EUROPEAN COMMISSION

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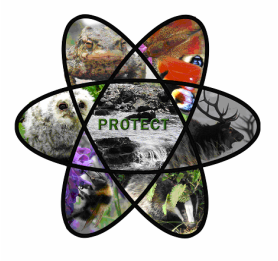
PROTECT

Protection of the Environment from Ionising Radiation in a Regulatory Context

(Contract Number:036425 (FI6R))



Workshop: Regulatory Approaches & Requirements (29th-30th April 2007, Chester, UK)

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Lead contractor: **Environment Agency**

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PU	Public	X
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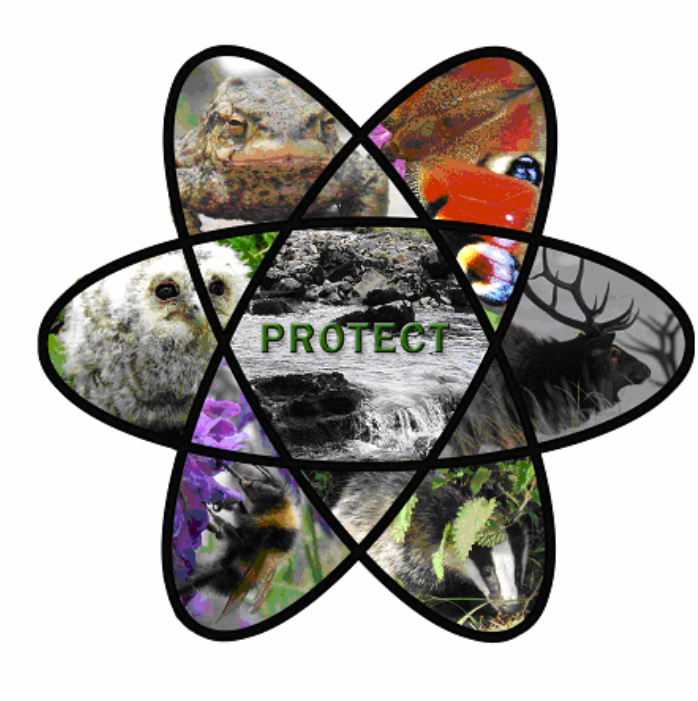
Name	Number of copies	Comments
EC, Henning von Maravic	1	pdf
	2	hard copy
PROTECT Partners	1	pdf
Work package 1 workshop participants	1	pdf
PROTECT website	1	pdf on Outputs page

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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Purpose of the Workshop

The workshop was held with environmental regulators, NGOs and some industry representation (although the focus of this first workshop was to elicit views from regulators). A summary document, which outlined responses to a questionnaire on current regulatory approaches and requirements, was circulated prior to the workshop. The aim of the workshop was to discuss and explore in more detail areas relating to the protection of the environment and in particular obtain views on the following:

- Expectations or requirements of environmental protection (as a whole)
- Expectations or requirements of both chemical and radioactive approaches
- Suitability of any approaches that derive numerical values for use as criteria or standards
- Suitability of any numerical values currently applied as criteria or standards

Issues discussed (in part defined by questionnaire responses) included:

- Justification for regulating the nuclear industry
- Alignment of chemical and radioactive substances regulation
- Appropriate targets for protection
- Demonstration of compliance against protection goals
- Credibility of currently suggested benchmark values for ionising radiation and appropriateness of methods used to derive them
- Treatment of background exposure within assessments

The following report records discussions during the meeting and does not necessarily reflect the views of members of the PROTECT consortium (N.B. no attempt has been made to comment on (or 'correct') the discussions during the preparation of this document). It is now for the PROTECT consortium members to review and extract relevant information for PROTECT from the record of the meeting for use in the other phases of the PROTECT project.

Agenda

When reading this document on-line, presentations made at the workshop can be accessed by clicking the title within the agenda below.

Time	Title	Presenter	Chair
	Thursday 29th March		
09:00	Welcome and PROTECT overview	Brenda Howard	
09:15	WP1 overview	David Copplestone	**Nick Beresford**
09:30	Questionnaire responses	Jo Hingston	
09:50	Protection of the environment from ionising radiation – views of a regulator	Riitta Hänninen (STUK, Finland)	
10:40	Development of Environmental Criteria in Canada: An AECL Ecologist's Perspective	Tamara Yankovich (AECL, Canada)	
11:10	Ethics of the existing ICRP statement	Deborah Oughton	
11:25	Breakout groups – 'Legislation & Regulation'		
12:45	Lunch		
13:45	Plenary discussion		**David Copplestone**
14:15	Protection of the environment – the driving forces	Jennifer Best (Natural England, UK)	**Brenda Howard**
15:00	Breakout groups – 'Protection goals'		
16:30	Plenary discussion		**Deborah Oughton**
17:00	Close		
	Friday 30th March		
08:30	SETAC Workshop on derivation of environmental standards	Paul Whitehouse	**Nick Beresford**
09:00	Derivation of environmental radiological protection benchmarks – an overview	Jacqueline Garnier-Laplace	
09:30	Breakout groups – 'Standards'		
11:30	Plenary		**David Copplestone**
12:00	Overview of meeting findings & 'what next'	Brenda Howard	
12:30	Close meeting		

