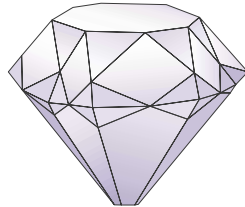


**FASSET**



**Framework for Assessment of Environmental Impact**

**Deliverable 2: Part 1**

**Formulating the FASSET assessment  
context**

**December 2002**

**Edited by**

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**A project within the EC 5<sup>th</sup> Framework Programme**







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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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## Executive summary

The FASSET (Framework for ASSESSment of Environmental impactT) project aims at the development of an assessment framework, with emphasis on European biota and ecosystems. It is intended to assist decision-makers and all stakeholders involved in assessing environmental effects of past, present and future sources of environmental radiation.

The aim of the present report (Deliverable 2: Part 1) is to take advantage of, and integrate into the FASSET framework, aspects of existing systems dealing with environmental risks from radioactive or hazardous substances. In the report, this information is used to *formulate the FASSET assessment context*. The development of the assessment context as well as the framework is supported by more detailed documentation on other existing systems, issued in Deliverable 2: Part 2.

### *Societal views and guidance*

The development of the FASSET framework needs to reflect societal views on environmental protection in general. Three ‘ethical views’ can be discerned, as follows:

- an anthropocentric view, in which human beings are the main or only thing of moral standing, and thus the environment is of concern only as it affects humans;
- a biocentric view, in which moral standing can be, and is, extended to individual members of other species; and
- an ecocentric view, in which moral standing can be extended to virtually everything in the environment, including abiotic features (the physical environment).

The philosophical, ethical and moral views with regard to environmental protection are ‘translated’ into numerous guidelines and laws in the form of international agreements and national legislation. Upon examination of such guidelines (of different character as well as legal strength), it becomes evident that environmental impact of ionising radiation cannot – for societal reasons as well as for scientific and logical reasons – be assessed by using only one target species, i.e., humans. Consequently, there is no basis for the *a priori* view that the environment is protected if humans are protected. Against this background, the need for an assessment framework that focuses on effects of radiation on non-human biota and ecosystems becomes a necessity.

### *General structure of assessment frameworks*

Twenty pathway-based ‘systems’ for environmental assessment have been considered and reviewed in Deliverable 2 (summarised in this report and detailed in Deliverable 2: Part 2). Nine of these systems deal directly with radioactive substances, and eleven with risks from hazardous substances. Structurally, there are numerous similarities between the different systems and approaches, as indicated in Figure I.

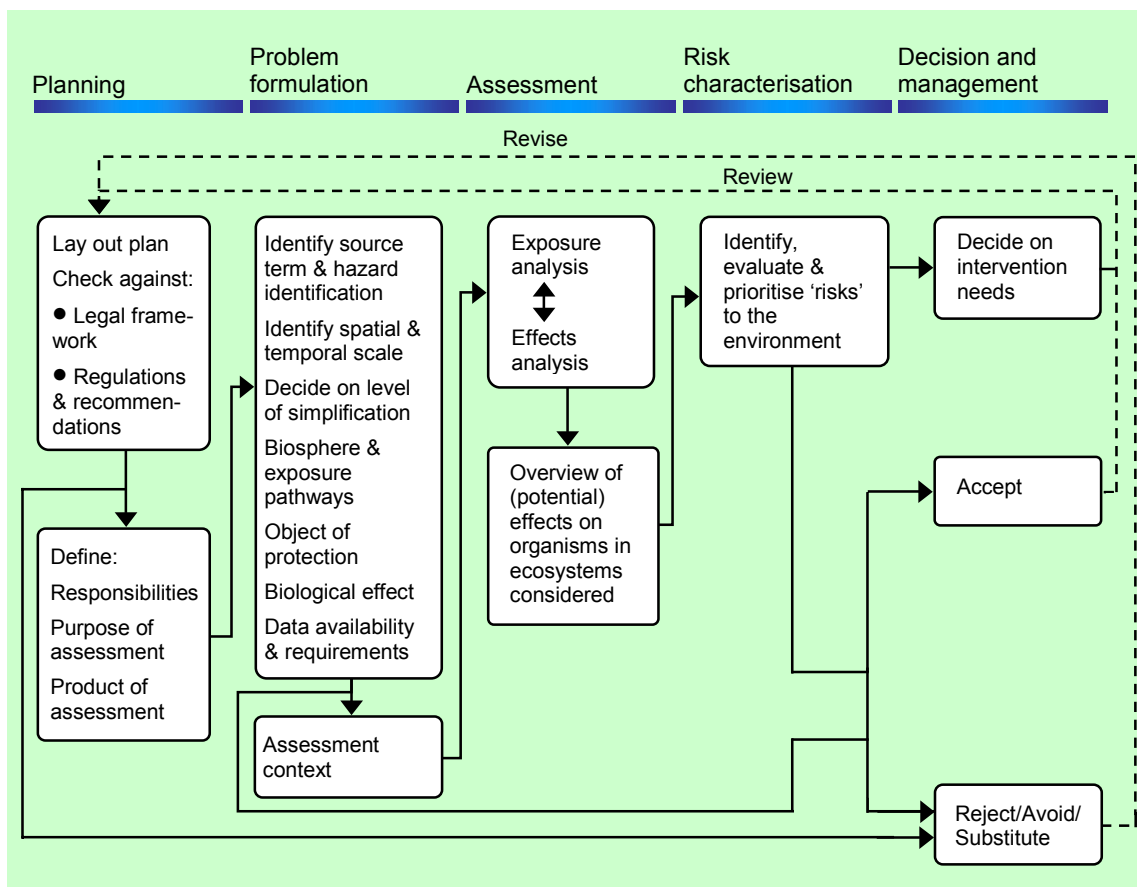


Figure I. Elements in a stepwise environmental assessment and management procedure.

### Formulating the FASSET assessment context

This report focuses on those elements that build up the FASSET assessment context, i.e.: the purpose of the assessment; source term and hazard identification; spatial and temporal scale; level of simplification; ‘biosphere’ system and exposure pathways to be considered; object of protection; biological effect; and data availability and data requirements (see Figure I). For each of these aspects, a number of issues and options have been identified from the system comparison in Deliverable 2: Part 2 as well as other sources, and/or were raised during the FASSET External Forum, held in Bath, UK, 8–9 April 2002. The Forum gave possibility to a number of invited organisations, representing a range of views and activities in the field of environmental radiation and environmental protection, to provide ‘guidance and critique’ to the project.

A number of aspects of formulating the assessment context can be highlighted:

- purpose – to present an estimate of environmental impact that is as realistic as possible, while still using general or generic information, to guide decision-making;
- source term and hazard identification – to be flexible in terms of sources, environmental properties, and effects of different nuclides, and to provide a means to prioritise;
- spatial and temporal scale – to consider acute and chronic exposures for the relevant environment;





- biosphere and level of simplification – to use generalised data for seven European ecosystems (three aquatic and four terrestrial), and to use a set of (currently) 31 ‘reference organisms’ as basis for impact analysis;
- object of protection – there may be cases where the object is predefined through legislation, i.e., in the case of rare and/or endangered species. In other cases, objects of protection may be identified on their significance to ecosystem function, exposure situation and sensitivity to radiation, and using multiple criteria. The ‘reference organism’ approach will assist in making these judgements.
- effects – to compile and assemble in a database information on effects of ionising radiation on different wildlife groups, organised in four ‘umbrella’ categories, morbidity, mortality, reproductive success, and cytogenetic effects, as a basis for estimating impact on individuals;
- data requirements and availability – to use ‘realistic’ data if available and extrapolate with reasonable caution when data are missing.

It was concluded that the environmental impact of ionising radiation can be assessed in a similar manner to other assessments, e.g. for hazardous substances. However, certain aspects of exposure (including dosimetry) and effects, particular to ionising radiation, need to be explored further before integration into the framework. Such technical developments are ongoing within the project, and the final FASSET framework, taking these aspects into consideration, is planned to be delivered towards the end of 2003.

This report, as well as all other Deliverables plus minutes from the External Forum, are available at the FASSET website ([www.fasset.org](http://www.fasset.org)).





## Table of contents – Part 1

<b>1. Introduction</b>	<b>13</b>
1.1 Aim, scope and structure of the report – FASSET Deliverable 2	13
1.2 Procedure for collating information	14
<b>2. Social and ethical aspects, and international guidance</b>	<b>17</b>
2.1 Social and ethical aspects on environmental protection	17
2.2 International guidance	18
<b>3. Systems for environmental assessment and management – brief overview and ‘synthesis’</b>	<b>23</b>
3.1 Brief overview of ‘systems’ considered	23
3.1.1 Planning	30
3.1.2 Problem formulation	30
3.1.3 Assessment, risk characterisation, and decision and management	31
<b>4. Formulation of the FASSET assessment context</b>	<b>33</b>
4.1 Purpose of the assessment	33
4.1.1 Issues and options	33
4.1.2 FASSET – definition of purpose of the assessment	35
4.2 Source term and hazard identification	37
4.2.1 Issues and options	37
4.2.2 FASSET – radionuclide selection	41
4.3 Temporal and spatial scale	43
4.3.1 Issues and options	43
4.3.2 FASSET – temporal and spatial scales	43
4.4 Biosphere system description, including level of simplification	44
4.4.1 Issues and options	44
4.4.2 FASSET – biosphere system description including level of simplification	45
4.5 Object of protection	46
4.5.1 Issues and options	46
4.5.2 FASSET – Object of protection	49
4.6 Defining the effects analysis	51
4.6.1 Issues and options	51
4.6.2 FASSET approach to effects analysis	53
4.7 Data availability and requirement	56
4.7.1 Issues and options	56
4.7.2 FASSET approach to data requirements and uncertainties	58
<b>5. Concluding remarks</b>	<b>59</b>
<b>6. References</b>	<b>61</b>
<b>Appendix 1</b> – Responses to issues raised and recommendations made during the FASSET External Forum, Bath, UK, 8–9 April 2002	<b>67</b>
<b>Appendix 2</b> – Glossary (Part 1 and Part 2)	<b>73</b>



## Table of contents – Part 2

<b>1. Introduction .....</b>	<b>13</b>
<b>2. Review procedure .....</b>	<b>15</b>
2.1 Collating the information .....	15
2.2 Systems for assessment of environmental effects of radionuclides and hazardous substances.....	15
2.3 Analysis of programmes .....	21
<b>3. General features of assessment and management schemes.....</b>	<b>23</b>
3.1 The problem formulation phase .....	24
3.2 Components of risk assessment schemes .....	25
<b>4. Aims and definitions of existing schemes.....</b>	<b>29</b>
<b>5. Identification of the object of the assessment.....</b>	<b>33</b>
5.1 Target level of biological organisation .....	33
5.2 Selection of endpoints .....	34
5.3 Critical and/or reference organisms, organs or ecosystems .....	36
<b>6. Defining of the degree of protection required .....</b>	<b>39</b>
6.1 Acceptable dose rates.....	41
6.2 Radiation quality and relative biological effectiveness (RBE) .....	44
6.3 Levels of protections and setting standards.....	45
<b>7. Approaches to modelling .....</b>	<b>47</b>
7.1 Comparison with standards .....	47
7.2 Simplified biosphere .....	49
7.2.1 Use of generic organisms .....	49
7.3 Reference biosphere.....	49
7.3.1 The selection of biosphere system.....	51
7.4 Site-specific approach.....	52
7.5 Probabilistic approach.....	52
7.5.1 Derivation of the probability distributions .....	54
7.6 Tiered approach .....	55
7.7 Exposure assessment in the different approaches .....	58
7.7.1 Exposure pathways.....	58
7.7.2 Dose estimation (radiation) .....	60
<b>8. Effects analysis.....</b>	<b>63</b>
8.1 Extrapolation methods .....	64
8.1.1 Distribution-based method .....	64
8.1.2 Safety factor method .....	64
8.1.3 Weight of evidence approach.....	65
8.1.4 Comparison between values for different groups of genera .....	68
8.2 Data requirements for effects analysis .....	68
8.2.1 Amount and type of data .....	68
8.2.2 Sufficient spread of data.....	68
8.2.3 Manipulation of data – data pooling.....	69
8.2.4 Evaluating data quality.....	71
<b>9. Ambient factors .....</b>	<b>75</b>
9.1 Accounting for background exposure .....	75
9.2 Influence of ambient factors – multi-contamination within the framework of ERA.....	76
9.2.1 The basic approach in radioecology and the multi-contamination context .....	76
9.2.2 Possible mechanisms of interactions between radionuclides and stable contaminants within biological systems .....	77
9.2.3 Framework perspectives.....	78
<b>10. Uncertainties .....</b>	<b>79</b>
<b>11. References .....</b>	<b>81</b>



## 1. Introduction

The requirement for assessments of the environmental effects of radiation is increasing due to public concern for environmental protection issues, scientific reasons, and to the evolving integration of environmental impact assessments into the regulatory process. A well-defined and agreed assessment framework would be of benefit to both regulators and organisations responsible for the development, implementation and operation of facilities handling or generating radioactive substances, and would help in decision-making and in setting standards for environmental protection. Such a framework may, in addition, help to make a clear and understandable presentation of the environmental effects to members of the public.

However, the current system for radiological protection, as outlined by the International Commission on Radiological Protection (ICRP) in its Publication 60 [ICRP, 1991] makes no direct reference to environmental protection. Instead, the view is held that the environment indirectly is afforded adequate protection through application of standards adequate for protection of humans. This indirect approach is nowadays, however, generally considered inadequate or even inappropriate [e.g., Strand & Larsson, 2001]. The statement may not only apply in situations where man is absent or not exposed, but may also be doubted on scientific grounds. Consequently, there is much international and national effort in the development of new assessment and management systems focusing on protection of the environment *per se*, or in linking together systems for protection of humans and the environment.

Ongoing international activities to establish frameworks for radiological impact assessments focusing on biota and ecosystems, and to various extents incorporating elements of frameworks created for non-radiological assessments, include those of the International Atomic Energy Agency, IAEA [2002], and the ongoing revision of the ICRP recommendations [ICRP, 2002]. On a national level, the US Department of Energy has developed a tiered approach to demonstrate compliance to certain derived environmental nuclide concentration standards to be applied in some DOE facilities [USDOE, 2000]. Approaches to assessment based on exposure and effects analysis have also been developed by the Environment Agency of England and Wales in collaboration with English Nature [Coppstone *et al.*, 2001; Environment Agency, 2002]; and by initiative from the Canadian Nuclear Safety Commission [AECB, 2001].

### 1.1 Aim, scope and structure of the report – FASSET Deliverable 2

The FASSET Technical Annex [FASSET, 2000] describes Deliverable 2 (D2) as a ‘report on existing programmes for environmental assessment and management of environmental risk from ionising radiation and hazardous chemicals’. A further description in the work package 4 (WP 4) outline D2 as a ‘report reviewing the aims and ambitions of existing programmes for environmental assessment and management of environmental risks associated with ionising radiation and hazardous, in particular genotoxic, chemicals’ [FASSET, 2000].

The aim of the present report, D2, is to take advantage of, and integrate into the FASSET framework, aspects of existing systems for dealing with environmental risks from radioactive or hazardous substances.



There is a large number of programmes for assessing and managing environmental risks, developed for different purposes and applying different methodologies. These programmes can be grouped into three categories:

- assessment and management through pathway-based analysis of exposure, often involving environmental standards expressed in terms of concentrations or doses/dose rates;
- management through process standards relevant to (a) specific source(s) based on best available technique (BAT) or similar criteria of technical status and performance; and
- pure management standards, which may include certification schemes or systems to ensure that positive actions are taken to protect the environment and where continuous performance improvement is sought, such as the EC Eco-Management and Audit Scheme (EMAS).

