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DELIVERABLE D4b: Overview of Ecological Risk Characterisation Methodologies

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ERICA (Environmental Risk from Ionising Contaminants: Assessment and Management) will provide an integrated approach to scientific, managerial and societal issues concerned with the environmental effects of contaminants emitting ionising radiation, with emphasis on biota and ecosystems. The project started in March 2004 and is to end by February 2007.

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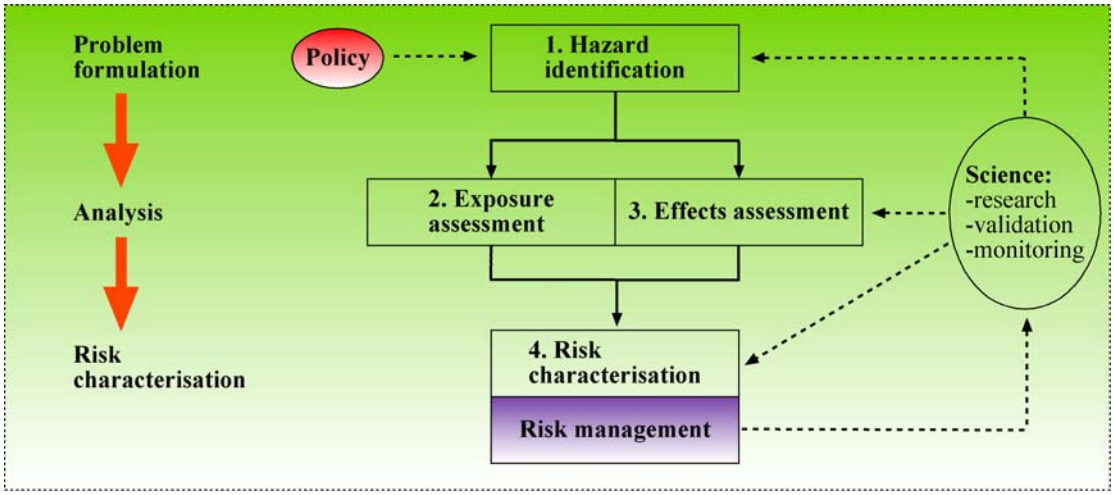
Executive summary

Ecological Risk Assessment (ERA) is an increasingly important component of any decision-making process that aims to provide transparent management decisions on environmental practices and associated problems. In ERA, risk characterisation (*i.e.* integration of information on exposure and effects as well as estimation of uncertainties) forms a vital link between the scientific assessment of risks, and the subsequent management of these risks (see figure below).



This document (D4b) presents a review and evaluation of methods and approaches in ecological risk characterisation. The scope of the review was to consider currently available risk characterisation methodologies for assessing risks of both hazardous chemicals as well as radioactive substances. Based on this review, an interim tiered approach to assessment and characterisation of risk has been developed, which is presented in Deliverable 4 Part a (D4a).

Although the focus and position as well as the definition of risk characterisation varied somewhat among the reviewed frameworks and approaches, there was a general agreement that risk characterisation strives to inform the decision-making process with descriptions and estimations of risk of contamination. The definition of risk characterisation developed within the FASSET project has been evaluated and found to be suitable for continued use when developing the ERICA integrated approach.

FASSET and ERICA definition of risk characterisation:

'*The synthesis of information obtained during risk assessment for use in management decisions. This should include an estimation of the probability (or incidence) and magnitude (or severity) of the adverse effects likely to occur in a population or environmental compartment, together with identification of uncertainties'*

The review also resulted in the identification of various key components that are usually included in risk characterisation. These components (and associated methods) are explained and discussed in detail in various sections of this Deliverable (see table below).

General component	Specific component	Description	Sections in the report
Risk characterisation		The process of integrating exposure and dose-response (effects) data and evaluating any associated uncertainties. The process uses exposure and stressor-response profiles developed in the analysis stage	3.1 – 3.4.
	Integration of exposure and effects	For each line of evidence, integration of available information on exposure and effects to generate estimations of the probability and magnitude of the adverse effects likely to occur. To the extent possible, these estimates should be a quantitative statement of risk (deterministic or preferably probabilistic).	3.3
	Estimation of uncertainties	Identification and estimation of sources of variability and uncertainty as well as evaluation of data quality and data gaps.	3.4
Risk description		Description and interpretation of the available information on risk for presentation to risk managers and a wider audience.	3.5
	Interpretation and weighing of evidence	Interpretation of the ecological adversity of estimated effects and determination of what estimate of risk (line of evidence) is most likely.	3.5
	Presentation of results	Should be clear, transparent (e.g. listing all assumptions), reasonable and consistent	3.5 + D6

Ecological risk assessments are generally performed in defined phases or tiers, where the complexity and data requirement of the assessment increases with each tier. This can be seen as a pragmatic approach to address the substantial complexity posed by ecological risk assessments by focussing resources to where they are most needed. The nature of the increasing complexity in subsequent tiers varies among different tiered approaches. Requirements could, for example, be increased on exposure (concentration, dose or dose rate) and/or more complex methods could be introduced (such as probabilistic methods and quantitative uncertainty analysis). Based on the review, we decided that within the ERICA integrated approach it would be most beneficial to adopt a tiered approach to ERA (as described in D4a).

Radiation protection and protection of humans and ecosystems from other contaminants have traditionally been clearly separated (e.g. institutionally, legally and scientifically). The review revealed, however, that there are many similarities between the assessment of ecological impact of radioactive and non-radioactive substances in terms of the consideration of exposure and effects. This means that the ecological risks of both these groups of environmental contaminants could be assessed using a similar approach. The main difference that needs to be accounted for in developing an ERA methodology is that effects of radioactive substances are generally assessed based on dose (rate) – response relationships whereas non-radioactive substances are generally assessed based on exposure concentration – response relationships. Finally, the review discusses possibilities of (as far as possible) integrating assessment of human health and ecological risks. Such a harmonised approach to risk assessment is desirable for a number of reasons, including avoiding unnecessary duplication of efforts and ensuring that the overall risk from multiple sources of exposure are assessed.

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1 Background

1.1 Connection with the FASSET project

The *risk characterisation* step within an ecological risk assessment (ERA) synthesises the information gained during the exposure and effect assessment, assesses its relative importance compared to other hazards associated with the source considered, and also forms the basis for prioritisation of stressors thus feeding into the decisions on actions (management) [Suter, 1993; Suter et al., 2000]. Such actions may be driven by formal regulations or be subject to scrutiny by involved parties ('stakeholders') before the decision on action is taken. The way the risk characterisation is carried out is, therefore, often highly influenced by regulatory criteria and standards, as well as by the scientific communities, public perception and societal views on what is acceptable. In this way, risk characterisation forms the bridge between the assessment of both exposure and effects of radioactive substances, and the management of these effects (potential or existing) in terms of decisions on, for instance, acceptance or rejection of proposed plans, discharge control, interventions, etc.

The FASSET (Framework for Assessment of Environmental Impact) project, pursued under the EC 5th Framework Programme, developed a framework for assessment of the impact of ionising radiation on biota, which includes guidance and tools for source characterisation, exposure assessment (including dosimetry for a range of environmental and target geometries), and effects analysis [FASSET, 2004]. The development of the FASSET framework was facilitated by a comparison of 20 different systems for assessment and/or management of risks associated with radioactive and hazardous substances [FASSET, 2002b]. During the course of systems comparison and associated development of the framework, a number of decisions were made on the scope of the FASSET framework, or its 'assessment context' following the terminology of the IAEA BIOMASS Programme [IAEA, 2003c]. With regard to risk characterisation, it was decided that "the present FASSET framework limits risk characterisation to a synthesis of the exposure and effects data obtained during risk assessment for the purpose of guiding management decisions" [FASSET, 2002a].

The ERICA project extends the assessment framework developed under FASSET to incorporate risk characterisation and, furthermore, to develop guidance on decision-making as well as performing a number of case studies, under the umbrella of creating the *ERICA integrated approach*. The relationships between different steps in an ecological risk assessment/management scheme, as well as the remits of FASSET and ERICA, are illustrated in Figure 1.1.

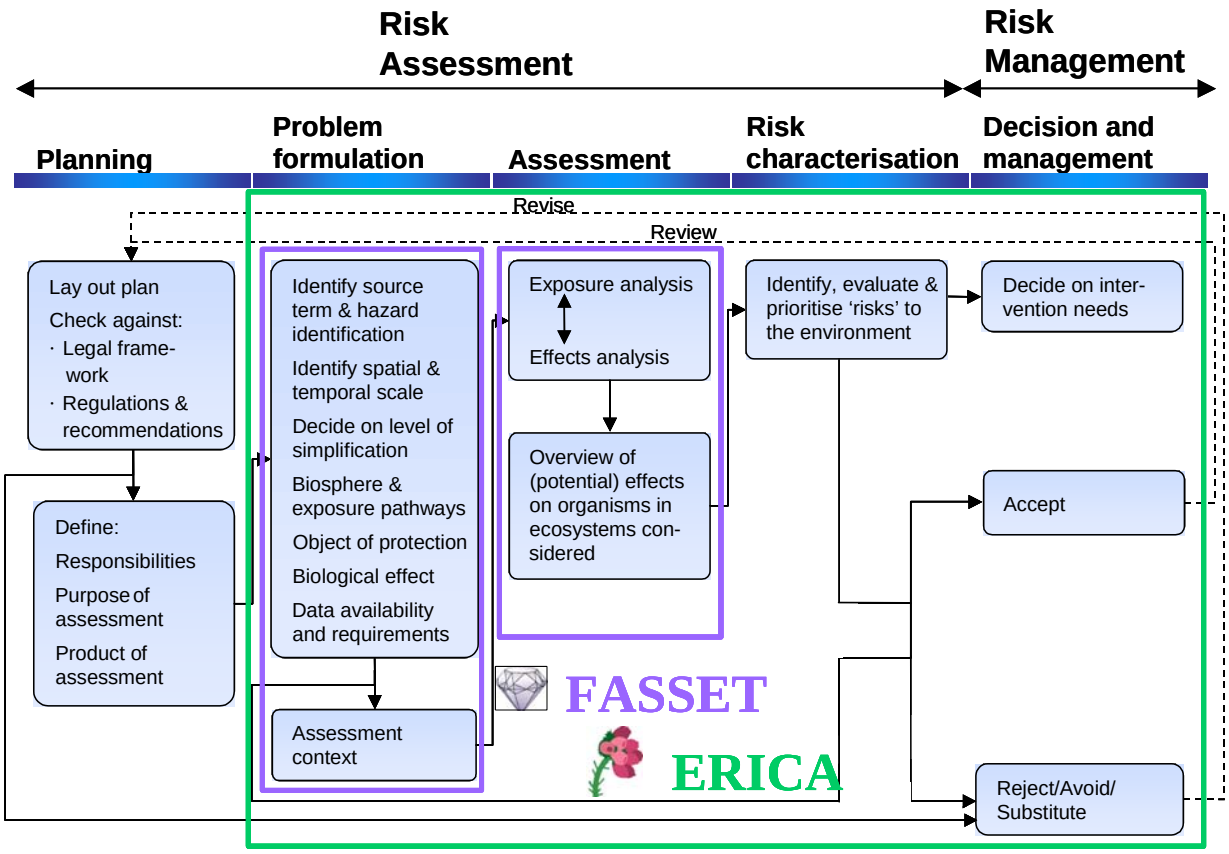

Figure 1.1. Schematic representation of different steps in ecological risk assessments, based on FASSET [2002a]. The scope of the FASSET project, as well as the wider scope of the ERICA project, is indicated in blue and green, respectively.

1.2 Scope and objective

The specific objective of Work Package 2 (WP2) of ERICA is to "provide risk characterisation methodologies for ecologically meaningful estimates of risk". The work plan of WP2 (see "Description of Work" on the ERICA website [www.erica-project.org]) is divided into three sub-tasks:

- risk characterisation methodologies;
- extrapolation issues including supporting experimentation; and
- development of good practice guidance.

This Deliverable of the ERICA project, D4b, considers currently available risk characterisation methodologies to provide information to be able to expand the capability of the FASSET approach within ERICA. The work described in this report started with a review (see Appendix Table 1) of various definitions, approaches and methods for risk characterisation. The results of this review (D4b)

are described in Chapters 2 and 3. These results were then used to develop an interim method for the ERICA integrated approach (D4a).

To provide a risk characterisation within reasonable uncertainties, detailed site–specific information forming the basis for hazard identification (agents causing adverse effects), dose – response assessments and exposure assessments is usually needed. Data gaps and uncertainties (important factors in characterising the risk) may, however, in many cases be approached by 'extrapolation' of knowledge from one area to another, unless specific research can be directed to solving such problems through, for instance, experimentation and/or specific biological surveys. The ERICA project will develop theoretical methods for extrapolation in certain areas, involving expert judgement, safety factors or modelling, and additional information obtained from new experimental studies, which will be reported in D5 of the project. The ultimate aim is to be able to produce a general handbook of radioecological risk characterisation (Deliverable 6).

This is, thus, a report developing the interim method of risk characterisation for the ERICA integrated approach on the basis of a critical review of various existing ecological risk assessment methodologies; the work will take into account what is being learnt from the development of assessment tools (WP1), from the development of extrapolations rules/methods supported by modelling and/or experiments (WP2), the application in test cases (WP4) and the views expressed by the end users group (EUG) established under WP3, as illustrated in Figure 1.2 below.

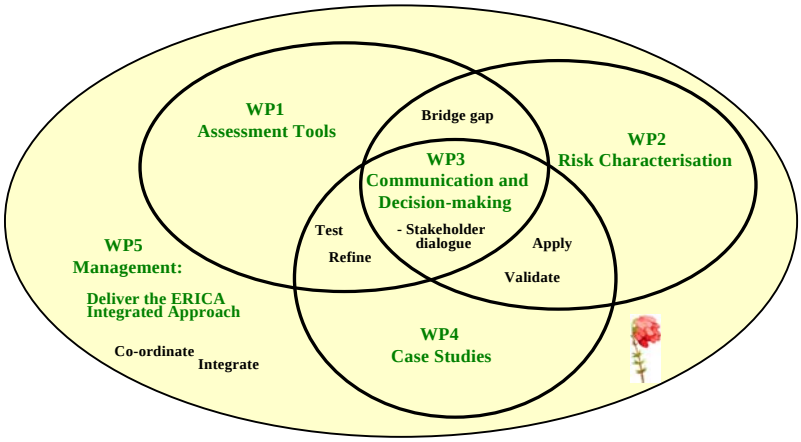

Figure 1.2. Position of risk characterisation and the work performed within WP2 in the development of the ERICA integrated approach

2 Ecological risk characterisation – general concepts

2.1 Defining risk characterisation

2.1.1 Position in the risk framework

Initially, risk assessment frameworks focused exclusively on human health protection. Subsequently, the demand for ecological risk assessment (ERA) has expanded and, as a consequence, ERA as a science has undergone considerable development during the last decades. There is currently a general agreement that risk assessment is best addressed in four stages, [Environment Canada, 1997; USEPA, 1998; Suter et al., 2000; EC, 2003b], where risk characterisation represents the final integration of the first three steps in the risk assessment process, namely hazard identification, effects assessment and exposure assessment (Figure 2.1). Ideally, risk characterisation should produce a quantitative estimate of the risk in exposed population or estimates of the potential risk under different plausible exposure scenarios. In short, the risk characterisation stage attempts to make sense of the available information on exposure and effects and to describe what it means [Williams and Paustenbach, 2002].

The general steps in ERA, as indicated in Figure 2.1, are:

1. Hazard Identification
   Identification of the inherent capacity of a substance to cause adverse effects. Including description of the source and affected environment, as well as identification of what is to be protected.
2. Exposure Assessment
   Estimation of the concentration/dose to which environmental compartments (e.g., aquatic, terrestrial and air compartments) have been, are, or may be exposed. This estimation entails the determination of the sources, emission routes and degradation pathways of the substance, and distribution between the various compartments.
3. Effects Assessment
   Estimation of the relationship between dose, or level of exposure to the substance, and the incidence and severity of an effect.
4. Risk Characterisation
   Estimation of the incidence, severity and probability of effects likely to occur in the affected ecosystem, due to actual or predicted exposure to a substance.

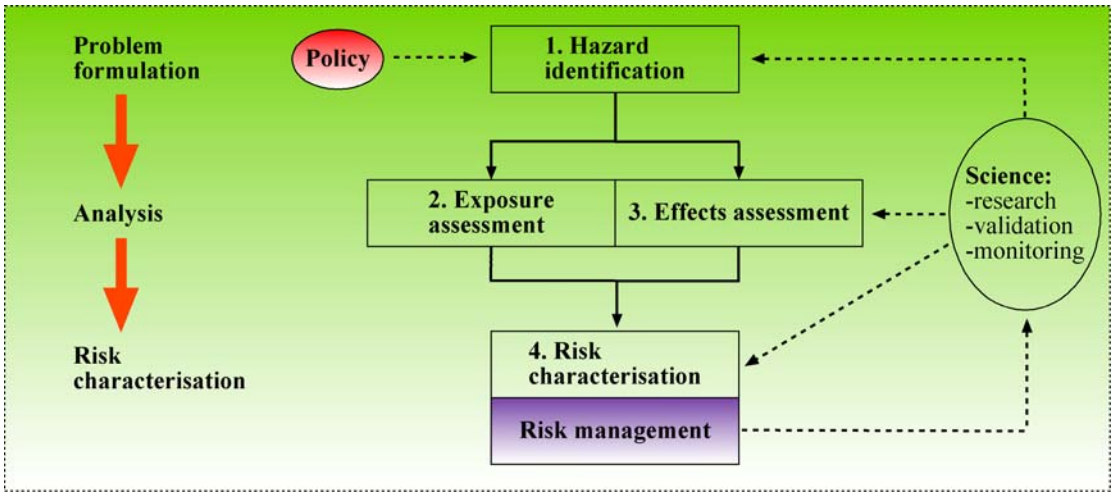

Figure 2.1. A generalised risk assessment framework.

Although the different phases (e.g. problem formulation, analysis etc) are presented sequentially it is stressed in the EPA ERA guidelines [USEPA, 1998] that ERAs are frequently iterative in the sense that something learned during, for example, analysis or risk characterisation can lead to a re-evaluation of the problem formulation or data requirements. Another example of where iterative is used as a description of the strategy is in the guidance for risk assessment of chemicals in the EU [EC, 2003b], where the identification of a chemical as being of concern will often lead to requirements on additional testing or other information. The EU guidance does, however, only identify this type of iteration (driven by identification of chemical concern) and is thus not iterative in the general sense (i.e. that all phases of the ERA can interact). In practice, the review of guidelines, reports and scientific literature conducted here indicates that sequential risk assessments are most common, even though some guidelines propose an iterative approach [USEPA, 1998; EC, 2003b].

The focus and position of risk characterisation within risk assessment has changed somewhat over the last two decades [Williams and Paustenbach, 2002]. Originally risk characterisation (human health) was viewed as serving as an intermediary summary phase between risk assessment and risk management, with the purpose of describing the nature, magnitude of risks and associated uncertainty [NRC, 1983]. Today, risk characterisation on human health risks is the integration of the first three steps in the risk assessment process, namely hazard identification, dose-response assessment and exposure assessment [Yassy et al., 2001]. It is also considered as an integral part of the entire decision-making process and it may reflect analysis and deliberation by all interested parties [NRC, 1996]. However, this development is not as apparent for ecological risk frameworks, where risk characterisation is mostly defined as part of risk assessment and hence separate from risk management [Suter, 1993; Environment Canada, 1997; USEPA, 1998; Suter et al., 2000; OECD, 2003]. Obviously, there are good arguments for both of these current views on the position of risk characterisation in the risk assessment framework (integral part of or separately feeding into decision making). Integration of risk characterisation could improve the utility of risk assessment as the risk management tool it is supposed to be [NRC, 1996]. On the other hand, limiting the interactions with risk managers to certain stages in the risk (e.g. problem formulation) can ensure that the process is based on sound science and also have positive implications on practicability. This is an issue that will need to be discussed further during the remainder of the ERICA project.

There has also been a development in both human and ecological risk assessment towards a greater emphasis on estimating and describing not just the magnitude and nature of risks but also providing improved descriptions and estimates of associated uncertainties [Williams and Paustenbach, 2002]. Such approaches and methods for estimating and describing uncertainties are discussed in Section 3.4.

Since the framework presented in Figure 2.1 is a general representation of a complex and varied group of assessments, the ERA sequence may differ among specific assessments or among groups of stressors (see Section 2.2 for discussion on general differences among hazardous chemicals and radioactive substances). For example, sometimes analysis of exposure and effects may be combined with integration of results (i.e. risk characterisation) [USEPA, 1998]. In other risk assessment schemes, risk characterisation is based on an exposure assessment, which is compared to predefined benchmarks or compliance levels (i.e. effects analysis is not an integral part of the risk assessment). This approach has often been used in developed frameworks [EA, 2002a,2002b; USDOE, 2002; EA, 2003b] or developing [ACRP, 2002; ICRP, 2003] assessing ecological risk of radioactive substances (Figure 2.2b). However, in the previous FASSET project a decision was made that the project aimed at developing a framework including effects analysis as an integral part [FASSET, 2004], (Figure 2.2a). In either case, the outcome of the effects analysis will feed into risk characterisation. Integrating effects analysis will have the advantage that it is easier to ensure that there is sufficient correspondence between the estimated effects profile and the assessment endpoints of concern. A

separate (non-interacting) effects analysis seems especially motivated in screening assessments or in situations where there are few or no site- or case-specific effects data, since this will simplify the risk assessment process. There is, however, a potential inherent uncertainty about how relevant and representative such a separately derived dose-response relationship is for the assessment endpoints of interest. This issue will need to be discussed further within the ERICA project.

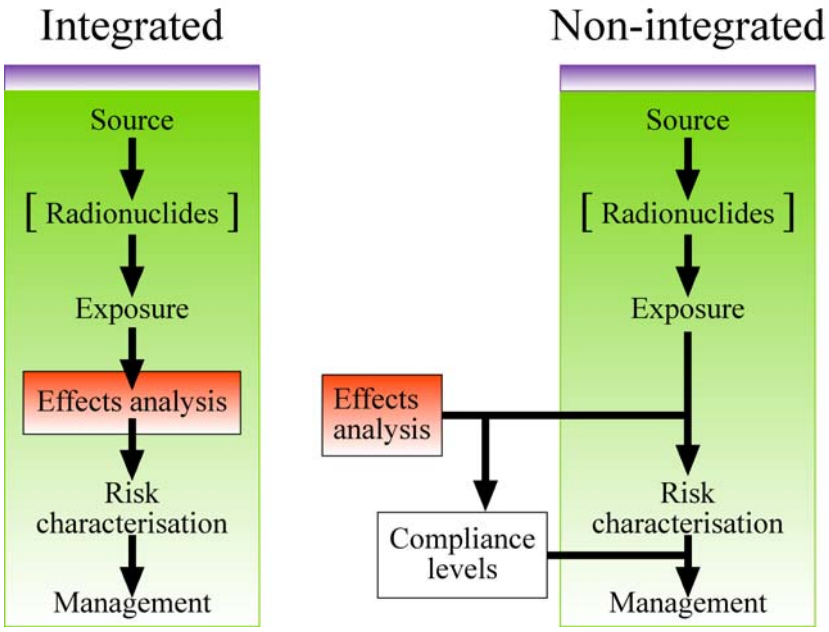

Figure 2.2a (left) and 2.2b (right). Position of the effects analysis in an assessment and management framework.

2.1.2 Scope, definitions and components

As outlined in the previous section risk assessors should during the risk characterisation stage, estimate and describe risks by integrating the results of the hazard identification, effects assessment and exposure assessment. A hazard is defined as "a factor or exposure that may adversely affect the health [Last, 1995]; it is basically a source of danger. Hazard is a qualitative term expressing the potential of an environmental agent to harm the health of individuals or populations if the exposure level is high enough and/or if other conditions apply [Yassy et al, 2001]. A risk is defined as the probability that an event will occur e.g. that an individual or population will be harmed within a stated period of time or the probability of an unfavourable outcome [Last, 1995]. It is the quantitative probability that an effect occur if individuals or populations have been exposed to a specified amount of a hazard. A hazard results in a risk if there has been exposure, not if the hazard is contained or if there is no opportunities for exposure [Yassy et al, 2001].

