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PROTECT

Protection of the Environment from Ionising Radiation in a Regulatory Context

(Contract Number:036425 (FI6R))

Deliverable 3

A review of approaches to protection of the environment from chemicals and ionising radiation: Requirements and recommendations for a common framework.

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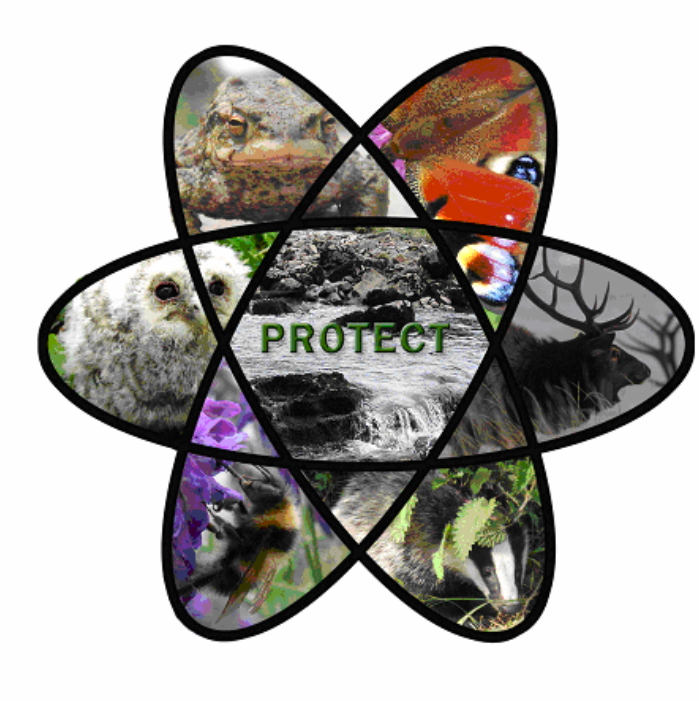
The EU EURATOM funded PROTECT project (FI6R-036425) will evaluate the different approaches to protection of the environment from ionising radiation and will compare these with the approaches used for non-radioactive contaminants. This will provide a scientific justification on which to propose numerical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

Executive Summary

The first stage of the PROTECT project has been dedicated to reviewing national and international regulatory methodologies and criteria currently applied to environmental protection from radioactive substances. This included assessing the regulatory instruments, procedures and underlying principles, and criteria currently applied in different countries. Environmental regulators, nuclear and non-nuclear industries, international organisations and NGO's were asked to identify the key regulatory instruments for assessment and give their views on how environmental regulation is applied.

The gathering of this information was completed through questionnaire (both verbal and electronic) and a workshop which included the participation of experts from outside he PROTECT consortium. Out of approximately 130 organisations contacted, questionnaires responses were received from 50. Regulators constituted 36% of the respondents, industry 36%, NGOs and international organisations 10% and advisory bodies, 18%. Although the questionnaires were primarily targeted at environmental regulators and representatives from industry within EU member states it was recognised that worldwide perspective would also be valuable and responses were also sought and obtained from, for example, Canada and Australia.

This review also assessed similarities and differences in approaches for chemicals and radioactive substances. It evaluated the extent to which the existing approaches fulfil the objectives of environmental protection by looking at what endpoints are being applied, what is acceptable in terms of permitted risks, what levels of compliance are required for chemicals and radioactive substances (and are there any differences) and are there common themes in the application of approaches for chemicals and radioactive substances.

The key recommendations that have come from the work so far are that:

- Protection should focus on the population level and that protection goals should be translated into measurable targets with advice provided on tolerable risks associated with these endpoints
- There is a strong advocacy for linking radiological protection to the processes used for chemicals assessment. Although there are some technical differences, the underlying protection goals are similar and broadly the same risk assessment approaches may be used. For example, the use of Species Sensitivity Distribution and Assessment Factor approaches to determine benchmark dose rates based on agreed tolerable risks should be encouraged and the use of purely expert judgement should be avoided where possible
- The use of the numeric values currently being applied, or suggested, should be assessed and the need for screening values and standards considered
- PROTECT should produce a clearly understandable document outlining the derivation of any numbers (for screening values and/or standards), in particular explanation of where there are limitations in the application because of poor data quality is needed. This document should be developed in consultation with stakeholders

Note: A draft of this deliverable was made widely available for comment prior to publication of this final version.

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Introduction

The need for a system to be able to demonstrate that the environment is adequately protected from the effects of radioactive substances has been recognised in light of new regulatory drivers for example, those associated with conservation. As a result, there has been a considerable international and national effort on this issue over the last decade with environmental protection now being referred to in the International Atomic Energy Agency's (IAEA) Fundamental Safety Principles and recommendations of the ICRP (IAEA, 2006; ICRP 2007). To date, the focus has been on collating relevant information and developing approaches to enable regulatory assessments. Alongside this, there has been extensive consultation with stakeholders. Validation and comparison of the radioecological and dosimetry components of various approaches has begun (Vives i Batlle *et al*. 2007, Beresford *et al*, in press; 2007). However, it is important that the approaches used are practicable, credible to stakeholders and appropriate to use in any future regulatory context. In particular, some groups are concerned about the regulatory impact of any further requirements.

PROTECT Co-ordinated action - overview

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

The specific objectives of the PROTECT project are to:

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

These aims are being achieved through three co-ordinated work packages (Figure 1). More general information on PROTECT and its work packages can be obtained from the project website www.ceh.ac.uk/protect. The website provides information on each work package and associated workshops. The website provides copies of workshop presentations, project deliverables and includes background information and links to external websites containing relevant information.

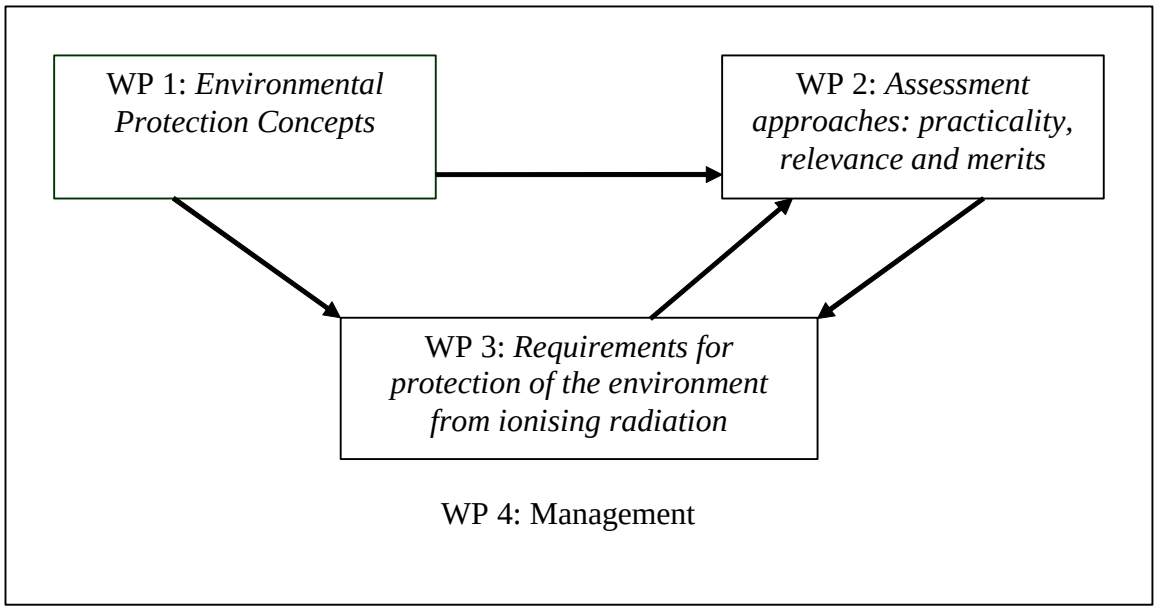

Figure 1. Work packages of the PROTECT CA

Objectives of this report

The objective of this report is to describe the outcomes of consultations with environmental regulators, nuclear and non-nuclear industries, non-governmental organisations and chemical industries, conducted by work package 1, to identify the:

- national and international regulatory instruments, procedures and underlying principles and the criteria currently applied in different countries to environmental protection
- industry views on how environmental regulation is applied, and comment on the costs and benefits of regulation
- similarities and differences in approaches for chemicals and radioactive substances

This information is for use within WP2 and WP3 of PROTECT. Some general aspects of the report will also be of use to standards setting bodies and authorities.

Methods of data collection

Several methods of data collection were used to maximise collation of information. These included one-to-one interviews, questionnaires (one aimed at industry and one aimed at regulators and their advisory groups), website searches and an open workshop. Responses were mainly elicited from environmental regulators and representatives from industry within EC countries. However, it was recognised that worldwide perspective was needed and responses were also sought from international organisations and regulators/industry in non-European countries (including those known to be actively considering protection of the environment from radiation such as Canada and the USA).

A workshop was held in Chester in 2007 to discuss issues highlighted in the questionnaire responses (received to that date) from regulators, advisory bodies, NGOs, international organisations and industry. The outcome of discussions at the workshop are used here to aid analyses of the questionnaire responses; a full record of the workshop can be found in Hingston *et al*. (2007).

This report presents the data collated as follows:

1. Brief description of the issue

2. Question put to consultees
3. Summary of responses, including level of consensus, key points and areas of disagreement
4. PROTECT response

Appendices give more detailed information from the questionnaires.

Review of approaches to protection of the environment

The results are discussed below in the same order as the questions were asked in the questionnaire (Appendix 1).

1. Nature of business/Regulatory role

Of approximately 130 questionnaires that were sent out, 50 responses were received (including the results of 1:1 interviews). Figure 2 shows the categories of organisations that completed the questionnaire; a roughly equal number of regulators and industry representatives responded. A full list of responders, their country and organisation type can be found in Appendix 2.

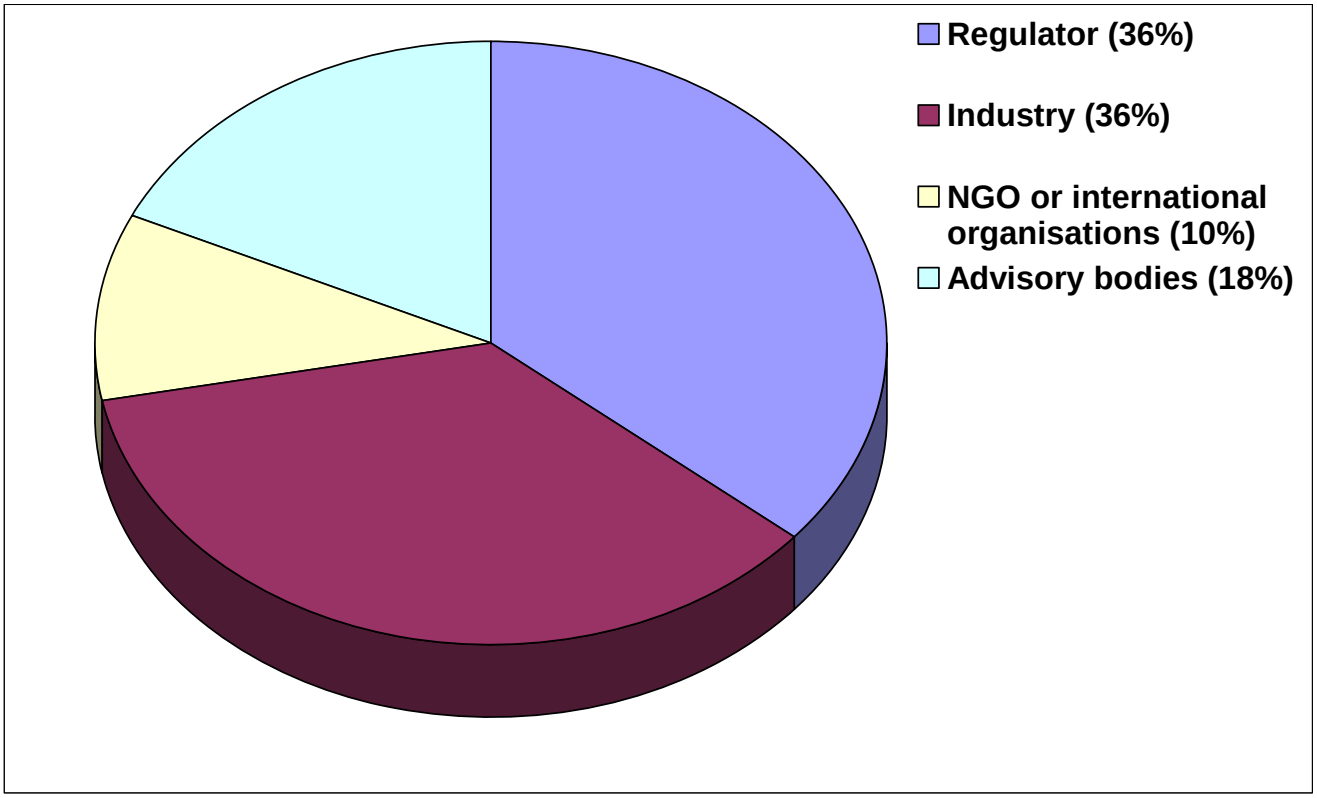

Figure 2. Nature of business as stated by questionnaire respondents (n=50)

Issue: To gain an understanding of which countries are regulating radioactive discharges with respect to protection of the environment.

Question: Does your organisation regulate to protect the environment from radioactive substances?

Replies: Of the 18 regulatory responses, 15 stated that their organisation regulates to protect the environment from radioactive substances (Figure 3). Further clarifications showed that most of the respondents did so on the basis of ICRP 60 which stated; *'The Commission believes that the standards of environmental control needed to protect man to the degree currently thought desirable*

will ensure that other species are not put at risk' whilst within respondents from the European Union, the United Kingdom, Finland and Sweden clearly indicated that they used additional approaches, which explicitly evaluated harm to non-human biota. Of respondents from countries outside of the EU there is current regulation specifically to protect the environment in Canada and the USA (N.B. the entry for the USA was compiled by the consortium from regulator websites and discussion with appropriate representatives).

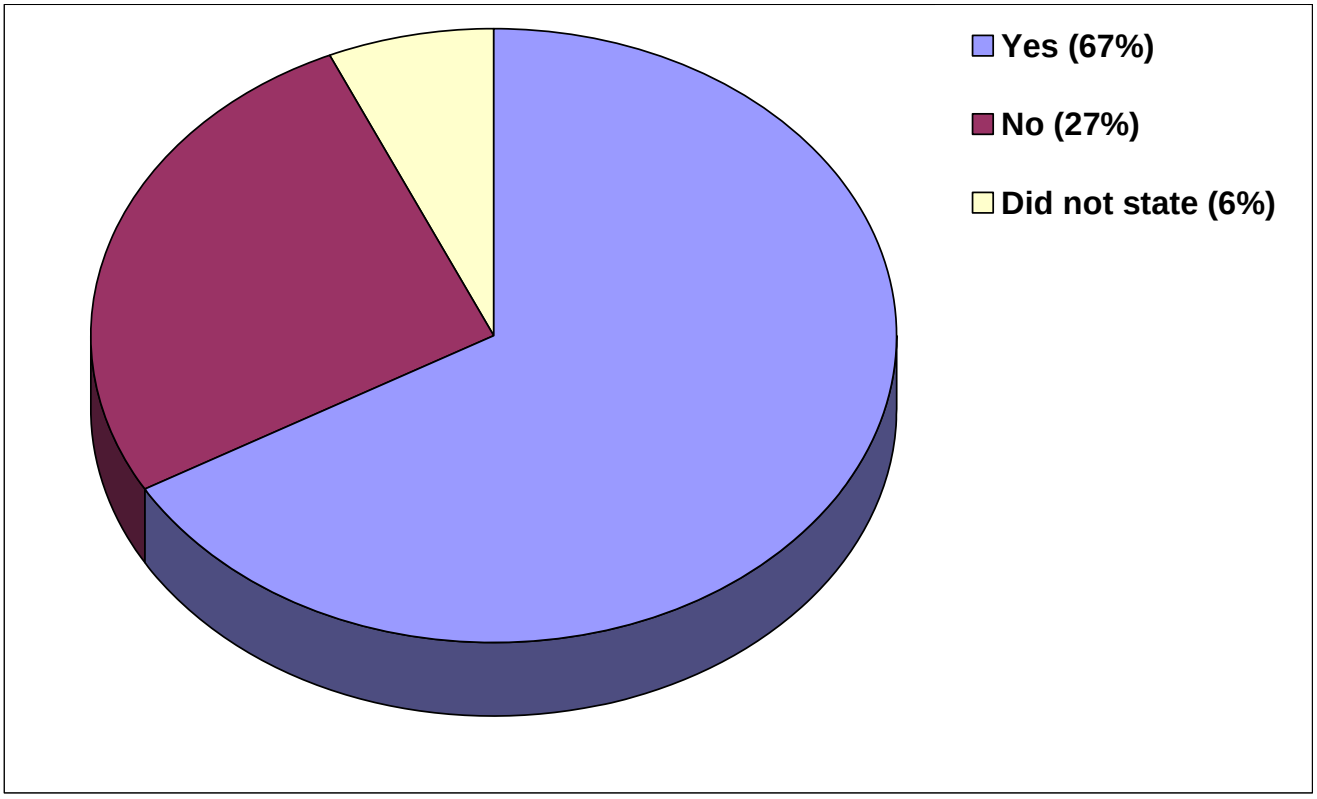

Figure 3. Are the regulators acting to protect the environment from radioactive substances? (n=18)

2. Regulatory Drivers

There are three issues highlighted under this heading:

a. Issue: To understand what drives the need for environmental protection.

Question: What determines why and how you regulate?

Replies: In nearly all circumstances, regulators quoted international and national legislation and guidance. Key documents identified by respondents and a record of their location can be found in Appendix 3. Only England & Wales and Scotland (two separate regulatory bodies within one EC member state) quoted EC legislation: Habitats (Council Directive 92/43/EEC) and Birds (Council Directive 79/409/EEC) Directives. For chemicals, key European legislation is covered in REACH and the WATER Framework Directive (WFD). Whilst the WFD makes passing reference to radionuclides as a possible pressure on water quality there is limited work being done in this area. Radionuclides are not covered by REACH.

PROTECT response: The reasons why only one EC member state interprets general EC environmental protection legislation (not specifically targeted at radioactivity) as requiring consideration of the impact of radioactive substances on the environment is unclear. Neither the current, or forthcoming, EC environmental protection legislation presently lists radioactive substances

specifically. However, the legislation may be more widely interpreted under the more general categories of pollutants such as 'other', 'hazardous' or 'mutagenic' substances. For example, whilst not intended to focus on radioactive substances, the Water Framework Directive could conceivably classify them as 'other pollutants', to be dealt with in 2015. Other potential drivers for changes in regulation of radioactive substances and the environment are considered in Section 9.

b. Issue: The role of optimisation within environmental radiological regulation.

Question: Although no question was specifically asked by PROTECT a lot of respondents commented on this when asked about the role of cost-benefit analysis in deriving numerical limits (Section 6).

Replies: Most respondents agreed that optimisation[1] is important when regulating discharging industries and that cost-benefit criteria were integral to this. Therefore, the optimisation principle As Low As Reasonable Achievable (ALARA) is often implemented in this process through studies of the Best Available Technology (BAT).. One respondent stated that in an extreme case where a significant risk to biota has been identified or predicted for releases of radionuclides (e.g. uranium at certain operating mines), costs are generally not taken into consideration and instead the licensee would simply be expected to meet the costs of what is necessary to achieve environmental protection. Nevertheless, any "necessary" mitigation does have to be defined in terms of "benefits" to environmental protection.

PROTECT Response: It should be noted that whilst ALARA remains an important part of the approach to assessing risks from radionuclides, in chemicals assessment greater emphasis is placed on risk mitigation e.g. reduction of emissions or even substitution of risky chemicals. Nevertheless, the use of thresholds based on environmental protection (as opposed to achievability) can provide a useful 'standard' to ensure that ALARA at least delivers – or exceeds – what is required for environmental protection.

c. Issue: Should technologically enhanced, naturally occurring, radioactive materials (TeNorm) be treated differently with respect to radiological protection?

Question: If you regulate radioactive substances are there/should there be a difference between TeNORM and artificially produced radioactive substances regulation?

Replies: For some countries, the regulators state that there are already established regulatory differences between TeNORM and artificially produced radioactive substances, with regulations being less stringent for TeNORM and that this is in agreement with the European Union Directives. As with all other substances, risk is interpreted relative to background risk and relative to the overall objective of pollution prevention. However, most European regulators did feel that these two categories should not be treated differently and that the protection of biota should be uniform regardless of industry type (e.g. uranium mining or fuel reprocessing).

PROTECT Response: On the basis of responses, the PROTECT CA will not treat TeNORM and anthropogenic radionuclides separately when considering protection goals and numeric benchmarks.

3. Environmental protection goals

Issue: Before methodologies for assessing risks to the environment from ionising radiations can be recommended, it needs to be clear what those assessments are intended to protect and what levels

[1] In this context optimisation can be considered to be that the likelihood of incurring exposures, the level and magnitude of exposure should all be kept as low as reasonably achievable, taking into account economic, societal and other environmental factors. Optimisation should be considered as a forward-looking, iterative process aimed at maximising the margin of benefit over harm and is not necessarily only directed at minimising radiological risk.

of protection they should deliver. The only truly safe level for any stressor is zero, but that is economically and practically implausible. Some level of 'tolerable risk' is therefore inevitable.

Question: What are your protection goals?

Replies: Protection goals are usually stated in the legislation of different countries and direct quotes relating to protection goals from this legislation can be found in Appendix 4a. Upon considering the questionnaire responses and discussion at the Chester workshop, it became apparent that the range of protection goals cited was quite broad. They were often aspirational and use unspecific terms such as to 'protect the environment', or to 'protect ecosystems'. The various protection goals mentioned by the respondents included 'nature', 'favourable conservation status', 'biological diversity', 'structure and function of habitat/ecosystem', 'protected species' and 'rare species'.

It seems to be generally accepted that the level of protection provided for humans must be greater than that for animals. For instance one respondent quoted: *'If 1 in a 1000 humans died this would be perceived as unacceptable but 1 in a 1000 sandpipers would not have a big impact.'* This raises an important point about population sustainability being the key goal, a feature that is implicit in much chemicals legislation. This implies an acceptance of some level of risk, at least to individuals. However, for rare species the protection of individuals might assume greater importance, especially for those species with low reproductive output.

Some responses reflected that the current system of radiological protection is based on the protection of man (ICRP 60, 1991).

PROTECT Response: The current system of radiological protection is based on the protection of man. This is because the international advisory body on such matters, the International Commission on Radiological Protection (ICRP), has historically focused on human health issues. Before going on to discuss this it is worthwhile to consider the previous ICRP statements concerning radiological protection of non-human biota (see Box 1).

Although many respondents relied on the ICRP 60 approach, several authors (e.g. Thompson 1988; Pentreath 1998, 1999; Oughton 2004) have criticised this approach and suggested that it has flaws. The ICRP statements are potentially invalid in certain situations, for example where pathways to man do not exist (e.g. sea disposal). Hence, there are cases where biota could be exposed to harmful doses whilst still maintaining doses to man well below the recommended dose limits (Pentreath1998). In addition, it has been argued that there are strong ethical grounds to provide explicitly for the protection of the environment and that, all other things being equal, there is no reason to treat ionising radiation differently to other environmental stressors (Oughton, 2003).

The ICRP has completed a revision of its Recommendations, which will be published as ICRP Publication 103 (ICRP 2007), in which explicit account on environmental issues is included. The ICRP will develop and clarify its position in this regard through its Committee 5, which started its activity in 2005 (building upon the concepts outlined in ICRP 2003). PROTECT will take account of the developments during the remainder of this project.

