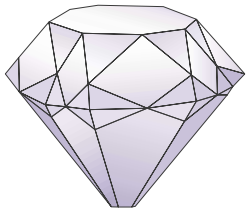
FASSET



Framework for Assessment of Environmental Impact

Deliverable 2: Part 2

Overview of programmes for the assessment of risks to the environment from ionising radiation and hazardous chemicals

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FASSET will bring to radiation protection a framework for the assessment of environmental impact of ionising radiation. The framework will link together current knowledge about sources, exposure, dosimetry and environmental effects/consequences for reference organisms and ecosystems. Relevant components of the framework will be identified on an ecosystem basis through systematic consideration of the available data. The application of the framework in assessment situations will be described in an overall report from the project. The project started in November 2000 and is to end by October 2003.

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Contractors:

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German Federal Office for Radiation Protection	BfS
German National Centre for Environment and Health	GSF
Spanish Research Centre in Energy, Environment and Technology	CIEMAT
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Executive summary

The aim of the FASSET (Framework for assessment of environmental impact) project is to develop an assessment framework that will assist decision-makers and all stake holders involved in assessing the environmental effects of past, present and future sources of environmental radiation. Within the FASSET framework, assessment models can be applied and results analysed for European ecosystems.

The aim of FASSET Deliverable 2 is to take advantage of, and integrate into the FASSET framework, aspects of existing systems dealing with environmental risks from radioactive or hazardous substances. The report Deliverable 2: Part 1, 'Formulating the FASSET assessment context', describes the FASSET assessment context, which is based partly on relevant aspects of the systems reviewed in this report. This report, Deliverable 2: Part 2, gives an overview of the structure and methods used in existing systems.

This report presents an overview of some existing programmes for the assessment of the risks to the environment associated with ionising contaminants and other hazardous substances. The aim of the review was to identify relevant aspects of existing programmes that could be incorporated into the FASSET framework. A number of aspects of existing systems are compared and discussed, in order to support, justify and help define the formulation of the FASSET assessment context. Deliverable 2: Part 1 presents the form of the framework to be developed within the project, which is based partly on material presented in this report.

Major international and national programmes addressing the assessment of environmental risks of ionising contaminants have been included in the review. As similar principles can be applied to the protection of non-human species from ionising contaminants and hazardous chemicals, a number of national and international programmes for assessing environmental risks of hazardous chemicals have been also been included.

The survey shows that assessment frameworks generally comprise three phases:

- problem formulation;
- the assessment phase; and
- risk characterisation.

Problem formulation

The problem formulation phase focuses on scoping and planning the assessment, and is best described as the scientific definition of the problem under study. The problem formulation phase defines:

- the objectives of the assessment;
- what we wish to protect (the assessment endpoints);
- the relevant spatial and temporal scales; and
- how we intend to measure the effects (the measurement endpoints or indicators).

The aims of the existing schemes determine choices made at all the assessment-stages and are inextricably linked with the way in which the assessment schemes are structured. The formulation of the aim of the scheme is also closely linked with the underlying environmental assessment philosophy. The aims of the schemes studied include:

- derivation of environmental standards (e.g. limiting values, screening levels, environmental quality standards);
- assessment of compliance with regulatory limits/guideline values;
- assessment of the hazard associated with chemicals released to the environment;
- assessments of the impacts of authorised releases; and
- assessment of the hazards of contaminants in various environmental media

The definition of an acceptable effect is also linked to the aim of the assessment. Many systems have their own definition of what is acceptable. In some systems, the definition of acceptable takes the form external standards. In other systems the definition of what is acceptable is made from case to case and is therefore specific to the assessment being carried out.

The identification of the part of the environment that is to be protected is also dependent on the aim of the assessment. Systems vary in their stated aims with respect to the level of biological organisation being protected. Many systems state that protection should be at the level of the population. This is often justified by the argument that individuals of species other than man are not of value, and that protection of populations prevents adverse effects at higher levels of organisation. Other systems also consider protection of individuals under some circumstances, e.g. threatened or endangered species, valuable individuals or where effects on individuals are considered to be unacceptable.

The choice of the endpoint of the assessment may be predefined by the system or may be made on a case-specific basis. The following criteria are often used in the choice of endpoint:

- importance to the structure and function of the ecological community;
- the degree of exposure expected from the distribution of the contaminant in the environment and the type and behaviour (e.g. habitat, diet) of the organism;
- the degree of sensitivity to the contaminant; and
- relevance to management goals.

In many assessment systems, the use of several endpoints is suggested, in order to cover a range of ecological functions, taxonomic groups and exposure routes. Critical or reference organisms are used in a number of assessment systems. Critical organisms are the maximally exposed or most sensitive organism in a particular situation, i.e., are defined on a site specific basis. Reference organisms are standard organisms adopted for assessment purposes. Reference organisms are not necessarily real organisms; they can be generic reference organisms, e.g. a bird or a benthic filter feeder.

The assessment phase

The assessment phase results in an overview of the potential effects in the environment and comprises the following main components:

- Entry characterisation – the amounts of a substance entering the environment, the form of the substance and the distribution of releases over time.
- Exposure assessment – the prediction of the exposure of a substance to the assessment endpoint. The exposure analysis can take the form of an intake of the contaminant by the endpoint organism, an environmental concentration. For radionuclides, exposure may be expressed as absorbed dose.
- Effects analysis – the analysis of the dose-effect relationship in order to identify doses resulting in various degrees of harmful effect.

A number of different approaches to the assessment phase have been adopted, arising from the need to balance the information value of the assessment against the availability of data and the need to keep the assessment manageable. These approaches range from the use of a simplified biosphere to a full site specific assessment. The simplified biosphere may provide little insight or information as to the real consequences in the environment, but may be useful for screening and for judging compliance against environmental standards. The ultimate level of complexity is reached when a full site specific assessment is made, incorporating mapping and measurements of all relevant parameters in the ecosystem in question. Some assessment systems define, or demonstrate how to define, reference biospheres in terms of the values of the parameters of the environment to be studied. In some cases, systems have been developed that allow for analysis at different levels of complexity depending on the requirements and outcome of the assessment, often referred to as a tiered approach. At all levels of simplification, both deterministic and probabilistic assessments can be performed.

In assessments of both environmental radiation and non-radioactive hazardous substances, dose-effect data is usually derived from observations on individuals. The techniques used to extrapolate from these data to effects at higher levels of biological organisation vary between the assessment systems studied. The main extrapolation methods are:

- The safety factor approach, in which a safety factor is applied to take into account the availability, quality and relevance of dose-effect data.
- Distribution-based or weight of evidence methods, in which the available toxicity data, after screening for suitability, are collected into a statistical distribution. Acceptable exposure or dose may then be defined as a certain percentile of the data set.

Risk characterisation

In risk characterisation, the actual or estimated potential effects are reviewed, together with the uncertainties associated with the assessment, to enable judgements about the significance and acceptability of the risk. Two main approaches have been adopted to take into account the uncertainties in the assessment: the use of a conservative, deterministic approach and the use of a probabilistic approach.

The risk characterisation step often consists of a comparison of the estimated exposure with guideline values, i.e., is based on a previous, separate analysis of dose-effect relationships for critical biological effects. Thus, the effects analysis is often not integrated into the assessment,

and is carried out by separate assessors. This approach is used mainly in generic, simplified biosphere assessments. Integration of the effects analysis, and the use of assessment specific effects data, is more typical of detailed, site specific assessments.

Background exposure may also be taken into account in the risk characterisation phase. Some of the systems studied consider only the incremental exposure from the source being studied. Other systems take into account the total exposure, including background, in the estimation or measurement of exposure. In site specific assessments, it is possible to adopt ‘reference background’ areas, i.e., a similar area in terms of geology and ecology, but unaffected by point sources of the contaminant. The influence of multi-contaminants may be a factor that should be taken into account in risk characterisation, though relevant methods are still under development.

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1. Introduction

The requirement for assessments of the environmental effects of radiation is increasing due both to growing public awareness and concern for environmental protection issues and to the evolving integration of environmental impact assessments into regulatory processes. A well-defined assessment framework would be of benefit to both regulators and to organisations responsible for the development, implementation and operation of nuclear and other facilities, and would help in decision-making on these issues and in the setting of standards for environmental protection. Such a framework would, in addition, aim to help to make a clear and understandable presentation of the environmental effects to members of the public.

The aim of the FASSET project is to develop a framework within which assessment models can be applied and results analysed for European ecosystems. As part of the development of such a framework, a review of existing systems for the assessment of environmental risks associated with ionising contaminants and other hazardous substances has been carried out. The aim of the review was to identify relevant aspects of existing programmes that could be incorporated into the FASSET framework. This report, Deliverable 2: Part 2 of the FASSET project gives an overview of some existing programmes for the assessment of risks to the environment. A comparison and discussion of some aspects of the existing systems are also given, in order to support, justify and help define the formulation of the FASSET assessment context. Deliverable 2: Part 1, 'Formulating the FASSET assessment context', presents the conclusions of the FASSET project concerning the form of the framework to be developed within the project, and is based partly on discussion of the material presented in this report by the FASSET group.

The review procedure adopted during the study is described in Chapter 2 of this report. The general structure of the existing assessment systems is presented in Chapter 3, together with a short discussion of the features common to many of the systems, as well as the major differences between them. A more detailed comparison and a discussion of component parts of the assessment systems are given in the remaining chapters of the report.

A glossary defining the terms used in Deliverable 2, Parts 1 and 2, of the FASSET project is given in Deliverable 2: Part 1.

2. Review procedure

2.1 Collating the information

As an initial stage in collating information, all FASSET partners have identified national and international assessment and management programmes that are relevant to FASSET, and this information has been further reviewed within Work Package 4 of the FASSET group. Out of the initial list, a further selection has been made which is overviewed in this chapter.

Major international and national programmes addressing the assessment of environmental risks of ionising contaminants have been included. Similar principles should be able to be applied to the protection of non-human species against radiation contaminants as are applied to protection against hazardous chemicals. Therefore, a number of national and international programmes for assessing environmental risks of hazardous chemicals have been included when their structures have been deemed appropriate to assessing impact of ionising radiation. A number of programmes for assessing risks of hazardous chemicals have *not* been included since they essentially corroborate other programmes. Thus, the final list represents a certain bias, but it should undoubtedly cover all aspects of assessment frameworks that are relevant to FASSET. A complete list of reviewed programmes is given in Tables 2-1 and 2-2.

2.2 Systems for assessment of environmental effects of radionuclides and hazardous substances

The assessment systems included in this review have been grouped into systems for the assessment of the environmental effects of radionuclides (Table 2-1) and systems for the assessment of the environmental effects of hazardous chemicals (Table 2-2). A list of acronyms used in the tables is given below.

AECB	Atomic Energy Control Board, Canada (now the Canadian Nuclear Safety Commission)
AECL	Atomic Energy of Canada Limited
BIOMASS	BIOsphere Modelling and ASSessment programme
CCME	Canadian Council of Ministers of the Environment
CNSC	Canadian Nuclear Safety Commission
EA UK	Environment Agency, United Kingdom
EU TGD	European Union Technical Guidance Document (published by the European Chemicals Bureau)
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiation Protection
ORNL	Oak Ridge National Laboratories, Tennessee, USA
OSPAR	Oslo-Paris Convention for the Protection of the Marine Environment of the North-East Atlantic
RIVM	National Institute of Public Health and Environment, Netherlands
Typhoon	Scientific and Production Association 'TYPHOON', Obninsk, Russia

Table 2-1 Systems for the assessment and management of the environmental effects of radionuclides.

System and organisation	Description
Current development of safety guidance (IAEA)	The IAEA has in recent years organised consultants' and specialists' meetings, in order to assist the Agency in developing its approach to environmental assessment and protection. The activities have resulted in publication of TECDOCs 1091 [IAEA, 1999] (reviewing environmental approaches in general and used in different member states) and 1270 [IAEA, 2002] (on the ethical basis for environmental programmes). The Agency is continuing its work in order to come up with guidelines as to exposure analysis, effects analysis, and dosimetric considerations, aiming at publication within the Agency's Safety Standards.
BIOMASS project (IAEA)	Theme 1 of the BIOMASS project has developed an approach for identifying the assumptions and hypotheses relevant to the definition of biospheres for practical radiological assessment of releases of radionuclides in the long term [IAEA, 2001]. The application of this approach is intended to provide consistency between assessments. A subset of example assessment biospheres has been developed. A number of task groups were formed to work on the following aspects of the development of reference biospheres: Principles for the definition of critical and other exposure groups; Principles for the application of data to assessment models; Consideration of alternative assessment contexts; Biosphere system identification and justification; Biosphere system descriptions; Model development. Some of the conclusions and methodologies developed within BIOMASS appear particularly important to carry forward within FASSET. A workshop was organised in Stockholm 30–31 October 2001 between FASSET and BIOMASS partners, to discuss these issues [FASSET, 2001].
Task Group on Environmental Protection (ICRP)	The current Recommendations from the Commission [ICRP, 1991] only consider the environment as an exposure pathway for humankind, not as *per se* a target for protective actions. The ICRP has as part of its ongoing revision of the basic Recommendations established a Task Group on Environmental Protection, which will report to the Main Commission for incorporation of environmental issues in the new Recommendations (due 2005). A reference approach, similar to the reference man concept, is being developed, and a consequence analysis based on consideration levels (radiation dose rates relative to background levels) guiding actions to protect the environment is being discussed [ICRP, 2002].
A graded approach for evaluating radiation doses to aquatic and terrestrial biota (USDOE)	This technical standard provides methods and guidance that the US Department of Energy and its contractors may use to evaluate doses of ionising radiation to populations of aquatic animals, terrestrial plants and terrestrial animals from DOE activities and off-normal events for the purpose of demonstrating compliance with applicable dose limits, based on previous IAEA reviews [IAEA, 1992]. A screening method and three more detailed analysis methods are provided, together with software to support assessments, RESRAD-BIOTA [USDOE, 2000].
Approach for assessment of the impact of ionising radiation on wildlife (EA UK, in collaboration with English Nature)	This report makes recommendations on an approach to assess the impacts on wildlife of ionising radiation from authorised discharges in England and Wales. The assessment approach is generic and focuses on three ecosystems representative of those considered potentially most at risk from the impact of authorised radioactive discharges: a coastal grassland, estuarine and freshwater ecosystems. A spreadsheet calculation tool to calculate doses supports the assessments. A criterion based on 5 % of the IAEA 'safe' levels [IAEA, 1992] is recommended [Copplestone *et al.*, 2001; Environment Agency, 2002].

Table 2-1 (continued)

System and organisation	Description
Risk assessment of releases of radionuclides from nuclear facilities (CNSC)	The impact of the release of radionuclides from nuclear facilities on non-human biota was assessed according to the guidance for conducting environmental assessments of priority substances developed by Environment Canada. The processes included in the assessment are the mining of uranium ore, milling of the ore to produce yellowcake, uranium refining and conversion, fuel fabrication, nuclear power generation and nuclear waste management. The assessment considers the chemotoxicity of uranium as well as its radiotoxicity [Environment Canada and Health Canada, 2000].
Radiological Benchmarks for Screening Contaminants of Potential concern for Effects on Aquatic biota (ORNL)	These benchmark values are intended for use in the screening process in order to determine whether contaminants warrant further assessment or are at a level that requires no further attention. The benchmark values differ from those presented by ORNL for non-radioactive contaminants in that the benchmarks are calculated from an acceptable dose rate to natural populations of aquatic biota. Both water and sediment screening benchmarks are based on the dose to fish, rather than benthic invertebrates, as vertebrates are assumed to be more radiosensitive than invertebrates (based on conclusions of the NCRP [NCRP, 1991]). There are two suites of benchmarks for water and sediment: those that consider exposures from only one medium and those that incorporate exposures from multiple media [ORNL, 1998].
Ecological approach to establishing dose criteria to biota (SPA 'TYPHOON')	In this approach, primary, generic dose limits are established on the basis of available information about the harmful effects of radiation on different species of organisms, taking into account background doses. Dose limits are established for a number of groups of species. Secondary (site-specific) dose limits are adaptations of the generic dose limits, taking into account other stress factors that the organisms are subject to. Three stress factors are used to evaluate the stress for populations associated with the local environment, climatic conditions, direct anthropogenic stress and natural stress. In this approach, the assessment is carried out for species and selected from the following categories: key species, critical populations (populations subjected to the highest radiation does rates), threatened/endangered species, economically/culturally important species, and rare/relict species. It is recognised that while screening level assessments may in many cases be sufficient for typical (common) ecosystems, more detailed assessments will be required for special (unique) ecosystems [Sazykina & Kryshev, 1998].
Method to assess environmental acceptability of releases of radionuclides from nuclear facilities (AECL)	This method, which was developed to evaluate the potential of radionuclide releases to harm the environment, has four steps. In the second step, predicted or measured radionuclide concentrations in soil, water and air are compared to environmental increment (EI) values for each radionuclide. The EI values are based mainly in natural variability and are useful for screening potentially unacceptable concentrations, defined by a level > 1 standard deviation above the mean. In the third stage, radiological doses are calculated to generic target organisms and compared to a dose criterion. The fourth step is an in-depth assessment, which would only be required if doses to the generic target organisms exceed the criterion [Amiro & Zach, 1993].

Table 2-2 Systems for the assessment and management of the environmental effects of hazardous substances.