It was recognised during the preparation of the project plan [FASSET, 2000] that management of environmental risks, in terms of setting standards and procedures for implementation of such standards, was a matter for national authorities to decide upon, and should not be a part of the assessment framework being produced within FASSET. Also, technical performance standards for certain practices or activities fall outside the scope of the FASSET project. The review, and the formulation of the assessment context, therefore focuses on the pathway-based approach to assessments. This does not mean that the ‘user-perspective’, nor other environmental effects such as contamination of the physical environment, is to be neglected. The construction of the framework must be flexible in order to take into account various risk management options, as well as societal concern, as these influence (and ultimately must make use of) the way in which a risk assessment is carried out. These aspects are considered in Chapter 2, which provides a review of ethical and social aspects, and their translation into international guidance on environmental protection.

Chapter 3 briefly reviews the pathway-based assessment frameworks considered in this study, and synthesises these into a general assessment and management scheme, part of which will become the basis for the FASSET framework. Chapter 4 discusses the formulation of the FASSET assessment context, setting out the reasoning that will guide the methodological development of the final framework. The role of this formulation is to:

- provide a means for discussion of the available choices with regard to targets, methodologies, etc., as well as an explanation and justification of the choices made for the purpose of the framework;
- guide the further development of the framework within the second half of the project; and
- facilitate addressing issues raised during the FASSET External Forum.

The development of the assessment context as well as the framework is supported by a more detailed comparison of existing systems, published in Deliverable 2: Part 2. All FASSET Deliverables, including Deliverable 2, are available at the FASSET website ([www.fasset.org](http://www.fasset.org)).

## **1.2 Procedure for collating information**

National and international assessment and management programmes relevant to FASSET were collated in a first instance by all FASSET partners. The information was then reviewed within WP 4 and a refined list was put together. Even when considering the limitations of the



scope discussed in Section 1.1, the documentation that has been analysed is selective. Major international and national programmes addressing assessment of environmental risks of ionising contaminants have been included; a number of national and international programmes for assessing environmental risks of hazardous substances have been included when their structure was deemed appropriate to assessing the impact of ionising radiation. A number of programmes for assessing risks of hazardous substances have *not* been included since they essentially corroborate other programmes. Thus, the final list represents a certain bias, but it should undoubtedly cover all major aspects of assessments frameworks that are relevant to FASSET.

The preparation of this report has also been guided by comments on the FASSET project received during the FASSET External Forum, held in Bath 8–9 April 2002, in conjunction with the third FASSET workshop [FASSET, 2002]. The External Forum was arranged to enable invited ‘external’ organisations, representing various interests and views within the field of environmental radiation protection, to provide ‘guidance and critique’ to the project. A summary table of issues and recommendations from the External Forum, as well as the responses from the project, can be found in Appendix 1.

Furthermore, the review has taken on board elements from the BIOMASS (BIOsphere Modelling and ASSEssment) project, lead by the IAEA. BIOMASS documentation was generously made available by the IAEA to FASSET participants [IAEA, 2001]. Also, a FASSET/BIOMASS workshop was arranged in Stockholm, 30–31 October 2001, to discuss commonalities and how BIOMASS experiences could be effectively taken on board by FASSET [FASSET, 2001a].

Finally, FASSET has gained from experiences from other EC-funded research projects, in particular EPIC (Environmental Protection from Ionising Contamination in the Arctic, ICA2-CT-2000-10032).







## **2. Social and ethical aspects, and international guidance**

### **2.1 Social and ethical aspects on environmental protection**

Environmental protection covers many topics, and it is important to have some idea of how they interface with other areas of environmental management. One of the more relevant is that between what is usually regarded as ‘pollution control’ and that which is generally referred to as ‘nature conservation’. This interface is often considered to be largely a matter of identifying what level of ‘protection’ is required under different circumstances, but it also involves a deeper understanding of more basic issues, including the various ethical and moral considerations that underlie the origin and practical consequences of different pollution control and nature conservation legislation.

Different ethical views have always affected the way in which people view the environment. It also affects reactions of society to their impacts upon it, and how best to manage their consequences. It therefore affects the way in which legislation evolves and the degree of consensus that may or may not be obtained amongst different countries. In this context, therefore, it is helpful to consider the findings of the recent IAEA [2002] study, in which a three-component ethical spectrum of views was identified (anthropocentric, biocentric, and ecocentric) within the context of the international, EU, and national legislation of the FASSET-participating countries. These three ‘ethical views’ essentially arise from philosophical debates about what has moral standing in the world, and why. They are briefly as follows:

- an anthropocentric view is that in which human beings are the main or only thing of moral standing, and thus the environment is of concern only as it affects humans;
- a biocentric view is that in which moral standing can be, and is, extended to individual members of other species, and thus obligations pertaining to such individuals arise as a consequence; and
- an ecocentric view is that in which moral standing can be extended to virtually everything in the environment, including abiotic features of landscapes – rivers and mountains – but where the focus lies more with the entirety and diversity of the ecosystem rather than, say, the moral significance of each and every individual component of it.

As one might imagine, there are considerable ranges of views within each of these three broad categories.

The anthropocentric view is easily recognised and dominates most of the existing legislation; but the other two are equally important. All of them vary considerably. A prominent feature of the biocentric view is recognition of the moral obligations that arise from the fact that many animal species can be shown, ‘scientifically’, to be sentient, in that they can experience pleasure and pain. The results of these considerations are reflected in attitudes to animal ‘welfare’, and thus in national laws – such as those relating to experiments on animals, for whatever reason. (They may therefore constrain the nature and extent to which experiments could be performed in order to obtain the data necessary to compile the missing data on dose-effects relationships for the FASSET programme.) Biological characteristics other than sentience may also be considered relevant, and extreme biocentric views assume that all individual living things have an inherent value and should be respected for what they are.



Ecocentric views also differ widely, particularly with regard to the reasons for, the evaluation of, and the solutions to, environmental degradation and ecosystem change; but all agree that it is the ecosystem that is the entity having moral standing.

Nevertheless, and notwithstanding these various basic ethical views, there is now a general international agreement on their practical implications for how we manage the environment, particularly with regard to conservation issues, and this is reflected in UN-level commitments by most countries. There are thus several international agreements relating to the conservation of both species and habitats. These essentially relate to the ‘importance’ or ‘vulnerability’ attached to individual species, or of areas where many species live – particularly with regard to the necessity for agreement at a multi-national level, such as the need to ensure that migratory species can safely travel and survive throughout their natural migratory range. The obligation to maintain biological diversity (within species, amongst species, and amongst habitats), which was a major component of the Rio Convention [United Nations, 1992], and supported by targeted commitments at the World Summit on Sustainable Development in Johannesburg [United Nations, 2002a] can thus be regarded as a direct consequence of holding a purely anthropocentric view – because humans may ultimately benefit as a result – or a reflection of either a biocentric or an ecocentric view. Indeed, such is the urgency of this task that in 2002 a Johannesburg Plan of Implementation was drawn up that contains commitments to reduce biodiversity loss by 2010; to restore fisheries to their maximum sustainable yields by 2015; and to establish a representative network of marine protected areas by 2012.

The IAEA study has also brought attention to another feature of the 1992 Rio Declaration, and that is the explicit responsibility to ensure that activities within national jurisdiction or control do not cause damage to the environment of other states. This, in turn, reflects the general principle of *environmental justice*: the need to take account of the fact that inequity can and does arise between the distribution of what might be termed ‘environmental benefits and harm’. Such inequity can occur across time (i.e. between generations), space (e.g. local, national or international distribution) and amongst economic and cultural groups (e.g., public and industry interests, sex and race). Where such differences obtain, it is expected that they be addressed either by redistributing the benefits, or by compensating for the harm. Such actions are, admittedly, more about how one goes about achieving environmental protection than defining what it actually is; but the concepts behind them are very important.

The imbalance of benefits and harm across national borders (such as trans-boundary pollution) is also relevant to the concept of distributive justice (or injustice); and the need for restitution or compensation for such pollution is relevant to the concept of retributive justice. It is also relevant to note that inherent in both concepts is the implicit ability to quantify damage to the environment, plus the moral need to restore it, or to compensate in some other way, when it has been damaged. The FASSET study therefore needs to keep this quantitative aspect in mind. A further analysis of these issues is being made, particularly with regard to drawing comparisons with other forms of pollution control.

## 2.2 International guidance

Many legal requirements already exist at national and international level with respect to the protection of the natural environment. The question is therefore really one of: how do we



demonstrate that we are providing the appropriate level of protection, in order to comply with existing or anticipated environmental legislation?

There are now many multi-lateral environmental agreements (MEAs) that legally frame the conservation aspects of environmental protection. Initially these were single-issue agreements, but the more recent ones have been more holistic in content and have been drawn up with the intention of supplementing – rather than replacing – earlier ones. Such agreements have a long history and reflect changing attitudes and improved scientific understanding. The first were essentially designed to regulate the exploitation of wildlife – such as fish, or even birds – and to maintain their economic utility, rather than to protect them for their own sake.

The focus of attention then turned to the need to protect endangered species, particularly from killing by any means, or from their removal from specific areas, or with respect to trading in them or in products derived from them. More recently such approaches have been supplemented by actions to protect the habitats of such species, particularly with regard to their breeding and feeding grounds and, where relevant, their feeding and resting grounds during migration. Indeed, the shift is now towards a more generalised protection of large environmental areas that are inclusive of the needs of both people and their ‘natural’ wildlife, rather than one of creating small and isolated pockets of the natural environment in order to protect specific aspects of fauna and flora – although both approaches still exist.

Many of the early MEAs were concerned with the marine environment and these also led to the creation of agreements with respect to ‘regional’ seas. There are now (in 2000) some nine ‘Regional Seas’ Conventions plus thirteen regional ‘Action Plans’.

A major shift away from ‘conservation’ and ‘sectoral’ pollution prevention agreements was that of the UN Conference on Environment and Development (UNCED) held in Rio de Janeiro in 1992 [United Nations, 1992]. A new Convention on Biological Diversity was also introduced that seeks to bring together issues relating to land use, fisheries management, and the needs of nature conservation, and to do so in new and sustainable ways. The Rio successor, the World Summit on Sustainable Development in Johannesburg, aimed to consolidate the intentions expressed within the Rio declaration and Agenda 21 into concrete implementation mechanisms incorporating targets and timetables. The final ‘Plan of Implementation’ [United Nations, 2002b], contained a number of sections relevant for FASSET including a long-debated section (22) on ‘chemicals’:

*‘Renew the commitment, as advanced in Agenda 21, to sound management of chemicals throughout their life cycle and of hazardous wastes for sustainable development and for the protection of human health and the environment, inter alia, aiming to achieve by 2020 that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures and science-based risk management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development, and support developing countries in strengthening their capacity for the sound management of chemicals and hazardous wastes by providing technical and financial assistance.’ [United Nations, 2002b]*



And a very specific section (33.bis) on radioactive wastes:

*'Governments, taking into account their national circumstances, are encouraged, recalling paragraph 8 of resolution GC (44)/RES/17 of the General Conference of the International Atomic Energy Agency (IAEA) and taking into account the very serious potential for environment and human health impacts of radioactive wastes, to make efforts to examine and further improve measures and internationally agreed regulations regarding safety, while stressing the importance of having effective liability mechanisms in place, relevant to international maritime transportation and other transboundary movement of radioactive material, radioactive waste and spent fuel, including, inter alia, arrangements for prior notification and consultations done in accordance with relevant international instruments.'* [United Nations, 2002b]

Such differences of opinion are to be expected at this level of 'legal' debate, and it is therefore important to note that the MEAs themselves are effectively 'soft' laws in that they are not, generally, strictly enforceable. Their implementation is therefore usually via national legislation that draws up the regulatory measures necessary to meet the objectives of the MEAs; these, in turn, usually result in 'hard' criminal law. Within the European Union the requirements of international conventions may be reflected within the Directives and other legal constraints set by the European Commission, and these requirements may then be enforced across all or any of the European Union member states.

As well as measures taken specifically to conserve particular species or ecological niches, there is an increasing trend to 'designate' large areas of land or sea in one way or another. The International Union for the Conservation of Nature (IUCN) uses the following classification system:

- scientific reserve, strict nature reserve;
- national park;
- natural monument, natural landmark;
- managed nature reserve, wildlife sanctuary; and
- protected landscape or seascape.

Within the framework of MEAs, the conventions that include provision for the designation of such protected areas in an international context are:

- Convention on Wetlands of International Importance (Ramsar, 1971);
- Convention on the Protection of the World Cultural and Natural Heritage (Paris, 1972); and
- Convention on the Conservation of Migratory Species of Wild Animals (Bonn, 1979).

Within the European Union, more specific measures now apply. The EC Wild Birds Directive [EC, 1979] not only protects a large number of birds themselves but areas upon which they are dependent – the Special Protection Areas (SPAs). Similarly, The EC Habitats Directive [EC, 1992], building upon the earlier Berne Convention on the Conservation of European Wildlife, identifies species and habitats of special interest that should be maintained or restored to favourable conservation status. Some 168 habitat types are listed, of which 42 are



considered to be a special responsibility of the EU because a significant part of their natural range occurs within the Community. The Directive requires the designation of Special Areas of Conservation (SACs). The SPAs plus the SACs are collectively referred to as a network of sites of Community interest – the Natura 2000 sites. The EC Habitats Directive [EC, 1992] also lists a very large number of animals and plants for which SACs need to be designated.

The aquatic environment has, for a long time, received special attention within Europe, as well as in a worldwide context. Apart from the many international conventions relating to pollution prevention of the marine environment generally – from dumping, from pollution from land-based sources at a regional level, to pollution from specific pollutants in any context – a considerable amount of conservation legislation has been introduced with respect to various forms of aquatic wildlife, particularly seals and whales, and of trade in their products. But of more specific interest here, however, are the specific measures that were taken via the EC's Freshwater Fish Directive [1978] to introduce water quality standards to ensure that different freshwater fish populations could thrive. Some of these standards (e.g. for Zn) were higher than those required of water to be abstracted for drinking water.

More recently many of the various EC water-related directives have been drawn together into a broad 'Water Framework' Directive [2000], based on the management of river basins and their adjacent marine areas. This Directive requires further designations to be made within member states with regard to surface waters – designations that embody concepts such as biological quality and ecological status.

Collectively, therefore, considerable areas of land (or sea) may be designated in one way or another with regard to their conservation status under trans-national (European) law, in addition to which many areas may be further designated at a national level. These are not small isolated areas: they can represent significant fractions (e.g. a quarter of Austria in 1994) of national territory, and these are continuing to grow. The full set of Natura 2000 sites, for example, has yet to be agreed. And across Europe a very large number of species of animals or plants, wherever they occur, are afforded protection under European or national law.

The interface between the requirements of all of these various 'protected habitats' and 'protected species', and the numerous human activities that can affect them is, admittedly, an ill thought out but still a developing one. The conservation legislation has largely provided for the protection of fauna and flora from 'harm' via direct human interference – the taking, maiming or killing of individual animals (including their unborn) and plants, or the deliberate physical destruction of their habitats. Their protection from 'pollution' has traditionally been catered for via legislation placed on emissions from specific industries, or on specific groups of 'hazardous' chemicals (e.g. pesticides and heavy-metals) via the setting of environmental quality standards.

The standards themselves may have been derived to protect fauna and flora (as is usually the case for the aquatic environment), or humans (as is usually the case for air quality), or both. With regard to the former, the standards have usually been derived on the basis of their 'toxicity' to 'batches' of test organisms. As such, they essentially apply to 'individuals'. Perhaps the best-known example is, again, that of the EC Freshwater Fish Directive [EC, 1978] where different standards apply to different 'types' of freshwater fish waters – salmonid and cyprinid. A lack of compliance here is based on failure to meet the relevant (chemical) standards.



