

Unclassified

NEA/CRPPH(2007)13



Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

25-Jul-2007

English - Or. English

NUCLEAR ENERGY AGENCY
COMMITTEE ON RADIATION PROTECTION AND PUBLIC HEALTH

NEA/CRPPH(2007)13
Unclassified

A Radiological Protection View of Protection of the Environment from Chemicals

Executive Summary: Please refer to 'Conclusions and Suggested Areas for Debate' on page 20

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JT03230562

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INTRODUCTION

Following presentation of (NEA, 2007) 'Environmental radiological protection in the law: a baseline survey' (NEA, 2007), CRPPH members commented that development of radiological protection of the environment should be consistent with approaches to protecting it from other pollutants, particularly chemicals. Similarly, ICRP's Committee 5 also expressed interest in the field of chemicals regulation.

This document addresses these comments and sits as a complement to (NEA, 2007). Given the broad nature of the topic this work is more selective than (NEA, 2007). Furthermore, a quite specific interest in how harmful chemicals are controlled has required this study to place more emphasis on policy level documents and technical guidance, since these form an important part of understanding commonalities and differences between the two areas of regulation. In particular, it also gives a perspective to ICRP Committee 5's work. Like (NEA, 2007), the study has focused on normal operational aspects, in order keep the scope of the study manageable. Most significantly, the study has not covered waste management, site remediation or accidents; the first two of these will be covered by an expert group operating under the NEA's Nuclear Development Committee.

This work is based on laws and documents set out in the bibliography and has aimed to cover legislation and approaches to regulation of chemicals harmful to the environment, particularly chemical safety, in the European Union (at European level), the United States, Japan and international law. It is worth noting that much work in the field of control of harmful substances and chemical safety has been done 'in-house' by the Environment Directorate of the OECD, the NEA's parent organisation. Since many of NEA's member countries are also member countries of the European Union, this work gives good coverage to a large number of NEA member countries, even if individual countries have implemented European law in their own manner or have additional requirements. Many international environmental protection instruments do not distinguish between radiological and other harmful substances or properties, therefore the analysis in (NEA, 2007) is broadly valid. In particular this concerns sustainable development and the prevalent 'trade-off' approach to decision making as well as 'information society' aspects, such as access to information.

The next section gives a broad introduction to chemical (and other) environmental protection; there then follows a more detailed discussion of the approach used for chemicals, followed by a section which discusses similarities and differences in radiological and chemical approaches. The final section attempts to identify the most relevant points for radiological protection and, in the spirit of provoking constructive debate, suggests some areas that could be addressed by the radiological protection community.

PROTECTION OF THE ENVIRONMENT FROM CHEMICALS

What is a chemical? ...Chemicals are all around us and the environment is made of chemicals. Even limiting consideration of chemicals to those generated or concentrated anthropogenically leaves a very large array of substances potentially released into the environment from a wide range of sources. Thus key differences compared to 'radiation' are that 'chemicals' are even more ubiquitous, there are a large number of them and they have a wide range of uses. This leads to problems of identification and assessment, which will be the main theme of this report. However, it is useful to note that these differences lead to a much broader array of policy instruments being applied to tackle problems from chemicals. In particular, labelling, economic incentives, provision for voluntary agreements and for information gathering programmes are widely used in all the legislation categories reviewed¹. It should also be noted that the sheer number and variety of chemicals and their uses means that, whilst the methodology for chemicals assessment and management which will be described is in principle effective, in practice it is hampered by a lack of data. In this regard, this work will repeatedly refer to the importance of information gathering for the chemicals sector.

Examination of works on environmental protection also shows that protection against hazardous substances, whether 'chemical' or radiological, forms only a small, albeit important, part of environmental protection. For example, transport policy², development policy, noise pollution, habitat protection and exploitation of natural resources can all form important aspects of national or international views of environmental protection. Nevertheless, it is emphasised that this does not mean that protection against hazardous substances is unimportant – the priority given to a member state's transport policy in, for example, an OECD Environmental Performance Review, with little mention of chemicals regulation, may to some extent reflect the state's relative successes in controlling these two areas rather than their relative importance.

This report will primarily cover regulation of large point sources as being most obviously relevant to the nuclear industry but it should be recalled that diffuse sources are also important in regulation of chemicals. In particular, many common products, such as cleaning materials, contain harmful chemicals and therefore consumer products can represent an important diffuse source of a chemical.

¹ In fact, analogies to many if not all of these can be found in the nuclear industry; nevertheless they are not usually the primary policy tool.

² Of course, transport policy and others mentioned here are connected with release of hazardous materials; nevertheless in overview they are generally framed in a different way or such that hazardous materials only appear as a small component. For instance, transport policy might mainly consider use of natural resources (fossil fuel), global warming or broad health considerations, with direct measures to abate emission of toxic chemicals being only part of this.

REGULATORY CONTROL OF CHEMICALS

This section focuses on direct regulatory control over chemicals, which is the area of control of chemicals of most interest here. The headings used are those used in (NEA, 2007) to help with comparison. The discussion focuses on how protection is carried out because interest is greatest in this area and it also has the added benefit of allowing work on radiological environmental protection to be placed into context.

Aims of the Legislation: What is Protected?

International instruments with a significant role in environmental protection directly mention the environment, unsurprisingly, and as noted previously, often do not distinguish between chemical and radioactive substances. Key themes include reduction or elimination of pollution and sustainable development. As argued in (NEA, 2007), sustainable development is a rather flexible term but, for OECD countries, environmental protection should be regarded as an important component. There are also international instruments to give special protection to threatened species or habitats.

However, a key difference when considering chemicals is that international instruments have been created to address particular problems, such as destruction of the ozone layer, global warming and acid rain. That is, agreements have been made in a reactive fashion to address specific harm that has been identified (e.g. acid rain) or is foreseen (e.g. climate change). These instruments therefore have a specific aim of tackling the corresponding harm. Sector specific international agreements exist for radiological substances but these are rather an extension of the 'source-control' regime rather than reactively tackling sources of an identified harm.

At a European and national level, study of legislation has suggested that there is some separation of radioactive substances regulation from 'mainstream' environmental legislation. 'Mainstream' environmental protection legislation is generally divided to separately cover environmental media; most prominently legislation aims to protect the environment through controlling air quality and through controlling water quality. At this European and national level there may also be (separate) legislation with the direct aim of controlling sources, particularly point sources. For example, the European Union Water Framework Directive (Directive 2000/60/EC) protects water and associated aquatic systems, providing for introduction of discharge controls and quality standards, whereas there is also a directive on Integrated Pollution Prevention and Control (targeted at specific categories of installations; Directive 96/61/EC) which also provides for permitting relating to emissions³. That is, one may think of two categories of environmental protection legislation: the first is based on the environment (what 'goes in' to the environment), the second is based on controlling sources (what 'comes out' from an installation). Nevertheless, as (NEA, 2007) identified, there does not appear to be a clear overall goal for environmental protection; reference is usually to 'protecting the environment' in general, protecting ecosystems, protection of flora and fauna or similar rather generic notions. However, reflecting international agreements, there is also legislation enacted in reaction to identified harm, such as damage to the ozone layer.