Conclusions presented in the risk characterisation should provide clear information to risk managers to be useful for environmental decision-making. Obviously, the exact focus of any specific risk characterisation must be influenced by the context in which it is performed since it will be influenced by assumptions, definitions and other choices made in the problem formulation phase [Suter et al., 2000]. Risk characterisation also usually differs substantially among screening [ORNL, 1998; Higley et al., 2003a; USEPA, 2003] and more elaborate risk assessments (i.e. higher tier [Environment Canada, 1997] or definitive assessments [Suter et al., 2000]). Differences in risk characterisation scope and methods at various levels in tiered ERA frameworks are discussed in detail in Section 2.1.3.

Various definitions of ecological risk characterisation can be found in the literature because of the inherent differences in the scope of various risk characterisations which depends on factors such as integration with risk management, the level in a tiered assessment or source and site specific considerations. These may differ somewhat in focus and complexity (as illustrated below by definitions from NRC [NRC, 1996], Environment Canada [Environment Canada, 1997], US EPA [USEPA, 1998], the European Commission (EC 1994), OECD (OECD 2003) and FASSET [FASSET, 2002a]) but all still generally aim at risk estimation and risk description as well as being a tool in decision-making. Therefore, despite the described difficulties in specifying one general definition of what constitutes a risk characterisation, it is possible to identify key components that are usually included in risk characterisation (Table 2.1.). These components are discussed and exemplified, based on the review, in detail in Section 3 (as specified in Table 2.1.)

NRC [NRC, 1996], defines risk characterisation as:

' a synthesis and summary of information about a potentially hazardous situation that addresses the needs and interests of decision makers and of interested and affected parties. Risk characterization is a prelude to decision making and depends on an iterative, analytic-deliberative process." They go on to refer to risk characterization as *"the process of organizing, evaluating and communicating information about the nature, strength of evidence and the likelihood of adverse health or ecological effects from particular exposures'.*

Environment Canada [Environment Canada, 1997] defines risk characterisation as:

'The objective of risk characterisation is to determine the likelihood and magnitude of adverse effects on assessment endpoints as a result of exposure to the priority substance'

US EPA [USEPA, 1998] defines risk characterisation as:

'Risk characterization is the final phase of ecological risk assessment and is the culmination of planning, problem formulation, and analysis of predicted or observed adverse ecological effects related to the assessment endpoint. Completing risk characterization allows risk assessor to clarify the relationships between stressors, effects and ecological entities and to reach conclusions regarding the occurrence of exposure and the adversity of existing or anticipated effects. Conclusions presented in the risk characterization should provide clear information to risk managers in order to be useful for environmental decision making'

The European Commission [EC, 1994][defines risk characterisation as:

´Risk characterisation is the estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental sphere due to actual or predicted exposure to a substance, and may include´ risk estimation´, i.e. the quantification of that likelihood´

The OECD [OECD, 2003] defines risk characterisation as:

´The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions´

FASSET [FASSET, 2002a] defines risk characterisation as:

'The synthesis of information obtained during risk assessment for use in management decisions. This should include an estimation of the probability (or incidence) and magnitude (or severity) of the adverse effects likely to occur in a population or environmental compartment, together with identification of uncertainties'

Table 2.1. General and specific components of risk characterisation.

General component	Specific component	Description	Sections in the report
Risk characterisation		The process of integrating exposure and dose-response (effects) data and evaluating any associated uncertainties. The process uses exposure and stressor-response profiles developed in the analysis stage	3.1 – 3.4.
	Integration of exposure and effects	For each line of evidence, integration of available information on exposure and effects to generate estimations of the probability and magnitude of the adverse effects likely to occur. To the extent possible, these estimates should be a quantitative statement of risk (deterministic or preferably probabilistic).	3.3
	Estimation of uncertainties	Identification and estimation of sources of variability and uncertainty as well as evaluation of data quality and data gaps.	3.4
Risk description		Description and interpretation of the available information on risk for presentation to risk managers and a wider audience.	3.5
	Interpretation and weighing of evidence	Interpretation of the ecological adversity of estimated effects and determination of what estimate of risk (line of evidence) is most likely.	3.5
	Presentation of results	Should be clear, transparent (e.g. listing all assumptions), reasonable and consistent	3.5 + D6

In general, there are large similarities between human risk assessment and ERA [Suter et al., 2000], since the basic framework adopted in ERA is a direct development from the risk assessment framework originally developed for assessing human health risks [NRC, 1983]. There are also substantial similarities in data requirements, for example concerning describing source characteristics, exposure routes and the exposure-response relationship. Integration of human health and ecological risk assessment is therefore both desirable and feasible [Suter et al., 2003], although several differences need to be addressed (i.e. concerning complexity and level of protection). The fundamental difference between ERA and human health risk assessment is the substantially higher complexity of ecological systems with respect to diversity in exposure routes, possible exposure-response relationships and possible indirect effects through ecological interactions (i.e. a chemical may affect a prey species by affecting its predator). Therefore, ERAs will include a larger array of different methods for assessing both effects and exposures than human risk assessments. It is also often argued that ERAs will usually rely more on actual exposure-response data (i.e. ecotoxicological tests and biological surveys) than human health risk assessment (which relies more on modelling). The main reason for this is that decisions concerning ecological risks need to be based on more convincing risk information than human health assessments, because of the higher value placed on human life [Suter et al., 2000].

2.1.3 Tiered approaches

Ecological risk assessments are generally performed in defined phases or tiers, where the complexity and data requirement of the assessment increases with each tier [Suter, 1993; OECD, 1995; Suter et al., 2000]. This is a pragmatic approach to address the substantial complexity posed by ecological risk assessments by focussing resources to where they are most needed. Different terminology to identify the different tiers can be found in the literature. Suter [Suter et al., 2000], for example, defines three separate tiers: scoping (determines whether an ERA is needed), screening (defines what contaminants, receptors and media need to be assessed) and definitive assessment (determine the nature and magnitude of risks). Environment Canada [Environment Canada, 1997], on the other hand, defines tiers by increasing number (tier 1, 2 etc). Still other terminologies can be found such as stage 1, 2, 3 [EA, 2003b] or a graded approach [USDOE, 2002]. The common denominator in these different tiered approaches are that complexity and realism increases with higher tiers and that the decision to continue from one tier to the next is based on identification of a credible hazard to ecological receptors. In chemical ERAs, this decision is often based on comparing measured or predicted exposure with ecotoxicological benchmarks (concentrations below which no adverse effects are expected) as described in Section 3.3. Tiered approaches thus differ from an iterative approach to the assessment, in the sense that iteration involves a continuous revaluation and refocusing of the assessment without any definitive triggers for when the iteration should start. Learning by iteration and defined tiers are, however, not mutually exclusive and ultimately a combination of both may prove to be most suitable in addressing the complexities of ecological risks (i.e. defining separate tiers but promoting iteration within tiers).

The first tier is usually a conservative or hyper-conservative screening stage, which attempts to narrow the scope of subsequent assessments by eliminating chemicals, media and receptors of ecological concern (as identified in the problem formulation). For hazardous contaminants, this stage is usually performed by using conservative assumptions to estimate both exposure (e.g. maximum end-of-the-pipe concentrations) and effects (e.g. screening benchmarks based on most sensitive species using large safety factors). Contaminants that are not eliminated in this process (i.e. they are still on the list of contaminants of ecological concern) will need to be assessed further in subsequent more realistic tiers [Environment Canada, 1997; Environment Canada and Health Canada, 2000; IAEA, 2000; Suter et al., 2000; USDOE, 2002] to estimate the significance and magnitude of the risk and associated uncertainties. A second purpose of the screening stage is to identify data gaps and thereby aid the planning of subsequent assessment tiers or becomes a basis for an uncertainty description. In the screening process lack of data is generally considered as a basis for including a hazard in the definitive assessment. For example, if a chemical is included in the source but has not been measured at the site of concern it should be included as a chemical of potential ecological concern [Suter et al., 2000].

The nature of the increasing complexity in subsequent tiers varies among different tiered approaches as illustrated for radioactive substances in Table 2.2. For example, Environment Canada [Environment Canada, 1997] and Bird *et al*. [Bird et al., 2002] suggest a generic approach in all tiers with increased realism of exposure and effects data in tier 2 compared to tier 1 and a progression from deterministic to probabilistic comparisons when moving from tier 2 to 3. The tiered framework developed by USDOE [USDOE, 2002], on the other hand, proposes increased site-specificity of primarily the exposure assessment at higher tiers, but do not mention probabilistic methods. Finally, IAEA [IAEA, 2000] suggests a combining increased site-specificity with probabilistic methods at higher tiers However, in all three approaches the benchmark value remains the same from tier 1 to tier 3. The composition of these (and other) tiered risk assessment frameworks are discussed in more detail elsewhere [FASSET, 2002b] and only those of relevance for ERICA will be referenced in Sections 3.1 – 3.3.

Table 2.2. Approaches to tiered assessments applied for radioactive substances.

	Increasing data refinement. Change from deterministic to probabilistic.	**Increasing site-specificity.**	**Combination. Increasing site- specificity and change from deterministic to probabilistic.**
Framework	**Environment Canada (1997)**	**USDOE (2000)**	**IAEA (2000)**
Tier 1	Hyper conservative. Worst case estimates for concentration of contaminants in environment and contaminant toxicity	Screening with generic guideline values.	Conservative, generic assumptions.
Tier 2	Conservative. Use of more realistic estimates, e.g. for bioavailability, toxicity data for relevant species.	Increasing site-specificity, e.g. consider biota specific to site, use of site-specific estimates of parameter values.	Increasing site specificity
Tier 3	Probabilistic. Distribution of concentrations and toxicity data.	Use of measured data; biota tissue data and environmental media samples.	Probabilistic Realistic site-specific model. Absorbed dose rate as probability distribution.

There are, however, consequences of adopting a tiered approach on risk characterisation and environmental decision-making that deserve to be mentioned here. Firstly, the objectives of screening and higher tier (definitive) assessment are fundamentally different in the sense that screening aims at eliminating contaminants from the list of those that have been identified as contaminants of potential ecological concern in the problem formulation phase. Higher tier assessments, however, usually aim at describing the nature and magnitude of hazards and the uncertainties connected with these hazards. The screening assessment becomes the definitive assessment (i.e. no further assessment is required following screening) only in those cases when all chemical of concern have been eliminated as potential hazards in the screening. Clearly, these different objectives of various tiers will imply that data requirements, methods and approaches in risk characterisation varies substantially among tiers (especially between screening and definitive assessments) [Suter et al., 2000].

Risk characterisation in screening assessments essentially generate a list of chemicals retained as chemicals of ecological concern and a second list of chemicals that have been eliminated as potential hazards (using extremely conservative assumptions to ensure a very low probability of falsely eliminating a chemical from the list of potential hazards), together with a justification for why the chemicals are on respective list. Thus, criteria for excluding chemicals are important issues. All relevant assumptions and choices concerning data assembly and choice of ecotoxicological benchmark should also be described. This is of special importance for substances for which the ecotoxicological benchmark is poorly scientifically defined or analogues are used. Higher tier assessments, on the other hand, aim at integrating available information on exposure and effects to estimate and describe, in a more realistic way, not only the existence or absence of a hazard but also the nature, magnitude, frequency and extent of the risk/effect as well as the confidence in this risk estimate. Field observations (such as radionuclide activity concentrations etc) and laboratory data from exposure tests relevant to the specific hazard agent will usually be required. Risk characterisation in higher tier assessments also often need to estimate and weight risk based on several lines of evidence such as chemical ecotoxicity data, biological surveys or biomarkers. Consequently, much more sophisticated methods concerning risk characterisation, uncertainty and weight-of-evidence as well as more

elaborate descriptions of the hazard, dose-response relationships and exposures experienced or anticipated under different conditions are ultimately required at higher tiers (as discussed and exemplified in Sections 3.3 to 3.5 below).

A second implication of tiered assessment approaches is on environmental decision-making. Traditionally, tiered approaches can, from a risk managers point of view, be described as a 'wait and see' system [Hansson and Rudén, 2004]. Indications of adverse effects obtained at lower tiers are not used as the basis for risk management decision; instead such decisions are only taken when more complete information has been generated at the highest tier (Figure 2.3.). An alternative combined approach was proposed by Hansson and Rudén [Hansson and Rudén, 2004], where a risk management decision is taken at each tier of the system so that the risk management is improved stepwise (Figure 2.4). Hansson and Rudén argue that the risk management decisions and measures taken in this combined approach should be proportionate both to hazard and the scientific database. One interesting application of such an approach is to make the required risk management measures at the lower tiers sufficiently stringent so that further assessment is optional. For example, suppose screening at a low tier indicates that a certain release of a contaminant is hazardous to the marine environment. The industry (or whatever/whoever is releasing the contaminant) will then be given two options, either to refrain from further assessment and take the measures appropriate for such a hazard, or to perform additional assessment at higher tiers (which, will probably decrease the estimated ecological risk due to increased realism). The advantage with such as system would be that economically unmotivated risk assessment is avoided. The industry has the option of either accepting the possibly over-cautious measures implied by the lower tier assessment or accepting the costs of additional assessments.

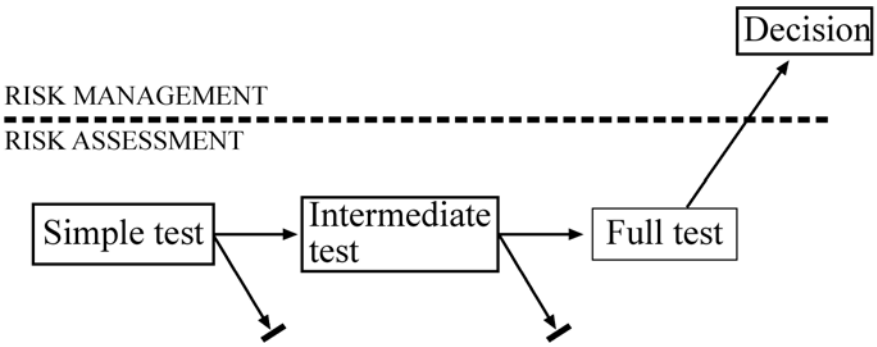

Figure 2.3. The traditional tiered approach and its connection with risk management (from [Hansson and Rudén, 2004]. The risk assessment boxes 'simple test' etc can be seen as synonymous to tier 1, 2 and 3 in a tiered assessment.

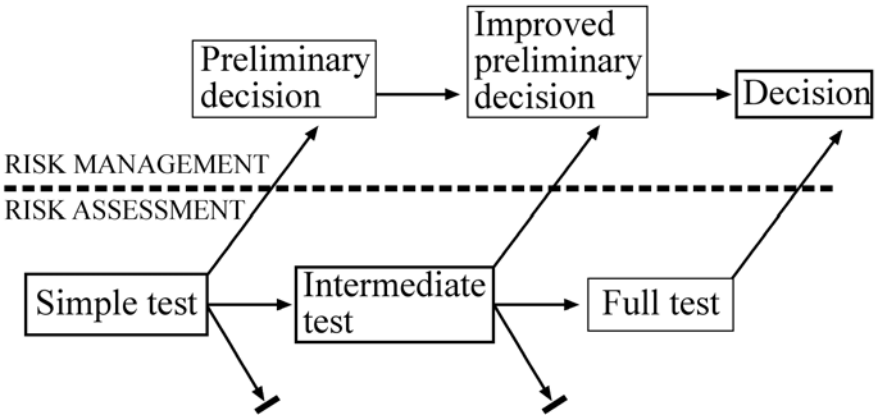

Figure 2.4. A new combined approach to tiered systems proposed by Hansson and Rudén [Hansson and Rudén, 2004]. The risk assessment boxes 'simple test' etc can be seen as synonymous to tier 1, 2 and 3 in a tiered assessment.

2.2 Similarities and differences in assessing radioactive substances and other hazardous substances

2.2.1 Introduction

This section considers the similarities and differences in assessing the environmental impact of radioactive substances compared to non-radioactive substances. Consideration is given to the assessment of both exposure and effects, and additional information and literature sources can be found in ERICA Deliverable 7b (available online at www.erica-project.org).

2.2.2 Exposure pathways

The extent to which an organism is exposed to a chemical/radionuclide is determined by a number of factors. It is dependent on the chemical's distribution within the environment, i.e. whether it occurs in the organism's habitat and also on its bioavailability to the organism. In other words, whether the substance is present in a form that can be taken up and/or exert an effect.

The pathways for internal exposure are similar for radioactive and non-radioactive substances. For both types exposure may be via air, water, sediment or soil and is dependent on how the substance is distributed within the ecosystem. This is determined by a number of factors including:

- *route of release* into the environment, e.g. emission to air or discharge to water;
- *physical/chemical properties* of the chemical, such as solubility or adsorption characteristics, which determine how it will partition to air, water or soil, leach from soil, adsorb to sediment etc.;
- *persistence* – rate of degradation;
- *bioaccumulation* – potential to accumulate in organisms and transfer within food chains, which is dependent on processes such as potential for uptake, elimination and metabolism within the organism.

The main difference between radioactive substances and chemicals is that radioactive substances are associated with both internal and external exposure in organisms. Unlike chemicals, the presence of radioactive substances in environmental media can bring about an increase in radiation dose (rate)

without the need for inhalation or ingestion of the radioactive substance. For both radioactive and non-radioactive substances greater understanding is needed of their fate and behaviour of chemicals in the environment, particularly in relation to their chemical form and their bioavailability.

2.2.3 Dosimetry

The impact of radioactive substances is dependent on the amount of radiation energy absorbed by an organism and is based on an assessment of the dose (rate) to which the organism has been exposed rather than the exposure concentration.

Radiation dosimetry is the process of calculating the quantity of energy absorbed by an organism from both internal and external sources. A variety of factors need to be considered including the size of the organism, its location (e.g. soil or surface dwelling) and the extent to which the, radioactive substances transfers from environmental media to biota.

The impact of non-radioactive substances however is primarily considered in terms of environmental concentration rather than the dose, with effects reported in relation to the concentration to which the organism was exposed. However, in toxicology, the 'dose' from non-radioactive substances is often defined as a rate of intake (i.e. mass/time or g/hr) and dose based experiments can be undertaken for higher animals, such as birds and mammals. Exposure to dose applied via injection, dermal absorption or oral intake is used to calculate a lethal or effect dose.

2.2.4 Degradation products

Radioactive isotopes undergo radioactive decay until a stable non-radioactive nuclide is formed. During the decay process a number of different radioactive elements, or daughters, can be produced which vary in their stability and the type of ionising radiation emitted. The instability of radioactive isotopes means that they have a finite lifetime in contrast to, for example, heavy metals. However, the existence of radioactive decay products increases the radiation impact of the original radionuclide, in many cases significantly since intermediate products are often more hazardous than the original radionuclide, due to a shorter half-life or the type of radiation emitted. Radon daughters are a well-known example. The decay chain for each radionuclide is generally well known and understood.

Non-radioactive substances such as organic compounds, undergo degradation via a range of processes including both abiotic (e.g., photolysis) and biotic (e.g., biodegradation processes). This results in the formation of by-products, which vary depending on environmental conditions and degradation process. Unlike radioactive substances, degradation pathways are only well known for a relatively small number of chemicals and in many cases, even where degradation products are known, limited work has been undertaken to assess their potential impact on the environment.

Available information indicates that degradation generally results in the formation of a by-product of lower potential hazard to the environment. There are exceptions, however, for example degradation of nonyl phenol ethoxylates results in the formation of nonyl phenol is more toxic to aquatic life than the parent compound. Although pure chemical elements such as heavy metals show no degradation as such, their speciation can change over time. Hence, the environmental impact of both radioactive isotopes and stable elements may either decrease or increase depending on the mobility and bioavailability of the resultant chemical species. For all pollutants, these processes include interactions with environmental media such as soils and sediments.

2.2.5 Background exposure

Background radiation arises from various naturally occurring sources. These include:

- radioactive substances in the earth's crust, e.g. uranium and thorium;

- emanation of radioactive gas from the earth, e.g. radon;
- cosmic rays from outer space which bombard the earth;
- trace amounts of radioactivity in the body.

For example, background radiation accounts for approximately 85% of the average dose to the UK human population. Exposure will vary across the country, as it is dependent to some extent on factors such as local geology.

Organisms are also exposed to natural concentrations of various non-radioactive substances including metals such as copper and zinc and essential elements such as selenium. As with ionising radiation, background concentrations will vary across the country, as their presence will be dependent on the local geology. Little information is available on the relative contributions of natural and anthropogenic sources to exposure of wildlife to naturally occurring non-radioactive substances. How background concentrations of non-radioactive substances are taken into account in the assessment of the potential impact of relevant chemicals is currently a matter of debate. Discussions under the Water Framework Directive, for example, are considering how to take into account background concentrations when setting environmental standards (see ERICA deliverable 7b). Questions arise due to local differences and also the bioavailability of the compounds and the resulting degree of exposure. In addition, it is thought that organisms may adapt to these natural concentrations with habitats consequently containing organisms able to cope with these elevated natural levels. This has been relatively well-documented for 'lower' organisms such as soil micro-organisms and plants, where the existence of heavy metal resistant species can be taken as an indication of environmental stress.

2.2.6 Type of biological effects (stochastic/deterministic)

Ionising radiation can result in both stochastic and deterministic effects. Stochastic effects are those effects of ionising radiation for which the severity of the effect – cancer induction or heritable genetic damage – is independent of the dose but the probability of the outcome increases proportionately with the dose. Deterministic effects such as effects on mortality, morbidity and reproduction are on the other hand effects for which generally a threshold dose exists. A consensus of opinion has developed that stochastic effects are likely to be of little relevance to nonhuman biota and that although they have been found to have an impact on individuals the effect on populations is less clear. As ecological assessments are primarily concerned with assessing impacts on populations the general consensus has been that deterministic effects should be considered within ecological assessments.

Non-radioactive substances can also have stochastic and deterministic effects, however, with respect to ecological impact assessment, deterministic effects have generally been considered. Therefore although certain chemicals, e.g. benzo(a)pyrene are known to have stochastic effects, ecological risk assessments have not yet developed to take account of this.

There are therefore significant similarities between non-radioactive and radioactive substances with respect to this issue. However in both cases consideration will need to be given in the future as to how stochastic effects are assessed, as effects on individuals will need to be considered in circumstances where such impacts are important, e.g. for rare organisms where populations are small and protection of individuals is very important. Finally, for both non-radioactive and radioactive substances, there has been an increased awareness of the importance of non-mortality endpoints within ecological risk assessment, particularly reproduction effects such as fertility and fecundity. The recent focus on endocrine disruptors is a typical example in ecotoxicology.

2.2.7 Availability of chronic effects data

The data available on the impact of radioactive substances relates primarily to acute effects, with a large proportion on mortality. However due to the long physical half lives of many radioactive substances and because radioactive discharges generally result in low level chronic exposure, chronic studies are considered to be the most useful in investigating impacts on biota.

For both radioactive and non-radioactive substances, there are often many more acute than chronic data available. Chronic studies suffer from the fact that they require more resources in terms of time and subsequently cost and therefore acute studies are often undertaken initially to provide an indication of potential impact. Steps have been taken to try and develop chronic tests of shorter duration to overcome some of these difficulties. As highlighted above, these include information on endpoints other than mortality.

Where both acute and chronic data are available for non-radioactive substances a general indication can be obtained on the relationship between acute and chronic data. Based on available data, there appears to be a factor of 10 difference between acute and chronic data. This information has been used to extrapolate from acute to chronic effects where no chronic studies are available, for example, in the derivation of environmental standards. However, this is only a general assumption and for many chemicals the ratio between acute and chronic effects is much smaller.

In view of the paucity of relevant information on chronic effects of radioactive substances the question arises as to whether it is possible to make extrapolations to fill some of the data gaps. However, based on the available data there is considerable evidence that low dose and dose rate chronic irradiation exposures are generally less damaging than high dose and dose rate acute exposures. There does not appear to be a robust and generally applicable basis for extrapolation between these two contrasting exposure conditions.

Some of the chronic effect data for radioactive substances has been obtained from field studies following incidents such as the Chernobyl accident. Whilst providing useful information, field studies are often difficult to interpret due to the influence of other factors that cannot be controlled or measured. This is also the case with field studies of non-radioactive substances. Although filed studies have been used to assess the impact of chemicals, for example following pollution incidents. However, it is often difficult to associate cause and effect with a particular chemical due to other potential influencing factors and in many cases limited data are available pre-incident and therefore the baseline is not known by which to measure effects.