System and organisation	Description
Ecotoxicological criteria for the characterisation of hazardous waste (Basel Convention)	This system is for the evaluation of the hazard of wastes, based on the intrinsic properties of the waste and its constituents, i.e. the ecotoxicological hazard of the material and chemical substances contained in the waste. The hazard evaluation is based on the following ecotoxicological parameters: acute and chronic toxicity (aquatic and terrestrial), bioaccumulation potential and biodegradability. The system proposes three tiers of analysis; the first based on the estimated content of hazardous substances, the second based on chemical analysis and the third based on ecotoxicological testing of leachate and waste [Basel Convention, 1999; 2001].
Technical guidance documents in support of the Commission Directive on environmental risk assessment for new, notified substances and existing substances (EU-TGD)	Commission Directive 93/67/EEC [EC, 1993] and Commission Regulation 1488/94 [EC, 1994] require that a risk assessment be carried out on notified new substances or on priority existing substances. This technical guidance document concerns the environmental risk assessment which forms part of these risk assessments. The risk assessment should include hazard identification, dose-response assessment, exposure assessment and risk characterisation. The risk assessment should be carried out for all three environmental compartments, i.e. aquatic environment, terrestrial environment and air. The technical guidance document is designed in part to use the minimum data set required for notified new substances as a starting point.
Risk assessment methodology for the marine environment (OSPAR)	OSPARs risk assessment methodology is a development and extension of the existing EU approach (TGD, see above) for priority substances. The methodology is adapted in order to take into account the long-term accumulation of hazardous substances in parts of the marine environments, the greater dilution of contaminants in marine environments and the physical and chemical characteristics of marine environments. The methodology is also intended to address the concern that remote areas of the oceans should remain untouched by hazardous substances resulting from human activity. The risk assessment methodology includes a PBT (persistence, bioaccumulation and toxicity) assessment using standardised tests. The methodology is for use in development of OSPAR background documents for priority substances [OSPAR, 2002a].
Environmental assessment of priority substances (Environment Canada)	This manual provides guidance for conducting environmental assessments of priority substances under the Canadian Environmental Protection Act. The assessment estimates and describes risks to receptors (e.g. plants, animals) exposed in the Canadian environment to priority substances. It incorporates the characterisation of entry to the environment, exposure to and effects of a substance. A tiered approach has been adopted. Substances indicated by the assessment to have or potentially have an immediate or long-term harmful effect on the environment or its biological diversity are considered for possible risk management measures [Environment Canada, 1997].
Guidelines for ecological risk assessment (USEPA)	The development of these guidelines was intended to help improve the quality and consistency of ecological risk assessments within the US EPA. The guidelines consider the ecological risk assessment to include three primary phases: problem formulation, analysis and risk characterisation. Because ecological risk assessments are used within the risk management context to evaluate human induced changes, the guidelines focus on evaluation of adverse ecological effects generated by anthropogenic activity. An assessment may involve one, or more, chemical, physical, or biological stressors and may be carried out retrospectively (effects caused by past exposure) or in order to predict the likelihood of future adverse effects [USEPA, 1992, 1993, 1998].

Table 2-2 (continued)

System and organisation	Description
Ecological soil screening guidance (USEPA)	This guidance provides a set of risk-based soil screening levels (Eco-SSLs) for many of the soil contaminants that are frequently of ecological concern for terrestrial plants and animals at hazardous waste sites. Eco-SSLs are screening values that can be used routinely to identify contaminants of potential concern in soils requiring further evaluation (i.e. soils which, following screening, require a baseline ecological risk assessment, described in USEPAs Guidelines for ecological risk assessment. Eco-SSLs are concentrations of contaminants in soils that are protective of ecological receptors that commonly come into contact with soil or ingest biota that live in or on soil. Eco-SSLs are derived separately for four groups of ecological receptors; plants, soil invertebrates, birds and mammals. Eco-SSLs do not constitute EPA regulations, and are therefore not legally binding requirements [USEPA, 2000].
Ecotoxicological screening benchmarks (ORNL)	A series of ORNL ecotoxicological screening benchmark values have been developed or obtained for the following types of exposure and classes of endpoint groups; exposure of aquatic biota to chemicals in water, exposure of benthic biota to chemicals in sediments, exposure of terrestrial plans, soil invertebrates and soil functional groups to chemicals in soil, and exposure of wildlife to chemicals in orally ingested materials. The values were developed using existing data and methods consistent with the practices of the US EPA. The benchmark values are concentrations of chemicals in ambient media that are believed to represent acceptable concentrations with respect to selected ecological receptors. The benchmarks are intended to provide a set of consistent, peer reviewed screening values, for use in screening assessments to identify contaminants, media and receptors that may be at risk and requiring further investigation. The benchmark values are not regulatory criteria [ORNL, 1996a, b; ORNL 1997a, b, c].
Environmental risk limits (RIVM)	Maximum Permissible Concentrations and Negligible Concentrations are risk-based guideline concentrations for substances in surface water, soil, air, groundwater and sediment, which are applied, in environmental policy in the Netherlands. The policy of safeguarding ecosystems against pollutants is based on protecting both the structure (the species) and functions of ecosystems. The Negligible Concentration represents the concentration of a substance below which the occurrence of adverse effects is considered to be negligible. The Maximum Permissible Concentration represents the concentration above which the risk of adverse effects is unacceptable. Standards for one compartment are set at a level where protection to organisms living in other compartments is ensured as well, thus transport of substances between media is taken into account [RIVM, 1999].

Table 2-2 (continued)

System and organisation	Description
Environmental quality guidelines (CCME)	CCME has developed environmental quality guidelines, which define nationally accepted indicators of environmental quality for protecting and sustaining aquatic and terrestrial ecosystems and their uses in Canada. These include sets of environmental quality guidelines for the protection of biota, which are based on the toxicological effects of contaminants. These guideline values are expressed as contaminant concentrations in environmental media. They are intended to be broadly protective tools that will support the functioning of healthy ecosystems. Environmental quality guidelines have a broad range of potential applications, but are most likely to be applied routinely as screening tools in assessment of sites as to the degree of concern posed by the contaminants in order to focus further investigations. Soil quality guidelines are concentrations in soil below which the ecological receptors that sustain the primary activities for the different types of land use that are protected. Water quality guidelines for the protection of (freshwater) aquatic life are set at such values as to protect all forms of aquatic life and all aspects of the aquatic life cycles. Sediment quality guidelines for the protection of aquatic life have been developed to support and maintain aquatic life associated with bed sediments. Tissue residue guidelines are intended to protect all wildlife in aquatic food chains, and are to be applied to the diet at the highest known aquatic trophic level, particularly for contaminants with a strong biomagnification potential [CCME, 1991, 1996, 1997].
Ambient water quality criteria for protection of aquatic life (USEPA)	EPA's ambient water quality criteria are designed to protect aquatic communities. The criteria are an estimate of the highest concentration of a substance in water, which does not present a significant risk to the aquatic organisms in the water and their uses. The criteria attempt to prove a reasonable and adequate amount of protection with only a small possibility of substantial over-protection or under-protection. Numeric aquatic life criteria are expressed as short-term and long-term averages, rather than as one number. The combination of a criterion maximum concentration (a short-term concentration limit) and a criterion continuous concentration (a four-day average concentration limit) is intended to identify average pollutant concentrations consistent with the maintenance of aquatic life and designated uses while restricting the duration of above average concentrations, so that total exposures will not cause unacceptable adverse effects. A minimum data set of eight specified families is recommended for criteria development, in order to represent a wide spectrum of aquatic life. Criteria have been developed both for fresh and for salt water [USEPA, 1995].
Ecological quality objectives for the North Sea (OSPAR)	Ecological Quality objectives are being developed as tools to support the development and application of an ecosystem approach to the management of human activities. Ecological quality elements, which are measurable aspects of marine ecosystems and are an expression of the ecosystem structure and function, have been identified. Ecological quality objectives are levels of these ecological quality elements in towards which management efforts are to be directed. Ten issues are being considered for the derivation of ecological quality objectives. For some of these issues, several objectives are being derived. The issues are; commercial fish species, threatened and declining species, sea mammals, seabirds, fish communities, benthic communities, plankton communities, habitats, nutrient budgets and production, oxygen consumption [OSPAR, 2002b].

2.3 Approach to analysis of existing assessment programmes

An initial survey of the assessment programmes studied showed that a number of different approaches are adopted, arising basically from the need to balance the information value of the assessment against the availability of data and the need to keep the assessment manageable. Figure 2-1 illustrates these approaches.

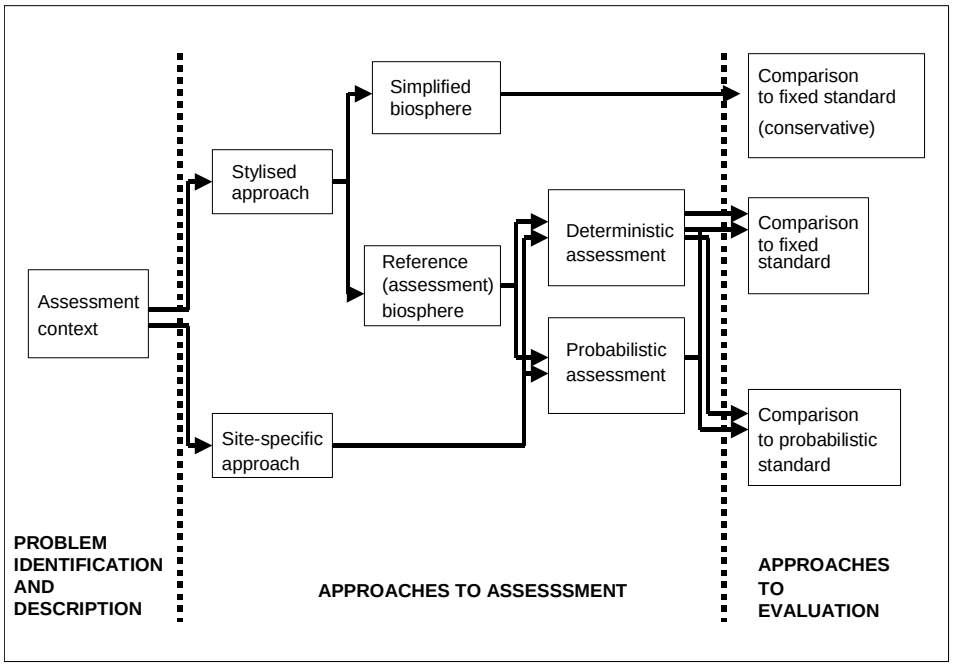

Figure 2-1 Overview of approaches to assessment and risk characterisation and evaluation.

The survey shows that assessment frameworks generally comprise three phases:

- problem formulation – for what purpose are you doing the assessment?;
- assessment – at the level of detail deemed necessary for the purpose; and
- risk characterisation – against standards or criteria defining the type and degree of effects, based on appropriate dose-effect and dose-response analysis.

The analysis of the programmes builds on these three elements, with a number of further qualifications:

The *assessment* can be performed in a number of fashions, each representing different information value, data requirements and complexity. The way in which assessments have been performed ranges from the use of a simplified biosphere to a full site-specific assessment. The simplified biosphere may provide little insight or information as to the real consequences in the environment; but may be useful for screening and for judging compliance against environmental standards. The ultimate level of complexity is reached when a full *site-specific assessment* is made, incorporating mapping and measurements of all relevant

parameters in the ecosystem in question. In some cases, systems have been developed that would allow for analysis at different levels of complexity depending on the requirements and outcome of the assessment, often referred to as a *tiered approach*.

The risk characterisation often consists of a comparison with guideline values, i.e., is based on a previous, separate analysis of dose-effect relationships for critical biological effects. Thus, the effects analysis is often not integrated into the assessment, and is carried out by separate assessors.

On the basis of the above considerations, information from different programmes has been collated under the headings shown in Table 2-3. This analysis essentially underlies the detailed analysis carried out in the remaining chapters of this report.

Table 2-3 Review of existing programmes for assessment and management of environmental risks from ionising contaminants and hazardous chemicals.

Analysis component	Questions or relevant issues to be considered
Assessment programme	Name of programme and/or organisation developing and applying it.
Problem formulation	
Purpose	What is the purpose of the assessment and what questions is it designed to address and answer?
Tiered approach, rationale	Yes/no, rationale.
Stylised approach, comparison with standard	The level of simplification, degree of conservatism, analysis supporting the standards.
Stylised approach, simplified biosphere	The level of simplification, degree of conservatism.
Stylised approach, reference biosphere	Representativity of the biosphere system, degree of conservatism and limitations in applicability, resolution.
Site-specific approach, deterministic	Methods for identification of key parameters, data requirement, conservatism and uncertainties.
Site-specific approach, probabilistic	Method for collecting distributions of data.
Expression of limit	Dose-effect and dose-response relationships, identification and selection of key effects, judgement of permissable environmental effects.
Methods	
Target, level of biological organisation	What is the system designed to protect, e.g., harm to individuals, populations, higher levels of organisation?
Type of exposure	Chronic/acute.
Representation of exposure	Measured or modelled. If modelled, are models/parameter values provided? What level of detail? Use of default models/parameters?
Selection of endpoint	What is the measurement endpoint, how is it chosen?
Effects analysis	How is the level of effect defined and quantified? Does the system give quantitative/qualitative estimates of the predicted effect or is the acceptable level of effect defined in the problem formulation?
Extrapolation methods	How is the available data on effects at the level of the individual used to predict effects at higher levels of organisation?
Treatment of background	How is background considered?
Other	Any relevant information.

3. General features of risk assessment and management schemes

Frameworks for risk assessment are often considered to follow three major steps [USEPA, 1998; Environment Canada, 1997]: (1) problem formulation, (2) analysis and (3) risk characterisation, as illustrated in Figure 3-1. All steps are not independent from each other and iterations between all paths are to be expected to ensure best results.

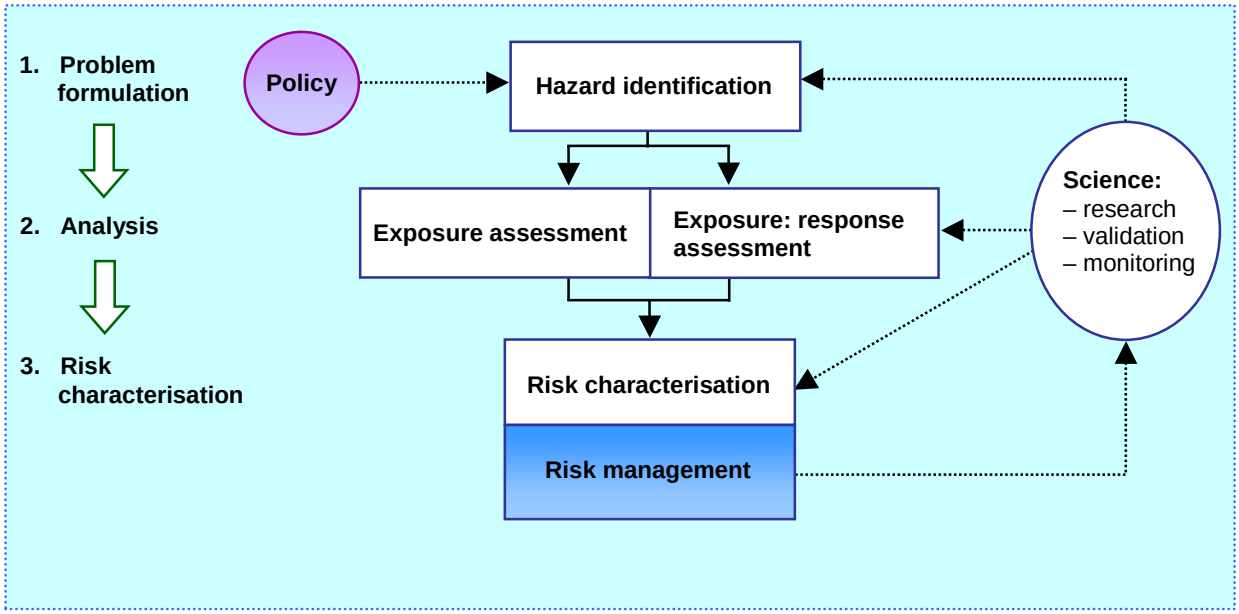

Figure 3-1 A risk assessment framework.

1. The problem formulation phase focuses on scoping and planning, and is best described as the scientific definition of the problem under study. The USEPA framework first introduced the term "Problem Formulation" in place of "Hazard identification" to define the nature of initial activities that should occur as part of the risk assessment process. The aim of problem formulation is to establish the goals, breadth and focus of the assessment. This includes the identification of receptors of a contaminant and the selection of assessment endpoints. Selection of the assessment endpoint is the definition of the environmental component(s) that is to be protected. As direct information is not always available for assessment endpoints, measurement endpoints are defined and used to estimate effects on assessment endpoints. Problem formulation includes the development of a conceptual model of the assessment case, e.g. the contaminant's entry and fate in the environment and its possible environmental effects. Data gaps that must be filled in order to complete the environmental assessment are identified during problem formulation. Problem formulation may involve all interested parties, which will help in securing proper implementation of the decision-making phase. Problem formulation may also need to take into account relevant 'policy' or regulations that direct the formulation of the assessment.

2. The analysis phase or assessment phase, which is the scientific component of the assessment, involves two main activities: the estimation of the exposure of parts of the environment to the contaminant and the characterisation of the dose-effect relationship, i.e. the consequences of a given exposure to the contaminant.
3. The risk characterisation phase involves the estimation of magnitude and probability of adverse environmental effects associated with the estimated contaminant exposure. This can be viewed as the final stage of an approach that relates the analysis results to the assessment endpoints. Ultimately the risk characterisation should synthesize and provide information that can be understood and applied to risk management, including identification and characterisation of uncertainties.

FASSET is concerned mainly with the analysis and risk characterisation phases. The problem formulation phase is, however, important in that it determines the structure of the framework and the way in which it is applied.

3.1 The problem formulation phase

One way of describing the general components of an ecological assessment is the ecological risk assessment (ERA) framework proposed by the USEPA [USEPA, 1992] and Figure 3-1. In this framework it is stressed that an extremely important problem formulation and endpoint definition step (called hazard identification in the figure) precedes the traditional ecotoxicological work of assessing exposure and dose-response. What is said is basically that without properly defining

- the objectives of the assessment (e.g. reactive/proactive, generic/case-specific);
- what we wish to protect (the assessment endpoints);
- the relevant spatial and temporal scales; and
- how we intend to measure this (the measurement endpoints or indicators),

the ERA will probably fail to provide sufficient relevant information for decision-makers managing the risks. There are primarily two reasons for this.

First of all, a clear statement of its goals and assessment endpoints is as important to an environmental impact assessment as a clear statement of the hypothesis is to an experimental research study. In other words, the assessment endpoints need to be clearly and operationally defined, e.g. the population decline of a specific species, so that the endpoints are accessible for measurement or estimation through indicators. Vague and undefined phrases such as ‘ecosystem health’ will not do (even though they express the general management goal of protecting the entire ecosystem), nor will endpoints that cannot be measured or otherwise estimated (e.g. through extrapolations to other species or from biomarkers/indicators).