If the need for specific environmental protection is accepted, it becomes clear that technical guidance is needed to translate the rather aspirational environmental protection goals into more tangible measurement endpoints (i.e. properties or features that can be measured in empirical studies such as survival, or reproductive output). PROTECT needs to consider how to encompass the broad spectrum of protection goals and provide guidance on tolerable risks. The measurement endpoints that could be used in practice to meet the higher level protection goals can be grouped according to different levels of biological organisation, as illustrated in Table 1.

Table 1. Cited protection goals and associated measurement and assessment endpoints

Assessment Endpoint	Cited Protection Goals	Measurement endpoint*	Applied in
Communities	Nature Favourable conservation status Biological diversity Structure and function of habitat/ecosystem	Population interactions Biodiversity indices	Field studies
Population	Protected species Favourable conservation status	Mortality Reproduction	Field and/or laboratory[+] studies
Individual	Rare species Protected species Favourable conservation status	Mortality Morbidity Reproduction Mutation	Field and/or laboratory[+] studies

*Endpoints to measure may include those cited but are not limited to them.

[+]Whilst it could be argued that field studies are the only way to assess endpoints, these are likely to be difficult to conduct/interpret in practice and hence laboratory studies (such as mesocosms for population studies) may provide a more practical approach if required.

Participants at the workshop were keen that regulation of radioactive substances was as consistent as possible with that for chemicals. There appears to be no reason why protection goals cannot be the same. Therefore, to be consistent with chemical regulation, the focus of attention should be on the protection of populations of organisms rather than individuals except in the case of rare species where greater protection of individuals may be warranted (Hingston *et al*., 2007). This means that the endpoints used to set thresholds should be ones that relate stressor levels to measurement endpoints such as morbidity and reproduction because ecological theory tells us these traits determine population sustainability (Newman, 2001; Forbes *et al*., 2001).

Box 1: Historical overview of ICRP Recommendations

ICRP 26 (1977) recommendations

"Although the principal objective of radiation protection is the achievement and maintenance of appropriately safe conditions for activities involving human exposure, the level of safety required for the protection of all human individuals is thought likely to be adequate to protect other species, although not necessarily individual members of those species. The Commission therefore believes that if man is adequately protected then other living things are also likely to be sufficiently protected."

ICRP 60 (1991) recommendations

More recently a clarification (which does not alter the overall intent of the original statement) concerning protection at the level of non-human individuals has been added:
"… individual members of non-human species might be harmed but not to the extent of endangering whole species or creating imbalance between species."

A review begun by the IAEA, commented on the ICRP assertion as follows:
This assumption has been generally accepted and adopted by those involved with radiation protection standards, even though 'sufficient protection' has never been quantified nor the assumption proven.

The ICRP clearly regards the assumption to be qualified rather than absolute. It is a prevailing viewpoint (e.g. Auerbach, 1971 and National Academy of Sciences, 1972) but not seriously challenged except for a recent paper (Thompson, 1988) or formally defended. However, the assumption has been shown to be tenable at specific sites (IAEA, 1992).

The main objective of the Commission's recommendations is to provide an appropriate standard of protection for man without unduly limiting the beneficial practices giving rise to radiation exposure. That this involves value judgements and assumptions has been acknowledged:
"… the aim of providing an appropriate standard of protection, rather than the best possible standard regardless of costs and benefits, cannot be achieved on the basis of scientific concepts alone. Members of the Commission and its Committees have the responsibility for supplementing their scientific knowledge by value judgements about the relative importance of different kinds of risk and about the balancing of risks and benefits. The Commission believes that the basis for such judgements should be made clear, so that readers can understand how the decisions have been reached."(ICRP website).

4. Methodology for assessing risks

Issue: A number of freely available approaches estimating exposure to and risk from ionising radiation to wildlife have been developed (USDoE, 2002; Beresford *et al*., 2007b; Copplestone *et al.,* 2001). An objective of PROTECT is to investigate what tools or models are being used to assess risks to non-human biota, including the three examples referred to in the previous sentence. There may also be benefits from considering what can be learnt from approaches being used in chemical assessments.

Question: What are the tools/models being used?

Replies:

Methods & tools commonly used in radiological assessments

For exposure assessments to radionuclides, public domain models and approaches namely RESRAD-BIOTA (USDoE), ERICA (EU) and R&D 128 (England & Wales) (USDoE, 2002; Beresford *et al*., 2007b; Copplestone *et al*., 2001) were cited by a number of respondents including industry and advisory bodies. In some instances, combinations of these models are being used by some organisations. Some respondents mentioned in-house models (although a larger number have been identified by the IAEA Biota Working Group (Beresford *et al*. in press)). Comparisons of these models and approaches within PROTECT began at the June work package 2 workshop held in Vienna, a summary of which can be found at *www.ceh.ac.uk/protect* (Beresford *et al*., 2007a).

Methods & tools commonly used in chemical assessments

Due to the small number of chemical regulator questionnaire responses most of the following information regarding methodology has been obtained from consortium members whose organisations also have responsibility for chemical assessments.

There are two types of chemicals risk assessment, (a) those dealing with risks which may already have occurred (e.g. contaminated land) and (b) assessments of potential risks e.g. registration of substances, before they are placed on the market (Figure 4).

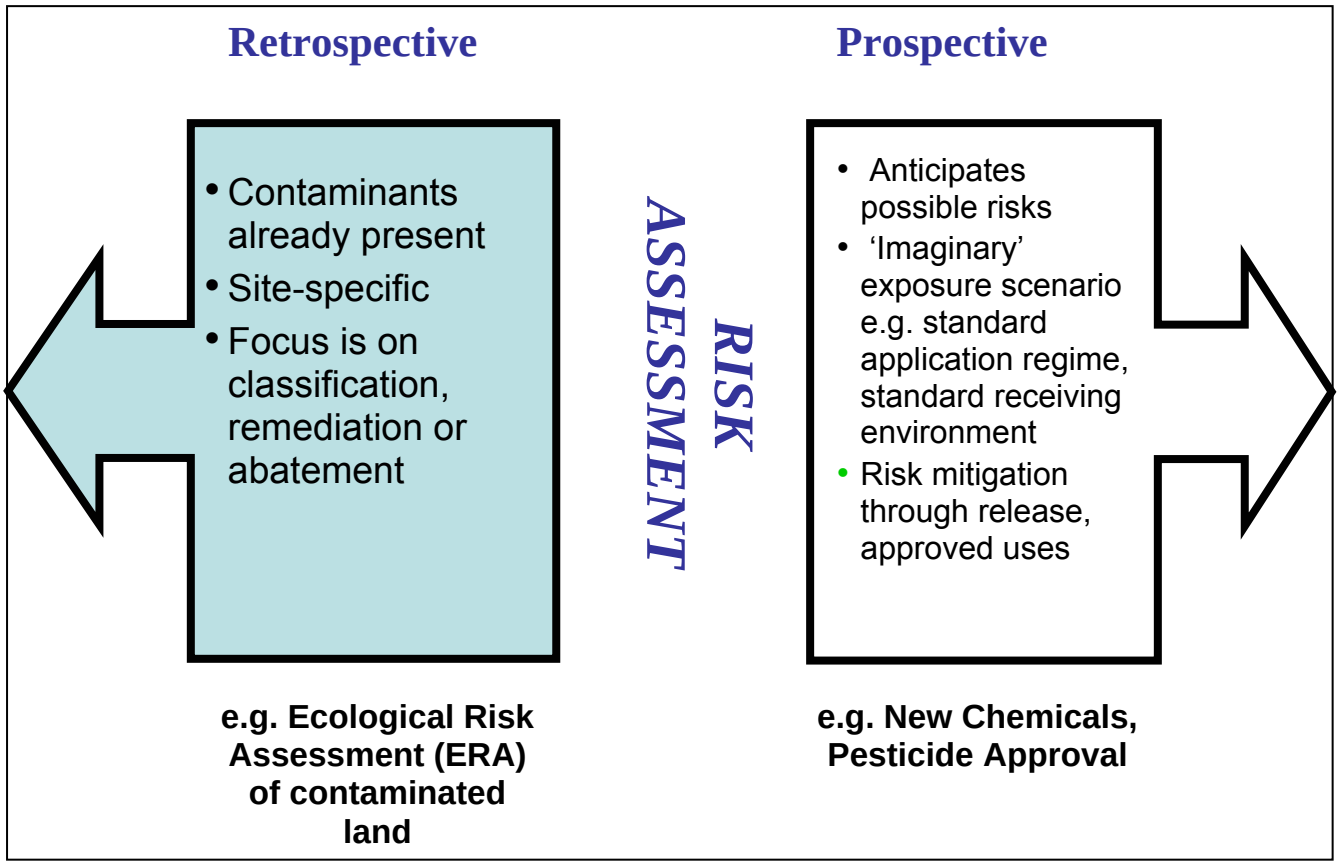

Figure 4. Chemical risk assessment approaches

Both these approaches follow a generic framework of Problem Formulation, Exposure Assessment (e.g., emission estimation tools, dispersion models and food-chain models), Effects Assessment (e.g., estimation of tolerable concentrations in the environment), Risk Characterisation and Risk Management. These steps are similar to those covered by the more developed radiological assessment tools (e.g., ERICA). However, this was intentional as practices in chemical assessment were considered in the development of these assessment tools.

An example of a prospective chemicals risk assessment is for new and existing industrial chemicals, plant protection products and biocides. The EU Technical Guidance Document (TGD) for risk assessment provides technical detail for undertaking risk assessments required for new substances (Directive 93/67), priority existing substances (Regulation 1488/94) and biocides (Directive 98/8) (European Chemicals Bureau, 2003). The TGD is supported by The European Union System for the Evaluation of Substances (EUSES) which comprises of computer-based models which predict environmental concentrations and effect concentrations based on available data (http://ecb.jrc.it/euses/). The models cover:

- emission estimates
- environmental distribution models for various environmental scales
- food chain modelling
- effects assessment

An example of a retrospective risk assessment is the Environmental Risk Assessment (ERA) for Contaminated Soils, an overview of which is shown in Figure 5.

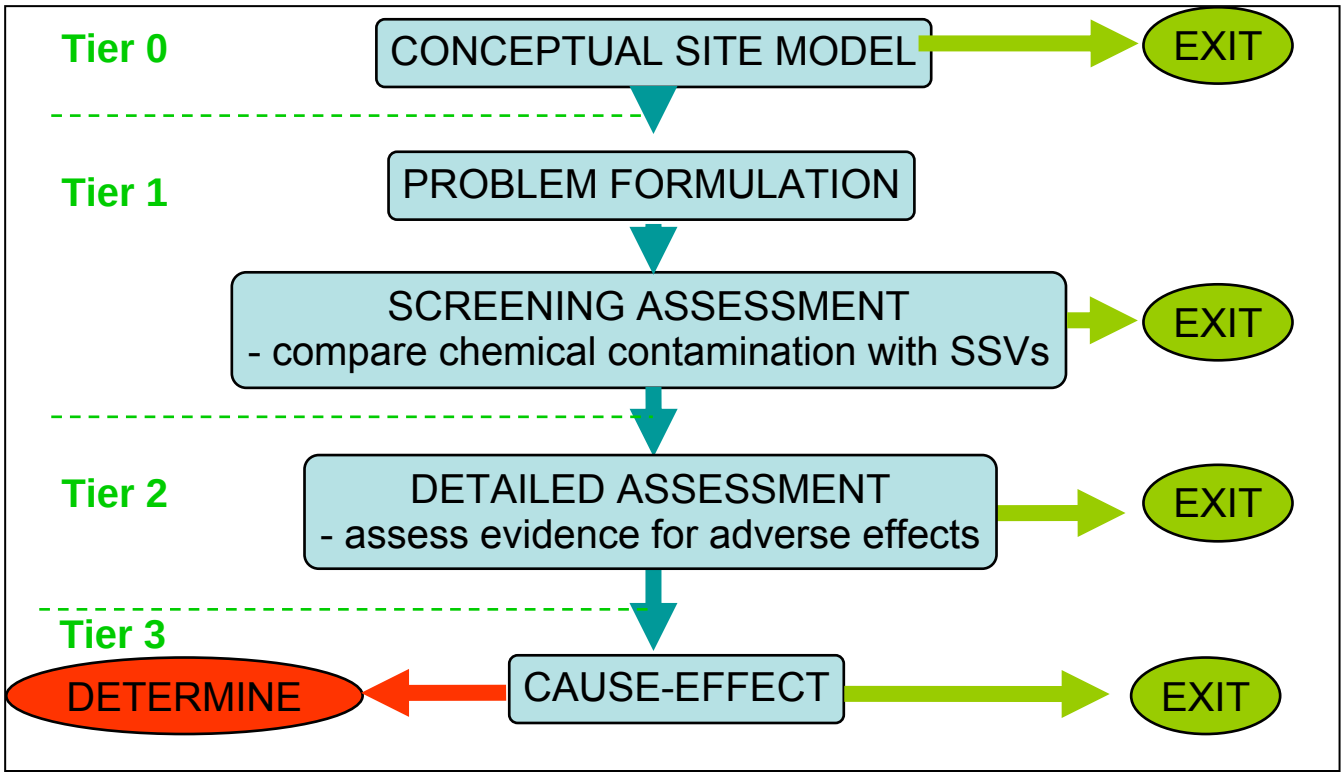

Figure 5. ERA Framework for contaminated soil overview

The ERA framework is a tiered approach with the aim of focusing on the sites most at risk. It can include the following stages:

- Development of a conceptual site model to determine whether there are any plausible links between sources, pathways and receptors (early exit if none present)
- Screening involving the comparison of environmental concentrations with available soil screening values (SSVs). SSVs are the equivalent to Predicted Effect Concentrations (PEC)/Predicted No Effect Concentrations (PNECs) and are effectively chemical thresholds. If concentrations are below the SSVs then the site is not considered further
- Detailed assessment (if concentrations are above the SSVs) which involves the use of a number of tools for example, a suite of biological methods such as ecological surveys, bioassays and models to predict biomagnification and tools to link impacts to causes under consideration

An important distinction between these two approaches is that the retrospective assessment is highly site-specific whereas prospective assessments deal with particular substances that may occur at many different locations. In the latter case the assessment focuses attention on the scenario judged to be most at risk. The chemicals ecological risk assessment and radiological risk assessment do have substantial similarities (for example, tiered approaches, consideration of exposure and effects). Further information on the similarities and differences between the two approaches is found in Table 2.

A summary of the methods and tools commonly used in chemical assessment has already been provided to WP2 via their workshop in Vienna to aid with the evaluation of assessment approaches and their practicality, relevance and merits (Beresford *et al*., 2007a).

Table 2. Similarities and differences between chemical and radiological risk assessments

Risk Assessment Stage	Similarities and Differences
Problem Formulation	Scoping and protection goals common to both approaches. *A priori* definition of ecosystems and reference organisms in radionuclide risk assessment
Exposure Assessment	Environmental transfer of contaminants is a common feature but attention to interactions between ambient environment and biological receptors different (chemical approaches consider factors that affect availability e.g. pH)
Dosimetry	Major differences: this is a significant feature of radionuclide risk assessment but not chemical assessments where the focus is just on ambient concentrations. Possible internal and external exposure from radionuclides but only internal residues are relevant to chemicals
Effects Assessment	Significant differences: assessment of chemicals is based on assessment of empirical ecotoxicological data relating concentrations to effects, whilst assessment of radionuclides uses data that relate effects to dose. Separate assessments are needed for each new chemical but radionuclide assessments need only consider a limited range of radiation types and qualities
Risk characterisation	Similar approaches for characterising risk are now being used for both chemicals and radioactive substances. For example, approaches for radiological protection of the environment have applied the SSD and assessment factor approaches to derive values to compare with predicted dose rates to determine the magnitude of any risks (Garnier-Laplace and Gilbin, 2006)

PROTECT Response: It is clear that the same basic risk assessment paradigm applies to both radiological and chemical assessment. Essentially, it involves comparing an estimate of exposure to some tolerable level or dose, If the actual or expected exposure is greater, then this might trigger some action, or at least prompt us to develop more accurate estimates. A key element within these risk assessment schemes is the need for thresholds that define acceptable levels of stressors which is considered in Section 5. At this stage PROTECT recommends that both the assessment factor and SSD approaches are taken forward for consideration, but an approach based entirely on expert judgement lacks the necessary auditability and transparency.

5. Development of numerical limits for environmental protection

Issue: There is no international agreement on numerical limits or how they are derived for radioactive substances in the environment. There is a need to assess what numeric values are being used (and how) in radiological environmental protection and if these are considered to be acceptable.

As well as being a key part of a risk assessment, numerical limits that define the interface between an acceptable stressor level and an unacceptable level can also be used as: triggers within a tiered risk assessment scheme; or as standards. They may also be referred to as criteria, thresholds or benchmarks.

Question: Do you use numerical limits?

Replies: As noted in Section 1 (Regulatory role), the majority of regulators involved in radiological protection indicated that they are protecting the environment through protecting humans. As a consequence most respondents cited 1mSv a^{-1} as the numeric limit although this is being applied to

humans and not specifically to wildlife. Numeric limits specifically for non-human biota were cited by four regulators (two of these regulators were non-EC). The values[2] of 5μGyh^{-1} and 40μGyh^{-1} were quoted by regulators from England & Wales and Scotland and have been agreed with the statutory consultee for conservation issues. These values are used as a screening value and action level respectively within the tiered approach that is used for habitats assessments (under the Habitats Directive). The screening value triggers the need for more detailed assessment, the action level requires the regulators to take steps to reduce the potential impact which may include taking regulatory action. Four regulators stated that they used, or were considering using, the screening dose rate of 10μGyh^{-1} proposed in the ERICA Integrated Assessment (Garnier LaPlace and Gilbin 2006).

In their graded approach the USDoE (2002) use a dose limit of 10 mGy d^{-1} (≈ 400 μGy h^{-1}) for native aquatic animals and benchmarks of 400 and 40 μGy h^{-1} for terrestrial plants and terrestrial animals, respectively, (based on the intent of appropriate DoE orders as no statutory dose limits were in place as of 2006). These are based upon the values of 40 μGy h^{-1} for terrestrial animals or 400 μGy h^{-1} for terrestrial plants and all aquatic species. from the IAEA (1992), NRCP (1991) and United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) (1996) reports. These are really benchmarks below which populations are unlikely to be significantly harmed based on reviews of the scientific literature. In Canada screening dose rates of 20 μGy h^{-1} have been proposed for fish, 220 μGy h^{-1} for terrestrial and freshwater invertebrates and 110 μ Gy h^{-1} for a number of other terrestrial and freshwater organism groups (Bird *et al*., 2003).

Question: How are your numerical limits derived?

Replies: There were few answers to this question. Consequently, the consortium has used its knowledge of how the values cited above have been derived in the subsequent text. Several options are possible:

a. One approach to deriving a numerical limit is to base it entirely on 'expert judgement'; this appears to be how the IAEA/UNSCEAR values discussed above were derived. A major criticism of this approach is that it is not auditable. Furthermore, the conclusions could change depending on the choice of experts and it can be difficult to demonstrate complete objectivity to the satisfaction of everybody.

b. Another potential method, currently being considered by the ICRP, is that of comparing dose rate predictions to that of natural background. The ICRP have termed this approach 'bands of consideration' originally outlined by the ICRP in its web consultation in 2005. For chemical assessments thresholds for naturally occurring substances, e.g. metals, may need to take account of natural backgrounds. If this is not done, spurious levels of risk may be indicated. The conventional approach for metals is to add the background into the assessment of risk (the so-called 'added risk' approach), ideally based on a local reference (unimpacted) site.

c. Environmental standards and 'Predicted No Effect Concentrations' (PNECs) for chemicals are typically based on lab data but with an extrapolation step. This extrapolation can be done in one of two ways as described in the Technical Guidance Document (TGD):

[2] The 5 μGy h^{-1} value now in use by the Environment Agency is not the same as the screening values recommended in the R&D128 publication. In R&D128 it was recommended that a screening value of 5% of the IAEA/UNSCEAR guideline values should be applied this equates to 2, 20 and 50 μGy h^{-1} for terrestrial, aquatic and deep ocean ecosystems respectively. However, in consultation with English Nature it was agreed that a single value of 5 μGy h^{-1} would be appropriate for the habitats assessments. The 40 μGy h^{-1} value was agreed with English Nature specifically for use in the habitats tier 3 assessment. Below 40 μGy h^{-1} it was agreed that it could be concluded that there is no adverse impact. Assessments above this value therefore might require regulatory action to reduce any potential impact.

1. A PNEC can be extrapolated by identifying the critical (i.e. most sensitive species/endpoint) data and apply a factor. Typically, an **Assessment Factor** between 1 and 1000 is used to translate critical effects or no-effects concentrations into a PNEC. A low Assessment Factor (10, or less) is applied where there is a higher degree of confidence, e.g. a large quantity of data from a range of taxonomic groups.
2. Statistical models can also be used that describe the number of species likely to be affected by any concentration of a substance. These models are called **Species Sensitivity Distribution (SSD)** models. Models, for instance log-log, log-normal, are fitted to the ranked toxicity data from which a concentration that will protect a high proportion of species can be extrapolated.

In the first approach, the size of the assessment factor (sometimes called an, extrapolation, uncertainty or safety factor) is strongly determined by the quantity of data available. When data are plentiful, the factor is relatively small (it could be as low as 1) but it can be large (up to 1000) when data are restricted to, for instance, a few short-term toxicity tests. In reality, even with an extensively studied stressor, e.g. for some metals, it is only possible to gather data on a relatively small proportion of the species and endpoints that might conceivably be exposed in the field. Uncertainty is therefore an unavoidable reality.

Because standards are set at a non-zero level, it is possible that some particularly sensitive species could unwittingly be placed at risk. The SSD approach recognises this because it predicts the concentration, or dose, that is required to protect a particular proportion of species, with a given level of confidence. Typically, the proportion of species afforded protection through an SSD approach is 95% of species. This meaning that 5% of species could be placed at risk if we were to set the standard at this level. We do not know the identity of those species or their ecological or commercial 'value' unless there are so many experimental data that some of the data points lie below the 5^{th} percentile. The estimated concentration corresponding to the 95^{th} percentile of protection is called the HC_5 (HDR_5 when considering dose rate) and may be used as the PNEC although some decision makers would normally apply a (small) Assessment Factor to the HC_5. The use of an AF applied to the HC_5 is intended to account for uncertainties not dealt with by the SSD, but it obviously adds a degree of further precaution. The size of the factor is typically much lower than that used in the deterministic (AF) approach but its use does introduce the possibility of introducing external factors that may not be entirely transparent. The relative merits and weaknesses of the AF and SSD approaches are summarised in Table 3.

Table 3. The relative merits and weaknesses of the AF and SSD approaches

	Merits	Weaknesses
AF	Process is simple and transparent	Uses only small part of available data
	Aims to protect all species	Can discourage generation of data
	Available data may permit no other approach	Provides no information on possible impact of a particular concentration or dose
	Permits expert judgement	Can be influenced by external factors e.g. political expediency, obscuring transparency
SSD	Uses all available data	'Data hungry'
	Uncertainty is quantified	Only deals with interspecies differences
	Resultant standard is less influenced by any particular dataset	Assumes that: • Fitted models are valid • 95^{th} percentile provides adequate

		protection • Toxicity tests data are random, independent trials
	Consequences of a particular environmental concentration can be predicted	

Such thresholds are rarely validated in the field but some studies have been undertaken, particularly with pesticides in artificial mesocosms. They indicate that standards derived using these approaches are generally protective (i.e. PNECs derived in this way < community NOECs) but we have to remember that any such validation study is only as effective as the endpoints we choose to (or can) measure, and our ability to discriminate a significant change.