Workshop Format

Invited presentations were made by a number of PROTECT participants and independent experts (see agenda above). The topics of the presentations were selected to aid discussion around issues highlighted in the questionnaire responses from those circulated to regulators, advisory bodies, NGOs and industry. The workshop was divided into three sessions with the questions being discussed in pairs. Each session started with one or more presentations and then the workshop participants split into three facilitated breakout groups to discuss two questions related to the session (session 1 dealt with questions 1 & 2, session 2 with questions 3 & 4 and session 3 with questions 5 & 6). It should be noted that the composition of the groups during the breakout session was the same for sessions 1 and 2, but was changed for session 3. For convenience only, the following record of the breakout groups are attributed to a group number but this was purely to facilitate the note taking and recording of the meeting. This was followed by a plenary session to feedback details of the breakout groups. Below is a record of the breakout group and subsequent plenary discussions. Note that the breakout groups are reported anonymously whilst points raised in plenary are attributed to participants.

Breakout Group Feedback

Question 1: With many potentially important environmental issues (e.g. climate change) is it justified to regulate the nuclear industry specifically for protection of the environment?

GROUP 1

To achieve a fruitful discussion, the group took the implicit underlying assumption that 'nuclear energy may be beneficial to combating climate change' at face value with no discussion of whether there was agreement with this assertion. It was also noted that there were 'real' environmental issues related to the nuclear industry not just 'potential' (or 'hypothetical') issues. It was also felt that, even if the environmental risk of nuclear power was considered to be 'low', this was not a justification for ignoring it.

It was pointed out that there is already environmental regulation of the nuclear industry. Specifically regulating the nuclear industry with respect to radioactivity and the protection of the environment was generally thought to be potentially beneficial to the industry (through demonstrating its social responsibility for example). Where there is a poor public perception of the nuclear industry, opposition to environmental regulation may be a backwards step. Responsible management was thought to be part of 'doing business'. Compliance against specific environmental protection regulation is/would be more easily demonstrated than against the ICRP 60 statement with its unsupported assertion.

The group agreed that science was only one component considered within policy making (science informing decisions). Social, ethical and economic factors all contribute to policy decisions such as how the nuclear industry should be regulated. Any regulation would need to be explicit with regard to assumptions, criteria and context, for example, to avoid situations where neither industry nor regulators are satisfied. In addition, it was emphasized that assessment and data collection (which are driven by science) should be kept separate from management and decision-making (which are typically driven by factors not related to science, such as economics, politics, social aspects and others).

Negative aspects of how industry is regulated may be a disproportionate or inappropriate use of resources. Group members also noted that industries other than the nuclear industry may release considerable amounts of radioactivity in to the environment (e.g. oil extraction, phosphates industry) and these also require regulation.

GROUP 2

It was recognised that, from an industrial perspective, burden of regulation might be a cause for concern. But nuclear sites (e.g. in UK) are often in the vicinity of protected sites and, therefore, there is a requirement to regulate to ensure environmental protection irrespective of whether this is justified. There is a lack of rationalisation at a national and furthermore international level. If money/resources are diverted from regulation of protection of the environment from ionising radiation, it will not necessarily be spent on other more "important" goals. Also, the point was made that perhaps the nuclear industry is not as carbon neutral and that there needs to be a clear analysis of the full nuclear cycle in terms of CO_2 emissions (i.e. mining and high level waste management etc. should be included in determining the carbon footprint of the nuclear industry).

There are benefits of regulation, for example the industry might be able to show explicitly that practices are leading to low environmental risks (negligible impact) contributing to acceptability. Industry might also be seen to be socially "responsible".

There is justification for performing an assessment because there may be harm from operations.

By becoming involved in the development of methodology, assessors (industry) may learn from others but also may influence the process. There are examples within the chemical industry where industry themselves are involved in driving the process through producing their own guidelines, e.g. on best practice instead of waiting on the initiative from regulators. The question was posed – "how might this feel from the industry's perspective?" There might be concerns over the regulation being "tight" and costly.

Harmonisation allowing for example comparison between the risks associated with different practices (nuclear and non-nuclear) would also be a means of rationalising resource allocation. Comparative risk assessment methods were considered to be crucial in ranking the importance of environmental stressors, although, it was recognised that there may be different time pressures for different industries.

Sustainable development should constitute part of the debate – the requirement to ensure the wellbeing of future generations through protecting the environment from stressors (including radioactivity) today. It was felt that is was important to consider the associated costs of regulation for the protection of the environment – (e.g. in the worse case, a nuclear power plant might be shut down under highly stringent regime) – getting the balance right in terms of weighing costs against benefits is therefore necessary.

Consideration of risk should allow some degree of harmonisation between approaches used in chemicals and radioactive substances regulation, nonetheless this was considered as a challenge. Assessment of risk might be different for different toxic substances – therefore complete harmonisation may not be possible. But the principles and methodology actually varies little between quite disparate classes of chemical e.g. industrial chemicals, pesticides, biocides. Standard methods e.g. derivation of a HC_5 value when considering impacts to a specific animal might not be appropriate. Estimating an HC_5 from an SSD integrates data for **all** species of plants and animals for which we have data There are approaches to circumvent this e.g. life cycle assessment, application of risk indices, consideration of the fraction of potentially affected species you get this from an SSD and these should be investigated further.