Secondly, decision-making always involves some sort of evaluation of different courses of action. Therefore, there is a need to somehow be able to understand the magnitude of the identified hazard and its probability of being realised. One important means of facilitating such an evaluation is to focus the assessment on endpoints that we perceive as important and wish to protect (see Chapter 5). The logic is simply that detrimental effects on ecological endpoints that we recognise as important (e.g. an ecologically important fish species) are worse than risks on other less important endpoints. Thus, the success of an ecological risk

assessment in terms of its utility for risk management is to a large extent dependent on a clear definition of the problem and on an adequate consideration of both scientific and decision-making requirements.

A method for hazard identification, which can be applied to problem formulation within an assessment framework, has been suggested by IRSN [Garnier-Laplace *et al*., 2002] and is described in Deliverable 2: Part 1 (Section 4.2.1).

3.2 Components of assessment programmes

A number of features are common to many of the studied programmes for assessments of the environmental effects of contaminants, both radioactive and non-radioactive. These features are shown in Figure 3-2.

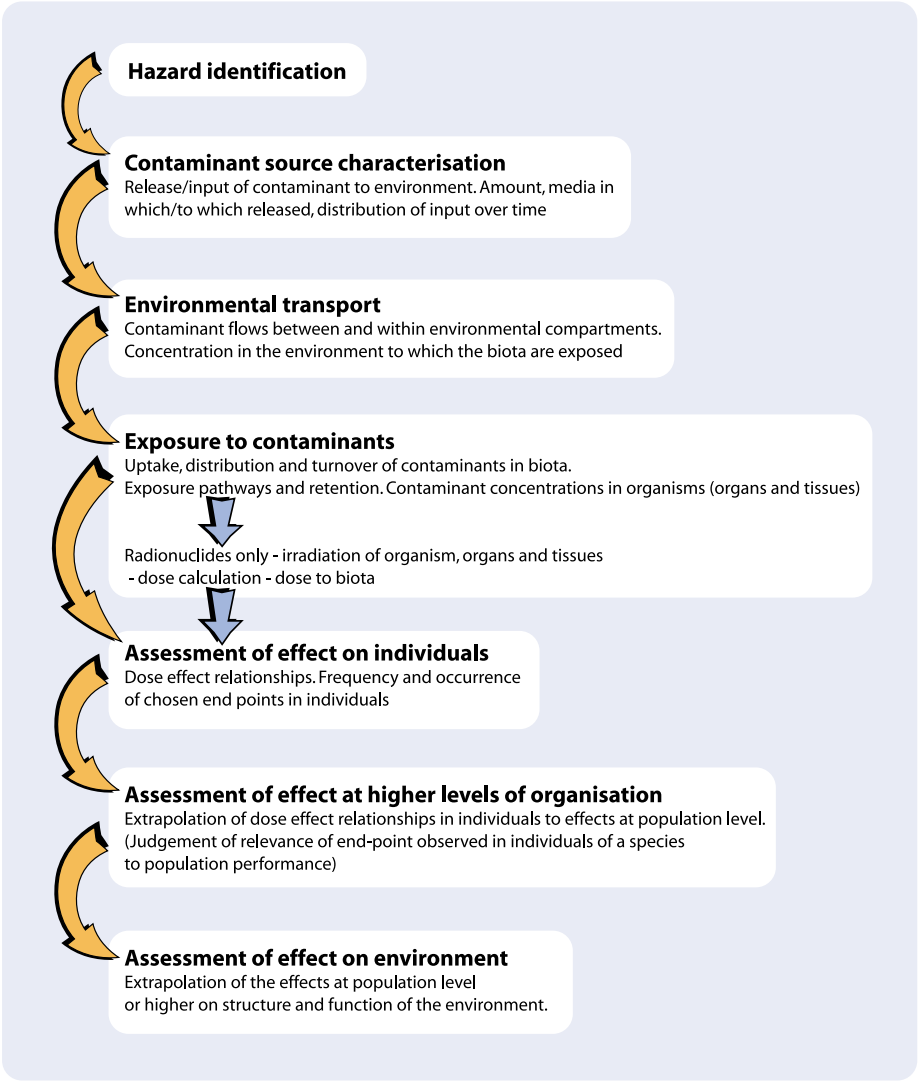

Figure 3-2 Stages in an assessment of the environmental effects of hazardous substances and radionuclides.

The assessment 'building blocks' within the analysis phase are often grouped into three major assessment phases:

- entry characterisation – determination of the sources (natural and anthropogenic) of a substance in order to determine the amounts entering the environment being studied and its distribution of releases over time;
- exposure analysis/assessment – prediction of the exposure of a substance to the assessment endpoint (the exposure analysis can take the form of environmental concentration of the contaminant, either predicted or measured, or may take the form of an intake of the contaminant by the endpoint organisms; with radionuclides, exposure may be expressed as absorbed dose); and
- effects analysis/assessment – analysis of the dose-effect relationship in order to identify doses resulting in various degrees of harmful effect.

For screening assessments, the risk characterisation phase can be simplified to a comparison of the exposure and effects assessment with the exposure or effects level at which it is assumed that unacceptable effects will most likely not occur. However, when no prior determination of the no adverse effect level is available, then risk characterisation is better defined as a synthesis of information on the expected magnitude, probability and duration of effects.

The way in which the existing assessment programmes approach each stage of the assessment is discussed in the remainder of this report. The main differences between the programmes studied are listed below with a reference to the relevant chapters of the report:

- Degree of specificity – This difference arises in the problem formulation stage. The chosen degree of specificity depends on both the aim of the assessment and on the level of detail used in the assessment. The most apparent difference is between systems intended for generic, screening level assessments and those intended for detailed, site-specific assessments (see Chapter 7).
- Assessments are carried out at several levels of detail, as in the tiered approach systems (see Chapter 7).
- The point in the assessment process at which the risk characterisation is carried out, i.e., the point at which a comparison is made between a criterion intended to represent 'what is acceptable' and a measured or predicted quantity. Systems differ in the point at which this comparison is made (see Chapter 6).
- Choice of endpoint for the assessment – The systems differ in a number of ways: the type of ecosystem to be assessed, the type of effect to be studied in toxicological tests, the species studied, the level of biological hierarchy to be studied and protected (see Chapters 5 and 8).
- Relationship between measurement and assessment endpoints. An extrapolation is used in order to interpret the measured effects in terms of the adversity in the environments. The way in which this extrapolation is carried out differs between systems in two ways:
  - In many systems, a wide range of organisms is studied in order to be representative of a wide spectrum of species in the environment. The assumption is then made that it is not necessary for the specific organisms tested to be present in the actual environment that is being studied. In other systems, organisms are chosen for their relevance to the

assessment case. The choice of these reference organisms may be based on criteria concerned with the relationship between effects on these organisms and effects at higher levels in the environment. In other systems, reference organisms are chosen because they are maximally exposed, or because they are the most sensitive organisms to the toxin and the effects estimated for these organisms are extrapolated to effects at higher levels in the environment.

- The statistical techniques used to carry out the extrapolation differ (see Chapter 8).

Comprehensive risk assessment schemes have been developed for hazardous substances in the aquatic and terrestrial compartments and for the exposure of consumer species via foodchain accumulation (bioaccumulation). However, most of the programmes for the assessment of the terrestrial compartment and consumer species are not supported by the same level of experience, validation and documentation as the ones for the aquatic compartment. Few assessment systems for hazardous chemicals allow a quantitative evaluation of the risk to biota in the air compartment, often because no adequate biotic testing system exists. However, this exposure pathway has often been included in assessment systems for radionuclides, and calculations of exposure to radionuclides in air, both via external exposure and inhalation, have been carried out.

For some contaminants, the systems studied jump over several of the stages in Figure 3-2 and look directly at the relationship between the environmental concentration and observed effects on environment, e.g. this approach is often used to assess the environmental effects of acidification (air pollutants). However, this type of assessment is usually based on a reasonable amount of prior information linking environmental concentration to effects.

4. Aims and definitions of existing schemes

The existing schemes studied are intended for a variety of purposes, as shown in Table 4-1.

Table 4-1 Aims of existing schemes.

Aim	Organisation
Derivation of environmental standards (e.g. limiting values, screening levels, environmental quality standards)	USEPA [2000], ORNL [1998], RIVM [1999], USEPA [1995], Typhoon [Sazykina & Kryshev, 1998] Environment Agency [2002]
Assessment of compliance with regulatory limits/guideline values	USDOE [2000]
Assessment of the hazard associated with chemicals released to the environment (new chemicals, existing chemicals, priority substances)	EC [1996], OSPAR [2002a], Environment Canada [1997]
Assessment of the impacts of authorised releases	Copplestone *et al*. [2001]
Assessment of the hazards of contaminants in various environmental media	IAEA [2000], USEPA [1998]

The aim of the existing schemes determines what choices are made at all stages of the assessment and is inextricably linked with the way in which the assessment scheme is structured. The formulation of the aim of the scheme is also closely linked with the underlying environmental assessment philosophy.

Many systems have their own definition of what is acceptable. In some cases the definition of 'acceptable' is done outside the assessment system, i.e. external standards are imposed. The external standards may be expressed as an acceptable exposure or dose, or may be expressed as an acceptable level of effect. The assessment systems may then either carry out calculations in order to demonstrate compliance with the external standard, or they may use the external standard as a starting point to calculate new, secondary standards that may be used for a variety of purposes. The way in which the acceptability of an effect is expressed has an important impact on the structure of a system. An example of this is found in the Netherlands, where an acceptable level of effect is defined as a situation in which 95 % of species in the environment are not affected, with a 95 % probability. The assessment procedure is then structured to demonstrate compliance with this statement. The definition of the appropriate level of 'harm'/protection may also depend on the demands made of the environment or a reduced function concurrent with a particular land or water use.

In other systems there is no definition of a safe level (e.g. USEPA's ecological risk assessment guidelines [USEPA, 1998]). The definition of what is safe is specific to the assessment being carried out, and is defined as part of the planning phase of the assessment, in co-operation with all the parties interested in the assessment.

The IAEA BIOMASS project has discussed the question of purpose and aim of assessments, and provided a review of different questions to be addressed within what has been termed the assessment context. The relevance and applicability of the assessment context elements for FASSET was discussed at a workshop in Stockholm, October 2001 [FASSET, 2001].

The fundamental questions need to be addressed at the beginning of an assessment, not at the end. While this may be obvious, some assessment projects have not been managed this way. Fundamental questions include:

- What is the purpose of the assessment? The end-users and the endpoints (such as what are we trying to protect?) need to be taken into account at this stage.
- How should uncertainties be approached, and what assumptions should be made?
- What site or system is to be investigated? Is a generic reference biosphere truly representative of what is being considered?
- What are the source terms and modelling interfaces?
- What are the best time frames to discuss?
- What assumptions does society make? Do humans affect the future or change these systems? The answer here comprises more than a scientific issue.

A checklist of fundamental issues and alternatives, as developed within BIOMASS, helps address the formulation of the assessment context. A list, with particular reference to waste repositories, is presented in Table 4-2.

Table 4-2 Examples of alternative assessment context components and/or required information, with emphasis on waste repositories. Based on the IAEA BIOMASS project documentation [FASSET, 2001].

Assessment context component	Alternatives and/or required information
Assessment purpose	Demonstrate compliance with regulatory requirements/regulatory development. Contribute to public confidence. Contribute to confidence of policy makers and the scientific community. Guide research priorities. Proof of concept. Guide to site selection and approval at later stages in repository development. System optimisation.
Assessment endpoint	Individual risk. Individual dose. Collective doses and risks. Doses to non-human biota. Modifications to the radiation environment. Distribution/concentration of repository radionuclides in the environment. Fluxes into or through parts of the biosphere. Estimates of uncertainties or confidence.
Assessment philosophy	Cautious Equitable
Repository system	Depth of repository, host geological medium, waste type.
Site context	Spatial extent, surface topography, current climate, surface lithology and soil types, fauna and flora, local surface water bodies and near surface aquifers, the need for biosphere change.
Source terms and geosphere-biosphere interface	Well Water body Below surface soil. Combination of above.
Time frames	From closure to 100 years. From 100 to 10,000 years. From 10,000 to 1,000,000 years. Beyond 1,000,000 years.
Societal assumptions	Intensive or extensive farming and use of modern technology. Simple technology associated with subsistence farming.

5. Identification of the object of the assessment

This chapter summarises the way in which the existing assessment programmes identify and define the part of the environment that is to be protected.

5.1 Target level of biological organisation

Effects in the environment resulting from exposure to radionuclides or chemical substances can occur at various levels of biological organisation. Effects at lower levels, such as biochemical effects, are not always transmitted to higher levels, such as ecosystems. Conversely, in cases in which effects at higher levels have occurred, lower levels of organisation will have been seriously affected. Therefore effects observed on the individual may be significant for threatened or endangered species, where population levels are low.

Few studies have directly tested priority substances for effects at the population, community or ecosystem level of organisation. Most toxicity studies are conducted in the laboratory using relatively small sample sizes relative to population sizes in natural communities. However, many of the effects measured in laboratory and field studies have implications for populations, communities and ecosystems. Effects such as endocrine disruption, lethality and reproductive impairment are closely related to the viability of natural populations. A strong link between toxicity study results (e.g. reduction in reproductive fecundity) and environmental parameters (e.g. population age structure) can provide good evidence for determining whether a substance has the potential to cause adverse effects on the environment. However, it is difficult to specify a rigid cut-off point at which effects measured in a group of organisms in toxicity studies are considered sufficient to declare the substance harmful at higher levels of biological organisation.

Systems vary in their stated aims with respect to the level of biological organisation being protected. Many systems state that populations of organisms should be protected, i.e. no adverse effect on populations of organisms should take place. This is often justified by the following two arguments:

- individuals of species other than man are not of value, therefore death of a small number of organims can be tolerated as long as the population as a whole does not suffer; and
- protection of populations prevents adverse effects at higher levels of organisation.

One problem is that for some organisms, the distinction between an individual and a population may not easily be made (e.g. vegetatively reproducing organisms), or be meaningful with respect to effects at the community level.

Two systems state that the object of protection is the functioning of the ecosystem [RIVM, 1999; CCME, 1996]. However, these systems base the estimation of environmental effects on the occurrence of effects that may be important at the level of the population, measured in toxicity tests. Where data are available, this estimation is crosschecked against estimations of the effect on ecological processes measured in laboratory or field studies.

Some systems [e.g., IAEA, 2000; Environment Canada, 1997] also consider protection of individuals under some circumstances. Examples include:

- threatened/endangered species;
- unacceptable effects on individuals (some effects observed on individuals, e.g. tumour growth, may indicate some level of environmental concern; because of their severity, these effects are not tolerated, even though there does not appear to be any effect at higher levels); and
- valued individuals (e.g. agricultural animals).

5.2 Selection of endpoints

In this section, the following two terms are used:

- measurement endpoint – the effect that will be measured or observed; and
- assessment endpoint – the effect that is inferred (via extrapolation sometimes) from the measured data and which the assessment is designed to study.

Often the assessment endpoint is not directly quantifiable. Therefore a sub-set of measurement endpoints (i.e. the indicator that is measured to detect potential changes in the assessment endpoint) will need to be chosen. This selection process (as is the case with assessment endpoints) needs to be documented and agreed upon. One important criterion for the selection of measurement endpoints should be its relevance to the assessment endpoint of concern (i.e. that a change in the measurement endpoint can be extrapolated to the assessment endpoint). Examples of indicators that can be linked to an assessment endpoint at a higher organisation level are the growth, reproduction and survival of individual organisms.

The relative importance of various criteria for the selection of the measurement endpoint will also differ depending on the assessment goals and specific ecosystem and stressor of interest. In addition, other uses for the measurement endpoint, such as sensitivity and early warning, may also influence the choice of endpoint adopted in the assessment. In most cases, a range of measurement endpoints will be the best approach.

Some frameworks include a predefined choice of endpoint. Some frameworks leave the choice of assessment endpoint to be made during the assessment.

Frameworks where the assessment endpoint is fixed have usually made a prior justification of the choice of endpoint with reference to one or more of the following criteria:

- importance to the structure and function of the community;
- high degree of exposure expected from the distribution of the contaminant in the environment and the type of organism (i.e. the way in which their habitat preference and behaviour influences the absorbed dose);
- high degree of sensitivity (variations between stages in the life-cycle and between tissues and organs within a species should be taken into account as well as between species or groups of species); and
- relevance to management goals (e.g. the assessment endpoint should be representative of the environment being studied).

These criteria deal with the importance of the assessment endpoint as an indicator of the likelihood of occurrence of environmental effects and the degree of their severity. Frameworks, which do not have a fixed assessment endpoint often give guidance as to how the choice should be made, for example, a list of criteria to be applied. IAEA [2000] lists criteria concerned with the usefulness of the endpoints in assessments:

- the extent to which the endpoint can be used as a measure of sustainability;
- its application as an early warning indicator of possible harm;
- its use to measure ecological significance;
- its measurability (for retrospective assessments);
- its predictability (for prospective assessments);
- its use as a measure of compliance;
- its relevance to societal issues (e.g. local and regional economy, culture and public concern);
- its use as a basis for comparison with other environmental hazards; and
- its ability to provide a measure of the additive effects of various environmental stressors.

Other assessments may have an assessment endpoint imposed on other grounds. There may be a public or commercial interest in a particular group of organisms, e.g. protection of rare or endangered species, protection of fisheries. In this case, the decision can be made as to whether protection of this organism is sufficient to protect the environment as a whole, i.e. how relevant is this assessment endpoint to the general aim of the assessment.

An example of the choice of assessment endpoint is that adopted in the Netherlands. The No Observed Effect Concentration NOEC is assumed to be the appropriate base for an ecological risk assessment. The NOEC values used should be determined on the basis of ecologically relevant criteria for a number of test species, and can only be set once a Lowest Observed Effect Concentration (LOEC) has been observed. Test organisms should preferably be selected on the basis of them representing the community to be protected. Suggested criteria for construction of a set of relevant test organisms are:

- ecological function – the set should include primary producers, consumers and saprotrophs;
- taxonomic groups – the set should include species from different taxonomic groups, since sensitivity is often correlated with physiologically determined mechanism differing between taxa (and different anatomies); and
- exposure route – the set should include species exposed to chemicals in different ways.