SSDs as proposed in the TGD for chemical assessment, were first used as the basis for setting numerical limits for radionuclides within the ERICA assessment tool (Garnier-Laplace and Gilbin, 2006). More recently, an Australian group has used SSD to derive a dose rate intended to protect 95% of aquatic species of 13μGyh^{-1} (Ferris and Twining submitted). They noted that when only chronic exposure data is used a dose rate of 0.5μGyh^{-1} is estimated although this was influenced by one set of experimental data.

The values used in Canada are the lowest observed effect level for each organism group (with consideration of data quality and appropriate endpoint) (Bird *et al*, 2003). The assessment factor (AF) used was 1. Previously a larger AF had been used but the resultant values were thought to be too conservative (Hingston *et al*., 2007).

As part of the comparison between chemical and radiological approaches to environmental protection the ERICA SSD method was reviewed by a chemical assessor who is a regular user of the EU TGD approach. Comments by this assessor and responses to these by the PROTECT consortium are in Box 2.

Box 2. Review of the ERICA SSD Methodology – views of a chemical risk assessor

The ERICA approach is adapted from the 'normal' chemicals approach, where it is usually assumed that no significant adverse effects will occur below a certain concentration.

The ERICA SSD approach is applied to more situations than is usual for other chemicals. For example, chemicals SSDs are not derived for combined aquatic and terrestrial data sets. The TGD contains a list of 'recommended taxonomic groups' and minimum dataset requirements for an aquatic SSD. This is a compromise rather than hard science, but the general idea was to ensure that a reasonable range of organisms are covered given the limited number of laboratory test methods available. There is still no formal agreement on which taxonomic groups should be included for marine and terrestrial SSDs. Radiation experts will need to assess whether they are comfortable applying the same ideas to smaller datasets, given the limitations of the available data.

The assessment factor used with an HC_5 is also a compromise. The original proposal was to use the HC_5 directly as the PNEC, but this received limited support from EU countries. In fact, many are still uncomfortable using AFs below 5 even when chronic datasets are extensive (>20 separate species NOECs). Our preference is for chronic data since they provide more relevant information for chemical assessment purposes than acute mortality data. Essentially, the use of any AF is just a method of managing 'uncertainty', and this is context specific.

Comment from PROTECT: the data set used to build the SSD within the ERICA approach is composed only of data derived from dose-response relationships that were rebuilt from experiments on different non-human species described in the literature using mathematical techniques. The

datasets (e.g. terrestrial and aquatic) were combined to increase the power of the single SSD assessment only after they were tested individually and no significant difference was observed in radiosensitivity. This is possible because of the use of dose rates and not concentrations in different media. Furthermore, the suggested ERICA screening dose rate of 10μGyh^{-1} is based on chronic data only.

The ERICA tier 3 proposal goes beyond what is done for chemicals at the generic EU level. This seems to be a sensible refinement for specific sites or scenarios.

One point that has been made for metal risk assessments in general is that laboratory toxicity tests are usually conducted with soluble salts. The results might therefore be conservative compared to the field, due to, for example, limited bioavailability.

Comment from PROTECT: whilst bioavailability may be an issue in terms of transfer of radioactivity it is not important when setting numeric limits as these are based on dose.

PROTECT Response: There will never be sufficient data to be confident that the risks of a stressor to biota are fully understood. Most environmental standards are derived on the basis of extrapolation from a set of laboratory or field data. Typically, these are experiments that relate different levels of exposure to adverse effects (e.g. dose-response experiments). The extrapolation step is needed to account for everything that is not known, e.g. species might be exposed for which there are no data, the possibility that organisms may be at greater or lesser risk under field conditions, certain life stages might be more sensitive than those covered by laboratory tests.

Any future numeric limit should not be derived purely by 'expert judgement' as the resultant numbers are not auditable and hence will be difficult to explain and justify. The TGD describes methodologies to be used to derive numeric limits for chemicals in Europe. A number of groups have now used these to try to derive values for radiological environmental assessments and they appear to be suitable for this purpose. These approaches will be used within WP 3 of PROTECT. Box 3 discusses, in further depth, how potentially derived thresholds should be used.

Box 3. How should the thresholds be used?

A numerical limit (expressed as a critical concentration or dose rate) may be used in a variety of ways as part of a regulatory scheme. When deriving numerical limits there is a need to consider their intended use. Two contrasting approaches are when a numerical limit is set as (a) a legally binding condition (a standard) or (b) a trigger within a decision-making framework.

When a threshold is used as a legally binding one it may take on the role of a standard. Such standards include Air Quality Guidelines and EQSs for the protection of aquatic life under the Dangerous Substances Directive. These would typically apply in the ambient environment but are translated into emission limits on direct discharges (to air or water) to take account of local factors such as available dilution and dispersion. In this type of direct regulation, compliance must be demonstrated and this is usually done by sampling of the ambient environment, or where the standard has been used to set permit conditions, by sampling of the undiluted discharge.

The consequences of failing the standard can be serious, possibly resulting in legal action and/or an obligation to take steps to reduce emissions to a level where they will comply. It follows that there must be a high degree of confidence that a breach is likely to result in an unacceptable risk. With this in mind, it may be appropriate to set a legally binding standard at a level illustrated by Type B (Figure 6).

Thresholds may also be used as trigger values (sometimes referred to as screening values) where exceeding the standard in itself carries no serious consequences. It merely requires some further work to better understand the risks (either the likely effects of a stressor, or a better understanding of

the extent and level of exposure). However, such a trigger must sit within some sort of tiered assessment scheme. Without this context, this type of threshold would be meaningless. Such 'triggers' are widely used in IPPC assessments, for assessing the environmental risks of chemicals prior to marketing. Most values being used in radiological assessments of the environment appear to being used in this manner.

It is sensible for the trigger to be rather precautionary, more like Type A in Figure 6, to try to ensure a low incidence of false negatives. The associated risk of false positives is reasonable because failure to comply with the trigger only prompts a fairly modest response. Under circumstances where the cost of doing more work is actually quite high, or if there are too many false positives to be manageable, it may be prudent to adjust the trigger. Under those circumstances the level of precaution is effectively traded-off against these practical and economic considerations.

Another approach, used in chemical assessments is to use the same threshold in both cases but require a much greater burden of proof that the standard has been truly exceeded when it is used as part of a regulatory scheme and where failure is more significant. Conversely the same 'value' could be applied in a screening mode with the requirement for a much lower burden of proof in order to trigger some action. This has the advantage that there is only one threshold but the methods used to judge compliance would differ.

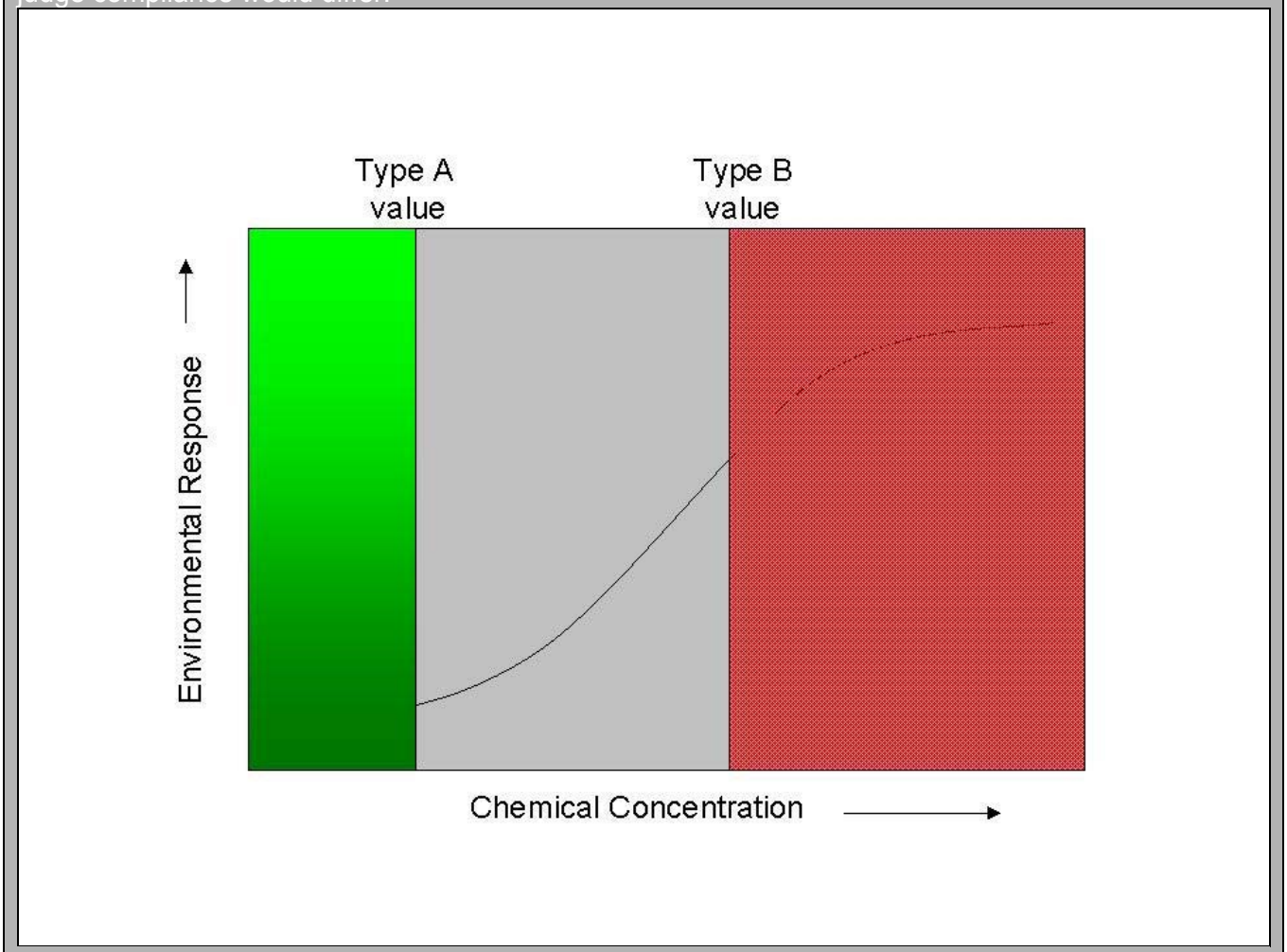

Figure 6. An illustration of screening levels (Type A value) and standards (Type B value).

Question: Do you think the criteria you work to are suitably conservative?

Replies: Of the regulators 72% (including those citing ICRP 60) said that the criteria they work to is suitably conservative (Figure 7). However, the responses again highlight the different approaches being used as discussed above. The industry response was similar with 67% saying that the criteria they work to are suitably conservative' (22% said they did not have criteria to follow; 6% said it was too conservative (N.B. 6% = 1 respondent).

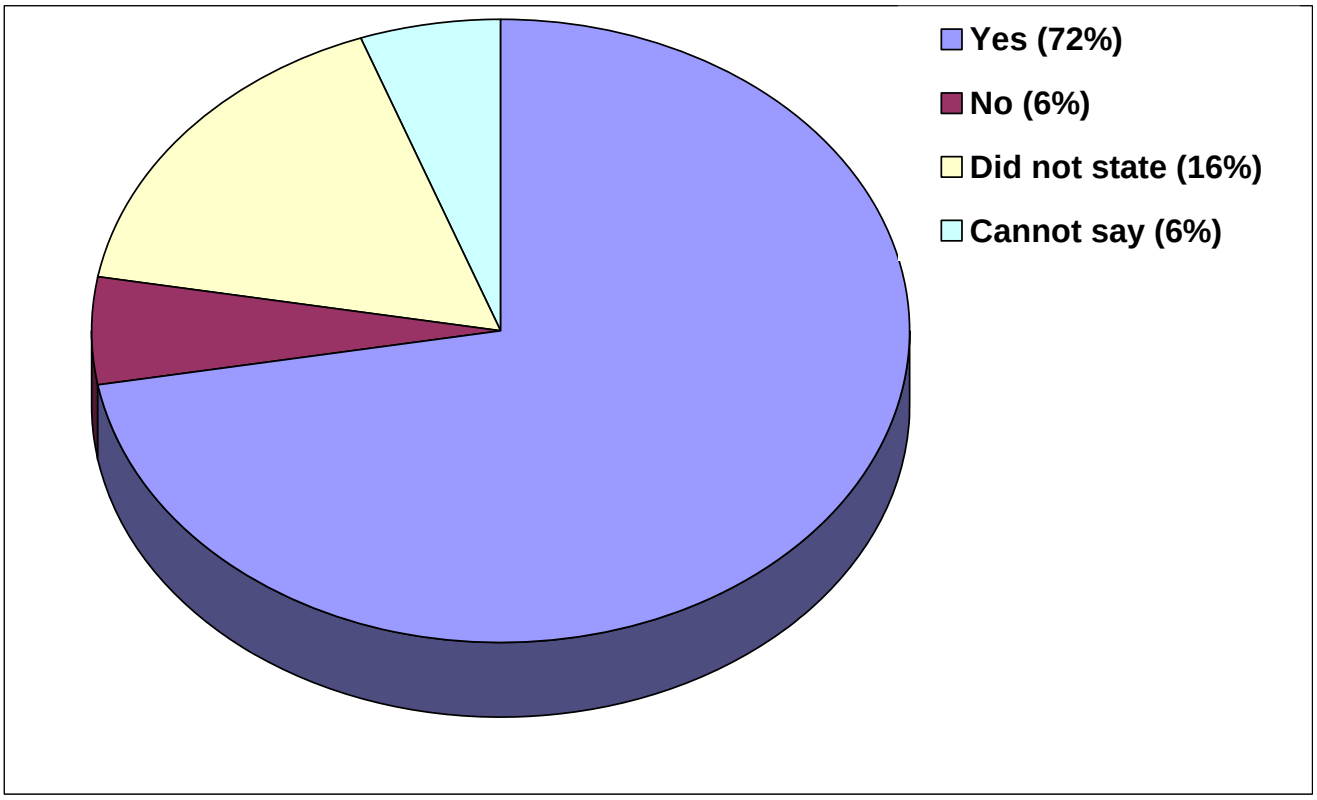

Figure 7. Do regulators think that the criteria worked to is suitably conservative? (n=18)

Question: Would you review your criteria in light of new work?

Replies: Most regulators respondents agreed they would review criteria in light of new work (Figure 8). Industry responses indicated that research, if undertaken, is not to challenge but to supplement existing data and fill in gaps to help progress the knowledge that regulators have (Figure 9) and may therefore influence a review of criteria.

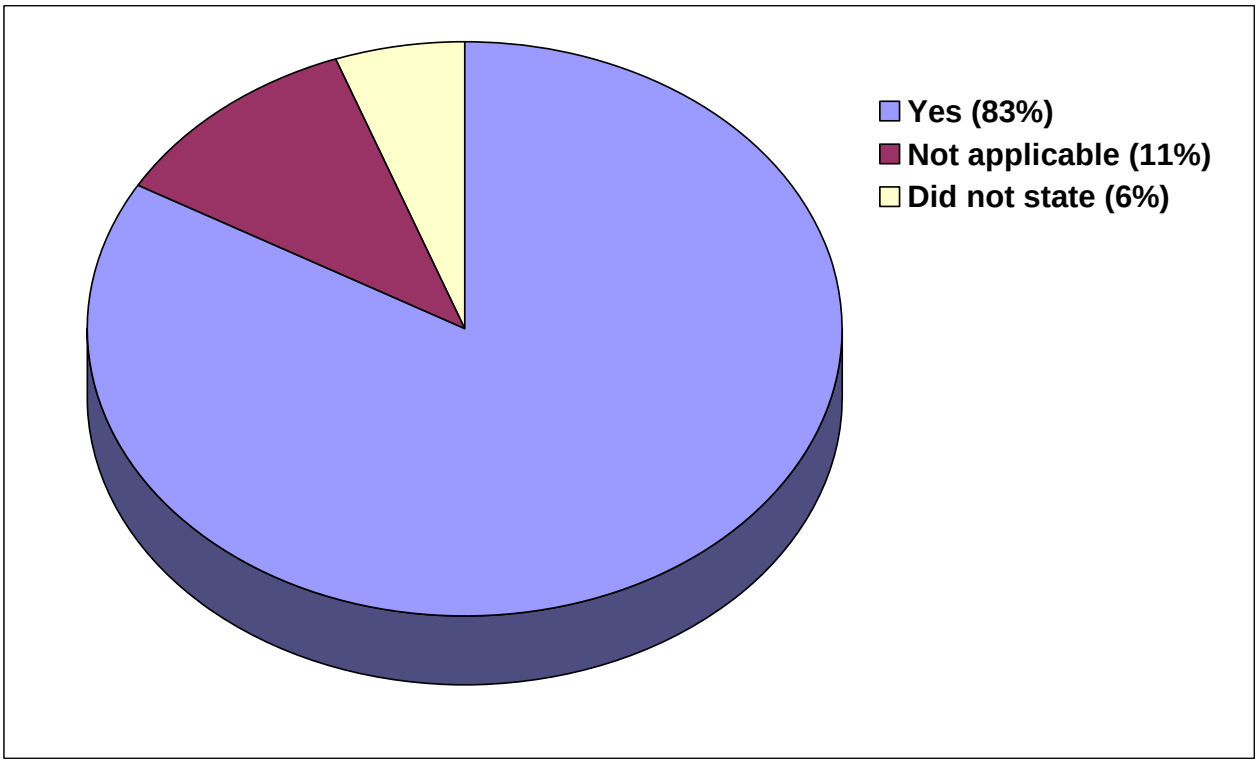

Figure 8. Would regulators be willing to review criteria in light of new work (regulatory response only)? (n=18)

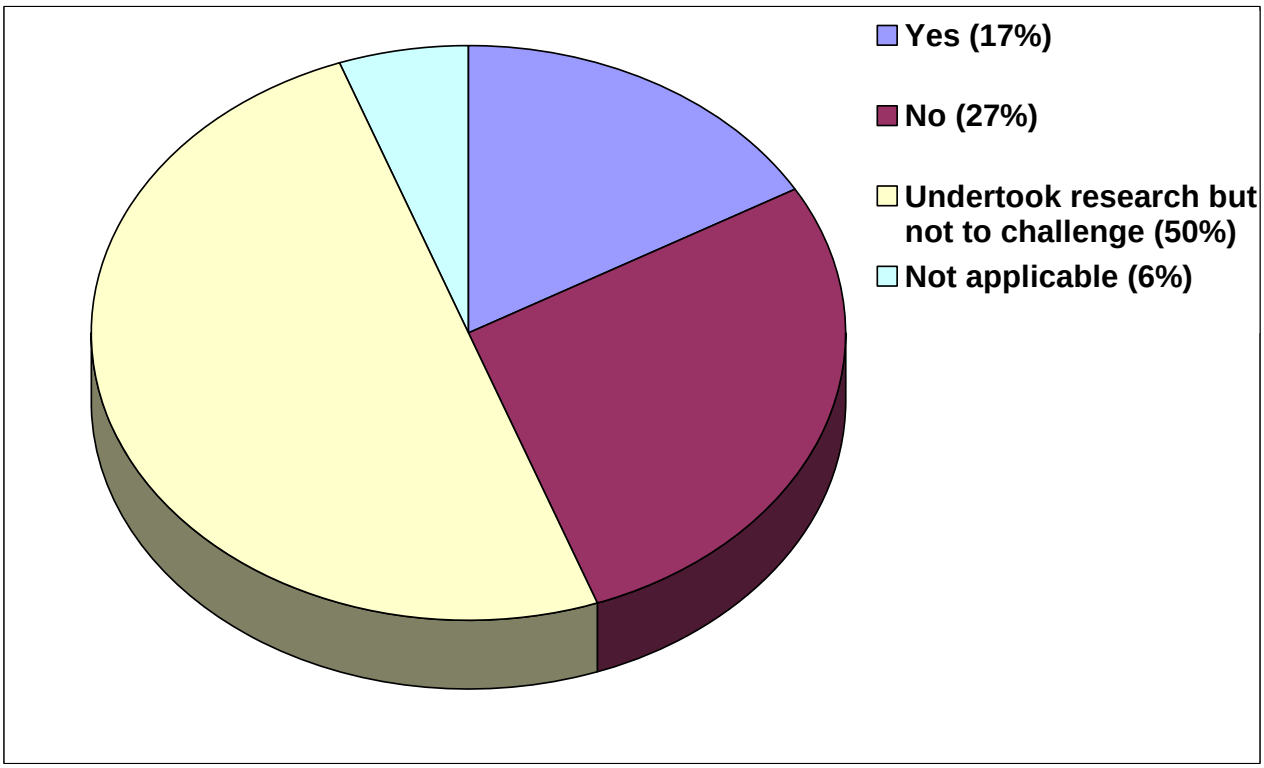

Figure 9. Does industry undertake research related to standards in order to challenge the regulators? (n=18)

Question: Have, or should, stakeholders be involved in criteria setting?

Replies: The majority of regulators agreed though 'involvement' can have many different meanings ranging from simply the opportunity to be heard through meaningful engagement to actual decision-making. For example, from '*Stakeholders have been involved to a limited extent…through a consultation process once the numeric values have been derived*' to '*Stakeholders are now consulted and have had an influence on the adoption of some important criteria*'. A number of respondents indicated that greater involvement with stakeholders would be beneficial although, the term stakeholder was defined differently by some of the regulators. For example, *'as long as stakeholders are part of the scientific community of radiation protection.'*

PROTECT Response: PROTECT will ensure that it engages adequately with radiation protection specialists and (radio)ecologists (drawn from industry, international organisations, NGOs, regulators etc.) over the derivation of any numeric values for consideration and recommend that stakeholder engagement is part of any assessment that may be undertaken within a regulatory process. This is consistent with the Åarhus Convention which requires public participation in preparation of regulations that may have significant effect (Åarhus Convention, 1998).

Question: Is/should cost-benefit be taken into account in deriving criteria?

Replies: As stated in Section 2, when asked this question most respondents referred to cost-benefit of regulation and not criteria setting. However, the following reply may provide an insight into why the question elicited those type of responses: '*Optimisation is one of the most important principles when implementing radiation protection and it implies also some kind of cost-benefit assessment… It is not obvious, however, how optimisation is done when deriving criteria.'*

Of the responses that specifically concerned standards setting, it was thought that any criteria would need to be set in relation to other activities and goals, for example, other releases and other hazards to the environment from accepted practices such as hunting and pest control.

In chemical approaches, cost-benefit is not considered in deriving PNECs. Currently the EU approach to Existing Substances Regulation (ESR) process) comprises two parts: a risk assessment based on consideration of the available data and then a risk management exercise where the risks are minimised. The latter stage is where cost/benefit issues are considered rather than within the actual risk assessment i.e. at the end of the process prior to proposed implementation. Costs and benefits in setting standards have been discussed recently at a SETAC workshop on chemical standards (http://www.setaceumeeting.org/qualitystandards/). An options appraisal approach such as Multiple Criteria Decision Analysis (MCDA) might be helpful, especially for highly contentious proposals because the process encourages a high degree of stakeholder involvement and consensus building.

PROTECT Response: Cost-benefit analysis should be part of the process of deriving criteria and WP2 should consider assessing the potential costs associated with implementing different numerical standards.

6. Compliance

Issue: If environmental risk assessments for radioactive substances are being conducted how are regulators/industry demonstrating whether or not the environment is subject to unacceptable risk?

Question: How do you ensure and demonstrate compliance?