³ This is not to suggest that in practice there is duplication of authorisation; indeed, the Water Framework Directive explicitly gives a route to avoid this.

Pesticides, biocides and agricultural chemicals in general represent an interesting case, since they are deliberately spread in the environment; yet the first two categories clearly have potential to damage the environment and fertilizers (the key component of the third category) can damage the environment through eutrophication. Here the aim of legislation is, in principal, to allow dispersion of these substances but to ensure restricted, or at least responsible, use of these substances.

Overall, it may be said that the aims of chemical and radiological substances regulation are similar (such as they exist) but below the international level there is a degree of separation in their regulation, with chemicals regulation generally having a stronger link to environmental protection.

The Legal and Regulatory Tools: How is it Protected?

Information Gathering

A key problem in regulating chemicals is knowing how harmful each chemical, or group of chemicals, is; this means both its intrinsic hazard and its level and nature of use. Thus underpinning control of chemicals is legislation requiring reporting, registration or authorisation of chemicals. Given the number of chemicals in use and the recent introduction of such legislation (relatively speaking), retrospective assessment is required. Prioritisation or screening of chemicals is generally needed in order to assess the most significant first. Newly introduced chemicals generally require assessment before production, import or use. Assessment procedures and responsibilities were not harmonised in the legislative regimes examined although of course European Union legislation requires harmonisation amongst its members; the OECD has also been active in promoting common approaches.

Note that, for humans, whilst research into the health effects of radiation is ongoing, this is supplementing a large body of previous work and a carefully thought out system of protection; because of this system, regulators or operators have not had to carry out assessments for each radionuclide they produce and there is general acceptance, if not complete agreement, on how exposure is linked to harm. By contrast, a chemical regulator, producer or user (depending on the regulatory system) has to carry out human and environmental toxicity testing for each chemical or group of chemicals; unsurprisingly, this is often based on limited or indirect data, especially for humans. In this light, it may be noted that of around 100 000 chemicals classified as being already in use, a 1993 European Union Regulation (Regulation (EEC) No 793/93) selected 110 as a priority for assessment and five years later assessment work had only begun on 39 of these, being finished for 19⁴ (although progress was not necessarily solely impeded by lack of data).

Intrinsic Hazard Assessment

Primary and secondary legislation generally set out which substances need to be tested⁵ and give some indication of how substances are to be tested. The detailed requirements may be set out in detailed guidance notes, as produced either by a national agency or the European Commission, often with reference to OECD guidance.

The guidance generally requires investigation of acute and chronic effects on human health and the environment. As already mentioned, legislation tends to leave a rather vague notion of what protecting the environment means; the presumption tends to be towards a rather holistic or ecosystem-type approach,

⁴ According to a European Commission report on the effectiveness of its chemical safety regulation, document DOC/XI/6462/99, available at http://ec.europa.eu/environment/chemicals/pdf/report-4-instruments_en.pdf.

⁵ For instance, this might be by volume of substance produced or used, expected persistence, bioaccumulation and toxicity in the environment.

other than for threatened species and habitats which are more specifically protected. This begs the question of how to evaluate the environment in a holistic way.

Understanding of ecosystems is in general not good enough to allow direct testing of a substance's effect on them. Empirically, measures of ecosystem quality exist but their use either requires a substance to have a very strong effect or would require comparison with a 'control' ecosystem over a number of years. The former implies that only immediate and serious effects would be detected, the latter would be resource intensive and require a valid control (i.e. the only difference being in the level of the substance of interest). Moreover, testing would be required for each substance and ecosystem, implying a tendency towards site-specific testing.

Given these difficulties, the approach usually adopted is to investigate harm to several biota from different characteristic parts of the environment (typically trophic levels). Such an approach is amenable to laboratory testing, since an organism can be chosen from each trophic level; this is illustrated schematically in Figure 1. The presumption is that this approach will protect the environment as a whole since it is assumed that, very broadly speaking, species in the same trophic level are likely to be reasonably similar; for example, feeding on and being eaten by similar biota and having similar habits.

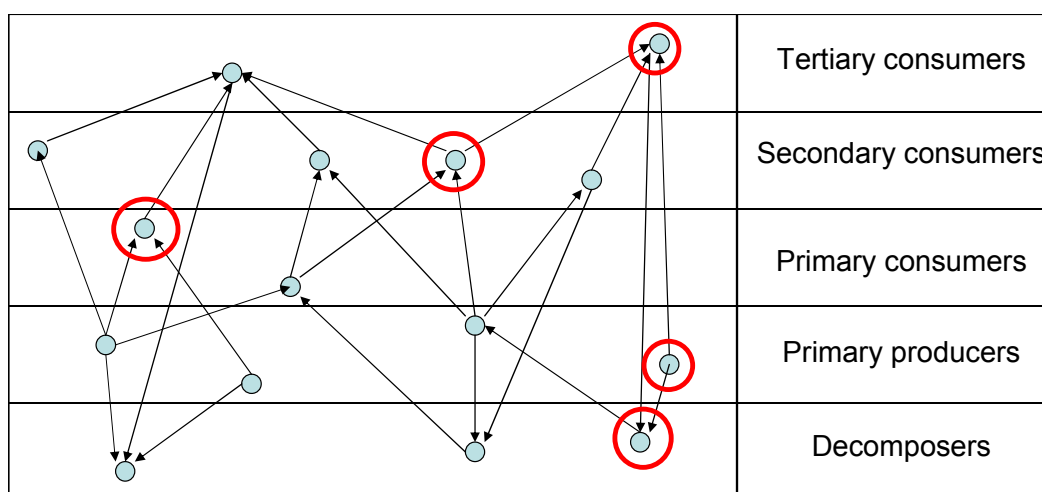


Figure 1 Schematic illustration of interrelations between species in an ecosystem. Each node (small filled circle) indicates a species; arrows show relationships between species (typically predator-prey; the arrows points towards the consumers). The red circle shows those species chosen for toxicity testing.

Assessment for both humans and the environment implies animal testing; societal distaste and dislike for this causes a tension over when to require it. Partly because of this, and partly because such tests are resource intensive, empirical toxicity data is likely to be scarce for many chemicals.

This scarcity of data requires other approaches to evaluating toxicity, principally extrapolation and 'Quantified Structure-Activity Relations' may be used. This latter approach attempts to predict toxicity of a substance on the basis of similarities between parts of its structure and toxicologically 'active' sites in known toxic compounds or receptor sites in biota.

Testing procedures generally aim to identify 'no observed effects levels' below which a substance can be assumed to be sensibly harmless i.e. *de facto* adoption of a threshold. The consequent aim will be to ensure levels of a substance that are below this level. However experimental results can vary and the 'threshold' may to a certain extent be a function of how it is measured.

Difficulties in obtaining empirical data are likely to require extrapolation between species and trophic levels and, within the same species, between different types of values (e.g. acute versus chronic exposure). Given the unreliability of this procedure, 'safety factors' are used which, in basis, are arbitrary. Various technical guidance may include recommendations on safety factors but essentially, in moving from one species (for which there is data) to another, the 'no observed effects level' will be divided by one to three orders of magnitude, depending on how closely related the species are.

