Minutes from

The FASSET External Forum

Bath

8–9 April 2002

FASSET
Framework for ASSessment of Environmental impacT

Foreword

The Technical Annex of the FASSET project (available at www.fasset.org) states that 'the project will adopt an open dissemination strategy'. Various forms for interaction with a wider audience have been discussed, and as a result, it was decided early during the project to organise an External Forum, where invited organisations would be offered the opportunity to provide guidance and critique to the project. It was decided that a proper time for organising this event would be in the middle of the project, thus coinciding with its mid-term review. Furthermore, it was decided that the Forum should be a two-day event, taking place on the 8th and 9th April 2002, immediately followed by the third workshop of the project so that the ideas generated during the External Forum could be effectively taken on board.

The External Forum was divided into two parts: a plenary session where invited speakers from outside the FASSET Consortium gave their views on what FASSET ought to consider; and a workshop session for discussions with the audience. The programme can be found in Appendix 1, and the list of organisations attending the External Forum is in Appendix 2.

These minutes reflect both the individual contributions made by the invited speakers, as well as the discussions that followed in the workshop sessions. The individual presentations (illustrative material) are, together with this report, available as pdf-files on the FASSET website. On the basis of the guidance and critique received, a 'condensed' list of recommendations was compiled subsequently (Appendix 3), together with the Consortium's comments on how FASSET is or will be addressing these recommendations during the second half of the project.

The organisers are pleased that 32 organisations, representing a wide range of interests in the FASSET subject area, participated in the External Forum. We would like to extend our gratitude to all those who provided their views on the project and contributed to the discussions. The FASSET Consortium welcomes feedback from all invited organisations – as well as from other interested parties – to the Forum. Please send comments to: carl-magnus.larsson@ssi.se

Irene Gize — *Forum organiser*

Carl-Magnus Larsson — *FASSET co-ordinator*

Contents

1. Summary of main ideas and concepts within the External Forum

The following is a summary of the main ideas and concepts arising within the FASSET External Forum, intended to inform and guide scientific discussions and to assist in determining the forward content of the four work packages (WPs) within the FASSET programme:

WP 1 – Environmental dosimetry

Gerhard Pröhl, work package co-ordinator

The objectives of WP 1 are:

- To define sets of generic fauna and flora that are appropriate to the marine, freshwater and terrestrial environments of Europe. The identification of relevant target organisms will depend on the output of both WP 2 and WP 3 as well as on a review of environmental dosimetry, which will highlight the factors influencing dose.
- To develop the radiation dosimetry models for the estimation of the actual or potential absorbed dose rates to the target organisms, from internal and external sources of α-, β- and γ-radiation, given information on the distributions of natural and contaminant radionuclides in the organism's environment.

The final output will be a tabulation of absorbed dose rate coefficients (Gy s^{-1} per unit radionuclide concentration in the relevant environmental compartment) for each target organism for the radionuclides selected in this project.

WP 2 – Exposure pathways

Per Strand, work package co-ordinator

The two main objectives of this work package are:

- To identify the components of representative European terrestrial and aquatic ecosystems for which external and internal exposure from radiation may be high and to present this information to WP 1 for consideration in selection of target organisms.
- To assess the transfer and uptake and turnover of radionuclides to the target organisms identified above. The result of this work will be the compilation of relevant ecological and transfer information and the adaptation of generic models, simulating radionuclide migration and uptake to the whole organism (and organs if applicable) for generic species living in representative terrestrial and aquatic European ecosystems.

WP 3 – Assessment of environmental effects

Dennis Woodhead, work package co-ordinator

- The primary task will be to develop criteria for the protection of the environment from radiation that would both demonstrate that the problem is being adequately and consistently addressed, and be generally acceptable to policy makers and the wider lay public, as well as within the scientific community. This will require a critical examination of the level at which protective action should be directed (the population, ecosystem, biodiversity etc.) taking due account of the available knowledge concerning the biological effects of radiation. A sound justification will be given for the choices made.
- The input to this work package will consist of existing reviews and assessments of the impacts of radiation in the environment; the wider radiobiological and ecological literature; and, feedback from WP 1. The output from this work package will help define the dosimetric target organisms for WP 1. This work package will also contribute to the development of a radiation protection framework for the environment within WP 4, especially in the determination of dose-rate thresholds or minimum dose rates at which effects in the environment are expected to be minimal with a high degree of certainty.