Replies: Both regulators and industry responded to this section by listing activities (see Appendix 4c). The methods used to demonstrate compliance (cited for both chemical and radiological assessments) were predominately monitoring: (i) concentrations of contaminants and comparing these with those specified in standards; and (ii) biological or ecological condition of the environment on the assumption that good biological status implies any contaminants must not be exceeding unacceptable levels.

Some responses listed a combination of both concentration and biological approaches (under the Water Framework Directive, for example, a combination is a requirement).

The three international organisations responding to how compliance should be demonstrated all stated there was a need for a firm definition of 'protection of the environment' from radioactive substances. For instance, one of the international organisations expressed the opinion that *'This [question] rather pre-judges the goal of environmental protection. Certainly, for example, sustainable development does not mean 'no risk/harm to the environment'. Moreover, not convinced that there is a firm idea of what 'protecting the environment' means, which makes life difficult since it begs the question 'comply with what?'*

PROTECT Response: The responses of regulators and industry cited common and logical approaches to demonstrating compliance. These approaches should be adaptable to most protection goals and new standards if adopted.

7. Flexibility

Issue: To understand how much flexibility there is in different countries regulatory processes.

Question: How much flexibility do you have in setting criteria and implementing the regulatory process?

Replies: The regulatory processes, on the whole, could be changed but they must be carried out within a countries' laws and regulations (and, within Europe, always within EU regulations). All the replies to this question can be found in Appendix 5.

8. Do current regulatory processes work?

Issue: To identify areas where regulators and industry think there should be improvements to regulatory processes. Also need to learn what works well so that it is retained.

Question: What works well and what could be improved?

Replies: It was apparent from the questionnaires, that industry want communication lines with regulators to remain strong or be stronger than they are now. Transparency was also key in knowing how criteria are derived.

In terms of how things could be improved, more guidance could be provided on ecological assessments and how population and biodiversity level effects should be assessed/evaluated.

PROTECT Response: PROTECT needs to be transparent in all recommendations arising from this work and anything PROTECT promotes. Any derived standards should be auditable and where possible, any identified protection goals should be measurable (see Sections 3 and 5).

9. Future regulation

Issue: To gain an understanding of how regulators and industry perceive changes to regulation of environmental protection in the future. In particular any national changes which PROTECT may be unaware of.

Question: What future changes do you see to environmental protection legislation?

Replies: Most regulatory responses for radiological environmental protection explained that any changes would be through international recommendations and guidance from the ICRP and the IAEA (Table 4 - see Appendix 7 for more detail). No changes at the national level were highlighted which would not be initiated by international developments.

Table 4. Foreseen routes of future regulatory changes

Source of future regulatory change	Number of regulators who cited source
ICRP	5
IAEA	6
EU	5
WFD	2
REACH (Chemicals)	4
Other (penalties for non compliance)	1
None foreseen	1

All of the questionnaire responses relating to chemical regulation stated that they were awaiting the imminent implementation and outcome of the Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH) regulations which came into force on 1 June 2007. REACH will broadly follow the same process as the current approach to chemical regulation. However the suppliers will do more of the assessment than the regulators and will also have more of a say in the risk management options. The detailed guidance for REACH is currently being developed. It is therefore too soon to comment on the likely changes and their implications.

Industry responses gave 'topics' that they thought would influence future regulation, for example, carbon emissions and climate change. For the majority of the industry responses it was not clear whether they thought these topics would or should influence legislation. However, one respondent did state that: '*Climate change is likely to lead to more legislation/trading of carbon credits. This is true environmental protection and regulators should be looking at this. The nuclear industry may have a part to play in 'solving' the climate crisis*.' and as a result this led to the issue of whether 'there was more to worry about than radiation' being discussed at the Chester workshop (Hingston *et al*., 2007).

PROTECT Response: The consensus at the Chester workshop was that there should be recognition of the positive benefits of regulation in terms of demonstrating that the process being regulated is behaving in an appropriate and responsible manner (which might promote the nuclear industry in a positive way within the energy debate) but there is a need to ensure that any regulation to protect the environment is applied in a proportionate way. This consensus was reiterated through the industrial questionnaires.

10. Radioactive substances versus chemicals regulation

Issue: Historically, there has been a different philosophy for regulation of radioactive substances and chemicals. Regulation of radioactive substances has been focused on the protection of man with the environment as a secondary consideration whereas for the regulation of chemicals. Therefore it is important for developing radiological environmental protection to learn from the evolution of chemical practices, bearing in mind any broader environmental protection objectives and to negate any confusion that may currently exist between chemical and radiological environmental protection.

Question: What are the similarities and differences between chemical and radioactive substance regulation in environmental protection endpoints and criteria setting and extrapolation? Can either regulatory process learn from the other?

Replies: Much of this has been documented and discussed above.

When asked the above question directly many regulators said they did not feel qualified to comment even if they worked in an organisation that regulated for both chemicals and radiation. However, one key observation was put forward:

Radioactive substance regulation with respect to environmental protection is not currently defined by international or European legislation. In contrast, chemical regulation is usually harmonised though the application of internationally accepted standards. A similar approach for radioactive substances could be seen as beneficial as harmonised regulations across Europe could facilitate the centralisation of knowledge and effective planning.

Seventy percent of industry responded on the subject of radioactive substances versus chemical regulation and they highlighted the following desires:

- Similar level of protection for both radiological and chemical contaminants through common assessment endpoints where possible
- Common measurement endpoints, for example, that could be normalized to risk – e.g. contaminant concentrations in environmental media
- Practical ways to account for differences in terms of how criteria for chemicals or radioactive substances are set. For example, criteria for radioactive substances are consolidated or summed to include all radionuclides and exposure pathways, whereas in most cases, criteria for non-radiological contaminants are based on single contaminants and exposure pathways

PROTECT response: It is recognised that total harmonisation of chemical and radiological environmental protection approaches may be desirable and ideal for addressing appropriate risks, but in practice this may be difficult to achieve. However, even though there are very different approaches for environmental protection for radioactive substances and non-radiological contaminants, it could be that complete harmonization between the two is not necessary.

Recommendations/Conclusions

WP1 makes the following recommendations for either work package 2 (WP2), work package 3 (WP3) or generally (G):

Regulation (Section 2)

- PROTECT should not treat TeNORM differently to other radioactive substances (**WP3**)
- The positive benefits of regulation for the nuclear and non-nuclear sectors are being able to demonstrate that they are behaving in an appropriate and responsible manner. Emphasising and highlighting this could be beneficial in terms of large scale environmental issues such as climate change (**G**)
- Optimisation of discharges should remain central to environmental/human radiological protection (**G**)
- PROTECT recommends the harmonisation of future international guidelines and recommendations (for example, IAEA Basic Safety Standards, EU-Directives, ICRP revised Recommendations) (**G**)

Protection goals (Section 3)

- 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 (**WP3**)
- The protection goals should be translated into measurable targets (e.g. Table 1) and advice provided on tolerable risks associated with these endpoints **(WP3)**
- It is clear from the responses we have received that there is a strong advocacy for linking radiological protection to the processes used for chemicals assessment. Although there are some technical differences, the underlying protection goals are identical and broadly the same risk assessment paradigms may be used (**WP3**)
- PROTECT should try to work together with the IAEA and the ICRP (**G**)

Methods for assessing risk (Section 4)

- PROTECT should consider the following **approaches to assessing radiological risks to biota** (**WP2**)
    - R&D 128
    - ERICA
    - RESRAD
    - Other approaches as identified within the IAEA EMRAS programme (http://www-ns.iaea.org/projects/emras/)
    - If within the timescale of the project an ICRP approach becomes available this should be considered

Risk characterisation (Section 5)

Methods of determining benchmark values in environmental radiological protection

- PROTECT should consider (**WP3**)
    - Literature values (expert judgement)
    - Assessment Factor approach
    - Species Sensitivity Distribution approach
    - Using background levels to determine bands of consideration (subject to potential ICRP recommendation)
- PROTECT encourages the use of SSD and AF approaches to determine benchmark dose rates based on agreed tolerable risks. The use of expert judgement should be avoided where possible (**WP3**)
- In determining benchmarks to comply with a protection goal, the level of conservatism in the benchmark should be identified and recorded (**WP3**)

Terms of criteria and the recommendation of one or two values (Section 5)

- PROTECT should assess the use of the numeric values currently being applied or suggested (**WP2**)
- PROTECT should consider the use of a screening value (**WP3**)
- PROTECT should consider the need for a standard[3] number (i.e. an equivalent to the 1 mSv for public) (**WP3**)
    - 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 (**WP3**)
    - 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' (PEL) is derived which is a value at which there is strong evidence of effects) (**WP3**).
- PROTECT should produce a clearly understandable document outlining the derivation of any numbers and in particular where there are limitations in the application of a number because of poor data quality is needed. This document should be developed in consultation with stakeholders (**WP3**)

Compliance (Section 6)

- Once thresholds or some other methods of environmental protection have been agreed, methods for demonstrating compliance should be evaluated (bearing in mind the use of the threshold for example, if a regulatory limit then clear strong compliance will be needed) (**G**)

[3] The term "standard" is used here to describe a threshold which should not be exceeded in any circumstance (see Box 3 above).

Improving the process (Section 8)

- Continue to communicate in an open and transparent manner with clear documentation. PROTECT should work with industry and others on the issue of regulating for protection of the environment to obtain their input into the process up front and throughout any regulatory developments (**G**)

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Appendix 1. Questionnaire templates for regulators and industry

See following pages

Protection of the Environment from Ionising Radiation in a Regulatory Context

PROTECT WP1 Questionnaire for Regulators & Advisory Bodies

The aim of this questionnaire is to:

- Gather information on the current regulatory approaches to both chemicals and radioactive substances in EU member states
- Centre on protection of the environment not humans
- Review the biological and ecological endpoints of protection currently used and the similarities and differences between approaches for chemicals and radioactive substances

Contact details
Name:
Organisation:
Address:
Phone/Fax/email details:
Your role in organisation: [clarify whether the views given are that of the organisation or of the individual]
1. Regulatory role
What do your responsibilities include (e.g. discharges, contaminated land)? [circle a, b or c] a. Regulatory – chemical [if a. go to Section 2] b. Regulatory – radioactive substances [if b & c go to next question in Section 1] c. Regulatory – chemical & radioactive substances d. Advisory – chemical/radioactive substances/chemical & radioactive substances
Does your organisation regulate to protect environment for radioactive substances? [if yes go to Section 2. If no continue with Section 1]
If not why not?
Do you think there will be a need to do so in the future?
If No why not?

If Yes why are you not already doing so?
2. Why and how you regulate
What determines why and how you regulate? [circle a, b or c] a. National legislation/guidance b. International legislation/guidance c. Other
Can you provide us with some background to the policy decisions that were taken?
Please identify key documents/reports/guidance/internal documents that we should be aware of that you use regularly
Please identify location of key documents (i.e. where can we access them?)
Are there other regulators involved in regulating sites?
3. Protection goals
What are you trying to protect (why)?
How relevant are these protection goals?
Can these protection goals be achieved?
If not why not

4. Methodology
What method do you use to achieve your protection goals?
Is your approach formally described (documented)?
Do you use any models/tools (brief details of what they do and accessibility)?
What environmental factors are taken into account when assessing risk (eg. background; bioavailability; spatial and temporal variability)?
Does your process include stakeholder involvement (by regulation)?
5. Compliance
How do you ensure and demonstrate compliance (i.e. no risk/harm to environment)?
6. Criteria
A. Do you use numeric limits? [if no go to B]
Do you use a single or multiple values for a given contaminant (e.g. tiered approach; ecosystems; organisms; maximum limit V's 'target value')?
How have these values been derived (e.g. what are the critical data, safety factors, SSD approaches)? [SSD = Species Sensitivity Distribution]
B. Do you use non-numeric criteria (e.g. good ecological status) instead or as well?
If yes what is the basis for this?
Do you think the criteria you work to are: Suitably conservative Y/N

If NO is it Too conservative? Not conservative enough? Justify your answer
If you regulate radioactive substances are there/should there be difference between e.g. TeNORM and artificially produced radioactive substances regulation - what should these be?
If you have criteria would you be willing to review in light of new work?
Have/should stakeholders be involved in criteria setting?
If so how (who/what/how)?
How was/should cost-benefit be taken into account in deriving criteria?
7. Flexibility
How much flexibility do you have in: Setting criteria? Implementation of the regulatory process?
8. Does it work
What works well? What areas could be improved? How could these areas be improved?
9. Future regulation
What future changes do you see to environmental protection legislation (and drivers for this)?

10. Radioactive substances V's chemical
What are the similarities and differences between chemical and radioactive substance regulation: In environmental protection endpoints In Criteria setting & extrapolation
Do existing differences give rise to any confusion?
Where could one area of regulation learn from that used to regulate the other (i.e. chemicals V's radioactive substances or vice versa)?
Can you explain how (if at all) policy development for radioactive substances is influenced by policy for chemicals (and vice versa)?

Protection of the Environment from Ionising Radiation in a Regulatory Context

PROTECT WP1 Questionnaire for Industry

The aim of this questionnaire is to:

- Gather information on the current regulatory approaches to both chemicals and radioactive substances in EU member states
- Centre on protection of the environment not humans
- Review the biological and ecological endpoints of protection currently used and the similarities and differences between approaches for chemicals and radioactive substances

Contact details
Name:
Organisation:
Address:
Phone/Fax/email details:
Your role in organisation: [clarify whether the views given are that of the organisation or of the individual]
1. Nature of business
a. Chemical b. Radioactive substances c. Chemical & radioactive substances
2. Why and how are you regulated
What determines why and how you are regulated? a. National legislation/guidance b. International legislation/guidance c. Other
Do you know of the background to external policy decisions taken by the regulators?
Do you have an internal policy on meeting the regulations? If so, could you give us some background?
Please identify key documents/reports/guidance/internal documents that we should be aware of that

you use regularly
Please identify location of key documents (i.e. where can we access them?)
Who are the regulators for your site(s)?
3. Protection goals
What are the regulators trying to protect (why)?
In your organisation's view, how relevant are these protection goals?
In your organisation's view, can these protection goals be achieved?
If not why not
4. Methodology
What method do you use to achieve the regulators imposed protection goals?
Is your approach formally described (documented)?
Do you use any models/tools (brief details of what they do and accessibility)?
What environmental factors do you take into account when assessing risk (eg. background; bioavailability; spatial and temporal variability)?
5. Compliance

How do you ensure and demonstrate compliance (i.e. no risk/harm to environment)?
6. Criteria
A. Do you use numeric limits? [if no go to B]
Do you use a single or multiple values for a given contaminant (e.g. tiered approach; ecosystems; organisms; maximum limit V's 'target value')?
Do you know how these values been derived (e.g. what are the critical data, safety factors, SSD approaches)? [SSD = Species Sensitivity Distribution]
B. Do you use non-numeric criteria (e.g. good ecological status) instead or as well?
If yes what is the basis for this?
Do you undertake research related to standards in order to challenge the regulators? If yes, how successful was this research? i.e. what did it achieve?
Do you think the criteria you work to are: Suitably conservative Y/N
If NO is it Too conservative? Not conservative enough? Justify your answer
Have/should stakeholders be involved in criteria setting?
If so how (who/what/how)?

How was/should cost-benefit be taken into account in deriving criteria?
7. Does it work
Do you see any benefit from regulation? What works well? What areas could be improved? How could these areas be improved?
8. Future regulation
What future changes do you see to environmental protection legislation (and drivers for this)?
9. Radioactive substances V's chemical
What are the similarities and differences between chemical and radioactive substance regulation: In environmental protection endpoints: In Criteria setting & extrapolation:

Appendix 2. Organisations that responded to the questionnaire

Organisation	Acronym	Country	Category
Australian Nuclear Science & Technology Organisation	ANSTO	Australia	Industry
AREVA	AREVA	France	Industry
Autorite de Surete Nucleaire (French Nuclear Safety Authority)	ASN	France	Regulatory
British Energy		UK	Industry
British Nuclear Group - Sellafield	BNGSL	UK	Industry
Bundesamt fuer Strahlenscutz (Federal Office for Radiation Protection)	BFS	Germany	Regulatory
Canadian Nuclear Safety Commission	CNSC	Canada	Regulatory
Canadian CANDU Owners Group (COG) Member Companies*	CANDU	Canada	Industry
Central Mining Institute	GIG	Poland	Advisory
Commissariat à l'Énergie Atomique	CEA	France	Industry
County Administrative Board of Vastra Gotaland		Sweden	Regulatory
National Research Centre for Energy, Environment and Technology	CIEMAT	Spain	Advisory
Coneju de Seguridad Nuclear	CSN	Spain	Regulatory
Devonport Royal Dockyard Limited		UK	Industry
Electricite de France-CIDEN (Centre d'Ingenerie de la Deconstruction et de l'Environnement)	EDF	France	Industry
Environment Agency for England & Wales	EA	UK	Regulatory
Finnish Environment Institute	SYKE	Finland	Regulatory
FMBA		Russia	Regulatory
Greenpeace International		International	International
Institute for Energy and Technology		Norway	Industry
Institute for European Environment Policy	IEEP	European	International
Institute of Physics (Vilnius)		Lithuania	Advisory
Instituto Superiore di Sanità (National Institute of Health)	ISS	Italy	Advisory
Institut de Radioprotection et de Surete Nucleaire	IRSN	France	Advisory
International Sakharov Environmental University		Belarus	Advisory
Swedish NGO Office for Nuclear waste Review/The Swedish Society for Nature Conservation	MKG/SNF	Sweden	NGO
Swedish Radiation Protection Authority	SSI	Sweden	Regulatory
Miljooverdomstolen (The Environmental Court Of Appeal)		Sweden	Regulatory
Nationale Genosseschaft Fur die Lagerung radioaktiver Abfalle	NAGRA	Switzerland	Industry
National Commission for Nuclear Activities Control		Romania	Regulatory
Nexia Solutions Ltd (formerly known as BNFL R&D department soon to be the National Nuclear Laboratory)		UK	Industry
Natural England		UK	Advisory
Nirex		UK	Industry
Norwegian Pollution Control Authority		Norway	Regulatory
Norwegian Radiation Protection Authority	NRPA	Norway	Regulatory
Nuclear Decommissioning Authority	NDA	UK	Advisory
Nuclear Research and Consultancy Group	NRG	Netherlands	Industry
OECD Nuclear Energy Agency		International	International
Posiva Oy		Finland	Industry

Radiation and Nuclear Safety Authority of Finland	STUK	Finland	Regulatory
Radiological Protection Institute of Ireland	RPII	Ireland	Regulatory
Riso National Laboratory		Denmark	Advisory
Studiecentrum voor Kernenergie - Centre d'étude de l'Energie Nucléaire (Belgian Nuclear Research Centre)	SCK-CEN	Belgium	Advisory
Scottish Environment Protection Agency	SEPA	UK	Regulatory
Scottish Executive		UK	Regulatory
Swedish Chemicals Agency	KEMI	Sweden	Regulatory
Swedish Nuclear Fuel and Waste Management Co	SKB	Sweden	Industry
The Norwegian Oil Industry Association	OLF	Norway	Industry
UKAEA		UK	Industry
Vattenfall AB		Sweden	Industry

* Note: CANDU owners group in Canada (COG) put in a combined response. COG are representatives from each of the 5 Canadian CANDU facilities – Ontario Power Generation, Bruce Power, New Brunswick Power, Hydro Quebec and Atomic Energy of Canada Limited.

Appendix 3. Documents cited as key to protection of the environment from radiation and chemicals by regulators and industry

	[Reference details for legislation documents]	[Location]
Australia	Environmental Protection & Biodiversity Conservation Act	http://www.deh.gov.au/epbc/
	Australian Drinking Water Guidelines	http://www.deh.gov.au/water/quality/nwqms/introduction/
Canada	P-223 Regulatory Policy, Protection of the environment, February 2001.	http://www.nuclearsafety.gc.ca/eng/regulatory_information/documents/index.cfm [CNSC]
	S-296 Regulatory Standard, Environmental protection policies, programs and procedures at Class I Nuclear Facilities and Uranium Mines and Mills, March 2006.	http://www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=65&par_actn=s1 [PSL2]
	G-296 Regulatory Guide, Developing environmental protection policies, programs and procedures at Class I Nuclear Facilities and Uranium Mines and Mills, March 2006.	
	G-320, Regulatory Guide, Assessing the Long-term Safety of Radioactive Waste Management, December 2006.	
	International Environmental Management System standard ISO:14001:2004	
	PRIORITY SUBSTANCES LIST ASSESSMENT REPORT, *Canadian Environmental Protection Act, 1999,* Releases of Radionuclides from Nuclear Facilities (Impact on Non-human Biota) - 2004	
	Technical Briefing, Ecological risk assessment (ERA), June 2004.	
	CMD-04-M39, The assessment of radiation effects of alpha emitters on biota, September 2004.	
England & Wales	Radioactive Substances Act 1993	http://www.opsi.gov.uk/acts/acts1993/Ukpga_19930012_en_1.htm
	Environment Act 1995	http://www.opsi.gov.uk/acts/acts1995/Ukpga_19950025_en_1.htm
	The Conservation (Natural Habitats, &c.) (Amendment) (England) Regulations 2000	http://www.opsi.gov.uk/si/si2000/uksi_20000192_en.pdf

Appendix 3. Documents cited as key to protection of the environment from radiation and chemicals by regulators and industry

	EC Birds Directive (Council Directive 79/409/EEC) EC Habitats Directive (Council Directive 92/43/EEC)	
Finland	STUK Guide YVL 8.4	http://www.stuk.fi
France	French and European Regulations	Available from internet - JO and JOCE
	International recommendations and safety guides edited by the ICRP, IAEA for example	Available from internet - JO and JOCE
	National guides and reports edited by expert committees (e.g. IRSN, INERIS)	Available from internet - JO and JOCE
	International databases (e.g. UNSCEAR, WHO, US-EPA)	Available from internet - JO and JOCE
Germany	Handbook on Nuclear Safety and Radiation Protection	www.bfs.de
	General Administrative Provisions	
	BfS concept on environmental protection ' Comparative evaluation of different approaches to environmental protection against ionising radiation in view of practicality and consistency (2006 IRPA meeting)	IRPA 12 proceedings not yet available on website
Netherlands	MR-AGIS – Guidelines for Radiation.	http://www.vrom.nl/pagina.html?id=9395 http://www.vrom.nl/get.asp?file=/docs/milieu/dovisA.pdf http://www.vrom.nl/get.asp?file=/docs/milieu/dovisB.pdf
	(Dutch) Framework Guideline Water	http://www.kaderrichtlijnwater.nl/start/nieuws/publicaties/
Norway	Act on Radiation Protection and Use of Radiation 12 May 2000	http://www.nrpa.no/old_eng/english/Publications/act.pdf
	Regulations on Radiation Protection and Use of Radiaition (Radiation Protection regulations 21 November 2003	http://www.nrpa.no/old_eng/english/Publications/regulations.pdf
	ICRP 60	http://w3.tue.nl/fileadmin/sbd/Documenten/Leergang/BSS/ICRP60_1990_Recommendations_of_the_ICRP.pdf
	IAEA Basic Safety Standard 115	http://www-pub.iaea.org/MTCD/publications/PDF/SS-115-Web/Start.pdf

Appendix 3. Documents cited as key to protection of the environment from radiation and chemicals by regulators and industry