Practical Values for Regulation

Assessment of the intrinsic hazard of chemicals with respect to the environment will give a range of values, usually 'no observed effects levels', for several species. This raises practical issues of how – or rather what – to regulate. Firstly, there is a good chance that one or several of the tested species may not be present in the environment of interest; even if it is, it may not be a species of concern. This implies a need for extrapolation, which will be applied using safety factors as described above. Even so, results for several species implies a large monitoring programme and several limits for which compliance testing would be required. This would be a resource intensive approach which relies on a number of assumptions, principally that the well-being of the species monitored are indicative of the wider health of the environment and that any extrapolations with safety factors are reasonable.

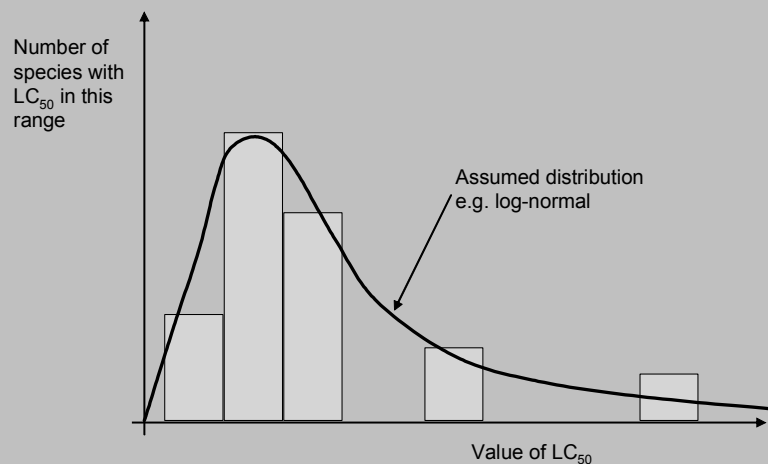
Clearly, it would be preferable to have a less resource intensive approach which might appear more proportionate given the uncertainties involved and perhaps also appear more holistic. With this in mind an approach has (or rather, several similar approaches have) been developed which allows one value to be derived for a given environmental medium; thus monitoring and compliance would only need to be carried out for (say) concentration of a substance in water. This approach relies on assuming that sensitivity amongst biota in the environment towards a substance varies according to an assumed distribution, typically log-normal. A standard is set by choosing a given point in the distribution (e.g. 95th percentile). The approach is explained in more detail in the text box.

Fundamental problems with this approach are the assumption of a species sensitivity distribution and that, even if this is more or less valid, protecting (say) 95% of species does not guarantee that an ecosystem or 'the environment' are protected⁶. For instance, the most sensitive 5% of species may include some that are vital for the operation of the ecosystem or that are highly valued or even protected.

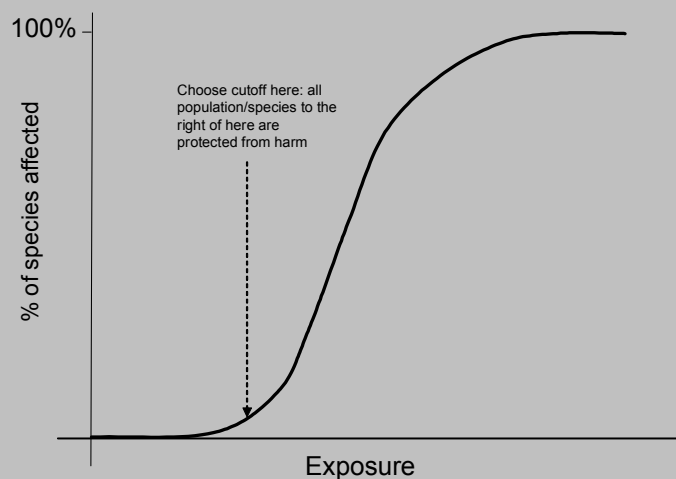
⁶ This highlights the absence of a clear goal for environmental protection: if it is assumed the species sensitivity distribution approach is correct, how is the cut-off chosen? Should it be 100th, 97.5th, 95th percentile?

Species sensitivity distributions

Toxicity data for a particular effect are obtained for a number of species. Although a rather extreme measure, 'LC₅₀' (the concentration of a substance killing half the test subjects in a specified time) is frequently used as there is usually more data available for this value. It is assumed that effect values (e.g. values of the LC₅₀) for all the species in an ecosystem vary according to a distribution, typically chosen to be a log normal distribution. It is further assumed that species for which data have been obtained are a random sample of all the species in the ecosystem of interest. Using these assumptions, parameters for the distribution can be estimated by fitting the assumed distribution to the available data. This is shown schematically below.



Re-plotting this in a cumulative fashion gives a 'species sensitivity distribution' which shows how many species in an ecosystem would be affected by a given concentration. A point on this curve, say the 95th percentile, can be chosen as the value for a standard. This is shown schematically below.



Thus if the graph above was constructed using LC₅₀, choosing the 95th percentile as a standard would mean that, at the level of the standard, 5% of the species in the environment would be exposed to a concentration greater than or equal to their LC₅₀, whilst the other 95% of species would be exposed at a level below their LC₅₀. Problems with the approach are how to choose a 'cut-off' and that the most sensitive species are unprotected.

Risk Assessment and Management

Chemicals will be screened to ensure the most important chemicals are examined first; this will to some extent depend on anticipated toxicity but also depends on usage and production volume. These three aspects are taken into account, notably in European Union legislation and give rise to a risk management approach to make sure that regulation is suitably directed. This type of approach is shown schematically in Figure 2.

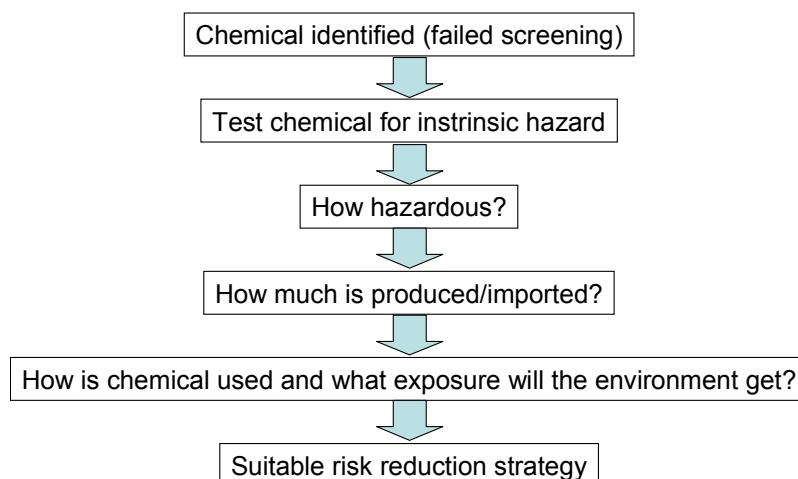


Figure 2 Typical process for choosing a risk management option for substance. This is iterative to a certain extent; particularly since the subsequent steps will probably be considered at the screening stage.