Biomarkers have been developed for both radioactive and non-radioactive substances. However, in both cases, although biomarkers can provide an indication that an effect is occurring it is often difficult to extrapolate the results to what that means to an individual or population. Their use in ecological risk assessment for both types of substances is therefore currently limited (see also Section 3.5.4).

2.2.8 Conclusion

It is clear that there are many similarities between the assessment of the ecological impact of both radioactive and non-radioactive substances in terms of the consideration of exposure and effect. These are outlined in Table 2.3.

In addition there are common areas of development, which would improve the risk assessment of both groups of chemicals. These include further consideration of how to assess stochastic effects and greater understanding of the fate of chemicals in the environment and in particular consideration of bioavailability.

Although there are similarities there are some key differences that need to be taken into account, especially that assessments of radioactive substances need to include external exposure and are based on dose (rate) whereas for non-radioactive substances assessment is based on the ambient concentration.

Table 2.3. Comparison of the assessment of radioactive and non-radioactive substances (from ERICA Deliverable 7b).

	Non-radioactive	**Radioactive**
Exposure Assessment	Background concentrations need to be considered for metals and naturally occurring chemicals Decision making generally based on assessment of ambient concentrations	Background concentrations are a key source and therefore need to be considered
Dosimetry	Dosimetry generally not applied – dose based experiments used for higher organisms (e.g. via injection or oral administration) Effectively one step: exposure-effect	Significant feature of radionuclide assessment Absorbed dose estimated on basis of organism geometry and radiation quality Requires understanding of toxicokinetics Two steps: exposure-dose and dose-effect
Effects Assessment	Range of modes of action Based on adverse effects at individual level Consideration of demographic end-points (mortality, morbidity and reproduction) Effects data expressed in terms of ambient concentration	Common mode of action Based on adverse effects at individual level Consideration of demographic end-points (mortality, morbidity and reproduction) Effects data expressed in terms of absorbed dose

2.3 Integration of ecological and human health assessments

2.3.1 General considerations

In many fields of risk assessment, equal emphasis is placed on both human health and ecological risks, and relevant risk assessments are performed concurrently [OECD/IPCS database; WHO, 2001; EC, 2003a, 2003b]. The increased recognition of the need to protect both man and the environment responds to the perceived need for an integrated and holistic approach to risk assessment [WHO, 2001; EC, 2003a]. Some information and data are likely to be relevant for both human and ecological risk assessment, and identification of common data needs at an early stage may avoid duplication of effort. A conceptual framework of the rationale for integration of human health and ecological risk assessment is provided by Suter [Suter, 2004] presenting both bottom-up and top-down arguments for integration. The bottom-up line of argument begins with transport, fate and exposure mechanisms (e.g.

physical chemical properties, distribution pathways, contaminant concentration in different media, bioaccumulation, background concentrations, etc) that could be considered as common data needs during problem formulation for both human and ecological risk assessment. The top-down line of argument, in contrast begins with the premise that humans reside in ecosystems, and changes in the environment (e.g. ecosystem services and recreational benefits) imply changes in human health and welfare. Ideally, integration should proceed from both directions. Obviously, an integrated approach offers opportunity for common environmental sampling, analysis and exposure modelling activities.

Independent of the regulatory needs, which may require independent assessment for human health, animal health and environmental protection, scientific evaluation of information and knowledge in a risk assessment framework would clearly benefit from a closer similarity and even integration of the protocols. The advantages, inconveniences and difficulties of integrated risk assessments are currently under consideration within the WHO and the EC [WHO, 2001; EC, 2003a]. A harmonised approach to risk assessment is highly desirable for a number of reasons:

- To aid the understanding of risk managers and other stakeholders.
- To enable work done by one scientific body to be utilised without unnecessary duplication of effort by other risk assessors who are concerned with the same stressors or processes.
- To facilitate the comparison of risk from different contaminants or processes
- To ensure that the overall risk from multiple sources of exposure is assessed
- To enable training of future risk assessors.

Effect assessment for vertebrates, and particularly for birds and mammals, has often deviated from a true ecosystem assessment by considering as unacceptable some effects on individuals such as lethality even if these effects have no consequences on populations and communities. Therefore, this assessment moves through protection goals typically considered in the human health (individual level) and animal health (population level) assessment, offering many opportunities for harmonisation (EC 2003b).

2.3.2 Integration of human and environmental radiation protection

ICRP work on Reference Animals and Plants

Radiation protection has always centred on human health protection, although the focus have shifted from deterministic effects on directly affected people (workers, patients) to stochastic effects in human populations, and recently, to effects in the environment. In the development of a framework for dealing with the environmental aspects of radiation, ICRP has stated the following objective:

*'..to **safeguard the environment** by preventing or reducing the frequency of effects likely to cause early mortality or reduced reproductive success in individual fauna and flora to a level where they would have a negligible impact on conservation of species, maintenance of biodiversity, or the health and status of natural habitats or communities'[ICRP, 2003].*

In drawing up a system for the radiological protection of the environment, the ICRP makes use of the concept of *reference animals and plants* or *RAPs*, which is analogous to the *reference man* introduced for the purpose of human radiological protection, and is closely related to the reference organism concept developed for the purpose of FASSET. Both RAP and reference man are references, with defined characteristics, and used as the object for calculation and as basis for effects estimates, ultimately guiding decisions directed to protection. The current working definition of the RAP, formulated by the ICRP Task Group on Reference Animals and Plants, is as follows:

"A Reference Animal or Plant is a hypothetical entity, with the assumed basic biological characteristics of a particular animal or plant, as described to the generality of the taxonomic level of Family, with defined anatomical, physiological and life-history properties, that can be used for the purposes of relating exposure to dose, and relating dose to different categories of effect, for that type of living organism."[1]

As guidance for decision-making for the protection of humans, the ICRP is currently developing an approach based on *levels of concern*; complemented by a set of derived consideration levels, tentatively defined as in Table 2.4 below [ICRP 2003].

Table 2.4. An example of how Derived Consideration Levels can be established for a reference animal or plant (modified from ICRP 1993).

Derived Consideration Level	**Relative Dose Rate** **(Incremental Dose or dose rate)**	**Level of Concern**
Level 1	< Background	Low concern. No action considered.
Level 2	Background range	Low concern. No action considered with regard to limiting e.g. operational releases to the environment, but potential releases may justify an in-depth assessment.
Level 3 and higher	>10 times background	Concern, dependent upon the nature of effects, the numbers and types of individuals affected, the spatial and temporal aspects, and so on. Remediation may be considered at extremely high relative doses.

Thus, substantial convergence is occurring in the systems for human and environmental protection now being considered by the ICRP, as illustrated in Figure 2.5 below.

[1] This definition differs from the definition adopted by FASSET, where *reference organisms* is defined as '*a series of entities that provide a basis for for the estimation of dose rate to a range of organisms which are typical, or representative, of a contaminated environment*'. The ERICA Consortium, during the third ERICA workshop (Chester, March 2005), however, concluded that the reference organism approach adopted by FASSET/ERICA is broadly consistent with the reference animals and plants defined by the ICRP, and the methodology developed within ERICA would be applicable also to ICRP RAPs.

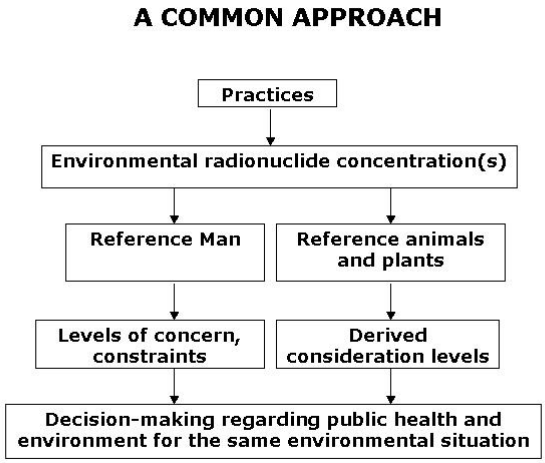

Figure 2.5. A common approach for the radiological protection of humans and non-human organisms from [ICRP, 2003].

IAEA Guidance

The International Atomic Energy Agency takes account of, and integrates, the recommendations of the ICRP within its hierarchical structure of Safety Standards, consisting of *Safety Fundamentals*, *Safety Requirements*, and *Safety Guides*. The Agency has dealt with the issue of environmental effects of ionising radiation, and protection of the environment against such effects, on several occasions. In recent years, this has resulted in TECDOCs 1091 on different approaches to environmental protection [IAEA, 1999], and 1270 on the ethical basis of environmental protection [IAEA, 2002], and in the organisation of the International Conference on the Protection of the Environment from the Effects of Ionizing Radiation, held in Stockholm, October 2003 [IAEA, 2003a] (full proceedings due in 2005).

The TECDOCs above do not deal specifically with risk characterisation. However, in support of the Stockholm Conference, a consultants' group produced working material to assist the discussions during the Conference and underpin the development of a Safety Standard. [IAEA, 2003b][2]

The consultants' group proposed a reasoning around risk characterisation and managerial decisions similar to what has been proposed by the ICRP; this includes an incremental degree of concern based on knowledge of background ranges of radiation and radiation doses as a 'reference'.

A first step in this process would be the comparison of measured or estimated dose (rates) to the existing data on dose(rate) – effect relationships. Under many circumstances, the estimated effects will be subtle (and not detected), and will not affect the health of the individual, or population (for instance, if incremental dose or dose rate is within the magnitude of the normal background range, or below). At incremental doses corresponding to the higher background range and above, detectable increases in mutation frequency, loss of reproductive success, increased morbidity and mortality are

[2] Note that the content of the working material has not been officially endorsed by the Agency, nor does it necessarily reflect the views of the governments designating the experts that took part in preparing the working material.

increasingly likely to have consequences that may be observed. Figure 2.6 illustrates the aggregation and overlap of effects that can occur as the incremental environmental dose increases.

There are factors, apart from lack of knowledge and data gaps, that complicate an analysis of this kind. Firstly, some organisms may experience high background doses that have already caused observable increases in mutation rate and frequency, that will be further aggravated by incremental doses caused by human activity. Secondly, many of the environmentally significant effects may not exhibit linear non-threshold dose-response relationships. Thus the level of background radiation may influence both the magnitude and nature of the effects caused by incremental exposure.

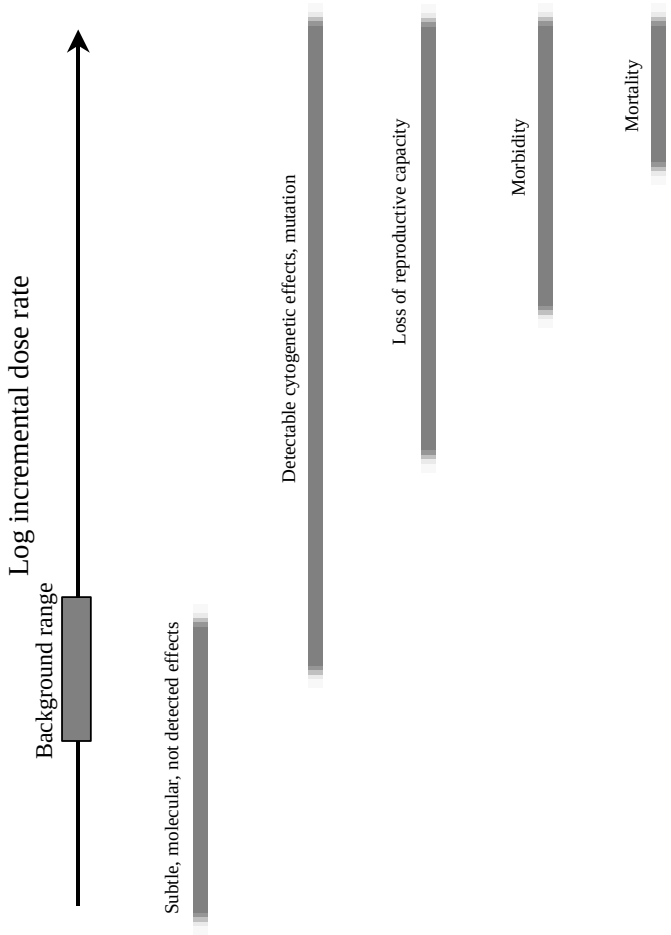

Figure 2.6 Illustration of potential development and overlap between effects categories at different levels of incremental dose (rate). The band labelled "background range" represents a range of incremental doses equal in magnitude to the range of natural radiation doses. [IAEA, 2003b].

Environmental significance

Any risk characterization may have to rest on this first analysis, and further interpretation in terms of 'environmental effects of concern' requires consideration of observed effects, extrapolations and expert judgment. The magnitude of environmental concern can, in analogy to Figure 2.6, be represented in Figure 2.7. A certain degree of caution should be applied, both when extrapolation is

applied between organism groups, and when predicting possible effects at a community or ecosystem level from data obtained for individual members of a restricted number of species.

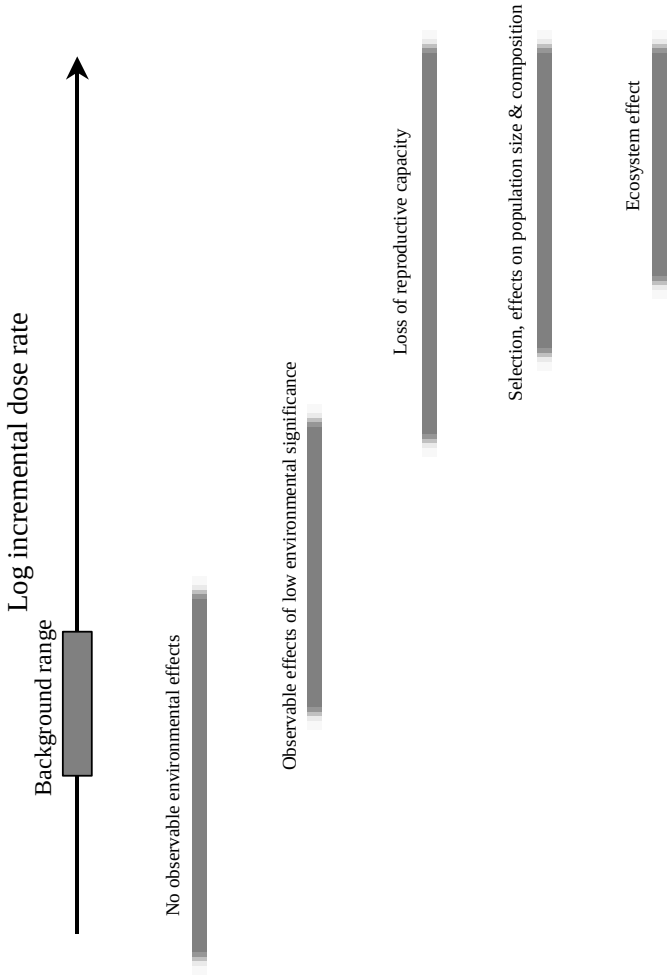

Figure 2.7. Schematic illustration of potential development and overlap between general environmental effects at different levels of incremental dose (rate). The band labelled "background range" represents a range of incremental doses equal in magnitude to the range of natural radiation doses. [IAEA, 2003b].

Level of concern and decision-making

Decisions on activities, practices or interventions that involve radioactive contamination of the environment may be informed through the technical assessment procedures described above but will also be influenced by many other factors, including stakeholder views, which often involve trade-offs. All these factors become integrated in the judgement of acceptability, which – in turn – guides decision-making. A key feature of such decision-making is that the process should be open and transparent, and that all factors considered should be clearly defined such that there is a basis for judgement on the acceptability of the decision.

The criteria whereby acceptability will be judged will obviously depend on the circumstances, and the regional or national context within which the assessment is being made. The actual set of factors to be

considered in any particular case might be fairly simple or highly complex. Even in simple situations, a decision will not necessarily be made on the basis of quantitative criteria (a value of annual dose, for example). Furthermore, (potential) radioactive contamination may not be the only factor which needs to be considered; an Environmental Impact Assessment (EIA) will consider all environmental consequences of the activity being evaluated. Figure 2.8 illustrates how the decisions, through an EIA procedure, or other form of assessment, may relate to the 'scientific' aspects of the assessment procedure (cf. Figures 2.6 and 2.7).

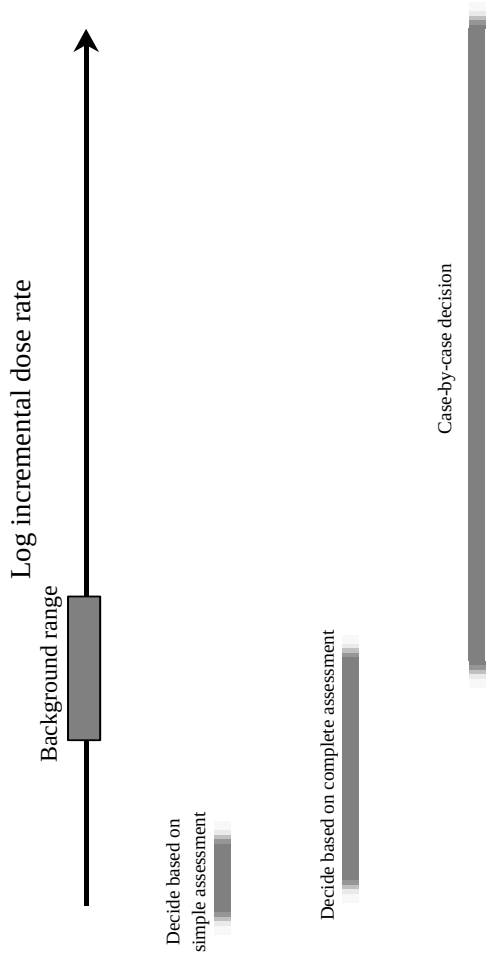

Figure 2.8. Illustration of how the decision-making process may be related to the dose (rate) in the concerned environment, and relating to the scientific aspects of the assessment outlined in Figures 2.6 and 2.7. Note that the ranges indicated are highly influenced by numerous factors, including stakeholder views, governing the decision in. The band labelled "background range" represents a range of incremental doses equal in magnitude to the range of natural radiation doses. Reproduced from [IAEA, 2003b].

3 Risk characterisation – approaches and methods

3.1 Estimating risks – an introduction

As discussed in Section 2.1, in the general ERA framework risk characterisation is identified as an integrative step of hazard identification and, exposure and effects assessment. A description and discussion of various approaches and methods in risk characterisation is given below. This review is not all–inclusive, but is intended to highlight the most important components of risk characterisation relevant to development of the ERICA risk characterisation methodology. Within each subsection the component of interest (in the order given in Table 2.1) will be described, discussed and highlighted with examples.

It is obvious that risk characterisation will neither be more accurate nor more precise than the data on which it is based. Poor exposure data and inadequate treatment of available effects information may instead lead to inadequate risk characterisations and subsequent indefensible decisions. Lack of data and oversimplified assumptions may also lead to inadequate results, as they would suffer from unacceptably large uncertainties. It has been argued that perhaps the most important shortcoming of historic risk assessments has been the often unjustifiably high level of confidence in risk estimates (as discussed further in Section 3.4.) [Williams and Paustenbach, 2002].

It is also fundamental to recognise and clearly describe the assumptions and other choices made during problem formulation and the analysis steps. For example, the risk estimate should be a formulation of risk that relates directly to the assessment endpoint identified in problem formulation. Furthermore, several assumptions concerning the source characteristics, including radionuclide speciation, spatial distribution and temporal scale, mobility and alternative routes (speciation dependent) and rate of exposure as well as extrapolations of effects among species or exposure scenarios are usually made during exposure and effects analysis. Uncertainties and limitations connected with these assumptions should be clearly described in the risk characterisation. Evaluation of an ecological risk or effect can never be a purely objective process. That is, the adversity of an ecological effect (and the weight it will be given in environmental decision–making) will not only be influenced by the magnitude and nature of the risk as estimated in the ERA, but also by how valued the ecological receptor is by the parties taking part in the decision. Thus, in the risk characterisation it must be specified why the assessment endpoint was chosen to begin with. There will also always be a need for interpretation of the results to aid risk managers and to promote understanding by stakeholders and the public [Suter et al., 2000]. For example, in some situations a predicted substantial effect in an assessment endpoint may not constitute an ecologically significant effect (e.g. due to a restricted spatial scale of the effect). Therefore, the significance of a risk will need to be interpreted with respect to the nature, intensity, spatial and temporal scale of the risk as well as the potential for recovery. Furthermore, communication of the overall uncertainties not only to risk managers but also to stakeholders and parties involved needs to be addressed.

3.2 Criteria for screening of hazardous substances

The aim of screening is to determine whether further in depth analysis is necessary, and if so, to identify data needs, and/or to prioritise resources. Several criteria have, singly or in combination, been used to screen chemicals (Table 3.1). Below, some of these screening criteria are described in more detail.

Table 3.1. Criteria used for screening contaminants.

Type screening property	Screening criteria
Potential for Exposure	Source
	Physical–chemical properties
	Detection
	Background
	Production volume
	Persistence
	Bioaccumulation
Potential for effect	Ecotoxicological benchmarks
	Criteria/standards
	Equilibrium partitioning benchmarks

3.2.1 Source, physico–chemical forms of chemicals and detection

Screening against source would be applicable when the source, for example, is well characterised (e.g. deposited waste or an effluent). If a chemical is not in the source and is known not to be the product of any decay or transformation from a chemical included in the source, the chemical can be eliminated from further assessment. Information on the physico–chemical forms (speciation) of chemicals can also be used as a basis to exclude a chemical as a contaminant of concern, separating chemical species into categories according to for instance, mass (inert particles), charge/reactivity (ionic species), valence (oxidation states), water solubility and volatility since such properties can imply that the chemical will not be present in some media at any significant levels. This type of screening could be applicable, for example, when screening of volatile organic compounds or extremely non–soluble chemicals in aquatic environments (since these might not be expected to present in the water at any significant level). For radioactive substances, an analogy can be seen when assessing potential future risks of waste repositories, since in such situations properties such as half–life and the speciation of radioactive substances (physico–chemical forms) influencing mobility and bioavailability will influence the classification of concern of various radioactive substances.

Screening against detection/determination limits is also possible. That is, if a chemical is not detected in the environmental media of concern it could be removed from the assessment. However, care must be taken to ensure that the detection limit is well below the concentration where ecotoxicological effects would start to appear. This could be especially problematic in situations where the ecological thresholds are poorly defined (e.g. exotic radioactive substances) or complex mixtures of contaminants are being assessed, since the total exposure to the contaminant mixture could be ecologically significant even if each individual contaminant is present at low concentrations. A connected potential problem is often encountered when analysing exposure. That is, if environmental samples include both detects and non–detects (i.e. samples where the chemical is not detected) setting non–detects to zero will censor the low end of the concentration distribution and consequently lead to an underestimation of exposure. In screening assessments this is often handled by simply using the detection limit for non–detects, the maximum concentration [Environment Canada, 1997; Bird et al., 2002; USDOE, 2002], or the upper 90 or 95 % percentile [ORNL, 1998; Jones, 2000] as the estimated exposure. In higher tier assessments such conservatism is, however, undesirable [Suter et al., 2003]. Instead the complete distribution can be estimated by fitting distribution functions [Newman et al., 1989].

3.2.2 Background level

For several reasons a number of potentially hazardous chemicals are present in the environment at background concentrations/doses. Some metals and radioactive substances, are naturally occurring, whereas others, such as ^{137}Cs (global fallout) and PCBs, may be the result of regional or global contamination. Generally ERA is performed on total concentrations/doses (i.e. it is the risk of the total dose or dose rate to biota that must be evaluated) [ACRP, 2002; Bird et al., 2002; USDOE, 2002; Jones et al., 2003]. Management decisions concerning effluent authorisations or restrictions will probably be expressed in terms of incremental exposures, even though these also need to be based on an estimate of the total risk [EA, 2002a,2002b]. To address this issue RIVM has developed an 'added risk approach' [RIVM, 2001b], which is used to derive the maximum permissible addition of a contaminant to the environment (based on the background concentration and a derived maximum permissible concentration of no effects). Consequently, this approach would lead to lower maximum permissible additions in areas with high background concentrations.

