in the Executive Summary.	
96		15	Para 5	This is interesting, but probably not very helpful in the context of the wide range of radionuclides of potential interest in solid radioactive waste management. Dosimetric quantities are useful in generalising	

				between radionuclides and to various mixtures of radionuclides.	
97		17	Table 2	This is a very helpful summary of the intentions of the various organisations.	
98		18	Para 2	This highlights the benefit of using dose rates, which includes all radionuclides, rather than concentration of separate radionuclides, but also the need to further develop understanding of synergistic effects of radionuclides and other contaminants and how to handle this issue during risk assessment - agreed	
99	4.2.2	21	Para 1	Note that the possibility of some effect below the screening level is here admitted - even though that effect is described as negligible.	
100		22	Para 1	'Concept of an upper value' - I agree with this approach.	
101		26	Para 3	This is a nice summary of potential approaches.	
105		36	para 6	Seems reasonable. Note that I have not checked the fitting procedures in detail, but the overall approach looks very reasonable.	
103		44	para 3	'80-200' This seems very plausible, being around 1 Gy/y. Experience suggests that significant effects on bone marrow and hence on the immune system are seen at this sort of dose rate.	
104		45		This seems an excellent chapter that would benefit from more detailed reading than I have had the opportunity to give.	
105				I have scanned through Deliverable 5B. Overall, I think that this is an extremely useful report. The only thing that is a bit disappointing is the Executive Summary that does not quite convey the understanding of the authors and the sophistication of the approach adopted. In particular, the report is extremely good at recognising the distinction between protection at the organism, population, community and ecosystem levels. Also, the reliance on objective analyses of information from the FREDERICA database is commendable. I think that this is by far the best approach that we have yet seen to defining threshold dose rates for screening purposes.	

Table 2. Comments on the October draft relating to PROTECT responses to comments on the September draft.

Number in Table 1	Additional comments	PROTECT response
16	Still think that the authors should consider adding a glossary to the document, as it is inconvenient for the reader to have to access other documents or the PROTECT web-site for definitions of acronyms and terminology that are key to the document. This is particularly important in documents, such as this one, that are using many different acronyms and terms.	We acknowledge the usefulness of a glossary but have produced one as a separate document to cover all PROTECT outputs – it is available on the PROTECT website.
27	Still think authors should be careful here. Perhaps the first bullet could be softened a bit and/or the order of the bullets could be reversed, since the example provided in the second bullet would likely be less destructive, more in line with monitoring that is in-place for human protection and more cost-effective. In addition, the information that is presented in this first bullet seems to contradict the statement that has been made at the start of the paragraph just below Bullets (i) and (ii) on page 12/71 of the revised document, which states that: *"There is no need to introduce a new protection (individual level) goal for rare species as in the assessment process it may be concluded that, to protect a rare species, no individuals could be severely affected without also putting the population at risk."* It might be worthwhile to clarify this.	The order of the bullets has been reversed. We do not think the bullet point (on monitoring conformity) and the comment that a separate individual level protection goal is not required for rare species is contradictory.
31	The following text has been deleted from Section 4.1: *'Under circumstances where the cost of doing more work is high, or if there are too many false positives to be manageable, it may be prudent to adjust the screening value (assuming there is confidence in the exposure assessment of screening tiers). Under these circumstances, the level of precaution may be traded-off against these practical and economic considerations.'* [Note that this has likely been deleted to keep aspects of the management-based Environmental Management phase at arm's-length from the technically-based Risk Assessment phase. Such decisions would likely be made nationally between a regulatory agency and a given facility taking account of site-specific or facility-specific aspects in the context of other considerations (e.g., socio-economic, etc.).] However, Paragraph 4 of Section 4.1 on Page 21/71 of the revised document states that *"it is sensible for the screening value to be precautionary to try to ensure a low incidence of false negatives."* That said, it should be noted that a true screening benchmark should be protective of even the most sensitive species to a point where it identifies situations where there might be concern. In other words, screening benchmarks are meant to screen things out and should be set to be highly conservative. Therefore, if exceeded, this would mean that additional work would be needed, likely starting with	We agree with the comment but consider that it is now encompassed in the subsequent sentence to that quoted.