The process will consider human health and environmental effects. Based on information, such as expected volume and mode of use, exposure to the substance will be assessed. For environmental effects, a key factor will be whether predicted environmental concentrations will exceed the predicted ‘no observed effect levels’; if they do, further effort to make more accurate assessments or reduce (or avoid) exposure will be made. That is, it will form the basis for a risk management strategy, which may include regulation of large point sources or setting of quality or discharge standards. The overall assessment process, including intrinsic hazard assessment, is resource intensive and time consuming; typically it may take several years and problematical substances may take over a decade⁷.

Risk reduction strategies, if deemed necessary, vary from restrictions on usage, through application of emission abatement technology to phase-out of a substance and its substitution by a less harmful one. For example, part of the risk reduction strategy for some pesticides may be that they are not to be sold to the general public⁸ whereas, at the other extreme, PCBs are being phased out. Often this works by using the outcome of assessments to assign substances to a list of priority substances or a list of other harmful substances, as appropriate. Then, for example, substances on the priority list might be phased out whereas those on the other list may be subject to discharge abatement requirements, such as ‘Best Available Techniques’.

⁷ That is most chemicals will not be studied to anywhere near the same extent as ionising radiation; notwithstanding any other differences this is because, essentially, each chemical needs to be separately assessed.

⁸ The presumption being that professional users will be more competent and distribution will be limited.

Regulation of Large Point Sources

The approach followed in regulation of large point sources of chemicals is similar to that for radioactive substances, with an exception that generally a license is not required by an installation *per se* (i.e. there is generally no equivalent of a nuclear site license). This is largely because of the wide range of ‘chemicals’: not every site with ‘chemicals’ demands a site licensing regime by virtue of the chemicals. Nevertheless, sites are generally subject to discharge limits and permitting. Qualification for coverage by such regulations may be through type and quantity of substance, type and size of installation or merely because of discharges from the site.

Permitting frequently imposes technology requirements; there are number of these, some of which have particular (and slightly different) meaning, including: Best Available Techniques, Best Available Technologies, Best Available Control Techniques, Best Conventional Control Technique, Best Practicable Means and Best Practicable Environmental Option. Nevertheless, they all essentially require the same thing: a trade off is to be made between reducing environmental effects and the cost of doing so. This approach is very similar to what is found in radioactive substances regulation, discussed in more detail in (NEA, 2007). One difference is that this type of approach tends to be more clearly developed in the chemical field since this requirement is very similar to ‘ALARA’ and therefore, historically, there has been less emphasis on development of an explicit technology approach for radioactive substances, since in practice it was largely used already.

Devices often exist in chemical regulation for setting standards, particularly air quality, although in some cases these may be quite ‘soft’. In the US and Japan, provision exists for declaring zones where standards are, or are liable to be, exceeded and here additional controls may be applied to pollution sources. For instance, in Japan, such highly polluted areas may be subject to a total emissions inventory, which sets the total emission from all pollution sources; the aim is to then adjust discharge limits to ensure that the total emission level is complied with. In addition to such zone setting, legislation often requires creation and implementation of an air quality improvement plan, often the responsibility of local or regional authorities with support from national bodies.

United States legislation places an obligation on the Environmental Protection Agency to set environmental quality standards for substances under certain circumstances and all the regulatory regimes studied had quality standards for certain problematical chemicals, such as nitrogen oxides. Again, these are not always ‘hard’ standards. Provisions also exist for water quality standards. With the exception of drinking water standards, the approach to water quality standards in the legislation studied was found to be most explicit in the United States, which adjusts quality standards according to foreseeable uses of a watercourse.

For substances identified as particularly harmful, production bans may be put in place which are also often extended to restrictions on usage and disposal of the substances, or the items that contain them (e.g. disposal of fridges is controlled where they contain CFCs).

Case Specific Regulation

Threatened or highly valued species and habitats are given special protection; such regulation covers all sources of harm and thus includes chemicals as well as radioactive substances. The limited extent of regulation – to a restricted geographical area – and the terminology used should result in strict protection for these habitats or species.

Legislation may be enacted to prevent or control specific identified or foreseen harm; examples are legal instruments adopted to control organo-tin compounds or to tackle indirect effects, which are

described in the comparative section, below. The risk management approach adopted in legislation varies, in some cases effectively banning substances (e.g. CFCs) or in other cases merely endeavoring to control releases (e.g. measures to tackle carbon emissions). Although beyond the scope of this study, it appears that the management approach taken rests on a trade-off approach.

Summary

Regulation of dangerous chemicals from large points sources is broadly similar to that of radioactive substances, requiring permitting and discharge authorisations with attached conditions, as appropriate. Perhaps because of the lack of a common ‘dose’ measure, trade-off based reduction of environmental effects is explicitly based on technology and therefore this technology based approach is more clearly developed in chemicals regulation; in radiological protection it has, essentially, been applied implicitly through ‘ALARA’.

The broad range of chemicals means that a large effort is put into identifying which chemicals are dangerous, and how dangerous they are, and then assigning management approaches. For environmental protection, this is based on testing on a number of biota with different roles in the environment. These may then be used to set a number of standards or one single one for a whole environmental medium. In practice there are difficulties implementing this system because of the broad range of chemicals and their uses, and the corresponding large requirements for data.

Particularly for air, environmental quality standards may be used in addition to discharge limits, although sometimes these are ‘soft’ limits and there may be other relatively ‘soft’ approaches, such as requirements for local air quality improvement plans.

Case specific regulation exists which may be either environment based (protecting specific habitats or species) or substance based (restricting use of substances with identified harmful effects on the environment).

Role of Information: “Information society” Developments

All the legislative systems studied used Environmental Impact Assessments (or similar) for new installations or major modifications; the exact application of these varied but may be expected to include any large point source of a chemical. As discussed in (NEA, 2007), environmental impact assessments inform decisions as to environmental impact of a development but do not usually have a direct, prescribed effect on such decisions.

The legislative regimes studied all had devices for making environmental information available to the public and often provided for a certain level of participation. Generally this was by similar legal mechanisms as for the nuclear industry, which are covered by (NEA, 2007). Nevertheless there are some differences, for example, there may be requirements to notify citizens when urban air pollution levels exceed certain thresholds. However, probably the most relevant for this study is the use of Pollutant Release and Transfer Registers (PRTRs). PRTRs give a publicly available inventory of the release and movement of potentially harmful chemicals, recording information such as type of chemical, quantity released, source (including point and non-point sources) and transfer between environmental media, and are periodically updated; for example, annually. Typically introduced at national level and usually mandatory, in 2006 over half of OECD member countries had PRTRs. However, their establishment on a national basis has resulted in some differences in the numbers of chemicals included and their reporting levels. European Union legislation to implement the requirements of the PRTR Protocol of the Aarhus Convention will require adoption and improve compatibility of PRTRs in its member countries. Beyond the EU, the OECD facilitates use and uptake of PRTRs amongst its member countries.