OSPAR [2002b] have identified measurement endpoints, which are intended to function as indicators of changes in the overall structure and function of marine ecosystems, particularly with regard to management of human activities. The endpoints are known as ecological quality elements, EcoQs, and are aspects of marine systems where levels can be established which can be measured, preferably quantitatively, but in some cases only qualitatively. Ecological quality objectives, EcoQOs, are defined levels of these ecological quality elements, which act as a target value for management activities aiming to ensure conservation, protection and sustainable management of the North Sea.

EcoQs have been identified for ten issues, which cover the range from structural (diversity) to functional (processes) aspects of the ecosystem. Within the ten issues, a number of EcoQOs have been proposed. Table 5-1 lists the issues and EcoQOs currently developed or under development, together with the aim of monitoring and management within each issue.

5.3 Critical and/or reference organisms, organs or ecosystems

Critical and reference organisms are identified in some of the frameworks. Critical organisms have been defined as the maximally exposed organisms in a particular situation and as the organisms most sensitive to the contaminant. This definition is situation dependent, and therefore the approach can only be adopted in site-specific assessments. Critical organisms are identified with respect to:

- type of nuclide;
- distribution of nuclides;
- sensitivity (of organs, organism, stage of life cycle, ecosystem);
- dose rate; and
- lifespan and time frame.

Reference organisms have been defined as standard organisms adopted for assessment purposes. These can be the ‘maximally exposed’ assumed organisms in generic assessment. The reference organism is not necessarily a real organism – it can be a generic reference organism, e.g. a bird, a planktonic organism or a benthic filter feeder. Criteria employed in the selection of critical or reference organisms differ slightly:

- Critical organism (site-specific)
  - high degree of exposure (distribution of radionuclide);
  - high degree of sensitivity (ecosystem, organism, organ, stage of development);
  - degree of importance to structure and function of community.
- Reference organism (generic)
  - high degree of radiosensitivity (e.g. fish in aquatic systems);
  - generally of high degree of importance to structure and function of community (e.g. carbon or nitrogen cycling).

Table 5-1 Issues for which Ecological quality objectives (EcoQs) have been (or are being) developed by OSPAR.

Issue	EcoQs proposed	Objective for the issues
Reference points for commercial fish species	Reference points for commercial fish species	Move, or keep spawning stock biomass above precautionary reference levels. Develop biologically and ecologically based target reference levels as a basis for management objectives.
Threatened and declining species	Presence and extent of threatened and declining species in the North Sea	Remove the threat or reverse the decline for threatened and declining species in the North Sea.
Sea mammals	Seal population trends in the North Sea	Indicate the intrinsic health of common grey seal populations and their habitat.
	Utilisation of seal breeding sites in the North Sea	Detect deterioration of habitat quality within a species geographical range.
	By-catch of harbour porpoises	Indicate the impact of fishing activities on marine mammal populations.
Sea birds	Proportion of oiled Common Guillemots among those found dead or dying on beaches	Monitor long term trends in background oil pollution.
	Mercury concentrations in seabird eggs and feathers	Determine the trends in the levels of mercury in the marine foodchain.
	Organochlorine concentrations in seabird eggs	Follow trends of organochlorine concentrations in the marine environment.
	Plastic particles in stomachs of seabirds	Follow trends in the occurrence of non-degradable litter in the sea.
	Local sand eel availability to black-legged Kittiwakes	Ensure that fishing activities do not reduce the supply of food for breeding black-legged Kittiwakes beyond an acceptable level.
	Seabird populations trends as an index of seabird community health	Evaluate seabird community health.
Fish communities	Changes in the proportion of large fish and hence the average weight and average maximum length of the fish community	Increase the proportion of large fish.

Table 5-1 (continued)

Issue	EcoQs proposed	Objective for the issues
Benthic communities	Changes/kills in zoobenthos in relation to eutrophication	Avoid kills in benthos and fish related to low oxygen concentrations and/or toxic phytoplankton species.
		Indirectly assess effects of nutrient enrichment.
	Imposex in dog whelk	Maintain a low frequency of imposex, occurring as a result of use of organotin compounds.
	Density of sensitive (e.g. fragile) species	Maintain or restore populations of sensitive indicator species.
	Density of opportunistic species	Maintain representative (low) abundance of opportunistic species.
Plankton communities	Phytoplankton chlorophyll a	Keep phytoplankton biomass below elevated levels.
		A direct assessment of the effects of nutrient enrichment.
	Phytoplankton indicator species for eutrophication	Reduce the risk of nuisance and toxic phytoplankton species as a direct effect of nutrient enrichment.
Habitats	Restore and/or maintain habitat quality	Reverse the decline and/or remove the threat of threatened and declining habitats.
		Restore and/or maintain a high natural quality with a low degree of anthropogenic disturbance for a selected representative subset of the main habitats of the North Sea.
Nutrient budgets and production	Winter nutrient concentration	Keep the concentrations of winter nutrients below elevated eutrophication levels.
Oxygen consumption	Oxygen	Keep the oxygen concentration above the eutrophication induced oxygen deficiency levels as an indirect effect of nutrient enrichment.

6. Defining of the degree of protection required

The expression of an acceptable level of exposure or effect depends mainly on:

- the perspective of the assessor (e.g. ethical standpoint);
- the technique used for extrapolation from tests on individuals to effects at higher levels; and
- where in the assessment chain the comparison is made between assessment case and limiting or 'acceptable' case, i.e. where risk characterisation is carried out.

Figure 6-1 shows the point in the assessment process at which a comparison is made between the limiting value and the estimated value. The figure shows four main types of system:

1. EEC's framework for risk assessment of existing chemicals and CCME assessment for priority substances [Environment Canada, 1997]. Both compare the estimated exposure (probable environmental concentration, PEC, or environmental exposure level, EEV, respectively) with an estimated environmental no-effects concentration (probable no-effect concentration, PNEC, and environmental no-effect concentration, ENEC, respectively).
2. Guideline values calculate an acceptable concentration in the environment with which environmental media concentrations can be compared.
3. Assessments that derive adsorbed dose rates, either by calculation, or by measurement of dose, or by using biota tissue data to calculate dose – compare with an 'acceptable' dose rate.
4. Assessments of observed environmental effects (e.g. monitoring programmes).

The limiting quantity may be the one most useful in limiting harm to the biota (i.e. the one most closely related to the effect from which protection is required). The most useful limiting quantity is often assumed to be the absorbed dose rate for radionuclides. For non-radioactive substances the dose rate (e.g. intake rate) or the concentration in environmental media to which organisms are directly exposed are often used. However, limiting values are often expressed as the environmental concentrations. These secondary measurable quantities are often useful for demonstrating compliance with standards, as environmental concentrations are more easily measured. However, there is not necessarily a one-to-one correspondence between a defined dose rate (assumed to be equivalent to an acceptable degree of an effect, though here again, there is uncertainty) and environmental concentrations. The relationship is very situation specific. Allowance is often made for the uncertainties in this relationship, e.g. with the use of conservative assumptions and safety factors. (The deposition rate for an airborne radionuclide is also a type of standard applied at the level of the environmental media.)

Some systems go even further and set limits on the release of contaminants to the environment. In this case, it is important to take into account the uncertainties in the calculations of transport and exposure route(s) of the contaminant.

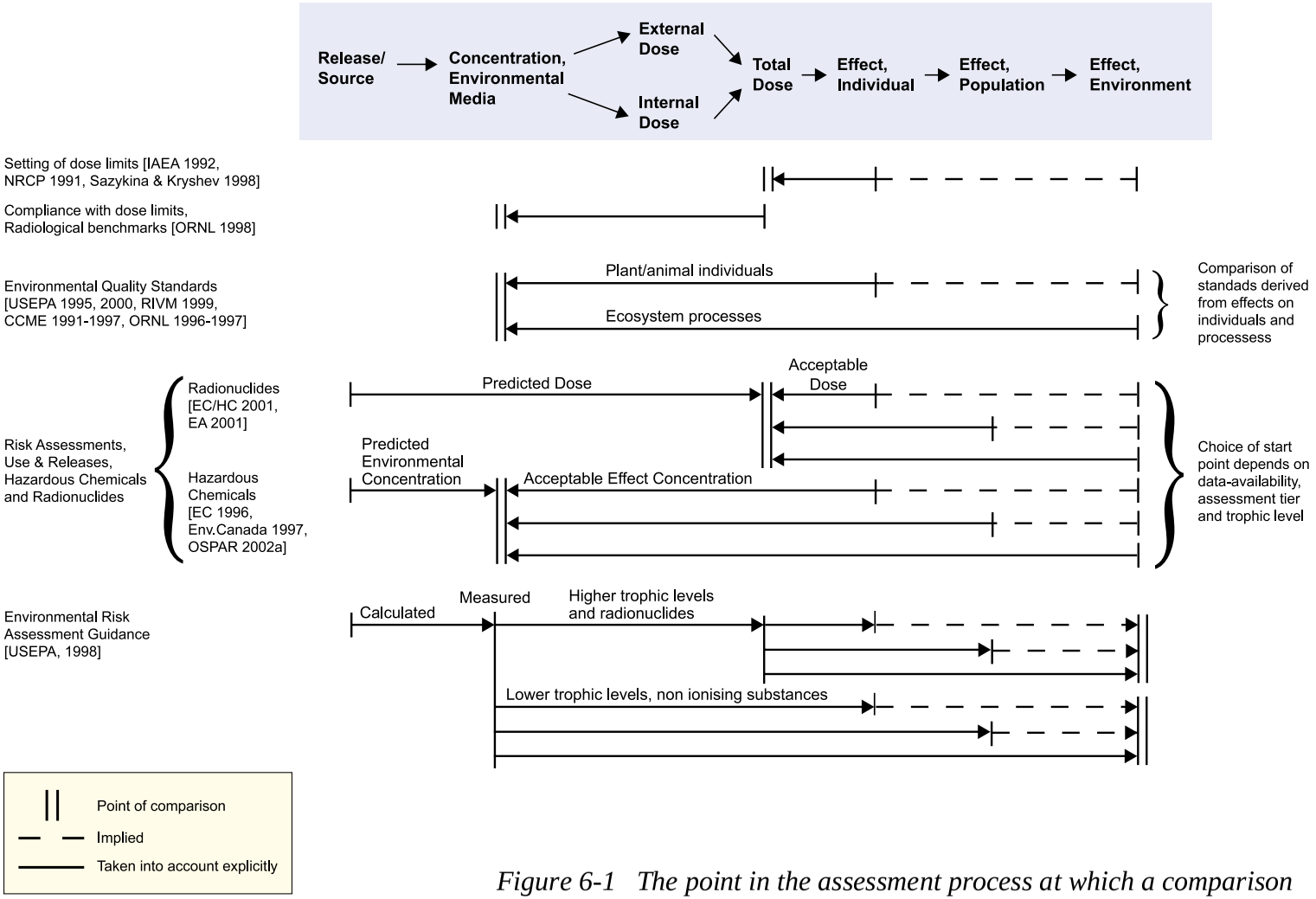

Figure 6-1 The point in the assessment process at which a comparison is made between the 'limiting or guideline value' and the 'estimated or measured value' (if a comparison is made at all).

Generally, the further to the left in Figure 6-1 the standard is set, the greater the uncertainty associated with the relationship between the criteria quantity and the effect, and the higher the degree of conservatism required if the risk for an effect is not to be underestimated. On the other hand, the further to the right that the standard is set, the greater the demand on the assessment for demonstration of compliance with respect to understanding of all the relevant processes and factors, data requirements, data quality and consideration of conceptual and data uncertainties.

Though there is little difference in the principles used to set standards for radioactive and other hazardous substances, there are practical differences, which lead to the standards being expressed differently, as discussed in Sections 6.1 and 6.2.

6.1 Acceptable dose rates

For radionuclides, acceptable or limiting dose rates are most often adopted. They are usually based on reviews of literature, which aim to identify the dose rate below which no effect is expected. A number of organisations have adopted this type of approach.

The NCRP [1991] reviewed the literature on the effects of radiation on aquatic organisms and provided guidance for protecting populations of aquatic organisms, concluding that a dose limit of 10 mGy/d would ensure protection of the population.

Dose rates below which no effects are expected at the level of the population were proposed by IAEA [1992] and 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 material 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 (4Gy/y) from exposure to radiation or radioactive material releases into the terrestrial environment.
- Terrestrial animals – The absorbed dose to terrestrial animals should not exceed 1 mGy/d (0,4 Gy/y) from exposure to radiation or radioactive material releases into the terrestrial environment.

The dose rates proposed by IAEA [1992] and NCRP [1991] were also proposed by UNSCEAR [1996].

Different dose limits can be used by the same organisation for different purposes. The IAEA guidelines have also been adopted by the Environment Agency, UK, for terrestrial animals, terrestrial plants and freshwater and coastal organisms [Copplestone *et al*., 2001]. Based on another IAEA review [IAEA 1988], a dose limit of 1,000 μGy/h (24 mGy/d) has been used for populations of organisms in the deep ocean. These dose limits are intended for use in assessments of the impact of authorised discharges on wildlife. However, 5 % of these dose limits has been adopted at the screening assessment level [Environment Agency, 2002], to indicate whether or not a full EIA is needed according to the UK implementation of the European Council Habitats Directive 92/43/EEC [EC, 1992].

The dose rates proposed by CNSC [Environment Canada and Health Canada, 2000] in their assessment of the releases of radionuclides from nuclear facilities, carried out as part of the assessment of priority listed substances, are shown in Table 6-1. These dose rates are under discussion and revised versions of this table can be found in ACRP [2002] and Bird *et al.* [2002].

Table 6-1 Limiting dose rates proposed in Environment Canada and Health Canada [2000].

	Chronic toxicity value (mGy/d)	Application factor	Environmental no-effects value (mGy/d)
Mammals	1.1	1	1.1
Amphibians/reptiles	0.2	1	0.2
Benthic invertebrates	1.6	1	1.6
Terrestrial invertebrates	24.1	10	2.4
Fish	0.5	1	0.5
Terrestrial plants	2.4	1	2.4
Aquatic plants	As from terrestrial		2.4

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. to take data quality into account, are applied in order 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 (see Section 8.1.2).

Recently, the Canadian Advisory Committee on Radiation Protection have recommended that the Canadian Nuclear Safety Committee consider a generic dose-rate criterion for protecting biota should be in the range 1–10mGy/d. For a simplified radiation protection scheme, ACRP suggested a value of 3 mGy/d (1 Gy/year) after applying appropriate radiation weighting factors (1 for all γ- and β-radiations, 10 for α-radiation; see discussion on radiation weighting factors in Section 6.2).

An adaptation of this dose-limit approach is proposed by SPA 'Typhoon' [Sazykina & Kryshev, 1998]. In their approach, primary dose limits to non-human organisms are estimated based on the available dose-effect data. However, the dose limits suggested by the IAEA and NCRP reviews were not adopted on the grounds of their being about 100 times natural background, and characteristic of exposure in very contaminated areas. Table 6-2 lists the dose limits proposed by SPA 'Typhoon'.

Table 6-2 Dose limits proposed by SPA 'Typhoon' [Sazykina & Kryshev, 1998].

Group of organisms	Dose limit (mGy/year)
Terrestrial and aquatic plants, insects	400
Poikilothermal animals	100
Hematothermal animals with a life cycle less than 5 years	50
Hematothermal animals with a life cycle longer than 5 years	25

These primary dose limits are for adult organisms living in natural, temperate ecosystems, which are not subjected to direct anthropogenic stress. It is 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.

Table 6-3 summarises the dose rates proposed by different organisations. The table shows the variation in the 'acceptable' dose rates caused by the different assumptions used by the different organisations.

Table 6-3 Dose rates proposed by different organisations (Gray/year).

	IAEA No effects expected at population level	CNSL Environmental no effects value	SPA Typhoon Primary dose limits
Aquatic animals	4	–	0.1 (poikilotherms)
Fish	–	0.2	–
Benthic invertebrates	–	0.6	–
Amphibians/reptiles	–	0.08	–
Terrestrial plants	4	0.88	0.4
Terrestrial animals	0.4	–	0.05 or 0.025 (life cycle < or > than 5 y)
Mammals	–	0.4	–
Terrestrial invertebrates	–	0.88 (SF 10)	0.4 (insects)

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 is assumed to be 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.

The species and ecosystems to be considered in an assessment must be pre-selected. Criteria for selection/classification of species and ecosystems have also been suggested in the Typhoon approach. For species, these criteria are:

- key species in the ecosystem;
- critical populations in the ecosystem; and
- threatened/endangered species, economically/culturally important species, rare/relict species.

Ecosystems are divided into two groups:

- Typical ecosystems – where the species forming the ecosystem are typical (common) species and where migration of all these species is possible to and from adjacent areas. No threatened/endangered species, economically/culturally important species, rare/relict species are present.
- Unique ecosystems – containing threatened/endangered species, economically/culturally important species and/or rare/relict species. The ecosystems are isolated so that migration of organisms to and from adjacent areas is difficult.

6.2 Radiation quality and relative biological effectiveness (RBE)

Radiation quality refers to the energy deposition pattern of the ionising particles of different charges and velocities in a biological system. Linear energy transfer (LET) – a measure of the average density of ionisations along the path of the track of an ionising particle – has been widely used as a description of radiation quality. X-rays and γ-ray photons are examples of low LET radiation that produce electrons of relatively high velocity and low average ionisation densities in irradiated media. High LET radiation, such as α-particles, can ionise atoms along its path, thus ejecting electrons, which may act independently further from the path. Particles of high-LET radiation have usually higher charges and are much more massive than electrons and, therefore, have lower velocities at the same kinetic energy.