Screening against background is often motivated by the low (if any) ecological risk of background concentrations/doses [ACRP, 2002; Jones et al., 2003] as well as the low probability of any risk management decision (e.g. remediation or restriction) ever being based on levels of exposure similar to background [Suter et al., 2000]. Following this line of reasoning ICRP [ICRP, 2003] has proposed the development of derived consideration levels (Section 2.3.2) for reference flora and fauna, with explicit reference to background dose rates. The idea is to aid in the consideration of different management options by compiling information of ecological effects on various reference organisms relative to natural background levels. This information could then be classified into bands of concern recommending various management actions. For example, dose rates in the background range would generally imply low concern with no actions considered.

There are, however, several problems with using natural background as screening criteria. First of all, there is the problem of defining which value to use as representative of the natural background at the impacted site. This could be a substantial problem due to potential anomalies and inhomogeneous distributions. Is it, for example best to use local or regional backgrounds? Should an average or maximum value be used or twice the average value (as has sometimes been proposed)? [Suter et al., 2000]. Care must also be taken to ensure that biota at the background locations really are unaffected and that background concentrations are comparable to those measured or estimated at the contaminated site. It is also possible that there are differences in bioavailability or routes of exposure to resident organisms that could lead to an underestimation of risk. Finally, using background for screening will often involve a kind of indirect comparison of doses from a set of specific nuclides with natural doses from a wider range of naturally occurring radioactive substances This comparison is motivated by the assumption that the natural background range is safe for the environment. However, even though the empirical evidence supports this assumption it seems preferable to base screening criteria on empirically derived safe doses of the specific radioactive substances being assessed.

Instead of using natural background as specific screening criteria it has often been proposed to check and calibrate the relevance and utility of derived effect based benchmarks against background levels. One application is to limit ecotoxicological benchmarks so that benchmarks cannot be set below the background [ORNL, 1996a; Environment Canada, 1997].

To conclude, consideration of background levels aids in the derivation of empirical effects based benchmarks and also forms essential information in interpreting the likelihood or magnitude of effect. In terms of management options it is evident that the probability and magnitude of various management actions will increase with the level of concern and that concern increases with the degree of contamination. ICRP´s derived consideration levels based on multiples of the natural background range seems to be a good way of describing and formalising this relationship.

3.2.3 Production volume, persistence and bioaccumulation

A different type of screening against potential for exposure is performed in the EC for risk assessment of chemicals [EC, 2003b] where production volume is used as an indication of the potential for exposure and is therefore used as a criteria for data requirements. That is, higher testing and assessment requirements are placed on chemicals with high production volumes. Similarly, total inventories of for example specific waste components or contaminants at a contaminated site can be used for priority setting. If the amounts of contaminants present at a site are relatively low (e.g. high concentrations in a restricted geographical area) it could be argued that there is a low risk for contamination of neighbouring ecosystems. Since ecological risk is the product of both the potential for exposure and the potential for effects some risk assessment systems have developed screening criteria that combine inventories with information on toxicity. For example, in the Basel Convention on the control of trans–boundary movements of hazardous wastes and their disposal [Basel Convention, 2002] the ecotoxicity of waste is classified based on a combination of toxicity and inventory.

In the risk assessment of classical hazardous contaminants one class of contaminants that have been identified as especially problematic are contaminants exhibiting PBT characteristics (Persistent, Bioaccumulative and Toxic) such as DDT, PCBs and PAHs. The problem with these PBT contaminants is the difficulty to assess their long-term environmental effects. PCB contamination of the Baltic Sea, for example, which led to detrimental effects on the reproduction of seals. A full risk assessment of PCBs prior to permitting its use should therefore have included chronic toxicity testing on seals or a good surrogate species. These types of test are not required today and also entail severe ethical drawbacks. As a consequence it is often argued today that that no safe level of PBT contaminants in the environment can be defined with an adequately narrow confidence interval. Therefore risk assessment of these contaminants consists of an identification and classification of their intrinsic PBT properties [EC, 2003b].

Naturally, there are major differences between the above discussed organic PBT contaminants (as e.g. PCBs) and the radioactive substances of interest in ERICA. There is, however, an analogy in the sense that hazardous properties such as longevity (physical half-life) in the environment and potential capacity to bioaccumulate (in combination with radiotoxicity) can be used to identify radioactive substances of special concern. This could, for example, be used to help prioritise among management options or research initiatives.

3.2.4 Ecotoxicological benchmarks

The use of various types of ecotoxicological benchmarks (concentrations assumed to be safe) based on exposure–response information (e.g. ecotoxicity test endpoints) is a simple and probably the most common way of integrating exposure and effects information [Suter et al., 2000]. Benchmarks used for screening are usually derived to be conservative to ensure that hazardous contaminants are not eliminated in the screening process. In some cases (e.g. if there is a concern that the benchmark is not conservative enough) expected safe concentrations are adjusted by safety factors (2–10) to derive the screening benchmark [Environment Canada, 1997; RIVM, 2001b; EC, 2003b]. If benchmarks are used (together with other lines of evidence) at higher tiers these are often chosen or derived to be less conservative and more realistic (e.g. by deriving benchmarks for a specific wildlife group) for the assessment endpoints of interest [e.g. Environment Canada, 1997; USDOE, 2002]. This is because higher tier risk characterisations often involve evaluation of different courses of action (e.g. restriction or remediation) and it is therefore more important that these deliver realistic estimates and descriptions of ecological risks.

A multitude of different methods and approaches have been used to derive benchmarks (especially for aquatic animals) and there is little consensus about which methods are best (Table 3.2) [Suter, 1996]. There are also inconsistencies among media (e.g. aquatic and soil environments) and organism groups (e.g. invertebrates, wildlife and plants) in how benchmarks are developed [Suter et al., 2000]. In a review of various available ecotoxicological benchmarks Suter [Suter, 1996] concluded that all types of benchmarks have advantages and drawbacks and that none of the benchmarks were consistently too sensitive or inadequately sensitive. Therefore, it is usually recommended that a battery of benchmarks (if possible) are used to decrease the likelihood of falsely inferring that the contaminant is not a potential risk [ORNL, 1996a]. Alternatively, 'consensus' benchmarks have sometimes been derived as the average of alternative benchmarks [Swartz, 1999]. As discussed below, radiological benchmarks are, however, not as diverse as, for example, benchmarks for effects of hazardous chemicals on aquatic biota [ORNL, 1998; Bird et al., 2002; USDOE, 2002]. Therefore, the approach of using a battery of benchmarks has not been adopted for screening or higher tier risk assessment of radioactive substances. However, it should be possible to derive a larger set of various radiological benchmarks based on the available effects data (e.g. the FREDERICA effects database being developed within FASSET and amplified in ERICA). These benchmarks could, for example, be derived to exhibit different degrees of conservatism as well as taxonomic or site specificity. The extent to which this is possible or desirable remains to be evaluated within the remainder of the ERICA project.

Table 3.2. General methods of deriving ecotoxicological benchmarks and criteria.

General method	Specific method	Examples	References
1) Toxicity test endpoints	a) Fitted functions (e.g. probit, logit)	LC_{50}, EC_{20}	[Suter, 1996]
	b) Hypothesis testing parameters	CV, LOEC, NOEC, NOAEL	[ORNL, 1996a; Suter, 1996; Suter et al., 2000]
	c) Distribution based	ORNL soil benchmarks	[ORNL, 1997a,1997c]
	d) Integrated population endpoints	test EC_{20}, sensitive species test EC_{20}, population EC_{25}, *r*	[Suter, 1996; Forbes and Calow, 2002b]
	e) Integrated laboratory and field data	ER–L, ER–M, TEL, PEL	[review in ORNL, 1997b]
2) Extrapolated	a) Safety factors	PNEC, ENEV	[Environment Canada, 1997; EC, 2003b]
	b) Regression models	Intertaxa extrapolation of test endpoints	[Calabrese and Baldwin, 1994]
	c) Allometric scaling and PBPK models	Interspecies extrapolation of wildlife toxicity	[Suter, 1993; Sample and Arenal, 1999; Suter et al., 2000]
	d) Equilibrium partitioning	Derivation of sediment benchmarks from water benchmarks	[ORNL, 1997b]
	e) QSAR	Extrapolation among contaminants	[OPPT, 1994]
	f) Species sensitivity	NAWQC, Tier II values, MPC	[USEPA, 1985; ORNL, 1996a; RIVM, 2001b]
3) Field endpoints	a) Field survey data	SLC, AET	[review in ORNL, 1997b]

Even though further work will be performed within ERICA D5 to evaluate which of these types of benchmarks are appropriate for use with radioactive substances, the most likely candidates are:

1. **Benchmarks based on species sensitivity distributions.**

These benchmarks are derived by fitting information on various species sensitivity to a mathematical distribution. The fitted species sensitivity distribution can then be used to calculate the concentration that affects only an acceptable fraction of the species (often 5% with a specified level of confidence). This method is described and discussed in more detail in Section 3.4.4.

2. **Benchmarks based on toxicity testing and safety factors**

This method is used when there is a limited amount of available effects data (e.g. few species or only acute toxicity). Usually the lowest available no–effect level from the effects database is used. This value is then divided with a safety factors (i.e. 10, 100 or 1000) to derive the benchmark. The size of the safety factor is chosen depending on the type, quantity and quality of the available toxicity data and depending on the intrinsic hazard of the contaminant. This method is described and discussed in more detail in Section 3.4.3.

Effects data and benchmarks based on field surveys or population level endpoints will also (if available) be of use, but probably primarily at higher tiers of the risk assessment. Once the assessment has advanced beyond the initial screening this type of site–specific and realistic data becomes more important. Often several lines of evidence increase the credibility of the results (e.g. if results indicate similar dose–response relationships). Sometimes, however, toxicity tests and field surveys contradict each other, leading to problems of interpretation. Multiple lines of evidence is discussed further in Section 3.5.

3.2.5 Radiological benchmarks

Radiological benchmarks, as used in this document, refer to a suggested dose, dose rate or activity concentration below which it has been determined (by some method) that biological effects on non-human biota would be unlikely. In some cases, the method of determining the threshold of biological effect is known and this is discussed below. In other publications, the benchmark referred to here has also been termed a guideline. The ERICA EUG felt that the term benchmark should be used to refer to a fixed level below which there would be no biological effect from the radioactive substances and that any safety factors should be applied to this benchmark number which should not change during the course of an assessment although, of course, the safety factor might vary as more information becomes available. Thus, if a benchmark value of 0.4 mGy h^{-1} is adopted, then at a tier 1 you might apply a safety factor of say 100, whereas at tier 2, a safety factor of 10 may be applied because more information on the actual radioactive substances present and their concentrations in the environmental media will be available [3].

Benchmarks developed for assessing ecological effects of radioactive substances have primarily been based on reviews of available information concerning relationships between dose rate and effects on flora and fauna. The key source for selecting a benchmark to use for assessments in many studies has been the reports by IAEA [IAEA, 1992] and UNSCEAR [UNSCEAR, 1996]. The work to determine a boundary between no or limited effects and significant biological effects started in the mid 1970s when reviews were conducted on the available effects literature for chronic exposure to radioactive substances. Within these reviews, various committees concluded that, for the majority of experiments and the majority of organisms in terrestrial and aquatic environments, no significant effects at the population level were expected below the values given below and reiterated in Table 3.3. The output from these reviews was never intended to be used as a limit value and the wording of the reports clearly states that these were guideline values below which significant effects caused by exposure to radioactive substances were thought to be highly unlikely. No guidance on the application of safety factors were given, which is natural given that, this studies were not delivering actual benchmarks.

The dose rates proposed below at which no significant effects were expected at the level of the population as proposed in IAEA [1992] and reiterated in UNSCEAR [1996] are summarised below.

- Aquatic animals – The absorbed dose to aquatic animals should not exceed 10 mGy/d (4 Gy/y) from exposure to radiation or radioactive substance releases into the aquatic environment. Limiting the dose to the maximally exposed individuals to less than 10 mGy/d would provide adequate protection of the population based on no ecologically significant effects on individuals below this level.
- Terrestrial plants – The absorbed dose to terrestrial plants should not exceed 10 mGy/d (4 Gy/y) from exposure to radiation or radioactive substance releases into the terrestrial environment.

[3] The safety factor values given here are for illustration only.

- Terrestrial animals – The absorbed dose to terrestrial animals should not exceed 1 mGy/d (0.4 Gy/y) from exposure to radiation or radioactive substance releases into the terrestrial environment.

At the time these values were suggested, the available literature for chronic exposure was limited mainly to low linear energy transfer (LET) radioactive substances and species studied and so the limits for terrestrial animals were largely based on experiments on mammals whilst those for aquatic animals were based primarily on fish species. However, basing the guideline values on mammals was felt to be adequate given that mammals have the highest radiosensitivity. Likewise fish, as vertebrates and in the absence of good data on marine mammals, were considered to have the best available data sets and a high radiosensitivity although noticeably less radiosensitive than terrestrial organisms.

During the reviews some limited data were identified on indicating effects on chromosome aberrations at doses below those proposed. However at that time the significance of chromosome aberrations was not clear in terms of significant effects at the level of a population and it was felt that chromosome damage would usually result in some form of cancer induction. There were few studies looking at the incidence of cancer induction, however, and it was generally accepted that most non-human biota do not live long enough for cancer to become a major effect. One area that was not covered in any detail because of a lack of available experimental studies was the implications of high LET radiation exposure.

Table 3.3. Dose rate benchmarks proposed for radioactive substances.

Reference	Brief Description	No-effect Dose rates mGy/d	Protected level
NCRP 1991	Literature review on effects of ionising radiations on aquatic organisms	Aquatic organisms 10	Population
IAEA 1992	Dose rates suggested as "safe" guidelines i.e. there are no convincing evidence that populations are affected at dose rates less than these values	Terrestrial plants 10 Terrestrial animals 1 Aquatic animals 10	Population
UNSCEAR 1996	Literature review on effects of ionising radiations on non-human species – Limits are maximum dose rates to a small proportion of the individuals, i.e. a lower average dose rates at the population level for the most sensitive species	Terrestrial plants 10 Terrestrial animals 1 Aquatic animals10	Population
Sazykina & Kryshev, 1999, 2002	No-effect dose rates for populations of marine species representing 1% of the LD_{50}	Marine plants 2.7 Marine animals 0.27	
US DOE 2002 ORNL 1998	Benchmark dose rates used in the screening Tier when applying the proposed graduated ecological risk assessment The used values come from : NCRP 91, IAEA 92, UNSCEAR 96 These values are used to derive screening benchmark concentrations i.e. contaminant concentrations in environmental media (water, sediment, soil)	Terrestrial plants 10 Terrestrial animals 1 Aquatic animals 10	Population
Bird *et al.*, 2002	No-effect dose rates for populations of wildlife groups as specified, applying safety extrapolation factor to the lowest critical radiotoxicity value as it is currently done in ecotoxicology Use as benchmarks values in the screening tier of the Ecological risk Assessment method developed by Environment Canada (1997)	Terrestrial plants 2,7 Terrestrial invertebrates 5,5 Small mammals 2,7 Algae/macrophytes 2,7 Amphibians 2,7 Benthic invertebrates 5,5 Fish 0,55	Species the most sensitive and consequently all species of the same taxonomic group
Environment Agency UK 2002a, 2003b Copplestone *et al.*, 2001	No-effect Dose rates used to retro-calculate screening discharge levels applied in the Environmental Impact Assessment method for radioactive substances authorisations developed by the Environment Agency (UK) The used values come from : IAEA 1992, reviewed and assessed for screening purposes For stage 2 of the method which aim is to identify whether the discharge authorisation presents a risk, benchmarks correspond to 5% of the IAEA guidelines	Terrestrial plants 10 *Including bacteria, lichen, fungus* Terrestrial animals 1 *Including aquatic animals which inhabit marine or freshwater environment but with more than 50% occupancy of the terrestrial environment* Marine mammals 1 Other freshwater and coastal marine water organisms 10 Deep ocean organisms 24	Population

Since the IAEA [1992] and UNSCEAR [1996] reviews a number of other studies have reviewed the available effects literature and have suggested different radiological benchmarks. Lower dose limits

have been proposed by other authors [Sazykina and Kryshev, 1999] because the dose rates proposed by the IAEA [1992] are many times higher than natural background, and characteristic of exposure in very contaminated areas. In their approach, Sazykina & Kryshev have estimated primary dose limits to non-human biota based on the available dose-effect data but modified because the dose limits are for adult organisms living in natural, temperate ecosystems, which are not subjected to direct anthropogenic stress. They noted that it may be necessary to reduce the dose limits for species with very radiosensitive early stages of their life cycle and for the most radiosensitive species in each group of organisms. Furthermore, the Typhoon system also suggests a method for derivation of site-specific, secondary dose limits. Site-specific dose limits are derived by adjusting the primary dose limits, using a number of coefficients intended to evaluate other stresses associated with the local environment to which populations are subjected. These coefficients are:

- A climate coefficient, indicating the general capacity of local ecosystems to resist stress factors. The least stress is assumed to be a temperate climate, the greatest stress an arctic climate.
- Coefficient of direct anthropogenic impact on the local ecosystem. Natural, virgin ecosystems are assumed to result in no additional stress whereas the maximum stress is experienced in industrial urban areas.
- A natural stress parameter, evaluating the severity of natural environmental conditions for the specified group of organisms in the local environment. Examples of natural stress factors are shortage of water or food and unfavourable living conditions during some periods of the year.

For screening purposes USDOE [USDOE, 2002] and ORNL [ORNL, 1998] back-calculate (using conservative dosimetric assumptions) from safe dose rates to benchmarks of safe environmental concentrations in various media. In contrast, many other sources use or propose comparison to benchmarks based on dose rate [Sazykina and Kryshev, 1999; Environment Canada and Health Canada, 2000; Copplestone et al., 2001; ACRP, 2002; Bird et al., 2002].

ORNL [ORNL, 1998] has calculated screening benchmarks for water and sediment based on two sizes of fish, and using an acceptable dose rate of 0.4 mGy h^{-1}. The dose rate is based on reviews summarised in NCRP report 109 [NCRP, 1991] and intended to apply to the most radiosensitive populations of aquatic organisms namely fish. However, some objections have been raised to using 0.4 mGy h^{-1} as an ecologically safe dose rate. NCRP recognises that other factors may modify ecological impact and suggests that where results of radiological modelling and/or dosimetric measurements indicate that a radiation dose of 0.1 mGy h^{-1} will be exceeded, a more comprehensive evaluation is desirable. Taking into account differing views on safe ecological dose rates and recognising the uncertainties of low level radiation effects on natural populations, ORNL also suggests a compromise initial screening approach, in that the maximum exposure concentration is compared with a threshold of 0.1 mGy h^{-1}.

The dose rates proposed by CNSC [Bird et al., 2002] in their assessment of the releases of radioactive substances from nuclear facilities, carried out as part of the assessment of priority listed substances, are shown in Table 3.3. These dose rates were derived with a slightly different approach to those described above. Chronic toxicity values (CTVs) were selected for a number of taxonomic groups, based on literature reviews. CTVs are based on the most sensitive response applicable to the survival of the species following chronic exposure. The application factors, selected to take into account the uncertainties associated with the chronic toxicity values, i.e. taking data quality into account, are applied to generate environmental no-effects values, with which there is little probability of underestimating the risk of effects. This procedure is analogous to that of applying a safety factor to NOEC values.

A similar approach of adopting a lower screening level set, in this case, at 5% of the IAEA guideline values was taken by Copplestone et al. [Copplestone et al., 2001] and the Environment Agency in England and Wales [EA, 2002a] for site specific assessments. In this case, this approach was selected because only a few radioactive substances were incorporated into the assessment tool and because of the associated uncertainties.

When considering a radiological benchmark for groups of wildlife (e.g. aquatic plants, aquatic animals, terrestrial plants, terrestrial animals) the benchmark should, ideally, be set using the most sensitive species or family representing that the overall wildlife 'group'. However, there are deficiencies in to our understanding and knowledge of all radioactive substances with respect to ecosystem behaviour (exposure) and specific biological endpoints which may need to be taken into account when setting a benchmark. For example, it may be that acute exposure data is available but needs to be extrapolated to reflect chronic low dose exposures or that analogue radioactive substances may need to be used to address knowledge gaps. In these cases, care may need to be taken when deriving an appropriate radiological benchmark. It is recommended that, when deriving a radiological benchmark and the derivation of any screening levels based on the benchmark, perhaps utilising the safety factors approach, all the information pertinent to the decision making process are recorded in an open and transparent manner to afford traceability.

3.3 Integrating exposure and effects

3.3.1 General considerations

Integration of exposure and effects into an estimate of risk can either be achieved via deterministic comparisons of point estimates of exposure and effects or via probabilistic methods. In the following sections these different methods are described (Sections 3.3.3 and 3.3.4, respectively). Both of these categories of risk characterisation methods are affected both by intrinsic assets and problems regarding issues such as realism, complexity and acceptance among various stakeholders. Deterministic methods are normally simple and easily communicated, but intrinsically unrealistic and non-quantitative. On the other hand, probabilistic methods are realistic and quantitative, but often complex (and consequently hard to communicate). This means that the use of these different risk characterisation methods needs to be optimised among the various tiers of the risk assessment. Generally, probabilistic methods are introduced at the higher (often at the final) tier of the assessment [Environment Canada, 1997]. However, the optimum design is influenced by factors such as data availability, regulatory requirements and stakeholder opinions. Therefore, there should be some allowance for 'evolution' of any new risk assessment system (such as the ERICA integrated approach).

A second general consideration relates to the fundamental differences between prospective and retrospective risk assessments. Prospective risk assessments will essentially depend on single lines of evidence, namely dose–response relationships derived from toxicity experiments (single– or multi–species, acute or chronic etc.). This effect information is subsequently compared to modelled anticipated exposures to ecological receptors of concern. In prospective assessments, the major uncertainties are often connected with understanding exposure of specific ecological receptors and with describing the temporal and spatial distribution of the exposure. Retrospective assessments can, on the other hand, include other lines of evidence apart from toxicity tests. If an already contaminated site is assessed it is for example possible to perform toxicity testing on contaminated media or measure biomarkers and other effects directly in exposed populations. In retrospective assessments it is usually possible to directly measure exposures (or at least to measure concentrations and thereafter to estimate doses based on these concentrations). Consequently, more information for both effect and exposure are generally available in retrospective assessments and remaining uncertainties are to a larger extent than in prospective assessments connected with lack of knowledge of effects. Because of these major differences among prospective and retrospective assessments it is not certain that the optimal trade-off

between risk characterisation methods should be identical in these two distinct classes of risk assessments.

3.3.2 Some general considerations on deriving exposure estimates

The extent of exposure of ecological receptors to contaminants is one of the fundamental input requirements to any risk characterisation. Therefore, it is important that all methods (e.g. methods for analysis, sampling. modelling etc.) used for estimating exposure are evaluated and justified.

It is beyond the scope of this report to review all problems and methods connected with assessing the exposure of organisms to ionising radiation. Instead, we briefly discuss some key choices and general considerations concerning estimation of exposure that are important for risk characterisation.

First of all, there needs to be a decision on which unit to use (concentration, activity concentration or dose/dose rate). Since most effects information describes effects as a function of dose or dose rate, there are strong reasons to quantify exposure primarily as dose rates. It is, however, possible to back–calculate effects benchmarks from dose rate to concentration using concentration ratios or kd values and dosimetric models [USDOE, 2002]. Especially in screening assessments, there could be an advantage to quantifying exposure using concentration units since this would imply a harmonisation with methods used for screening hazardous chemicals. Concentration is also an easier concept to understand than dose, and therefore easier to explain to some stakeholders during the screening phase. One complicating factor is that exposure to hazardous contaminants is usually quantified differently in various groups of organisms [Suter et al., 2000]. For invertebrates and plants estimated exposure is usually based on concentrations of contaminants in separate environmental media (e.g. soil, sediment, water). For wildlife, such as birds and mammals, exposure is usually estimated as the summed rate of exposure from all possible routes (e.g. water, food, air, soil). When it comes to assessment of radioactive substances this means that it may be appropriate to screen for effects on earthworms based on concentrations in soil, whereas screening of effects on a predatory mammal such as the fox might best be based on calculated dose rates. However, it would still be possible to back–calculate the more complicated exposure situation of the fox from dose rates to concentrations in various environmental media.