Knowledge of the ‘source term’ for a chemical is a fundamental piece of information. Whilst such information is available in the nuclear field, it is somewhat fragmented and a picture of releases of radioactivity and its movement would need to be built from several sources of information. Moreover, this would give a ‘snapshot’ rather than an up-to-date record.

Rationale for Decision-Making: What Level of Protection is Given?

The studied legislation for control of chemicals is, in general, consistent with the trade-off approach described in (NEA, 2007), therefore much of the analysis in that document is valid. Even where severe measures have been taken against substances, in many cases this can be argued to be consistent with a trade-off approach, depending on need for the substance and the ease of replacing it (or doing without the function it provides). Nevertheless, some legislation is apparently harm based since phase-out may be required for chemicals presenting a high enough threat to the environment although this may also be phrased in a way that admits a trade-off (e.g. in the European Union ‘Water Framework Directive’ requires ‘appropriate steps’ to be taken to eliminate pollution by such substances). In general, though, little guidance is given on how a trade-off decision is to be made but it is implicit that chemicals with an obvious, harmful effect on the environment will be subject to strong efforts to control them, since there is legislation addressing particular groups of harmful substances.

A key feature of chemicals regulation is identification of which chemicals represent a threat to the environment; overall the level of protection that is given will depend on the effectiveness of the identification process. For new substances, this is less of a problem since they need to be tested before being introduced but there are many substances that were already in use when regulations were introduced.

DISCUSSION OF SIMILARITIES AND DIFFERENCES BETWEEN CHEMICAL AND RADIOLOGICAL REGULATION

There are a number of similarities and differences between regulation of chemicals and radioactive substances with regard to protection of the environment; these are discussed in the following sections. However, in the context of current work in the field of radiological protection of the environment, particularly the work by ICRP Committee 5 and that sponsored by the EC, the first point gives the most important difference.

Assessment of Harm to the Environment

The key difference between assessment of harm from chemicals and from radioactive substances is that chemicals are routinely explicitly tested for the harm they cause to the environment. This is generally not a requirement for routine testing but rather an initial assessment at national or international level to establish a suitable risk management strategy for use of the chemical. This assessment may then be reviewed from time to time.

Radioactive substances regulation has not carried out such a definitive assessment to date (although research has been done in this area). Rather it has been presumed that there is little point in such an assessment since the result of this assessment would give rise to the same risk management strategies adopted by virtue of assessment of harm to humans. It was concluded in (NEA, 2007) that this was probably correct; nevertheless, current civil society has changed and the key issue is whether or not the

radiological protection profession needs to explicitly assess harm to the environment, even if only to give a clear justification of its position.

Diversity of Chemicals

There are a large number of chemicals produced and available in products, perhaps up to 70 000 (EEA/UNEP, 1998) to 100 000 in OECD countries⁹. These range from apparently innocuous chemicals to those whose production relies on the fact that they have properties harmful to biota, pesticides being the prime example here. Thus the first problem in chemicals regulation is knowing what chemicals are being produced and used, and the second problem is knowing whether they are harmful and if so, how harmful. Compounding these problems, and as a problem in its own right, is the fact that chemicals are used in many different ways and, in terms of environmental protection, may represent diffuse and difficult to control sources. For example, pesticides are generally fairly toxic (otherwise they would not be pesticides), are deliberately distributed over large areas and generally are not used in an operational environment that is amenable to direct control.

By contrast, as discussed in the section on doses and additivity, it is relatively straightforward to predict the intrinsic hazard from radionuclides¹⁰, whereas as this is generally not so for chemicals (leading to a large requirement for data). Moreover, most 'radioactive material' is confined to well-defined, directly controlled sources; generally uses of the material are well known and do not create a diffuse, uncontrollable source¹¹.

Thus, it may be expected that information gathering, including hazard assessment, is a much greater feature of chemicals regulation than for radioactive material. Also, since there are many different degrees and modes of harm from chemicals, accordingly it may be expected that chemicals will be divided into different groups either by level of harm or by type of harm. Given the range of uses of chemicals, classification may also be expected with respect to mode or manner of use to a much greater extent than for radioactive substances.

This varying nature and range of chemicals to be controlled implies that their regulation will be more fragmented than that of radioactive substances. This suggests that separate regulation of radioactive substances is not particularly unusual; rather it is a specialised regulation of a specialised hazard amongst all the varied aspects of protection of the environment from harmful substances. Nevertheless, this still leaves room for debate over how resources are allocated, standards are set or similar, for radioactive substances compared to other substances.

Doses and their Additivity

The use of doses in regulation for radioactive substances, and the use of the 'Linear-No-Threshold' assumption, which permits their additivity, is a very powerful pragmatic tool which has allowed great resources savings for the nuclear industry. The assumption means that it is straightforward to predict the intrinsic hazard from a radioactive substance and it allows ionising radiations being treated as equivalent to each other so that exposure to radiation can be added.

⁹ The European Inventory of Existing Commercial chemical Substances (EINECS) contains around 100 000 chemicals, according to http://ec.europa.eu/environment/chemicals/exist_subst/index.htm

¹⁰ It is acknowledged that this is not always the case; for instance, uranium mill tailings were found toxic to the environment under Canadian Federal law based primarily on their chemical toxicity. Another example: for humans, the hazard from radon is not treated in an identical way to other exposure to radiation.

¹¹ For the moment 'cleared' material, such as from authorised discharges, is not included since in principle, it is 'safe' and so not a 'source' any more.

This is generally not the case for chemicals. Thus one could legally be exposed to 100 harmful chemicals at 99% of their respective limits which would not happen in radiation since the exposure to, say, ^{60}Co and ^{137}Cs would contribute to the same limit. In chemicals regulation, additivity is only used for limited numbers of chemicals and harmful effects; for example, ozone depleting and infra red absorbing potentials have been assigned to some chemicals for destruction of the ozone layer and global warming, respectively. Therefore, chemicals regulation has a 'gap' that is very difficult to tackle yet is only a problem for radioactive substances when considering their combined effect with other substances or properties. Unsurprisingly, the absence of such a ready means of predicting intrinsic hazard leads to more effort being put into information gathering in the field of chemicals regulation.

A logical consequence of the current methodology for quantifying radiation exposure is that regulation is often expressed in terms of dose rather than concentration of each substance. However, a frequently mentioned problem of the use of dose is that it makes assessment and compliance much more complicated than for chemicals, which are regulated on the basis of substance concentration that can be directly measured. In fact, with the current dose-additivity system this should not be a major issue; a possible scheme to address this is outlined in Appendix 1.

All ionising radiation is assumed to lead to the same types of effects whereas chemicals can have a range of effects. However, even if exposures to different chemicals are not additive for the same effect (e.g. risk of cancer) one should consider overall environmental stress (e.g. for humans risk of, say, asthma plus risk of cancer giving an overall detriment). It is known that exposure to a second hazardous substance may either promote or inhibit harm from a first substance; nevertheless this 'mixture effect' is generally not known. This feature implies that standards for individual chemicals might be expected to be stricter than for radiation and, indeed, that standards for all harmful substances may be lower than consideration of each in isolation would suggest. However, the lack of understanding in this area means that probably little has been done explicitly to address the issue in regulation. Nevertheless, the additivity of dose still represents a large advantage in radiological protection.