WP 4 – Development of framework

Carl-Magnus Larsson, work package co-ordinator
(also co-ordinator of the FASSET project)

- Within the over-all objective of creating a framework to link sources to effects/consequences of ionising radiation in the environment, WP 4 will review existing frameworks for environmental assessment used in different environmental management or protection programmes. This review will extend outside the field of radiation protection, where such schemes are presently scarce, and consider, *inter alia*, frameworks for managing risks from genotoxic chemicals. A 'generic' framework will thus be created. This generic framework will be used as input to WPs 1–3. The relevant elements of a framework related to ionising radiation in the environment, identified in WPs 1–3 in discussions with WP 4, will be incorporated into the framework. Thus, a framework, which specifically addresses the environmental impact of ionising radiation, may be created, which will be the final product of the project.

The External Forum was structured to inform participants of FASSET overviews of progress in each work package, presented by the work package co-ordinators, and structured guidance and critique from invited speakers (see presentation N° 4). Each session concluded with questions and comments from

all participants. Following these introductory sessions, individual workshops, centred on individual elements of the FASSET Framework, were convened for more detailed debate of key issues and concerns or comments raised (see Programme in Appendix 1). Feedback from each workshop was summarised by the nominated chairperson and, again, further comment (particularly from workshop attendees) was invited in plenary session.

Further details of the project structure, objectives and timetable for the production of deliverables within the work packages can be found on the FASSET website (www.fasset.org).

2. Introductions

Joe McHugh, Environment Agency & Ernst-Herman Schulte, EC Directorate-General RTD-J4
Presentations Nº 1 and 2

Key questions have been growing throughout the international arena, and the EU in particular: why should we protect the environment, what should we protect and how can we demonstrate protection of species other than humans? It is this last which FASSET seeks to address, through consideration of sources, exposure, dosimetry and effects on target organisms and ecosystems. FASSET thus supports decision-making mechanisms for regulating approaches to protecting the environment from the effects of ionising radiation. The programme involves fifteen organisations in seven countries. FASSET was launched in November 2000 and is due to conclude in October 2003.

3. Objectives for the External Forum and FASSET project overview

Carl-Magnus Larsson, FASSET co-ordinator
Presentation Nº 3

The primary objective of the External Forum is to inform discussion within the FASSET project, as the programme reaches its mid-term, to ensure that the final phase of the study addresses the areas of major concern.

Broadly, the 'acceptability' of discharges of materials, and impacts on the environment, are likely to be linked to the severity and permanence of the consequent effects.[1] At the same time, there is a general trend towards setting limits on acceptability at lower and lower levels. Moreover, the acceptability of an impact is determined within the context of the contaminant material. Thus, whilst eutrophication (for instance as a result of nitrate discharges) may be considered acceptable (at least over short periods), it is highly unlikely that *any* observable effect from ionising radiation would ever be acceptable.

Within FASSET the following considerations are raised:

- Identifying relevant sources and exposure pathways for major European ecosystems;[2]
- Identifying relevant biological effects;
- Explaining environmental consequences;
- Determining (and justifying) appropriate levels of simplification;
- The issue of risk management is specifically excluded.[3]

The approach of FASSET is to define a series of reference organisms, being representative of ecosystems and habitats. These hypothetical entities provide a common basis for estimating the radiation dose rate to a range of organisms that are typical for a contaminated environment.[4]

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[1] Concepts of 'contamination' (low level effects only), 'critical load' (the threshold for reversible or recoverable effects) and 'pollution' (leading observable or to irreversible effects) were introduced.