But criminal offences for ‘causing or permitting’ pollution of aquatic environments that are subject to legislative control may also usually be brought merely by providing conclusive evidence that links a substance or activity with the death, distress, or injury of an unspecified number (or type) of fauna and flora. And increasingly the trend in ‘pollution prevention’ and ‘water management’ legislation is that of a more general requirement not to cause ‘harm’ and the need to take steps, in advance – by way of environmental impact assessments and so on – to reduce the chances of causing ‘harm’ to the environment. It is then for the Courts to adjudge whether or not ‘harm’ has been caused or permitted in any particular case or in any particular circumstances. Similarly, the requirements of conservation and habitat protection are based on the absence of the risk of ‘harm’, or of causing or permitting damage, or by the ‘absence’ of ‘pollutants’ – a criterion often met by reference to compliance with relevant environmental quality standards.

It is in this respect, therefore, that the control of radionuclides – based entirely on human criteria and standards – is inadequate. And the situation will get worse. Within the EU a number of requirements are arising that cannot easily be met without some form of direct assessment of the effects of radiation on wildlife. These include:

- The Oslo/Paris Convention (OSPARCOM)’s requirements (with respect to the prevention of pollution of the northeast Atlantic marine environment from land based sources) to ‘undertake the development of environmental quality criteria for the protection of the marine environment from adverse effects of radioactive substances and report on progress by year 2003’ (Sintra, 1998).
- The new EC [2000] Water Framework Directive to protect the ecology of surface waters with respect to classes or groups of pollutants and ‘priority hazardous substances’, which include ‘substances ... which have been proved to possess carcinogenic or mutagenic properties or properties which may affect ... reproduction or other endocrine related functions in or via the aquatic environment’.
- The need to meet conservation criteria that are required before consents can be issued for any activities that are potentially damaging with respect to SPAs and SACs (Natura 2000) sites, or other sites that are ‘listed’ in one way or another.



### **3. Systems for environmental assessment and management – brief overview and ‘synthesis’**

#### **3.1 Brief overview of ‘systems’ considered**

Documentation relevant to 20 pathway based ‘systems’ for environmental assessment and management, developed within 14 organisations have been considered and reviewed.

Nine of the pathway based ‘systems’ for environmental assessment that were reviewed deal directly with radioactive substances, and are summarised in Table 3-1. Furthermore, eleven systems for dealing with risks from hazardous substances have been considered and are briefly reviewed in Table 3-2.

These tables briefly review basic characteristics of the two types of systems considered. More details and comparisons of different aspects are provided in Deliverable 2: Part 2. A list of acronyms used in the two 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
USDOE	United States Department of Energy
USEPA	United States Environmental Protection Agency



**Table 3-1 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, 2001a].
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 <i>per se</i> 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 [Copplesstone <i>et al.</i> , 2001; Environment Agency, 2002].





**Table 3-1 (continued)**

System and organisation	Description
Risk assessment of releases of radionuclides from nuclear facilities (CNSC)	<p>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].</p>
Radiological Benchmarks for Screening Contaminants of Potential concern for Effects on Aquatic biota (ORNL)	<p>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].</p>
Ecological approach to establishing dose criteria to biota (SPA 'TYPHOON')	<p>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 doses 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 &amp; Kryshev, 1998].</p>
Method to assess environmental acceptability of releases of radionuclides from nuclear facilities (AECL)	<p>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 &gt; 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 &amp; Zach, 1993].</p>



**Table 3-2 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)	OSPAs 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 3-2 (continued)**

System and organisation	Description
Ecological soil screening guidance (USEPA)	<p>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].</p>
Ecotoxicological screening benchmarks (ORNL)	<p>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 plants, 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].</p>
Environmental risk limits (RIVM)	<p>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].</p>



**Table 3-2 (continued)**

System and organisation	Description
Environmental quality guidelines (CCME)	<p>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].</p>
Ambient water quality criteria for protection of aquatic life (USEPA)	<p>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 provide 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].</p>
Ecological quality objectives for the North Sea (OSPAR)	<p>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].</p>



Structurally, there are numerous similarities between the different systems and approaches described in Tables 3-1 and 3-2. For the purpose of establishing and defining the FASSET framework, it is useful to divide the environmental assessment and management system into five different steps (Figure 3-1):

- planning;
- problem formulation (to guide further assessment, i.e. to define the assessment context);
- assessment, using the appropriate methods according to the assessment context;
- risk characterisation; and
- decision and management.

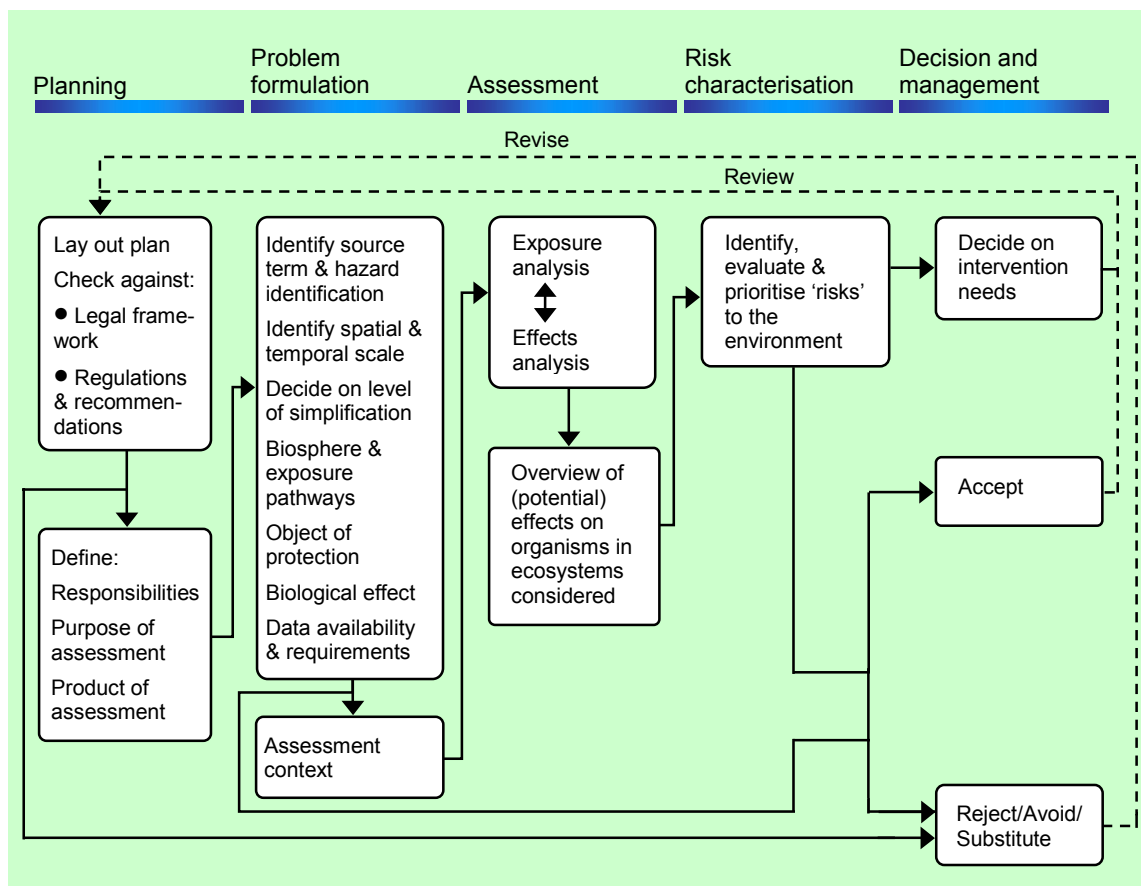


Figure 3-1 Elements in a stepwise environmental assessment and management procedure.

Although these steps can be arranged in a sequential manner, it is obvious that there are iterations and loops, so that, e.g., assessment conditions can be adjusted to the managerial options that are available, and *vice versa*. Also, each of these steps involves numerous considerations, including availability of methodologies and data, lack of which may delay further assessment or cause a proposed concept to fail. A brief description of the different steps follows below.



### 3.1.1 Planning

It is obvious that any plan for a project or major activity (including intervention) needs to be checked against the legal framework and existing regulations and recommendations. Any failure to do so may result in plans being rejected on the basis of lack of compliance or on the basis of lack in public confidence. The public view is solicited through a public consultation procedure that can be arranged in different ways. There is Community legislation that governs both the planning and the consultation processes, such as the Council Directives 85/337 and 97/11 [EC, 1985, 1997]. Public consultation is not only limited to the planning stage but is commonly involved until decision-making. However, it is important to bring early on the views of different 'stakeholders' as these may shape the assessment context.

Provided that the initial screening against legal questions and public perceptions does not call for rejection or revision of the plan in question, further consideration is required concerning the division of responsibilities (normally defined in legislation), purpose of further assessment, and product of further assessment. Normally, the final product would be an Environmental Impact Statement (EIS), where radiological consequences are one out of many environmental consequences to be considered. Hence, treatment of radiological consequences in an analogous manner to other environmental hazards facilitates comparisons and enables the radiological consequences to be considered within the context of the 'full' environmental impact.

### 3.1.2 Problem formulation

Provided that the purpose and product of further assessment have been defined, the problem formulation step is carried out in order to formulate the context for the assessment. A number of points need be considered. A systematic approach to the problem formulation step was done within the IAEA BIOMASS project, with special emphasis on waste repositories [IAEA, 2001; see also FASSET, 2001a]. For the purpose of FASSET, the essential parts to be addressed are:

- source term and hazard identification;
- the spatial and temporal scale;
- the appropriate level of simplification;
- the choice of 'biosphere' system and exposure pathways;
- object of protection;
- what biological effect(s) in the environment should be considered; and
- data availability and data requirements.

In recognition of the issues to be considered in formulating the assessment context, USEPA has recommended that 'problem formulation' should be used instead of the older 'hazard identification' to describe the pre-assessment stage. This can make the distinction between hazard identification (or analysis) and impact assessment somewhat blurred and, consequently, the process of formulation of the assessment context may actually lead to the rejection of a proposed concept before a full assessment of environmental effects has been undertaken. For example:

- The mere introduction to the environment of a hazardous substance in the environment could be deemed unjustifiable and any activity leading to the presence of such substances



should be rejected, avoided or substituted [see, e.g., the view of Greenpeace International toward hazardous substances in FASSET, 2002].

- If there are reasonable grounds to suspect that a substance released into the environment can lead to harmful effects, although there is lack of full scientific proof of such effects, an appeal to the *precautionary principle* may call for implementation of cost-effective measures to reduce, or eliminate, releases of such substances. However, such decisions may be reverted if further analysis reveals that the resulting risks are negligible or possible to manage.

### **3.1.3 Assessment, risk characterisation, and decision and management**

The assessment steps involve the analysis of dispersion and exposure through different pathways to specified biological endpoints, as well as an account of effects. This is often said to represent the ‘scientific’ part of the assessment and is usually carried out in as quantitative a way as possible. The analysis can include an estimation of the magnitude, spatial scale, duration and intensity of adverse consequences and their associated probabilities as well as a description of the cause and effect links, due to predicted or actual exposure.

Descriptions of risk characterisation vary between different systems, but the general objective is to collate and summarise the information obtained during the previous stages. The characterisation should include an estimation of the incidence (or probability) and severity (or magnitude) of the adverse effects likely to occur in an environmental compartment, as well as identification of uncertainties. It may include guidance on how to present information in order to illustrate how individuals or populations may be affected, or recommendations for synthesis for use in management decisions. In more evaluative definitions, characterisation is extended to a ranking or prioritising of risks, but this can be problematic as it often implies judgements on acceptability. For screening purposes, characterisation may involve comparison of risk estimates with previously derived standards. Since FASSET has explicitly stated that it does not aim to set standards or determine acceptability of risks, the present FASSET framework limits risk characterisation to a synthesis of the exposure and effects data obtained during risk assessment for the purpose of guiding management decisions. Risk evaluation is defined as the part of risk assessment and management concerned with questions of acceptability.

Decision and management involves evaluation of intervention needs or decisions on licensing conditions and acceptance of a proposed concept, and possibly the rejection, avoidance or substitution of a certain activity. As also indicated in Figure 3-1, a decision of acceptance normally requires recurrent reviews; a decision to reject/avoid/substitute can be reversed by revision of concept and renewed assessment. One example of the latter is the use of tiered approaches, where a low-tier conservative and simple assessment can be replaced by more complex, realistic and non-conservative assessments, if derived standards are exceeded in the initial, low-tier assessment.







## **4. Formulation of the FASSET assessment context**

As becomes evident from the review in Chapters 2 and 3, a number of societal, ecological and methodological considerations need to be made when formulating the assessment context. The legal background, including division of responsibilities and the public consultation procedure, is regulated by national law, in some cases after implementation of EU Directives into the national framework. Although societal concerns are important to FASSET, the framework focuses on biological (ecological) effects. The formulation phase builds up the FASSET assessment context, i.e. defines (see Figure 3-1 for comparison):

- the purpose of the assessment (Section 4.1);
- source term and hazard identification (Section 4.2);
- spatial and temporal scale; level of simplification (Section 4.3);
- biosphere system and exposure pathways to be considered (Section 4.4);
- object of protection (Section 4.5);
- biological effect (Section 4.6); and
- data availability and data requirements (Section 4.7).

Each of these factors will be considered in the sections indicated above. For each of them, a number of salient issues as well as a number of options will be discussed, on the basis of the review of existing systems in Deliverable 2: Part 2, and other sources, including the FASSET Technical Annex [FASSET, 2000] and External Forum [FASSET, 2002]. On the basis of this, a presentation is made of the choices made for further development within FASSET, and integration into the final framework.

### **4.1 Purpose of the assessment**

#### **4.1.1 Issues and options**

In a majority of the systems studied, assessment frameworks consider ‘what is safe’; in some cases the systems have developed to show compliance to certain standards. The standards are normally derived from criteria related to population viability (biological impact, loss of species from an affected area, etc.), and expressed in terms of concentrations or doses. The derivation of such standards requires that a pre-analysis has been performed of potential or actual effects at different levels of contamination, and the assessment eventually leads to comparison between an estimated or measured value, and the standard. Table 4-1 gives an overview of different purposes indicated for the different systems considered in the report.

The use of a standard in compliance assessments also allows for the use of a tiered approach, where extremely robust but simplified and conservative models can be used for a first screening for potential effects. This is a cost-effective approach to assessment that requires in-depth analysis only under circumstances where a first-tier, conservative assessment has indicated that standards may be exceeded. Such in-depth analyses may involve site-specific data on the ecosystem considered, as well as more detailed data on effects endpoints and dosimetry. Tiered approaches allows for increasing degrees of complexity and realism in the assessments, although this increase in realism is not always mirrored in the setting of standards.



**Table 4-1 Examples of different aims of existing schemes.**

<b>Aim</b>	<b>Organisation</b>
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], UK EA [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	UK EA [2002]
Assessment of the hazards of contaminants in various environmental media	IAEA [2000], USEPA [1998]

During the FASSET external Forum, a number of issues were raised relevant to the purpose of the framework:

- it should be as flexible as possible, to accommodate for different sources, exposure situations, disposal routes, etc.;
- it should as best possible be tuned to systems for assessing and managing risks from other hazardous substances, and at the same time not differ substantially from the system in place (and currently being revised) for radiological protection of humans;
- it should be user-friendly, manageable and understandable for implementers, regulators and society at large.

In addition, there were a number of detailed remarks, e.g., on the usefulness of a tiered approach. There was also the more general remark that management through assessment is a flawed approach; management should be based on hazard identification and subsequent substitution when hazard is identified. However, differences between hazard identification and impact assessment are often grounded in uncertainties as to the probabilities and consequences of effects. In a narrow sense, hazard identification can be limited to an acknowledgement that a situation (such as presence of a known pollutant in the environment) has a potential to bring about harm. For situations where the probability and magnitude of the potential effects are reasonably well established, hazard identification may be sufficient grounds to demand substitution. When this is not the case, a more detailed assessment of the effects of the hazard, as well as the proposed substitute, will need to be undertaken. Hazard identification and substitution would not be in conflict with the general assessment and management scheme outlined in Figure 3-1, but an assessment framework would still be needed to analyse possible effects of already existing contamination, as well as consequences of different disposal options.