	conducting a more realistic evaluation of the situation at a higher assessment tier.	
33	A key element of the Fish Habitat Policy in Canada is the guiding principle of "no net loss of the productive capacity of fish habitat". This principle, which supports the conservation goal, is applied when proposed works and undertakings may result in a harmful alteration, disruption or destruction of fish habitat. Prior to issuing an authorization under the Canadian Fisheries Act, Fisheries and Oceans Canada (DFO) applies the "no net loss" guiding principle, so that unavoidable habitat losses as a result of development projects are balanced by newly created and/or restored fish habitat. This can be accomplished through compensation, which is defined as the replacement of natural habitat, increase in the productivity of existing habitat, or maintenance of fish production by artificial means in circumstances dictated by social and economic conditions, where mitigation techniques and other measures are not adequate to maintain habitats for Canada's fisheries resources. If unacceptable losses of fish habitat cannot be prevented by these measures, the Habitat Policy calls for an authorization not to be issued. Furthermore, where deleterious substances result in harm to fish or damage to fish habitat, compensation is not an option. Compensation is an important concept because it acknowledges that some human activities would be expected to potentially impact fish habitat and it creates a mechanism whereby this can be balanced through positive action. This would be a comparable concept to the 'transfer of risk' between workers and the public for humans, as noted in Section 5.2 (Page 48/71, end of Paragraph 5) in the revised D5b document. Therefore, the authors might consider mentioning the concept of compensation as an environmental example. In addition, some of the text that was originally in Section 4.2.4 before it was deleted from the document has been moved to Section 5.2 (Page 48/71, Paragraph 3) of the revised D5b document.	We still do not agree that compensation is comparable to risk transfer in the way that we discuss risk transfer in the report. Although an important concept we think it is outside the scope of this report.
34	Section 4.2.4 has now been deleted from the document and this statement has been moved to Section 5.2 (last paragraph on Page 48/71) of the revised D5b document. The text stating that screening levels are sometimes set at or near background radioactivity can be found in the top paragraph of Page 37/71 of the revised document. It would still be worthwhile to clarify that doses to biota would only be of interest if they significantly exceed background values (i.e., in Section 4.2.4, last paragraph, of revised D5b document).	As noted in Table 1, the potential to optimise below the screening level reflect the majority view expressed by independent experts during PROTECT workshops.

	It should also be noted here that although protection of humans is based on a linear no-threshold (LNT) model (i.e., stochastic effects), protection of non-human biota is typically based on deterministic effects with a threshold. In doing so, it is assumed that below that threshold, significant effects to biota would not be expected and therefore, the benefits of optimisation would not be clear. That said, however, the uncertainty around the threshold would be a key concept here and in situations where uncertainty is high, either additional work to improve understanding or optimisation might be considered.	
35	Section 4.2.4 has now been deleted from the document and moved to Page 49/71 (1st full paragraph) of the revised document. The concept of scale or size of the problem (e.g., size and/or quality of area showing an exceedance with respect to the potential impact on the population) still appears to be missing and can be very important in determining a reasonable course of action for contaminated lands, for example, in terms of weighing out whether the fix is worse than original situation. That said, it is unclear why remediation is being discussed, since its relevance to the development of screening benchmarks is unclear.	The second part of the report puts the derived benchmark values into regulatory context. It is therefore relevant to discuss how the values might be used within existing radioprotection approaches. The one discussed here being optimisation. Remediation is only discussed in the context of how benchmark values may be applied. Furthermore we emphasis that any remedial activities would require justification that they will result in 'more good than harm'. Considerations of scale would naturally be part of any optimisation/justification process.
37	A reference to EC (2003) has been added as the source for these assumptions. That said, it remains unclear as to whether these assumptions would be applicable in all situations in natural ecosystems. Would it be possible to provide the rationale for this assumption?	This is a description of the TGD (EC 2003) and the assumptions that are underlying the concept that protection of the most sensitive species (and therefore all other species too) will also protect the ecosystem.
82	A reference to EC (2003) has been added as the source for these assumptions, but again, it would be useful if the authors could add the rationale underpinning these assumptions to the document. For example, it remains unclear as to whether these assumptions would be apply in all situations. In addition, with respect to the newly-added Assumption (iii), which states that *"input data are drawn at random from the distribution of possible species sensitivities."*, it should be noted that the practicality of accomplishing this will likely be dependent upon the type(s) of stressor(s) being considered. In addition, there are many species for which little information is available. That said, the amount and quality of the work that has been done so far to compile the available information is impressive and provides an excellent basis for future development.	PROTECT attempted to apply approaches used to define benchmark values for chemicals to radiological protection of the environment. In Europe the guidance for setting chemical benchmark values is given in EC (2003). Whilst we have noted the assumption made in EC (2003) an evaluation of these is outside of what can be achieved within PROTECT.

Table 3 Additional comments on the revised PROTECT Deliverable 5 draft version 22nd October 2008.