The biological effectiveness differs with radiation quality, which implies that equal absorbed doses of different types of radiation may not produce equal biological effects. This influence of radiation quality on biological systems is usually quantified in terms of RBE (relative biological effectiveness). The RBE for a given type of radiation is defined as the ratio of dose required to achieve a specific biological effect from a standard (reference) radiation (typically γ-rays) to that required for a test radiation, with all physical and biological variables, other than radiation quality, constant. The expressed value is a ratio of two radiation doses and not a ratio of the magnitude of effect produced by the same absorbed dose of different types of

radiation. The RBEs of particular relevance in radiation protection are those that apply in the true low dose region.

Radionuclides that release low energy electrons upon decaying have been shown to be more radiotoxic than expected. This situation seems to be especially relevant if these types of radionuclides are located close to the DNA. Tritium is one example. The low velocity of the tritium β-particle may result in a relatively high ionisation density over a short path-length.

In radiation protection the absorbed dose averaged over tissue or organ and weighted for differences in the biological effectiveness of different radiation qualities, forms the equivalent dose. The applied radiation weighting factor is based on experimentally derived RBE values related to relevant biological endpoints for radiation protection. The equivalent doses are assumed to give the same biological response in all types of cells, irrespective of type of radiation and can thus be compared. Therefore appropriate radiation weighting factors need to be identified for organisms other than man.

In human radiation protection, where the endpoint of concern is cancer and genetic changes, ICRP have recommended that a weighting factor of 20 is used to account for the greater effectiveness of α-particles, based on experimental data. One suggestion [e.g. IAEA, 1992] has been to retain the factor of 20 from human radiation protection for the purpose of non-human species. However, it has been argued that the deterministic endpoints of cell death and reproductive failure are more relevant to the protection of non-human biota than the stochastic endpoint of cancer induction. Therefore a value of 10 to 20 has been suggested for non-human biota.

A weighting factor of 1 has been suggested [see e.g. NCRP, 1991], based on the degree of conservatism built into dose assessment. UNSCEAR [1996] proposed a value of 5, based on deterministic effects. For endpoints and doses and dose rates that are more ecologically significant, the ACRP [2002] has suggested that a value of 10 might be appropriate for weighting doses in order to evaluate the impact of α-emitters at the population level. On the other hand, Environment Canada and Health Canada [2000] proposed a radiation-weighting factor of 40 for α-emitters, based on a number of studies reporting high RBE values. The value of 40 was also based partly on observations that the RBE values for high LET radiation are higher at low doses, i.e. at environmentally relevant doses.

6.3 Levels of protections and setting standards

In assessments of the effect on the environment, the appropriate level of protection is defined in different ways, and the definition is dependent on the aim of the assessment.

Some systems work on a predefined level of protection. For example, in the Netherlands the main principle in setting guideline values is the maintenance of multi-functionality, i.e. the environmental quality is a measure of the ability to carry out ecological functions. It is argued that in order to protect an ecosystem, it is not necessary to protect the most sensitive species. Instead, small effects are considered acceptable in the light of the resilience and the regulatory capacity of ecosystems. It is assumed that if most of the species populations in an ecosystem are protected, then the functions of that ecosystem will also be protected. Correspondingly, it is assumed that if the number of disturbed species is small, there is only a small chance that the disturbed species are important in terms of ecosystem function. Ecosystem function is damaged if the species composition is changed, i.e. if the relative sizes of the populations

vary. Risk to the environment is then expressed as the probability that more than a certain percentage of species will be affected by the contaminant at the level of the population. A serious threat is defined as 50 % of the species being affected (with a confidence of 95 %). An acceptable concentration in the environment of a contaminant is defined as 5 % of the species being affected (with a confidence of 95 %).

CCME [1991] state that their water quality criteria are protective of all forms of aquatic life and all parts of the aquatic life cycle. Criteria are intended to be sufficiently conservative to avoid changes in the populations of any aquatic species.

In other systems, e.g. CCME's method for derivation of soil quality criteria [CCME, 1996], different levels of protection are defined, depending on the demands made on the ecosystem. Four different levels of protection are defined, depending on the land use. For the most sensitive land uses, the level of protection is designed to ensure multi-functionality, but for the less sensitive land uses, e.g. industrial land use, some reduction in the soils capacity to carry out certain functions is accepted.

In some systems, no appropriate level of protection is defined, leaving the definition to be made in the problem formulation stage of the assessment.

7. Approaches to modelling

The structure of the existing assessment programmes is determined largely by the aim of the programmes.

The majority of the systems studied consider only chronic exposure, e.g. USDOE, ORNL, CCME, AECB and RIVM. USEPA's ambient water quality criteria [USEPA, 1995] are derived for both acute and chronic exposure from data from acute and chronic toxicity tests, respectively. At present, the dosimetry models almost exclusively assume equilibrium conditions, i.e. equilibrium values for the CF/TF/K_d, etc. This assumption would be appropriate more or less for routine discharges, or long-term leakages, e.g. from a waste repository. However, it would not be relevant for assessments of an accidental situation. Such assessments would be very dependent on the availability of relevant input parameters, and need to be based on a very careful choice of parameters.

A number of approaches to the modelling of the distribution and transport of contaminants in the environment and the exposure of biota to the contaminants can be identified. These systems can be divided into the groups shown in Table 7-1 and will be discussed in the remainder of this chapter. The chapter is therefore primarily concerned with the models used to estimate exposure of organisms to contaminants in the environment.

7.1 Comparison with standards

Environmental standards, or guideline values, can be set at different stages in the assessment system, e.g., concentrations of substances in environmental media or dose-rates. They are usually back calculated from a defined acceptable degree of exposure/effect to the level at which compliance with standards is to be demonstrated. This means that the risk characterisation is based on a previous, separate analysis of dose-effect relationships for biological effects. Examples of this type of system are the CCME guidelines [e.g. CCME, 1991], RIVM guidelines [RIVM, 1999] and USEPA, ambient water quality criteria [USEPA, 1995]. Standards have a wide range of uses, e.g. the uses given by CCME [1991] include:

- goals or interim targets for national/regional toxic substance management programs;
- benchmarks or targets in the assessment and remediation of contaminated sites, or as the basis for the development of site-specific objectives;
- environmental benchmarks for discussions on emission reductions (international);
- environmental guidelines in reports of the state of regional or national environmental quality;
- assessment of the efficacy of environmental regulations or remedial actions;
- evaluation of potential impacts of developmental activities;
- design, implementation and evaluation of environmental quality monitoring programs; and
- assessment of potential risk of exposure to substances and in formulating management decisions (e.g. prioritisation of sites, required remediation/further investigation).

Table 7-1 Approaches to modelling in the assessment programs studied.

	Deterministic	Probabilistic (Section 7.5)
1. Comparison with standards (Section 7.1)	USDOE (tier 1) ORNL benchmarks USEPA Eco-Soil Screening levels. USEPA Ambient Water Quality Criteria RIVM Environmental Risk Limits	
2. Simplified biosphere (Section 7.2)	IAEA (tier 1) USDOE (tier 2) Canada Priority Substances Risk Assessment (tier 1) USEPA – Environmental Risk Assessment Guidelines EA, UK – Impacts of authorised discharges	
3. Reference biosphere (Section 7.3)	IAEA (tier 2) Canada Priority Substances Risk Assessment (tier 2) EEC Assessment of existing and new substances OSPAR Environmental risk assessment, marine	Canada Priority Substances Risk Assessment (tier 3)
4. Site-specific (Section 7.4)	IAEA (tier 3) USDOE (tiers 3 and 4) USEPA – ERA	USEPA – Environmental Risk Assessment Guidelines
5. Tiered approach* (Section 7.6)	IAEA, USDOE, Canada Priority Substances Risk Assessment, USEPA – Environmental Risk Assessment Guidelines	

* The type of modelling in the respective tiers shown in rows 1–4.

Systems for the derivation of environmental standards are often based on relatively simple models. A conservative, deterministic approach is often used, in which conservative assumptions are adopted in order not to underestimate the probability of environmental effects occurring. Many of the systems are generic, and therefore the assumptions made are sufficiently conservative to avoid underestimation of the probability of effects in a large number of different ecosystems. Often, the concept of reasonable conservatism is introduced; i.e., assumptions are sufficiently conservative to avoid underestimation of risks under most circumstances, but not under extreme circumstances. However, it is difficult to be certain of the degree of conservatism, particularly where several different transport and exposure pathways are considered for a contaminant. A conservative assumption for one pathway may not be conservative for another pathway, e.g. the assumption of high sorption to soil may be conservative for organisms exposed directly to soil, but not to organisms in the recipient surface water body.

Comparison with standards is often used in the first tier of tiered systems. In some systems, comparison with standards may even be used in the problem formulation stage in order to screen contaminants and focus the assessment on the most important contaminant [e.g. USEPA, 1998].

7.2 Simplified biosphere

The approach involves the use of simple model to describe the environment. These models often use empirical relationships or lumped parameters to describe transfers between different parts of the environment. The values of these parameters may however be based upon a much more detailed understanding of environmental processes. The use of generic organisms is an example of a simplified approach to modelling.

7.2.1 Use of generic organisms

Generic organisms have been used in the estimation of radiation dose to biota in a number of cases [e.g. Amiro, 1992; Environment Agency, 2002]. This approach involves the use of simplified geometries, e.g. spheres or ellipsoids of appropriate dimensions, to represent organisms for modelling purposes.

For the calculation of internal dose, the proportion of radiation absorbed within the volume of the organism is estimated using formulae that describe the distribution of radiation doses around point sources within the organism. Integration of the resulting radiation doses over all hypothetical point sources within the organism is done analytically or numerically.

For the calculation of external dose, the location of the organism relative to soil, water or sediment is also represented with simplified geometries. Environmental media are often represented as infinite media, in which an organism is totally immersed, (e.g. for pelagic organisms in water, or soil-dwelling organisms), or semi-infinite media (e.g., as in the case of exposure to a contaminated soil surface, or for organisms living on the water surface).

The use of generic organisms has also been suggested as an approach to overcome the lack of empirical data for radionuclide or contaminant uptakes, especially for wildlife species [e.g. USDOE 2000; USEPA 1993; 1998]. For many substances, lumped parameter values (e.g. bioconcentration factors) are not available from the literature. An allometric approach has been suggested for estimation of the intake of substances in food (North America), i.e. equations expressing the relationship between body weight, energy requirements and parameters related to the supply of metabolic requirements are used to determine intake of a substance from contaminant concentrations in environmental media. Steady state concentration in organ/organism is then calculated from information on distribution and turnover of contaminant after uptake (fraction deposited in organ and biological half-life in that organ).

7.3 Reference biosphere

This approach often involves the use of a simple model to represent a standardised environment, defined as a series of values of the parameters used in the model.

This approach is adopted in EC [1996] for the risk assessment of existing substances. The aim of the EU system is to produce one risk characterisation at the EU level. The exposure situation in different parts of the EU can vary greatly. Therefore, in the first stage of the exposure assessment where exposure models are used, so-called generic exposure scenarios are applied. This means that it is assumed that substances are emitted into a non-existing model environment with predefined agreed environmental characteristics. These environmental characteristics can be average values or reasonable worst-case values, depending on the parameter in question. Generic exposure scenarios have been defined for local emissions from a point source and for emissions into a larger region. The system gives average or typical default values for the parameters characterising the environmental compartments. For the local environment, characteristics of the water, suspended matter, sediment and soil compartments are given (see Table 7-2) and the distribution of contaminants between the compartments is calculated using substance-specific distribution coefficients. Degradation, both chemical and biological, of contaminants in each of these compartments is also accounted for. Removal of the substance from the local compartments is also considered as a rate constant. Transport between compartments is not specifically taken into account. At the regional level, several further generic environmental characteristics, e.g. the sizes of the environmental compartments and mass transfer coefficients between the compartments, are given.

Environment Canada [1997] also adopts this approach. However, the degree of detail of reference biosphere depends upon the tier of the assessment (see Section 7.7).

Table 7-2 Definition of the standard characteristics of the local environment in the EEC model.

Parameter	Parameter
General	**Sediment**
Density of solid phase	Volume fraction solids in sediment
Density of water phase	Volume fraction water in sediment
Density of air	Weight fraction organic carbon in sediment solids
Temperature	
	Soil
Surface water	Volume fraction solids in soil
Concentration of suspended matter (dry weight)	Volume fraction water in soil
	Volume fraction air in soil
Suspended matter	Weight fraction organic carbon in soil solids
Volume fraction solids in suspended matter	
Volume fraction water in suspended matter	
Weight fraction organic carbon in suspended solids	

7.3.1 The selection of biosphere system

The stylised assessment requires a proper definition of the assessment biosphere, which in a generic assessment will be a reference biosphere. General guidance relevant to this point has been provided by the BIOMASS project, whose's methodology is summarised in Figure 7-1.

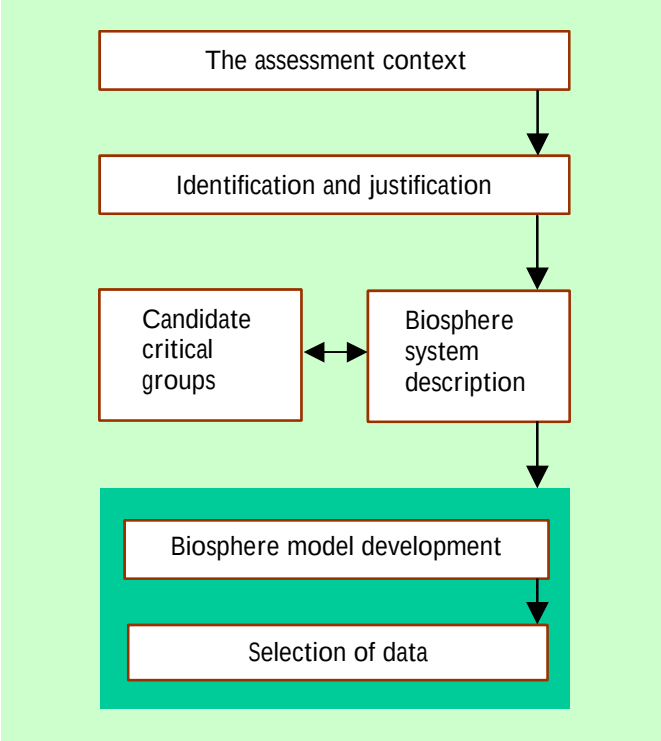

Figure 7-1 Overview of the BIOMASS methodology [FASSET, 2001].

In the BIOMASS methodology, the selection of the biosphere system is made and justified on the basis of a thorough discussion of the assessment context. The biosphere system is subsequently described, taking into consideration:

- the primary components;
- the mechanisms that cause change (internal and external driving mechanisms responsible for transfer of material and energy within the system);
- the potential impacts (can be described in an interaction matrix); and
- possible future events and processes (FEPs).

While these considerations are generally relevant, they were also partly considered already at the outset of the FASSET project, as can be seen in the Technical Annex [FASSET, 2001]. This is dealt with further in Deliverable 2: Part1.

The BIOMASS project has developed a list of screening criteria for use in defining the biosphere system, within assessments of the impacts of radioactive waste disposal, see

Table 7-3. Some of these screening criteria are relevant to the FASSET project, though the list will need to be complemented with further criteria. This will be addressed in the final Framework Deliverable D6.

Table 7-3 Screening table for ecosystem community characteristics, from the BIOMASS project [FASSET, 2001].

Component	Comment
Net primary productivity	Rate at which energy is bound or organic material created by photosynthesis after accounting for respiration per unit area per unit time.
Net secondary productivity	Net productivity of heterotrophic organisms – animals and saprobes.
Biomass/Standing Crop	Dry weight per unit area. Plants, animals, other organisms.
Cropping	Rate of removal by humans. Animals and animal products, plants and plant products, other organisms and their products.
Population dynamics	Plants, animals and other organisms.
Vegetation canopies	Physical structure. Interception of light, water, aerosols, vapours and gases.
Plant roots	Structure and distribution with depth. Absorption of nutrients and water with depth.
Animal diets	Composition and quantity.
Behavioural characteristics	The part of the ecosystem in which an animal forages and the time it spends foraging in different parts of the ecosystem, including management aspects where applicable. Animals and other mobile organisms.
Chemical composition and chemical cycles	Including sources and sinks. Major and minor nutrients, trace elements.
Metabolism	Animals, plants and other organisms.

7.4 Site-specific approach

Assessments are considered to be site-specific if account is taken of the local conditions in the assessment, and are therefore only appropriate for a particular, well-defined site. The degree of specificity does, however, vary. In some systems, site-specificity arises from the use of parameter values relevant for a particular site in a generic model. The site-specific values may be estimated or measured in the field. In other systems, a site-specific model is constructed after a detailed investigation of the site in question. A large number of site-specific parameter values are often used, though generic values may be used where site-specific values are difficult to determine.

7.5 Probabilistic approach

A deterministic approach involves comparisons of point estimates of the exposure and the estimate of response to that exposure. The comparison is often expressed as a risk quotient

(RQ), i.e. the ratio between the exposure to a stressor and the reference value adopted for this stressor, which is related to the effects [e.g. hazard quotients in USEPA, 1998].

In any practical risk assessment it is necessary to deal with uncertainties associated with the possible outcomes (see Chapter 10). One way of dealing with the uncertainties is to be conservative in the assessments. For example, one may compare the maximal exposure to a stressor with a conservatively chosen reference value. In this case, if the exposure is below the reference value, it is possible to assure that the risk is low. Because single values are compared, this approach is commonly called 'deterministic'. Its main advantage lies in the simplicity and in that it requires minimum information. However, problems arise when the reference values are actually exceeded or might be exceeded, as in the case of potential exposures, and when the costs for realizing the reference values are high. In those cases, the lack of knowledge of the degree of conservatism involved impairs a rational weighing of the risks against other interests.

An alternative way for dealing with uncertainties is the so-called probabilistic approach. This approach consists of explicitly quantifying the uncertainties in terms of probabilities. The essence of the probabilistic approach is to treat the exposure and the reference value as random variables. In this case, the RQ is also a random variable that can be described with a probability density function, commonly known as the 'risk profile' (see Figure 7-1). A deterministic RQ is just one value among the universe of all values that the RQ can possibly take. The probability that the RQ is above 1 (indicated area in Figure 7-2) is a quantitative measure of the risk. In contrast, the deterministic approach provides only a qualitative risk estimate.