[2] Note that EPIC (Environmental Protection from Ionising Contaminants in the Arctic) is a similar EU funded project, but aimed specifically at protecting the Arctic ecosystems whereas FASSET provides a more general approach across a range of organisms and ecosystems.

[3] FASSET is not intended to propose standards for protection, but to provide the information and framework from which standards can be derived. The framework developed should enable the comparative effects of contaminants other than ionising radiation to be placed into context.

[4] An analogy to 'reference man' may be made – a hypothetical individual exhibiting a specific set of characteristics from within a range which includes the effects of age, sex, race, state of health etc. A reference organism should thus not be confused with a real organism.

An initial list of thirty-one reference organisms has been identified within FASSET. Mid-way through the project, guidance and critique of the programme is sought from external commentators.

Questions and comments

Max Wallis (FoE) noted that an emphasis has been placed throughout the introduction on the identification of 'relevant' information (e.g. relevant pathways, relevant reference organisms etc.). This is grounded on an acceptance, and assuming the purpose, of the Euratom Treaty (i.e. it assumes the acceptable use of nuclear energy and hence of the discharge of ionising contaminants). But there is another approach to environmental protection, for instance the Precautionary Principle as applied within OSPAR, which essentially drives towards zero discharges irrespective of identified impacts. Likewise the European Treaty adopts an approach of *absolute* protection of fauna and flora per se. Why is FASSET based only on Euratom approach?

Carl-Magnus Larsson, with Lars-Erik Holm, stated that the project has the clear objective to organise existing information into a framework to support an assessment, *not* to determine what is acceptable or unacceptable, or to set limits. That is for each legislature to determine. Since the study is EU funded it accepts the premises of the Euratom Treaty. It is not the purpose of this forum to determine the appropriateness or otherwise of the Euratom Treaty, only to consider the scientific use of information to determine decision making.

4. Introductions by workshop chairpersons

4.1 Assembling a framework

Carol Robinson, IAEA
Presentation N°5

The IAEA has a number of responsibilities implied through various legal instruments, including the development of protection standards and to make provision for their application. From this basis, the following issues are identified for consideration.

- Has FASSET identified the correct elements of ecological risk assessment? For instance, should there be greater emphasis on problem formulation and management of issues?
- Has the project addressed the relevant level of simplification by applying reference organisms?
  - Problems in selecting organisms;
  - Treatment of uncertainties;
  - Effects on ecosystems or on organisms/species only.
- Is the project harmonised/integrated with protection from other contaminants?
- What tools should FASSET provide to aid decision making and how can the results be used?
  - Identify gaps in knowledge;
  - Demonstration of compliance through appropriate (achievable) monitoring;
  - Definition of relevant endpoints;
  - Consideration of time and spatial distribution of dose and impacts.

Questions and comments

The question of optimisation was raised. However, Carol Robinson felt that optimisation is really a management (implementation) rather than a framework issue and thus lies outside the direct scope of FASSET. FASSET will provide the data and information framework for decision making.

4.2 Exposure and dosimetry

Norman Gentner, UNSCEAR
Presentation Nº6

The following questions and points for consideration were raised.

- Does absorbed dose adequately cover bystander effects and genomic instability or should some alternative quantity be used?
  - Weighted absorbed dose may be too simplistic, and ignores, for instance, the effect of adaptive responses leading to protection at a cellular level;
  - Epigenetic effects indicate that the effective target for detrimental effects of radiation may be much greater than single cells;
  - Neoplasia induced by radiation presumably occurs through a combination of direct damage and non-targeted epigenetic effects;
  - There is need to cover both high and low LET, through a transparent mechanism, rather than through an assumed conservatism in dose assessments, which leads to the concept of 'weighted absorbed dose', although RBE has inherent problems of its own.
- Should more realistic dosimetry models be applied? These might consider:
  - Radionuclide distribution;
  - Range (temporal and spatial) of species;
  - Occupancy factors;
  - Absorbed fraction;
  - Radiation weighting factor.
- Should use be made of average or maximum values to characterise impact?
  - Average values may be best if populations (rather than individuals) are to be protected, but averages need to be relevant (spatial and temporal) for the organisms.
- How many 'reference organisms' is appropriate?
  - Avoid too many reference organisms (many have the same uptake rates as expressed at stasis);[5]
  - Put major emphasis on internal dose conversion factors (DCFs).