A second and far more complicated issue is how to provide a quantitative description of the exposure. Again requirements differ significantly between screening and higher tier assessments. Screening assessment usually require a ‘conservative’ point estimate of exposure, whereas higher tier assessments require a ‘good realistic’ assessment of exposure. However, the question is what constitutes a ‘conservative’ or ‘realistic’ exposure estimate? In screening assessments, the maximum measured or modelled concentration in each relevant environmental media is usually taken as a conservative estimate of exposure, but it is also possible to choose a 95% upper confidence limit of the mean. It is also generally assumed in screening assessments that there is 100% bioavailability and 100% occupancy of the ecological receptor in the contaminated area. It has, however, been argued that the mobility of the organism should influence the way the conservative exposure estimate in screening assessments are calculated [Suter et al., 2000]. Relatively immobile organisms (such as plants and soil/sediment dwelling invertebrates) will experience fairly constant exposures and maximum measured/predicted concentration or an upper percentile of the distribution of concentrations (e.g. 90%) are usually recommended for screening. However, for organisms that average exposures over space (e.g. terrestrial wildlife) or time (e.g. fish and other organisms in flowing water) it may be more appropriate to use the 95% upper confidence limit of the mean.

Even though the generation of realistic estimates of exposure is a primary goal only at higher tiers of the risk assessment, there should already be a plausible and relevant link, at the screening level between the measured or modelled environmental concentration and the ecological receptor. Sampling

and pooling of environmental sampled should be performed to ensure that exposures are not underestimated in the screening assessment. If, for example, a surface layer of soils/sediments is contaminated, the apparent exposure concentration (Bq/kg) will decrease with sampling depth and doses to surface living organisms can be underestimated.

In higher tier assessments, the exposure concentration/dose should represent a more realistic estimate of exposure, which means that factors influencing interpretation of measured or modelled concentrations such as temporal and spatial (horizontal and vertical) differences, bioavailability and bioaccumulation need to be considered. Often it is preferable if possible, in higher tier assessments, to establish exposure distributions (with respect to space or time) as a basis for comparisons with benchmarks or distributions of benchmarks (i.e. to use probabilistic risk characterisation methods)

To summarise, the degree of detail and conservatism in the exposure analysis depends on the level of tier. Various ways are listed below in which the exposure analysis can be refined moving from screening to higher tier assessments. In general, the initial assessment of tiered risk assessment methods will start with methods corresponding to the first level(s), and exposure will be refined, if required by methods from higher levels. However, the methods may not necessarily be applied in sequence, in each case, the available information and the scope of the assessment must be considered to decide which refinement tool is more appropriate.

- **Prospective risk assessment**
    - *Generic deterministic worst–case scenarios*. This level constitutes an initial screening evaluation using a limited amount of information. Non–realistic worst–case scenarios are developed using for example, the most conservative data and the 90th or 95th percentile for each individual parameter, as default value in the models. Exposure is basically considered to be constant over time and homogenous in space, using equilibrium partitioning and/or the highest predicted level.
    - *Generic scenarios using probabilistic estimations.* Single data are replaced in the models by probabilistic estimations. Then tools such as Monte Carlo analysis may be used for setting the final probability distribution of the exposure.
    - *Realistic scenarios covering changes in time and space.* Default values are replaced by realistic estimations. The time and/or space changes in the exposure level are included in the models, which are not longer defined on the basis of homogeneity. More realistic assumptions, are included considering, for example, that organism will move between contaminated and non–contaminated areas.
    - *Field studies.* Controlled emissions in field situations allow realistic estimations as well as calibration and validation of models.
- **Retrospective risk assessment**.
    - *Basic exposure assessment based on real measurement*. Sampling and analysis of a restricted set of environmental samples to determine maximum concentrations in relevant environmental media.
    - *Detailed exposure assessment based on real measurements*. Monitoring program designed to describe the spatial distribution (horizontal and vertical) of contaminants concentrations. It is also often motivated to analyse concentrations in key organisms and to assess bioavailability.

3.3.3 Risk quotients

Definitions and approaches

The most common approach to integrate exposure and effects data and characterise ecological risks of chemical contaminants is to calculate risk quotients (RQ) of estimated exposure (Section 3.3.2) and assumed safe benchmarks (Section 3.2.4). As discussed previously in Section 3.3.2, the RQs can be calculated either based on concentrations or on doses, and represents thereby a concentration ratio or dose ratio. Most frequently RQs are generated as deterministic point estimates, however, probabilistic approaches are sometimes recommended at a higher tier (see Section 3.3.4). The quotient method is well described in various guidelines on ecological risk assessment [Environment Canada, 1997; USEPA, 1998; EC, 2003b]. A critical value of the RQ may form the basis for some regulatory action, including possible collection of more information or performing a more refined assessment.

Within the European framework for new and existing chemicals [EC, 2003b], Predicted Environmental Concentrations (PEC) are compared to Predicted No Effect Concentrations (PNEC) to give a variety of ratios (i.e. RQ = PEC/PNEC) for the different environmental compartments considered (Figure 3.1). RQ values lower than one are generally deemed to be acceptable and no further action is taken. Values greater than one either require reconsideration, such as further information and/or testing for refinement of PECs and/or PNECs, or suggest the need for action, i.e. risk reduction. Typical PEC refinement options are based on use of real emissions instead of the default values included in the TGD. PNEC values can be refined by additional chronic toxicity data or moving to higher tier assays such as mesocosms or field studies. However, this second option, while common for plant protection products, is rarely considered in the case of industrial chemicals. Where it is deemed that further refinement will not decrease the RQ below one, no further testing should be required, and the substance in question should be a candidate for risk reduction [EC, 2003b].

A similar approach is used by Environment Canada with different levels of conservatism in the risk quotient, where tier 1 results in hyper conservative RQs, tier 2 in conservative RQs and tier 3 is a probabilistic analysis of risk (e.g. comparing the exposure distribution with the point estimate of effects benchmarks or comparing distributions of both exposure and effects.)

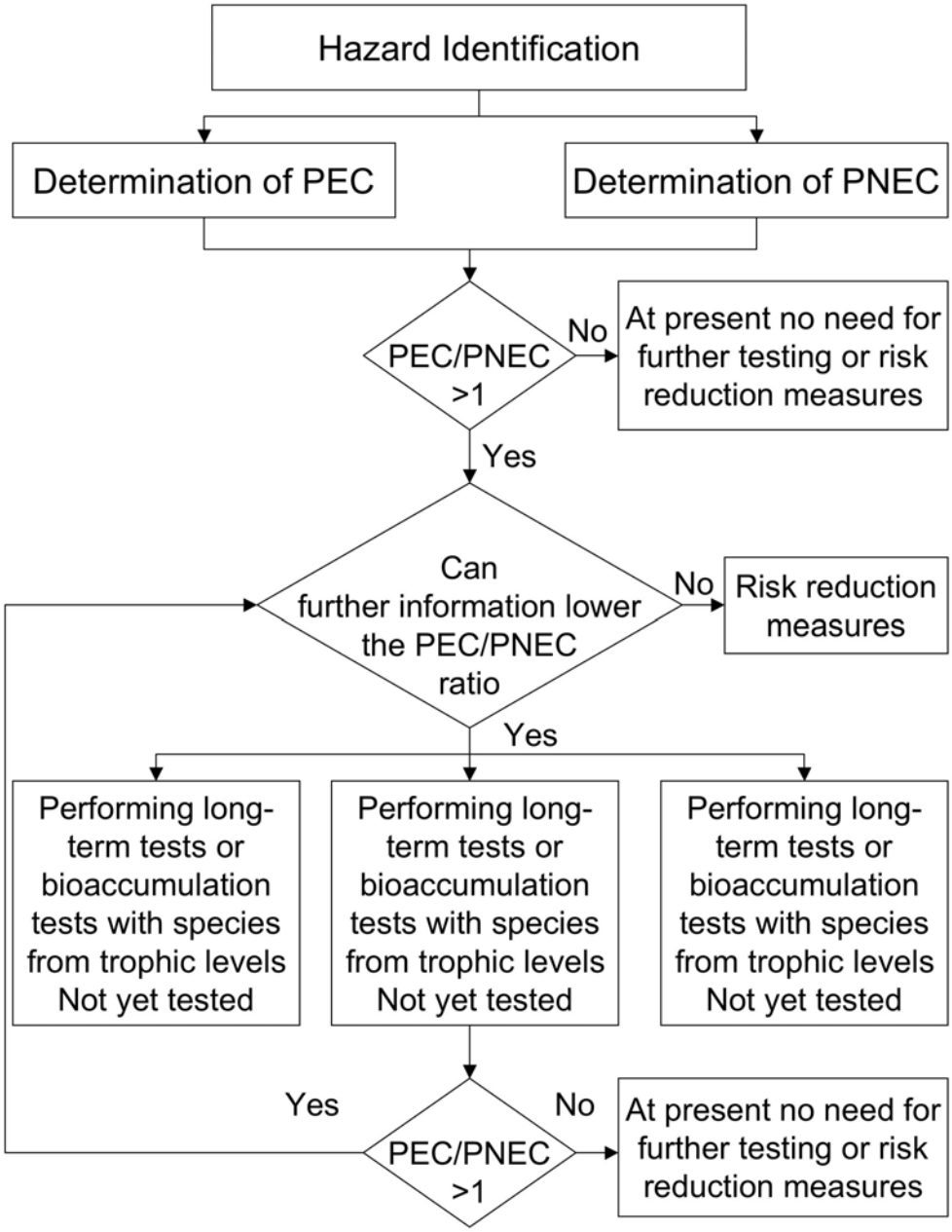

Figure 3.1. General procedure for ecological risk assessment within the EC [EC, 2003b].

The quotient method is widely recognised and easy to use and communicate, which makes it a useful tool in screening and lower tier assessments. However, in higher tier assessments a lot of information is lost when deriving deterministic point estimates of exposure and effects. For example, a RQ of 10 may be inferred as a much larger risk than a RQ of 2, however, the RQ value does not quantify the incidence and severity of the adverse effects. Thus, to interpret these concentration or dose ratios there is a need to calibrate against effects induced. Furthermore, the estimated RQ is influenced by the uncertainties connected with exposure and effects analyses. This means that a high RQ calculated

from uncertain data may constitute no larger a risk than a low RQ calculated from more precise data (Figure 3.2).

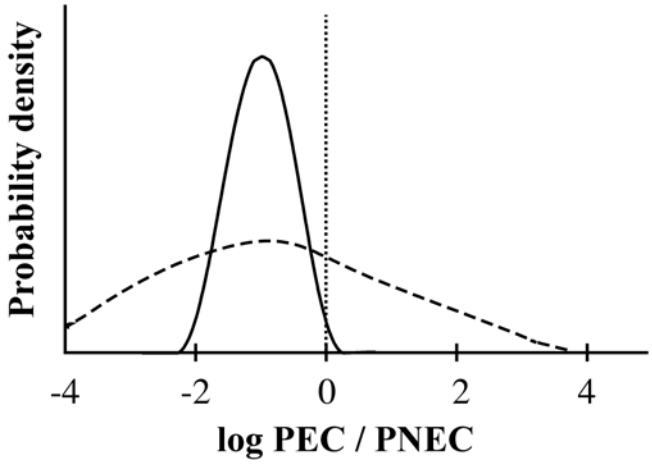

Figure 3.2. Probability distribution of two hypothetical chemicals with the same median PEC/PNEC ratio.

Multiple contaminants

Risk assessments are typically carried out on single substances. Real exposure situations, however, are often more complex with mixtures of contaminants and background levels of naturally occurring chemicals. Generally, contaminants may be regarded as stressors, where the combined exposure of all contaminants adds up to the total stress the target organism experience (e.g. oxidative stress, inhibition of protein synthesis etc.). However, the biological effects observed for a contaminant taken in isolation may be both enhanced or reduced as a function of the potential interaction of all the contaminants occurring simultaneously. An interaction is usually expected for contaminants having a common metabolic pathways, common target tissue or organ, and/or common mode of action.

The most common approach to address multiple exposure is to treat the contribution of each contaminant as additive (that all effective mixture components contribute to the overall effect). The concept of concentration addition is assumed to be valid for contaminants with the same site of action and/or for contaminants with the same mode of action. Consequently, if this is not the case and contaminants having different sites of action and/or dissimilar mechanisms of action, independent action of the contaminants is expected. Thus, at least some basic knowledge of the mode of action of each contaminant in the mixture is needed. Several models have been proposed to deal with toxicity of mixtures ranging from non-polar narcotics (general mode of action) to TCDD-equivalents (specific mode of action). The most common method to assess toxicity of mixtures when interaction is known is probably the Toxic Unit approach (TU). For binary combinations, TU is given by Equation 1:

$$TU = \frac{EC50(A\_mix)}{EC50(A\_alone)} + \frac{EC50(B\_mix)}{EC50(B\_alone)} \quad (1)$$

Where A and B are chemicals, EC50 (mix) is the effect of each component in the binary mix and EC50 (alone) is the EC50 of A and B applied as single components. Thus, a TU of 1 indicates additive interaction whereas a TU>1 is less than additive (antagonistic) and a TU<1 greater than additive (synergistic). Given that the toxicity is additive, the total risk of the mixture can also be assessed as the sum of risk quotients of each of the contaminants (Equation 2):

$$RQ = \sum (PECi / PNECi) \quad (2)$$

Where RQ is the risk quotient, PEC is Predicted Environmental Concentration and PNEC is Predicted No Effect Concentration. If RQ exceeds 1, contaminants contributing with i) a RQ larger than a predefined value (e.g. 0.1) or ii) giving rise to more that a certain part of the risk (e.g. >10%) requires consideration (Suter et al. 2003). Concentration addition models does not always accurately predict mixture toxicity, but may be the best approximation available and appropriate to use in screening assessments, since a complete analysis of multiple contaminant toxicity would require assessment of combination data using full dose-response curves and different mixture regimes.

For low linear energy transfer (LET) radioactive substances, the concept of equivalent dose provides a method of integrating effects of exposure from multiple radioactive substances. The equivalent dose, developed for human risk assessment, is the absorbed dose averaged over tissue or organ and weighted for differences in the relative biological effectiveness (RBE). The applied radiation weighting factor is based on experimentally derived RBE values related to relevant biological endpoints. The equivalent dose is assumed to give the same biological response in all types of cells, irrespective of type of radiation, and thus is directly additive. However, to use the equivalent dose concept in ecological risk assessments appropriate radiation weighting factors for organisms other than man needs to be identified. A more thorough discussion on this issue can be found in FASSET [, 2002b, 2003].

3.3.4 Probabilistic methods

Definitions

Frequently, risk quotients (RQ) are generated as deterministic point estimates as described in Section 3.3.3. While deterministic point estimates simplify assessment and may be sufficient in a screening context, it is not possible to quantify the uncertainty related to the estimate, and worst-case assumptions in the assessment may be multiplied such that the final conclusion is overly conservative or unrealistic. Probabilistic risk assessment methods, in contrast, aims at ranges of plausible values, rather than single values or point estimates (Figure 3.3) [Avila and Larsson, 2001]. In more simple probabilistic risk analysis, risk estimates can be derived by comparing an exposure or effects distribution with a point estimate (Figure 3.3 A and B), e.g. in scenarios with only one principal route of exposure and a single response variable [Environment Canada, 1997]. Often though, risk estimates have to be based on more complex models, taking into account factors such as multiple sources and routes of exposure. Both the exposure estimate and the benchmark can be considered as random variables taken from probability distributions (Figure 3.3 D), and the probability that RQ exceeds unity (Figure 3.3 C) equals the probability of the relevant adverse effects [Avila and Larsson, 2001]. Uncertainties associated with any of the steps in the risk assessment framework may be combined, using statistical techniques, e.g. Monte Carlo simulation, to characterise, quantitatively, the uncertainty and variability in the end estimate of risk. Several examples and recommendations of probabilistic risk assessment methods can be found in various guidelines on ecological risk assessment [e.g. Environment Canada, 1997; USEPA, 1997].

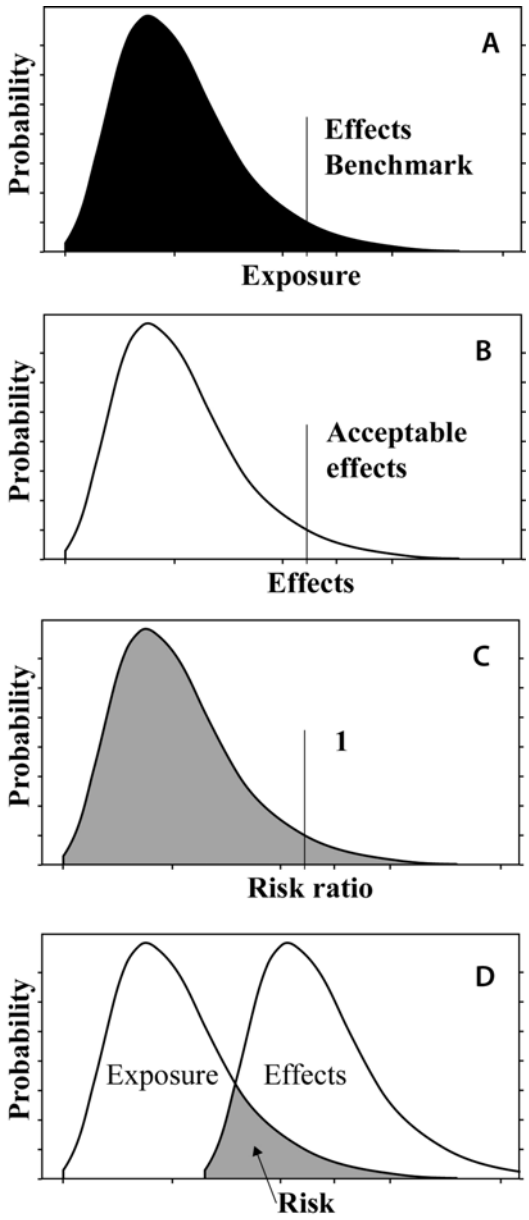

Figure 3.3. Schematic presentation of different ways to utilise probability distribution data of exposure and/or effects in probabilistic risk assessments. Modified from [Jager et al., 2001].

Probabilistic exposure assessments

Most commonly, probabilistic risk assessments are only carried out on exposure data (Figure 3.3 A). The reason for this is that the exposure assessment is typically one of the weakest components in the risk assessment framework. The availability of measured data is, if not non-existent, often scarce. Given this uncertainty, the challenge is how to estimate exposure and how to take into consideration its temporal and spatial variations. To refine the exposure assessment and develop more realistic exposure estimates, probabilistic exposure models taking into account the distribution of the

appropriate exposure variables is the logical way to tackle the problem [Avila and Larsson, 2001; EC, 2003a; Higley et al., 2003b]. For example, environmental transfer data has been evaluated using a probabilistic method (i.e. Monte Carlo simulation) and utilising kinetic/allometric data to estimate concentration ratios across multiple species [Higley et al., 2003b].

In theory, any exposure variable, e.g. physiological, behavioural, or environmental, can be described with a probability distribution and be utilised in a probabilistic exposure assessment. However, identifying important pathways and parameters where assumptions about distributional form contribute significantly to overall uncertainty may aid in focusing data gathering efforts [USEPA, 1997]. Once model input parameters are selected and assigned appropriate probability distributions, the set of samples is entered into the model. The model is then solved as for any deterministic analysis. The model results are stored and the process is repeated until the specified (large) number of model iterations is completed and a distribution of output samples is obtained [Cullen and Frey, 1999]. Paustenbach [Paustenbach, 2000] describes the basic steps in performing an exposure assessment using Monte Carlo simulation as:

- The probability distribution of each equation parameter (input parameter) is characterised, and the distribution is specified for the Monte Carlo simulation. If the data cannot be fitted to a distribution, the data are bootstrapped into the simulation, meaning that from each parameter distribution, and the equation is run. Many iterations are performed, such that the random selections for each parameter approximate the distribution of the parameter. Five thousand (or more) iterations are typically performed for each dose equation.
- Each iteration of the equation is evaluated and saved; hence a probability distribution of equation output (possible doses) is generated.
- Changes in variability dependent frequency distributions under the influence of parameter the input values are randomly selected from the actual data set without a specified distribution.

Uncertainty can be quantified by second order or 2-dimensional Monte Carlo simulation [Cullen and Frey, 1999]. It simply consists in two Monte Carlo loops, one nested inside the other. The inner one deals with the variability of the input variables, while the outer one deals with uncertainty. For each uncertain parameter value in the outer loop, a whole distribution is created in the inner loop based only on variability.

Joint probabilities of exposure and effects

In theory, nothing precludes the use of multiple or hierarchical probability simulations to account for variability and uncertainty in both exposure and effects parameters (Figure 3.3 D). In practice though, such simulations may be hampered by poor availability of environmental exposure and effects data, since knowledge of each probability distribution is needed. This may require the use of professional judgment or costly site-specific studies or data collection efforts. Some possible strategies to derive the required probability distributions to estimate RQ for biota exposed to ionising radiation have been outlined by Avila and Larsson [2001]. They suggest that a probabilistic approach could be implemented gradually. This allows for probability distributions to be successively incorporated in the estimate of RQ, and thereby improving the estimate, when new data and knowledge becomes available. They also point out that the probabilistic method permits for deriving screening values of RQ with the desired level of conservatism, and further, that the probabilistic method is more robust than the deterministic in the sense that new information will have less dramatic influence on a probabilistic risk estimate.

The procedures for probabilistic risk assessment are sufficiently developed that they provide a practical alternative to the application of deterministic risk assessment, and there are good scientific

reasons to justify their adoption since they have a number of potential advantages. At the same time the introduction of probabilistic approaches also may produce difficulties in understanding. Therefore, a phased approach to their use for risk assessment purposes is recommended [EC, 2003a]. Probabilistic risk assessments techniques typically delivers a more transparent, realistic and non-conservative approach to estimate risks, and the use of probabilistic risk assessments will undoubtedly increase in the future. At the moment though, as probabilistic approaches are dependent on more data and labour, they are typically only recommended at higher tier assessments to reduce the uncertainty in the conservative estimates of lower tiers. To meet the demand for probabilistic risk assessments, regulatory agencies have already begun to publish guiding principles on how to conduct and interpret such analyses [Environment Canada, 1997; USEPA, 1997]. Even though the paper developed by US EPA [1997] has its focus on Monte Carlo analysis, it presents a framework and a broad set of principles important for ensuring good scientific practices applying generally to various techniques for conducting quantitative analyses of variability and uncertainty.

3.4 Uncertainties and data requirements

3.4.1 General definitions

The concept of risk implies uncertainty where the available tools and data for prediction of risk have imperfect predictive power [Goodman, 2002]. As such, uncertainty analysis may be applied to all components of ERA, at each tier of a graded approach. Clearly, any risk assessor may be uncertain about assessment endpoints, whether they are expressed as probabilities or as fixed values. Measurements, exposure models, dose-effect relationships, and ecotoxicological thresholds are examples of ERA components subject to uncertainty. For each of these components, the risk assessor should strive to distinguish between variability and uncertainty prior to analysis. This distinction has become conventional in risk assessment [USEPA, 1997; Warren-Hicks and Moore, 1998; Suter et al., 2000].

- Uncertainty (type I uncertainty) refers to lack of scientific knowledge, whether qualitative or quantitative, about specific factors, parameters, or models and can partly be reduced through further study. For example, type I uncertainty includes parameter uncertainty (measurement, sampling errors, systematic errors), model uncertainty (uncertainty due to necessary simplification of real-world processes, miss-specification of the model structure, model misuse, use of inappropriate surrogate variables), and scenario uncertainty (descriptive errors, aggregation errors, errors in professional judgment, incomplete analysis), The uncertain belief about the likelihood of the variable (random variable) having different possible values is generally represented by a probability distribution.
- Variability (type II uncertainty) refers to natural variability due to true heterogeneity or diversity in a data set or population, and is usually not reduced through further study. Examples of type II uncertainty include variation in sensitivity within a population or differences in radionuclide concentrations in a given compartment of the environment. There can also be a type I uncertainty about the variability, if for example, the population is poorly sampled, and the estimate deviates from the true population variability. Variability is typically characterised through a frequency distribution (discrete random variable) or through a probability density function (or pdf for continuous random variable).