Natural Background Levels

A further aspect of additivity of radiation exposure is that radiation is measured against a (usually) relatively large background; that is, it can usually be considered as a very small addition to what people are normally exposed to. Many chemicals however are measured against essentially zero background. Thus it might be expected that restrictions on release to the environment of radioactive substances would not be as severe, up to the point where doses are above the 'noise' from variation in exposure to background radiation. Nevertheless, the existence of natural background probably makes little difference since society often seems more concerned over what is added to the environment, weakening any arguments relating to background radiation. This can also be understood by taking a legalistic viewpoint: hazard 'owners' have absolute liability for their hazard. Thus in case of chemicals and radioactive substances, the ultimate objective, or rather, the ideal, is likely to be 'close to zero [additional] exposure'.

Environment-based Protection Versus Source-based Protection

At the national and EC level, environmental protection legislation often falls under two categories: environment based protection (e.g. quality standards) and source based protection (e.g. discharge limits). For radioactive substances, typically only the second category applies since the relatively strict control of radioactive substances means that this is a feasible approach. In particular, traditionally the nuclear industry has been regarded as the main source of (anthropogenic) radiation in the environment and this industry has been amenable to source control, since essentially it consists of large point sources. This is related to the historical reasons for separation of radioactive substances that is described in a later section.

External Exposure

The harmful effect of radioactive substances is usually exclusively considered in terms of the radiation they emit. Therefore it is necessary to take into account the harmful effect of these substances even when they are not within or in direct contact with biota. It is thus necessary to monitor environmental media, whether by measuring dose emitted directly, or based on knowing the quantity of radionuclides in the media. Since chemicals do not give rise to external exposure, this may be expected to be a key difference between regulation of 'chemicals' and radioactive substances. In practice, assessment related to chemicals generally involves consideration of the concentration of a chemical in environmental media, therefore external exposure does not necessarily imply a large difference. However, it may be easier to maintain direct monitoring of external dose rate rather than evaluate concentrations of a substance, which would imply some differences in a system of quantified standards.

Degradation

Chemicals may be removed from the environment by chemical degradation, whereas radioactive substances are only removed by radioactive decay. This can make it less easy to identify the threat posed by a chemical, since a substance with a long chemical half-life will endure in the environment and be more likely to accumulate but the half-life may be difficult to establish; for a radionuclide it is usually well-known. This implies more emphasis being placed on information gathering for chemicals. Biological half life may be an important criterion in the hazard posed by a chemical or radionuclide and this may be easier for chemicals, since by definition a chemical will have a given set of chemical properties which will affect its uptake and accumulation whereas a radionuclide may be in a range of chemical forms, each with different chemical and biological properties. With respect to degradation, a further complication with chemicals is that they may degrade or react into a more harmful substance¹². Overall, these considerations may be expected to lead to a somewhat increased emphasis on information gathering for chemicals, particularly on their degradation, but they identify challenging areas for radiological substances.

Historical Differences

A further point to be made on chemical versus radioactive substances regulation regards their histories. Radioactive substances regulation grew up in a quite coherent fashion, originally inspired by an organisation built around a single industry with good international links (medico-research industry). This organisation then became a natural resource for further developments in the field which were driven by a single, rather centralised (indeed, often state-run) industry. This coherent international background and the specialised nature of the hazard has led to development of a coherent, internationally adopted approach. By contrast, 'chemicals' are not only used in the 'chemical industry' but in numerous fields with varying histories, and different chemicals present different hazards to the environment. Therefore, 'chemicals' regulation may be expected to demonstrate less coherence, especially at the international level, than that surrounding radioactive substances.

Indirect Effects

Protection of the environment against chemicals includes legal instruments dedicated to tackling indirect effects on the environment, or at least, biota, such as depletion of the ozone layer. Nevertheless, these instruments have tended to be in reaction to an identified serious problem and so would only be expected in response to a particular indirect harm or effect for radioactive substances.

¹² This also occurs in radiological protection through 'daughter' products but their production is well-known and quantified, since product fractions and physical half-lives are known.

Such ‘indirect’ effects highlight the range of problems to be addressed in chemicals regulation so that whilst only direct effects of radioactive substances on the environment are known at present, several classes of chemicals have important indirect effects; examples of these are given in the text box.

There are many lessons to be learnt from examination of the case studies given in the text box, and others, but the key point here is that chemicals regulation can throw up unexpected challenges in a way that (so far!) radioactive substances do not and can also be less straightforward (again, as far as is known!). They also illustrate areas where the goal of regulation has not directly been to prevent harm but to prevent an effect and also areas where chemicals regulation has needed to achieve a high level of international agreement. Since control of sources is key, one may expect similarities with the nuclear industry; however, the aim of stopping large scale effects rather than direct harm suggests that alternative policy instruments may be used; for instance, economic incentives rather than discharge limits.

For radioactive substances regulation, probably the main lesson here is to be alert to the possibility of indirect effects, even if none are known at present for radioactive substances.

Indirect effects of chemicals: three examples

CFCs and other halogenated compounds. Originally popular because of their stability, these compounds are stable enough to reach the stratosphere, where the high level of UV radiation leads to their breakdown and subsequent catalytic ozone-destroying action; the consequent reduction in the ozone layer gives a higher intensity of UV radiation at ground level, causing (increased) harm to biota. This example also illustrates how relatively small amounts of substance may have a large effect (in this case owing to catalytic action), in contrast to what is known about the action of radiation, which is in proportion to the quantity of contaminant.

Carbon dioxide and other IR radiation absorbing compounds. Carbon dioxide is a stable, non-toxic product of combustion of fossil fuels and is ‘re-converted’ to oxygen in the carbon cycle; it was thus believed to be a harmless by-product of combustion. However, the speed of its generation has altered the IR radiation absorbing properties of the atmosphere, leading to net increased energy capture and thus to global warming (rather like swapping a thin duvet for a thick winter one in the height of summer). Other chemicals, including CFCs and halogenated compounds, also contribute to this effect.

Oxides of sulphur and nitrogen. These chemicals are formed as minor by-products in the combustion of fossil fuels, notably coal. When released to the atmosphere from power stations, these compounds can react to form soluble acids, leading to precipitation that is acidic, with harmful consequences for the environment, including forests and aquatic ecosystems. Owing to transport of the compounds, this is frequently a trans-boundary effect. Oxides of nitrogen are also formed in internal combustion engines and thus tend to be released in large quantities in areas of high population; when in the atmosphere they may contribute to formation of ozone around ground level with health effects for the population.

Reduction of Pollution: Optimisation

Notwithstanding the range of diffuse or difficult to control sources, many actual or potential sources of harmful chemicals are from large ‘point’ sources, such as conventional power stations, which are amenable to the same types of control as nuclear installations. Discussion in this work and in (NEA, 2007) shows that control over large point sources is quite similar for both chemicals and radioactive substances, resting on a trade-off approach.