Romania	The Romanian Law 111/1996 as republished in 2006	http://www.cncan.ro/bd/legi/legea%20111.pdf
	Basic Radiological Safety Norms (2000)	http://www.cncan.ro/bd/norme/nsr01.pdf
	Activity/Practice specific regulations	www.cncan.ro
Scotland	Basic Standards (Scotland) Direction (2000)	http://www.opsi.gov.uk/legislation/scotland/ssi2000/20000100.htm
	Environment Act 1995	http://www.opsi.gov.uk/acts/acts1995/Ukpga_19950025_en_1.htm
	Natural Habitats Directive	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0043:EN:HTML
	Water Framework Directive	http://eur-lex.europa.eu/LexUriServ/site/en/oj/2000/l_327/l_32720001222en00010072.pdf
	Basic Safety Standards	http://www-pub.iaea.org/MTCD/publications/PDF/SS-115-Web/Pub996_web-1a.pdf
Spain	Nuclear Energy Act	*Consejo de Seguridad Nuclear (CSN) website www.csn.es.*
	Royal Legislative Decree on Environmental Impact Assessment	*Consejo de Seguridad Nuclear (CSN) website www.csn.es.*
	Regulation on Nuclear and Radioactive Facilities	*Consejo de Seguridad Nuclear (CSN) website www.csn.es.*
	Regulation on health protection from ionising radiations	*Consejo de Seguridad Nuclear (CSN) website www.csn.es.*
Sweden	Radiation Protection Act (1988:220)	http://www.ssi.se/forfattning/pdf_eng/1988_220E.pdf
	Radiation Protection Ordinance (1988:293)	http://www.ssi.se/forfattning/pdf_eng/1988_293E.pdf
	Regulation of final management of spent nuclear fuel (1998:1) and corresponding guidelines (2005:5)	http://www.ssi.se/forfattning/PDF_Eng/1998-1e.PDF http://www.ssi.se/forfattning/pdf_eng/2005_5e.pdf

Appendix 3. Documents cited as key to protection of the environment from radiation and chemicals by regulators and industry

	Regulation of releases from certain nuclear facilities (2000:12)	http://www.ssi.se/forfattning/pdf_eng/2000_12e.pdf
Switzerland	Nuclear Energy Ordinance	http://www.nagra.ch/downloads/kernenergieverordnung_engl.pdf
USA	USDOE, 1993. Radiation protection of the public and the environment. DOE Order 5400.5.	http://www.directives.doe.gov/pdfs/doe/doetext/oldord/5400/o54005c2.pdf
	USDOE, 2003. Environmental protection program. DOE Order 450.1.	http://www.directives.doe.gov/pdfs/doe/doetext/neword/450/o4501.pdf

Appendix 4a. Protection goals as cited in legislation (concerning radioactivity)

Australia	ARPANS Act (2005). Code of Practice and Safety Guide : Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing. Radiation Protection Series Publication No. 9, August 2005. Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act 1999) Environment Protection and Biodiversity Conservation Regulations 2000 (EPBC Regulations 2000).
	ARPANS Act (2005): "The objective of this Code is to provide a regulatory framework to manage the protection of workers, members of the public and the environment from harmful effects of radiation exposures arising from mining or mineral processing and from the waste resulting from these activities both now and in the future". Section 3.6.6 of **ARPANS Act (2005)** states that "For the purposes of the Code it is assumed that by achieving adequate protection of human health, an acceptable level of protection will be afforded to the environment. However, this assumption may not be valid in all circumstances and specific additional control measures may be required". The objective of the **EPBC Act 1999** are: (i) "to provide for the protection of the environment, especially those aspects of the environment that are matters of national environmental significance; and (ii) to promote ecologically sustainable development through the conservation and ecologically sustainable use of natural resources; and (iii) to promote the conservation of biodiversity; and (iv) to provide for the protection and conservation of heritage; and (v) to promote a co-operative approach to the protection and management of the environment involving governments, the community, land-holders and indigenous peoples; and (vi) to assist in the co-operative implementation of Australia's international environmental responsibilities; and (vii) to recognise the role of indigenous people in the conservation and ecologically sustainable use of Australia's biodiversity; and (viii) to promote the use of indigenous peoples' knowledge of biodiversity with the involvement of, and in co-operation with, the owners of the knowledge". Paragraph 3A, Chapter 1, states that "the conservation of biological diversity and ecological integrity should be a fundamental consideration in decision-making" Schedule 1 of the **EPBC Regulations** states that environmental impact statement or a public environment reports should include "an assessment of the relevant impacts of the action" (including nuclear actions). Schedule 2, part 5 of the **EPBC Regulations** details requirements for describing the nature and extent of the likely impacts of the action, which include: "5.01 A description of the affected area that refers, as appropriate, to relevant maps. 5.02 The nature and extent of likely impacts on any of: (i) the World Heritage values of a World Heritage property; (ii) the ecological character of a Ramsar wetland; (iii) the members of a listed threatened species (except a conservation dependent species) or any threatened ecological community, or their habitat; (iv) the members of a listed migratory species or their habitat; (v) part of the Commonwealth marine area;

	(vi) Commonwealth land. 5.03 The nature and extent of the likely impact on the environment, and whether the action is: 1. a nuclear action; or 2. an action by the Commonwealth or a Commonwealth agency; or (a) to be taken in a Commonwealth marine area; or 3. to be taken on Commonwealth land." Nuclear actions include "establishing, significantly modifying, decommissioning or rehabilitating a facility where radioactive materials at or above the activity level mentioned in regulation 2.02 are, were, or are proposed to be used or stored".
Canada	Canadian Nuclear Safety Commission (2001). Protection of the Environment. Regulation Policy P-233. Canadian Nuclear Safety Commission (2006). Environmental Protection Policies, Programs and Procedures at Class I Nuclear Facilities and Uranium Mines and Mills. Regulatory Standard S-296 Canadian Nuclear Safety Commission (2006). Developing Environmental Protection Policies, Programs and Procedures at Class I Nuclear Facilities and Uranium Mines and Mills. Regulatory Guide G-296. Canadian Nuclear Safety Commission (2006). Assessing the Long Term Safety of Radioactive Waste Management. Regulatory Guide G-320. Environment Canada (2004). Releases of Radionuclides from Nuclear Facilities (Impact on Non-human Biota). Canadian Environmental Protection Act, 1999: Priority Substances List Assessment Report. Nuclear Safety and Control Act 1997 Class I Nuclear Facilities Regulations (SOR/2000-204)
	Policy P-233: "Applicants for CNSC licenses must demonstrate through performance assessments, monitoring, or other evidence, that their provisions to protect the environment are adequate. The measures taken by CNSC licensees to protect the environment should: Be commensurate with the likelihood and significance of adverse environmental effects; o Recognize that variability exists in potentially adverse environmental effects as a consequence of differences in regulated activities, substances, equipment, facilities, the environment and its human components; o Recognize that uncertainty exists in science, and therefore prevent unreasonable risk by keeping all releases to the environment as low as reasonably achievable, social and economic factors taken into account (ALARA); o Be judged against performance indicators and targets which are based on sound science." **Standard S-296: "**The objective of the environmental protection policies, programs and procedures is to establish adequate provision for protection of the environment at Class I nuclear facilities and uranium mines and mills. This shall be accomplished through an integrated set of documented activities that are typical of an Environmental Management System (EMS)." The licensee shall "establish, implement and maintain an EMS that meets the requirements set by the Canadian Standards Association's ISO 14001:2004, *Environmental Management Systems—Requirements with Guidance for Use*." Expanding on clause 3.5 of ISO 14001:2004, the environment refers to the components of the earth, including:

	(a) land, water, and air, including all layers of the atmosphere; (b) all organic and inorganic matter and living organisms; and (c) the interacting natural systems that include components referred to in (a) and (b). "Expanding on "environmental impact" from clause 3.7 of ISO 14001:2004, environmental effect includes any change that an activity, substance, equipment, facility or prescribed information may cause in the environment, including any change it may cause to a listed wildlife species, its critical habitat or the residences of individuals of that species, as those terms are defined in subsection 2(1) of the *Species at Risk Act* whether any such change or effect occurs within or outside Canada" **Guide G-296: "**For non-human biota, assessment of risks from nuclear substances is an evolving issue. Guidance on methodology should be taken from recognized, authoritative sources (e.g., the framework published by the International Commission on Radiological Protection [ICRP]). CNSC staff assessment of programs to manage these risks complements their assessment of programs to manage risks from hazardous substances. This approach is consistent with approaches adopted by provincial and federal agencies (e.g., Ontario Ministry of the Environment [OMOE], Environment Canada, Canadian Council of Ministers of the Environment [CCME])." **Guide G-320:** Since the NSCA and regulations specify protection of both the environment and persons, long term assessments should address the impact on humans and on non-human biota from both radioactive and hazardous non-radioactive constituents of the radioactive waste, as reflected in regulatory policy P-290, *Managing Radioactive Waste* (CNSC 2004). "The regulatory requirements for protection of persons and the environment from both radiological and non-radiological hazards of radioactive wastes lead to four distinguishable sets of acceptance criteria for a long term assessment: 1. Radiological protection of persons; 2. Protection of persons from hazardous substances; 3. Radiological protection of the environment; and 4. Protection of the environment from hazardous substances." "For the protection of nonhuman biota from radiation exposure, the primary concern is the total radiation dose to the organisms resulting in deterministic effects. The development of benchmarks for radiation protection of nonhuman biota is not as mature as the development of benchmarks for hazardous substances, due to the historic assumption that protecting humans from radiation is sufficient to protect the environment. However, benchmark values for mean radiation doses to nonhuman biota have been derived for various types of organisms (National Council on Radiation Protection and Measurements (NCRP) 1991, IAEA 1992, EC 2003). Development of criteria for ensuring radiological protection of the environment should follow the protocols established for hazardous substances" **Environment Canada (2004):** "The *Canadian Environmental Protection Act, 1999* (CEPA 1999) requires the federal Ministers of the Environment and of Health to prepare and publish a Priority Substances List (PSL) that identifies substances, including chemicals, groups of chemicals, effluents and wastes, that may be harmful to the environment or constitute a danger to human health. The Act also requires both Ministers to assess these substances and determine whether they are "toxic" or capable of becoming "toxic" as defined in Section 64 of the Act, which states: *...a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that* *(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;* *(b) constitute or may constitute a danger to the environment on which life depends; or* (c) *constitute or may constitute a danger in Canada to human life or health*." **Nuclear Safety and Control Act 1997:**

	"The purpose of this Act is to provide for the limitation, to a reasonable level and in a manner that is consistent with Canada's international obligations, of the risks to national security, the health and safety of persons and the environment that are associated with the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information" "The objects of the Commission are (*a*) to regulate the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to (i) prevent unreasonable risk, to the environment and to the health and safety of persons, associated with that development, production, possession or use, (ii) prevent unreasonable risk to national security associated with that development, production, possession or use, and (iii) achieve conformity with measures of control and international obligations to which Canada has agreed." **Class I Nuclear Facilities Regulations:** "An application for a licence in respect of a Class I nuclear facility, other than a licence to abandon, shall contain the following information in addition to the information required by section 3 of the *General Nuclear Safety and Control Regulations* the proposed program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects on the environment and the health and safety of persons that may result from the activity to be licensed" (amongst others!) "An application for a licence to prepare a site for a Class I nuclear facility shall contain the following information in addition to the information required by section 3: a) a description of the site evaluation process and of the investigations and preparatory work that have been and will be done on the site and in the surrounding area; b) a description of the site's susceptibility to human activity and natural phenomena, including seismic events, tornadoes and floods; c) the proposed program to determine the environmental baseline characteristics of the site and the surrounding area; d) the proposed quality assurance program for the design of the nuclear facility; and e) the effects on the environment and the health and safety of persons that may result from the activity to be licensed, and the measures that will be taken to prevent or mitigate those effects." "An application for a licence to operate a Class I nuclear facility shall contain the following information in addition to the information required by section 3: f) the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects; g) the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics; h) the proposed measures to control releases of nuclear substances and hazardous

	substances into the environment; i) the proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of security"
Denmark	www.sst.dk – website entirely in Danish. Alternative searches undertaken and all information presented below is as a result of searches, not from questionnaire response. Ministry of Environment website – nothing on nuclear/radioactivity in English version. Consolidated Environmental Protection Act No. 698 of September 22, 1998 OECD (2007). Nuclear Legislation in OECD Countries - Regulatory and Institutional Framework for Nuclear Activities: Denmark
	Environmental Protection Act: (1) The purpose of this Act is to contribute to safeguarding nature and environment, thus enabling a sustainable social development in respect for human conditions of life and for the conservation of flora and fauna. (2) The objectives of this Act are in particular: 1) to prevent and combat pollution of air, water, soil and subsoil, and nuisances caused by vibration and noise, 2) to provide for regulations based on hygienic considerations which are significant to Man and the environment, 3) to reduce the use and wastage of raw materials and other resources, 4) to promote the use of cleaner technology, and 5) to promote recycling and reduce problems in connection with waste disposal. 2.-(1) This Act applies to: 1) all activities which by emission of solid, liquid or gaseous substances, by release of microorganisms likely to harm health and the environment or by generation of waste may cause pollution of air, water, soil and subsoil, 2) vibrations and noise, 3) products or goods likely to cause pollution in connection with manufacture, storage, use, transport or disposal, 4) means of transport and other mobile facilities likely to cause pollution, and 5) animal husbandry, pests and other matters likely to cause problems of hygiene or significant nuisances to the surroundings. (2) This Act also applies to activities involving hazardous processes, and to storage of substances with dangerous properties, in such a way that interruption of operation or accidents may result in imminent risks of pollution as specified in subsection (1) above. **OECD (2007)** - An Act on Nuclear Installations [Act No. 244 of 1976]* was adopted in 1976 but has not yet entered into force. This act governs the safety and environmental conditions applicable to nuclear installations. At present Denmark has no nuclear power programme. In 1985, a resolution of the Danish Parliament determined that nuclear power was not to be generated in Denmark and that the sites that had been reserved for the construction of nuclear power plants were to be released. The 1976 Act will only come into force if the 1985 Resolution is reversed and a decision is made to implement a nuclear power programme. *Actual act could not be identified.
England & Wales	Environment Agency (2003). Habitats Directive: Work Instruction (Appendix 8). Functional Guidance on Applying the Habitats Regulations to Radioactive Substances Authorisations.

	The Conservation (Natural Habitats, &c.) Regulations 1994 Radioactive Substances Act, 1993 Environment Act 1995 Environment Agency (2005a). Radioactive Substances Regulation Environmental Principles (Interim). Environment Agency (2005b).Considerations for Radioactive Substances Regulation under the Radioactive Substances Act 1993 At Nuclear Sites in England and Wales.
	Environment Agency (2003) "The Environment Agency, in liaison with English Nature and the Countryside Council for Wales have put in place an approach to the assessment of the impact of ionising radiation on the environment, pending any broader international developments. This approach provides for the adoption of new data and methods as they become available." "This Work Instruction establishes a staged assessment process to fulfil the requirements of the EU Birds and Habitats Directives (79/409/EEC & 92/43/EEC) and the UK Conservation (Natural Habitats &c.) Regulations 1994 (the 'Habitats Regulations')." For Stage 1 assessments under the habitats Regulations the effect of radioactivity on "interest features of a Natura 2000 site" should be considered. **Habitats Regulations**: "These Regulations make provision for the purpose of implementing, for Great Britain, Council Directive 92/43/EEC[8] on the conservation of natural habitats and of wild fauna and flora (referred to in these Regulations as "the Habitats Directive")." Regulation 8 – "The Secretary of State shall establish priorities for the designation of sites in the light of- (a) the importance of the sites for the maintenance or restoration at a favourable conservation status of- (i) a natural habitat type in Annex I to the Habitats Directive, or (ii) a species in Annex II to the Directive, and for the coherence of Natura 2000; and (b) the threats of degradation or destruction to which those sites are exposed." Regulation 48 – "A competent authority, before deciding to undertake, or give any consent, permission or other authorisation for, a plan or project which- (a) is likely to have a significant effect on a European site in Great Britain (either alone or in combination with other plans or projects), and (b) is not directly connected with or necessary to the management of the site, shall make an appropriate assessment of the implications for the site in view of that site's conservation objectives." "Where in such a case the competent authority consider that any adverse effects of the plan or project on the integrity of a European site would be avoided by making any consent subject to conditions, they may give consent, or cause it to be given, subject to those conditions." – *Note – this is not directly related to RSA consents, but applies to EPA licences/consents and those granted under the Water Resources Act 1991 (control of pollution of water resources) and Part II of the Control of Pollution Act 1974* **RSA93:** Regulation 22 "Subject to the provisions of this section, if the chief inspector is of the opinion, as respects the keeping or use of radioactive material or of mobile radioactive apparatus, or the disposal or accumulation of radioactive waste, by a person in pursuance of a registration or authorisation under this Act, that the continuing to carry on that activity (or the continuing to do

	so in a particular manner) involves an imminent risk of pollution of the environment or of harm to human health, he may serve a notice under this section on that person." **Environment Act 1995:** Regulation 4 – "It shall be the principal aim of the Agency (subject to and in accordance with the provisions of this Act or any other enactment and taking into account any likely costs) in discharging its functions so to protect or enhance the environment, taken as a whole, as to make the contribution towards attaining the objective of achieving sustainable development mentioned in subsection (3) below" Under Regulation 5 "The Agency's pollution control powers shall be exercisable for the purpose of preventing or minimising, or remedying or mitigating the effects of, pollution of the environment" and "In this section, "pollution control powers" and "pollution control functions", in relation to the Agency, mean respectively its powers or its functions under or by virtue of the following enactments, that is to say… Radioactive Substances Act 1993;" Under Regulation 6 "It shall be the duty of the Agency, to such extent as it considers desirable, generally to promote— (a) the conservation and enhancement of the natural beauty and amenity of inland and coastal waters and of land associated with such waters; (b) the conservation of flora and fauna which are dependent on an aquatic environment; and (c) the use of such waters and land for recreational purposes;" Regulation 7 "It shall be the duty of each of the Ministers and of the Agency, in formulating or considering— any proposals relating to pollution control functions of the Agency, to have regard to the desirability of conserving and enhancing natural beauty and of conserving flora, fauna and geological or physiographical features of special interest" **Environment Agency, 2005a**: Radioactive substances regulation (RSR) fundamental principles include: "The Environment Agency's objective is that, consistent with Government policy and legislation, radioactive substances are managed to meet the needs of current and future generations by preventing and minimising effects on people and the environment and that environmental damage is remedied." "Radioactive substances shall be managed to avoid placing a burden on future generations and their environment such that it compromises their ability to meet their needs". Developed Principle 13 states that "Limits and levels shall be established on the quantities of radioactivity that can be discharged into the environment where these are necessary to secure proper protection of human health and the environment". To this end "Limits and levels shall be established on those radionuclides and/or groups of radionuclides which: are of significance in terms of radiological impact for humans and non-human species, including those which may be taken up in food; Under Developed Principle 14 it is stated that "The objectives of operator and Environment Agency environmental monitoring programmes are to: o Enable doses to vulnerable reference non-human species to be independently estimated (*wildlife monitoring*); o Establish background levels of radioactivity in the environment (*background monitoring*); o Provide a long term measure of the state of the environment (*environmental indicator monitoring*);" NB only those bullets relating to the environment have been added. Developed Principle 16 relates to requirements and conditions for the disposal of radioactive waste. The intent of the requirements and conditions are to:

	o "Protect the health of people, now and in the future"; and, o "Protect the environment, now and in the future" Below all from **Environment Agency (2005b):** The "overall system of regulatory control at nuclear sites includes: o deciding whether or not applications for new authorisations or applications for variations to existing authorisations should be granted, and setting appropriate limits and conditions in any authorisations issued which ensure that the public and the environment are well protected; o periodically reviewing authorisations and operators' environmental performance and varying authorisations as appropriate to ensure that the authorisation's limits and conditions are up to date and effective and continue to ensure that the public and the environment are well protected". Paragraph 3.5.12, in relation to assessing impacts on non-human biota, states that "FASSET and ERICA are expected to deliver, as an eventual outcome, a systematic basis to provide protection of non-human species. Once this systematic basis is delivered our policies and processes will be modified accordingly to take it into account." In October 2000, draft *Statutory Guidance to the Agency on the Regulation of Radioactive Discharges into the Environment from Nuclear Licensed Sites* (draft Statutory Guidance) was submitted for public consultation by DEFRA and DoH. The draft Statutory Guidance sets out a number of general and specific principles that should be applied to regulation of radioactive discharges. It states that "radioactive waste management policy should be based on the same basic principles that apply more generally to environmental policy and in particular that of sustainable development" and these include that "ecological impacts must be considered, particularly where resources are nonrenewable or effects may be irreversible". Paragraph 4.3.20 notes that "The UK Sustainable Development Strategy was updated in 2005 with the publication by the Government of The UK Government's Sustainable Development Strategy (March 2005), Cm 6467. This states that "Our [UK] Strategy for sustainable development aims to enable all people throughout the world to satisfy their basic needs and enjoy a better quality of life without compromising the quality of life of future generations" and introduces five guiding principles". These include "Living Within Environmental Limits - Respecting the limits of the planet's environment, resources and biodiversity – to improve our environment and ensure that the natural resources needed for life are unimpaired and remain so for future generations". Paragraph 4.3.21 states "Section 5 of EA 95 sets out the statutory purpose for which the Environment Agency's pollution control powers, including our powers under RSA 93, must be exercised, namely "*preventing or minimising, or remedying or mitigating the effects of, pollution of the environment*"." Paragraph 4.3.27 states "The Habitats Regulations (Reg 50) require that the Environment Agency reviews existing permissions/ authorisations that we have issued with regard to their effects on all European Sites. Such authorisations may include those issued under RSA 93 for the disposal of radioactive waste."
Germany	**Act on the Peaceful Utilization of Atomic Energy and the Protection against its Hazards (Atomic Energy Act) 1959, as Amended to 2002** BfS Safety Codes and Guides – Translations: Edition 5/95: Ordinance on the Procedure for Licensing of Installations under § 7 of the Atomic Energy Act (Nuclear Licensing Procedure Ordinance) or February 18, 1977, as amended and promulgated on February 3, 1995.
	Atomic Energy Act: The purpose of this Act is 1. to phase out the use of nuclear energy for the commercial generation of electricity in a

	structured manner, and to ensure on-going operation up until the date of discontinuation, 2. to protect life, health and property against the hazards of nuclear energy and the detrimental effects of ionising radiation and to provide compensation for damage and injuries caused by nuclearenergy or ionising radiation, 3. to prevent danger to the internal or external security of the Federal Republic of Germany from the application or release of nuclear energy, 4. to enable the Federal Republic of Germany to meet its international obligations in the field of nuclear energy and radiation protection. Edition 5/95 of the BfS Safety Codes and Guides requires: (1) "An Environmental Impact Statement shall be provided in accordance with the provisions of this Ordinance with respect to projects relating to the construction and operation, decommissioning, safe confinement or dismantling of a installation referred to in § 7 of the Atomic Energy Act, or the dismantling of components of a installation or a major change of a installation or its operation, provided these projects have to be announced in accordance with § 4 of this Ordinance ("projects requiring an EIS")." (2) "As a subordinate part of the procedures referred to in § 1, the Environmental Impact Statement shall include the identification, description and assessment of the impacts which a project requiring an EIS will have on 1. men, animals and plants, soil, water, air, climate and scenery, including the relevant interactions, 2. cultural properties and other physical properties and which are of importance for the examination of the approval prerequisites. " Section 3, paragraph 9 requires that an application be accompanied by "data relating to other environmental effects of the project…in accordance with provisions relating to the conservation of nature and the maintenance of landscapes"
Finland	STUK (2001). Long-term safety of disposal of spent nuclear fuel. Guide YVL 8.4.
	Guide YVL 8.4 on long term safety of spent nuclear fuel specifies in 2.5 "Considerations of protection of other living nature" that: "Disposal of spent fuel shall not affect detrimentally to species of fauna or flora. This shall be demonstrated by assessing the typical radiation exposures of terrestrial and aquatic populations in the disposal site environment, assuming the present kind of living populations. These exposures shall remain clearly below the levels which, on the basis of the best available scientific knowledge, would cause decline in biodiversity or other significant detriment to any living population. Moreover, rare animals and plants as well as domestic animals shall not be exposed detrimentally as individuals.
France	IRSN (2005). Protection of the environment: IRSN orientation. IRSN 2005-48
	Chapter 3 on the general strategy for NHB assessments proposed by the IRSN states that "The IRSN believes that an environmental radiological protection system must aim to preserve the structure and function of ecosystems. This will require consideration of 1) the biotic and abiotic compartments which form both the sources of exposure and the habitats of the living organisms, and 2) the interactions within and between these components". "The IRSN follows the approach adopted by the ICRP which aims to provide a degree of consistency between protection systems targeting the environment and that designed for humans". "The IRSN believes that it is essential that the method used to assess the risk to the environment from radionuclides should be consistent with that used for chemical substances. This consistency is all the more necessary as it is sometimes difficult to separate radiotoxicity and chemotoxicity in some particular cases of internal exposure".