#### **4.1.2 FASSET – definition of purpose of the assessment**

As reviewed above, and more extensively in Deliverable 2: Part 2, a variety of programmes aim at assessing the environmental impact against certain pre-defined standards, set to be environmentally ‘safe’. Thus, a definition of acceptability acts as the starting point for the assessments. This facilitates the use of simplified and conservative approaches to assessment, where the system is used as a compliance tool.

Unlike such systems, the FASSET project aims at providing a systematic approach for the determination of ‘realistic’ consequences in the environment. While the framework should allow for conclusions on environmental consequences, the acceptability of these consequences is to be judged outside the framework by decision-makers and stakeholders involved in the decision process. The emphasis will be on assessments of effects on non-human biota that require a realistic approach (without in-built over-conservatism) in order to:

- guide decision makers and the public in environmental issues;
- act as a basis for comparison of different options;
- act as a basis for the development of regulations and standards;
- act as a basis for the development of screening tools;
- act as a basis for the comparison of human health effects and environmental effects;
- be applicable to site-specific situations and monitoring programmes; and
- act as a basis for research, including development of tests.

#### ***Consequences of choices made***

The FASSET project recognises that a generic screening assessment may be an appropriate first step of an assessment. However, it is clear that:

- a realistic assessment will in certain cases be required to follow up a screening stage with more specific assessments (e.g. when the margin of safety in the screening assessment is insufficient);
- the screening methodology should be designed in such a way that it facilitates rather than hinders subsequent specific assessments (e.g. by using similar basic criteria for choice of endpoints); and
- several plausible contamination scenarios are site-specific by nature (e.g. nuclear facilities and waste repositories) which implies that there will be a strong demand to use valued components of the surrounding ecosystems in the risk assessment of such facilities (i.e., a site-specific assessment).

The FASSET approach integrates the effects analysis within the assessment, rather than targeting pre-specified levels set for compliance or general reasoning on ‘what is safe’ (Figure 4-1). This effects analysis will be aided by the FASSET Radiation Effects Database, which is currently being developed as a separate Deliverable of the FASSET project.



In this way, the framework should be capable of covering the following aspects:

- ongoing, past and future releases – the framework should enable the assessment of actual effects on the basis of measurements and direct observations in the environment, which makes it relevant to environmental monitoring, and should enable forecast of effects caused by future or potential releases of ionising contaminants;
- chronic and acute effects – the framework should allow for assessment of effects of exposures ranging from chronic low dose rate radiation to acute high doses following e.g. accidental releases (thus, the ranges of biological effects and environmental dose rates considered have to be wide); and
- it be appropriate for various purposes, e.g. licensing, demonstration of compliance, assessments of accidents, decisions concerning remediation – the framework has to be able to be used to support decision-making.

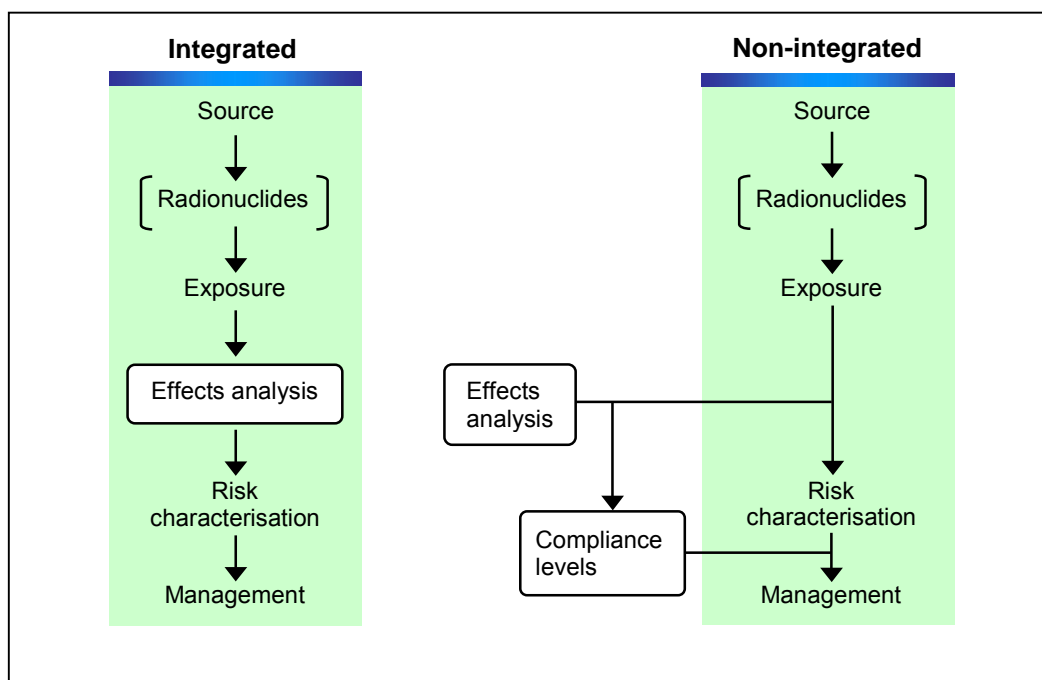


Figure 4-1 Position of the effects analysis in an assessment and management framework. The integrated (left) effects analysis is being pursued in FASSET.

### Limitations

The following limitations of the framework have been agreed:

- FASSET will not be a complete management tool but focus on the assessment context and the actual assessment; and
- FASSET will deal only with the effects of radioactive substances – the effects of other contaminants and synergistic effects will not be taken into account directly, though they may be dealt with as uncertainties.



A note of caution is also necessary with regard to the use of the term ‘realistic’ in connection to environmental assessments. Under many circumstances, the shortage of data would only make it possible to identify a plausible range of environmental effects at a certain level of environmental radiation. Any estimate of a ‘realistic’ effect must be accompanied by an equally realistic estimate of uncertainties, either these uncertainties are of fundamental nature (e.g. biological variability), or originates from lack of data. Thus, ‘realistic’ does not indicate high level of precision, but that the assessment is balanced, taking all uncertainties into account.

## **4.2 Source term and hazard identification**

### **4.2.1 Issues and options**

Within frameworks of ecological risk assessment, a screening methodology is often adopted to identify the contaminants of potential concern that may require further investigation. In general, such hazardous substances are selected on the basis of their persistence, the likelihood of them being translocated over long distances, and their potential for bioaccumulation. Participants in the External Forum only indirectly addressed source identification and hazard identification; comments on the possibility of considering different exposure pathways and disposal options are, however, relevant to the selection of radionuclides for further assessment. It can also be noted the view maintained by Greenpeace International that the hazard identification is the basis for managerial decisions (see Section 4.1.1).

The hazard identification starts with a broad approach, considering various nuclides, and their environmental fates and effects. An example of a rationale to perform the hazard identification, developed by IRSN, is summarised in Figure 4-2 and further described in Table 4-2.

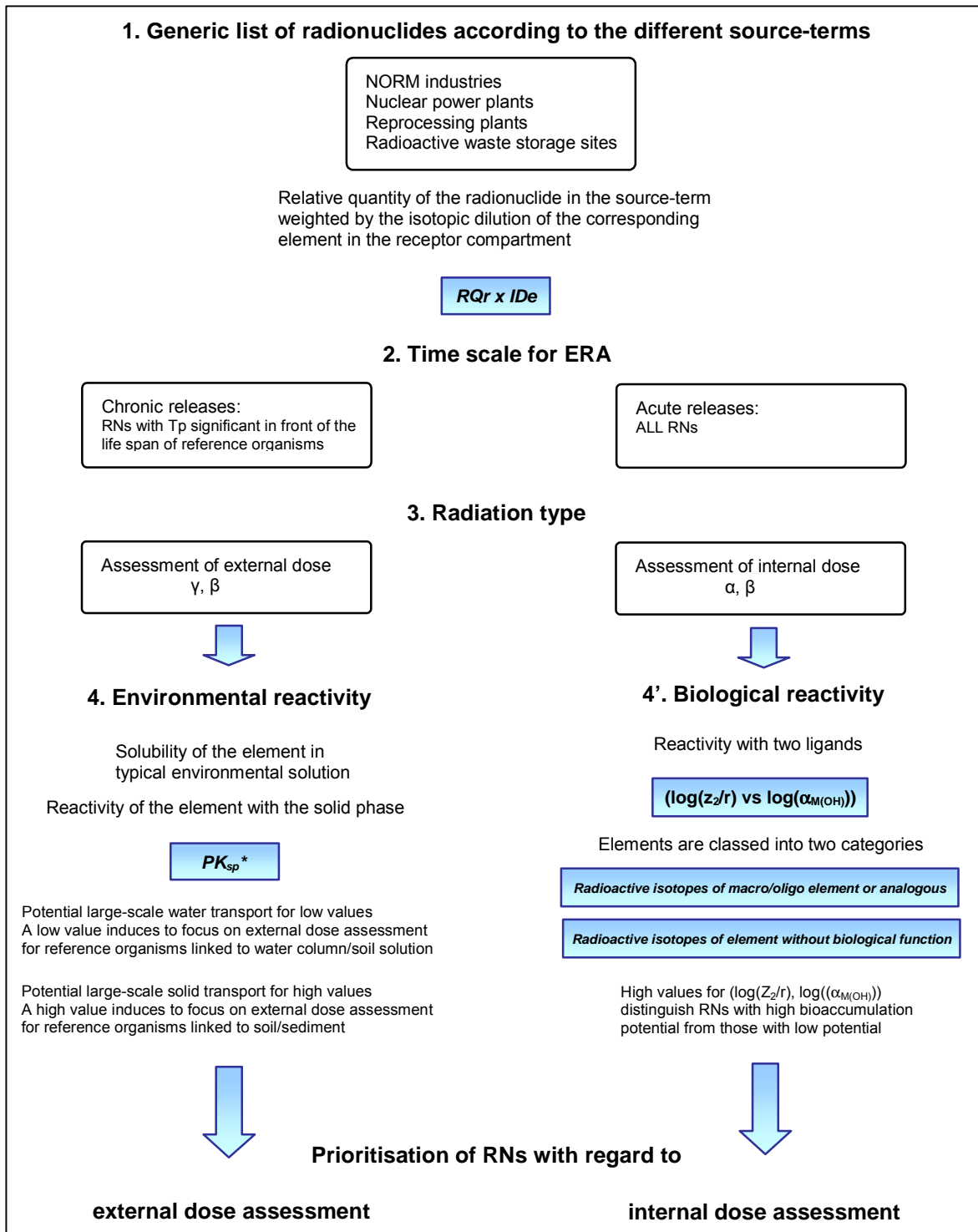


Figure 4-2 Flow chart for radionuclide screening (hazard identification). Example of rationale, developed by IRSN.



**Table 4-2 Criteria to be used in screening of radionuclides (hazard identification). Approach developed by IRSN.**

Type of criteria	Criterion
Source term	<p>Origin of radionuclide</p> <p>Selection of radionuclides based on knowledge of the source term; i.e. the radionuclides being processed/released/generated by the activity for which an assessment is made. If site-specific data are available, these can be used. Alternatively, generic information is available.</p> <p>For chronic releases, four categories of activity related to the nuclear fuel cycle have been identified;</p> <ul style="list-style-type: none"> <li>- ore-mining and other NORM industries,</li> <li>- electronuclear plants,</li> <li>- reprocessing plants,</li> <li>- storage sites for radioactive wastes.</li> </ul> <p>In France, default lists of radionuclides have been drawn up relevant to radioactive waste management and to effluents from nuclear power stations.</p>
Total quantity of radionuclide Relative contribution of the radionuclide Isotopic dilution	<p>For accidental releases, similar default lists could be used, but should also take into account the relative contribution of each radionuclide to the total released quantity (see below).</p> <p>Expressed as moles or Bq.</p> <p>The relative contribution to the total activity released. Site-specific or generic estimates (based on the nuclear site category) can be used.</p> <p>Isotopic dilution of the radionuclide in the receptor ecosystem, i.e. released radionuclide/(released radionuclide + stable isotope + known analogues).</p>
Physical parameters	<p>Half life</p> <p>The half-life is significant with respect to the time scale of interest.</p> <p>For chronic releases: The half life of the radionuclide or of its daughter radionuclides should be significant with respect to the lifespan of the reference organism, e.g. radionuclides with a <math>T_{1/2} &gt; 30</math> days would be relevant to the phytoplankton bloom in a lake.</p> <p>For acute releases, radionuclides with shorter half-lives should also be considered.</p> <p>The importance of radionuclides with respect to the type of radiation depends upon the way in which organisms are exposed; i.e. external radiation, internal radiation and chemo-toxicity.</p> <p>In the case of internal contamination, <math>\alpha</math>- and <math>\beta</math>-emitters are prioritised, as well as radionuclides with a chemotoxic mechanism.</p> <p>In the case of external contamination, <math>\gamma</math>- and <math>\beta</math>-emitters are prioritised.</p>
Type of radiation	



**Table 4-2 (continued)**

Type of criteria	Criterion
Environmental fate	<p data-bbox="371 286 451 1442">Solubility product, (<math>pK_{sp}</math>-value), calculated from available thermodynamic data on the formation of mineral precipitates and complexes in solution with the main inorganic ligands (i.e., ignoring at this stage the effect of organic ligands). The solubility product is calculated for four sets of environmental conditions:</p> <ul data-bbox="459 589 579 1442" style="list-style-type: none"> <li>- freshwater/soil solution, low hardness, oxic conditions (<math>pK_{sp}</math> for hydroxides,</li> <li>- freshwater/soil solution, high hardness, oxic conditions (<math>pK_{sp}</math> for carbonates),</li> <li>- estuarine and marine, oxic conditions (<math>pK_{sp}</math> for chlorides),</li> <li>- anoxic conditions, any ecosystem (<math>pK_{sp}</math> for sulphides).</li> </ul> <p data-bbox="587 488 619 1442">If data are available, a site-specific water composition may also be used to calculate <math>pK_{sp}</math>.</p> <p data-bbox="627 253 707 1442">Low <math>pK_{sp}</math>-values indicate high degree of transport in the liquid phase, affecting the scale of the spatial extent of the area to be covered by the risk assessment, and the choice of environments and organisms to be considered. Conversely, high <math>pK_{sp}</math> values indicate high reactivity with the solid phase (important sorption).</p>
Biological activity	<p data-bbox="730 1541 786 1800">Reaction with biological ligands (<math>\log(z^2/r)</math>)</p> <p data-bbox="786 1576 818 1800">Degree of hydrolysis</p> <p data-bbox="730 297 786 1442">Two variables considered together indicate biological speciation and allow a distinction to be made between radionuclides with a high bioaccumulation potential from those with low potential.</p> <p data-bbox="794 248 850 1442">Represents affinity for hydroxyl groups, thiols and/or phosphates. Depends on the tendency to hydrolyse (treated as a separate criteria), the net electric charge (<math>z</math>) and the ionic radius (<math>r</math>).</p> <p data-bbox="858 801 890 1442"><math>\log(\alpha_{M(OH)})</math>, where (<math>\alpha_{M(OH)}</math>) is the hydrolysis coefficient.</p>
Potential chemical toxicity	<p data-bbox="914 1541 970 1800">Allocation to two classes</p> <p data-bbox="914 271 970 1442">In order to take into account their potential chemical toxicity, radionuclides are then classed into two categories with regard to the biochemical properties:</p> <ol data-bbox="978 237 1066 1442" style="list-style-type: none"> <li>1. trace elements with competitor; involved in the constitution of living matter as macro-nutrients or oligo-elements by behavioural analogy with its stable isotope or biochemical analogy (known as competitor),</li> <li>2. elements without stable competitor having no known biological function to date.</li> </ol>





#### 4.2.2 FASSET – radionuclide selection

Full source characterisation and hazard identification, as indicated in Section 4.2.1, were not performed before the radionuclides, for which tools are to be developed within the FASSET project, were chosen. Instead, sub-sets of radionuclides were considered, on the basis of:

- radionuclides routinely considered in both regulatory assessments of waste disposal and releases from different facility types, and emergency planning for accidental releases;
- a range of environmental mobilities and biological uptake rates;
- both anthropogenic and natural radionuclides; and
- representatives of  $\alpha$ -,  $\beta$ - and  $\gamma$ -emitters.

