Protection of the environment from ionising radiation in a regulatory context (**PROTECT**): Review of current regulatory approaches to both chemicals and radioactive substances

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INTRODUCTION

The need for a system to protect the environment from ionising radiation is now recognised (ICRP, 2007) and there has been a considerable international and national effort on this issue over the last decade. The focus has been on collating relevant information and developing approaches to enable regulatory assessments with the aim of demonstrating whether the environment is adequately protected from the exposure to ionising radiation released under authorisation. The key is to be able to demonstrate that the environment is protected. Whilst many people believe that the ICRP statement (ICRP, 1991) ('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') continues to be valid, most accept that it is difficult to explicitly <u>demonstrate</u> that the environment is protected using the original ICRP statement. Given developments in conservation objectives and legislation, there is now a need to be able to demonstrate environmental protection (e.g. as the EC Habitats Directive has been interpreted and implemented in England and Wales (Copplestone et al., 2004)).

Concerns have been expressed both from the nuclear industry and the scientific community that the developing approaches may lead to costly regulation. However there has been a considerable amount of work funded by non-industrial sources to develop tools and approaches that can be used for the purpose of environmental assessment. Some of these tools are freely available can be used by industry to provide assessments to their regulatory bodies. Furthermore, it is recognised that the potential requirement for, and consequences of, regulation should be weighed against the possible role that nuclear power generation may have in (e.g.) combating climate change. Being able to explicitly establish whether radioactive substances are/are not having an environmental impact will contribute to the debate of the use of nuclear power in the future.

It is noted however that validation and comparison of the radioecological and dosimetry components of various approaches is required and this has also begun through the Biota working group of the IAEA's EMRAS programme. However, it is also important that any approaches used are practicable, credible to stakeholders and fit for purpose in any regulatory context.

The EU EURATOM funded **PROTECT** project (http://www.ceh.ac.uk/PROTECT/) is evaluating different approaches to protection of the environment from ionising radiation and will compare these with the approaches used for non-radioactive (chemicals) contaminants. The project aims to provide a scientific justification on which to propose numerical targets or standards for protection of the environment from ionising radiation which could be used in a regulatory context to aid in demonstrating whether the environment is adequately protected. To achieve this aim, the PROTECT project has consulted widely within Europe, and the broader international community, with industry and regulators. This paper will report on the critical review that has been conducted within Work Package 1 of the PROTECT project.

METHODS

The first stage (Work Package 1) 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 website searches, questionnaires (both verbal and electronic) and a workshop which included the participation of experts from outside the PROTECT consortium. Out of approximately 130 organisations contacted, questionnaires responses were received from 50. Regulators and industry each constituted 36% of the respondents, 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.

RESULTS & DISCUSSION

The review 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.

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 the environment has traditionally been a focus. 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.

Radioactive substance regulation with respect to environmental protection is not currently defined by international or European legislation. In contrast, regulation of chemicals is usually though the application of internationally accepted standards. A similar approach for radioactive substances could be seen as beneficial as such regulations across Europe would facilitate the centralisation of knowledge and effective planning and this may be the end result of current and future developments in the field of environmental protection from ionising radiation. Harmonisation between approaches for chemicals and radioactive substances was considered desirable; particularly as a similar level of protection for both using common assessment endpoints where possible would have a number of advantages. For example, a series of common measurement endpoints, which could be normalised to risk, would allow comparison of the relevant impact from different contaminants. It was recognised that there are practical reasons for differences in terms of how criteria to demonstrate protection 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.

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 than the tolerable level, then this might trigger some action, or at least prompt more accurate exposure estimates. A key element within these risk assessment schemes is the need for thresholds that define acceptable levels of stressors which is considered further by Andersson et al., (these proceedings). The basic generic framework for both radioactive substances and chemicals is: 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., the ERICA Integrated Approach (Beresford et al., 2007). However, this was intentional as practices in chemical assessment were considered in the development of these radiological assessment tools.

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

- Environmental protection goals are often stated in a country's legislation but these are often broad ranging and aspirational in nature using, for example unspecific terms such as: 'to protect the environment', 'to protect ecosystems' or to maintain 'favourable conservation status', 'biological diversity', 'structure and function of habitat/ecosystem', 'protected species' or 'rare species'. Following detailed discussions it was determined that protection should focus on the population level and that protection goals should be translated into measurable targets with advice provided on what the tolerable risks associated with these endpoints should be. Endpoints that relate stressor levels to measurement endpoints such as morbidity and reproduction should be targeted because ecological theory shows that these traits determine population sustainability (Forbes et al., 2001). A caveat is that individuals (e.g. those that are rare or endangered species) may need to be considered specifically.
- It is clear 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 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 (dose rate) values currently being applied, or suggested, should be assessed and the need for screening values and standards considered. Where possible, harmonisation of future international guidelines and recommendations should be attempted (for example, IAEA Basic Safety Standards, EU-Directives, and ICRP Recommendations).
- PROTECT should produce a clearly understandable document outlining the derivation of any numeric benchmark values, in particular explanation of where there are limitations in the application because of poor data quality is needed and the level of conservatism in the values should be clearly identified. This document should be developed in consultation with stakeholders.
- Furthermore, once numeric values or some other methods of environmental protection have been agreed, methods for demonstrating compliance should be evaluated (bearing in mind the use of the numeric value for example, if a regulatory limit then clearly strong compliance will be needed).
- Optimisation of discharges should remain central to environmental/human radiological protection.
- The benefits of regulation for the nuclear and non-nuclear sectors should be identified as they are likely to demonstrate that users of radioactive substances are behaving in an appropriate and environmentally responsible manner. Emphasising and highlighting this could be

beneficial in terms of large scale environmental issues such as climate change with respect to nuclear power generation.

Further details are available in the final deliverable report (Hingston et al., 2007). The information in this report is contributing to other PROTECT work packages to determine the appropriateness of numeric benchmarks suggest for use to demonstrate environmental protection from the effects of ionising radiation and to address the issues of the cost, or burden, of any environmentally derived regulation (Beresford et al. and Andersson et al. these proceedings). The overall outputs from the PROTECT project will contribute to the debate on the environmental consequences of nuclear power generation and radioactive waste disposal.

In summary, assessment tools have been developed that allow environmental assessments to be conducted and which can be used to demonstrate whether non-human species are protected, or not, from the impact of exposure to ionising radiation released under regulation. There is still work to do to evaluate whether these approaches are fit for purpose and this is underway. Frameworks are often tiered, increasing in the level of complexity, input data requirements and need for expert involvement. These are conceptually based on, assessment approaches available for chemical risk assessment. What criteria, and how these should be defined, for use in tiered assessments is currently under debate but are likely to make use of approaches developed for setting assessment criteria for chemicals. However it will be necessary to ensure that any assessment criteria that are developed are fit for use in a regulatory context.

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