It was noted that international conventions, e.g. maintenance of biodiversity (Earth Summit) mean that assessment for radioactive substances is unavoidable. Although it was noted that the broad range of approaches and disparate methods used within chemical regulation might be one reason why the nuclear industry has concerns over the future direction of any environmentally led regulation.

A partnership approach between industry/regulator was seen as a good way forward. There was a brief discussion on the application of environmental quality standards and the application of uncertainty factors – linked to the Water Framework Directive.

Environmental Liability Directive – this might provide a useful support to the argument for the need for explicit environmental protection (from radioactive substances).

GROUP 3

It was considered that it is justifiable to regulate as it is important to go through the exercise to demonstrate the potential for risk but there needs to be transparency in any work conducted and the legislation needs to be transparent. This is the case for chemicals and radioactive substances and so there is no reason to exempt the nuclear industry from this process. But it was recognised that there is a need for consistent, transparent regulation for radioactive substances as it is for hazardous chemicals substances. Furthermore, it was felt that the provision of tools to carry out assessments would be useful and remove some of the burden on industry, particularly as it was recognised that there is a cost for industry to perform an environmental impact assessment. The question was asked whether there is really a high cost to industry if a tool was to be provided to them. Additionally the question of what is the cost of doing nothing was posed?

If nuclear industry can be a solution to climate change it was felt that it is important to be able to identify and quantify any environmental issues related to the release of radioactive substances. It was also noted that there is already considerable concern over the use of radioactive substances and the question was posed as to whether improving risk assessment would actually help to address this concern or whether, perhaps through communication issues, it would actually make the concern worse.

A few other points were noted: 1) the application of the ALARA principle was generally considered as appropriate; 2) we need to understand the implications of regulating when there is a naturally occurring (variable) background level of radiation; and 3) it is important to know where and why we want to regulate.

Question 2: Can we, and how should we, align radionuclide and chemical regulation with respect to protection of the environment?

GROUP 1

There was some discussion of the question: what was it asking and why; what was the level of alignment - 'regulation', 'mechanism' or 'science' (etc.)?

Regulation of chemicals has a different history to that of radioactive substances, but it should also be noted that environmental protection regulations also have evolved differently in different contexts (e.g. marine pollution control compared with controls applied to hazardous installation). These different histories explain some of the

different features of existing regulations in the different fields but are not in themselves a fundamental barrier to alignment where appropriate. Moreover, there was thought to be much common ground, including a common aim 'to protect the environment'. Alignment at the level of very detailed aspects of regulation is probably not applicable although the principles are the same. It was noted that regulation could be sub-divided into three key processes, which include application of safety fundamentals (e.g. the need to protect the environment), the need to conduct monitoring in a representative way (i.e. to ensure environmental protection, as part of operational infrastructure), and the development and application of regulations and guidance (i.e. nationally, as well as internationally, such as through IAEA Safety Standards). One group member noted that such processes also need to be well defined with respect to 'closure of the loop', for example, to re-evaluate the monitoring frequency or the need to continue monitoring after remediation or mitigation has been successfully completed to address historical or legacy issues.

Benefits to alignment were felt (potentially) to be: improved protection, transparency, synergy (shared resources), learning (of approaches and benefit of experience). Conversely, some potentially negative aspects were also identified: weaken protection, increased cost, loss of relevance (e.g. due to over simplification).

There was some comment on the EU Water Framework Directive (WFD): whilst not listed in the WFD radionuclides are 'hovering in the depths' – if have to consider radionuclides within the WFD then may have to 'treat them as chemicals'.

GROUP 2

Perhaps this is not an easy task, for example because research and scientific knowledge can be dissimilar. There is also the problem of dealing with external dose for radiological protection but not for chemicals. However, it was recognised that although endpoints are not framed in the same way it may be possible to "align" so that some comparison can be made (i.e. to consider the principles of protection). It was also noted that it may be best to start with the exposure part of the assessment as components here may be easiest to align and it was also noted that with respect to new substances the first stage is to collate LD_{50} information: there may be no requirement to go further to produce reproduction relevant data in chemicals, this might not be the case for radioactive substances which are not 'new' chemicals.

The question of who could be involved in harmonising the process was asked. It was suggested that industrial associations, crop/pesticide, crop protection associations and regulators could be involved and that ideally some level of European involvement would be beneficial. However it was noted that the fact that the chemicals sector has not been particularly enthusiastic to be involved in PROTECT project may be related to "timing" i.e. they are busy with implementation of new approaches, e.g. REACH and this may be something that the PROTECT project might wish to ask the chemicals sector.

It was also noted that, currently, there may be different drivers for regulating radioactive and non-radioactive substances. However, areas of common ground (e.g. with regards to methods) needs to be explored. A number of examples of common ground were provided: e.g. release limits, BAT application, derivation and setting of limits.

So the answer to "can we harmonise regulation?" is - "Yes in principle but in practice there may be obstacles". With regard to "should we harmonise regulation?" - there was at least one view of a strong yes for the sake of harmonisation and the necessity to assess for a mixture of stressors.

The group then explored suggestions of what should be harmonised, the categories were identified for further investigation were:

- Principles of environmental protection
- Principles and (practical aspects of) regulation
- The need to consider alignment with human radiological protection for environmental protection from ionising radiation was also highlighted.