Italy	Only information identified is in Italian. The following websites were identified and searched (where possible) for relevant information: o APAT - L'Agenzia per la protezione dell'ambiente (http://www.apat.gov.it//site/it-IT/) o Dipartimento della Protezione Civile (http://www.protezionecivile.it/) o ISS - Istituto Superiore di Sanità (http://www.iss.it/) o Ministero dell'Industria, del Commercio e dell'Artigianato (http://www.sviluppoeconomico.gov.it/) o MURST - Ministero dell'Università e della Ricerca Scientifica e Tecnologica (http://www.miur.it/DefaultDesktop.aspx)
Lithuania	Lithuanian Republic Ministry of Environment (2001). Limitation of radioactive discharges from nuclear facilities, permitting of discharges and radiological monitoring. Normative document of environmental protection of Lithuanian Republic, LAND 42 – 2001. The Republic of Lithuania Law on Radiation Protection, 12 January 1999 No. VIII-1019. (from http://www.rsc.lt/index.php/pageid/445) Law on Environmental Protection of the Republic of Lithuania, Parliamentary record, 1992-03-01, Nr. 3. from (http://www.rsc.lt/index.php/pageid/445)
	Lithuanian Republic Ministry of Environment (2001): "The objective of this normative document is to protect humans, other living organisms, natural resources (the land, forest, water) and other environmental entities from harmful influence of ionising radiation and contamination by radionuclides from nuclear installations." "Assessment of impact to the environment shall be based on principles according which protection measures ensuring an adequate safety for human are sufficient to protect both the environment and natural resources. In the case there are no population in the vicinity of the nuclear facility, a hypothetical critical group, members of which could live within this area, shall be considered." **Law on Radiation Protection**: "This Law shall establish the legal basis of radioactive protection allowing to safeguard people and the environment from the harmful effects of ionising radiation" Under Article 10, "A legal person or an enterprise without the status of a legal person licensed to conduct practices specified in paragraph 1 of Article 8 of this Law and conducting activities specified in the licence must: 10) in accordance with the procedure established by the Government or an institution designated by it, conduct monitoring of the impact on the environment;" **Law on Environmental Protection**: Article 2 - "This Law shall establish the main rights and duties of legal and natural persons guaranteeing: 1. the right of the population of the Republic of Lithuania to healthy and safe environment; 2. harmonic development of the interaction between the society and nature; and 3. the preservation of the species of animate organisms and their habitats." Under Article 8 – "State authorities, administrators, and inspectors, pursuant to their jurisdiction, must: 1. establish ecologically based standards of environmental protection which can be achieved by technological means, supervise their changes, and inform the public thereof;" Article 12 – "The objects of special utilization shall be: 1. protected territories: reserves of the state, national parks, regional parks, natural reserves, protective zones, and areas of local significance and special purpose; 2. the natural framework, identified and formed as the system of territories of ecological compensation, consisting of protected and other ecologically significant and

	sufficiently natural territories which maintain the stability of the landscape; and 3. natural monuments, species and communities of flora and fauna protected by the State".
Norway	Act on Radiation Protection and Use of Radiation (No. 36 of 12 May 2000) Regulations No. 1362 of 21 November on Radiation Protection and Use of Radiation (Radiation Protection Regulations)
	Act No 36: Section 1 details that "The purpose of this Act is to prevent harmful effects of radiation on human health and contribute to the protection of the environment." Section 5 provides that "All production, import, export, transport, transfer, possession, installation, use, handling and waste management of radiation sources shall be justifiable to ensure that risks do not arise to those performing any such activity, to other persons or to the environment." **Regulation No 1362:** **Section 1 – "**The purpose of these regulations is to ensure proper radiation use, prevent harmful effects of radiation on human health and contribute to the protection of the environment."
Poland	Act of Parliament of 29 November 2000, Atomic Law, Polish Official Journal of 2007 No 42, Item 276. (from http://www.paa.gov.pl/en/)
	Atomic Law: Article 2 – "Activities referred to in Article 1(1)(1) and Article 1(3) shall be permitted after undertaking the measures defined in appropriate regulations, aimed at ensuring safety and protection of human life and health, as well as protection of the property and environment." Under Article 7.1 – "Organizational entity conducting activities for which a licence is required, shall develop and implement a nuclear safety and radiological protection program, which includes at least the description of the equipment and procedures designed for protection of the worker, of general public and of the environment." Article 8.1. "Prior to the start of activities involving new types of ionizing radiation application, the head of organizational entity shall prepare a justification for the activity, which should demonstrate that scientific, economic, social and other benefits expected from this activity will prevail over possible human health detriment and damage to the state of environment resulting from this activity". Article 50. "Radioactive waste and spent nuclear fuel shall be stored in conditions allowing their segregation and in a manner ensuring protection of humans and environment".
Russia	Regulations available to purchase, but are in Russian – may be able to pay for translation
Scotland	The Environment Act, 1995 Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy
	The following are extracts from the **Environment Act, 1995**: Article 32 "General environmental and recreational duties

	(1) It shall be the duty of the Secretary of State and of SEPA, in formulating or considering any proposals relating to any functions of SEPA— (a) to have regard to the desirability of conserving and enhancing the natural heritage of Scotland; (b) to have regard to the desirability of protecting and conserving buildings, sites and objects of archaeological, architectural, engineering or historic interest; (c) to take into account any effect which the proposals would have on the natural heritage of Scotland or on any such buildings, sites or objects; and (d) to have regard to the social and economic needs of any area or description of area of Scotland and, in particular, to such needs of rural areas. (2) Subject to subsection (1) above, it shall be the duty of the Secretary of State and of SEPA, in formulating or considering any proposals relating to any functions of SEPA— (a) to have regard to the desirability of preserving for the public any freedom of access (including access for recreational purposes) to areas of forest, woodland, mountains, moor, bog, cliff, foreshore, loch or reservoir and other places of natural beauty; (b) to have regard to the desirability of maintaining the availability to the public of any facility for visiting or inspecting any building, site or object of archaeological, architectural, engineering or historic interest; and (c) to take into account any effect which the proposals would have on any such freedom of access or on the availability of any such facility." Article 33 "General duties with respect to pollution control (1) SEPA's pollution control powers shall be exercisable for the purpose of preventing or minimising, or remedying or mitigating the effects of, pollution of the environment. SEPA shall, for the purpose— (a) of facilitating the carrying out of its pollution control functions; or (b) of enabling it to form an opinion of the general state of pollution of the environment, compile information relating to such pollution (whether the information is acquired by SEPA carrying out observations or is obtained in any other way). (3) If required by the Secretary of State to do so, SEPA shall— (a) carry out assessments (whether generally or for such particular purpose as may be specified in the requirement) of the effect, or likely effect, on the environment of existing or potential levels of pollution of the environment and report its findings to the Secretary of State; or (b) prepare and send to the Secretary of State a report identifying— (i) the options which SEPA considers to be available for preventing or minimising, or remedying or mitigating the effects of, pollution of the environment, whether generally or in cases or circumstances specified in the requirement; and (ii) the costs and benefits of such options as are identified by SEPA pursuant to sub-paragraph (i) above. (4) SEPA shall follow developments in technology and techniques for preventing or minimising, or remedying or mitigating the effects of, pollution of the environment." Article 34 "General duties with respect to water (1) It shall be the duty of SEPA—

	(a) to promote the cleanliness of— (ii) rivers, other inland waters and ground waters in Scotland; and (iii) the tidal waters of Scotland; and (b) to conserve so far as practicable the water resources of Scotland. (2) Without prejudice to section 32 above, it shall be the duty of SEPA, to such extent as it considers desirable, generally to promote— (a) the conservation and enhancement of the natural beauty and amenity of inland and coastal waters and of land associated with such waters; and **(b)** the conservation of flora and fauna which are dependent on an aquatic environment." **Habitats Directive**: Article 2 states: 1. "The aim of this Directive shall be to contribute towards ensuring bio-diversity through the conservation of natural habitats and of wild fauna and flora in the European territory of the Member States to which the Treaty applies. 2. Measures taken pursuant to this Directive shall be designed to maintain or restore, at favourable conservation status, natural habitats and species of wild fauna and flora of Community interest. 3. Measures taken pursuant to this Directive shall take account of economic, social and cultural requirements and regional and local characteristics." Under Article 4 "Once a site of Community importance has been adopted in accordance with the procedure laid down in paragraph 2, the Member State concerned shall designate that site as a special area of conservation as soon as possible and within six years at most, establishing priorities in the light of the importance of the sites for the maintenance or restoration, at a favourable conservation status, of a natural habitat type in Annex I or a species in Annex II and for the coherence of Natura 2000, and in the light of the threats of degradation or destruction to which those sites are exposed." Under Article 6 "Any plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon, either individually or in combination with other plans or projects, shall be subject to appropriate assessment of its implications for the site in view of the site's conservation objectives. In the light of the conclusions of the assessment of the implications for the site and subject to the provisions of paragraph 4, the competent national authorities shall agree to the plan or project only after having ascertained that it will not adversely affect the integrity of the site concerned and, if appropriate, after having obtained the opinion of the general public." **Water Framework Directive:** Article 1 states "The purpose of this Directive is to establish a framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater which: (a) prevents further deterioration and protects and enhances the status of aquatic ecosystems and, with regard to their water needs, terrestrial ecosystems and wetlands directly depending on the aquatic ecosystems; (b) promotes sustainable water use based on a long-term protection of available water resources; (c) aims at enhanced protection and improvement of the aquatic environment, inter alia, through specific measures for the progressive reduction of discharges, emissions and losses of priority substances and the cessation or phasing-out of discharges, emissions and losses of the priority hazardous substances;"

	Under Article 16 “When necessary in order to meet the timetable laid down in paragraph 4, substances shall be prioritised for action on the basis of risk to, or via the aquatic environment, identified by a simplified risk-based assessment procedure based on scientific principles taking particular account of: o evidence regarding the intrinsic hazard of the substance concerned, and in particular its aquatic ecotoxicity and human toxicity via aquatic exposure routes, and o evidence from monitoring of widespread environmental contamination, and o other proven factors which may indicate the possibility of widespread environmental contamination, such as production or use volume of the substance concerned, and use patterns.”
Spain	All legislation identified is in Spanish. Web based translations are dubious.
Sweden	1988:220, Radiation Protection Act
	1 § The purpose of this Act is to protect people, animals and the environment against harmful effects of radiation “ (1998:1, regulation of final management of spent nuclear fuel) 3 § Human health and the environment shall be protected from detrimental effects of ionising radiation. 6 § The final management of spent nuclear fuel and nuclear waste shall be implemented so that biodiversity and the sustainable use of biological resources are protected against the harmful effects of ionising radiation. 7 § Biological effects of ionising radiation in habitats and ecosystems concerned shall be described. The report shall be based on available knowledge on the ecosystems concerned and shall take particular account of the existence of genetically distinctive populations such as isolated populations, endemic species and species threatened with extinction and in general any organisms worth protecting. (2005:5 guidelines on 1998:1). “When a biological effect for the identified organisms can be presumed, a valuation should be made of the consequence this may have for the affected ecosystems, with the view to facilitating an assessment of impact on biological diversity and a sustainable use of the environment”. “The organisms included in the analysis of the environmental impact should be selected on the basis of their importance in the ecosystems, but also according to their protection value according to other biological, economic or conservation criteria. Other biological criteria refers, among other things, to genetic distinctiveness and isolation (for example, presently known endemic species), economic criteria refers to the importance of the organisms for different kinds of obtaining a livelihood (for instance, hunting and fishing), and conservation criteria if they are protected by current legislation and local regulations. Other aspects, for instance, cultural history, should also be taken into consideration account in the identification of such organisms” (2005:5 guidelines). (2000:12 regulation of releases from certain nuclear facilities) 3 § Human health and the environment shall be protected from the harmful effects of ionizing radiation during the operation of a nuclear facility as well as in the future.
Switzerland	Nuclear Energy Ordinance (NEO) of 10 December 2004 (status as of 1 February 2005) (Not much of direct relevance, but quotes included below – bit of a reach) Nuclear Energy Act (NEA) of 21 March 2003

	From NEO: Article 23 requires that, for a general nuclear facility, applications for a general licence must be accompanied by (amongst others) an Environmental impact report; Article 45, in relation to decommissioning requires documentation to be submitted in relation to "measures to protect personnel against radiation and to prevent the release of radioactive substances into the environment" and an "environmental impact report" **From NEA:** "The aim of this Act is to regulate the peaceful use of nuclear energy. Its main purpose is to protect human beings and the environment against the hazards of nuclear energy." Article 4 of the NEA provides the following principles for the utilisation of nuclear energy: 1. "In the utilisation of nuclear energy, human beings and the environment must be protected against harm due to ionising radiation. Only harmless quantities of radioactive substances may be released into the environment. Special care must be taken to prevent the release of impermissible quantities of radioactive substances and to protect human beings against impermissible levels of radiation during normal operation and malfunctions. 2. Long-term impacts on genetic material must be taken into account. 3. In order to prevent harm to human beings and the environment, precautionary measures must be taken that: a. are required in accordance with experience and the status of scientific and technical knowledge; b. contribute towards an additional reduction of risk insofar as they are appropriate." Article 13 details the conditions that govern the granting of a general licence. "A general licence may be granted if the following conditions are met: a. the protection of human beings and the environment can be ensured; b. the granting of the licence does not conflict with any other provisions of federal legislation, in particular legislation governing environmental protection, preservation of local natural and cultural heritage, and spatial planning"
USA	National Environmental Policy Act (1969, as amended) Nuclear Waste Policy Act 1982 (as amended). Order DOE 5400.1 – General Environmental Protection Program, 11-9-88 Order DOE 5400.5 – Radiation Protection of the Public and the Environment, 2-8-90 DOE Standard: A Graded Approach for Evaluating Radiation Doses to Aquatic and Terrestrial Biota, DOE-STD-1153-2002, July 2002
	NEP Act: The purposes of this Act are: To declare a national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation; and to establish a Council on Environmental Quality. NWP Act and Subtitle A The purposes of this subtitle are (1) to establish a schedule for the siting, construction, and operation of repositories that will provide a reasonable assurance that the public and the environment will be adequately protected from the hazards posed by high-level radioactive waste and such spent nuclear fuel as may be disposed of in a repository;

	DOE 5400.1: “It is DOE policy to conduct its operations in an environmentally safe and sound manner. Protection of the environment and the public are responsibilities of paramount importance and concern to DOE. All DOE activities should recognize and reflect this concern and public trust. To that end, DOE is firmly committed to ensuring incorporation of national environmental protection goals in the formulation and implementation of DOE programs. It has an equal commitment to advance the goals of restoring and enhancing environmental quality, and ensuring public health. Accordingly, it is DOE policy to conduct the Department’s operations in compliance with the letter and spirit of applicable environmental statutes, regulations, and standards. In addition, DOE is committed to good environmental management of all its programs and at all its facilities to correct existing environmental problems, to minimize risks to the environment or public health, and to anticipate and address potential environmental problems before they pose a threat to the quality of the environment or the public welfare. Finally, it is DOE’s policy that efforts to meet environmental obligations be carried out consistently across all operations and among all field organizations and programs.” Article 6 “In recognition of the environmental significance of Departmental activities authorized by the Atomic Energy Act (AEA), this Order addresses and, of necessity, emphasizes requirements for radiation protection. It also is written to reflect the DOE organizational structure for operations that implement AEA activities. It is understood and expected that other DOE elements, e.g., power marketing administrations. will design and manage their environmental protection programs in such a manner so as to be equivalent to requirements contained in this Order and in compliance with applicable statutes and regulations.” Under Chapter 3, paragraph 2 details the requirements for an implementation plan – “Each field organization shall prepare a plan for implementing the requirements of this Order. An implementation plan shall be prepared for each facility or group of facilities, the purpose of which is to provide management direction, including assignment of responsibilities and authorities, to ensure that all DOE facilities are operated and managed in a manner that will protect, maintain, and. where necessary, restore environmental quality, minimize potential threats to the environment and the public health, and comply with environmental regulations and DOE policies.” Order 5400.5: “Purpose. To establish standards and requirements for operations of the Department of Energy (DOE) and DOE contractors with respect to protection of members of the public and the environment against undue risk from radiation.” “In addition to providing protection to members of the public, it is DOE’S objective to protect the environment from radioactive contamination to the extent practical.” “In addition to limiting dose to members of the public (onsite or offsite) to the primary radiation protection standards established in this Order and to the applicable limits of EPA and State regulations, additional controls on the release of liquid wastes are adopted to reduce the potential for radiological contamination of natural resources such as land, ground and surface water, and ecosystems.” “Interim Dose Limit for Native Aquatic Animal Organisms. To protect native animal aquatic organisms, the absorbed dose to these organisms shall not exceed 1 rad per day from exposure to the radioactive material in liquid wastes discharged to natural waterways.” DOE-STD-1153-2002: “The technical standard assumes a threshold of protection for plants and animals at the following doses: for aquatic animals, 1 rad/d (10 mGy/d); for terrestrial plants, 1 rad/d (10 mGy/d); and for terrestrial animals, 0.1 rad/d (1 mGy/d). Available data indicate that dose rates below these limits cause no measurable adverse effects to populations of plants and animals.”

Appendix 4b. Protection Goals, Methodology & Criteria for Environmental Protection from Radiation and Chemicals (detailed questionnaire responses)

Organisation & Country	Protection Goals	Methodology	Criteria
Radiological Regulator 1	Protect the **public and workers** from the risks resulting from ionising radiation Done in accordance with the international recommendations	Authorise and control all practices involving radioactive substances Monitoring and surveillance of radioactive contamination in the whole Spanish territory Models used to assess radiological impact on the public	Numeric limits are those specified in regulations and in accordance with international regulations Limits are set as effective dose Do not use non-numeric criteria
Radiological Regulator 2	Under Environmental Impact Assessment Law (UVP) **animals plants and the biological diversity** have to be protected on a qualitative basis UVP is mandatory in the licensing procedures of many projects	Methodology still to be developed Protection goals currently met through qualitative expert judgement	Only non- numeric criteria used - expert qualitative judgement
Radiological Regulator 3	Contribute to the **protection of the environment** There is a need to describe the protection goals in more precise concrete terms (in the regulations they are vaguely defined)	Environmental monitoring and reporting of discharges Onus on industry to perform risk analyses/characterisation with regards to environmental risks Approaches used generally not of advanced nature Plans to use ERICA methodology	Current authorisation numeric limits are only based on **human** radiological protection criteria e.g. calculation of doses to humans, BAT criteria
Radiological Regulator 4	**Specific species** at an individual level **All species** at a population level **Favourable conservation status**	R&D 128 and subsequent outputs Now subject to outputs from ERICA	5 μGyh^{-1} is used as a screening level at Tier 2 of R&D 128 40 μGyh^{-1} is used as screening level at Tier 3 of R&D 128. Action may be required if this value is exceeded
Radiological	Preventing	Analyse estimated	Do not use numeric

Regulator 5	**'unreasonable risk' to biota** is the legal objective Broader goals – protection of ecosystems, biodiversity, pollution prevention and sustainable development	individual exposure through multimedia pathways analysis using realistic-conservative models of exposure and a range of possible toxicity/dose benchmarks Rely on models in public domain FASSET, ERICA, US DoE	criteria in a prescriptive sense only in the context of ecological risk assessment: • Exposure to a contaminant is assessed relative to NOAELs and LOAELs • Critical Toxicity Value is derived with the application of a safety factor
Radiological Regulator 6	Protect **workers and members of the public**	Licence conditions, inspections, enforcement activities and guidance Risk assessments are primarily the responsibility of the licensee	Numeric limits are discharges authorised on the basis of risk analysis and doses in compliance with the BSS Directive (Directive 96/29/Euratom)
Radiological Regulator 7	Protect **workers, patients, the environment, the population and property**	Regulatory and guidance activities, authorisations, inspections, law enforcement	Numeric limits used are mainly maximum acceptable limits in accordance with ICRP recommendations, IAEA Basic Safety Standards, EURATOM Basic Safety Requirements Sometimes use qualitative criteria which characterise practices' or activities' performance
Radiological Regulator 8	**Humans and environment**	Evaluation of the radiological condition of the environment (radionuclide concentrations, dose burdens and compliance with specified norms) – models to assess dose burdens, risk assessments and spread of radioactive substances in the atmosphere, soil and water by foodchains	Criteria used is the numeric norms of radiation guaranteeing safety for workers and public Do not use non-numeric criteria

		Improvement of environmental condition Radiological situation forecasting techniques	
Radiological Regulator 9	Statutory responsibility to protect **Man** General duty to **monitor the environment for radioactivity** Have powers to **protect/remedy/mitigate the effects of pollution on the environment** Have duties for **conservation and enhancement of the natural beauty and amenity of inland and coastal waters**	Prospective and retrospective assessments of discharges and impacts Use of models listed as - R&D 128 for Habitats Assessments - RIMNET plume to predict concentrations - National Dose Assessment Working Group NDAWG models - NRPB/HPA models W63, small user assessments and PC Cream dispersion	1mSv for the public (lower limits for individual sites) 400μSv as a screening level for biota
Radiological Regulator 10	**Sustainable development,** protecting the **environment** in everything it does Protection of the environment is a side benefit and in the absence of evidence that other species are being harmed, using protection of the **public** means that environmental protection is also achieved	See SEPA response - SEPA does all the monitoring for radioactivity and it covers all environmental media and foodstuffs, the endpoints are more than just human	1mSv for the public (lower limits for individual sites) 400μSv as a screening level for biota
Radiological Regulator 11	Protect **people**, **animals** and the **environment** against harmful effects of radiation Note: Direct and more detailed quotes from legislation available	As existing regulated sites are not assessed directly for environmental effects no stipulated methodology is used. The upcoming final repository for spent fuel is a good opportunity for applying a relevant method. At present industry (SKB) are undertaking the first EIA	Do not use numerical limits regarding biota. For humans use calculated doses from controlled emissions should be lower than 0.1mSv/year to critical group from each nuclear facility Non-numeric criteria

		and SSI reviewing it (most likely by a parallel assessment to decide whether the methods, results and analysis are acceptable Models/tools in use are: • Transport models used by SKB • Other transport models developed in-house by consultants • ERICA tool	includes adequate biological diversity and biological resources
Radiological Regulator 12	In addition to the impacts on **man**, potential impacts on **species of fauna and flora** Specifically, disposal of spent fuel shall not cause decline in biodiversity or other significant detriment to any living population. Moreover, **rare animals and plants** as well as **domestic animals** shall not be exposed detrimentally as **individuals** Note: Direct and more detailed quotes from legislation available	Uses most relevant radiation and nuclear energy legislation (YVL guides) No specific models or tools concerning assessment of exposure to biota are used.	Do not use numeric limits Non-numeric criteria such as not affecting biodiversity are only used when looking at spent nuclear fuel`
Chemical Regulator 1	Specific protection goals are often unclear or very broad. Examples **include minimise risk, protect soil quality** or **protect soil fertility**	Soil screening values (using the TGD approach), air quality standards, water quality standards (future water standards to use TGD approach) Tiered risk assessment approaches which often make use of multiple numerical values e.g. upper and lower effect levels Models/tools used	EQSs are used for aquatic life. However, some water quality based EU Directives (e.g. the freshwater fish directive) have imperative and guideline values for a specific parameter Numerical values are commonly derived using safety standards though SSDs have also been used