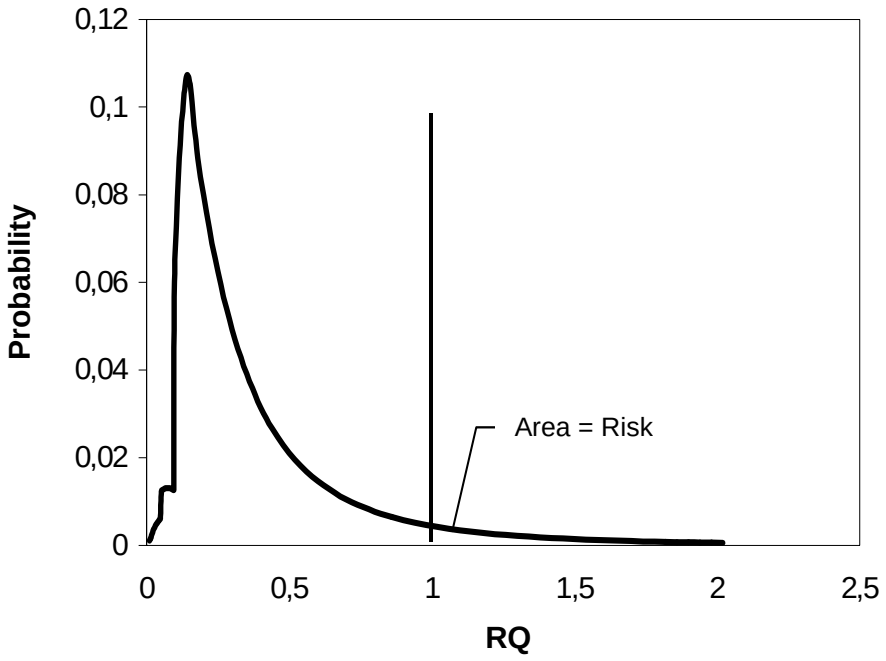

Figure 7-2 Example of probability density function corresponding to the risk quotient, commonly known as the 'risk profile'. The area under the curve for RQ > 1 is a quantitative measure of the risk.

Another informative risk communication tool is a curve with exposures (or effects) on the x-axis and probabilities on the y-axis (Figure 7-3). To estimate the probability that the exposure (effect) is above a particular level, simply draw a line up from the x-axis to the curve, and then draw a line to the y-axis. Such curves can be estimated for each scenario of concern, or in cases where the risks are additive, they can be integrated to estimate the total risk. Examples of the use of this kind of tool are:

- An assessment of the probability of exceeding an environmental no-effects level by comparing the exposure distribution with a point estimated of a no-effects level. In addition to developing point estimates of exposure concentrations it might be possible to develop a distribution of exposure levels based on the potential variability in various exposure parameters. Probabilities of exceeding a threshold for adverse effects might then be estimated.
- When a curve or function relating the exposure to the magnitude of response is available, the risks associated with many different levels of exposure can then be examined. These estimates are particularly useful when the risk assessment outcome is not based on exceedance of predetermined criteria, such as a toxicity benchmark level or a dose limit.

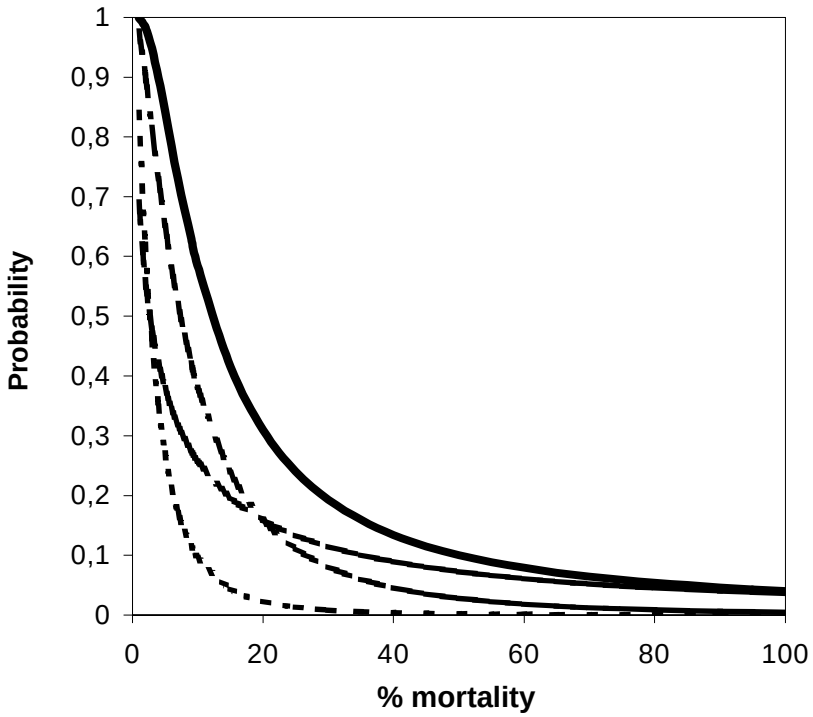

Figure 7-3 Inverse cumulative distribution of the mortality associated with three different stressors (in %) showing the probability that the mortality is above a certain value (risk). The bold line corresponds to the total risk.

7.5.1 Derivation of the probability distributions

The acceptance and practical application of the probabilistic approach hinges on sufficient support from data and knowledge to obtain the necessary probability distributions. A discussion on possible strategies for deriving the probability distributions of the exposure and the reference values can be found in Avila & Larsson [2001]. The probabilistic approach could, in principle, be implemented gradually. This means, that probability distributions could

be incorporated in the RQ as they become available and be successively improved as new information and knowledge are obtained.

When sufficient data are available, the probability distributions can be directly estimated using standard statistical techniques. This would be the case, for example, when the RQ are expressed in terms of environmental concentrations, which could be obtained by means of environmental monitoring. Models can also be used for indirect estimations of the exposure from available data. The indirect estimates require propagation of the model uncertainties. When the models are relatively simple, analytical methods such as variance propagation could be used. When the models are more complicated the propagation of uncertainties can be carried out by means of Monte Carlo analysis.

The basis for a Monte Carlo analysis is straightforward: point estimates in a model equation are replaced with probability distributions, samples are randomly taken from each distribution, and the results tallied, usually in the form of a probability density function or cumulative distribution. Several variations of the Monte Carlo technique for sampling from input distributions are available, including:

- Importance sampling, where values of particular importance (usually the tails of the input distributions) are sampled more often and then given reduced weight to improve resolution in the tails of the output distribution.
- Stratified sampling, where the input distributions are divided into intervals and input values obtained by random sampling from within each interval. The most popular version of stratified sampling is Latin hypercube sampling, which divides input distributions into intervals of equal probability. Latin hypercube sampling is more precise than conventional Monte Carlo sampling, because the entire range of the input distributions is sampled in a more even, consistent manner.

The probabilistic approach provides a more complete quantitative characterisation of the uncertainties and is less likely to include a bias, than the more simple deterministic approach. When combined with sensitivity analyses, the probabilistic approach allows a more informative ‘what-if’ assessment of the impact on the risk estimates of a change in an individual parameter or a group of parameters, thus providing a cost-effective tool for making risk management decisions.

The main disadvantage of the probabilistic approach is that time and effort is required in order to set up the database and document the rationale for the probability density functions for individual parameters in the risk algorithm. The distribution patterns for some parameters are often not definitively known, requiring the use of credible professional judgment or costly site-specific studies or data collection efforts. Also the impact of interdependencies between or among variables may be difficult to quantify if their co-relations are not well known, as is often the case.

7.6 Tiered approach

Tiered approaches are used to ensure that assessments are effective, i.e. proceed only to the level of refinement required for effective decision-making. Several organisations adopt or suggest tiered approaches. The tiered approach brings together a range of approaches, already discussed in this chapter.

Generally, the first tier (Tier 1) involves using a simple, screening approach. At this stage, conservative assumptions are used to avoid underestimating the risk of adverse effects from a certain exposure to toxic substances. Substances for which no risk of adverse effects is indicated in Tier 1 do not need to be considered further. However, substances indicated by the conservative methodology of Tier 1 to be associated with a risk of adverse effects, need to be studied further to see whether the indicated risk is realistic and/or to estimate the severity of the risk. One or more (often two) further assessment tiers, with increasing realism, may be carried out in order to refine the assessment and reduce the degree of excess conservatism. This usually involves improving the relevance and quality of the data used in the assessment. However, the way in which this is done varies between the methods studied. Assessment systems suggesting the use of a tiered approach include Environment Canada [1997], USDOE [2000] and IAEA [2000]. Table 7-4 illustrates these tiered approaches.

Table 7-4 The tiered approaches suggested by Environment Canada [1997], USDOE [2000] and IAEA [2000].

	CCME	USDOE	IAEA
Description	All tiers generic. Increasing data refinement. Change from deterministic to probabilistic.	All tiers deterministic. Increasing site-specificity.	Increasing degree of specificity. Change from deterministic to probabilistic.
Tier 1	Hyperconservative. Max concentration in environment. Lowest toxicity value.	Screening with generic guideline values.	Conservative assumptions.
Tier 2	Conservative. Modify concentration – bioavailability. Toxicity data for relevant species.	Development of site-specific guideline values, several stages, increasing site-specificity.	Generic/Reference organisms.
Tier 3	Probabilistic. Distribution of concentrations and toxicity data.	Use of measured data; biota tissue data and environmental media samples.	Realistic dosimetry model. Absorbed dose rate as probability distribution.

IAEA [2000] suggests a stylised approach with a simplified biosphere as the first tier. The conservative assumptions concern both the calculations of absorbed dose rate and the concentrations of radionuclides in environmental media. The maximum observed radionuclide concentrations in environmental media are assumed. In calculations of the internal dose to biota, the maximum concentration factor is applied in order to give a conservative tissue concentration. Complete retention of energy emitted by internal sources, i.e. an infinitely large organism, is also assumed. In calculations of the external dose, infinite media are assumed and the organisms are assumed to have no self-shielding (i.e. infinitely small organisms). In addition, conservative assumptions are used about the retention of radionuclides in an environmental compartment, e.g. a high K_d value.

Tier 2 involves the use of generic or reference organisms. The organism is selected for assessment on the basis of criteria discussed in Chapter 5.

Tier 3 is a full site-specific assessment, with realistic dosimetry models for the organisms of interest together with site-specific input for radionuclide behaviour and distribution parameters. This tier of the assessment is probabilistic. For example, the absorbed dose rate may be expressed as a probability distribution, taking into account the uncertainty in radionuclide transport models, dosimetry models, dose-response relationships, etc.

Environment Canada's framework for assessment of priority substances is intended to be generic in all tiers, with parameter values being chosen to represent Canadian conditions. The risk characterisation is based on the comparison of an estimated exposure (expressed as the estimated exposure value, EEV) for the substance being studied and the toxicity of that substance (expressed as the critical toxicity value, CTV). The degree of detail involved in the estimation of the EEV and CTV is dependent on assessment tier, as shown in Table 7-5. Refinement of data is the main feature in the progression from Tier 1 to Tier 2, whereas the change from a deterministic to a probabilistic approach is the main feature of the progression from Tier 2 to Tier 3.

Table 7-5 Tiers in the Environment Canada framework for assessment of priority substances [Environment Canada, 1994].

	Estimated Exposure Value (EEV)	Critical Toxicity Value (CTV)	Risk characterisation
Tier 1	A hyperconservative estimate: The maximum measured or estimated concentration in Canada.	CTV for the most sensitive species tested.	EEV compared with ENEV. ENEV = CTV/application factor (AF). AF = 10 to 1,000, depending on data quality.
Tier 2	A conservative estimate of the EEV, e.g. based on more recent data, based only on the bioavailable fraction.	CTV for the most sensitive of the species that are most relevant to the assessment endpoint.	EEV compared with ENEV, as above. The application factor applied to the CTV may be reduced, taking into account knowledge about the environmental behaviour of the substance. It may be necessary to carry out research to generate exposure/effects data to complete Tier 2.
Tier 3	A distribution of exposure values, based on a quantitative uncertainty analysis e.g. Monte Carlo simulation, of the exposure calculations.	Considers effects distributions rather than point estimates.	Comparison of exposure and effects distributions to determine the likelihood of adverse effects in the environment.

In the tiered approach suggested by the USDOE [2000], the first tier consists of the application of screening values, known as biota concentration guides (BCGs) for soil, sediment and water. The concentration of radionuclides in environmental media is assumed to

be uniform, and the maximum measured concentration is compared with the BCG values. The radionuclide specific BCG values represent the limiting radionuclide concentration in an environmental medium that will not exceed the NCRP's absorbed dose limits for biota. BCGs are tabulated for different groups of organisms: aquatic animals, riparian animals, terrestrial plants and terrestrial animals. They are calculated using conservative assumptions in both the dose calculations and the exposure calculations (e.g. conservative bioconcentration factors, BCFs).

The next tier consists of a second screening stage, known as a site-specific screening, in which more realistic, site-representative lumped parameters (e.g. bioaccumulation factors and K_d values) can be used in place of conservative default parameters. The environmental media and organisms, which are likely to be limiting for each radionuclide, are identified and site-specific BCFs are calculated for these organisms and data using the refined, site-specific data. Mean radionuclide concentrations can be used for comparison with these new site-specific BCFs, taking into account temporal and spatial variations.

The third tier consists of a site-specific assessment. This stage is only applied to the media and organism types identified as likely to be limiting for each radionuclide. For these organisms, kinetic modelling tools may be applied to calculated absorbed dose. A large number of parameters, which are important to the internal dose of the organism (e.g. body, consumption rate and biological elimination rate) can be modified to be site-specific or organism-specific. Allometric equations can be used to relate body mass to internal dose parameters.

Tier 3 is a site-specific biota dose assessment involving the collection of biota samples and environmental media samples, then using the resulting biota tissue data and environmental concentration data to calculated absorbed dose rates.

A further approach, suggested by ANSTO [2001], is to use a screening approach for Tier 1, a probabilistic approach using available data from the literature for Tier 2 and a probabilistic approach using site-specific data for Tier 3.

7.7 Exposure assessment in the different approaches

The preceding sections of this chapter have outlined a number of different approaches to the modelling of exposure to contaminants. Generally, the simpler systems, or the earlier tiers in tiered systems, adopt conservative approaches, or conservative values of parameters. The more detailed approaches adopt more specific models, or adapt parameter values to represent particular conditions. In the remainder of this chapter, a brief summary is made of the ways in which simplifying assumptions are made in the assessment systems studied.

7.7.1 Exposure pathways

In the simplest of the assessment systems, comparison with standards, the calculation/ modelling of exposure of organisms is not required. The relationship between exposure and effects is expressed on the basis of the incidence of effects at a particular concentration in environmental media; therefore the assessment is based on the contaminant concentration in the relevant media. This system is particularly appropriate for organisms where contact with the contaminated medium is direct and continuous. The contaminant concentration may be

predicted or measured. In systems where the contaminant concentration is predicted, a conservative prediction may be used at screening level. For example, the contaminant is assumed to be homogeneously distributed in the medium and predicted concentration is based on a number of conservative assumptions, such as maximum sorption in soils and sediments and no removal by sorption to particulates in water.

The exposed organism is often assumed to be exposed to all of the contaminants in the medium, i.e., there is no fraction of the contaminant that is assumed to be unavailable to the organism. However, modifications can be made to the exposure calculations if contaminant-specific or site-specific information is collected to indicate the bioavailability of a contaminant. Such modifications are usually based on information about the sorption of the contaminant of the surface of solids (e.g. in the RIVM system for soil quality criteria, sorption to clay materials and organic matter are taken into account at a range of soil pH values). Other factors, such as biodegradation over time, may also be taken into account.

In more detailed assessments, exposure modelling is often considered in two parts: the modelling of contaminant distribution and transfer in the environmental media, and the exposure of organisms to contaminants in each of the media.

Distribution and transport in environmental media

Models for the transport of contaminants between various environmental compartments are not included in this review. In the case of input from the atmosphere, FASSET is making the assumption that inputs into ecosystems will be available for the assessment (see Section 4.3 in Deliverable 2: Part1) and is not considering atmospheric transport models. Transport between environmental compartments will be reviewed for aquatic ecosystems within Deliverable 5. Within terrestrial ecosystems transport between soil compartments will be considered to a limited extent.

It should be noted that a reference environment is adopted in some of the systems studied, e.g. [EC, 1996; OSPAR, 2002a]. The reference environment includes the definition of a number of parameters, which affect contaminant behaviour, and therefore affect the values of a number of parameters used to describe the availability of contaminants and the resulting exposures. Examples are the definition of organic matter content in soils and sediments, and the definition of the suspended matter content and composition in surface waters.

The parameter used most often to describe the environmental behaviour of contaminants is the partition coefficient between the solid and liquid phase, K_d. For organic pollutants the partition coefficient between the organic carbon and water, K_{oc}, or the partition coefficient between octanol and water, K_{ow}, is used. Again, conservative values of K_d are often adopted in simpler systems, or in the earlier tiers, whereas values adapted to particular conditions are adopted in more site-specific or more detailed assessments.

Exposure of organisms to contaminants in the environmental media

Dose-effect relationships are often expressed as the incidence of effects at a particular total contaminant intake. In order to calculate the contaminant intake, the assessment systems studied consider a number of exposure pathways. The simplest exposure calculations consider

uptake from the contaminated medium as a simple bioconcentration factor. Other systems consider uptake via a number of exposure pathways:

- intake of contaminated food, where the contaminant concentration in food is often calculated from the concentration in environmental media and a bioconcentration factor for the relevant foodstuff;
- intake of contaminated soil/sediment; and
- intake of contaminated water.

Inhalation of contaminants and dermal contact with the contaminated media are not usually considered, both because of the difficulty of estimated intake via these pathways, and because of the lack of dose-response data.

Rates of intake of food and water have been studied and reported for a limited number of organisms. However, allometric relationships have been derived to allow intakes to be estimated for species for which there are no direct observations (see Section 7.4).

Conservative assumptions are often made about the fraction of the total food/water/soil intake, which is contaminated. Again, attempts to quantify the fractional contribution of the contaminated area, either in terms of the time the organisms spend in the area, or the fraction of food or water derived from the area, are made in more detailed models.