The various suggestions should be explored and the "best approach" selected as the way forward. This would involve a detailed consideration of the different fields and of how nuclear versus non-nuclear/chemicals is regulated.

ACTION – PROTECT Consortium to explore the above options and consider the best approach (risks, methods, approaches, benefits)

As a final point, communication issues between chemicals and radioactive substances need to be addressed.

GROUP 3

- Important to have the same level of risk as in chemical regulation.
- Public will not be happy not to regulate.
- Align chemicals and radioecological – Yes, can in terms of principles.
- We can align to have the same protection goals.
- The EC treaty: You shall protect the environment.
- Practical problems, different levels of protection in different countries, different constitutions within the same country. Practical problems but principles could still be aligned.
- Take into account that radionuclides also have chemical effects.
- Address environmental impact management as a whole from point of view of principles.
- Use of a dose level of 1 mSv/yr was felt to be adequate for both humans and non-human species.
- ICRP: Align assessment procedure for biota with procedures used for man. Is this compatible with aligning chemicals and radioactive substances?
- There will be problems in implementation of numeric values as indicators. For chemicals this is done.
- Do not call it a limit if it is not a limit.
- Maybe it is unwise to compare chemicals and radioactive substances.
- There is no straightforward way to align radionuclide and chemical regulation.

Question 3 What is the appropriate target for protection of the environment?

GROUP 1

The group did not reach any firm conclusions on this question. One problem in addressing the question was that there is not a single definition of 'protection of the environment'. It was felt that the target of protection may differ. For instance, you might be considering a protected species, a national park or an industrial area and hence the target guideline value for soils (for example as used in the Netherlands for chemical regulation) may vary considerably. It was noted that in order to evaluate the potential for risk, knowledge of the 'normal' range of conditions would be required.

There was some agreement that a target/goal should be long-term sustainability (i.e. prevent irreversible anthropogenic impact, ensure no systematic increases in environmental concentrations, is the practice sustainable in the long-term or will accumulation of contaminants prevent this). Some group members expressed the opinion that maintenance of 'pristine environments' could be a goal in some areas. One member suggested that this may however be unachievable. During this discussion, a distinction was made between aspirations (i.e. ideologies for environmental protection, that could include desires, such as maintenance of pristine environments, genetic diversity, etc.) and goals (i.e. concrete measurement endpoints, such as percent change in species abundance or change in population size, that provide an indication of environmental protection).

There was general agreement that the object of protection would always be biological (although this may be expressed via regulation of concentrations in abiotic media). A question as to whether, and if so how, to account for beneficial effects to humans (e.g. with respect to economics, sustainability, social and spiritual aspects) was raised.

GROUP 2

The list prepared in the background material to the meeting was referred to: population, habitat, structure and functioning of ecosystem, biodiversity etc.. The emphasis of the discussion was then more on what target we should be concerned with and why.

The first suggestion was that the ecosystem (structure and function) should be the target as this will encompass abiotic and biotic components, the good services (to humans and within the ecosystem), all components (and maximise the chance that all particular cases will be covered). In a practical sense, however, it was noted that it is appropriate to work from the individual upwards. It was agreed that both approaches were complimentary and necessary: top down and bottom up. It was however noted that the ecosystem concept required defining in more precise terms (boundaries).

Several questions arose – should we protect all ecosystems equally? Where do we focus resources? It was felt that regulation/legislation could be used to inform the prioritisation, with existing legislation provided an initial view of what should be protected. For example, on a European scale sites have been designated as important: Natura 2000 sites, site of community importance. However, EU member states have implemented their protection differently (although it is not clear why this has occurred). It was noted that there are other approaches to prioritising sites for assessment: for example where the highest risk to the environment is (near to emission point, dispersion zone etc.). All agreed though that we should be aiming for "realistic assessments".

Several specific points were made during the discussion:

- Population level endpoint – extrapolation (population models) could be used but the information obtained may be limited.
- Individual level endpoint – much information is available and most assessments are conducted for individuals.
- The importance for compatibility with human radiological protection was reiterated.
- Issues such as predator-prey relationships were deemed important – a top down approach might capture this, but not a bottom up, individual-based one may not.
- Ecological methods would require monitoring of ecological status – biological indicators, e.g. number of bird species or the use of ecological indices such as species richness, trophic network (shrinking trophic network = ecosystem malfunction). It was noted that this would help tell you if a site is subject to impact but not what is responsible, or how far off an acceptable limit your emissions are.
- The approach adopted in ERICA where reference organisms covering several trophic levels are selected was felt to inform the assessment approach.
- Other disciplines can be explored to see how the top down approach is implemented. It should be noted that this type of approach is not stressor specific nor can it necessarily identify a causative agent.
- Reviewing the content of the Water Framework Directive was again noted as it might provide a useful insight particularly for issues such as ecological status, use of weight of evidence etc. However, it was acknowledged that the top down process could be resource demanding and that teasing apart the components contributing to the overall detriment in the environment problematic. With regard to demonstrating compliance, it may be possible to learn from the Water Framework Directive ecological status indicators, which inform the selection of organisms to include (for aquatic). Other directives may also be helpful include: Soil thematic strategies; Pesticide strategy; HAIR (EC project).
- The bottom up approach could be used as a screen informing whether a more intensive ecological approach was necessary.
- The ICRP are taking the approach of using a (logarithmic) banded scale of consideration levels related to background radiation dose rates.
- There is a requirement to consider biomagnification in the foodchain.
- A concern was raised in relation to genotoxicity and mutagenicity: little is known about the importance of changes to the genome of the organism over protracted generations. This is a case where you may not necessarily protect the population if you protect the individual. A discussion about adaptive responses and genetic integrity ensued.
- The question was asked whether people preferred using dose-rates or concentrations. Because of communication problems (how to get from Bq to dose-rate etc.) a number of the group expressed a preference for activity concentrations.