The trade-off may be somewhat implicit; for example, in the case of a ban where the trade-off is made before the legislation. Often however, the trade-off requirement is explicitly stated in law, through the requirement for 'ALARA' or application of 'Best Available Techniques' or similar. Chemicals regulation focuses on technology or technique based approaches, presumably because of the absence of an additive dose, whereas radioactive substances regulation has relied on a harm (i.e. dose) – centred approach. Technology centred approaches are becoming more important for the nuclear industry; nevertheless, in practice such approaches are turning out to be very close to 'ALARA', particularly since the regulatory tools applied, such as discharge limits, permitting and enforcement, tend to be very similar.

For radioactive substances and chemicals believed to be harmful, a key aim is to prevent their presence in the environment from anthropogenic sources. As discussed in (NEA, 2007), the stringency of control will depend on the trade off between the perceived benefit from the polluting activity and the level of harm resulting from it; a key factor in this is also the difficulty in addressing the harm e.g. is substitution by a less toxic substance easy? In some cases it might even lead to an outright ban on a class of substances e.g. phase out of PCBs and CFCs. This desire for stopping releases combined with a pragmatic 'trade-off' approach means that a cornerstone of both chemical and radioactive substances regulation will be doing as much as one can, within reason, to avoid release into the environment (and may be observed through the application of several named approaches e.g. As Low As is Reasonably Achievable, Best Available Techniques for reducing discharges, application of Best Practicable Means etc.).

Abandonment of a 'no-threshold' assumption for radioactive substances is potentially a threat to this common approach but it is proposed that this is unlikely for two reasons. Firstly, it may well be that consequent thresholds will be so low that a trade-off approach needs to be maintained. Secondly, even though chemicals have identified (*de facto*) thresholds, relevant domestic and international instruments still require emissions of pollutants into the environment to be, in practice, reduced so far as is reasonably practicable, or equivalent phraseology.

The trade-off approach, which is essentially optimisation, remains a very important similarity between chemical and radioactive substances regulation. Arguably, drives to 'harmonise approaches' between chemicals and radioactive substances are about finding common means to judge the trade-off, rather than harmonising the (common) approach itself.

Numerical Standards: Limits and Constraints

Whilst the cornerstone of environmental protection and pollution abatement may be expected to be doing everything that is 'reasonable', regulators and legislators will frequently want to give some indication of what this means. An obvious way of doing this is through setting some sort of limit or standard.

Standards can be thought of as falling into two categories: emission or discharge standards and environmental quality standards. Those in the former category are essentially the same for chemicals as for radioactive substances and restrict the total amount of substance that can be released in (say) a year or the maximum concentration of a substance in effluent, or both of these. They are generally strict limits in the sense that exceeding them will lead to regulatory action. Often these standards will form part of the conditions of a permit which may also have other conditions attached, such as a requirement to use Best Available Techniques to reduce discharges.

Environmental quality standards by contrast are levels of concentration in the environment that should not be exceeded. However, these limits are often somewhat 'softer' than discharge standards, presumably because it can be difficult to attribute responsibility to a particular source. Nevertheless, even if 'soft', these standards set a target and often provision exists for taking action if they are exceeded, as discussed

regarding total emission limits under Japanese legislation. For strict standards, the equivalent for radioactive substances is the dose limit or concentration limits in drinking water, with both applying to humans rather than the environment. Probably the best analogy for 'soft' standards is dose constraints. In the field of chemical regulation, such standards may be set to directly protect the environment from priority chemicals; this has not been done for radioactive substances but then it is not clear that they qualify as 'priority' substances with respect to the environment.

Thus whilst quantified levels based on protecting humans and the environment, rather than discharges, are observed in both areas of regulation (such as radiological dose limits for humans and quality standards for environmental media for certain substances) these approaches are not as uniformly applied as might be expected.

Justification

A fundamental tenet of radiological protection is that use of radioactive substances should be justified in the sense that, at the most basic level, the benefit from their use exceeds the detriment from their radioactivity. Although the transparency with which this declaration of justification is made varies, it is invariably considered within the radiological protection community.

By contrast, justification is not considered, or rather is implicit, for chemicals¹³. This is presumably because of the range of chemicals; for example, salt is a chemical and one might ponder the utility of having to justify the use of salt for each meal it is added to (as opposed to optimising how much to add!). Nevertheless, there is no formal requirement to consider the justification of adding salt to roads to inhibit formation of ice, which can contaminate roadsides and run-off (although analogous discussions may well have taken place). Rather, 'reverse justification' is applied to substances identified as particularly harmful, with such substances subject to dedicated legislation such as phase-out. Requirements to consider substitution or to do without a particular product altogether are part of a 'chemicals' approach and could, however, be considered as being similar to justification.

Moving away from an anthropocentric viewpoint, it is difficult to see how the principle of justification *per se* can be applied to environmental protection although it can certainly be used for options appraisal. So, presumably intrinsic justification would rest solely on human need (do we need electricity?), since it is difficult to see how most human activity directly benefits the rest of the environment¹⁴ but, by contrast, environmental protection can clearly play its part in comparative aspects of justification (should we generate electricity using *nuclear* power?).

Coupled to this, it might be expected that there would be a single overarching aim for environmental protection that applied to both chemical and radioactive regulation, which would assist in making judgments over justification. However, as discussed in (NEA, 2007), such a goal is difficult to identify, if indeed it exists.

¹³ There are limited exceptions to this: for example European Union pesticide legislation requires the benefits of a pesticide to be considered but arguably this is closer to an optimisation argument.

¹⁴ Again, a problem here is 'what is protecting the environment?' Are humans part of 'the environment' for environmental protection; if so, what rights do they have compared to other species? If they are not part of the environment, most (if not all) human activity damages the environment and so, from an environmental perspective, cannot be justified.

Summary

The key difference between protection of the environment from chemicals compared to radioactive substances is that, generally, the danger to the environment from chemicals must be tested and assessed explicitly. This has not been done for radioactive substances, probably because it is felt that it would make no difference to the adopted risk management strategy.

For sources of chemicals most similar to the nuclear industry (i.e. large point sources), regulation is very similar to that for radioactive substances in the nuclear industry. Namely, there is strict control over sources based on a trade-off between the cost of protective measures and harm to the environment.

At national or European Union level, there is some separation between radioactive substances and chemicals regulation, with the latter often covered by regulation protecting the environment directly as well as by control of sources. Arguably, the risk management strategy adopted for radioactive substances means that this second layer of control, direct protection of the environment (i.e. in addition to strict control of sources) is not needed. Nevertheless, it is in place for chemicals.

The diversity of chemicals and their uses means that their regulation is more diverse than for the nuclear industry; thus much more emphasis is placed on information gathering (since generally data is needed for each substance including its usage) and, furthermore, in this context, specialist regulation of radioactive substances does not look particularly unusual.

Given that there is no unifying chemical 'dose' as there is for radioactive substances, it might be expected that there is some other means for addressing additivity of detriment; nevertheless, this subject area is relatively intractable so this may not be directly addressed. The relatively large amount of background exposure to radiation might be expected to lead to differences but societal concern appears to be over added effect, therefore limited differences may be expected in this area, too.