[5] That is, the same concentration ratios.

- What types of tools should the project deliver?
  - Cannot be determined in the absence of understanding the endpoints of concern;
  - Use of multi-tiered 'screening levels'.
- Is assuming a uniform distribution too simplistic?
  - If dose-rate criteria are set only for whole organisms, is there any advantage in considering organ or cellular distributions;
  - The dosimetry approach should be consistent with the regulatory approach.

The most important measure, which needs to be retained in mind, is the biological *endpoint* considered to be of significance.

Questions and comments

Steve Jones (WSC) commented that the distribution of radionuclides within reference organisms is not normally available from literature. Furthermore, the distribution is of little value unless it is linked to an endpoint and there is little information on this. Pragmatically, the appropriate approach may be limited by the current state of knowledge.

Norman Gentner accepted this argument. Part of the purpose of the External Forum is to lay open the process of simplification to gain understanding.

Max Wallis (FoE) proposed protection of ecosystems as opposed to species or individuals.

Norman Gentner noted that ecosystems are interacting individuals and species. If the most sensitive part is protected (at the most sensitive stage of the life cycle), the ecosystem will be protected. However, Paul Johnston (Greenpeace) responded that this concept contains an element of 'myth'. Coming from a background of chemical toxicology it has proved impossible to identify the most sensitive species, due to variations between species and life cycle stages across time.

Norman Gentner agreed this position but noted that the study cannot consider all parts separately and simultaneously. It is justifiable therefore to consider the more sensitive parts to protect, by implication, the whole. However, Steve Jones (WSC) believed that the identification of a number of reference organisms, covering types and pathways of uptake, precisely negated the need to identify 'most sensitive' species.

Other concerns were raised about multi-tier screening, which may be overly complex. However, Norman Gentner believed it necessary to differentiate between acute and chronic exposure, since most studies do not truly investigate protracted (chronic) doses.

4.3 Radiation effects

Dave Copplestone, ERC, University of Liverpool
Presentation Nº 7

The following discussion points were raised in response to a number of generic questions.

- Does FASSET identify the relevant 'umbrella effects'?
  - FASSET currently addresses morbidity, mortality, reproduction and mutation;
  - Should FASSET look at other indicators such as, at ecosystem level, biodiversity?
- Use of scorable cytogenetic effects?
  - Many different types of test are available (chromosome translocations, DNA strand breaks, oxidative stress etc.);
  - There is no clear relationship to endpoints of concern;
  - Perhaps cytogenetic information should be used to refine (rather than determine) decision making tools;
  - Biomarkers may have a potential to provide a 'universal damage index'.[6]
- Is it appropriate to use acute exposure studies to extrapolate to chronic exposure impacts? Points to consider include:
  - Adaptive responses, radiosensitivity, dose thresholds;
  - Effect of co-stressors;
  - Related problem of extrapolation between species.
- Should harm be expressed on a probabilistic basis?
  - Requires acceptance of a level of risk, as opposed to an absolute no effects threshold.
- Should FASSET address data gaps?
  - It is possible to identify gaps and make recommendations for research requirements, but the purpose needs to be clear (i.e. is this to provide a comprehensive dataset for all species and ecosystem types, or to ensure that the 'reference organisms' are adequately defined?);
  - In identifying data gaps, and proposing research requirements, FASSET could consider definition of protocols for determining required data.

[6] For example, expressing the effects of radionuclides, heavy metals, POCs, etc., on the same scale.

- Should FASSET determine or derive ‘safety factors’? This raises many issues about defining ‘safety’.
  - Are safety factors and ALARP mutually compatible?

Dose limitation needs to be pragmatic and set in the context of natural radionuclides in the environment. An overly simplistic application of the ‘precautionary principle’ can lead to an unworkable system.