GROUP 3

The often mentioned target to protect biodiversity or ecosystems is an understandable desire. However, there are problems in defining what is meant by this and how you show compliance. If ecosystem functioning is the protection goal, there are difficulties in finding the keystone species (now and in the future) and being confident that the right species are chosen. An argument against a goal of protecting the individual is that we do tolerate lethal effects to the individual in many everyday situations, e.g. we catch and eat fish.

An argument favouring a lower level protection than the population is that there might be genetic changes within the population although you can not see the effect when looking at population dynamics over a short time scale. An example given was that the population living downstream from a facility was genetically different from a population living upstream. This could have implications if the affected population has become more susceptible to other stressors that turn up in the future. Another argument for the individual level is that most data considering effects are on the individual level (and there is also a lack of chronic exposure data). There are then questions on how one should extrapolate effects on the individual to effects on the population.

In risk management one always balances the negative effects of the practice with the benefit. The vague expression of protection goals in legislation is one way to make possible these "cost/benefit" considerations. One example being "no unreasonable risk to the environment". This also implies that risk assessment should be kept separated from risk management with the result from the independent assessor is handed over to the decision maker who performs the risk management.

When considering protection goals you have to consider spatial and temporal scales of the situation to be assessed (including animal movements and migratory species).

Considering chemicals there is a system looking at the intrinsic properties of the substance. A substance that is found to have intrinsic properties of great concern (e.g. persistent, bioaccumulating, highly toxic) has to be dealt with (e.g. substitution of the substance, only permit the substance in certain processes etc.) regardless of the estimated exposure. This is due to great uncertainties in the exposure estimate. This means that the protection goal is not necessarily defined). In conclusion the group identified a need for different protection goals depending on the situation. It was a consensus that in general, the goal is to protect populations, but when it comes to species of special concern (keystone species and endangered species) the protection goal has to be the individual.

Question 4 How do we demonstrate compliance against the agreed protection goals?

GROUP 1

There was general agreement within the group that if there was sufficient scientific knowledge (some questioned if there was sufficient knowledge) to derive dose rates below which organisms would be protected, then compliance could be demonstrated by monitoring media activity concentrations (knowledge of both effects and transfer have to be sufficient for this).

It was felt that if such values were defined, then validation, review and refinement would be required as knowledge increased in the future.

One group member raised the concept of 'compensation' – i.e. if a habit was affected was it acceptable to improve a similar habitat elsewhere rather than seeking to restore the affected habitat?

GROUP 2

See previous question as Group 2 amalgamated their answers for this.

GROUP 3

Biomarkers were discussed, but the relevance of the effect noted in the biomarker to the vitality of the individual and to the population is often unclear. Another complicating factor is that other stressors may give the same symptoms.

There are two main ways of showing compliance. Either measuring radionuclide concentrations in different media to show that they are under an agreed screening value that correspond to what was thought to be safe when performing the risk assessment, or doing some type of biological surveillance to ensure that the most

likely effects that you want to avoid are avoided. The group was in favour of a tiered approach. If the risk assessment postulates a low risk facility, the monitoring might be kept to a minimum, whereas if the risk assessment gives rise to concern about the facilities possible effects on populations, a more comprehensive monitoring program, including biological surveillance, might be needed.

When one demonstrates compliance by measuring concentrations, there is a need to ensure that the measurements are representative.

Question 5. How justifiable are the current suggestions of benchmark values for use in radiological impact assessments of the environment – and how appropriate are the methods used to derive them and is this done better within chemical regulation?

GROUP 1

The group noted that all values proposed to date are 'trigger' (or screening) values, exceedance of which prompts further actions. It was agreed that these should be conservative to ensure the minimisation of false negatives. One group member expressed the opinion that there was not a requirement for both trigger values and standards (or legal limits).

The group considered the suggested values reviewed by JGL in her presentation. It was noted that values used in Canada are the lowest observed effect level for each organism group (with consideration of data quality and appropriate endpoint). The safety factor (SF) used was 1. Previously a larger SF had been used but the resultant values were thought to be too conservative. One group member commented that the use of SF=1 may be acceptable for larger datasets (e.g. as available for fish) but not for organisms for which few data are available as the resultant screening value may not be stringent enough.

With the exception of the proposed ERICA screening value, the other values considered by JGL were the same originating in IAEA, NCRP and UNSCEAR documents. These values were selected by expert judgement and the group did not consider their derivation to be transparent.

The use of SSD (as used to derive the ERICA screening value) was thought to have the advantages that it is more transparent, allows discussion, and pools available data. A potential disadvantage is that organism specific (e.g. if assessment is for reptiles) values are not predicted. It was also suggested that SSD can be used to inform cost benefit analyses. The accepted use of SSD within the setting of chemical standards values over a period of more than 30 years was considered to give an implicit 'peer review' of the methodology; adaptation by the radiological community also led to harmonisation between chemicals and radioactive substances.