With the exception of specially protected species and habitats or legal instruments mitigating a particular effect, it is difficult to identify an overall goal for environmental protection in law, except inasmuch as releases of pollutants are to be reduced.

Justification is a difficult issue for environmental protection if one moves away from an anthropocentric viewpoint and since (formally) it is not required in chemicals regulation, there is little to be directly learnt about its application from this field.

CONCLUSIONS AND SUGGESTED AREAS FOR DEBATE

This final section uses the previous discussion, centred on regulation of chemicals, to draw conclusions for radiological protection of the environment and to suggest pertinent points for discussion.

Overall, radiological protection benefits from a stable, coherent and pragmatic system of protection. In contrast the diversity of chemicals, their modes of use and effects, has led to a more fragmented approach. However, with respect to environmental protection, chemicals regulation is more advanced in that it tends to explicitly consider environmental effects. This is probably arises from the range of chemicals in use and simple lack of knowledge over how harmful they are, coupled with known severe toxic effects of some chemicals. By contrast, radiological protection only considers one toxic ‘substance’ (ionising radiation) whose harmful effects are relatively well known. Nevertheless, the lack of a formal assessment process for harm to the environment (which is explicitly adopted as part of the radiological protection system) removes transparency and openness from radiological protection of the environment.

For large point sources of chemicals, which probably offer the best analogy to the nuclear industry, the basic approach to regulation is the same. The emphasis is on technology requirements in the absence of a measure of harm that could be reduced ‘ALARA’; nevertheless, the requirement is broadly the same. A technology based approach makes it clear that background levels are of little relevance in considering approaches to abatement; it is in any case argued that background levels are unlikely to be broadly accepted as a basis for standards.

The additivity of dose allows considerable efficiency gains for regulation of radioactive substances; maintaining a system that allows summation of an effect is desirable. Indeed, where feasible, this has been adopted in chemicals regulation (e.g. creation of an ‘ozone depleting potential’). However, a key drawback of using doses is the added complication and resources that might be needed, however, it should be possible to devise a dose based system that is much simpler to apply by using concentration as the measurable quantity (as illustrated in Appendix 1).

At the national and European level, chemicals regulation is more directly linked with environmental protection in that chemicals tend to be covered by legislation that directly protects the environment through standard setting (i.e. numeric standards for environmental media), in addition to regulation that is focused on sources (discharge controls). Although environmental quality standards do exist for radioactive substances in some cases, this is not uniform.

Based on the legislation and guidance studied, protection of the environment from chemicals and radiation lacks a clear goal when viewed in the broader context of environmental protection. Sustainable development is perhaps the nearest idea to an aim that balances the immediate well being of humans with everything else, yet as argued in (NEA, 2007), this idea is rather anthropocentric and open to many interpretations.

Overall, by analogy with chemicals, the risk management strategy applied to radioactive substances is (probably) the correct one, effectively requiring discharges to be as low as is reasonably practicable, and as such is unlikely to change significantly. However the difficulty for radiological protection is that this strategy has been chosen based on protection of humans; whilst subsequent research suggests that the strategy is indeed suitable, attitudes towards the environment have changed and the current system of

radiological protection does not explicitly address the assessment stage. That is, the system is clear about *what* is done to protect the environment (i.e. discharges to be reduced through a trade-off approach) but not *why* it is done.

Based on the preceding discussion, the following points are suggested for debate:

- **Is risk assessment of radioactive substances with respect to harm to the environment needed, given that an appropriate risk management strategy (covering humans and the environment) has been adopted?**
- **How should risk assessment of the effect of radioactive substances on the environment be carried out?** For instance, should the outcome of ICRP's Committee 5 form an authoritative assessment or should the NEA/IAEA conduct a peer review? Or is pressure to address environmental protection so great that detailed case-by-case assessment and evaluation are required?
- **Should regulation of environmental radiation protection use concentration?** If so, how can the benefit of additivity of dose maintained? Should 'species sensitivity distributions' be used to allow comparison with an activity concentration in an environmental medium? What about measurement of external exposure?
- **Should the radiological protection 'industry' adopt environmental quality standards?** If so, what type of standards should they be: strict 'limits' or 'constraints' to inform decisions on ALARA/Best Available Techniques/etc.? (The necessity of standards would presumably be related to adoption of a risk management strategy following assessment).
- **How should the system of radiological protection approach justification for environmental protection?** Justification for chemicals is implicit but this is not so for radiological protection. This question is linked to the following question.
- **What is the aim of protecting the environment from harmful substances?** More specifically, what is 'harm' and 'pollution' (as discussed in (NEA, 2007))?

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Note: implicitly, legislation in (NEA, 2007) is included, which in some cases also covered non-radioactive substances; it also includes coverage of international legal instruments.

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Note: (1) testing and information requirements in relation to Regulation 793/93 have been regularly altered through regulations e.g. Regulation (EC) No 2161/1999 Regulation (EC) No 2592/2001 Regulation (EC) No 1217/2002 Regulation (EC) No 642/2005 Regulation (EC) No 565/2006. (2) Regulation 1907/2006 (REACH) replaces Regulation 793/93 in June 2007.

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Annex 1: EXAMPLE SCHEME FOR USING DOSE AND CONCENTRATION FOR STANDARDS SETTING

This methodology is given as an illustration of a possible approach; it draws on commonly used techniques in radiological assessment and in regulation.

Firstly, it should be recognised that a species chosen as a reference is in practice likely to be treated as exhibiting limited variation, since protection is not likely to aimed at the individual organism level. Secondly, it should be recognised that in practical radiological assessment, factors are used to calculate concentrations in one environmental compartment based on the measured concentration in another environmental compartment. Similarly, factors are used to estimate dose in humans (and presumably reference organisms) from concentration. Overall, therefore, a linear relationship is typically assumed between concentration in an environmental medium and dose to biota, for example:

$$[\text{concentration of X in water}] \times A = [\text{concentration in sediment}]$$

$$[\text{concentration in sediment}] \times B = [\text{concentration in biota}]$$

$$[\text{concentration in biota}] \times C = \text{dose to biota}$$

where A, B and C are numerical factors. One may also wish to consider dose from water and directly from sediment; nevertheless, these can also be related to water concentration. This process is typically used to estimate the dose to biota (including humans) from the concentration of a substance in an environmental medium but, conversely, it could also be used in the other direction to set a concentration based standard from, say, the 'no observed effects level' dose.

Due to the additivity of the dose system an indexing system can be used to judge whether an overall limit has been exceeded:

$$\text{Limit exceeded if } \sum_i \frac{X_i}{X_{\text{standard } i}} > 1$$

where X_i is the concentration of the i th radionuclide and $X_{\text{standard } i}$ is the concentration of the i th radionuclide corresponding to the dose standard.

Indexing can also be used to scale the area affected against a reference area, since the extent of an impact it relevant to environmental protection or, for accidental releases, to give a measure of recovery time against a reference value.