The sub-set of radionuclides from 20 elements was selected for consideration within the development of the FASSET framework on the basis of these criteria and also data availability, see Table 4-3 [FASSET, 2001b]. The framework designed to assess these radionuclides should be sufficiently robust as to be readily applicable to the consideration of others.

FASSET intends to provide guidance/tools about how to choose radionuclides for an assessment. This will be developed further until the final Deliverable (D6) of the project, due autumn 2003, and consider elements of the IRSN approach outlined in Figure 4-2 and in Table 4-2. This may require the following information:

- total release of radioactivity and the relative contribution of each isotope;
- distribution of release over time;
- changes with time in the relative contribution of each isotope;
- isotopic dilution of radionuclides in the receptor ecosystems;
- physical parameters of radionuclides (i.e. half-life, type and energy of radiation);
- chemical form of the radionuclides;
- origin of radionuclides; the way in which radionuclides reach the receptor ecosystem, e.g. from below ground, as release directly to surface water, deposition to land or water surfaces; and
- background radionuclides.



**Table 4-3 Radionuclides selected for consideration within the FASSET project [FASSET, 2001b].**

Radionuclide (Element Group)	Principal Radio-isotopes ( $T_{1/2}$ )	Radiation type	Sources
H (Ia)	$^3\text{H}$ (12 y)	$\beta^-$	Cosmic, Fission, activation
C (IVb)	$^{14}\text{C}$ (5600 y)	$\beta^-$	Cosmic, activation
K (Ia)	$^{40}\text{K}$ ( $1.3 \times 10^9$ y)	$\beta^-, \gamma$	Primordial
Cl (VIIb, halogen)	$^{36}\text{Cl}$ ( $3.01 \times 10^5$ y)	$\epsilon, e^-$	Neutron activation
Ni (VIII, heavy metal)	$^{63}\text{Ni}$ (96 y) $^{59}\text{Ni}$ ( $7.5 \times 10^4$ )	$\beta^-$ $\beta^+, \epsilon$	Neutron activation
Sr (IIa)	$^{89}\text{Sr}$ (50.5 d) $^{90}\text{Sr}$ (28.5 y)	$\beta^-, \gamma$	Fission
Nb (Va)	$^{94}\text{Nb}$ ( $2.03 \times 10^4$ )	$\beta^-, \gamma, e^-$	
Tc (VIIa,)	$^{99}\text{Tc}$ ( $2.13 \times 10^5$ y)	$\beta^-, \gamma, e^-$	Fission
Ru (Group VIII, heavy metal)	$^{106}\text{Ru}$ (368 d)	$\beta^-$	Fission
I (VIIb, halogen)	$^{129}\text{I}$ ( $1.57 \times 10^7$ y) $^{131}\text{I}$ (8.04 d)	$\beta^-, \gamma, e^-$ $\beta^-, \gamma$	Fission
Cs (Ia)	$^{134}\text{Cs}$ (2.06 y) $^{137}\text{Cs}$ (30 y) $^{135}\text{Cs}$ ( $2.0 \times 10^5$ y)	$\beta^-, \beta^+, \gamma$ $\beta^-$ $\beta^-$	Fission
Po (VIb,)	$^{210}\text{Po}$ (138 d)	$\alpha, \gamma$	$^{238}\text{U}$ decay series
Pb (IVb, heavy metal)	$^{210}\text{Pb}$ (22 y)	$\beta^-, \gamma$	$^{238}\text{U}$ decay series
Ra (IIa)	$^{226}\text{Ra}$ (1600 y)	$\alpha, \gamma$	$^{238}\text{U}$ decay series
Th (Actinide series)	$^{227}\text{Th}$ (18.7 d) $^{228}\text{Th}$ (1.9 y) $^{230}\text{Th}$ ( $7.7 \times 10^4$ y) $^{231}\text{Th}$ (25.5 h) $^{232}\text{Th}$ ( $1.4 \times 10^{10}$ y) $^{234}\text{Th}$ (24.1 d)	$\alpha, \gamma, e^-$ $\alpha, \gamma$ $\alpha, \gamma, e^-$ $\beta^-, \gamma, e^-$ $\alpha, \gamma$ $\beta^-, \gamma, e^-$	Natural, U & Th series decay chains
U(Actinide series)	$^{234}\text{U}$ ( $2.45 \times 10^5$ y) $^{235}\text{U}$ ( $7.04 \times 10^8$ y) $^{238}\text{U}$ ( $4.47 \times 10^9$ y)	$\alpha, \gamma$ $\alpha$ $\alpha, e^-$	Natural
Pu (Actinide series)	$^{238}\text{Pu}$ (88 y) $^{239}\text{Pu}$ ( $2.4 \times 10^5$ y) $^{240}\text{Pu}$ ( $6.5 \times 10^3$ y) $^{241}\text{Pu}$ (14.4 y)	$\alpha, \beta^-, \gamma$ $\alpha, \gamma$ $\alpha, e^-$ $\alpha, \beta^-, \gamma$	Activation-Neutron capture
Am (Actinide series)	$^{241}\text{Am}$ (432 y)	$\alpha, \gamma$	Activation-Neutron capture decay of $^{241}\text{Pu}$
Np (Actinide series)	$^{237}\text{Np}$ ( $2.1 \times 10^6$ )	$\alpha, \gamma, e^-$	Activation-Neutron capture
Cm (Actinide series)	$^{242}\text{Cm}$ (163 d) $^{243}\text{Cm}$ (28.5 y) $^{244}\text{Cm}$ (18.1 y)	$\alpha, \gamma$ $\alpha, \gamma, \epsilon, e^-$ $\alpha, \gamma$	Activation-Neutron capture



## 4.3 Temporal and spatial scale

### 4.3.1 Issues and options

There are a number of aspects concerning the temporal scale that will determine the most appropriate methodology for further assessments of radionuclide transfer and exposure. These include:

- whether the discharge into the environment is at one given point in time (e.g. as for accidental releases);
- whether the discharge is continuous;
- whether steady state can be assumed; and
- whether persistence of the discharge is such (e.g. in the case of repositories for high-level and long-lived waste) that the ecosystems affected are likely to undergo physical or ecological changes or transitions.

Spatial considerations may be very specific to a particular assessment, whether site-specific or generic. Although dispersion and transport models are not being developed within FASSET, the interface with these models is important, as they will provide the basis for the definition of the area to be included in the assessment.

The External Forum did not identify any issues that were strictly coupled to the temporal and spatial aspects of the assessment context. The general issues of flexibility, as mentioned in Sections 4.1.2 and 4.2.2, have implications on the spatial and temporal scales.

### 4.3.2 FASSET – temporal and spatial scales

It is apparent from the discussion on the purpose of FASSET (see Section 4.1.2) that the framework must be able to consider:

- acute and chronic exposures – which implies that the assessment will have to consider both long- and short-term effects; and
- ongoing, past and future releases – which implies that different time and spatial scales will need to be considered.

The need to consider both acute and chronic releases results in different input quantities being required for calculation of transfer in the different environmental compartments. For instance, in terrestrial systems the framework will need to be able to predict transfer from inputs as  $\text{Bq m}^{-2}$  (acute deposition) and  $\text{Bq m}^{-2} \text{ y}^{-1}$  (chronic deposition). In the case of aquatic ecosystems inputs may be  $\text{Bq y}^{-1}$  (chronic input),  $\text{Bq}$  (acute release) or  $\text{Bq m}^{-2}$  (accidental deposition).

It should be noted that no specific consideration of changes in the biosphere with time, or of the transition between one biosphere state and another, is made within the FASSET framework. However, FASSET should be applicable to future biosphere states (assumed and predicted) or past situations.



## 4.4 Biosphere system description, including level of simplification

### 4.4.1 Issues and options

There is a large number of factors within an assessment framework that can be treated with different levels of simplification depending upon the assessment requirement. This usually means that the assessments become more conservative as they become simpler (depending on the assessment purpose). The level of simplification becomes an extremely important factor in the choice of ‘assessment biosphere’, considering the innumerable interactions within natural ecosystems. Examples of extreme simplification are to assume immersion in undiluted discharge in air or water streams, or maximising external and internal exposure by assuming that the target organism is infinitely small and infinitely large respectively. In all cases, there is a trade-off between the information value and the difficulties in performing the assessment, for instance simplifications may be required because of data gaps. Similarly, whilst a full site-specific approach may provide the most information it will be at highest costs.

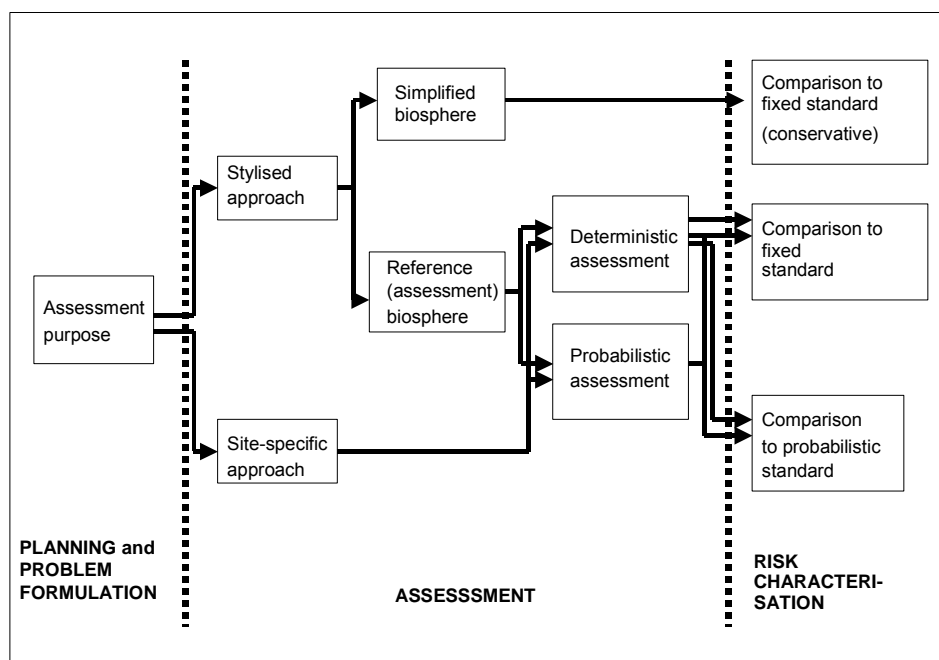


Figure 4-3 View of assessment procedures incorporating different approaches to simplification.

Figure 4-3 illustrates some of the choices relevant to the level of simplification and the choice of assessment biosphere (note that *biosphere* is used throughout the text – although other terms like, e.g., *ecosystem* or *habitat* may function equally well, *biosphere* is used since it is general and well established in radioactive waste management). The figure distinguishes between:

- The stylised approach – in which a number of representations are introduced relevant to one or several factors, e.g. the radionuclide transfer and the geometries and exposure situations of radiation targets. The stylised approach can be (although somewhat arbitrarily) divided into either
  - a simplified biosphere, e.g. tier one of multi-tiered systems, or



- an assessment biosphere in which generic (e.g. based on lists of biosphere features, events and processes, FEPs), or generalised (when data are available) but less simplified and conservative parameter values are used.
- The full site-specific approach, including analysis of the actual ecosystems, in terms of, e.g., the organisms therein, their interactions and productivity.

Figure 4-3 also illustrates how the assessment outcome may be in the form of discrete numbers (such as averages) or as a probability distribution. This relates to data availability (See Section 4.7) and to uncertainties. Also environmental standards may be in the form of distributions, thus allowing for computation of environmental ‘risk’ in a probabilistic fashion. For the simplified, ‘tier one-type’ assessments, only deterministic assessments would be relevant.

The audience of the External Forum addressed this aspect of the assessment context only in general terms. The concepts of reference biosphere and reference organisms were mentioned as possible means of simplifying the assessment while retaining substantial information value. Also the urge for a flexible assessment tool that can be applied to a multitude of sources and discharge conditions necessitate the use of a ‘generic’ approach.

#### **4.4.2 FASSET – biosphere system description including level of simplification**

Already from the discussion of assessment purpose, source term and hazard identification, and spatial and temporal scales, it is clear that the framework built up within FASSET needs to use an approach that optimises information value relative to data requirements, costs and managerial aspects. During the 3<sup>rd</sup> FASSET Workshop (April 2002), it was argued that, in order to fulfill the purpose of FASSET:

- FASSET will provide ‘realistic assessments’ and will not be overly conservative – a precautionary approach (the adoption of which is a management decision outside the FASSET framework) can be based on this;
- FASSET will, as far as possible, be based on generalised ecosystem-specific empirical data;
- inevitable data gaps will be identified and filled when possible on the basis of modelling and expert judgement (including interpretation of FASSET databases); and
- reference organisms will be used as a basis for modelling (using simplified models where appropriate) and to pool data – the use of reference organisms is coherent with the approach used by ICRP (reference man).

The selection of biosphere systems was predefined from the outset of the project. Thus, generalised data and models (rather than FEP-based assessment biospheres) will be used, to the extent available, relevant to:

- the terrestrial ecosystem:
  - forests;
  - semi-natural pastures and heath lands;
  - agricultural ecosystems; and
  - wetlands.
- the aquatic ecosystem:
  - fresh-water ecosystems;
  - brackish ecosystems; and
  - marine ecosystems.

A further aspect of simplification – the reference organism concept – will be dealt with in Section 4.5.



## 4.5 Object of protection

### 4.5.1 Issues and options

#### *General considerations*

Programmes for environmental assessment or management generally focus on the maintenance of population integrity, to avoid or limit changes in population characteristics that would affect ecosystem characteristics and functions. This does not imply that ecosystems can be preserved in a state of no change; ecosystem characteristics are bound to change for natural reasons but changes caused by anthropogenic input of contaminants are considered undesirable.

Ideally, the selection of the object of protection identifies the ecologically relevant target for assessment calculations, which combined with the effects analysis (see Section 4.6) forms the basis for estimates of actual or potential impact on non-human biota. The selection of the object of protection is thus vital to the identification of the measurement endpoints (the measured or predicted values that the assessment produce) and the assessment endpoints (the effects inferred from the measurements or predictions and which the framework is designed to study).

The selection of the organisms or ecosystem features to be studied in an assessment, and the selection of the quantities to be predicted or measured in order to study the degree of protection, is again carried out differently in different assessment systems. The endpoints to be studied can be:

- specified by national legislation – e.g. rare or endangered species, or species of cultural or economic value;
- specified by the assessment system – the specification is usually justified, e.g. a number of criteria are given to pin-point organisms and ecosystem features to be studied;
- chosen for each individual assessment – guidance as to how to choose the organisms to be studied is often given, e.g. sets of criteria for application in generic or specific assessment; and
- identified by the purpose of the assessment – e.g. in a particular component of the recipient environment, such as downstream fisheries.

#### *Criteria for choice of assessment endpoints*

Criteria for identifying ecological assessment endpoints have been the subject of substantial scientific debate [see e.g., Cairns, 1995; Cairns & Niederlehner, 1992; Calow, 1994; Jones & Kaly, 1996; Kelly & Harwell, 1989]. An array of criteria has been proposed to characterize the ‘ideal’ endpoint. Criteria used in the justification/guidance to the choice of organisms or ecosystem features are most often:

- importance to the structure and function of the community;
- importance to issue of concern to humans;
- expected to have a high degree of exposure;
- displaying a high degree of sensitivity (including variations between stages in the life cycle and between tissues and organs); and
- relevance to management issues.