It was unclear to the group why ERICA had selected to incorporate an SF of 5 within the derivation of their screening value by SSD. There was also some concern expressed that setting the level of protection to 5 % of species within SSD was not appropriate to the consideration of protected species. However, it was suggested that if the percentage was reduced then the statistical confidence in the resultant screening value would be poor.

No consensus was reached as to if the currently proposed values were suitably conservative.

GROUP 2

The Facilitator asked should we have benchmark values? The response from the group was that it was a good idea to have 'bands of constraint' but a limit needed to be set. This would be broadly similar to that used in the chemical industry.

There was some discussion on the use of SSD's derived from data combined across ecosystem types. The group felt it was better to use SSD's based on single endpoints or ecosystems where there was enough data to do so. The use of a combined SSD may be OK to define a screening (trigger) level but maybe not so good in a regulatory situation.

Points to consider

It was noted that there are not many other alternatives to the SSD available. Conventionally, the chemicals approach takes the results from the most sensitive species and endpoint determined and then add a level of

conservatism (safety factor). However it was noted that there could be a problem in that SSDs are generally defined for one species at one point in time. They are logical to use up to the population level but become more difficult at the community/ecosystem level due to the impact of other processes. The chemical industry use microcosms and trophic levels when defining a SSD. The question was asked about whether SSDs have really been used in anger. The fact that predation stress can also affect toxicity tolerance was noted.

There are web enabled probabilistic tools used for pesticide contamination available – these have been extrapolated from larger datasets to create a dose response slope. The use of statistical methods to cope with data gaps is acceptable but the first priority should be to fill the gaps with good quality data (data availability will improve with time). There is also a problem of level of understanding in the use of complicated statistics and the communication of them – the regulators find them difficult to explain so the stakeholders struggle to understand. There is a need for a simple guide.

PROTECT should identify any limitations (make it clear what are the knowns and the unknowns) of the benchmark values they define and provide 'hand-holding' guidance as the level of understanding differs dramatically.

GROUP 3

The group discussed the values presented in JGL's talk and the question was posed as to if the lowest numbers derived by SSD (with a safety factor) for generic ecosystems were better than those from literature reviews. However the available suggested benchmark values were thought to be derived for different purposes and hence not directly comparable. One group member felt that it was appropriate to have values within Tiers 1 and 2 of the ERICA-Tool which applied an SF of 5 (the maximum advised). However, too much should not be read into the value used and it was noted that conservatism does not necessarily equal precautionary. In addition, it is important to consider the conservatisms that are likely being incorporated during the assessment process with respect to the assumptions being made (for example, assuming maximum levels of exposure and full-time occupancy in the most contaminated areas, etc.). The USDoE values were recognised as trigger values prompting interventions. The source of the 'IAEA' values was discussed and was thought to be expert judgement. The group was unclear as to the interdependence of the values appearing in IAEA, UNSCEAR and NCRP. The FREDERICA database used to derive the ERICA value was quality-controlled and this gives some confidence. However, it was questioned as to whether all data considered by the Canadian review were in the FREDERICA database. The Former Soviet Union (FSU) data/numbers should be further explored. The advantage of SSD is that it is compatible with the chemicals approach and has been used for decades. However, 6 to10 data points are needed for SSD in chemical assessment so it is not used much because of a lack of data. The opinion of the group was not to use SSD exclusively and more should be known about the SF approach. It would be important to conduct SSD analyses at intervals to incorporate new data, possibly investigating the derivation of specific values for different organism groups. It was felt that SSD would get closer to meeting a population protection goal. Whilst it was felt that SSD derived values were more traceable, the methodology is difficult to understand and needs to be understood by regulators to gain wider acceptance.

The group did not like the term 'safety' factor (as it implies 'safe') and would prefer the term assessment factor (as sometimes used in chemical regulation). The group also wanted to know why SF approaches produce more stringent values than SSD.

The group recognised that the suggested values were for screening purposes however they felt there was a potential for the numbers to taken out of context and misused. It was suggested that the EA approach of having a low and then high value at different stages of the assessment may be difficult to communicate to the public.

It was also suggested that PROTECT should look at other approaches e.g. *de-minimis* criteria.

Also the workshop has focussed on 'environmental' but should there also be consideration (as in chemicals regulation) of substances (i.e. what can be used) and infrastructure.

The group felt that any benchmark values should be transparently and credibly derived, and robust.

It was suggested that the existing benchmark values should be re-evaluated.

Screening values may be generic or targeted depending upon the application.

Question 6: Should benchmark values include background exposure (i.e. be a 'total' exposure) or be in excess of background exposure?

GROUP 1

It was generally agreed that most screening values should be applied in excess of background exposure. However, this is dependent on the screening value in relation to the range of background dose rates (i.e. if a screening level is considerably in-excess of background dose rates it probably does not matter if it is applied to total rather than excess dose rate but if the screening value is close to background then it should be applied in excess).

Variability in natural background dose rates was discussed and the need to derive local values for an assessment generally agreed. There was also some discussion as to what 'background' was: (i) natural radioactivity or (ii) natural radioactivity + existing anthropogenic contamination. In some countries this may already be defined (e.g. Canada).