Questions and comments

Steve Jones (WSC) queried what level of risk or uncertainty is acceptable? It is easy to define probability functions mathematically, but there is a need to determine in advance the uncertainty parameters to be applied, otherwise the end result might look more impressive than it is in reality. However, the application of probability distribution functions on dose and effects may dispense with the need for safety factors.

Other commentators noted that comparison of deterministic and probabilistic models in Canada had generally indicated much the same impact.

Norman Gentner agreed with the caveats on use of cytogenetic biomarkers, and commented that RBE should fold in observed cytogenetic effects. However, on the question of compounding effects UNSCEAR noted that unless co-contaminants act on the same pathways and processes in the organism there is no need to be concerned too far about synergy.

Paul Daniel (WSC) pointed out that epigenetic effects (bystander effects etc.) are known almost wholly from cytogenetic work. It is true that it is hard to determine the relevant endpoint for an organism but the cytogenetic studies have highlighted otherwise undetermined effects pathways.

David Copplestone agreed but noted that a decision making framework can be set only on the basis of known endpoints.

5. Assembling a framework

5.1 Overview of work package on the framework

Carl-Magnus Larsson, SSI
Presentation Nº 8

Different approaches to decision making can be envisaged. For instance, site specific determinations can be assessed, or a more stylistic (probabilistic or deterministic) approach adopted. There are no 'correct' approaches for all circumstances. The key question for FASSET is to determine that an appropriate approach has been adopted, with suitable justification at each consequent step. The approach adopted should be cognisant of the many international initiatives considering toxicological effects on biota. Three steps in environmental protection are recognised:

- Problem formulation:
  - Assessment context.
- Assessment method:
  - Exposure analysis;
  - Effects analysis;
  - Risk characterisation.
- Management framework:
  - Prevention, mitigation or elimination of consequences.

FASSET is concerned only with problem formulation and development of an assessment method. Management is a governmental/regulatory issue.

FASSET, being generic in nature, sets out to be as realistic as possible. It adopts caution without being overly conservative.

To make the work programme manageable, a number of limits on the study must be introduced. For instance, twenty elements only are considered for impact. This is not open to discussion at this stage. Reference organisms have been defined, based on major European ecosystem types, and effects are based on individual organisms (rather than higher level ecosystems or groups of inter-acting organisms). For the present, the effects to be scored are based on morbidity, mortality, reproduction and scorable cytogenetic effects.

Reference natural radiation backgrounds need to be established. Moreover, it is not assumed that doses and impacts are linked in a simple linear fashion, so that the determination of the cumulative, combined effect of the target contaminant and the prevailing natural background is not straightforward.

Questions to be addressed include the selection of key elements, the level of simplification to be introduced in assessment methods, the interpretation of results in the context of environmental protection, the relationship to human radiation protection and the tools required to implement management decisions to be made.

5.2 Guidance and critique

5.2.1 Experience in the chemical industry

Paul Johnston, Greenpeace
Presentation Nº 9

There are many parallels between FASSET and the chemical toxicology domain, where work has been conducted over many years, with both successes and failures. There is a danger that FASSET will reproduce the process for radiological protection, including the failures. The following gives an overview of the approach adopted by Greenpeace.

Table 1
Current and aspirational regulation of chemical hazards (full table in presentation Nº 9).