The different proposed criteria often represent extremes of biological continua (such as sensitivity, abundance and longevity), where the selection of endpoints from either extreme can be advocated. For example, one can support an argument for selecting the most abundant species, those that are moderately common or the least abundant species in a community. In fact, if all advice were taken on which species to choose, one would have to examine virtually all species present in some communities. Consequently, there is a need to reduce the number of selection criteria, and to reduce the importance of double-ended criteria.

A common selection criterion in ecological risk assessments has been to try to identify the most sensitive species in an ecosystem. This search for the most sensitive species is based on the observation that the sensitivity of organisms to chemical stress varies considerably, from two up to seven orders of magnitude, and thereby the response of a single arbitrarily chosen organism will not protect all other organisms. Although it is possible to extrapolate from a response of one species to the response of another closely related species, the reasoning behind the alleged ability to do so is far from robust. In most cases lack of knowledge is the major problem. Furthermore, since the relative sensitivity of different organisms varies depending on environmental conditions and the type of toxicant, it might even be theoretically impossible to identify the most sensitive species for any given contaminant.

A further conclusion that can be drawn based on the ecotoxicological literature is that no single organism, taxon or ecosystem process can on its own be used to guard against detrimental ecological effects. Instead there is a need to consider a variety of hierarchical levels, a variety of taxa from a number of habitats and functional groups. The proper length of the list of assessment organisms and endpoints can only be defined in the context of the goals, the impacted ecosystem and the scales of the specific assessment.

Another line of argument is that the most useful criteria to apply in order to reduce the measures of ecosystem health down to a manageable level is their relevance to human concern. These 'human concerns' include endpoints of ecological, economic, cultural or aesthetic value. This would secure that the environmental risk can be evaluated in a manner that supports risk management.

Naturally, other selection criteria such as accessibility to measurement and sensitivity are important and need to be considered to be able to design cost-efficient assessments. Therefore, from a managerial point of view, it can be observed that:

- endpoint selection should be based on the goals of the assessment and what is to be protected; and
- there is a danger of having a rigid set of criteria built into the regulatory framework, since the optimal set of organisms will vary considerably depending on objectives, and specific ecosystem and impact of interest.

### ***The use of representations for calculation purposes***

The organisms or ecosystem features to be studied can be of different types:

- theoretical – e.g. distribution based systems look at a certain proportion of all species showing a certain type of effect;
- generic – certain organism 'types' are adopted in many assessment systems, e.g. a pelagic fish or an aquatic macrophyte (generic organisms are often used in order to allow



extrapolation of data from one species to organisms relevant to the assessment; generic organisms, defined in terms of their geometry, have also been used to simplify dose calculations for biota);

- specific – species or features of the ecosystem, in the case of site-specific assessments where data availability is good, or data can be collected (e.g. key species or key ecosystem processes such as keystone predators, soil respiration, nitrogen fixation and decomposition).

Whether a full site-specific assessment is performed or not, there is, in most if not all cases, a need for the development of calculation tools that make use of ‘images’ of organisms, to serve in calculations of external and internal exposure of various organisms. In human radiological protection, such images – known as the reference man – has been used for several decades to assist calculation of exposure. A similar concept for representation of non-human biota in exposure calculations may be required, e.g. reference flora and fauna (or reference organisms – as defined in Section 4.5.2) as proposed by Pentreath and others [Pentreath, 1999; Strand *et al.*, 2000; Pentreath & Woodhead, 2001]. In view of the enormous diversity of natural ecosystems, there is a need to limit the number of representations while not losing information value, which reflects on the reasoning in Section 4.4. However, as suggested by Pentreath [2002a, 2002b], secondary reference organisms more adjusted to a particular assessment situation, may be derived from a fairly limited number of primary reference organisms.

There are two considerations that have to be made in the selection of reference organisms:

- the criteria necessary to select them; and
- the manner by which to describe them, taxonomically, once selected.

With regard to the former, some suggestions have already been made [Pentreath & Woodhead, 2001]. Again, one might like to select those organisms known to be particularly sensitive to radiation or those that are vital components of a particular ecological community. But if one had the extensive knowledge to select the reference organisms on these criteria alone, then one would never need to resort to the approach that FASSET is attempting in the first place (see also discussion on criteria for endpoint selection above). When considering candidate reference organisms one therefore has to be pragmatic and also take note of:

- the extent to which they are considered to be representative organisms of a particular ecosystem;
- the extent to which they are likely to be exposed to radiation (or of any other hazardous substance in general) from a range of radionuclides in a given situation, both as a result of bioaccumulation and the nature of their surroundings, and because of their overall lifespan, lifecycle and general biology;
- the stage(s) in their life-cycle likely to be of most relevance for evaluating total dose or dose-rate, and of producing different types of dose-effect responses;
- the extent to which their exposure to radiation can be modelled using relatively simple geometries;
- the chances of being able to identify any effects at the level of the individual organism that could be related to radiation exposure;





- the amount of radiobiological information that is already available on them, including data on probable radiation effects;
- their amenability to future research in order to obtain the necessary data on radiation effects; and
- most importantly – for a project and system like FASSET which is a tool to aid decision makers – the extent to which they have some form of public or political resonance, so that both decision makers and the general public at large are likely to know what these organisms actually are, in common language.

A substantial amount of arguments were raised during the External Forum regarding the use of reference organisms. These ranged from support to some scepticism – that the assessor would most likely prefer to work on real organisms than on representations. However, arguments were also raised to keep the number of reference organisms small, i.e. to start with < 10, and then derive secondary reference organisms as necessary. It should also be noted that the use of reference organisms is intended to – amongst other uses – facilitate exposure analysis including the dosimetric conversion. It should also be borne in mind that there are movements in society that would consider the introduction of any anthropogenic and/or hazardous substance as unjustified on ethical grounds, and thus not recognise biological endpoints as relevant. Again, however, this lies outside the scope of the FASSET project that, from the outset, has targeted the biological impact of radiation.

#### **4.5.2 FASSET – Object of protection**

##### ***Reference organisms***

For the purpose of FASSET, the reference organism approach has been selected on the grounds that it makes possible pooling of diverse information on exposure and effects for a range of organisms, while still keeping the number of models and conversion factors necessary for assessment to a minimum. Thus, the reference organism approach contribute to make the framework manageable. Through the successive FASSET workshops, a definition of the reference organism has been agreed:

*‘a series of entities that provide a basis for the estimation of radiation dose rates to a range of organisms which are typical, or representative, of a contaminated environment. These estimates, in turn, would provide a basis for assessing the likelihood and degree of radiation effects’.*

Essentially, the reference organism will be identified as a biological component of ecological significance, to which geometric representations are fitted for calculation purposes. The biological component plus its geometric representation makes up the reference organism. A preliminary list of biological components (termed ‘candidate reference organisms’) was drawn up on the basis of radionuclide transfer (radioecological sensitivity) data for the different ecosystems considered [FASSET, 2001b]. It has subsequently been agreed, during the 4<sup>th</sup> FASSET workshop, in October 2002, that the project will retain all these, whereas the work on dosimetry carried out within WP 1 of the project will fit appropriate calculation tools to these biological components.



The factors determining the radioecological sensitivity are:

- whether the habitat or feeding habits of the organism are likely to maximize its potential exposure to radionuclides, based on an understanding of the distribution of the different radionuclides within the ecosystem;
- whether the organism exhibits radionuclide-specific bioaccumulation which is likely to maximize internal radionuclide exposures in particular circumstances; and
- whether the position of the organism within the food chain (e.g. top predator) is such that biomagnification of radionuclides up the food chain may lead to enhanced accumulation.

Table 4-4 lists the biological components or ‘candidate reference organisms’ under consideration. For the aquatic environment it has been considered appropriate to distinguish between sediment and water column in the selection of organisms; for the terrestrial environments it was considered appropriate to distinguish between soil, herbaceous layer and canopy.

**Table 4-4 Biological components (‘candidate reference organisms’) identified from an exposure pathways analysis.**

<b>Terrestrial ecosystems</b>	<b>Aquatic ecosystems</b>
<b><i>Soil</i></b>	<b><i>Sediment</i></b>
Soil micro-organisms	Benthic bacteria
Soil invertebrates, ‘worms’	Benthic invertebrates, ‘worm’
Plants and fungi	Molluscs
Burrowing mammals	Crustaceans
	Vascular plants
<b><i>Herbaceous layer</i></b>	Amphibians
Bryophytes	Fish
Grasses, herbs and crops	Fish eggs
Shrubs	Wading birds
Above ground invertebrates	Sea mammals
Herbivorous mammals	
Carnivorous mammals	<b><i>Water column</i></b>
Vertebrate eggs	Phytoplankton
	Zooplankton
<b><i>Canopy</i></b>	Macroalgae
Trees	Fish
Invertebrates	Sea mammals

The final definition of reference organisms will be an iterative process taking into account of dosimetric considerations. Work on the specification of geometries is under way in WP 1, and an example of such geometries selected for various animals is shown in Table 4-5.



**Table 4-5 Characteristic of reference organisms for the estimation of external exposures.**

Targets	Example	Shape	Length, cm	Diameter, cm	Location relative to soil surface, cm	Shielding layer, cm
Soil invertebrate	earthworm	cylinder		0.5	0, -5, -20	0
Small burrowing mammal	mole	ellipsoid	10	5	0, -15, -25, -35	0.1
	mouse					
Reptile	snake	cylinder	100	3	0, -25	0
	rabbit					
Herbivorous mammal	roe deer		60	27	40	0.3
	cattle		150	70	50	
	fox		30	12	30	
Carnivorous mammal	wolf	ellipsoid	60	27	20	0.1
	pigeon		10	3	300	
Herbivorous bird			30	12	1 000	0.3

## 4.6 Defining the effects analysis

### 4.6.1 Issues and options

Any system for assessing the impact of a contaminant on the environment necessitates an effects analysis. Either the effects analysis can be a part of the assessment framework. It can also be performed separately to derive permissible levels of exposure in the environment, mainly for the purpose of compliance assessments (see Section 4.1.1 and Figure 4-1). In either case, the effects analysis must:

- identify relevant biological effects for assessing impact (relationship between exposure and effect; dose-effect relationship);
- identify the severity of specific effects at different levels of exposure (relationship between exposure and degree of response; dose-response relationship);
- be relevant for the protective aim, which usually is to maintain population viability so that contaminants do not provoke additional changes in ecosystem structure and function; and
- be manageable, i.e. the effects information should be organised into categories that are relevant for the purpose of the impact assessment, and its quality should be checked.

A general complication in the effects analysis is that the direct effect of an environmental contaminant may occur at, e.g., the molecular or cellular level, and that these effects 'propagate' to higher hierarchical levels where they become observable as disease in an individual organism or loss of population viability. For the purpose of environmental protection, the assumption is often made that an effect must be observed at the level of the individual organism in order to provoke effects at higher hierarchical levels, such as the population. Although this bottom-up approach is both appealingly pragmatic and is based on simple and sound logic, there has in previous ecotoxicological risk assessment frameworks



been a concern that small, statistically undetectable effects on individual life-history traits could be magnified into ecologically relevant effects at the population level and above.

In response to this concern, Forbes & Calow [2002] reviewed the available literature and Forbes *et al.* [2001] performed population simulations. The conclusion of these studies was that individual level responses (e.g. morbidity and reproduction) in most cases were protective of population level effects. Some issues can, however, be identified where lack of knowledge currently adds to the uncertainty connected with extrapolating from individual level traits to higher hierarchical levels:

- The extrapolation from individual traits to the population is often based on the most sensitive life stage paradigm, which assumes that the population will be protected if the most sensitive stage of the life history is protected. However, the most sensitive life stage might not be the most important stage for maintaining population viability. For example, in species that produce a large number of offspring, contaminant effects on other stages of the life cycle will be more important for the population even if larval stages are most sensitive to contaminants. A further complication is that contaminant sensitivity of various stages of the life cycle also may vary among toxicants as well as among species.
- Density dependent factors (e.g. increased reproduction at lower population densities) are generally believed to render populations less sensitive than the individual organism. But theoretical and empirical studies have also indicated that the opposite can be true (i.e. more severe effects at the population level) [Forbes *et al.*, 2001]. Based on current knowledge it is therefore hard to make general conclusions on how density dependence influences extrapolations from individuals to populations.
- Theoretical models have indicated that certain types of population dynamic features may result in increased sensitivity at the population level (e.g. rapidly growing populations, and in small populations as described below).
- Especially in small isolated populations increased mutation rates due to chemical contamination or radiation may lead to reduced fitness (i.e. mutation load), and potentially to population decline and extinction on purely genetic grounds (i.e. mutational meltdown). In this detrimental process other factors such as environmental and demographic instability can act as accelerating factors.
- When extrapolating from ecosystem structure to function the presence of key species or low redundancies within functional groups may lead to severe functional effects with the loss of especially important species. If such ecological knowledge exists it can increase the reliability of the assessment, especially in site-specific assessments. Most of the time, however, we will not know the identity of the keystone species. Therefore, protection of species in general is vital so that key species are not lost.

To summarise, even though several factors complicate simple extrapolation of individual level effects to populations, current knowledge supports the conclusion that, in general, individual level effects are protective of population level effects. Further, it does not seem warranted to use additional safety factors during the risk characterisation phase of the risk assessment to account for these remaining extrapolation uncertainties.

A number of aspects of particular relevance to the effects analysis was discussed during the FASSET External Forum. The use of the radiation dose or dose rate is widely recognised as relevant quantities when relating effects to environmental radiation. However, there still



remain discussions on how relevant quantities and units should be derived for non-human biota. Furthermore, there are substantial gaps in the knowledge on relevant effects in many organisms groups, as well as discrepancies between the ways effects data have been obtained – partly as a consequence of lack of agreed test procedures.

As to the effects, a number of aspects were considered, including the need to be able to scale effects data to higher levels of biological organisation and that effects (and targets) should be meaningful and understandable from the public perception point of view.

#### **4.6.2 FASSET approach to effects analysis**

##### *Choice of radiation dose (rate) as basis for relating exposure to effects*

Formulating the analysis of effects and responses within FASSET is based on knowledge of the radiation dose rate, or dose in the case of acute effects. The environmental concentration of a particular radionuclide is the ‘mirror image’ of the radiation dose. However, the degree of biological effect is related to the radiation dose (rate) in a manner that varies not only with the internal and external concentration of the radionuclide, but also depends on the nature of the radionuclide. This is expressed through different degrees of biological effectiveness. For practical purposes, the effectiveness may be expressed as the relative biological effectiveness, RBE. These aspects are subject to studies within the FASSET project and considered in FASSET Deliverable 4 (due April 2003).

The use of dose (rate) as the basis for the effects analysis requires the development of dosimetric tools for the different external and internal exposure geometries that are relevant for different organisms occupying different habitats (see further Section 4.5.2). The effects analysis may select a range of targets that might be of significance for the purpose of dosimetry, possibly including:

- the whole body, if there is no information on the differential distribution of radionuclides within the organism (this would be relevant for mortality, including stochastic mutation rates in somatic tissues, and morbidity);
- the gonads (fertility and heritable mutations) and the meristems in plants (both for mortality, damage to growth potential, and the gamete bearing tissues);
- externally developing embryos and seeds; and
- specific tissues or organs if data are available.

##### *The individual organism as target level in biological hierarchy*

While the FASSET approach does not deviate from the general goal of protecting populations and ecosystems, FASSET has taken the direct view that assessments should centre on individual organisms. This decision is based on the simple grounds that effects on higher hierarchical levels such as populations and ecosystems must first be manifest at the level of individual organisms. There are, as far as current knowledge goes, no indications that radiation can affect higher organisational levels directly, without being observable at the individual level. However, it needs to be recognised that this is presently a pragmatic approach supported by logic reasoning, but – as reviewed above – there may be scientific



reasons to maintain a critical attitude to the generality of this view, as well as to acknowledge the difficulties in scaling effects from lower to higher hierarchical levels.