GROUP 2

The group thought there were two options:

- Added risk (analogous to human risk protection)
- Total exposure

In general they felt it was a good idea to have 'bands of constraints probably related to background or some other form of reference level' but there may be a need for a limit as a backstop to this approach – i.e. not possible to go above a set value e.g.:

Dose= 0----[----------]

Where:

[= an intervention level or trigger level

] = an upper Limit (set at X (but may vary by site))

It was also noted that it is possible to have different scenario for existing sites and planed sites e.g. :

Existing

Adapt according to scale/cost/objective (although there are some issues as to how to cost the environment). Could use natural background as a source of reference. Possibility of sub-population adaptation (could have a higher exposure limit) – although could use x % of natural variation.

Planned

There will be a baseline understanding of the site (including natural background measurements) available through the Environmental Impact Assessment. Could then identify species of concern and focus on added risk. Could set a discharge limit as this is easy to control.

General issues to consider

Background measurements in the chemical industry are generally much higher than those for radionuclides. In the chemical industry background can be dealt with in different ways: spatially - locally derived background (e.g. from an uncontaminated area within a larger contaminated site) or the use of national or regional measurements. Need to define what the 'added risk' to the environment is. In general there is a need to define all terms used. Must consider 'adapted communities' within contaminated sites (some areas are protected in themselves because of this adaptation).

There could be different ways of setting the Intervention level. Derive the protection goal first as there needs to be some flexibility. For example what if there was a situation where high temperature could cause mortality. Here you might have a situation where at 29° all individuals are OK but at 30° all killed. In this example, there is a clear threshold, then the total risk/exposure should be considered however if we accept that there is a linear-no-threshold type dose/response regime then it would be more appropriate to look at added risk.

Would the limit include background? – one group member thought not as if it was it would be a 'moving limit'.

Could have pollution zones (as used in the chemical industry) – have an upper limit (i.e. dose constraint) for an area and once this is reached nothing more is allowed. The Upper limit should never be set at the maximum, there needs to be a degree of precaution. Also, how would timescales be dealt with: an annual average or 1 in 20 year maximum?

There will be different approaches depending upon the situation and radionuclides may have some similarities to heavy metals so links here should be explored.

When do you set the point in time when the background is taken? There is the need to consider issues to do with natural radionuclide levels due to geology, mining waste etc.. Need to consider social issues: in general the stakeholders are concerned about how much of a pollutant is being discharged into the environment.

Ethical considerations are difficult to cost (size, scale, cost, 'does it matter').

There are currently issues with different countries doing different things – time will be required to standardise.

There was no discrepancy between the inclusion of background in 'effects' data and its use in deriving action/trigger values even though 'Effect' experiments are usually performed in areas with very low concentrations. Cannot do anything about natural background.

GROUP 3

The group considered that benchmark values should not include background dose rate because background levels vary considerably and can be comparatively high(relative to benchmark values).

As background levels will often be known this does not exclude anything from the assessment. It was felt that it may be necessary to consider background in detailed assessments (e.g. to provide a perspective with respect to estimated dose rates). However, it should be clear what is included and what is not.

This approach is consistent with that taken in human radiological protection.

Plenary Discussions

Session 1 'Legislation and Regulation'

George Brownless mentioned that there has been some work on carbon footprints commissioned by NEA. He will provide the references[1].

Simon Carroll – 'must recognise that regulating chemicals is one aspect of protecting the environment' and that the totality of "protecting the environment" was addressed by a combination of different, overlapping, regulations focussed on particular aspects of the issue (i.e. separate regulations concerning environmental media, installations and chemicals worked together to deliver an overall level of protection).

David Copplestone - 'will circulate minutes and notes from this workshop in draft format as this may influence how WP3 focuses on some of these issues'.

Paul Whitehouse - 'where do you consider the point of protection is in a release cycle: point of discharge, downstream? If you look too far upstream you constrain the limits you can set. PROTECT is correct in looking at environmental limits'.

David Copplestone - 'we need to work out how to get there'.

Session 2 'Protection goals'

Simon Carroll - Commented on the Group 1 summary by saying 'there is no one single definition for every single activity of protecting the environment. You need to provide the context i.e. "we are protecting the environment from…x by regulating y with the goal of z"

Stefan Mundigl - Following Group 1 summary 'This (demonstrating compliance with protection goals) looks like a full scientific research project.'

[1] See also - http://www.sd-commission.org.uk/publications/downloads/IsNuclearTheAnswerpdf

Nick Beresford answered – 'No the science is required to set the concentration guidelines and there needs to be review of any new science to re-evaluate'.

Tamara Yankovich added – 'That protection goals can change and should change with time. There is a lot of guidance based on this type of knowledge and we are adding to it.'

Simon Carroll – It depends upon who is demonstrating the compliance to whom – this may be differences for example in the way a regulator demonstrates that legislative obligations are being met and industry reporting on compliance with licensing requirements.

Deborah Oughton – It may help if PROTECT could provide clearer definitions of what is meant by protection "targets", "goals" and "aspirations". The terms can be interpreted differently by different people and in different contexts[2].

Session 3 'Standards'

Paul Whitehouse - Mentioned some work by Sheffield University and the Netherlands looking at differences in SSD results for temperate species compared to tropical specieswhich found little difference.