	Current regulation	Aspiration	Comment/relevance to nuclear industry
Objective	Risk management of chemical, i.e. control of exposure to level yielding 'acceptable' risk	Cessation of all discharges, losses and emissions of hazardous substances by 2020.	OSPAR has already adopted similar target for radioactive substances, as well as two Decisions stressing the urgency of abandonment of nuclear reprocessing.
Coverage	<5% of all existing chemicals	100% of existing chemicals.	
Basis	Risk assessment	Hazard assessment, and substitution with less- or preferably non-hazardous alternatives.	Consider that risk assessments do not adequately provide a measure for protection.
Pre-sumption	Chemicals do not pose a risk unless otherwise indicated	All contaminants are treated as if potentially harmful unless there is sufficient evidence to the contrary. Use and release of hazardous substances considered inherently unsustainable.	Nuclear industry might stress that all radioactivity is acknowledged to be harmful, but a fuller and more transparent structure based on preventing introduction of harmful substances to the environment should be introduced.
Structure	Incoherent and non-transparent	Coherent and transparent.	
Confi-dentiality	Extensive	All data to be made publicly available.	
Labelling	Substances and preparations	Substances, preparations and goods.	
Approach	One by one	By groups.	Believe this not to be the case for the nuclear industry.
Responsi-bility	Member States, delegated to industry	Independent body.	
Costs	Member States	Producers.	

One major sticking point for FASSET is the over-reliance on risk assessments. Risk is generally better understood at the cellular/organism level, and within a laboratory context, than at ecosystem level or application of results from the laboratory to the natural environment. It is very difficult, if not impossible, on the basis of current understanding to extrapolate from organism impacts to ecosystem impacts. The dynamics of large complex systems are virtually non-reproducible. Risk assessment requires determining outcome. Whilst this is not generally possible in a simple fashion,[7] particularly in the context of life-cycle assessments, it is possible to identify the *hazard* presented.

The only certain method to ensure protection is to prevent contaminant materials entering the environment (i.e. prevention at source, rather than mitigation post-release).

Need to avoid misinforming regulators and to move toward a zero emissions policy. Radiation protection is about 20 years behind the chemical industry, although the move from a biophysical risk to a biological basis of assessment is to be broadly welcomed.

Questions and comments

Norman Gentner (UNSCEAR) commented that, for radiation, dose is the unifying entity so that radionuclides can be, and are, dealt with by groups (as advocated). For chemicals, this can be much more complex.

Steve Jones (WSC) noted that there appears to be a predication that we should adopt an approach purely to justify a move towards a zero discharge philosophy. Norman Gentner suggested that a move toward a zero emission philosophy may have large, negative, societal (possibly even environmental) consequences.

General comments were made that a scientific programme should not have a pre-set answer, particularly within a context of natural risks.

Paul Johnston suggested that the move towards zero discharges is inevitable. This is not necessarily linked to a pure science argument, since there is no area of 'pure' science (i.e. all science has been impacted by socio-political and economic considerations), although there is substantial scientific reasoning underlying the approach. Regulation of radioactive materials hazards needs to be cross-fertilised from the regulation of the chemicals industry, where there is now an increasing acceptance of the precautionary approach (i.e. programmed reduction in hazardous environmental releases, with the target of their cessation within a given timeframe; assumption that substances are harmful until demonstrated otherwise).

[7] Impacts in the environment can often be determined only through complex multi-variate statistical analysis, e.g. impact footprint of offshore oil platforms previously supposed to be about 500 m, but now indicated through Multi-Variate-Analysis to be several kilometres radius.

In response to a point of clarification from Clive Williams (EA), Paul Johnston confirmed that, in his opinion, FASSET should include the management (regulation) decisions.

5.2.2 The role of FASSET in defining a strategy to protect the environment

Lars-Erik Holm, ICRP
Presentation Nº 10

The official ICRP position remains that outlined in ICRP 60.[8] The problem is that protection of the environment cannot be demonstrated transparently from this philosophy. A Task Group was set up in 1991 to address this issue.

Several approaches have been considered, including calculations of doses to biota where doses to man are limited to 1 mSv a^{-1}. However, the need and goals for protection of the environment have been defined by society. The role of ICRP (and the broader scientific community) is not to determine what the goals should be, but to determine how best to achieve the goals, which have been set. To aid decision making, however, there should be a mechanism to compare the effects of radiation with those of other hazards released into the environment.

The ICRP Task Group believes that there needs to be a clear set of objectives, principles, units and quantities, with an internationally accepted system for protection of the environment.