The concepts of uncertainty and variability are distinct and it is not meaningful to combine these two types of uncertainty into a single uncertainty distribution. Separating uncertainty and variability is necessary to provide greater accountability and transparency, and to identify parameters for which additional data may be needed. Monte Carlo simulation is one common method for propagating uncertainty or variability in the risk assessment, and maintaining the distinction between these two

types of uncertainty. Uncertainty distributions that result from mixing type I and type II uncertainties are difficult to interpret, and can only be used as a worst case approach to see if there might be a potential problem. Interpretation of probabilistic model results relies on the uncertainties that have been allowed for, and how these uncertainties are addressed, including those uncertainties that have been considered but not incorporated into the actual assessment. It is therefore important that all the assumptions adopted in the probabilistic risk assessment are made clear to risk managers and to other stakeholders. [USEPA, 1997; EC, 2003a].

A systematic uncertainty analysis provides insight into the level of confidence in estimates, and can aid in assessing how various possible model estimates should be weighted. Further, it can lead to the identification of the key sources of uncertainty (such as data gaps) with merit further research, as well as the sources of uncertainty that are not important with respect to a given response. Suter [Suter, 1997] proposed to categorise the various types of representation of an assessment endpoint to acknowledge their associated uncertainties (see Table 3.4). Both variability and uncertainty can be expressed as probability. Suter et al. [1997] suggested to designate probabilities and their distributions that result from variability by the terms “likelihood” and “likelihood distribution” respectively. Those due to uncertainty should be termed “credibility” (see example in Table 3.4).

Table 3.4. Types of representation of endpoints for ERA categorised in terms of their acknowledged uncertainties; examples are given in small characters using the terminology recommended by Suter et al. [2000].

Knowledge	Endpoint defined as Single value	Endpoint defined as Probability
Determined	Fixed point value [e.g. the reduction in population size]	Probability from a specified distribution [e.g. the likelihood of extinction of the population]
Uncertain	Probability of an uncertain value [e.g. the credibility of a x% reduction in population size]	Probability of a probability from an uncertain distribution [e.g. the credibility that the likelihood of extinction is greater than 50%]

3.4.2 Management of uncertainties throughout a tiered approach

For any tiered approach, uncertainty may be incorporated into exposure and effect analyses in various ways, often depending on the tiers [Suter et al., 2000]. For the lower tier, the uncertainties may be so large and so poorly specified that any quantitative uncertainty analysis is impossible. Applying the so-called precautionary principle, the risk management decision associated to this situation should simply be to ban the use of the substance. For tiers corresponding to screening, uncertainty is still high as conservative assumptions are made and result in a worst-case estimate of risk. The conservative assumptions, i.e. hypothesising levels of exposure higher than are credible for any population in the ecosystem, ensure that exposure, even if uncertain, is overestimated. The other way is to use expert judgement to apply safety factors or extrapolation factors for the components of the assessment (often for the effects analysis) ensuring a margin of safety. These factors that vary usually from 10 to 1000 combine multiple sources of uncertainty with an unclear degree of conservatism [Chapman et al., 1998; Forbes and Calow, 2002d]. Finally, for the higher tiers of an ERA, a quantitative uncertainty analysis while selecting a given likelihood of effect for a given assessment endpoint [Warren-Hicks and Moore, 1998; Suter et al., 2000].

3.4.3 List of what contributes to uncertainties

Risk characterisations are influenced by both the variability and the uncertainty in the exposure (distribution of exposure in space and time) and the effect (distribution of responses of organisms, populations, communities) assessments. Many types of uncertainty in risk characterisations exist, such as parameter uncertainty, model uncertainty and scenario uncertainty [Williams and Paustenbach, 2002]. A brief overview of these different types is given in Table 3.5 and some of them are developed further as examples.

Table 3.5. Simplified overview of the main types of uncertainty in risk characterisation and illustrations. Modified from [Williams and Paustenbach, 2002].

Type of uncertainty	Illustration	Way to perform uncertainty analysis
Model uncertainty	Model structure	To compare alternative sets of model assumptions and structure (including model boundaries)
	Model detail (degree of refinement)	To compare the predictions of simplified models to those of more detailed models.
	Extrapolation	To evaluate the relevancy of the use of a given model in a domain where the model was not validated (also include model time and/or space resolution)
	Validation	To estimate the accuracy of the prediction in a given parameter space of interest.
Parameter uncertainty	Random error Statistical variation Systematic error	To estimate various sources of imperfections in measurement techniques
	Value parameters (and distribution if needed)	To categorise parameters into those accepted by convention, by preferences, by expert judgement; to estimate uncertainty due to lack of knowledge

The uncertainty on the result of a measurement or determination may arise from many possible sources. Typical sources of uncertainty [EURACHEM, 2000] are: (1) sampling and sub-sampling, (2) storage conditions, (3) instrument effects, (4) reagent purity, (5) assumed reaction stoichiometry, (6) measurement environmental conditions, (7) sample matrix effects and interferences, (8) computational effects as truncation and rounding, (9) blank correction, (10) operator effects, and (11) random effects.

Some specific sources have to be considered due to the random nature of radioactive decay and radiation counting [Romero, 2004]. The predominant source of uncertainty is the counting uncertainty, particularly at the low activity concentrations encountered in environmental samples, other possible causes of uncertainty include: radioactive standards, counting efficiency, background, source geometry and placement, variable instrument backgrounds and efficiencies, time measurements used in decay and in growth calculations, instrument dead-time corrections, approximation errors in simplified mathematical models, impurities in reagents, and radiation emission probabilities.

A model contains a structure that may be developed on theoretical or empirical considerations. The purpose of the model is to represent as accurately as necessary a system of interest. The degree of accuracy needed depends on the intended model application. For example, models developed for screening purposes may not need to be accurate; they may only need to be conservative. The structure of the model is embodied in the form of the equations used and in the selection of parameters, which are treated as model inputs versus calculated quantities or model outputs. Models are always a simplified version of the reality of the system being simulated, so they have implicit uncertainties. The model uncertainties are classified in (1) parameter uncertainty, (2) scenario uncertainty and (3) conceptual, mathematical and numerical models (Table 3.5).

The classification of sources of uncertainty allows the decomposition of complex problems, simplifies the identification of several uncertainties, facilitates traceability of uncertainties to risk estimates and eases the incorporation of new advancements to the solving of the problem. The key sources of variability and uncertainty in exposure and effect analyses need to be clearly identified and discussed to improve the transparency of any risk characterisation. Moreover, they could help prioritise research needs as uncertainty can be reduced with relevant additional data/knowledge.

Uncertainty and methods for Exposure

Modelling (mechanistic, generic etc)

When is a model necessary? One widely held view is that you do not need to use a model when you have actual data for the problem in which you are interested. Thus, if you have exposure monitoring data, no model is needed. Even in this situation, however, models can be used to interpolate within a dataset, by using a mathematical formulation of a theoretical or empirical construct, which is shown to be consistent with existing data. For example, it may be useful to fit a parametric distribution to the dataset.

The overall uncertainty in exposure assessment can be split up into three parts: (1) uncertainty regarding parameters (parameter uncertainty), (2) uncertainty regarding missing or incomplete information needed to fully define exposure and dose (scenario uncertainty) and (3) uncertainty regarding gaps in scientific theory required to make predictions on the basis of casual inferences (model uncertainty).

Parameter uncertainty

Parameter uncertainty results from a lack of knowledge about the correct inputs to models. The estimation of parameter values, even if directly obtained from experiments, is tainted with uncertainty because of (1) the measurement uncertainty associated with any observation; (2) the stochastic nature of some parameters; (3) the differences sometimes observed between field data and data obtained from laboratory experiments; (4) the dependence of some parameters on factors that were not controlled during measurements/estimations; (5) large variations of parameter values through space and time; (6) the failure to take account properly of actual correlations between certain parameters; (7) the use of values obtained under different conditions from those currently set by the assessment context; (8) the use of parameters outside their range of applicability, the inappropriate use of generic values, even if such uses are sometimes unavoidable; and (9) the aggregation of short-term processes in one single parameter in models [IAEA, 2003c].

Model uncertainty

Model uncertainty also arises because perfect models cannot be constructed. Uncertainties in the model formulation can occur due to (a) model Structure, since alternative sets of scientific assumptions may be available for developing a model. It is possible to evaluate alternative models using traditional sensitivity analysis, (b) Model detail - Simplified models tend to be more transparent

to the user and to have faster run times, enabling probabilistic analysis, (c) Verification, means the process of ensuring that the computer codification of the model is doing what should be doing, (d) Validation, implies the quantitative evaluation in terms of accuracy and precision of the model predictions. Validation may be possible for only some components of the model or for some parts of the model domain, (e) Extrapolation is a key source of uncertainty. Models that are validated for one part of a parameter space may be completely inappropriate for making predictions in other regions of the parameter space, and (f) Model Resolution, includes temporal and spatial resolution. The modeller must decide if time dependent or time-integrated results are required. The spatial resolution implies whether generic parameter values are sufficient, or if site specific values are needed. (g) Model boundaries.

Empirical data and statistical distributions

The decision to pursue empirical and/or subjective approaches to the development of an exposure model input distribution must be driven by the quantity and relevance of the available information about that input. Inputs can be partitioned on the basis of what is known about them. When empirical data are plentiful, and relevant to the exposure of concern, distribution development may proceed using statistical techniques. Alternatively, inputs characterised by a complete absence of empirical data are candidates for distributions developed using subjective approaches (e.g., elicitation of expert judgments using accepted protocols [IAEA, 2003c]. Finally, inputs for which directly relevant data are unavailable, but for which data obtained in alternative locations, populations or time frames exist, are candidates for a combination of statistical approaches and judgment. Most inputs fall in the latter category since available empirical information is often: (a) unsatisfactory with respect to specific questions in a given assessment; (b) nonexistent; or (c) impossible to obtain [Frey and Cullen, 1995].

Scenario uncertainty

Scenario uncertainty includes uncertainties resulting from false or incomplete information, such as description, aggregation or judgement errors or an incomplete analysis.

The objective of a scenario analysis is to cover a broad range of possible outcomes. Nevertheless, averaged values are normally used for each scenario. Scenario uncertainty can be taken into account by defining a number of calculation cases corresponding to a range of scenarios identified in the process of scenario development. To reduce the risk of overlooking potentially important scenarios, a systematic methodology should be applied.

Statistical regressions

A number of extrapolations are generalised kinds of statistical regressions, and as such, involve a prediction error variance. This latter arises from simple lack of fit of the regression model, input error in the values used for the independent variables, random error in the predicted value for the dependent variable and uncertainty about the values for the regression coefficients. The regression prediction might be improved by more data to better specify the values of the input independent variables or more data for improving the estimated regression coefficients.

A number of examples for the derivation of interspecies uncertainty factors on the toxicological and phylogenetic basis use logistic regression [Calabrese and Baldwin, 1995]. QSAR relationships are other examples to extrapolate exposure and/or effect from one toxicant to another.

Uncertainty and methods for effects extrapolations

Uncertainty/Safety/Extrapolation Factors

Uncertainty is also an integral component in the effect assessment part of risk assessment, and will always exist [Schwartz, 2000]. It is mostly dealt with by use of so-called safety factors, if a threshold

for toxicity is assumed to exist. For instance, these can involve adjusting a point estimate (e.g. an EC_{50} endpoint, i.e. the effective concentration at which 50% of a particular population is affected in a toxicity test) by a certain factor, typically 10, 100 or 1000) to estimate a safe concentration. According to the review and critical evaluation of this concept by Chapman et al. [1998], the term safety factor includes any means by which known data are extrapolated to deal with situations for which there are no data. It can be characterised, as a conservative approach for dealing with uncertainty that has no or little relevance to acute uncertainty, but that is able to greatly reduce the probability of underestimating an effect. Safety factors are not intended as mathematical absolutes but rather as screening tools that are surrounded by some unquantifiable level of imprecision [Chapman et al., 1998]. Safety factors are popular at the interface of science and policy, because they provide clear-cut answers. The selection of magnitude is more a policy decision than a scientific result, often caused by an insufficient database. Extrapolations involving safety factors are carried out on an ecosystem level and for human health risk assessment and include, theoretically, four basic areas: (1) inter- and intraspecies, (2) time (acute to chronic, subchronic to chronic), (3) lowest to no-observed effect concentration and (4) laboratory to field extrapolations. For the latter, it is recommended not to use the concept [Chapman et al, 1998]. For all other fields, a standard safety factor of 10 is commonly applied notwithstanding the fact that differences up to 4 log units in human health risk assessment [Schwartz, 2000] and up to 5 log units on the ecosystem level were observed [Chapman et al., 1998]. However, safety factors range in general from 0 to 3 log units and the most commonly used factor is 100 [WHO, 2000]. An additional factor of 10 is recommended when further sources of uncertainty are taken into account. The use of safety factors must be accompanied by some principles [Chapman et al., 1998]: (1) When appropriate data are available, they should be used rather than safety factors. (2) Any use of safety factors should be based on existing scientific knowledge. (3) Safety factors should be used only for screening, not as threshold or absolute values. (4) Safety factors should encompass a range, not a single number, because extrapolation is uncertain. (5) Safety factors should be scaled relative to different substances, potential exposures and effects.

Species Sensitivity Distributions

In response to criticism of the uncertainty factors in deriving PNECs (or the so-called benchmark values), an alternative approach has been proposed to approximate a community-Species Sensitivity Distribution by incorporating effects observations on a variety of species from ecotoxicological tests [Aldenberg and Slob, 1993]. This approach is based on the hypothesis that the species for which results of ecotoxicological tests are known are representative, in terms of sensitivity, of the totality of the species in the environment, for a specific taxon, a selected species assemblage and/or a natural community. A likely distribution of species sensitivity is estimated from these results, which enables calculation of a concentration that is assumed to protect a given percentage of the species in the environment. Within the Technical Guidance Document [EC, 2003b], the agreed concentration is the hazardous concentration affecting 5% of species with 50% confidence (HC5p50%); equally, 95% of the species are thus protected with a confidence limit of 50%. This statistical approach raises a number of questions [Forbes and Forbes, 1993; Forbes and Calow, 2002c]. The true distribution of toxicity endpoint is not known and the SSD is estimated from a sample of ecotoxicity data. Generally, it is visualised as a cumulative distribution function, plotting no-effect concentrations derived from chronic toxicity tests (Figure 3.4). One of the advantages of this approach is to make use of the whole range of selected toxicity data (not only the lowest value as it is done for the application of uncertainty factors). This allows identification of the most sensitive groups of species (left tail distribution). However, it is obvious that the quality of the derived HC5 strongly depends on the quality of the selected data set. This remark underlines the importance of the approach used to acquire ecotoxicity data by properly applying laboratory testing. It also stresses the importance of applying adequate statistical data treatment to estimate the critical toxicity endpoints (i.e. the NOEC, and or the EC10 for chronic

exposure condition) that constitute the primary information for the establishment of any SSD (see Table 2 in Appendix and appendix to D5). From a theoretical point of view, this approach depends on the acceptance of a number of underlying assumptions (Table 3.6). From a practical point of view, irrespective of validation and criteria used for selecting the results of ecotoxicological tests used in SSD, this approach is still under debate due to questions about the extent to which errors in the underlying data, and those introduced in curve-fitting log-normal (or other) distributions are adequately reflected in the derived HC5. A number of assumptions in the application are listed below: (1) the sample of species used to construct the SSD is an unbiased sample of the target community or group of species (species of interest are often species from traditional laboratory testing); (2) the endpoint is ecologically relevant (data to build SSD are often a mixture of endpoints); (3) the chosen level of protection and the confidence limits around the protection threshold are appropriate and need to have scientifically based justification; (4) the shape of the statistical distribution is appropriate and well selected (as the distributional shape choice greatly influences the tail where the critical concentration is derived); (5) the number of species (and/or data) to fit properly the distribution is adequate.

Table 3.6. List of the major assumptions underlying the Species Sensitivity Distribution approach, each of them is associated with a brief explanation of arguments against or in favour. Adapted from [Forbes and Calow, 2002d; Forbes and Calow, 2002c].

Assumptions behind the theory
Interaction between species do not influence the sensitivity distribution Cons: Community are governed by complex interactions between species, e.g. trophic or competitive interactions Pros: the fewer the species in the community are impaired, the lower the likelihood that interaction effects will have an influence on the SSD
All species are weighted equally Cons: the loss of any species is of equal importance to the ecosystem Pros: Keystone species are distributed randomly in the SSD and be as equally likely as other species to fall in the left tail of the distribution
Ecosystem structure is the target of protection Cons: Community structure (i.e. species composition) is not equal to ecosystems that are combination of community structure and underlying processes ensuring the functioning (fluxes of energy and matter). Pros: Whatever the relationship between community structure and ecosystem process, the species composition is at least as sensitive to stress as changes in processes such as decomposition, photosynthesis…etc)

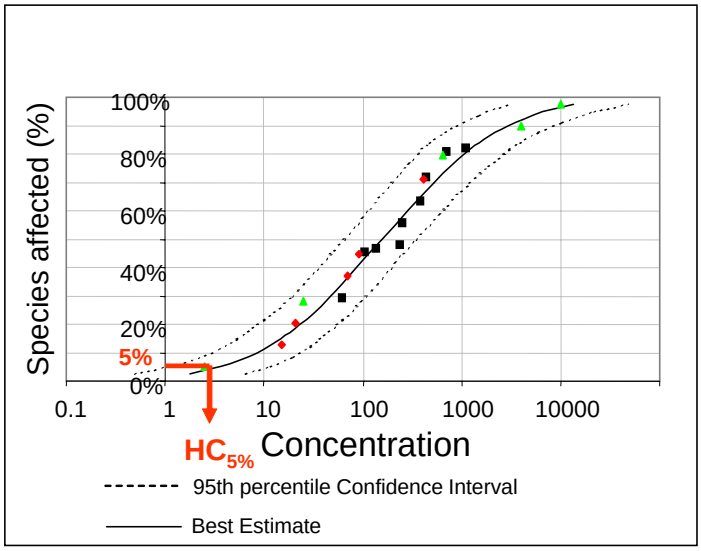

Figure 3.4. Species Sensitivity Distribution. The example shows the five percent protection level and the corresponding HC5 (Hazardous Concentration 5%) used to determine the PNEC.

3.4.4 Extrapolations

In ERA, the common way to deal with uncertainty is to propose extrapolation rules. Extrapolations over time, space, taxa, stressors, and level of biological organisation are common practice to produce ERAs. This can apply for exposure and effects analyses, and for risk characterisation. This is generally done while using more or less refined conceptual mechanistic models (transport and fate models, multimedia models, biokinetics models), empirical "black box" models based on regression relationships (allometric scaling, phylogenetic extrapolation etc), and/or less elaborate "safety" or uncertainty factors" and/or statistical models based on probability distributions. The two first categories are mainly used for exposure assessments while the latter two have been developed as methods for effect and risk (see Section 3.2.4 and 3.3.2).

3.4.5 Sensitivity analysis: basic concepts and tools

Sensitivity Analysis (SA) studies how the variation in the output of a model can be apportioned to different sources of variation. This is important for (1) evaluating the applicability of the models, (2) determining parameters for which it is important to have more accurate values, and (3) understanding the behaviour of the system being modelled.

The technique of parameter sensitivity analysis is a powerful tool that ranks parameters and processes in a model with respect to their relative influence on both the magnitude and the uncertainty of the model output [Whicker et al., 1999]. To some extent, this technique can also be used to test model structure, since entire pathways can be turned on or off by the numerical values of parameters.

In general, SA is conducted by: (1) defining the model and its input parameters and output variable(s), (2) assigning probability density functions to each input parameter, (3) generating an input matrix through an appropriate random sampling method, evaluating the output, and (4) assessing the influences or relative importance of each input parameters on the output variable[Chan et al., 1997].

Many approaches are available for sensitivity analysis, including (a) Differential analysis, which involves approximating a model with a Taylor series and then using variance propagation formulas to obtain uncertainty and sensitivity analysis results. (b) Response surface methodology, based on using classical experimental designs to select points for use in developing a response surface replacement for a model. (c) Variance-based methods. (d) Fourier amplitude sensitivity tests (FAST), based on using techniques from Fourier analysis to decompose the variance of a model prediction into the components due to individual model inputs. (e) Sampling-based methods

Methods recommended for risk analysis [Saltelli et al., 2000] because they are global, quantitative, and independent from model assumptions are the variance-based methods, also known as importance measures or sensitivity indices. These methods provide a factor-based decomposition of the output variance that is sufficient to describe output variability.

On the other hand, the sampling-based approach is usually a suitable, and quite often the best approach [Helton and Davis, 2001], for various combinations of the following reasons: (i) conceptual simplicity and ease of implementation (e.g., unlike other methods, there are no requirements for model differentiation, complex experimental designs and associated response surface construction, or high dimensional integrations), (ii) dense stratification over the range of each sampled variable, especially when Latin hypercube sampling is used, (iii) direct provision of uncertainty analysis results without the use of surrogate models as approximations to the original model (e.g., Taylor series or response surfaces), (iv) availability of a variety of sensitivity analysis procedures, and (v) effectiveness as a model verification procedure (i.e., exploration of the mapping from uncertain inputs to model results provides a powerful tool for the identification of errors in model construction and analysis implementation).

In a sampling-based simulation, parameter values are randomly chosen from the distributions of each stochastic variable; the model is run to produce an output value, then the process is repeated many more times (e.g. perhaps 100 or 1000 times) to produce a distribution of output values. A concern often expressed about sampling-based methods is that the number of required model evaluations would make the cost of the analysis prohibitive. In practice, this is usually not the case. In most analyses, a sample size of considerably less than 1000 [Helton and Davis, 2001] is sufficient to obtain useful uncertainty and sensitivity analysis results.

The data are next analysed by several measures. Following Helton [2001], where several examples are exposed, linear measures including Correlation Coefficients (CCs), Partial Correlation Coefficients (PCCs) and Standardised Regression Coefficients (SRCs) perform well on the linear test problems. Examples of application to non-human biota exposed to ionising radiation can be found in Avila et al. [2004]. Measures based on rank transforms as Rank Correlation Coefficients (RCCs), Partial Rank Correlation Coefficients (PRCCs) and Standardised Rank Regression Coefficients (SRRCs) perform well on the monotonic test problems. Measures predicated on searches for non random patterns considering Common Means (CMNs), Common Locations (CLs), Common Medians (CMDs) and Statistical Independence (SI) performing well on the non-monotonic test problems.

Graphical methods useful for showing the relationship between input parameters and output results are scatter plots.

3.4.6 Methods for quantitative uncertainty analysis

The common approach to handle uncertainties is to investigate diverse exposure scenarios and to represent them in terms of probability distributions (Probabilistic Exposure Assessment, also known as the Monte Carlo Technique). In practice, in any risk assessment exercise, the risk quotient approach has most often used single numbers for both PEC and PNEC, ignoring therefore the uncertainty associated within these estimates. There is always uncertainty in PEC and PNECs and both can be represented by fitting values to a statistical distribution. Combining the distribution of PECs with the distributions of PNECs (through SSDs) allows quantification of the probability that the PEC exceeds the PNECs given the uncertainty of each. It provides a quantitative probability of risk.

Ideally, uncertainty estimates for a given model prediction should include contributions from all relevant sources (see Section 3.4.3). Nevertheless, parameter uncertainty is the most common way to execute the uncertainty analysis. Semi-quantitative approaches to take into account sources of uncertainty different from parameter uncertainty are discussed in Bäverstam et al., [1993].

The main steps in a sampling-based parameter uncertainty analysis are [Bäverstam et al., 1993]:

1) Identify the parameters that could contribute significantly to the uncertainty in the final model prediction. To perform this task it is useful to conduct the sensitivity analysis explained in Section 3.4.5.
2) For each parameter, construct a probability density function (PDF) to reflect the belief that the parameter will take on the various values within its possible range.
3) Account for dependencies (correlations) among the parameters.
4) Propagate the uncertainties through the running of the model to generate a PDF of the predicted values.
5) Derive confident limits and intervals from the PDF of predicted values to provide a quantitative statement about the effect of parameter uncertainty on the model prediction.

Recommended procedures for assigning distributions to parameters, [Bäverstam et al., 1993; Mishra, 2002] are:

1) If enough data are available, (a) Define an empirical distribution in terms of frequency plots or cumulative probability plots. (b) Use of parametric models to fit the data.

2) If only a limited amount of information is available, (a) Use a protocol of expert elicitation. (b) Use the maximum entropy approach for selecting a distribution. (c) Develop subjective distributions based on informal expert judgements.

Although an infinite number of theoretical distributions can be used to fit an empirical data set, the key features of the most used distributions are described in 3.7.