7.7.2 Dose estimation (radiation)

Simplifying assumptions are adopted with respect to internal and external dose estimation for radionuclides in a number of models.

Internal dosimetry

- Absorbed fractions of radiation.

  One simple approach that has been used for screening purposes is to assume that all the energies emitted by the radionuclide are absorbed within the organism, tissue or organ under consideration. This approach is reasonable for α- and β-radiation, unless the dimensions of the organism are very small. This approach is, however, very conservative for γ-radiation. Other less conservative simplifying assumptions have been used, e.g. in IAEA [1992], where the absorbed fraction was assumed to be 1 for α- and β-radiation (with the exception of 0.5 for P-32 high energy β-radiation), 0.1 for γ-radiation in plants and 0.5 for γ-radiation in the reproductive tissues in animals.

  In order to calculate the absorbed fractions for β- and γ-radiation, the point source dose distribution method has been used, assuming simple geometries for the organisms, e.g. ellipsoids, cylinders and spheres. In a number of studies [e.g. NCRP, 1991; IAEA, 1976] reference biota have been defined in terms of their geometry and dimensions, though there are no generally agreed reference biota, geometries or dimensions. The use of reference biota has been discussed in Section 7.4.

- Radionuclide distribution in tissues and organisms.

  Uniform radionuclide distribution throughout the organism is often assumed in dosimetric calculations, as data on the distribution of radionuclides in tissues and organs are generally

not available. This can result in under-estimation of doses to specific tissues for radionuclides that concentrate in them (e.g. bone seekers in fish). The method of dose calculation in these cases should be consistent with that used in the determination of the dose effect relationship from which the dose criteria may be derived.

- Radiation weighting factors.
  This subject has been addressed in Section 6.2.

External dosimetry

Relatively simple models have been used for external radiation received by biota surrounded by homogeneous environmental medium or at the interface between two environmental media (e.g. air/soil and water/sediment). Generally, the environmental medium is assumed to be infinite in extent (or semi-infinite in the case of organisms at the interface between two media).

No self-absorption is assumed in the organism, i.e. the organism is assumed to be infinitely small.

The dose rate calculated is that delivered to the surface of the organism. This is conservative, as the biologically significant dose is usually delivered at some depth that depends on the locations of sensitive organs and tissues (i.e. internal dosimetry). The degree of conservatism can be quite large, depending on the nature of the organism and the energy of the radiation.

Calculations of external dose rates often assume that the organism is exposed to the contaminated medium 100 % of the time. For animals, which roam over large areas, e.g. birds, this assumption is likely to be very conservative.

Disadvantages of the simplified approaches

The methods described above are more simplified than methods currently being developed (within the FASSET project). In order to avoid the considerable conservative bias implied by the simplified approaches, especially for external and γ-radiation and for the terrestrial environment, the following factors must be taken into account:

- radiation transport and the interaction of radiation with matter must be treated accurately from the physical point of view, taking into account the difference in density between the organisms and the surrounding media;
- the simulation of inhomogeneities in the media;
- the simulation of complex geometries; and
- simulation of self-shielding.

The effect that these factors have on radiation transport between sources and target, necessitates the use of Monte Carlo methods to derive dose coefficients. The results derived using Monte Carlo techniques are associated with much less uncertainty concerning the physical aspects of exposure than the simplified approaches.

8. Effects analysis

This chapter is focused on ecological assessments of non-radioactive hazardous substances, as few systems for the assessment of impacts of ionising substances exist at the moment. However, the considerations introduced are highly relevant to radiological assessments. Because existing systems are built upon extrapolation from ecotoxicological tests, it is useful to give some definitions of the various endpoints commonly measured:

- NOEC – no observed (adverse) effect concentration. This is the highest concentration that does not result in an observable effect.
- LOEC – lowest observed (adverse) effect concentration. This is the lowest concentration, which results in an adverse effect.
- EC_x – the environmental concentration at which some adverse effect is observed in x % of the test population.
- LC_x – the concentration, which is lethal to x % of the population.

Data from tests of long-term exposure are preferable for studies of chronic exposure to a contaminant. Data from short-term tests are relevant to assessments of acute exposure. Tests measuring sub-lethal effects are also more relevant to the aims of assessment systems reviewed in this report, rather than studies of lethal effects (i.e. LC_x values). EC_x values may be appropriate for assessments of chronic exposure if the tests are performed over a long enough period and the measured effect is appropriate, i.e. is not a lethal or very severe effect.

The quantities most often chosen as the relevant endpoint in the systems studies are the NOEC and LOEC values. The error associated with LC_x and EC_x can be quantified by confidence intervals. However, traditionally, this has not been possible with LOEC and NOEC values, as these data have been estimated without considering the dose-response curve. LOECs and NOECs must be one of the test concentrations used in the study and are thus dependent on the range of concentrations used in the test. Recently, methods have been adopted for extrapolation of the dose/concentration response curves by low-dose/ concentration interpolation, to obtain NOEC and LOEC values. Thus extrapolated or interpolated values are possible if no direct measurement is done.

The statistical significance of effects

The level of effect considered unacceptable is often based on statistical hypothesis tests, but may also be defined in terms of a specified percent reduction from the controls. A lower level of confidence may be accepted in the assessment when the effect is greater. A small percent reduction might be considered acceptable even if it is statistically significantly different from the control. On the other hand, a large percent reduction (e.g. 30 %) might be considered unacceptable even if it is not statistically significant (often because of insufficient replication). Acceptability is dependent on the assessor's aims and falls outside this project's remit.

Relevant effects

In the assessment programme used in the Netherlands [RIVM, 1999], it is stated that only those ecotoxicological data on parameters that affect the species at the level of the population,

are accepted. Examples of relevant parameters are mortality, growth, photosynthesis and reproduction (including effects on reproductive organs, fertility, egg fertility, etc.)

In ecotoxicological studies with essential elements, the effects observed can be caused, in theory, by element limitation instead of toxic effects. To prevent these data from being included, special attention is paid to studies resulting in low NOEC (or $L(E)C_{50}$) values for the metals antimony, cobalt, molybdenum, selenium, vanadium, chromium, copper and zinc.

8.1 Extrapolation methods

For the estimation of a safe level below which no adverse effects in the environment are expected to occur, usually an extrapolation is applied to the results. The extrapolation is used to predict effects in complex, poorly understood ecosystems of the measured or estimated concentrations in a single medium. The extrapolation from available toxicity data to effects at the ecosystem level is associated with a number of assumptions and uncertainties. Alternative approaches, such as using batteries of tests, field observations, ecoepidemiology and population and ecosystem modelling, can be used to estimate risk, and each has its own assumptions and associated uncertainties.

Various extrapolation methods have been proposed to enable the use of the available toxicity data, often single-species toxicity data, to derive a concentration that is protective at the level of the ecosystem, with a certain degree of confidence. These methods are outlined below.

8.1.1 Distribution-based method

This method has been used when there are an acceptable number of reported toxicity threshold values representing a wide spectrum of genera (e.g. RIVM – a minimum of four NOEC values is used).

The sensitivities of species within a large community can be described by a statistical distribution, e.g. in the Netherlands, NOEC values are described by the log-normal distribution. The hazardous concentration is then defined as the n^{th} percentile of the NOEC values of a toxic substance. In the Netherlands, the maximum permissible concentration is the 5^{th} percentile of the log-normal distribution of NOEC values, and is assumed to be the concentration in soil at which 95 % of the species present will not be adversely affected by a contaminant. Allowance can be made for the uncertainty associated with the derived value by broadening the distribution. A second distribution is adopted, with the same mean value but a greater value of the parameter β, which describes the width of the distribution (analogous to a greater standard deviation in the normal distribution). The value selected for β depends on the degree of confidence required and the number of data points to which the distribution is fitted.

8.1.2 Safety factor method

This method is widely used when there is limited data about the effect of the hazard of the chemical of concern. It is generally applied if the data set is small or when only acute data are available. Generally, the lowest reported value is chosen from the toxicity data available and then assessment factors (also known as application factors, uncertainty factors, or safety factors) are applied. This entails dividing the toxicity value by a value designed to take into

account the shortcomings of the data. Often, a safety factor is applied for each of the following situations:

- the type of toxicity data available (i.e. extrapolation from acute data to chronic exposure, extrapolation from data on lethal effects to sub-lethal effects);
- the amount of toxicity data and the coverage of different genera (i.e. extrapolation from data on one or two genera to a large number of genera at different trophic levels); and
- the severity of the hazard posed by the contaminant, i.e. account is taken of the persistence and bioaccumulation potential. In the OSPAR system, an extra safety factor is applied if the chemical is known to be an endocrine disruptor.

Table 8-1 shows the safety factors recommended in the Environment Canada's, the EEC's and OSPAR's risk assessment methodologies for chemical substances (priority substances and notified and existing substances, respectively). Safety factors proposed by Environment Canada [2000], in this case called application factors, are shown in Table 6-1.

A comparison of the EEC and OSPAR safety factors is interesting, as the OSPAR risk assessment methodology is a development of the EEC methodology for application to marine environments. In the OSPAR methodology, the distribution of sensitivities of species is assumed to be broader because of the greater species diversity in the marine environment (compared to freshwaters), including the presence of a number of taxa that only occur in that environment. Thus, data for only the standard three taxa (algae, crustaceans and fish) is possibly insufficient to represent the entire distribution in sensitivity to a toxic substance. When only the 'three taxa' data are available (either freshwater or saltwater species), a greater safety factor is adopted. The additional assessment factor is also considered sufficient to cover the situations where low species diversity might result in high ecosystem dependency on individual species. When data are available for additional taxonomic groups, e.g. molluscs, the uncertainties in the extrapolation are reduced and the magnitude of the assessment factor can be lowered.

Other examples of the use of this type of method are CCME's water quality criteria for the protection of aquatic life and the USEPA's ambient water quality criteria. These two methods include rigorous demands on the type, quality and suitability of data to which the method should be applied.

8.1.3 Weight of evidence approach

This method is used in the CCME environmental quality guidelines for soil and sediments, and is based on the method proposed by Long & Morgan [1990] for the NOAA sediment quality guidelines for the Great Lakes. Similar approaches have been adopted for sediment quality guidelines by the USEPA.

The available toxicity data are collected and screened for their suitability. All accepted data are collected and threshold values or guideline values are defined as a certain percentile of the frequency distribution of the data set. The data set may be examined to see if bias has been introduced by one type of data dominating the distribution (e.g. if more than 50 % of the data points are LC_{50} or EC_{50} values, or 75 % of the data points are LOEC or NOEC values).

Table 8-1 Safety factors adopted in the risk assessment methodologies Environment Canada [1997] and EC [1996].

CCME		EEC		OSPAR	
				Lowest short-term L(E)C_{50} from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels.	10,000
Lowest acute LC_{50} or EC_{50} from a data set of one or two species.	1,000	At least one short term L(E)C_{50} from each of three trophic levels of the base data-set (Daphnia, fish, algae).	1,000	Lowest short-term L(E)C_{50} from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels + two additional marine taxonomic groups (e.g. echinoderms, molluscs).	1,000
				One long-term NOEC from freshwater or saltwater crustacean, reproduction or fish growth studies.	1,000
				Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish).	500
Lowest acute LC_{50} or EC_{50} from a base data set (e.g. fish, daphnid, and algal species).	100	One long-term NOEC (either fish or Daphnia).	100	Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish).	100
		Two long term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae).	50	Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish) + one long-term NOEC from an additional marine taxonomic group (e.g. echinoderms, molluscs).	50
Threshold (e.g. IC_{25}) of sublethal toxicity from a base data set (e.g. fish, daphnid and algal species).	10	Long term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels.	10	Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) + one long-term NOEC from an additional marine taxonomic group (e.g. echinoderms, molluscs).	10
		Field data or model ecosystems.	Case by case		
Chronic to acute.	10				
Adequate to inadequate data set.	10				

Differences between the risk assessment frameworks arise regarding the types of data points accepted for inclusion in the data set and the percentile used to determine the threshold or guideline value. These differences depend partly upon proposed use of the derived value. Values to be used in risk assessments to represent conditions with a low degree of environmental effects may be based on low percentiles of distributions including LOEC and NOEC data. Values to be used to represent conditions where some degree of effect is expected may be based on higher percentiles of distributions including effects data (LC_x and EC_x data). An example of the derivation of different quality indicators according to the purpose of the guideline, are the Canadian soil quality guidelines [CCME, 1996]. The threshold effects concentration (TEC) is used for sensitive land uses (e.g. agricultural land) whereas the effects concentration low (ECL) is used for commercial and industrial land. The more conservative TEC value is based on the 25th percentile of a data set including LOEC and NOEC data, together with EC_x and LC_x data. An uncertainty factor may be required if more than 25 % of the data below the 25th percentile are definitive effects data (i.e. EC_x or LC_x) or if the available studies are few or represent few taxonomic groups. The less conservative ECL value is based on the 25th percentile of a data set including only 'effects' data, i.e. EC_x of LC_x data.

Table 8-2 summarises the types of data used in the distribution approaches and weight of evidence approaches in some of the frameworks studied, together with the point on the distribution used as the guideline value.

Table 8-2 The derivation of guideline values using the distribution and weight of evidence approaches.

Guidelines		Data in distribution and acceptable level
NOAA sediment quality guidelines*	ERL (effects range low)	10th percentile, effects data
	ERM (effects range medium)	Median, effetcs data
CCME soil quality guidelines	TEC (sensitive)	25th percentile (LOEC, NOEC, EC<25) * SF
	ECL (less sensitive)	25th percentile Ecx and LCx data
Florida sediment quality guidelines**	TEL (threshold effects level)	Geometric mean of: 15th percentile – effetcs data set (EC<20) 50th percentile – no-effects data set (NOEL)
	PEL (potential effects level)	Geometric mean of: 50th percentile – effetcs data set 85th percentile – no-effetcs data set
RIVM	MPC (maximum permissible concentration)	5th percentile – NOEL data
	SRC (serious risk concentration)	50th percentile – NOEL data

* NOAA sediment quality guidelines [Long & Morgan, 1990].
** Florida sediment quality guidelines [described in ORNL, 1997a]

8.1.4 Comparison between values for different groups of genera

Some methods, e.g. those used to derive the Canadian soil quality guidelines and the Dutch environmental risk limits, include the derivation of indicator values based on data for different groups of organisms. For example, values are derived for invertebrates, plants, microbial processes and wildlife, using one or other of the methods outlined above. The final indicator value is then derived from these values. The lowest of the different values is usually adopted as the final value. Particular weight is given to the comparison of toxicity data for groups of plants and animals with data representing ecosystem processes, e.g., soil microbial processes (a value derived from toxicity tests on a number of heterotrophic processes).

8.2 Data requirements for effects analysis

Many of the methods studied specify requirements, which the data used in the risk assessment, must fulfil. These demands are primarily concerned with data quality and with ensuring that sufficient data are used and that the data are representative of the object of the risk assessment, or sufficiently wide-ranging to be generally applicable (e.g. should cover a range of taxonomic groups).

8.2.1 Amount and type of data

Many risk assessment systems that are concerned with chronic exposure state that the preferred toxicological endpoint is NOEC data from long term exposure. However, the scarcity of data often necessitates the use of acute data. Use of acute data can however steer the choice of extrapolation method. For example, in RIVM's system at least four NOEC values from chronic studies are required for use of the preferred distribution method (see Section 8.1.1). In the absence of four chronic values, data from short-term studies (LC_{50}) data can be used after the application of a safety factor. However, the extrapolation method chosen in this case is the safety factor method (see Section 8.1.2), and the resulting value is regarded as less certain, being given the status of preliminary value. Similarly, when less than four values are available, the safety factor method must be used.

The toxicological endpoint chosen is to an extent dependent upon the aims of the system, e.g. in USEPA's ambient water quality criteria [USEPA, 1995], chronic values are required for the derivation of chronic criteria, whereas values from short-term exposures (acute values) can be used for derivation of acute criteria.

8.2.2 Sufficient spread of data

RIVM [1999] state that data must be available for at least four taxonomic groups before an assessment can be carried out. Only one value per species is chosen. If there are several values for the same endpoint in a single species, the geometric mean of these is chosen. If there are several values for different endpoints in a single species, the lowest value is chosen.

Other examples of data requirements designed to ensure that the data cover a sufficiently wide range of species are included in the method for the derivation of USEPA's ambient water quality criteria, AWQC [USEPA, 1995], and CCME's water quality standards for the protection of aquatic life [CCME, 1991].

The minimum data requirements for the derivation of USEPA's AWQC are the results of acceptable tests with at least one species of animal in at least eight different families. The different families to be considered are specified and vary according to whether the quality criteria are to be derived for fresh or salt water. The families specified cover different trophic levels and ecological niches (e.g. benthic and pelagic organisms). In order to avoid domination of data from one group of organisms, mean values are calculated over each species, then over each genus. The final values are derived from the cumulative probability of the genus mean values.

The goal of CCME's freshwater aquatic guidelines is the protection and maintenance of all forms of aquatic life and all aquatic life stages in the freshwater environment. Therefore it is essential that data from fish, invertebrates and plants be included in the derivation process. The minimum data set requirements are:

Fish:
- At least three studies on three or more freshwater species resident in North America, including at least one cold-water species and one warm-water species.
- Of the above studies, at least two must be chronic (partial or full life-cycle studies).

Invertebrates:
- At least two chronic (partial of full lifecycle) studies on two or more invertebrate species from different classes, one of which includes a planktonic species resident in North America.

Plants:
- At least one study on a freshwater vascular plant or freshwater algal species resident in North America.
- For highly phytotoxic substances, four acute and/or chronic studies on non-target freshwater plants or algal species.

8.2.3 Manipulation of data – data pooling

Data shifting

Data shifting is used to account for differences between endpoints or effects in order to increase the amount of data available for an endpoint. An example is the use of acute:chronic ratios. Where insufficient data from chronic tests are available, data from acute tests are used after application of a suitable correction factor. USEPA's [1995] protocol for the derivation of ambient water quality criteria includes a protocol for the derivation of acute to chronic ratios. The value of the ratio is derived from studies where both acute and chronic values are given. The ratios may then be applied to studies where only acute data are reported. In other systems, acute data may be used in assessments of chronic effects after the application of a safety factor, e.g. an LD_{50} value.