The system of dose coefficients for man, defined for internal and external exposure, does not readily apply to protection of the environment. The work to define 'reference man' began in the late 1940s and was not published until 1975 (ICRP Publication 23). The updated 'reference individual' is due for publication 2002. By analogy, reference organisms for determining impacts on the environment may take many years to identify and define.

ICRP believe that protection of the individual remains core to adequate protection of higher systems. But where to set the taxon for defining a reference organism (phyla, order, class, family, species or variety)? Currently the ICRP Task Group is of the opinion that the reference organisms should be 'typical' of different habitats and have public or political recognition.

The ICRP Task Group does not intend to define dose limits for biota. It will recommend a framework with 'derived consideration levels' that can be used for advice and guidance and help regulators and operators demonstrate compliance with existing environmental legislation.

In the first instance about ten primary reference organisms should be defined, with further consideration to the development of secondary organisms and secondary measures of impact (e.g. concentrations in the environment). The

[8] That is, limiting exposure of man to ionising radiation to the level thought desirable to ensure protection of the individual will also ensure protection of the environment, at least at the species level.

Task Group recommends that the biological endpoints be summarised into three broad categories: early mortality, reduced reproductive success, and scorable DNA damage. These categories comprise many different and overlapping effects and recognise the limitations of the current knowledge of such effects. There is recognition that the risk assessment approach may be premature.

Table 2
Derived consideration levels for fauna and flora.

Level of exposure (relative to natural background)	Effect	Level of concern
x1 000	Early mortality	Serious
x100		
x10		
normal background		
< background	None identifiable	Trivial

Questions and comments

Max Wallis (FoE) was concerned to define properly the principles for a study. It seems that a castle has been erected, but without foundations. Risk assessment is complex. Nobody in the audience has expertise in risk typologies or assessments. There has been no adequate definition of the goals to be achieved, nor consultation on the approaches and rationale to be adopted.

Lars-Erik Holm responded that the principles adopted by the ICRP are intended precisely to move to a more transparent system of demonstrating protection of biota, incorporating scientific debate.

Per Strand (NRPA) agreed. It is not easy to see what the objection is to the philosophy of the studies being pursued.

5.2.3 Requirements to aid international standard setting

Carol Robinson, IAEA
Presentation Nº 11

The IAEA has a special focus on producing International Safety Standards for the protection of the environment. The most recent publication on Ethical Considerations in Protecting the Environment, includes different views on valuing the environment encompassing:

- Sustainability;
- Biodiversity;
- Conservation.

In implementing protection measures, legislation must also ensure:

- Environmental justice;
- Respect for human dignity.

The process of decision making should be transparent and, as far as possible, should not be limited by national boundaries.

The IAEA believe that in order to take protection measures further, a quantitative relationship needs to be established between dose and consequent effects, within a framework usable for decision making.

If FASSET is concentrating primarily on risk assessment, the IAEA are concerned primarily with problem definition and risk management.[9] This entails, for instance, identification of when generic assessments are adequate and when site-specific assessments may be required. Considerations include:

- Timescales (from short term accidents not in equilibrium to geological disposal);
- Managed environments;[10]
- Endangered species;
- Public perceptions of ecological value.

It is probable that 'the range of environmental and cultural values may make it difficult to assign universally acceptable standards'. Nonetheless, FASSET should seek consistency with approaches for other pollutants and with schemes for the continued protection of humans.

Suggest that not just reference organisms but reference biosphere types should be included within FASSET (water bodies, terrestrial, desert etc).

A tiered approach to risk assessment and management is envisaged (with increasing complexity and realism in assessments required as progressive screening levels are exceeded).[11] However, some questions remain. Should FASSET consider non-equilibrium approaches? Should assessments be probabilistic? Is there a need to ensure compatibility with current environmental transfer models?

[9] See comments above.

[10] For example farms.

[11] But this still relies on a single, universally accepted, backstop threshold dose limit.

6. Exposure and dosimetry

6.1 Overview of work package on exposure

Per Strand, NRPA
Presentation Nº 12a

The objective is to estimate the exposure (expressed as internal and external doses) of biota (defined by the reference organisms) at the individual level, for scenarios defined by:

- Contamination patterns;
- Habitats.