Table 3.7. Applicability of the most frequently used Probability Distribution Functions.

Probability Distribution Function	Applicability
Uniform (log uniform)	Appropriates for uncertainty quantities where the range can be established (maximum and minimum values can be defined) based on physical arguments, expert knowledge or historical data. If the range of parameter values is large (greater than one order of magnitude), a log uniform distribution is preferred to a uniform one.
Triangular (log triangular)	Little relevant information exists, but extremes and most likely values are known, typically on the basis of subjective judgement. If the parameter values cover a wide range a log triangular distribution is preferred.
Empirical	Useful when some relevant data exists, but cannot be represented by any standard statistical distribution. A piecewise uniform (empirical) distribution is recommended in this case.
Normal	A substantial amount of relevant data exits. Can represent errors due to additive processes. It is useful for modelling symmetric distributions of many natural process and phenomena. Is often used as a “default” distribution for representing uncertainties.
Log normal	It is useful as an asymmetrical model for a parameter that can be expressed as a quotient of other variables, so they are useful for representing physical quantities, such as concentrations.
Poisson	It is useful for describing the frequency of occurrence of random, independent events within a given time interval.
Beta	It is often used to represent judgements about uncertainty. Also to bounded, unimodal, random parameters.

To take into account correlations between parameters, the covariance matrix method is recommended [Bäverstam et al., 1993] for assessment models.

To propagate the parameter uncertainties to the results, the model needs to be run several times. Two approaches can be taken to determining the number of calculations required. The first relies on general statistical relationships to determine the required number of samples *a priori*. The second approach is based on repeated examination of the calculated results to determine whether they adequately represent the system or if more calculations are required.

The *a priori* determination of the number of calculations required is based on the premise that, if samples are drawn at random from the input distributions, then the output distribution can be regarded as a random sample of the output population (model space). However, determining how many samples are required to ensure that this random sample is an adequate representation requires further assumptions about the form of the model surface. Assuming, for example, that a "95% confidence of at least one value being above the 99th percentile" is a reasonable measure of adequacy has an implicit assumption about the form of the output. If these implicit assumptions are not met, for example if the distribution is highly skewed, then the number of calculations may not be sufficient to provide a reasonable estimate of the expectation value.

Various points need to be kept in mind when considering the computational cost associated with sampling-based uncertainty and sensitivity analyses [Helton and Davis, 2001]. First, high quantiles of distributions representing subjective uncertainty are typically not needed, and in addition, are usually not meaningful. Specifically, a general idea of the uncertainty range in a model's predictions is important to have but to know something such as the 0.999 quantile of the distribution is usually not very useful. Further, in most analyses, the resolution at which the subjective uncertainty in a model's inputs can be assessed does not justify ascribing any real meaning to very low or very high quantiles of resulting uncertainty distributions. Second, the belief that estimates for extreme quantiles is needed often comes from confusing stochastic and subjective uncertainty. Third, the uncertainty in a given analysis result is usually dominated by the uncertainty in only a few inputs. As a result, a large sample size is not always needed for an effective uncertainty and sensitivity analysis.

The final overall uncertainty can be presented as graphical or numerical output [Wilmot, 2003]. The types of graphical output are:

Methods for illustrating behaviour of individual parameters

- Probability distribution functions
- Cumulative distribution functions
- Complementary distribution functions
- Box-whisker plots

Methods for showing time-dependent behaviour

- Dose / risk vs. time plots. Time variation of the results with the 90 % confidence interval (as best estimate values of the deterministic results with the uncertainty stated as 5 % and 95 % quantiles representing the endpoints) if the time evolution of the system is followed.

Numerical output is less intuitive, includes various measures of central tendency as mean, median or other percentiles.

3.5 Interpretation and weighting of evidence

Confidence in the conclusion of a risk assessment may be increased by using several lines of evidence. Rather than relying on a single approach, batteries of tests, modelling and/or field observations can be used to estimate risk. Obviously, there is a difference between prospective and retrospective

assessments in the availability of data being used, and hence the lines of evidence available. In the retrospective assessment, monitoring and field data (Sections 3.5.2 and 3.5.3) is often available and can be supplemented with additional sampling as the assessment moves through tiers. Further, it may for example be possible to perform toxicity testing on contaminated media or measure biomarkers and other effects directly in exposed populations. With prospective assessments, field data is usually unavailable or very limited and there is a reliance on modelling approaches and standard toxicity data to predict environmental exposure and effects. In cases where a practice is granted based on a prospective assessment, there may be a requirement to reassess data after a certain time to compare model outcome with actual measured data.

Another aspect that limits the lines of evidence is the availability of ecotoxicological data for radioactive substances. Generally, there is a bias towards short-term acute toxicity data and one of the major difficulties in the implementation of ecological risk assessments for radioactive substances is the lack of data from chronic studies at low levels of exposure. Within this context, tools for chronic testing (Section 3.5.1) constitute a key (i) to establish robust extrapolation rules necessary for the effect analysis in any ERA exercise and (ii) to improve our scientific knowledge about the effects of ionising radiation on non-human biota. Further, expected safe levels of exposure are typically derived from dose-response relationships for effects that are generally assumed to be deterministic. However, stochastic effects may be important if protection of individual organisms is the aim (e.g. threatened and endangered species), see Section 2.2.6 for more detail.

Tools for the assessment of chronic toxicity must be chosen according to their utility in programs of environmental management, to the questions to be addressed and to practical issues, such as cost and possibility of repeated application under standardised conditions. There is an impressive array of tools available for effects testing, from highly specific organism-level responses to indicators of environmental state, highly relevant to ecosystem functioning. They can be classified into [Adams, 2002]:

- Bio-indicators, that correspond to an anthropogenically induced variation in biochemical, physiological or ecological component or processes, structures, or functions that has been either statistically correlated or causally linked, in at least a semi-quantitative manner, to biological effects at one or more of the organisms, population, community or ecosystem levels of biological organisation.
- Biomarkers (Section 3.5.3), that are functional measures of exposure to environmental stressors, which are usually expressed at the sub-organism level of biological organisation

In some way, biomarkers can be operationally defined as bio-indicators if they are causally correlated to an effect at the level of organism or above.

It must be underlined that there is no perfect choice of methods as generally biomarkers are of little direct relevance to ecosystem health and conversely, indicators of ecosystem status rarely provide information on the causes of toxicity, due to indirect effects induced for example by prey-predator relations [EA, 2002c]. Moreover, the lack of specificity of the methods means that there is no stand alone method and several tools must be used at different biological organisation levels to give “weight of evidence” of a cause-effect relationship.

Each method has its own assumptions and associated uncertainty and assessors must evaluate each separate line of evidence, organise these in a coherent fashion, and then use a weight of evidence approach to estimate risk [Suter, 1993; USEPA, 1998]. By using a weight of evidence approach, risk assessment can reduce, but not eliminate, the biases and uncertainties associated with using only one

approach to estimate risk. A weight of evidence approach is also a useful tool for identifying areas where research is most needed [Environment Canada, 1997].

A rigid approach that defines that one source of data is always more important than another is clearly not appropriate. However, it is evident that the identification of the data deemed important for a specific risk assessment is a matter of judgement by the experts. There are certain generally agreed criteria in identifying the quality of individual data sources. Some principal factors that should be considered in evaluating each line of evidence is given below, adopted from US EPA [USEPA, 1992]:

- Relevance of the evidence to the exposure scenario of interest
- Relevance of the evidence to the assessment endpoint (toxicity tests that closely mimic field conditions and yield results that are directly related to ecologically significant parameters are given more weight than tests that are less pertinent to field conditions and environmental effects)
- Confidence in the evidence or risk estimate (confidence is a function of the sufficiency and quality of data and estimation techniques, including a adherence to protocols, appropriate experimental designs and associated estimates of statistical power, and theoretical plausibility)
- Likelihood of causality (some lines of evidence, such as observed field effects, may include a variety of stressors in addition to the priority substance of interest.

Each of these factors should be carefully examined, but all data should be accounted for, even poor or conflicting data when weighting and reporting the lines of evidence. Weighting the lines of evidence is based on expert judgement, however, a scoring approach could be used to make the basis for the judgement as clear as possible [Suter et al., 2000].

3.5.1 Tools for chronic testing

Globally, chronic testing aims at detecting the potential for harmful effects before those effects occur. They constitute tools that complement traditional chemical analyses and are part of the weight of evidence approach implementing to reduce uncertainty in bioaccumulation and/or in toxic effects. They can be used for the early tiers of a graded approach for ERA when they are simple and cheap to perform. At higher tiers they are more site-specific with a choice relevant for the site under examination.

At the European level, standardised methods are recommended in the Technical Guidance Document or TGD [EC, 2003b] to assess effects of chemical substances. These methods are based on very well defined protocols, and have been checked through interlaboratory comparisons. It is important to ensure continuity and consistency as far as possible between methods used for stable contaminants and radioactive substances, to simplify effect assessment and to take advantage of well-tried tools. Hence, these methods should be re-evaluated to retain those of them that are compatible with the assessment of chronic exposure to radioactive substances.

The methods described in the TGD or other documents [Environment Canada, 1997; USEPA, 1998; ASTM, 1999] to assess the effect of chemical substances, rely on the use of bioassays. They are usually monospecific assays, performed under controlled laboratory conditions, in situations going from a single spike of contaminant into a closed system, to flow-through systems. These bioassays can be defined as acute or chronic toxicity assays, depending on the duration of the experiment (from a few hours to several weeks in function of the life cycle of the biological model). Generally, acute toxicity tests are not sensitive for the range of concentrations occurring under chronic exposure conditions. To the contrary, chronic toxicity assays are well suited to long-term effects.

The biological models used in these assays are chosen according to their ecological reliability, in function of their role in ecosystems. They are representative of the various trophic levels, and must be sensitive to contaminants and easily maintained in the laboratory. The endpoints are chosen according to the toxicity mechanism of the contaminant, and to the percentage of effect observed at the end of the exposure period for the range of concentrations tested. Evidence of sublethal effects are looked for at the organism level, on the basis that they result from the sum of alterations having occurred at suborganism levels. Moreover, the endpoints generally chosen, mortality, growth and reproduction, are good bioindicators since they are measured at the organism level, but can be related to effects at the population level. At the present time, responses at the suborganism level (biomarkers) are not accepted as standard methods for effect assessment, but can provide additional information in terms of mechanisms, early warning and sensitive signals. Biomarkers will be described further in Section 3.5.4. Whatever the methods used, several criteria should be met [Adams, 2002]:

- specificity of the association between cause/exposure and effect
- consistency, i.e. association repeatable among varying exposure situations
- mechanistic plausibility, i.e. results supported by controlled laboratory experiments that determine the mechanism of toxicity and demonstrate the link with higher biological organisation levels
- sensitivity and early warning, liable to respond at exposure levels typical of exposed ecosystems

Bioassays are conducted according to a general scheme, in which organisms are exposed to a range of increasing concentrations of the contaminant, to obtain dose-effect relationships. The statistical treatment of these data allows determination of classical ecotoxicological values, such as the No Observed Effect Concentration (NOEC) corresponding to the maximal concentration that does not induce an effect. Other values can be calculated, such as the EC_{50}, the concentration inducing an effect of 50 % (e.g. a growth inhibition of 50 % as compared to the control group). The principles, guidelines and statistical analysis applied when designing and carrying out controlled laboratory experiments to investigate biological effects of stressors in non-human organisms are summarized in an appendix to D5. Its main aim is to ensure that ERICAs planned experiments will be performed under these commonly agreed principles and fully consistent with those existing for ecotoxicity tests. These principles and basic agreement on how to study dose(rate)-effects relationships for chronic (long-term) exposure of organisms to low-level of radioactive substances are of major importance as a number of quality criteria must be applied to produce new data on effects. The higher their quality and robustness, the higher will be the confidence in their potential use into any methodology to derive benchmark values.

Recommended tests

A large number of recommended procedures for chronic testing can be found in different guidelines. The chronic tests recommended in ISO or OECD procedures are listed with their reference in Appendix, Table 2. For freshwaters, the effect assessment focuses on the toxicity data for three taxonomic groups: fish, invertebrates and algae. At first, the exposure is *via* water column (sediment toxicity may be added if necessary) and the standard EC or OECD tests guidelines are the recommended protocols. The most popular assays used are related to algae and daphnids. For algae, the 72 hr-growth inhibition assay aims at evaluating the concentration inhibiting the growth of a freshwater microalgae, taken during exponential growth, at the end of a 72 hrs-exposition. This test is considered as a chronic one. As regards daphnids, two assays are generally used. First, the 24 hr-acute immobilisation test, where the EC_{50}, the concentration immobilising 50 % of the daphnids, is estimated. This assay can be used as an acute toxicity assay or as a preliminary test to determine the

concentration levels to be used in the second test, the reproduction test, that is a chronic toxicity assay. The purpose of the reproduction test is to evaluate the effect of a substance on the total number of living offsprings produced per parent alive at the end of the test (21 days). Other tests are conducted using fish species. Two acute toxicity tests can be performed, aiming at determining the fish mortality over a period of 96 hrs (acute toxicity) or of 14 days ("prolonged" acute toxicity). The juvenile growth test provides also a good indication of toxicity. The purpose of this test is to estimate the growth of juvenile fish over a fixed period of 28 days. Other tests study parts of the life-cycle of the fish, the short-term toxicity test on embryo and sac-fry stages, or the fish early-life stage toxicity test (FELS). These two tests cover several life stages of the fish, from the newly fertilised egg, to the end of the sac-fry or to early stages of growth, respectively. The FELS test is considered as the most sensitive of the fish tests. These tests use fish species having a short life cycle, like the zebra fish or the medaka, so as the test duration varies from 30 to 60 days. For marine ecosystems, the TGD recommend test protocols from ASTM [1999] or OECD [OECD, 1998] on different taxonomic groups (saltwater algae, crustaceans and fish, but also echinoderms, molluscs).

To assess sediment compartment toxicity, the TGD [EC, 2003b] recommends at least two categories of tests using spiked sediment. The test needs to be selected according to the behaviour of the substance considered and to the feeding strategy of the test species: long-term test with *Lumbriculus variegates* (a true sediment feeder); long term test with *Chironomus riparius* or *Chironomus tentans* (a collector-gathered that feeds mainly on material deposited on submerged substrate). A number of other tests exists both for freshwaters or marine organisms [OECD, 1998].

For terrestrial ecosystems, the effect assessment is more difficult as it has been traditionally divided into the soil and the above soil compartments. This simplistic distribution creates problems for the effect assessment as, although some organisms can be clearly defined as soil dwelling or surface ground dwelling organisms, a large percentage of species, including plants, different invertebrates and even some vertebrates, are distributed simultaneously or alternatively between both compartments. In the TGD, only bioassays on terrestrial species linked to the soil compartment as well as to microbial and enzymatic processes are available. As such, the base-set of ecotoxicity data for the soil compartment is composed by microorganisms, plants and earthworms. Monospecific tests are performed according the relevancy of the exposure route of the species considered and we distinguish: species living in the soil and exposed to soil particles (*e.g. Folsomia candida*) and species living in the litter layer that are to be exposed through the food (*e.g. Orchesella cincta*).

Whatever the ecosystem considered, the base set bioassays can be completed to assess the "secondary poisoning" through a simple food chain (Water->aquatic organisms->fish->fish-eating mammal or fish-eating bird for aquatic food chains and soil->earthworm->worm-eating birds or mammals for terrestrial food-chains).

Adaptation to radioactive substances

On the basis of a review of conventional ecotoxicity tests, the Environment Agency has recently developed guidance to recommend test species and to perform experiments to properly acquire missing knowledge in the domain of chronic exposure to ionising radiation of representatives of different wildlife groups [EA, 2003a]. Within the ERICA project, D4 specifically examines the adaptation of the EA recommendations and of the European technical guidance in this domain, focusing on (1) the management of radioactive substances specificities within this framework and (2) the adaptation of two popular reproduction tests (earthworm and daphnid), with a particular emphasis on the establishment of dose-effect relationships for a number of vital rates such as *e.g.* reproduction effects (which are basic parameters in modelling from individual to population effects). The main radioactive substances specificities are listed below:

- When it comes to a weight of evidence approach, the large dependence of effect analysis on laboratory effects testing data since site-specific biological surveys in most cases are not sensitive enough.
- The need to refer to dose or dose rate to establish dose(rate)-effect relationship, implying the use of robust dosimetric models
- The relevancy of examining effects on reproduction endpoints, without forgetting the potential existence of stochastic effects even if research is needed to understand its ecological significance.

3.5.2 Field surveys

Dose calculations for biota are based on dosimetry; the calculation of the total radiation dose received by an organism from both external and internal sources. Three types of doses must be considered:

- radiated external dose, the dose received from radioactive substances not in direct contact with the organism itself;
- deposited external dose, the dose received from radioactive substances deposited directly on the surface of the organism; and
- internal dose, the dose received from radioactive substances ingested or inhaled by the organism.

Only one of these three doses, the radiated external dose, can be reliably measured in the field. For the other two sources, dosimetric models are needed to relate measurements of radionuclide activity to the dose absorbed by target tissue. The geometry of the organism, the ability of different radioactive particles to penetrate various tissues, and the partitioning of radioactive substances within the organism all influence the dose received by target tissues.

Direct radiation monitoring is used to detect radiation exposure caused by sources that emit X rays, gamma rays, charged particles and neutrons. Such monitoring can be done in real time by use of the appropriate survey meters or by pressurized ion chamber (PICs) to obtain exposure rate by various types of solid-state dosimeters to obtain the total exposure.

In field surveys the ambient radiation is monitored continuously with different devices such as thermoluminescent dosimeters (TLD) [Mihok, 2004] or ionisation chambers located in the appropriate medium of the organisms of concern. These devices are calibrated and corrected to express the radiation exposure in dose magnitudes for the biota (in *absorbed dose* or *kerma*) [Taranenko et al., 2004].

A basic unit for assessing exposure to ionising radiation is the absorbed dose. The term *absorbed dose* refers to the mean energy imparted by ionising radiation to the matter in a volume divided by the mass contained in the same volume. The other magnitude utilized for dose measurement in air, is the *kerma*, the *kinetic energy released in matter*, which is the sum of the initial kinetic energies of all the charged ionising particles liberated by uncharged ionising particles (indirectly ionising particles) per unit of mass. Both absorbed dose and *kerma* are measured (in SI units) in Jkg^{-1}; the special name for this unit is the Gray (Gy). Which can also be expressed as the absorbed dose rate (absorbed dose delivered over a specified unit of time, *e.g.* $Gy.h^{-1}$). An older unit, still in restricted use, is the rad: 1 rad = 10^{-2} Gy [ICRU, 1980].

3.5.3 Biological surveys

Biomonitoring studies correspond to the repeated measurement of biological characteristics in target organisms, to detect changes or trends in its state, to apply corrective actions if these changes are

harmful. They include a variety of techniques for enumeration and characterisation of ecosystems at different organisational level [Suter et al., 2000].

These field studies can provide much information on the toxic effects, such as indirect effects, bioavailability or biodegradation. At the present time, there is no international standard or guideline for field studies, but general guidance can be given [Adams, 2002]. Biomonitoring programs must clearly define the scope of the study, the cause and effects to be associated, the frequency of sampling, the nature of the measurements to be done, the geographic area to be monitored. The sampling strategies must be defined according to the temporal and spatial trends, to discriminate statistically significant differences in responses between sites and times. A particular care should be given to sampling strategies, including randomisation, definition of reference sites, replication and criteria for target species (e.g. residency, sensitivity, size, uniformity, density and tolerance at affected sites).

In the context of ecological risk assessment and biological surveys for radionuclide discharges, the concentrations released are managed according to the precautionary principle and consequently, they are low-level concentrations. Hence, the parameters to be measured must be sensitive and respond adequately over a chronic exposure. A possible approach could be the combined use of ecological/ecotoxicological methods such as community analysis and measurements of functional endpoints such as community respiration together with biomarker (Section 3.5.4) measurements. Community analysis implies measurement of changes in abundance and biomass of species in specified communities impacted by pollutants. By the use of this type of bioindicator, effects can be directly extrapolated to the ecosystem. Several components of the biota can be used, the most widely studied group being benthic macroinvertebrates (e.g. polychaetes, crustaceans, bivalves). However these methods for evaluating pollutant effects in ecological communities are almost exclusively retrospective, and consequently there are often major difficulties in delineating causality between stressors and the measured effects. Therefore, to increase knowledge of causality, there are good reasons to combine ecologically 'relevant' endpoints such as effects on species distributions with contaminant specific biomarkers.

3.5.4 Biomarkers

Biomarkers and their application in a regulatory sense to biota exposed to ionising radiation.

Biomarkers may be defined as a functional measure (usually of a molecular, biochemical, cytogenetic or physiological endpoint) that may be indicative of exposure to, or effects of, environmental stressors [Adams, 2002]. As a result, there is increasing interest in the application of biomarkers as early warning indicators of exposure and potential harm for assessing environmental (non-radioactive and radioactive) contamination. Their potential use in assessing the risk of ionising radiation to non-human biota has also been recognised by several researchers [e.g. Copplestone et al., 2004]

Much of the biomarker developments have, to date, focused on adapting techniques used for assessing the effects of ionising radiation on humans. The use of biomarkers in humans [Imamura and Edgren, 1994; Ilyinskikh et al., 1998; Bothwell et al., 2000] is now well established and they are routinely used to determine exposure to ionising radiation. They have been used to monitor workers routinely [Tucker et al., 1997; Tawn et al., 2000] and also for post accident exposure assessment [Wojcik *et al*., 2004]. The key to the use of these techniques for human assessments is the fact that the measurement endpoints and dose response relationships are well established and internationally agreed upon. For instance, chromosomal aberrations are routinely used to evaluate human radiation exposure and are classed as the most reliable marker in biodosimetry with value in medical law [Amaral, 2002]

Given the potential of biomarkers as early warning indicators and their application in measuring subtle effects of ionising radiation that may be observed under normal environmental conditions, a number of

biomarker techniques have been selected, adapted and tested for use on non-human biota [Salagovic et al., 1996; Ulsh et al., 2000]. There is still much validation work to be conducted and, in particular, experimental work undertaken to establish the dose response relationship curves for ecologically relevant endpoints (e.g. those affecting reproductive capacity) before these techniques gain the equivalent acceptance as those applied in human biomonitoring. Consequently developing a regulatory position which utilises biomarkers for biota-based radiological assessments is currently not feasible because of the lack of data on the relationship between the biomarker response and an endpoint of relevance [Copplestone et al., 2004]. Furthermore, although there is a consensus that the main focus for biota should be on protection of populations, the current state of knowledge (based on the radiological protection framework for humans) only allows this situation to be assessed by considering likely effects on individual organisms and using generalisations to assess how any likely effects at the individual level may become manifest at the population level (Figure 3.5). Consequently there is a need to understand the linkage between the biomarkers (measured on individuals) and the effect at the level of the population.

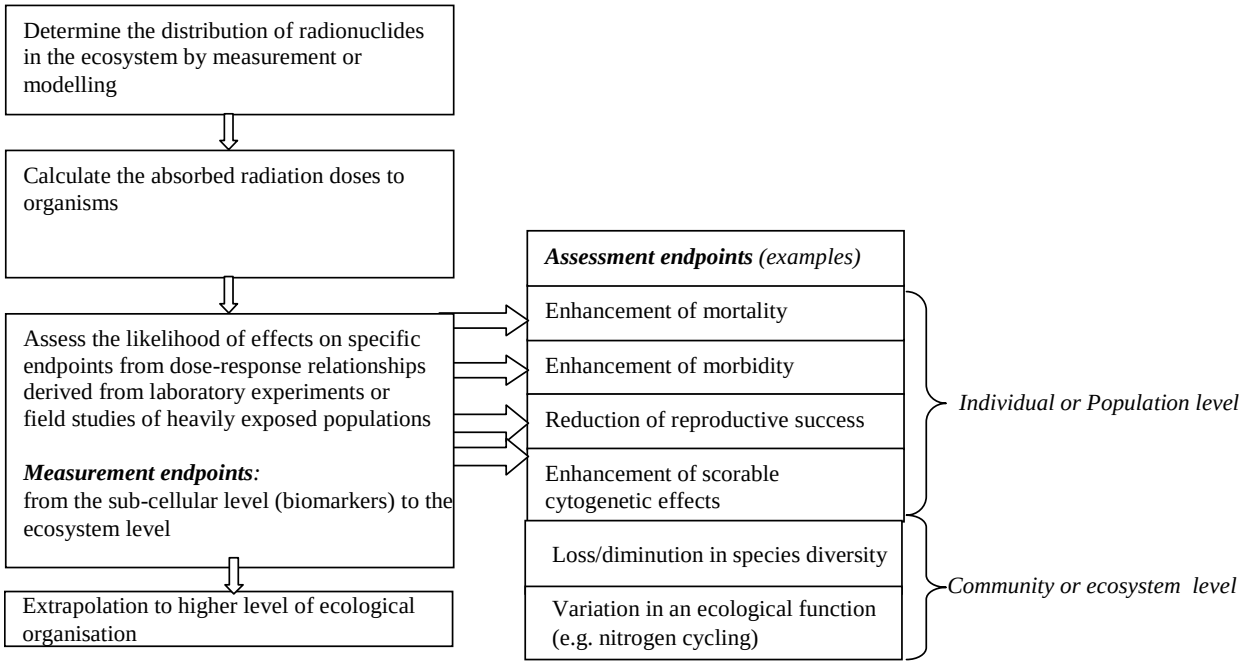

Figure 3.5. Illustration of where biomarkers are applied in the current assessment approach.