Equilibrium partitioning method

This method is used often in risk assessments of contaminants in soils or sediments. The assumption is made that the soil or sediment dwelling organisms are exposed to contaminants via the soil pore water, i.e. the contaminant sorbed to the soil or sediment solid phase is unavailable to the organism. Thus, the toxic effect of a contaminant in pore water can be

estimated from toxicity data from standard aquatic organisms. The soil pore water concentration is estimated from the total soil or sediment concentration using equilibrium partitioning theory, i.e. the aquatic toxicity threshold value is multiplied by a linear partition coefficient (e.g. a K_d value) to determine the soil concentration equivalent to the toxicity threshold value.

Accounting for bioaccumulation

Direct exposure to a compound can lead to accumulation in organisms, which may result in deleterious indirect effects in higher members of the food chain. This mainly occurs with organic compounds with a relatively high hydrophobicity and with some metals.

Several of the systems studied include methods for assessment of risks to higher trophic levels, e.g. RIVM have derived 'secondary poisoning values' for the three food chains:

water → fish → fish-eating bird or mammal;

water → mussel → mussel-eating bird or mammal; and

soil → worm → worm-eating bird or mammal.

In Canada, tissue residue guidelines for aquatic biota have been derived, which are contaminant concentrations in food organisms, e.g. fish, which are considered to be protective of the species that consume them, e.g. birds and aquatic mammals. USEPA's guidelines for ecological risk assessment [USEPA, 1998] both include similar methods.

These methods take one or more exposure pathways into account. All of the methods take into account the ingestion of contaminated food. Some of the pathways also take into account the ingestion of soil and contaminated drinking water, and inhalation of contaminants.

The basic assumption of the method is that a concentration in food is directly related to the concentration in the environment through bioconcentration and bioaccumulation. Hence, it is in principle possible to translate the no-effect concentration in food to a no-effect concentration in the environmental media (surface water or soil) to which the prey of the top-predators are exposed, if the appropriate toxicity and bioaccumulation data are available.

No-effect concentrations in food are derived from laboratory experiments, dietary studies, etc. A correction factor may need to be applied to dietary studies to account for the different calorific values, and thus food intake rates, of the experimental diet and the diet in the food chain. Data from these studies are used to derive a no-effect concentration in food in a similar way to those described in Section 8.1.

Bioconcentration factors – BCFs (the ratio between the concentration in food and the concentration in the relevant environmental media for the organisms) – can be derived empirically, from field observations or experiments. As with the toxicological data, the derivation of representative BCF values imposes demands on data type, amount and quality. BCFs can also be derived using qualitative structure-activity relationships – QSARs (i.e. from knowledge of the contaminants' physical and chemical properties). RIVM use the following QSARs to derive BCFs for fish and mussels:

fish: $BCF = 0.048 \cdot K_{ow}$ (l/kg); and

mussel: $BCF = 0.013 \cdot K_{ow}$ (l/kg).

RIVM have concluded that for soil organisms BCFs are not so dependent on the hydrophilic properties of a contaminant, but are dependent on the soil characteristics and the lipid content of the organism, and BCF values for all organic compounds and earthworms lie between 0 and 19.

The models consumer species that take bioaccumulation into account may be general or food chain specific. The models can take into account several trophic levels, deriving separate BCFs for each level. Alternatively, a BCF can be derived only for the organism for which the assessment is being carried out.

Bioavailability adjustment

The toxicity of a contaminant is influenced by its bioavailability. Many factors influence the bioavailability of contaminants, particularly the physical and chemical conditions in environmental media, for example in soils the bioavailability is dependent on the pH, clay content, cation exchange capacity (CEC), organic matter content, presence of metal oxides and hydroxides, presence of humic substances and other complexing agents. The bioavailability in estimates of both the exposure and effects of a contaminant should be similar for comparisons to be made between them. Generally speaking, toxicity studies are conducted under conditions that maximise bioavailability. For example, tests with aquatic organisms are often conducted with soluble forms of a substance in test water free of dissolved organic matter and suspended solids. Some of the methods studied take the influence of such factors on the bioavailability of contaminants into account.

In the Netherlands, algorithms have been developed at RIVM [RIVM, 1999] for some metals to standardise toxicity values in terms of the clay and organic matter contents of soils. The algorithms were derived from analyses of soil parameters from uncontaminated sites. Their data are standardised to a soil with 10 % organic matter and 25 % clay content. These adjustments are, however, applicable only to a well-defined region and set of organic conditions. Similar relationships are suggested by CCME [1996], where the metal content of plants may be normalised to the soil's pH, clay and organic matter content and the metal content of molluscs may be normalised to the organic carbon content of the host sediment.

Where algorithms are not used, it is possible nevertheless to take into account the influence of a number of factors on bioavailability when choosing the value of parameters such as the concentration factor, which represents radionuclide uptake into organisms. This approach was suggested in the EA assessment system [Environmental Agency, 2001].

8.2.4 Evaluating data quality

USEPA [1992] give a list of criteria that should be considered when evaluating the quality of data from the studies or observations making up their database:

- Relevance of data to exposure scenario of interest. Lines of evidence that are most relevant to exposure scenarios in region/site of interest are given the greatest weight.
- Relevance of the evidence to the assessment endpoint. Toxicity tests that closely mimic field conditions and yield results, which 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 of risk estimate. Confidence is a function of the sufficiency and quality of the data and estimation techniques, including 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. The relationship between a priority substance and an observed adverse environmental effect must be assessed carefully, taking several factors into account.

Most of the data derive from single-species, laboratory studies. Sometimes field studies are also available. CCME [1996] have further developed a list of criteria for the evaluation of laboratory and field data for terrestrial media. These criteria are shown below.

Criteria for evaluation of laboratory data

- Bioassay test procedures should conform to currently acknowledged and accepted soil toxicity testing practices or protocols.
- Exposure time and recognised toxicological endpoints (e.g. mortality) must be identified. Information from the dose-response curve should be used to estimate the LOEC and NOEC endpoints.
- Environmental test conditions (e.g. pH and temperature) should be recorded so that factors affecting contaminant availability and toxicity can be evaluated.
- Appropriate statistical analysis should be performed and reported in the study.
- Tests that measure contaminant toxicity in combination with other environmental stressors to the test organism (e.g. soil temperature changes) can be used, provided that these stressors have been accounted for in the test design.
- Experimental effect must be attributable to the contaminant of concern (avoid contaminant mixtures, such as sludges, unless it is clearly evident that the effect is due to the contaminant of concern).
- Studies that report measured values of contaminants in the soil must use comparable analytical methods for use in the derivation process, and should consider all uncertainties from the various methods used.

Criteria for assessment of reliability of field studies

- Effects data must be collected from the same site during the same time period and must be confirmed with matching soil chemistry data.
- Collection, handling and storage of samples should conform to standardised or accepted practices.
- The acceptability of other field related variables (e.g. sampling design) should be evaluated case-by-case.

It may be argued that a laboratory-to-field extrapolation factor should be estimated to take into account the differences between the two sets of conditions. As yet, no such factor has been quantified, and would vary from case to case.

Environment Canada [1997] discusses at lenght data quality in effects assessment, divided into pelagic biota, benthic biota, groundwater biota, soil biota and consumer species (taking into account bioconcentration in the foodchain) – including a compendium of recognised test methods.

9. Ambient factors

9.1 Accounting for background exposure

Some substances, such as metals, have natural sources, and therefore exhibit natural background concentrations. In addition, some of these metals are essential for life, so organisms require a certain amount of these essential elements. However, organisms experience toxic effects when exposed to very high concentrations of these elements. The natural background concentrations of those metals are thus essential. Naturally occurring chemicals may also impose a stress factor, though these 'effects' can be separated from the 'adverse effects' associated with anthropogenically derived amounts of the same metal.

In many methods, the background exposure is added to the exposure from anthropogenic sources. Background is included in estimation of exposure [EC, 1996], or is included in the measurement of exposure [Environment Canada and Health Canada, 2000]. The combined exposure is then compared with the environmental concentration that is indicated by toxicological studies to correspond to a no-adverse effects concentration.

For some metals, the toxicological environmental no-adverse effects concentration is actually lower than background concentrations. In many methods, when this occurs, the natural background concentration is adopted instead of the toxicological risk-based value as the environmental criteria.

RIVM have proposed a method to take into account background concentrations, called the 'added risk approach'. It is a modification of the extrapolation method (the distribution method, see Section 8.1.1) and is used to derive the additional contaminant concentration above background, which the environment is able to tolerate before adverse effects are likely to occur.

The USDOE [2000] suggest that in a site-specific assessment, background exposure to radionuclides should be assessed by means of comparison with a nearby 'background reference' area, i.e. an area similar in terms of geology and ecology, but unaffected by point sources of anthropogenic radionuclides.

CCME's framework for the assessment of priority substances [Environment Canada and Health Canada, 2000], which adopts the tiered approach, also adopts the tiered approach to estimating risks due to anthropogenic sources of substances that occur naturally. The risk assessment takes into account naturally enriched areas and the tolerance of organisms occupying these areas to elevated concentrations. Such an analysis is only required when a Tier 1 analysis indicates a potential for harmful effects and there is evidence of areas being naturally enriched in Canada, i.e. when the natural background concentration of bioavailable forms of the substance exceeds the Tier 1 environmental no-effects value. In such cases the environmental no-effects value is refined in the following ways:

- in areas with elevated natural background concentrations, the environmental no-effects value is given a lower bound (the value cannot be set below the natural background concentration, which is assumed to be the 90^{th} percentile of the measured concentrations in the area); and
- measurement and assessment endpoints should not include organisms likely to develop tolerance to the substance being assessed (the potential for tolerance is evaluated from the literature).

Part of the approach suggested by AECB [Amiro & Zach, 1993] involves the use of background radiation as an assessment criterion. This method involves the estimation of an environmental increment (EI) for each radionuclide, which is the increment in the baseline environmental concentrations of radionuclides and which will ensure protection of the environment as a whole. The estimates of EI are based on existing concentrations in the environment and on natural variability. Many radionuclides found in radioactive wastes are naturally present in the environment, and biotas tolerate these natural conditions, or have been selected to do so through natural evolution.

The EI approach considers that natural concentrations of radionuclides in the environment are acceptable. It is also assumed that naturally occurring concentrations of radionuclides are not harmful to biota, nor are they in a range where small increases may have large detrimental effects. Quantitatively, a statistical basis is used to define the EI values on the basis of the natural distribution, i.e. it is assumed that an additional concentration of up to one standard deviation of the local natural spatial variability is environmentally acceptable and equal to the EI. However, the value of one standard deviation is arbitrarily adopted and it is possible to use more or less stringent values. The EI method cannot easily be applied to nuclear fuel radionuclides that are not present in nature. However, the concept of background 'dose' could be used in the EI method to account for these radionuclides.

9.2 Influence of multi-contamination within the framework of ERA

This section is based mainly on the material in Garnier-Laplace *et al.* [2002]. The full references to data sources can be found in that report.

9.2.1 The basic approach in radioecology and the multi-contamination context

Until now, the basic approach in radioecology has tended to analyse and model knowledge concerning only radionuclide transfers within the different abiotic and biotic components of ecosystems (modelling pathways of exposure for living organisms), without considering non-radioactive contaminants. However, human activities result in the occurrence of the dispersal of a wide range of pollutants and contaminants in the environment. The multi-contamination issue for ecosystems at a local or global scale, i.e. the concomitant presence of various kinds of xenobiotics, including radionuclides, becomes therefore increasingly realistic. Nevertheless, the possible synergy or inhibition of radionuclide uptake and depuration processes by living organisms in conjunction with other pollutants are totally ignored in both radioecological or non-radiological risk assessments.

In order to determine whether multi-contamination in radioecological assessment models should be included, the question of whether a prior and/or a concomitant exposure to other toxicants modifies radionuclides' bioaccumulation characteristics must be addressed. In other words, the first challenge is to understand and quantify how these stable xenobiotics, which can induce stress or alter the organism's physiology, act and/or interact on the behaviour of radionuclides within biological systems.

9.2.2 Possible mechanisms of interactions between radionuclides and stable contaminants within biological systems

Generally, the mechanisms of bioaccumulation in organisms are associated with the processes of detoxification for chemical elements without known biological function or for those whose concentration is regulated within a certain range, becoming toxic beyond that. In the context of multi-contaminants, the systems of protection are intensively used and can no longer guarantee the defence of the organism. The effects linked to a particular pollutant may be enhanced or triggered more rapidly. An example that perfectly illustrates this situation is the phenomenon known as spillover for the metallothioneins (MT). MT concentrations are generally low in non-stressed organisms, and an increase in their concentration is often associated with the presence in the environment of metals in larger quantities. When the accumulation of metals becomes excessive, they may bond with other intracellular ligands engendering a high level of cellular toxicity.

Recently, a research programme carried out at IRSN in laboratory-controlled conditions, proved the evidence for the interaction between radionuclides (present at ultra-traces) and stable toxicants (metal and/or organic micopollutants, both at concentrations representative of those occurring in the environment) [Garnier-Laplace *et al*., 2002]. These results initiated several suggestions and further work to:

- link the stable pollutant-induced stress in organisms (especially biomarkers of oxidative stress and protein synthesis) and the modification of the radionuclide bioaccumulation level and kinetics; and
- provide evidence of the mechanisms involved, e.g., change in uptake rate and cellular redistribution of toxins.

In complex environments, the biological effects observed for a pollutant taken in isolation may be exacerbated or reduced as a function of the potential for action or interaction of all the pollutants occurring simultaneously. These combined effects may be the result of the similarity of the metabolic pathways taken by the pollutants considered, or of the physiological state of the organism in relation with the efficiency of the detoxification processes likely to be induced by one or other of the pollutants. However, tolerance and adaptation processes may be involved.

The example of the phenomenon of tolerance to metals evidenced in various aquatic organisms subjected to chronic exposure illustrates the continuum of the different physiological states linked to exposure to these metals. A model has been proposed which links alterations in tolerance to metals with concentration levels and duration of exposure in the environment.

For increasingly high levels of exposure, they distinguish schematically four successive alterations of the response of organisms to exposure to metals:

- for low levels of exposure in response to geochemical background noise, no alteration of tolerance to metals;
- for levels inducing bioaccumulation processes, increase in tolerance by the gradual mobilisation of various systems of protection that are effective against toxic effects;
- maximum tolerance where all the protection systems are mobilised, corresponding to the highest level of compensation of toxic effects; and
- net decrease of tolerance up to the death of the organism.

9.2.3 Framework perspectives

Globally, the interactions between stable pollutant(s) and radionuclide(s) are case-specific with respect to the biological model and to the biochemical properties of the studied chemical elements. To provide a rational basis for extrapolation between chemical species and radionuclides, several research topics will be investigated:

- to understand and quantify the links between the stable pollutant-induced stress in organisms (especially biomarkers of oxidative stress and protein synthesis) and the modification of the radionuclide bioaccumulation endpoints; and
- to provide evidence of the mechanisms involved for each chemical element alone, to understand how they can interfere when they are in combination.

Moreover, two questions remain: at which concentrations of stable pollutants in the environment will a modification of radionuclide bioaccumulation occur? Should interactions be the same in the case of radionuclide long-term exposures (i.e. significant in terms of life span of organisms)?

Under chronic exposure conditions, radionuclides in the environment (external irradiation) and/or within organisms (internal irradiation) may induce biological effects. In a multi-contamination context, these effects may be exacerbated or reduced as a function of the potential action or interaction of all the pollutants occurring simultaneously. These combined effects may be the result of the similarity of the metabolic pathways taken by the considered pollutants, or of the physiological state of the organism in relation with the efficiency of the detoxification processes likely to be induced by one or several pollutants.

This knowledge will enable increase confidence in operational radioecological assessment models by including:

- other stressors such as the presence of other classes of pollutants than radionuclides;
- the variations of the physico-chemical characteristics of the aquatic biotopes, acting simultaneously on the pollutant bioavailability and on the physiological functions of the organisms; and
- the trophic route of exposure, *via* contaminated prey ingestion.

These points are being addressed within the framework of the ENVIRHOM programme recently launched at IRSN, which aims towards the improvement of radiological risk assessment linked to internal contamination of living organisms within the multi-contamination context.

10. Uncertainties

In carrying out an assessment of environmental effects at any level, sources of uncertainty must be identified and described either qualitatively or quantitatively. Environment Canada [1994] discussed the uncertainties arising in ecological risk assessments. They concluded that uncertainties in problem formulation include the choice of appropriate endpoints, models, time scale and spatial scale. In the analysis and risk characterisation phases, potential sources of uncertainty include:

- incomplete knowledge of the physical and chemical properties of the substance;
- incomplete understanding of the temporal and spatial scales of exposure and the matching of those scales with the ecological scales of the risk assessment;
- incomplete knowledge of substance transformation due to chemical, physical and biological actions;
- poor understanding of the heterogeneity of the populations at risk;
- incomplete knowledge of how contaminants act upon a population or community and the interactions among multiple contaminants;
- inadequate reproducibility of laboratory and field studies;
- incomplete knowledge of the extrapolation of laboratory toxicity test results to field conditions; and
- incomplete knowledge for the extrapolation of toxicity test results for measurement endpoints of assessment endpoints.

Approaches to accounting for uncertainties in the analysis phase vary:

- Conservative deterministic approach.

  Many of the systems discussed above take a conservative deterministic approach, at least in part of the assessment. The use of safety factors associated with the dose-response data is an example of this. The main advantage of this approach is its simplicity, and therefore it is used often in the derivation of screening values. However, there are several disadvantages associated with the approach. It is not possible to quantify the degree of uncertainty derived from the conservatism adopted. The models may be insufficiently conservative, or may on the other hand be unrealistically conservative. As no estimate of the uncertainty associated with the outcome of the assessment is given, the application of the results of the assessment is limited if potential exposure exceeds the value regarded to be safe.

- Probabilistic approach.

  Environment Canada [1997] discussed a number of methods available for probabilistic risk analysis and recommend different techniques for different types of assessment.

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