	Section in October 2008 draft	Page in October 2008 draft	Content/location	Comment received	PROTECT Response
1	4.4.3	40/71	3rd full paragraph	In the paragraph stating that initial screening level assessments were carried out, the authors may also wish to mention that: *Although it should be noted that the results of such screening do not necessarily reflect actual potential risk at the case study sites, as the data sets were used for illustrative purposes only, and detailed knowledge of the sites was not applied.*	Text amended as suggested.
2	4.4.3	41/71	1st paragraph	The first paragraph on Page 41/71 of the revised document states that *"Table 9 results indicating organisms which would exceed the organism group screening levels proposed by PROTECT."* It should also be noted here that more realistic assessments to determine whether or not an issue truly exists at a given site would be required, since such screening-level assessments are based on highly conservative assumptions with respect to exposure that do not take account of reasonable site-specific considerations. In addition, the authors could point to Figure 4 in the revised D5b document, which depicts this idea very well. A footnote might also be added to Table 9 to clarify this idea.	Amendment in response to the above comment has addressed this issue..
3	4.4.3	42/71	Top paragraph	The top paragraph on Page 42/71 of the revised document is a bit difficult to follow. In addition, the last sentence in the paragraph states that *"Most of the assessed sites are by their nature have comparatively high environmental concentrations and a refined assessment is likely to be warranted (N.B. in the case of the Pickering NPP freshwater assessment some end of pipe-line activity concentrations were used in the assessment)."* It is interesting to note that when a realistic assessment is carried out, doses fall orders of magnitude below the dose benchmarks.	Text clarified The reader is now directed to SENES 2007 for the results of more refined assessments.
4			General	The concept of a screening benchmark, what it represents and how it should be used needs clarification. Some parts of this document do not seem to be consistent with the general screening concept that should define a level below which there is no concern. All the discussions of what to do or not do if the benchmark is exceeded seem out of place. Exceedance	We do not support the concept of different benchmark values for use in higher tier assessments. Any second higher benchmark should be derived to represent a greater risk than the screening value (here derived as the

				only indicates the need for a more realistic and/or more sophisticated assessment. In the same context, the need for a second higher screening benchmark is conceptually confusing. A more useful concept might be a higher benchmark that is a more realistic tier 2 or 3 benchmark which is used with a higher tier exposure assessment.	predicted no effects level). If more than a basic screening assessment is required then the assessment should be refine NOT the benchmark. The screening level would still have a role in more refined assessments.
5			General	The document seems to contain much material on risk management which appears to be outside the implied scope of the document, i.e. the development of transparent, scientifically sound methods of calculating screening benchmark levels.	The comment may be correct in suggesting that some of the discussion is outside the original envisaged scope of the deliverable. However, this has been included as a consequence of comments received during the various workshops etc. (see above).
6			General	The discussion of false positives and negatives also seems out of place. A false negative implies that the screening benchmark may not have been set properly for its purpose, and false positives should never exist. Exceeding the screening benchmark only means that you can't dismiss the potential concern by using the simplest method (i.e. how can that be considered "false" at the screening stage).	We do not consider that the existing text is in disagreement with the comment.
7			General	The concept of a generic screening benchmark implies that it covers everything, but the vertebrate group screening benchmark is lower. That implies that the generic screening benchmark may be set at the wrong level.	As discussed in the report the generic benchmark is set to protect 95% of ALL species. Therefore, if any given grouping is comparatively more radiosensitive a generic benchmark will not be protective of that grouping to a 95$^{\%}$ level.
8			General	The concept of optimization for non-human biota (perhaps at doses above a certain benchmark) should include recognition that we generally protect non-human biota from deterministic effects. If the benchmark (presumably a higher tier benchmark) represents a threshold for deterministic effects, then optimization below the benchmark/threshold is not required as there is no effect to reduce, and optimization at doses above the benchmark/threshold may be irrelevant as the appropriate actions to correct the situation are a matter for the site owner and regulator to agree upon.	As noted above the comment that it may be decided to optimise below the screening level has been included as a consequence of comments received/discussions during PROTECT workshops. See above re 'higher tier benchmarks'.
9	3.1	15/71	paragraph 5	Level of targeted protection; ("ICRP (2007b) discuss effects which are....."). To follow the same rationale than in previous paragraphs (which describe the endpoints considered in each organization), a new text is proposed as follows: "ICRP (2007b) considers morbidity, mortality, reproduction impairment (fertility and fecundity) as well as DNA damage (chromosome aberrations and mutations) for the 12 RAPs selected or related	Text amended as suggested

				individuals". The remaining text of the paragraph could be deleted ("They acknowledge that no attempt .....") because what it says is not exclusive of ICRP 2007b, as it is perfectly explained in the next paragraph of D5 ("All of the above reviews have predominantly looked at effects that are measured at the.....")	Deleted as suggested
10	3.3	19	Table 2	Some dose rates are given in μGy h^{-1} and others (the ones from IAEA) in mGy d^{-1}, despite in Table 1 all the dose rates are given in μGy h^{-1}. It would be better to use the same units in Table 1 and 2.	Table 2 gives direct quotes from original work and is therefore kept as it is.
11	4.2	22		Sections 4.2 and 4.2.1 have almost the same "name". In this new version of D5 I think it is not necessary the subsection 4.2.1 (Just leave the text of 4.2.1 under the section 4.2).	Edited as suggested

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