Jacqueline Garnier-Laplace - Noted that IRSN had done some work on this and also found little difference (see Garnier-Laplace J., Della-Vedova C., Gilbin R., Copplestone D., Ciffroy P. 2006. First Derivation of Predicted-No-Effect Values for Freshwater and Terrestrial Ecosystems Exposed to Radioactive Substances. *Environmental Science & Technology* **40**(20): 6498-6505).

Patsy Thompson - Cited the example of some work on uranium using laboratory rats which were not representative of species in the contaminated area. When the work was repeated using appropriate species, little difference was seen ('The benchmark change was negligible').

Simon Carroll - Suggested that PROTECT could look at the development of application of the *de-minimis* concept for application in the context of the London Convention, not as a replacement, but as some of the *David Copplestone* asked if there were any 'take home messages' for PROTECT.

Patsy Thompson - Said there was a tendency for the words 'environmental protection' to mean different things. PROTECT must define the term to avoid wrong expectations.

Simon Carroll - 'PROTECT must be clear on what it is seeking to do and what it can deliver. Essential to clearly state what you mean i.e. make it clear what it is you are addressing and what you are NOT addressing'.

Paul Whitehouse - 'Consider the type of standard and what action you take. We can afford to be more cautious if the consequences of failing the trigger are not too onerous'

George Brownless - Said he had thought the original intention was to set a numerical standard. But having been at the meeting has now heard discussions on the importance of using a tiered approach which he thinks is useful.

Francois Brechignac (representing ICRP) was invited to provide a brief overview of the ICRP's position on the environment. He stated that ICRP 91 (concept of reference animals and plants - RAPs) had led to ICRP Committee 5 to investigate developments consistent with the chemical industry. The ICRP are working towards providing an explicit ability to demonstrate how, and to what extent, non-human biota are protected (from radioactivity).

Brenda Howard closed the meeting by saying that she thought although we have had a variety of opinions we have a thread to take forward which will hopefully avoid major disagreements! PROTECT now has some clear take home messages and put things into context. She also stated that it was important to note that PROTECT was not a follow on from ERICA – the consortium will criticise the ERICA approach along with any others if appropriate.

[2] A glossary (to be added to as the project progresses) will be available on the PROTECT website by 31st May 2007

Take home messages for PROTECT

The following are, in the opinion of consortium members, important points arising from the workshop which PROTECT needs to try to address.

1) There is already regulation in place for the nuclear and non-nuclear sector and therefore there is a need to regulate them for the protection of the environment. However the question should be to what extent do we need to change the regulations in order to protect the environment?

2) Action on PROTECT to review the background to the ICRP statements, their derivation and history of change, along with details of the developments in environmental protection legislation which are driving the protection of the environment issue.

3) There should be recognition that there can be positive benefits of regulation in terms of demonstrating that the process being regulated is behaving in an appropriate and responsible manner but there is a need to ensure that any regulation to protect the environment is applied in a proportionate way.

4) PROTECT should work with industry on the issue of regulating for protection of the environment to obtain their input into the process up front and throughout any regulatory developments.

5) It is easy to say that we should align protection of the environment from chemicals and radioactive substances, however, it is not as easy to do this. Parts of the process should be straightforward to align (for example, the application of the technical approaches to effects analysis) but it is less clear how to do this with other parts. In particular 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 talking about chemicals or radioactive substances.

6) PROTECT should consider the role of optimisation in terms of environmental protection and how this should be incorporated into the process.

7) PROTECT should consider the use of standards/limits versus the use of trigger/screening values, which are what organisations/nations are tending to develop.

8) PROTECT needs to consider how to incorporate the different protection goals (e.g. at one end of the spectrum protected species through to ecosystem structure and function at the other) and provide guidance on appropriate levels of conservatism with regard to protection goals.

9) In terms of the endpoint measurement (i.e. dose rate or environmental media activity concentration) then provided you have confidence in the science underpinning the derivation of the endpoint measurement (i.e. effects and transfer data) you can generally use monitoring of environmental activity concentrations for compliance measurements. However there is a need to document the derivation in an open and transparent manner.

10) 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 (links to previous point on understanding the history of the protection of the environment issue).

11) 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.

12) Generally the discussion groups felt that there is no discrepancy between the inclusion of background in the derivation of the effects data that is used to derive the trigger/action values. This is for two reasons (a) because the effects data are often calculated as a percentage change compared with the control data (with both the experimental and control being exposed to similar levels of background) and (b) often the experimental exposures are considerably greater than the natural background dose rates (and experimental background dose rates minimised).

13) The use of methods such as SSD and SF 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.

14) 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.

15) Any derived benchmark should be considered in relation to the natural background range which should be treated as a source of reference. For example, if the benchmark value is well above the natural background range then there is no need to be concerned about natural background. However, if the benchmark falls within the range of natural background then this will need to be evaluated.

16) The inclusion of natural background within an assessment will depend upon the type of situation (existing or planned). For example, for planned practices these should include the natural background when establishing baselines and the risk from the releases of radioactivity be considered in terms of additive risk. However, from existing situations then the inclusion of natural background may be necessary especially if there no baseline exists for comparison.

17) Generally the discussion groups felt that any benchmarks should consider the additional contribution of anthropogenic releases (over natural background) although there was no consensus reached on what background is and whether this should include any previous anthropogenic releases.