Hinton and Brechignac [2004] have recently emphasised the lack of these defined relationships between biomarker response and ecological relevance mentioned in the previous paragraph and have also highlighted the importance of operative environmental changes in influencing the biomarker response. The implication is that factors such as availability of food, changing temperature, social dominance and predation can affect the biomarker response in the same way as environmental contaminants. Consequently, it may be difficult to determine the causative agent or stressor giving rise to the biomarker response. Complicating this further is the fact that not all species or individuals are affected in the same way by these external stressors. For example, some species have greater tolerance to contaminants than other species [Williams et al., 1984]. Therefore, in terms of ecosystem health, monitoring changes in community diversity (Section 3.5.3) may be deemed of more relevance than biomarkers given the current state of knowledge. However, given our state of understanding over the

complex ecological issues when assessing environmental impact from contaminants the use of more than one approach to gathering data is strongly advised.

Many assessment approaches now incorporate this idea of multiple methods in assessing impact as a central theme using a 'weight of evidence' approach. Ecological risk assessments should therefore incorporate both community and biological endpoints (as mentioned in the previous section), especially as it has already been concluded that a field study which uses complimentary biomarker techniques combined with methods that relate to organism fitness and site chemistry, will provide the most profound data [Anderson et al., 1998]. Even though the exact relationship between biomarker and ecological endpoints is unknown at present, by undertaking multi-endpoint assessments, biomarker data can be accumulated which would help ascertain and confirm the relationship. Indeed developments in the application of biomarkers within the field of chemical risk assessment are promoting their future general acceptance for use as a regulatory tool. The Environment Agency and the water industry are currently undertaking a demonstration programme investigating the effects of chemicals on endocrine disruption in fish. By using the biomarker vitellogen and pathological techniques the link of chemical exposure to imposex (male secondary sexual characteristics in females) is being assessed and its use as part of a regulatory tool validated. The results of this study will not be available for some time. However, this data coupled with further research over the next decade could clarify the relationship between individual endpoints and population response and thus enable biomarkers to become a powerful predictive regulatory tool with regards to radioactive substances and ecosystem health. Furthermore, biomarkers hold the potential to act as a biological dosimeter and this may be of use in validating the calculation of absorbed dose to different non-human species.

Another key advantage of biomarkers is their potential to respond to a wide range of contaminants. This may allow, for example, the impact of the waste discharges of one type of industry (e.g. radioactive substances from nuclear sites or from medical practices) and put it in perspective with the biological impact of other industrial processes (e.g. heavy metals from the mining or smelting industry). Currently environmental impact assessments (EIA) do not assess the total impact of both radioactive and non-radioactive substances to any particular site [Strand et al., 2000]. This introduces a risk that different approaches will be developed for different situations [Pentreath, 1999].

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Appendix 1 - Reviewed material

Table 1. List of ERA programmes, methods and scientific literature that was reviewed.

Organisation and Program/Method	Reference
Radionuclides	
ACRP, Protection of non-human biota from ionising radiation	[ACRP, 2002]
AECL, Methods to assess environmental acceptability of releases of radionuclides from nuclear facilities	[Amiro, 1992; Amiro and Zach, 1993]
CNSC, Risk assessment of releases of radionuclides from nuclear facilities	[Environment Canada and Health Canada, 2000; Bird et al., 2002]
Environment Agency, UK (in collaboration with English Nature) Approach for assessment of the impact of ionising radiation on wildlife	[Copplestone et al., 2001; EA, 2002a,2002b, 2003b]
FASSET, Framework for the Assessment of Environmental Impact.	[FASSET, 2004]
IAEA, Biomass project	[IAEA, 2003c]
IAEA, Current development of safety guidance	[IAEA, 1999, 2000, 2003b]
ICRP, Task Group on Environmental Protection	[ICRP, 2003]
ORNL, Radiological Benchmarks for Screening Contaminants of Potential Concern for Effects on Aquatic Biota	[ORNL, 1998; Jones, 2000]
SPA 'TYPHOON'., Ecological approach to establishing dose criteria to biota	[Sazykina and Kryshev, 1999, 2002]
USDOE, A graded approach for evaluating radiation doses to aquatic and terrestrial biota	[Domotor, 2002; USDOE, 2002; Higley et al., 2003a; Jones et al., 2003]
Hazardous Substances	
Basel Convention, Ecotoxicological criteria for the characterisation of hazardous waste	[Basel Convention, 2000, 2002]
CCME, Environmental quality guidelines	[CCME, 1991, 1995, 1996, 1998]
Environment Canada, Environmental assessment of priority substances	[Environment Canada, 1997]
EU-REACH	[EC, 2004]
EU-TGD. Technical guidance documents in support of the Commission Directive on environmental risk assessment for new, notified substances and existing substances	[EC, 2003b]
ORNL, Ecological screening benchmarks	[ORNL, 1996a,1996b, 1997b,1997a,1997c]
OSPAR, Risk assessment methodology for the marine environment for use in development of OSPAR background documents for priority substances	[OSPAR, 2002]
RIVM, Environmental risk limits	[RIVM, 2001a,2001b]

USEPA, Ambient water quality criteria for protection of aquatic life	[USEPA, 1985]
USEPA, Ecological soil screening benchmarks	[USEPA, 2003]
USEPA, Guidelines for ecological risk assessment	[USEPA, 1992, 1998]
Others	
Multi-contaminants	[Garnier-Laplace et al., 2002]
Probabilistic for RNs	[Avila and Larsson, 2001]
Reference flora and fauna (CF (ICRP)	[Pentreath, 2003]
Ecological Risk Assessment	[Suter, 1993]
Ecological risk assessment of contaminated sites	[Suter et al., 2000]
Ecotoxicological benchmarks	[Suter, 1996]
Chemical ecological risk ass – definition/basics	[Calow, 1998]
Radioprotection vs ERA	[Brechignac, 2003]
Risk characterisation: principles and practise	[Williams and Paustenbach, 2002]
Approaches in risk characterisation	[Sorensen et al., 2004]
Trends in ERA	[Power and McCarty, 2002]
Integrated risk assessment	[Suter et al., 2003]
Better Chemicals control within Reach	[Hansson and Rudén, 2004]
Trends in chemical RA in the EU	[Bodar et al., 2002]
Opportunities for probabilistic ERA in the EU	[Jager et al., 2001]
Limitation in probabilistic ERA	[Verdonck et al., 2003]
Species sensitivity distributions in Ecotoxicology	[Posthuma et al., 2002]
Species sensitivity distr: a critical appraisal	[Forbes and Calow, 2002c]
Examples of probabilistic ERA	[Moore et al., 1999; Crane et al., 2003]
Background radiation in ERA	[Meyers-Schone et al., 2003]
New method for NOEC prediction with few data	[Roelofs et al., 2003]
Derivation of site-specific AWQC	[Moore et al., 2003]
Critical evaluation of safety factors	[Chapman et al., 1998]
Extrapolations in ERA	[Forbes et al., 2001; Forbes and Calow, 2002d; Goodman, 2002; Munns, 2002]
Uncertainty in ERA	[Smith and Shugart, 1994]
ERA of mixtures	[Norwood et al., 2003]
Indirect effects in ERA	[Preston, 2002]
Weight-of-evidence in ERA	[Burton et al., 2002a; Burton et al., 2002b; Forbes and Calow, 2002a]

Table 2. Overview of the recommended long-term tests in the TGD (EC, 2003) or in ASTM (1994-2004).

Test organisms (FW – Freshwater – M Marine)	*Duration*	*Umbrella Endpoint*	*Reference*	*Comments*
Aquatic compartment: Algal or macrophyte testing				
Pseudokirchneriella subcapitata (FW green algae) *Scenedesmus subspicatus* (FW green algae) *Navicula pelliculosa* (FW diatoms) *Anabaena flos-aquae* (FW blue-green algae) *Synechococcus leopoliensis* (FW blue-green algae)	72 hrs	Growth – inhibition during the exponential phase	OECD TG 201 2002 ISO 8692 1993	Low volumes (c.a. 150 ml) Rapid Closed systems where chemistry could be influence by algal growth (pH, organic exudates…) Represent a multi-generation test Can be considered as a true chronic test albeit the short duration
Gonyaulax polyedra (M dinoflagellates)	Up to 7 d	Bioluminescence inhibition	ASTM E1924 1997	Low volumes (ca 100 ml) Closed systems where chemistry could be influence by algal growth (pH, organic exudates…) Represent a multi-generation test
Oryza sativa (rice – FW vascular plant)	14 d	Growth – Chlorophyll production	ASTM E1841 1996	High volume Time consuming culturing conditions Representative of freshwater emergent macrophytes, important for wetlands
Champia parvula (M seaweeds)	Up to 7 d	Sexual Reproduction - egg fertilization	ASTM E1498 1998	Volume dependant on the species Wild population or laboratory cultures
Lemna gibba (FW floating vascular plant) *Lemna minor* (FW floating vascular plant)	7 d	Growth – dry weight	ASTM E1415 1998	Small volume Important source of food in FW ecosystems Easy laboratory cultures Fast growing and reproduction compared with other vascular plants
Myriophyllum sibiricum (FW submersed macrophyte)	14 d	Growth – Inhibition of root number and length, of dry weight, of chlorophyll production	ASTM E1913 1997	Small volume Important components of FW ecosystems Contribution to primary productivity and cycle nutrients; source of food and habitat Representative of submersed rooted macrophytes Wild population or laboratory cultures Rapid growth
Aquatic compartment: invertebrates				
Daphnia magna (FW Crustacea)	21 d	Reproduction	OECD 211 1998	Low volumes (ca 100 ml) semi-static or flow-through system
Aquatic compartment: Fish				
Danio rerio (FW Cyprinidae) *Pimephales promelas* (FW Cyprinidae) *Cyprinus carpio* (FW Cyprinidae) *Oryzias latipes* (FW Teleost) *Onchorynchus mykiss* (FW Teleost)	10 to 60 d	Fish short-term toxicity test on embryo and sac-fry stages	OECD 212 1998	High volume Static, semi-static or flow-through systems Time consuming rearing conditions Various diet, long generation time Important food source and potential route of bioaccumulation by higher organisms. Large size/ease of handling. heavily cultured/maintained in the laboratory.

Test organisms (FW – Freshwater – M Marine)	*Duration*	*Umbrella Endpoint*	*Reference*	*Comments*
idem	30 to 60 d	Fish early-life stage (FELS) toxicity test	OECD 210 1992	Idem
Oncorhynchus mykiss *Danio rerio* *Oryzias latipes*	>28 d	Fish juvenile growth test	OECD 215 2000	idem
Aquatic sediment compartment: invertebrates				
Chironomus sp. (FW Insect) *Hexagenia* sp. (FW Insect) *Lumbriculus variegates* (FW Oligochaete) *Tubifex tubifex* (FW Oligochaete) *Hyalella azteca* (FW Amphipod) *Gammarus* sp. (FW Amphipod) *Diporeira* sp. (FW Amphipod) *Caenorhabditis elegans* (FW Nematode)	3 to 28 d	Survival, growth, feeding, reproduction, Emergence	ASTM E1706 1995 OECD 218, 219 (Draft)	Short generation time Supplementary feeding required for some species (Chironomus) Important prey organisms Various tolerance of sediment granulometry/quality according to the species Various feeding strategy Ecological importance (structure and function with e.g. bioturbation)
Corophium sp. (M Amphipod) *Leptocheirus plumulosus* (M Amphipod) *Nereis/Neanthes* sp (M Polychaete) *Neanthes arenaceodentatakan* (M Polychaete) *Arenicola marina* (M Polychaete) *Echinocardium cordatum* (M Echinoderm)	10 to 28 d	Survival, growth, reproduction	OECD 1998 ASTM E1611 1994 ; E1367 1999	Degrader organisms, potentially field-collected organisms Ecologically important organisms Ring-tested Various tolerance of sediment granulometry/quality according to the species Various feeding strategy
Terrestrial soil compartment: Microbial Processes				
N-Transformation	>28 d	Metabolism	OECD 216, 2000 ; ISO 14238, 1997	Short-term adverse effects, based on soil microflora nitrate production.
C-Transformation	>28 d	Metabolism	OECD 217, 2000 ; ISO 14239, 1997	Short-term adverse effects, based on soil microflora respiration rate.
Potential nitrification, test based on ammonium oxidation		Metabolism	ISO 5685, 2000	Short-term adverse effects, based on the measurement of the potential activity of the nitrifying population
Abundance and activity of the microflora based on respiration		Metabolism	ISO 17155, 2000	Based on measurement of the respiration rate (CO2 production and O2 consumption)

Test organisms (FW – Freshwater – M Marine)	*Duration*	*Umbrella Endpoint*	*Reference*	*Comments*
Terrestrial soil compartment: invertebrates				
Eisenia fetida/andrei (Oligochaete) *Folsomia candida* (Arthropod-Collembola) *Enchytraeus albidus* (Oligochaeta)	1 to 8 weeks	Survival, reproduction	OECD 2000, ISO 1999, 2001 ASTM E1676 1997	Important ecological function (role in soil organic matter breakdown and nutrients recycling) Important food source and potential route of bioaccumulation by higher organisms. Large size/ease of handling. Readily cultured/maintained in the laboratory. Reproduction (juvenile number), various generation time (earthworms present the longer with 8 weeks)
Caenorhabditis elegans (Nematode)	1 to 3 d	Survival, growth, reproduction	ASTM 1999	Important ecological function, important in decomposition and cycling of organic materials Growth and reproduction assessed after 3 days. Abundant and readily retrieved from soil and cultured.
Terrestrial soil compartment: plants				
Grass crops (Monocotyledonae - Gramineae), Brassica sp. (Dicotyledonae – Cruciferae) bean crops (Dicotyledonae – Leguminosae)	5 to 21 d	Emergence, growth	OECD 208 2000	Seed emergence, early life stages of growth Root growth of pre-germinated seeds Number of species tested: minimum of three test species: one monocotyledon and two dicotyledon

OECD (1993 to 2002). Economic Cooperation and Development Guideline for the Testing of Chemicals -Ecotoxicity (main text and successive addenda), Paris.

ASTM (1994-2004). ASTM Standards on Biological Effects and Environmental Fate, 2nd Edition. American Society for Testing and Materials (ASTM).

ISO (1993-2000). International Organisation for Standardisation (ISO).

EU Annex V Testing Methods, relevant Directives and Official Journals; ECB web page <http://ecb.jrc.it/testingmethods>.

Appendix 2 - Acronyms and Glossary

Accuracy	The tendency of values of an estimator to come close to the quantity they are intended to estimate. See also Precision.
Assessment endpoint	An explicit expression of an ecological value to be protected.
Benchmark	Concentration or dose that are assumed to be safe based on exposure–response information (e.g. ecotoxicity test endpoints).
Beta Distribution	Is a flexible, bounded Probability Distribution Function described by two shape parameters. It is commonly used when a range of the random variable is known.
CC	Correlation coefficient. A measure of the linear relationship between two quantitative variables. It is denoted by the letter r and its values range from -1 to +1, where 0 indicates the absence of linear relationship, while -1 and +1 indicate, respectively, a perfect negative (inverse) and a perfect positive (direct) relationship.
CDF	Cumulative Distribution Function, F(x), expresses the probability the random variable X assumes a value less than or equal to some value x, F(x)=Prob(x. x). For continuous random variables, the cumulative distribution function is obtained from the probability density function by integration. In the case of discrete random variables, it is obtained by summation.
CLs	Common Locations. Use of the Kruskal-Wallis statistic to identify changes in the distribution of y across the range of individual xi's.
CMDs	Common Medians. Use of the χ2statistic to identify changes in the median value of y across the range of individual xi's.
CMNs	Common means. Use of the F-statistic to identify changes in the mean value of y across the range of individual xi's.
Conceptual model	Representation of the environmental system and of the physico-chemical and biological processes that determine the transport/transfer of contaminants from sources through environmental media to ecological receptors within the system.
Confidence	Is used to represent trust in a measurement or estimate.
Confidence interval	An interval for which one can assert with a given probability, called the degree of confidence or the confidence coefficient, that it will contain the true value of the parameter it is intended to estimate. The endpoints of a confidence interval are referred to as the (upper and lower) confidence limits; they are generally values of random variables calculated on the basis of sample data.
Correlation	In general, the term denotes the relationship (association or dependence) between two or more qualitative or quantitative variables. See also CC (Correlation Coefficient).
CTV	Chronic Toxicity Value

Distribution Function	A function whose values F(t) are the probabilities that a random variable assumes a value less than or equal to t.
Ecological receptor	Living organisms at various organisation level (i.e. ecosystems, communities, populations, individual organisms (except humans – note that humans are included when the term “environmental receptors” is used) potentially exposed to and adversely affected by stressors because they are present in the source(s) and/or along stressor migration pathways.
EC	Effective Concentration
ERA	Ecological Risk Assessment
Hazard	The term is used to indicate the likelihood that a contaminant will cause an adverse effect, to man or the environment, under the condition in which it is produced or used. Thus, the hazard is a function of two broad considerations, the potential of the contaminant to harm biological systems and its potential for exposure such that the adverse effect can occur.
LC	Lethal Concentration
LET	Linear Energy Transfer. A measure of how, as a function of distance, energy is transferred from radiation to the exposed matter. Radiation with high LET is normally assumed to comprise of protons, neutrons and alpha particles (or other particles of similar or greater mass). Radiation with low LET is assumed to comprise of photons (including X-rays and gamma rays), electrons and positrons.
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
Lognormal Distribution	Is the distribution of a variable whose logarithm is normally distributed.
Measurement endpoint	A measurable response to a stressor that is quantifiably related to the assessment endpoint.
Median	The median value of a sample is the value which divides an ordered sample into two equal halves. If there are 2n + 1 observations, the median is taken as the (n + 1)th member of the ordered sample. If there are 2n it is taken as being halfway between the nth and (n +1)th.
Monte Carlo Analysis	(Monte Carlo Simulation) Is a computer-based method of analysis developed in he 1940's that uses statistical sampling techniques in obtaining a probabilistic approximation to the solution of a mathematical equation or model. It is a method of calculating the probability of an event using values, randomly selected from sets of data repeating the process many times, and deriving the probability from the distributions of the aggregated data.
MPC	Maximum Permissible Concentration (RIVM)
NAWQC	National Ambient Water Quality Criteria
NOAEL	Lowest Observed Adverse Effect Level

NOEC	No Observed Effect Concentration
Non-parametric approach	Is one that does not depend for its validity upon the data being drawn from a specific distribution, such as the normal or lognormal; a distribution-free technique.
Normal Distribution	(Gaussian distribution) Is a probability distribution for a set of variable data represented by a bell shaped curve symmetrical about the mean.
Parametric	Category of statistical tests based on the following assumptions: (i) data are normally distributed, (ii) variance is homogeneous, (iii) about 25 samples for each variable analyzed, (iv) relations among variables are linear.
PBT	Persistent, Bioaccumulative and Toxic substances.
PCC	Partial Correlation Coefficient. Is a statistic that is calculated to measure the association between two variables after controlling (or adjusting) for the effects of one or more additional variables.
PDF	Probability Density Function of a continuous random variable. Is a function which can be integrated to obtain the probability that the random variable takes a value in a given interval.
PEC	Predicted Environmental Concentration
PEL	Probable Effects Level
PNEC	Predicted No-Effect Concentration
PNEDR	Predicted No-Effect Dose Rate
PRCC	Partial Rank Correlation Coefficient. Measures the degree of relation between two variables, when a third variable is held constant. Estimates non linear monotonic relationship and gives the unique contribution of an input parameter to the resultant dose.
Precision	The precision of an estimator is its tendency to have its values cluster closely about the expected value of its sampling distribution; thus, it is related inversely to the variance of this sampling distribution - the smaller the variance, the greater the precision.
QSAR	Quantitative Structure-Activity Relationship
Quantiles	A generic name for statistics such as deciles, percentiles, and quartiles. The qth quantile of a list ($0 < q <= 1$) is the smallest number such that the fraction q or more of the elements of the list are less than or equal to it. i.e., if the list contains n numbers, the qth quantile, is the smallest number Q such that at least $n \times q$ elements of the list are less than or equal to Q.
Random Error	Is the result of a measurement minus its expected value. Random error is equal to absolute error minus systematic bias. Because only a finite number of measurements can be made, it is possible to determine only an estimate of random error.
RBE	Relative Biological Effectiveness

RCC	Spearman Rank Correlation Coefficient. It is usually calculated on occasions when it is not convenient, economic, or even possible to give actual values to variables, but only to assign a rank order to instances of each variable. It may also be a better indicator that a relationship exists between two variables when the relationship is non-linear.
Receptor	See ecological receptor.
Risk	A statistical concept describing the expected frequency or probability of undesirable effects arising from exposure to a contaminant.
Risk characterisation:	The synthesis of information obtained during risk assessment for use in management decisions. This should include an estimation of the probability (or incidence) and magnitude (or severity) of the adverse effects likely to occur in a population or environmental compartment, together with identification of uncertainties.
RQ	Risk Quotient
Sensitivity Analysis	The systematic investigation of the reaction of the simulation and response to either extreme values of the model's quantitative factors (parameter and input variables) or to drastic changes in the model's quantitative factors (modules). So the focus is not on marginal changes in inputs.
SI	Statistical Independence. Use of the χ2statistic to identify non random joint distributions involving y and individual xi's.
SLC	Screening Level Concentration
SRC	Standardised Regression Coefficient. The regression coefficient that would result from data that have been standardised.
SRRC	Standardised Rank Regression Coefficient. Estimates non linear monotonic relationship and provides "shared" contribution of an input parameter to the resultant dose.
SSD	Species Sensitivity Distribution
Systematic error (Bias)	(i) In problems of estimation, an estimator is said to be biased if its expected value does not equal the parameter it is intended to estimate. (ii) In sampling, a bias is a systematic error introduced by selecting items from a wrong population.
TEL	Threshold Effects Level
TGD	Technical Guidance Documents
Tier	The common denominator in tiered approaches are that complexity and realism increases with higher tiers and that the decision to continue from one tier to the next is based on identification of hazard to ecological receptors.
Triangular Distribution	A distribution with a triangular shape. It is characterized by its minimum, maximum and mode (most likely) values. It is often used to represent a truncated log-normal or normal distribution if there is little information available on the parameter being modelled.

TU	Toxic Unit
Uncertainty	Uncertainty is a statistical term that is used to represent the degree of accuracy and precision of data. It often expresses the range of possible values of a parameter or a measurement around a mean or preferred value.
Uncertainty analysis	In uncertainty analysis values of the model inputs are sampled from pre-defined distributions to quantify the consequences of the uncertainties in the model inputs, for the model outputs. So in uncertainty analysis the input variables range between extreme values investigated in sensitivity analysis.
Validation	Is the establishment of sound approach and foundation. The legal use of validation is to give an official confirmation or approval of an act or product.
Variability	This refers to observed differences attributable to true heterogeneity or diversity in a population or parameter. Sources of variability are the result of random processes. Variability is usually not reducible by further measurement or study, but can be characterised.
Variance	The variance of a sample is (i) the square of the standard deviation (ii) the second central moment of a population.

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