### *The use of reference organisms to pool effects data*

The reference organism concept allows for pooling of effects data and thus provides a broader basis for assessing impacts, than if the impact assessment has to rely on a single organism for which few if any data are available.

A list of factors may be considered for use as a basis for the definition of reference organisms, on the basis of effects data:

- Metabolism and physiology – This allows consideration of the potential of the organisms to accumulate radionuclides. It has been concluded that the use of metabolic/physiological models of radionuclide accumulation for input to the dosimetry models is probably an unwarranted degree of sophistication for the FASSET system. It is proposed that equilibrium concentration factors, transfer factors and  $K_d$  should be used.
- Trophic level – This is probably relatively unimportant for  $\gamma$ -emitters but is a significant determinant for  $\alpha$ - and  $\beta$ -emitters. It allows consideration of organism mobility, life cycle and lifespan.
- Reproductive strategy – This will include considerations of the influence of the number of offspring on ecological sensitivity, asexual and clonal reproduction, and life cycle.
- Biological complexity – This will allow account to be taken of taxonomy and it will be necessary to explain what level, e.g., the family, the reference organism represents.

### *The choice of types of effect and their relationship to specific effects*

Because all the observed endpoints at the individual level could be presumed to have a consequence at the population level, FASSET decided to group these endpoints into four types of effect that have significance at the population level. It is assumed that these four ‘umbrella effects’ include all the observed effects at the individual level.

- mortality – the death of organisms directly attributable to radiation;
- morbidity – loss of functional capacities generally manifested as reduced ‘fitness’, which may render the organisms less competitive and more susceptible to other stressors, thus reducing the life span;
- reduced reproductive success – any effect that would reduce the number of offspring;
- cytogenetic effects – mutations, etc.

It is recognised that these four categories of effect are not mutually exclusive, e.g., effects leading to changes in morbidity may simply result in a change in the age-dependent death rate, and an increase in mutation rate may lead to changes in reproductive success. However, they provide a convenient means of summarising the available information in a structured way that is meaningful within the objectives of the FASSET project.

This means that a number of specific effects may contribute to each group of effect, but also that some specific effects may be included in more than one effect group. This relationship is illustrated by a number of examples given in Table 4-6.



**Table 4-6 Examples of relationships between specific effects and umbrella effects.**

Type of effect	Specific effect
Mortality	Includes the stochastic effect of somatic mutation and its possible consequence of cancer induction as well as deterministic effects in particular tissues or organs that would change the age-dependent death rate.
Morbidity	Includes growth rate, effects on the immune system, the behavioural consequences of damage to the central nervous system from radiation exposure in the developing embryo.
Reduced reproductive success	Including fertility (the production of functional gametes) and fecundity (the survival of the embryo through development to an entity separate from its parents).
Cytogenetic effects	Indicators of mutation induction in germ and somatic cells, of potential consequence for the affected generation and its offspring.

***Organisation of effects data – the FASSET Radiation Effects Database***

The FASSET framework integrates the effects analysis within the assessment procedure. A solution was therefore needed for the selection and organisation of existing effects data. The problem of organising, evaluating and integrating effects information within the framework is paramount. A total number of 234 725 references in the last 50 years on radiation effects were found after searching two databases for information – yet, none of these consider morbidity in wildlife categories such as soil fauna, amphibians and reptiles. Thus, the wealth of effects data contrasts sharply with data gaps for certain combinations of effects and wildlife of vital importance to FASSET.

A structured database of radiation effects, the ‘FASSET Radiation Effects Database’, is being developed within FASSET WP 3, and will serve as a basis for the analysis of radiation effects. A number of exclusion criteria need be applied, *inter alia*:

- the information concentrates on the most relevant papers due to the vast quantity of published papers (for certain organisms), using informed judgement on the requirements of the FASSET project, and data such as dose, dose rate and umbrella effect;
- note references that cannot be accessed;
- collection of data back to 1945 – due to problems in accessing the earlier literature; and
- need to be open and transparent in collation exercise, which will be as important as the information itself.

The database considers the four relevant umbrella effects described previously, and a number of wildlife groups, those being: fungi, plants, moss/lichen, bacteria, zooplankton, aquatic plants, amphibians, reptiles, fish, mammals, soil fauna, crustaceans, molluscs, birds, insects, and aquatic invertebrates.

The selection of wildlife groups is from a taxonomic point of view arbitrary. It is principally based on the need to separate broad organism categories that may for a multitude of reasons become important during assessments, and in order to make reasonable use of available data



on radiation effects. Undoubtedly, the exercise will indicate where significant data gaps exist, and may hopefully also guide future research in this area.

The FASSET Radiation Effects Database will be available as a separate project deliverable on the FASSET website, together with the FASSET Deliverable 4 dealing with effects to be published in April 2003.

## **4.7 Data availability and requirement**

### **4.7.1 Issues and options**

Estimates of uncertainty/or confidence need to be transparent and clearly demonstrated. The level of uncertainty depends on how probabilistic or deterministic, and how cautious/conservative or realistic the assessment is, as well as on the availability and reliability of data. Models and data have a strong relationship, which is dependent on the quality of the data. It is important to have consistency within the choices of data, from the formulation of the assessment context through to the development of the model. However, data are often supplied from a number of sources, which can lead to uncertainty in the results. There are essentially three types of data sources:

- generic data from reliable and traceable sources;
- well-known local data; and
- poorly characterised data.

The alternative options for data requirements are:

- the necessary data is prescribed prior to the assessment, the risk in this case is that there is no available data; and
- all available information is used and the data sources are clearly recorded and specified. If necessary data is lacking there will be a need for extrapolating, e.g. from acute to chronic or between species. This may lead to a need to introduce safety factors – with the choices supported by scientific arguments. This option can be regarded as a default option.

If the biosphere system being assessed is part of a site-specific situation, data will be the key issue. If data is missing or incorrect, it is important to investigate ways of identifying the correct data. This can be done, for example, through a formal elicitation process, such as an expert group.

A further complication is the treatment of background. The environmental effect of radionuclides in the environment is related to the total dose, which includes the natural background, anthropogenic background and the dose increment from the source being assessed.

The IAEA BIOMASS project has linked the data requirement to the assessment context in the schematic way presented in Figure 4-4.



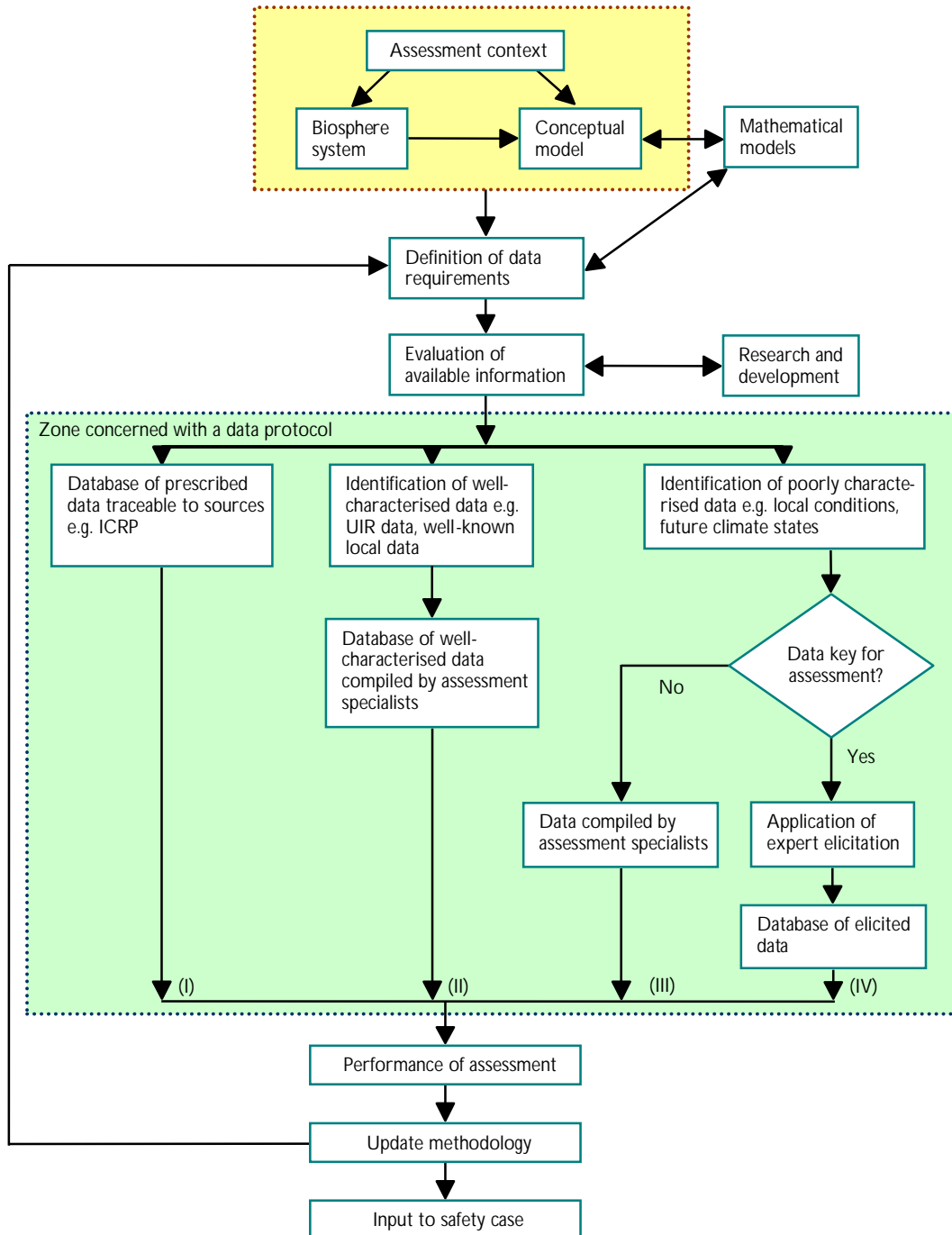


Figure 4-4 Relationships between data types, data availability and data requirements for structured data management [BIOMASS, 2001].



#### **4.7.2 FASSET approach to data requirements and uncertainties**

FASSET is based on the use of measured data from traceable sources for European ecosystems. Quality checks are being carried out on the data, and use of data is being maximised by pooling the available data. Where data are insufficient, a reasonable degree of caution will be adopted, accompanied by clear statements about the assumptions made and the introduced uncertainties. Different types of data have different sources.

- effects data (literature) – existing data;
- transfer factors – calculated (empirical) data; and
- extrapolations – derived from other data.

Data origin must be stated for transparency, and uncertainties and constraints associated with the data must be stated. Data assumptions made during the assessment must be clearly documented. When data are poor, reasonably cautious values should be selected on the basis of extrapolation.

Since effects of radiation are related to the total dose, i.e. including the background, and since the dose-response relationships in many instances are non-linear; assessments of environmental impact would need to consider background separately. FASSET will need to give guidance to the assessor about how to measure or derive background levels, including the consideration of all sources into the receiving environment, which is to be assessed.



## 5. Concluding remarks

From the review and comparison of systems, and from the attempt to create an assessment context for FASSET, it becomes clear that the environmental impact of ionising radiation can be assessed in a similar manner, as is the impact of hazardous substances in the environment. It may be unfortunate from this perspective that ionising contaminants have not previously been included in frameworks dealing with environmental risks. The reason for this may be the position of the ICRP as expressed in Publication 60 [ICRP, 1991] that the environment is already protected through the actions taken to protect man.

Although there are commonalities in the ways environmental impact of radioactive and hazardous substances can be assessed, there are still aspects of assessments that are particular to ionising radiation, such as the exposure (including dosimetry) and effects analysis. Work packages 1, 2 and 3 of the FASSET project deal with these aspects [FASSET, 2000] and the formulation of the FASSET assessment context in this report serves as guidance for this technical development. These technical aspects will finally be integrated in the final framework, to be delivered towards the end of 2003.





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## Appendix 1

# Responses to issues raised and recommendations made during the FASSET External Forum, Bath, UK, 8–9 April 2002

A condensed list of issues raised and recommendations made during the External Forum is presented below, based on the presentations and discussions held during the event. Responses from the FASSET Consortium on how these matters are, or will be, addressed during the finalisation of the project are also summarised. The list concentrates on new issues and recommendations that the FASSET project ought to consider; it excludes comments that support the project, as those have been described in the Technical Annex and subsequently evolved. The full text is available at [www.fasset.org](http://www.fasset.org).

### Exposure and Dosimetry

Issue/Recommendation	FASSET Response
<p>An 'equivalent dose for fauna and flora' will have to be developed and the concept of a 'weighted absorbed dose (rate)' could be useful.</p> <p>Absorbed dose rate is perhaps a flawed quantity, but uncertainty can be addressed with reasonable conservatism, and the use of ecodosimetry weighting factors appropriate for chronic exposure of biota.</p>	<p>The issue of Relative Biological Efficiency (RBE) has since long been debated. The problem is particularly difficult when examining environmental effects, due to the wide range of possible effects endpoints. One of the objectives of FASSET is to critically examine effects data and existing estimates of RBE in order to develop guidance. Tissue weighting may be discussed but may presently be premature to include in the guidance. Weighting factors specifically addressing effects categories may be discussed on the basis of the outcome of the work of WP 3 (Effects). Since the framework is intended to give as realistic estimates of environmental effects and consequences as possible, conservatism in the assessments is generally not aimed for.</p>
<p>We need to know how to do a much more realistic job in estimating dose.</p> <p>A uniformly distributed dose is not too simplistic, given the tremendous diversity of organisms and ecology in the real world, and given the data collected to meet regulatory requirements.</p>	<p>Under a wide range of circumstances and for a large number of nuclides and organisms, it is likely that uniformly distributed doses are adequate for the assessment purpose. For certain nuclides and certain organisms, however, internal distribution of nuclides and doses may affect the assessment. These problems are considered by WP 1 (Dosimetry) and WP 3 (Effects), and when possible, FASSET is collating organ-specific transfer data.</p>



Exposure and Dosimetry (continued)

<b>Issue/Recommendation</b>	<b>FASSET Response</b>
We need to know effects of dose protraction on the assessment and measurement endpoints.	WP 3 (Effects) are considering 1) the influence of dose rate on the response of organisms; and 2) whether the available information on acute (high dose rate) exposures can be extrapolated to the low dose rate situation.
FASSET ought to consider the use of 'reference biospheres' as well as organisms.	The reference biospheres is outside the scope of FASSET, since FASSET already in the initial stage identified the seven major European terrestrial and aquatic ecosystems that should be considered, and assessed the exposure pathways in Deliverable 1.
Need to consider background levels.	This is an area where input will be required from WP 1 (Dosimetry), WP 2 (Exposure) and WP 3 (Effects). It is recognised within the Consortium that attention has to be given to background, partly since dose-response relationships in most cases are non-linear, which excludes basing impact assessments on only incremental doses.

Effects

<b>Issue/Recommendation</b>	<b>FASSET Response</b>
Effects on higher organisational levels than the individual should not be lost.	FASSET has identified populations and ecosystems as the target organisational level for protection, whereas individuals are considered the target organisational level for assessments. This choice is based on the fact that there are no ways, known to the Consortium, whereby radiation affects populations and ecosystems without affecting individuals. Thus, targeting individuals will automatically afford protection to higher organisational levels. Furthermore, a significant number of species are protected for being endangered or for other reasons, which necessitates assessments as well as protection actions targeted to individuals. Focus on individuals is also justified on practical grounds, since data on higher organisational levels are scarce and less specific. However, scaling from individuals to populations and ecosystems represent a significant problem for the consequence analysis, and will be considered by both WP 3 (Effects) and WP 4 (Framework) during the second half of the project.
Consideration for extrapolation and safety factors is needed.	Partly considered above. The use of safety factors would be more appropriate when managing environmental risks – FASSET is intended to provide as realistic information on environmental impact as possible.