		• EUSES • TGD • BLMs • SSD • Assessment Factors Methodologies used are in some cases more suitable for some types of chemicals than others e.g. often not as applicable to inorganics and pesticides	Some non-numeric criteria is used in consent setting for certain parameters e.g. *'discharge shall contain no visible oil or grease'* is often used in terms of regulation of emissions of oil
Chemical Regulator 2	Human health & environment with main focus on the **aquatic environment**	Regulations direct and indirect (classification and labelling of chemicals), discharge permits and control and supervision Limited use of tools – some in connection with off-shore sector	Use numeric criteria derived from test data based upon TGD and OECD guidance with safety factors in conjunction with NOAEL values Hopefully approach will be improved by REACH Do not use non-numeric criteria
Chemical Regulator 3	Protect the **ecosystem** (i.e. **all species** should be safe from chronic toxic effects of metals)	Setting up site specific criteria Modelling the outcome using different techniques of decreasing the discharges of metals from the mining residues Select techniques in accordance with BAT Control that the selected technique is modelled to keep concentrations below criteria Write conditions ensuring that BAT will be used	The numeric limits used are values three times that of background concentrations. These are checked to confirm that they are lower than literature values of PNEC regarding chronic exposure It is not clear how the PNECs in the literature were originally derived
Chemical Regulator 4	**Human health** and **environment**	Main tool for assessments of hazards and risks is the calculation of the PEC/PNEC ratio. Safety	Numeric limits used are for the classification and labelling of chemicals.

		factors depending on availability of reliable data are taken into account. If the ratio exceeds 1 the result calls for risk management measures to reduce the risk The model EUSES is used for performing calculations used by the assessments	Limits are also used for emission control and some biodegradation limits are established for certain product groups e.g. detergents Non-numeric criteria are defined as environmental monitoring and expert judgement which are used to prioritise activities to reduce risks Awaiting implantation of REACH regulation
Chemical Regulator 5	**Ecosystem structure and functioning**	Measure/model environmental concentrations and compare with derived 'safe concentrations' (through ecotoxicity tests). If ratio greater than 1 then reduction measures have to be taken	Numeric limits are used – PNECs are derived for several ecosystem compartments Numeric criteria derived mainly by safety factor though prefer the term 'assessment factor' or 'uncertainty factor' – there is no 'safety' guaranteed. In certain cases SSD have been used Non-numeric data is used when there is no or few data available or in the case of PBT substances. A qualitative assessment is done instead and based on ALARA and BAT principles Awaiting implantation of REACH regulation
Radiological and Chemical Regulator 1	Sustainable development whereby present and future generations will be guaranteed a healthy and	The court mainly deals with judgements concerning BAT. One base for the judgement is the	Numeric limits = EQSs

	good environment - the health of humans and the environment is protected against damage and nuisance, irrespective of whether these are caused by pollution or other influences) - conservation of valuable natural and cultural environments - preservation of biological diversity	use of environmental quality standards	
Radiological and Chemical Regulator 2	Prevention and limitation of detrimental effects and hazards resulting from the operation of basic nuclear installations (BNIs) and of inconvenience to the neighbourhood or for **public health**, safety and hygiene, **agriculture, nature** and **environment** protection purposes or for the **conservation of sites and monuments**	Impact assessments The impact is determined on the basis of the source term and reference groups identified in the impact assessment. These are homogeneous groups of persons receiving the highest average dose from among the population exposed to a given installation according to realistic scenarios. To assess the impact of the installation, other neighbouring industrial activities and all sources of exposure must be considered. This approach in particular allows comparison between the total dose and the annual allowable dose limit for the public.	Numeric criteria = 1mSv for human health Non-numeric criteria defined as ecological surveillance
Industry 1	**Humans and environment**	Existing guidelines on dose limits to the population Models calculations using IAEAs Safety Reports Series No. 19 and PC-	Numeric criteria used is for human critical groups. In the discharge authorisation the limits are set to 1 µSv per year for water and 100 µSv per

		CREAM	year for air. The dose limits for human protection are very low – this is believed to ensure environmental protection For the environment use ICRP recommendations
Industry 2	NRPA, NPCA, Petroleum Safety Authority, The Norwegian Labour Inspection Authority - **Environment** against negative/adverse effects In the context of environmental management the population probably represents the appropriate level of protection NPCA – protect nature's ability for production and self-renewal	For radiation - no methods available except for produced water reinjection For chemical – DREAM model (Dose related Risk and Effects Assessment Model). A 3D hydrodynamic model for simulating advection and dispersion of contaminants	For radionuclides - the numeric limits are set on a case by case basis in the discharge authorisations For chemical – there are standards specified in the regulations and discharge permits
Industry 3	NII – **workforce and public** Environment Agency – **public and wider environment (biota)**	Methodology used includes: - Specific impact models to improve understanding of the effects of radionuclides on the environment - Predictive tools - Flow sheet models for particular radionuclides	Numeric limits = authorisation values Non-numeric criteria not really used though biodiversity reviews are undertaken
Industry 4	NII – **workforce and public** from exposure to ionising radiations as a result of an organisation's operations and activities Environment Agency – **public and environment** from potentially harmful effects of an	Use a range of models to assess: • radionuclide content of materials and waste • long and short-term impact of discharges • doses to critical group	Numeric limits = activities and volumes of radioactive waste disposals and discharges Non-numeric criteria = minimising waste arisings using BPM

	organisation's disposal and discharges	• radioactive waste discharges and disposals	
Industry 5	HSE/NII – focus on protection of human health from ionising radiation (on nuclear licensed sites) Environment Agency/SEPA – focus on protection of human health and the environment (controlled waters and ecosystems/wildlife) from radioactive (off site) and non-radioactive contamination and discharges and for radioactive waste disposal facilities	For the environment – monitoring programme, assessment models and validation with any observed measurements if possible Models/tools used: • CLEA, SNIFFER, ReCLAIM (contaminated land assessment tools) • GoldSIM/AMBER (more process driven complex tools that model decay and the migration of contaminants • SimER (simulation of environmental risks – a new tool that models the source-pathway-receptor process • R&D128 • Will make use of ERICA	For radioactive waste disposal and post-closure assessments involving many thousands of years, then usually calculate an annual effective dose to the PEGs and through a dose-risk factor of 0.06 Sv^{-1} compute annual risk values for comparison to a risk target of 1E-6 y^{-1}. For assessments of impacts to non-human biota from ionising radiation, environmental concentrations are used to calculate absorbed doses to the various classes of organism. Future assessments will follow the ERICA methodology. Impacts to ecosystems from non-radioactive contamination will be assessed in line with the EA's framework for ecological risk assessment and Soil Screening Values (currently draft). Non-numeric criteria involves the concept of optimisation and demonstrations that impacts are As Low As Reasonably Achievable (ALARA)

Industry 6	NII - protection of **people** Environment Agency – focussed on protection of the **environment**	Methodology used includes: • Authorisation limits • BPM • Best Practicable Environmental Option Studies • Environmental Impact Assessments • Environmental monitoring programmes Models used: PC-Cream and Microshield (to make dose assessments to workers and environment); Source-pathway-receptor models (to assess impacts to contaminated land)	Radionuclide discharges to air, water and solid waste disposals under RSA authorisations
Industry 7	CNSC – **'unreasonable risk to the environment'** at the population/ecosystem level, with the exception of Species at Risk, which are protected at the individual level Ministries of the Environment – **environment via water and air quality objectives** DFO (Fisheries and Oceans Canada) – **no deleterious substances in fish habitat, no harm to fishes or to fish habitat** Environment Canada - **Species at Risk, regulation of non-radiological toxic substances** Provincial Environmental	ALARA principle of management, environmental and ecological risk assessment and design of mitigation measure, routine effluent and environmental monitoring to verify compliance, implementation of special study and follow-up programs Air models IMPACT and AIRMOD are used as well as consultant models consistent with international protocol for Ecological Risk Assessments Canadian Standards Association guidance is used for 'derived release limits' calculations for the protection of humans Toxicity testing is used for compliance purposes	Numeric limits are used often in a tiered approach. Limits are internal, administrative and regulatory - Tier 1 screening has conservative benchmarks = NOAELs - Higher tier screening has more realistic benchmarks = LOAELs, EC20s etc) The Ontario MISA Regulation (Municipal/Industrial Strategy for Abatement) uses toxicity testing for Daphnia magna and rainbow trout Non-numeric criteria is also used for risk

	Protection Acts – **Management of provincial contaminated lands**		assessment (but not for compliance). These include: - Reversibility of an effect - Presence of a potential contaminant source - Professional judgement/experience - Public perception - Stakeholder interest - Preservation of ecosystem integrity - Human aspects to risk assessment
Industry 8	SSI, county administrative boards and environmental courts aim to protect **populations**. Special attention is given to **endemic species** and other **species with high protection values**. The approach used is more directed to species compared to Agenda 21 which is also points to ecosystem functions and sustainable development	Site specific ecosystem modelling to achieve concentrations of radionuclides in environmental media and in different organisms • Dose rates are calculated using DCCs taken from FASSET and ERICA • ERICA tool has been used at Tier 1 in the SR-Can safety report regarding final waste repository	Uses the ERICA screening value of 10μGyh-1 Also aim to highlight any releases which give a dose rate greater than 1/500 of that from background
Industry 9	SSI, SKI, Environmental Protection Agency, Regional County Board and the Environmental Court set the protection goals as **man, domestic animals and the environment**	BAT applied to minimise release of radionuclides into the environment. Regulations from SSI (thought to be based in ICRP 60 statement)	No numerical limits are specified as thresholds of passing or failing. However, data from environmental monitoring programmes on concentration levels may be ranked as 'benchmarks' for ecological surveillance (>30 years)

Industry 10	STUK – **biota and habitats** in general. Specifically **biodiversity, populations and individuals of rare and domestic biota**	ERICA approach It is intended that the adapted ERICA method will be incorporated into the Pandora tool that provides a box-model approach	Do not use numeric limits. Comparison is against qualitative and effects data
Industry 11	ASN, Nuclear defence installation authority, DRIRE – the **workers** and the **public** and therefore environment according to the ICRP 60 principle	Perform discharge measurements and environmental monitoring CEA models foe atmospheric and liquid releases in the context of normal or accidental situations	Numeric limits = discharge limits and the dose limit for public Non-numeric criteria is not used
Industry 12	ASN (French Nuclear Safety Authority), DRIRE for ICPE and DSND for national defence installations – all trying to protect the **workers** and the **public** and therefore the **environment** according to ICRP 60's principle	Take discharge measurements, assess radiological and chemical impacts by calculation from annual discharge statement, local data (e.g. weather conditions, dietary habits), recognised data and methods Tools = IRSN tools and databases (COTRAM, ECRIN) and GRNC tools (ACADIE software for La Hague site)	Numeric limits = discharge limits and dose limit for public
Industry 13	ASN – **humans** and the **environment in the 'global' meaning of the term**	Environmental Impact Assessments Radioactive monitoring and ecological surveillance Dispersion codes and transfer models for radionuclides in the various components of the human food chain – it is planned to adopt an integrated software program called SYMBIOSE in 2008 For chemical – also run SSDs to estimate PNEC and the code 'OURSON' to	1mSv per year for public In terms of the environment-chemical = PNEC radiation = implicit Non-numeric criteria = ecological surveillance

		calculate health impact/risk	
Industry 14	HSK (Swiss Federal Nuclear Safety Inspectorate – focus on **humans** and the **future availability of resources**	Ensuring safe disposal No specific tools used for the protection of non-human biota	Numeric criteria used are the limits for human protection
Industry 15	Environment Agency, SEPA, Scottish National Heritage, Natural England – **environment in total but people in particular**	Monitor discharges, use BPEO, BPM, comply with authorisation and monitoring and use of ERICA assessment tool	Use discharge limits
Industry 16	Ministry of Industry – **people at work**	Occupational risk assessments	Concentrations in the work environment
Industry 17	ARPANSA (radiological) and Australian Federal Government (non-radiological) – **people** and the **environment**	Controlling discharge releases and monitoring Tools = PC-cream for estimating airborne dose to humans Emergency response software (ERAIMS) for near real-time modelling of airbourne plumes Have developed methodology using a combination of FRED, R&D128 and AQUARISK to assess risk to non-human species Plan to use the ERICA assessment tool	Use human dose based radiological limits for airborne radioactive releases
Industry 18	Ministry of VROM (Housing, Spatial Planning and Environment) – protection of the **human population** and **workers**	Based on impact of emissions Tools = PC-cream, NUDOS (Nuclear Doses Calculation based on the National Atmospheric Dispersion Model), 3D Dispersion models (for chemical pollutants), THREETOX and COASTOX for specific studies. Also POSEIDON for the marine environment, LAKECO for lake ecosystems and NRG	1 mSv per year for the public.

		coastal model made for the North Sea coast	
Advisory 1	Numeric criteria used for **human critical group** and **environment**	Existing standard on dose limits to the population. Models calculations using IAEA Safety Report Series No.19 with setting up site specific criteria with statistical approach Site specific ecosystem modelling for radionuclide concentration assessment in environmental media and different organisms. ERICA tool has been used at Tier 1-2.	1 mSv per year for the public. Lithuanian Hygiene Standard HN73 :2001. 0.2 mSv per year dose constraint in the vicinity of Nuclear Energy Objects (NPP & radioactive waste discharges) Lithuanian Hygiene Standard HN87: 2002
Advisory 2	Protection of **humans**	Use monitoring programmes and in the case of unusual findings estimates of dose to humans	Do not use numeric limits
Advisory 3	Natural state of **aquatic ecosystems** within the Chernobyl nuclear accident zone	Long term radioecological monitoring	Numeric criteria used = maximum permissible activities of radionuclides in water and food products as adopted by government

Expressed opinions

Radiation	
Protection Goals Regulatory	We currently use the following interim framework for major decisions to be as clear as possible, without being prescriptive, on what is to be achieved: "*An effect on biota will be deemed significant when a risk quotient greater than 1 is predicted to occur over a proportion of habitat or home range such that a decline in a regional population may occur. An adverse effect on biota would also be determined to be significant if recovery of a local population would not occur within several generations after removal of the source of contamination.*" The general requirement of the nuclear energy legislation that environment must be protected can be seen as a goal which is certainly valid target but does not help in actual concrete assessment of the activities or setting limits to radioactive releases. Therefore, the existing explicit requirements concerning reactor waste and spent nuclear fuel can be expected to be models or starting points of the thinking in setting radiation protection goals also in other contexts. It can be also expected that environmental goals of radiation and nuclear energy legislation are viewed more and more in light of the goals presented by environmental protection and nature conservation legislation since this legislation has been developed only relatively recently. On the other hand, the evolving international views on the need to explicitly address protection of the environment and the methods

	developed may increase the activities to specify the present very vague goal of "protecting the environment".
Protection Goals Industry	Still believe though, if look after humans you look after wildlife so would be concerned if the regulations got too detailed (in the UK there are hardly any places with no people). We take seriously any acute effects on the wider environment –signed up to avoiding release of toxics which would destroy habitats. It is sometimes difficult to demonstrate protection at a population level and so there is a tendency to look at individual risk. Too much focus (i.e. disproportionate effort) is being placed on radiological risk where impacts are typically not found to be significant. The definition of biodiversity as a protection goal has not been fully defined and a means of ensuring compliance with this criteria is difficult since biodiversity is difficult to measure. There are also issues prevailing with the available assessment methodologies.
	• The goal to protect populations is relevant. Also regarding species that are endemic, protected, or have other high conservation values, protection of populations should be the starting point. This *might* lead to a conclusion that individuals of this species need to be protected, but it is not necessarily so. • There is a problem with conservation of species on a site over time as there might be a natural dynamic of species turning up on site and disappearing again with no coupling to any discharges of radioactive substances This has to be acknowledged.
Methodology & Criteria regulatory	Total dose matters irrespective of origin: NORM, TeNORM or artificial radionuclides. Natural background should be taken into account. If natural background is of significance, the anthropogenic increments should be regulated.
	NORM, TeNORM or artificial radionuclides should not be treated differently from each other and our regulatory practice is not to distinguish between these categories.
	Have concerns about use of SSD approaches to derive criteria, but in all honesty have not had the time to critically review the use of this approach for biota and radionuclides. Experience with a similar approach in developing LEL and SEL criteria for benthic invertebrates indicated many pitfalls in using these sorts of statistical approaches even with a "large" database of relevant data. Due consideration needs to be given to the quality of the data, and the stability and sensitivity of the derived criteria under different assumptions or for different subsets of data. A rigorous analysis may simply not be possible at present. Similarly, the use of statistical techniques such as bootstrapping for simulating stochastic effects may not help resolve this generic issue if the quality of the data is poor overall (dosimetry, duration, exposure conditions in general), or the data are inherently biased (e.g. mostly laboratory studies on endpoints that are not relevant or on species that are not relevant).
Methodology & Criteria	We do not know the reasoning behind the numerical limits. The reason for the difference in dose limits for discharges to air and to water is unknown to us and

Industry	we think it illogical
	Impacts of physical stressors (thermal effluents, impingement, entrainment) are important, but difficult to quantify in a meaningful way. Details on fish populations are often not known, making an analysis of the impact of individual facilities difficult. Other factors, such as over-fishing, can over-complicate such assessments.
	There are many confounding factors that make it difficult to determine the impact of a single industry. These include: • Other industry in the vicinity; • Urban area effects; • Climate change; • Combined effects of these other factors (synergistic effects); • Activities, such as over-fishing; • Natural spatiotemporal and geographical variability in populations; and Other factors.
	• It is still unclear how the screening value of 10 □Gyh-1 was derived. The statistical evaluation of the 10% effect on each species, and the 5 percentile on the SDD are understandable. But the safety factor of 5 that is applied on this figure is not explained. • 10µGy/h might be OK for screening purposes but it needs to be clear that higher dose rates might be acceptable when a thorough site specific assessment is done • One should also consider the relation between effects on individuals and on populations which might constitute a "safety factor" in itself. There needs to be more discussion on the relationship between effects on individuals and the resulting effect on the population. • There might be other relevant studies than those currently included in the derivation of the screening value that should be included. • One problem with the ecotoxicology test is that e.g. *Daphnia* virtually is one individual rather than a population of individuals. It should be noted that a biological population is the genetic population not the statistical group of related or unrelated number of individuals.
Chemical	
Protection Goals Regulatory	Should be greater involvement of stakeholders in defining protection goals. One approach being discussed is the use of Multi Criteria Decision Analysis (MCDA)
Protection Goals Industry	The protection goals are relevant. Effects might not be expected from the levels of radiation exposure under the operating regime, nevertheless monitoring is important. There is a question as to whether radiation effects are irrelevant within a context in a wider environmental impact assessment. If a low level of discharge/radiation does not harm the environment a few meters away from the discharge point, there is no need for a strict regulation. Risk models and adequate monitoring can give sufficient information.
Methodology & Criteria	PNECs are generally derived using a safety factor approach due primarily to a limited dataset. Where sufficient data is available SSDs can be used to derive the

Regulatory	PNEC. The TGD provides guidance as to data requirements for derivation of the SSDs and gives guidance in general on the derivation of PNECs. SSDs have been used for a small number of chemicals where data has been sufficient – led to some discussion e.g. the potential for the data to be skewed due to the specific mode of action of the chemical, e.g. bisphenol A. The safety factor approach provides a level playing field when data sets are consistent, e.g. specific alga, invertebrate and fish but where data are available on a wider range of species there is the potential to vary these factors since more sensitive species may be available which would mean substances with more data are penalised. Assessment factors are empirically rather than statistically derived which is why the use of SSDs was introduced where datasets are sufficiently large to allow their use. Both approaches are generally accepted as good approaches with pros and cons associated with each. One of the concerns with SSDs is that by using the 95%ile then saying will protect 95% of the species but not the remaining 5% - some concerns over this philosophy. In general EU regulators prefer a safety factor added to justify total protection, though in principle a safety factor of 1 could be applied
Methodology & Criteria Industry	Some problems with the SSD approach. Not always is data distributed as is assumed in the statistical evaluation. There is a need to treat the exposure in a statistical way as well which is not always done. There is a problem with the 5% species which is assumed to be affected, which species are these? Could whole ecosystem functions be relying on these?
International organisations & Advisory opinions	
Protection goals	Our study looking at legislation (i.e. not actual practice or policy) did not identify clear environmental protection goals. Legislation gives quite general directions e.g. to 'protect the environment', to 'protect ecosystems' etc. Even where legislation appears quite strict, it may not be as strict as it appears. For example, the United Nations Convention on the Law at Sea may say that pollution must be stopped but pollution is defined as a substance that causes harm (so what is harm...). Note also that the same instrument discusses exploitation of sea bed resources and fisheries which could be regarded as harming the environment. Sustainable development is potentially a goal but it is rather anthropocentric and is open to wide interpretation (and was almost certainly taken up this way). Generally, regulation boils down to a trade-off between costs and benefits. An exception is certain Australian legislation ([Federal] Environment Protection and Biodiversity Conservation Regulations 2000) which sets numerical criteria.
	The strongest driver from EU law is the habitats directive - achieving favourable conservation status. Primarily in 2 areas; maintenance of habitats with reasonable populations of species and at sites protecting rare species of low population.

	Generally, the level of protection provided for humans must be greater than that for animals, if 1 in a 1000 human died this would be perceived as unacceptable but 1 in a 1000 sandpipers would not have a big impact. However, for rare species the protection of individuals becomes very important and this driver needs to exist in EU law. Regulations need to apply on a site to site basis and take account of differences in species between locations.
	Refer to the protection goals of OSPAR and London Convention. - long-term protection of the environment (using sustainability criteria)
Methodology	George Brownless has reservations about the use of background as a basis for standard setting (might live in an area of low background but might still not like the local nuclear installation being able to discharge more radioactivity than in a high background area!). Thinks that the spatial aspect is one that needs to be more fully considered; only aware of its use for Major Accident Hazards to the Environment (for the COMAH regulations in England and Wales)
	Should be: • Cessation of discharges, emissions and losses • Avoidance of dumping of wastes at sea In other words, act as far as possible 'upstream' rather than trying to intervene in the environment OSPAR uses tools to identify and prioritise hazardous substances and their uses, and could apply similar to radioactive discharges ('deal with the worst first'). London Convention has the de minimis guidance and requirements for specific assessment tools to be applied when something is not clearly de minimis. This guidance also implies application of the precautionary approach, which could also be seen as a tool.
Criteria	For numeric studies our studies found that, by and large, large point sources have strict controls on their discharges. These will include numeric limits. Environmental quality standards tended to be 'softer' and less routinely applied, particularly in the case of radioactive substances. In general, in radiological protection, 'optimisation' is the key principle; in this context there is an emphasis on numerical criteria to help optimisation rather than on 'hard' limits. For non-numeric criteria George states 'I have seen an example of this, which confirmed my impression that it probably has limited use as a tool for monitoring the effects of radioactivity. The main problems are: finding a suitable 'control' ecosystem; that a significant effect is only likely to come from (unacceptably) large discharges and; even given these two points, it might be difficult to attribute harmful effects to radioactive discharges (as opposed to other contaminants/stressors). I'd suggest that such approaches form an overall 'health-check' for a system and would be appropriate for looking at total/combined stressor effect.'