Effects (continued)

<b>Issue/Recommendation</b>	<b>FASSET Response</b>
<p>Information on responses to acute exposures is insufficient to extrapolate to low chronic exposures.</p> <p>Recommend FASSET to try to extrapolate from acute to chronic with available datasets.</p> <p>We need to know how to convert what are essentially dose data to dose-rate criteria.</p>	<p>The Consortium is generally pessimistic on the possibility to extrapolate from acute to chronic effects, inter alia because dose-response relationships may be non-linear and that different types of effects may predominate at different levels of dose (rate). The FASSET radiation effects database may help in indicating where such extrapolation is possible. If so, WP 3 (Effects) will address the issue.</p>
<p>Consider the credibility (public acceptance) of providing results for many species.</p>	<p>The radiation effects database will provide a background to the overview of effects data that will be made in Deliverable 4 of the project. Inevitably, data will have to be analysed and pooled for broad categories of organisms, and – equally inevitably – there will be substantial data gaps identified that may guide future research. Data shortage for individual species may in the assessments be partly compensated for by pooling data for reference organisms.</p>
<p>Use of standard test organisms, as in other jurisdictions.</p>	<p>Standardised and relatively simple biological test systems have been extensively in use for test of chemical toxicity, and the use of such systems may also be ethically more defensible than performing substantial testing on, e.g., mammals. It is possible that review of effects data may lead to suggestions of possible test organisms that are similar to those used for determining chemical toxicity. The question of development of tests might be appropriate to address in a possible follow-up to FASSET.</p>
<p>Provide guidance to interpret data.</p> <p>Limited QA on database entry.</p>	<p>These comments are directed to the assembly, and use of, the FASSET radiation effects database. Use of data from the database is the users responsibility – FASSET can not guarantee the data quality as the data will be entered as they are presented in the literature. QA exercises have been performed in order to ascertain as uniform data entry as possible. Data will be evaluated in order to see whether entered data are suitable for derivation of RBE values.</p>



Framework structure

Issue/Recommendation	FASSET Response
<p>The framework should be applicable to various assessment situations.</p> <p>Need to consider effects of radiation from all point sources into a given receiving environment.</p> <p>Will FASSET consider the impact of different disposal routes?</p>	<p>FASSET is intended to be used for assessments of past, ongoing and future releases from essentially all sources, and will consider acute and chronic exposure situations. Thus, exposure will be considered for both steady state and dynamic situations (WP 2). Models/look-up tables for aerial and underground deposition will be provided, together with freshwater and marine aquatic models. The effects analysis and database assembly already consider a range of dose (rates) that covers chronic to acute effects.</p>
<p>For practical application the following are important:</p> <ul style="list-style-type: none"> <li>• a structured approach to problem formulation and assessment,</li> <li>• transparency of assumptions included in the framework,</li> <li>• compatibility with established assessment procedures.</li> </ul> <p>Industry would wish to see FASSET providing output compatible with developing ICRP thinking.</p> <p>The FASSET approach should learn from other chemical approaches.</p>	<p>The Consortium has agreed to restructure Deliverable 2 into two parts. Part 1 systematically analyses the FASSET assessment context, reviews different choices, and justifies the approaches taken by FASSET. Part 1 will be backed up by Part 2 reviewing approaches to problem formulation and assessment in existing systems for assessment and management of environmental risks from radiation and hazardous substances. The current development in certain international fora, notably ICRP, IAEA and UNSCEAR, is followed closely by the project, and in several cases FASSET participants also take active part in that development. It is apparent that the development in all these fora converge towards compatible approaches, with similar aims.</p>
<p>Use tiered risk assessment approach: use of thresholds for triggering higher tier testing, or for regulatory action.</p> <p>Consider thresholds for judging acceptability of effects at each stage.</p> <p>Need to develop guidelines to determine acceptability of effect (how to incorporate/interpret 'close to zero' emissions).</p>	<p>FASSET will not use a tiered approach since FASSET is not primarily a compliance tool targeted to predefined dose or concentration thresholds. FASSET aims at a realistic assessment of impact, with the effects analysis in-built in the framework, not separated from it. The framework may secondarily be used for developing a tiered compliance tool. FASSET will not itself provide guidance of acceptability since this is for national authorities to decide upon. FASSET may nevertheless guide decision-making.</p>



Framework structure (continued)

Issue/Recommendation	FASSET Response
<p>There is a need for a primary set of reference organisms (&lt; 10) and then secondary reference organisms as necessary.</p> <p>The reference organism database should be much smaller – due to poor database for no-effect values and the main purpose to be served, i.e., regulatory not academic.</p> <p>The concept of reference organisms is not universally agreed.</p>	<p>FASSET has through ecosystem pathways analysis formulated a list of 31 candidate reference organisms (see Deliverable 1). These are relevant for the European ecosystems considered in the project. Numbers of reference organisms for a given ecosystem type are ca 10. The list may become shortened, but it is equally likely that all organisms will have to be retained, although FASSET within its three years of duration may not provide the necessary parameter data for all organisms. FASSET will continue to develop the reference organism approach, since the Consortium feels that this provides a reasonable approach to the necessary simplification. However, the project will continue to develop the justification to the reference organism approach, and take into account criticism that has been raised.</p>
<p>What tools? Look-up tables?</p> <p>EXCEL spreadsheets should be delivered to aid decision makers of conservative or realistic RQ (risk quotient) estimates for a comprehensive list of radionuclides, for a simple set of generic reference organisms.</p>	<p>WP 1 (Dosimetry) and WP 2 (Exposure) will provide tabular parameter values. However, simple tables may be misleading if not coupled to guidance on how to use them, data uncertainty and limits of applicability. FASSET intends to provide such guidance. WP 3 (Effects) intends to facilitate data screening through assembling a radiation effects database, and will also make an interpretation of these data in Deliverable 4. No software-based computational tools are foreseen within the project. RQ values will not be given since RQs would have to be based on judgements of acceptability, which is outside the scope of the FASSET project.</p> <p>FASSET will adapt the BIOMASS methodology and come up with checklists to help guide decision makers in carrying out assessments.</p>
<p>Risk concept premature.</p>	<p>The use of 'risk' is always debatable if the term is not clearly defined. Risk may be used to describe anything from the general level of impact, to probabilistic estimates involving the probabilities of events and consequences. The Consortium feels that the framework need not to be limited to just impact analysis but could include a probabilistic element, possibly at a later stage or developed in a follow-up to FASSET.</p>
<p>Avoid academic 'overkill'.</p> <p>Consider the ability of regulators to review QA-complex, detailed submissions.</p> <p>Consider the ability of licensees to use the information wisely, for the intended purpose.</p> <p>Consider management issues when designing a framework.</p>	<p>There is a concern that the framework will be complicated to use, either the users are implementers, regulators or the informed public, due to the complex information that supports it. However, the Consortium intends to build up the framework in an as user-friendly form as possible, but backed up by sound science. If implemented on a national level, the framework may also assist in the development of compliance criteria that may facilitate assessment and scrutiny by licensees and regulators, respectively. The framework will to a degree assess management issues in its formulation stage. Tools will help decision makers, but the framework is not intended to prescribe management options.</p>



Framework structure (continued)

<b>Issue/Recommendation</b>	<b>FASSET Response</b>
Address monitoring requirements to validate risk assessments.	Possibly, this issue is best dealt with by linking the effects analysis of WP 3 to identification of biomarkers, or simply environmental concentrations, that can be useful for environmental monitoring. Deliverable 4 will briefly consider this aspect.
Consider socio-political issues.	FASSET Deliverable 2 puts the framework into context, including a review of guidance in high-level documents and international recommendations.
Management based on assessments is a flawed approach, and should be replaced by a management scheme based on hazard identification, thus leading to substitution of hazardous substances or activities.	Management issues are outside the scope of the FASSET project. Environmental contamination or pollution from radioactive substances already exist and will not cease to exist within the nearest future, and a proper methodology for assessing the environmental impact is thus needed.





## Appendix 2

# Glossary (Part 1 and Part 2)

### **Allometric**

Correlation of changes in any organism part (i.e. contaminant concentration) to organism size and metabolic needs.

### **Assessment endpoint**

The biological effect inferred from the measurements or predictions and which the assessment framework is designed to study.

### **Assessment framework**

Identification and demarcation of the assessment boundaries. In FASSET, the framework contains the process from problem formulation through to characterisation of the effects of radiation on individuals. The overall assessment system describes the tools, methods and information flow used to carry out the impact assessment.

### **Bioaccumulation**

The process whereby an organism accumulates substances in living tissues to concentrations higher than those existing in the surrounding media (e.g., soil, water and water).

### **Bioassay**

A test to determine the relative strength of a substance by comparing its effect on a test organism with that of a standard preparation.

### **Biological diversity**

The number and abundance of species found within a common environment. This includes the variety of genes, species, ecosystems, and the ecological processes that connect everything in a common environment.

### **Biomass**

The total weight of all living organisms in a biological community.

### **Biological half-life**

The time required for a biological system (e.g., animal) to eliminate, by natural processes, half the amount of a substance that has been absorbed into that system.

### **Biomagnification (Biological magnification)**

Situations where the concentration of certain substances increases as one moves higher up the food chain.



### **Biosphere**

That part of the environment normally inhabited by living organisms.

In practice, the biosphere is not usually defined with great precision, but is generally taken to include the atmosphere and the Earth's surface, including the soil, surface water bodies, seas and oceans and their sediments. There is no generally accepted definition of the depth below the surface at which soil or sediment ceases to be part of the biosphere, but this might typically be taken to be the depth affected by basic human actions, particularly farming.

In waste safety in particular, the biosphere is normally distinguished from the geosphere.

### **Biota**

The animal and plant life of a given region.

### **Contaminant**

Any physical, chemical, biological, or radiological substance or matter that has a potentially adverse effect on air, water, or soil, with the implication that the amount is measurable.

### **Cytogenetic effect**

An observed effect in chromosomes that can be correlated with adverse hereditary effects or genetic effects (effects that are inheritable and appear in the descendants of those exposed).

### **Dose-effect**

The relationship between dose (usually an estimate of dose) and the gradation of the effect in an exposed population, that is a biological change measured on a graded scale of severity.

### **Dose-response**

A correlation between a quantified exposure (dose) and the proportion of an exposed population that demonstrates a specific effect (response).

### **Ecological impact**

The total effect of an environmental change, natural or man-made, on the community of living things.

### **Ecosystem**

The interacting system of a biological community and its nonliving surroundings.

### **EC<sub>x</sub>**

The concentration of a substance that is estimated to cause some sublethal toxic effect on x % of the test organisms under specified conditions. The duration of the exposure must be specified.

### **Effect**

A biological change caused by an exposure.

### **Environment**

Water, air, land, plants and man and all other organisms living therein, and the interrelationships which exist among them.



### **Environmental impact statement**

A document providing information for decision makers on the positive and negative effects of an action, practice or policy, which identifies and evaluates the environmental impacts of the hazard source and feasible alternatives, including taking no action.

### **Environmental justice**

Environmental justice, often used interchangeably with the term environmental equity, refers to the distribution and effects of environmental problems and the policies and processes to reduce differences in who bears environmental risks. In a general sense, it includes concern for disproportionate risk burden placed upon any population group, as defined by gender, age, income, race, nationality or generation.

### **Environmental quality criteria**

The levels of pollution and lengths of exposure, above which adverse effects may occur on health and welfare.

### **Environmental quality standards**

The level of pollutants prescribed by law or regulation that cannot be exceeded during a specified time in a defined area.

### **Exposure assessment**

The process of measuring or estimating the intensity, frequency, and duration of exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment.

### **Fecundity**

The survival of offspring.

### **Fertility**

The ability to produce offspring.

### **Hazard**

A condition or physical situation with a potential for an undesirable consequence, such as harm to health or environment.

### **Hazard identification**

Recognizing that a hazard exists and trying to define its characteristics. The process of determining whether exposure to an agent can cause an increase in the incidence of an adverse health or environmental effect.

### **Hazard analysis**

Procedure used to (1) identify potential sources of release of hazardous materials from fixed facilities or transportation accidents; (2) determine the vulnerability of a geographical area to a release of hazardous materials; and (3) compare hazards to determine which present greater or lesser risks to a community.

### **Indicator organisms**

A species, whose presence or absence may be characteristic of environmental conditions in a particular area of habitat; however, species composition and relative abundance of individual components of the population or community are usually considered to be a more reliable index of water quality.



**Lowest observed effect concentration (LOEL)**

The lowest observed effect concentration in a toxicity test that causes a statistically significant effect in comparison to the controls.

**Measurement endpoint**

Measured or predicted value that an assessment produces.

**Morbidity**

A loss of functional capacities generally manifested as reduced ‘fitness’, which may render organisms less competitive and more susceptible to other stressors, thus reducing the life span.

**Mortality**

Death; the death rate; ratio of number of deaths to a given population.

**No observed effect concentration (NOEC)**

The highest concentration in a toxicity test not causing a statistically significant effect compared with the controls.

**Pollution**

The presence of matter or energy (e.g., smoke, gas, hazardous or noxious substances, light, heat, litter or a combination thereof) in sufficient quantities and of such characteristics and duration as to produce, or likely to produce, undesired environmental effects.

**Precautionary principle**

‘In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.’ (UNCED, Rio principle 15, 1992)

**Relative biological effectiveness (RBE)**

For a given type of radiation, RBE is defined as:

$$\text{RBE} = \frac{\text{Dose of the reference radiation needed to produce the same effect}}{\text{Dose of the given radiation needed to produce a given biological effect}}$$

**Reference organisms**

A series of entities that provide a basis for the estimation of radiation dose rate to a range of organisms that are typical, or representative, of a contaminated environment. These estimates, in turn, would provide a basis for assessing the likelihood and degree of radiation effects.

**Response**

The proportion or absolute size of an exposed population that demonstrates a specific effect. May also refer to the nature of the effect.

**Risk**

A measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard. A technical estimation of risk is usually based on the expected value of the conditional probability of the event occurring times the consequence or magnitude of the event given that it has occurred.



### **Risk assessment**

A qualitative or quantitative evaluation of the risk posed to human health and/or the environment by the actual and/or potential presence of pollutants. It includes problem formulation, exposure and dose-response assessment and risk characterisation

### **Risk characterisation**

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

### **Risk communication**

The exchange of information about health or environmental risks among risk assessors and managers, the general public, news media, interest groups, etc.

### **Risk evaluation**

A component of risk assessment in which judgments are made about the significance and acceptability of risk.

### **Risk management**

The selection and practical implementation of regulatory and non-regulatory responses to risk. Practical implementation of procedures, actions or policies to mitigate, reduce, remove or monitor health or environmental risks.

### **Safety factors**

Measure of degree of uncertainty, caused by lack of effects data. For example, an estimated lowest observed effect concentration may, as a precautionary approach, be divided by a safety factor (normally within the range 10 to 10 000) to safeguard against harmful effects, where the magnitude of the safety factor reflects the degree and type of uncertainty (e.g., lack of chronic exposure data, lack of data for different taxonomic groups or trophic levels, etc.).

### **Sustainability**

The ability of an ecosystem to maintain ecological processes and functions, biological diversity, and productivity over time.

### **Synergism**

An interaction between two substances that results in a greater effect than both of the substances could have had acting independently.

### **Threshold**

A pollutant concentration (or dose), below which no deleterious effect occurs.

### **Toxicant**

A substance that kills or injures an organism through chemical or physical action or by altering the organism's environment; for example, cyanides, phenols, pesticides, or heavy metals; especially used for insect control.