	Numeric limits, particularly on discharges are the ideal way to regulate - operators can't operate without a number! However it may not be possible to use numbers through the whole system. For example, there may be a very rare species present with little or no information available. There is an obligation to ensure that the species is OK and the limits must be revised if the negative impact on the species is seen to be too large. Upper limits with target values should be used for single contaminants, expressed to the operator that they should achieve x but cannot discharge more than y. Complicated limit values appear to work well, discharge no more than z in a year or x in any one day. There could be a non-numerical generalised condition. Under the EU Habitats Directive there are non-numerical limits which member states must abide to. If something happens to a protected species in the UK, the UK would be liable even though it may not be directly regulated under UK law.

Appendix 4c. Methods for demonstration of compliance

Regulator responses
Routine monitoring of releases
Monitoring and surveillance programmes
Risk analysis for practice activities
Screening investigations, monitoring and enforcement
Assessment, validation and dose response relationships
Dose assessments and surveys
Inspection and enforcement
Legal requirements for emergency preparedness, the reporting of radiological incidents and accidents and appropriate countermeasures
Biological investigations (e.g. trout population dynamics) and monitoring
Monitoring concentrations and assessment of fauna and flora
Monitoring concentrations and biological parameters
Monitoring for focus of surveillance activities
Assessing condition of the environment
Monitoring and biological surveillance
Industry responses
Environmental monitoring and biological surveillance
Environmental monitoring and ecological surveillance e.g. fish populations
Risk assessment, monitoring and control of emissions of effluents
No requirements so no need for demonstration
Protection of humans
Authorised limits, monitoring programmes and modelling
Keeping to authorised limits and monitoring the environment
Minimising discharges and comprehensive environmental radioactivity monitoring programmes
Extensive environmental monitoring programmes, keeping to authorised limits, minimising discharges
Do not need to demonstrate protection of the environment
Monitoring, BPM, complying with authorisation and ERICA assessments
Compliance with authorisation and discharge limits, expert judgement and environmental monitoring programmes
Probablistic model calculations of dose/risk to humans primarily and qualitative arguments
Periodic measurements on releases within the environment
Assessment results compared against qualitative regulatory criteria
Discharge permits, best tools and techniques and environmental monitoring
Protection of humans and ERICA methodology

Appendix 5. Flexibility in regulatory approaches (detailed questionnaire responses)

Organisation	Flexibility	
	In setting criteria	**In implementation of the regulatory process**
Radiological Regulator 1	Flexibility is possible provided compliance with the EU regulations	The regulatory process could be changed but it must be carried out within the laws and regulations (and always within the EU regulations)
Radiological Regulator 2	To some extent	To some extent
Radiological Regulator 3	Relatively flexible in comparison to EU member states. The Economic Free Space agreement allows Norway to opt out of selected clauses within EURATOM regulation	Great flexibility. The relative 'vague' statement to protect the environment gives room for flexibility for regulators to interpret the statement
Radiological Regulator 4	Very flexible as framework is our own and set up to our discretion	Very flexible
Radiological Regulator 5	Staff have the legal mandate as an independent regulator to set criteria in licences for radionuclides released to the environment (e.g. CNSC licences could include Ra-226 limits that are lower than those in the Metal Mining Effluent Regulations, if they were justified). However, the CNSC has made a commitment to "co-operate with other jurisdictions to protect the environment". In practice, this means that significant consultation occurs before adoption of any new criteria. Also, when criteria are available through authoritative international consensus, it is rare for the CNSC to adopt other values, unless they have been proposed for a specific Canadian context by other federal or provincial authorities.	Have the responsibility for the licensing process under the Nuclear Safety and Control Act, but there is significant participation by other federal, and sometimes provincial, authorities during the environmental assessment process under the CEAA prior to licensing. The CNSC is the responsible authority for environmental assessments, but may act in a joint capacity with other federal or provincial authorities.
Radiological Regulator 6	Compliance with national legislation is the bottom line	Compliance with national legislation is the bottom line
Radiological Regulator 7	Very limited	Not applicable
Radiological Regulator 8	It is necessary to use scientifically substantiated data which must be verified by experts and discussed in detail from every point of view. It is also possible to use expert assessment technique	[no comment given]
Radiological Regulator 9	No flexibility in using the 1 mSv for protection of the public. However, there is some flexibility in the use	The regulatory process is often broadly controlled by statute such as consultations. However, modification

	of threshold values when used in a screening tool, it is largely dependant on site specific issues and whether the assessment is a screening assessment or a detailed site assessment. If a detailed site assessment is being undertaken there may be a need to have flexibility in setting the criteria.	to the implementation of the process can be made on a site by site basis.
Radiological Regulator 10	[See regulator 9]	[See regulator 9]
Radiological Regulator 11	Can be very flexible in this process	Can be very flexible in this process
Radiological Regulator 12	At the moment there is much flexibility due to no international criteria or guidance	The legislation and the practices adopted guide the implementation
Chemical Regulator 1	Less flexibility than we used to. The methodologies for waters tends to be very prescriptive	Some flexibility as can use the implantation stage to 'tweak' the criteria
Chemical Regulator 2	Little	None
Chemical Regulator 3	Has some flexibility to set own criteria based on what they find most appropriate. This is however, done with stakeholder involvement	The process with stakeholder involvement and EIA is fairly well described in the environmental code so the flexibility is lower in that sense
Chemical Regulator 4	Involved in the setting of criteria by commenting on proposals for new legislation and by participating as expert advisors in political negotiations	As supervising authorities we have some flexibility in applying non-numerical criteria.
Chemical Regulator 5	There is always some expert judging on how to treat data or which data is to be included	This is done in cooperation within the EU. So the flexibility is given by the possibility to influence the EU.
Radiological and Chemical Regulator 2	Not involved in setting criteria	There is flexibility in the process but each regulation is stringent

Appendix 6. What works well in regulation and what could be improved (detailed questionnaire responses)

Organisation & Country	**What works well? Benefits of regulation**	**What areas could be improved?**	**How could these areas be improved?**
Radiological Regulator 1	The environment radiation surveillance is working properly	Aspects related to exposure to natural radiation could be improved	By being more specific about the responsibilities of the concerned parties
Radiological Regulator 2	It seems to work well	[No comment]	No experience [in setting criteria] yet
Radiological Regulator 3	Authorisation process; data collation has operated satisfactorily, relevant contacts have been established with few problems	International harmonisation is desirable. More precise criteria and guidance is required. Furthermore, there is room for improvement in the way industrial data are used and in the underpinning scientific data for evaluation (e.g. data gaps in effects from chronic, low level irradiation of plants and animals)	Further improvement in the data underpinning impact assessments could be attained through analyses of the available data and targeted studies to address data deficiencies. This is being carried out, to some extent, through projects like the EU funded project ERICA. The ICRP and other international groups (e.g. IUR) may need to provide guidance on where further studies are required to underpin assessments in a robust manner
Radiological Regulator 4	The system works well and gives a good degree of assurance that we are protecting biota this is because it is tiered, pragmatic, conservative and practicable	Need to fill in the gaps regarding dose response for various wildlife groups. Good to start with the ICRP reference animals and plants as this would help us to put 'corners' on the assessment	[No comment given]
Radiological Regulator 5	Ecological Risk Assessment when conducted on a quantitative, realistic-conservative basis with a harmonized approach to both nuclear and hazardous substances is a useful framework for providing context and detailed information	There is far too much uncertainty in dose benchmarks for ecologically-relevant individual-based endpoints and for relevant Canadian species; similarly there is almost no information on criteria for useful population endpoints.	Ecological theory needs to be included as a component of risk assessment for biota since protection of populations appears to be the ultimate goal of most organizations. However, this will be a worthless exercise

	for decision making. A weight-of-evidence approach has been sufficient for regulatory purposes as protection of biota (for radionuclides) has rarely been the trigger for difficult licensing decisions. Simple considerations of pollution prevention and protection of human health have greatly limited exposure of biota to radionuclides. Hence, there are some doubts about the need for a sophisticated system of radiation protection for biota if generic principles of environmental protection are simply adhered to	There is similar uncertainty in exposure, which is typically based on model estimates rather than measured values. Lastly, there has been a disproportionate investment of time in improving biota dosimetry to obtain precise dose estimates for organisms. This does not make sense when effects and exposure in real-world situations are very poorly quantified	until individual-based exposure estimates and dose benchmarks are more precise. To obtain precision will require research, preferably field research. Considerable insights may be possible from the study of contaminated areas, but some of the experimental approaches used in the 1970s and long since forgotten will also be useful. Regardless of the emphasis placed on laboratory versus field studies, the key to reducing uncertainty is to design studies that are “relevant”
Radiological Regulator 6	[No comment given]	[No comment given]	[No comment given]
Radiological Regulator 7	[No comment given]	[No comment given]	National assessment with international aid of the ‘peer review’
Radiological Regulator 8	[No comment given]	[No comment given]	[No comment given]
Radiological Regulator 9	RIFE works well and is broadly understood	Environmental Quality Standards for radioactive substances which would allow direct comparison with other environmental stressors to determine which is the key stressor on any environment. An integrated assessment of all stressors on a system would be the only manner to determine whether a complex pollutant, chemical, physical and radiological could have an effect on a system even if all three values are below any given	A tool for integrated stressors

		threshold	
Radiological Regulator 10	[No comment given]	Exemption orders could be improved (they are currently under review).	The review will hopefully shed light on this
Radiological Regulator 11	[No comment given]	[No comment given]	[No comment given]
Radiological Regulator 12	[No comment given]	[No comment given]	[No comment given]
Chemical Regulator 1	Development of greater transparency in decisions for the more recent standards e.g. under WFD	One area is the notion that a standard is not a singe number and that there is much additional information required to make sure that the standard is able to be implemented Transparency and auditability could be improved, especially in relation to historical standards where significant financial decisions may be made on the basis of the standards but the background to their derivation is unknown Cost-benefit considerations could be improved	Use of Multi Criteria Decision Analysis (MCDA) as part of the technical assessment could help improve cost benefit issues
Chemical Regulator 2	[No comment given]	The process of risk assessment, classification and labelling is slow	REACH
Chemical Regulator 3	The systems and the tools to regulate through the environmental code is OK	What might be lacking is resources in the form of competence and time at the authority	[No comment given]
Chemical Regulator 4	The resources allocated to chemical management are limited but used efficiently. The National Programme on Dangerous Chemicals is an effort to focus and prioritise activities and further improvements	[No comment given]	[No comment given]
Chemical Regulator 5	[No comment given]	[No comment given]	[No comment given]

Radiological and Chemical Regulator 1	The procedure to decide on permits based on BAT, in general, works well	[No comment given]	[No comment given]
Radiological and Chemical Regulator 2	The integrated approach for each installation	1) The level of integration could be enhanced with the support of BAT and by an in depth synthesis of the lessons learnt from all the nuclear installations of the nuclear cycle 2) The issue of the impact on the environment per se while performing research to fill in gaps	[No comment given]
Industry 1	Limits are necessary and authorities have to demonstrate control. What works well? – Act and regulations on radiation protection and use of radiation	The Norwegian atom energy act should be updated. Discharge authorisations	Better communication and collaboration between operator and regulator
Industry 2	Chemicals: In general works well – where an effect has been seen for a given discharge, regulation has been an effective tool to reduce levels Radionuclides: Quite newly regulated so too early to evaluate results	More contact between authorities and industry. Predictable framework with constant objectives. Harmonisation of all discharge authorisations	Cooperation and collaboration between the authorities
Industry 3	Sound regulation that is proportionate is key to success of industry. Do not advocate either self regulation or straight jacket. If have informed regulation can have discussion (ability to have dialogue)	Concentrate on discharges most significant to the environment	Looking to reduce the number of limits and the complexity of the system. At this level do we really need a whole set of numbers or just guidance?

	What works well? – A numerical system • Easy to manage • Procedures more easily set up for a numerical system than implementation of best practice		
Industry 4	Benefit is that discharges to the environment are controlled and minimised and the impact assessed What works well? – Good working relationship with the regulator	Clearer Exemption Orders and a deminimus level for liquid wastes	The Exemption Order review is currently underway
Industry 5	Environmental discharges from nuclear installations	Ecological assessments need further development (Traditionally it has been considered that protection of human health will automatically ensure protection of the environment. This view point is being increasingly challenged with, e.g. increasing requirements for nuclear licensed sites to consider impacts to non-human biota and controlled waters, however, such assessments are still in their relative infancy)	Increasing recognition of the importance of considering impacts to environmental receptors will lead to improvements in assessments undertaken. However, there is a need to recognise all of the issues associated with ecology and biodiversity and address these issues more in a systematic manner. There are also data issues to be addressed such as missing dose per unit concentration values and the adequacy of concentration ratios (organism: media) used
Industry 6	Regulation ensures that the environment and people are protected. Public relations are improved by the nuclear industry being seen to	In some cases, there is room for improvement in the relationship between inspectors/regulatory bodies and the site operator as views of one	Clearer guidance & better communication between the NII and the UK environmental regulators

	be under scrutiny from regulators. Auditing by regulators can help to identify improvements What works well? – The relationship that is established between nuclear site operators and their site inspector, if a positive one, can have a positive impact on the way the regulations are applied and can assist in pragmatic regulation being carried out.	party can sometimes be too detached from that of the other. There is also room for improvement in the clarity of procedures for compliance e.g. guidance, from the regulator	
Industry 7	Yes, regulation is beneficial when the level of regulation is commensurate with the level of risk. In addition, benefits are gained through oversight by an independent, external body in terms of building credibility with the public and demonstrating protection using a transparent process. In terms of what works well: • Ecological Risk Assessment for screening contaminants for risk • Monitoring of effluents and the environment to ensure compliance and responsible management of releases	Great benefit would be gained from the development of a comprehensive guidance document to address details that would be required to demonstrate compliance. For example, when contaminant risk is shown to be low through ecological risk assessment or after measures have been taken to remediate historical areas of concern, a process to reduce emphasis and monitoring requirements is needed, so that resources may be focussed on the highest priorities (i.e. that are commensurate with risk)	Through development of criteria to re-evaluate environmental conditions and corresponding requirements to track environmental performance

Industry 8	Benchmark values are useful in that you get something to compare with and relate to. Regulations gives the industry a chance to show compliance to environmental protection criteria	[No comment given]	[No comment given]
Industry 9	Would find it useful if there was a system available that more directly could show that the environment is protected, provided that this system is based on sound science and societal concerns. The method proposed within ERICA therefore needs to be independently evaluated and reviewed by scientists and experts with knowledge in predominantly radiation biology and dosimetry. At present there is a limited amount of scientists active in the environmental field and to increase the creditability it is necessary to bring in “new experts”	[No comment given]	[No comment given]
Industry 10	Provides clarity compared to broader protection goals	More guidance could be provided on how population and biodiversity level effects should be assessed/evaluated	Unsure or improvements would have been made
Industry 11	Clear and simple rules, implemented by well accepted and validated methods taking into account local particularities (i.e. local population and environment)	Better balance between challenge and allocation of resources	[No comment given]
Industry 12	Clear and stable rules	Better balance between	[No comment given]

	with specific application taken into account i.e. local setting/population	protection objective and allocation of resources	
Industry 13	Benefits – public acceptability, the transparency of the process and the public understanding of the criteria that are applied What works well? – Same approach used as that for chemicals and human radiological protection	A reasoning and the associated knowledge concerning the definition of a BAT which could be done at European level	A common database in Europe
Industry 14	The current approach is considered to provide environmental protection through protection of humans (nb. this is specifically related to waste repositories). Repository plans ensure that non-human biota will not be exposed to a greater degree than humans	It would be useful to have guidance on the inclusion of non-human biota assessments to ensure that any questions on the subject are answered	[No comment given]
Industry 15	Challenge from independent and knowledgeable people	Continued development of partner approach and sector plans	Continued development of partner approach and sector plans
Industry 16	[No comment given]	[No comment given]	Need regulation to be established and enforced
Industry 17	Active conversation between regulator and regulated. Tiered approach where information required increases the higher the tier	No criteria has been set specifically for non-human species yet	FASSET, ERICA & PROTECT have been very credible projects working to facilitate regulatory decision making. The FREDERICA database represents one of the useful aspects as well as work on dose-estimation
Industry 18	Impact-based regulations with sound basis and clear application guidelines lead to effective	Protection of nature in uninhabited regions could be considered	Guidelines

	evaluation		

Appendix 7. Future regulation of radiation and chemicals (detailed questionnaire responses)

Organisation	Future Regulation?
Radiological Regulator 1	Foresee changes in environmental protection legislation regarding radioactive substances resulting from changes of the **ICRP recommendations** and the **IAEA Basic Safety Standards**
Radiological Regulator 2	Depends on outcome of projects like PROTECT. Very much aware of them. Changes will be according to future **EU-Directives**
Radiological Regulator 3	New **ICRP basic recommendations** will lead to changes (this is one of the drivers). **New IAEA Basic Safety Standards** will also provide the tools to allow environmental protection legislation to be put into practice. **EU and IAEA guidance on exemption levels for TeNORM** (RP-122 and WS-R-3). Changes to other Norwegian pollution regulation (relating to chemicals) may serve as a basis for changes to existing radiation protection regulations in Norway
Radiological Regulator 4	**Don't see any changes in the immediate future**. The drivers would be European Directives and International Conventions and we don't see any new regulation coming through Europe at present (for radioactive substances). If changes were to come about it is envisaged it would be **through the IAEA co-ordinating group (basic safety standards) and Euratom basic standards** One thought though is **what impact the WFD will have on ionising radiation discharges**. The WFD never intended to focus on IR waste as no radionuclide is on the WFD lists however ionising radiation could be classified under the list entitled 'other pollutants' to be dealt with in 2015
Radiological Regulator 5	None that will affect the current regulatory approach for protection of biota against significant adverse effects from exposure to radionuclides
Radiological Regulator 6	In terms of own country foresee greater penalties being imposed for non compliance
Radiological Regulator 7	Upgrading of the current regulations, taking into account **new international recommendations** as applicable
Radiological Regulator 8	According to the ICRP-2007 new recommendations, no revolutionary changes in setting the radioactivity norms related to biota and fauna, are proposed. The above problem has just been stated (ecocentric approach in radiation safety in parallel to anthropocentric approach has been announced) and so, the problem needs to be addressed from every side. In **ICRP's opinion**, other radiation-hazardous situations may emerge, when we will need consider possible after-effects for the environment. The Commission is also aware that there is a need in special state authorities, which would demonstrate, in unambiguous manner, that the environment should be protected even in the situation of planned exposure to radiation. That is why, at present, the Commission suggests to develop a more well-defined framework base for evaluation of exposure-to-dose relation, and also of the relation between the dose and its effect and consequences of such effects to other than humans, on a general scientific basis. The existing system of public radiation protection has been guaranteeing, up to now, a sufficiently efficient indirect protection of the environment. The main objective in the development of the framework base consists of the need to fill the conceptual gap in the radiological protection sphere. The ICRP's goal is not to set the regulatory standards in this sphere. ICRP is trying to do so that the above framework base would be accepted and

	used by other organizations, regulators and operators. The key concept of the above framework base is the “preservation (and augmentation) of the biologic diversity” Enhance the role of regulatory authorities. As concerns the tasks that were set- yes. There is no special legislation in this country yet, covering the issues of past environmental responsibility, including the **aftereffects of military defense actions**
Radiological Regulator 9	Revision of **Basic Safety Standards IAEA/EC**
Radiological Regulator 10	The present system works well so what benefits would result from changing it? Achieving protection of the environment through a system of dose assessment seems to work, pushing discharges down
Radiological Regulator 11	Gradually more environmental consideration when dealing with radiation. Major industrial plans will affect the development e.g. **potential new build and the waste issue**
Radiological Regulator 12	Will be affected by **future international recommendations and guidance from ICRP and IAEA**. In addition it could be possible that **European legislation** (either general or specific to radiation protection) will include requirements that affect radiation protection of fauna and flora
Chemical Regulator 1	**REACH**
Chemical Regulator 2	**REACH**, **Water framework directive** and **IPPC** (Integrated Pollution Prevention and Control)
Chemical Regulator 3	**EU** might come up with new directives that will have to be implemented. Possibly these directives will be more detailed considering target values etc and thus decreasing the flexibility and the possibility to do site specific considerations when regulating with conditions in the permits
Chemical Regulator 4	Starting to implement the newly reformed legislation on chemicals (**REACH)** will give new experiences and probably disclose new gaps in risk management. The risk management related to nano-materials and nanotechnology is still underdeveloped. New endpoints for testing and assessment of risks and benefits caused by nano-materials will be developed
Chemical Regulator 5	**REACH** is coming up this year and we have not looked far beyond this.
Radiological and Chemical Regulator 1	Detailed regulation with numerical limits will probably increase as **EU** directives are produced. An increase in the number and the use of **environmental quality standards** is also awaited
Radiological and Chemical Regulator 2	Change could occur through social pressure
Industry 1	New recommendations from ICRP A system for environmental protection is acceptable but it must be practicable
Industry 2	[No comment given]
Industry 3	1) **More regulations concerned with the effects to biota** – this has been worked on for quite some time and not sure how it will end up. It may be sticking to just human regulations but not convinced 2) **Climate change** – likely to lead to more legislation/trading of carbon credits. This is true environmental protection and regulators should be

	looking at this. A lot of people in nuclear are heavily regulated and as a result may have a part to play in 'solving' the climate crisis
Industry 4	Greater focus on non-human species (driven by **revision of ICRP recommendations**). However, great care needs to be taken in applying regulations/legislation to non-human species particularly at a practical level
Industry 5	Impact of **WFD**
Industry 6	Risk based regulation is likely to be further developed to allow regulatory resource to be focussed on the sites which require greater regulatory scrutiny and management, and allow good performance to be rewarded Health and safety processes and regulation are converging with environmental into systems and regulation that are more combined. This will mean that the environment is no longer an add-on but should go hand in hand with safety. UK legislation is enabling this and pushing the environment higher up the agenda
Industry 7	1) **Combined effects (chemical and radiation and other industries**) leading to tighter regulation 2) **Thermal effects** – US regulation 3) **Impingement/Entrainment** – International Joint Commision, a joint body that is focussed on protection of the Great Lakes
Industry 8	[No comment given]
Industry 9	[No comment given]
Industry 10	The legislation and drivers for the repository are quite clear at present and so no particular future changes are envisaged
Industry 11	At the time being **no major changes are foreseen**
Industry 12	Not for industry to say
Industry 13	**1) Radiological protection of the environment** **2) CO2 emission reduction** 3) Impact of **WFD**
Industry 14	It is anticipated that there will be specific requirements to assess potential impact on non-human biota as a result of new ICRP recommendations on this subject. This will be the specific driver for change at the national level
Industry 15	Increasing importance of the WFD and the marine protection act
Industry 16	[No comment given]
Industry 17	Specific consideration of non-human species. Lowering of current protection criteria. All driven by public interest and following along current and developing approaches to protection of the environment from non-radiological chemicals
Industry 18	For radiation – protection of the environment For chemicals – clear approaches for identifying target organisms