Priority was given to identifying organisms likely to receive high exposures (e.g. due to bioconcentration in the individual organism or bioaccumulation through trophic levels) and to assess transfer pathways and mechanisms for uptake of radionuclides through simplified terrestrial and aquatic food webs. Ecosystem types include forests, semi-natural pastures, heathlands, rivers, estuaries and coastal environments. Assessment types include acute and chronic releases into the environment, and residual contamination from past practices and accidents. Other considerations include radiosensitivity and perceived conservation value of organisms or organism types.

This work has already been documented. The choice of reference organisms is not considered perfect, but is transparent and does provide a platform, which can be built on, for future studies.

The determination of exposure levels is currently defined as (in very broad terms):

$$Dose = Q * (AF * DCF_{int} + DF * DCF_{ext})$$

where Q is a quality factor (for instance covering weighting factors relevant to RBE),

AF is the accumulation factor,

DF is the distribution factor, and

DCF is the Dose Conversion Factor.

AF and DF are considered by WP 2; DCF_{int} and DCF_{ext} by WP 1, and Q jointly by WPs 1 and 3.

The next step is to compile the assessment process into a handbook of uptake pathways, radioecological models, parameter data, sensitivity and uncertainty factors.

Questions and comments

Max Wallis (FoE) noted that generic concentration factors (analogous to the Accumulation Factors above) for technetium in crustaceans under-represented uptake to lobsters by a factor of 30. Given this, how can a reference organism approach cope with variability in uptake between closely related species?

Per Strand agreed that not all cases can be covered by single reference organism approach, but the assessment method will encompass provision for site specific (or species specific) determinations.

6.2 Overview of work package on dosimetry

Gerhard Pröhl, GSF
Presentation N°12b

The work package on dosimetry has three main objectives. There appears to be three prime requirements to assess dose to biota:

- To develop dosimetric models for the assessment of internal and external exposures to plants and animals;
- To identify plants and animals with high exposure;
- To assess background exposure to plants and animals in different habitats.

To achieve this, it is necessary to consider:

- The exposure to α-, β- and γ-radiation;
- The geometry of the organisms;
- Materials and their shielding properties in the environment;
- The energy that is emitted by the radionuclide.

From this input data, a set of dose conversion factors will be established in units of Gy s^{-1} per m^3 (for organisms in soil, water or air) or per m^2 (for above ground plants and animals).

The exposure to biota is presently calculated as absorbed doses. The effective dose that is designed to quantify radiation exposures and stochastic effects to humans is no adequate endpoint for biota.

The dose equivalent requires knowledge on radiation weighting factors (RWF) for biota. The recommendations for RWF applied in dosimetry for humans refer to stochastic effects in humans and appear inappropriate to the endpoints considered for biota.

The weighting factors to be applied to biota for α- and low-energy β-radiation are under discussion. Input from the work package on effects will be awaited, in which data on relative biological effectiveness are collected and analysed. Until

then doses will be given by WP 1 as absorbed dose. Additionally the fraction of energy dose that is due to α- or low-energy β-radiation will be indicated. At a later time any selected weighting factors can be taken into consideration for the dose calculations.

Dose conversion factors to various reference organisms were presented for mono-energetic gamma sources on the soil or in the soil. Gamma energies varied from 50 keV to 3 MeV. The clear conclusion is that the exposure is linked primarily to the energy of the emission, rather than to the organism type (size or shape).[12]

For internal exposure the absorbed fraction is dependent both on the size of the target and on the energy of the emission (thus, for instance, gamma absorption is almost always < 1, whereas for alpha it is usually 1, except for organisms less than about 1 mm in diameter).

6.3 Guidance and critique

6.3.1 A Canadian approach to assessing risks to biota from radioactive contamination

Steve Mihok, CNSC
Presentation Nº 13

CNSC requires current protection of biota. Pragmatically, the approach adopted is to use existing ERA framework developed since the 1980s.[13]

Separate issues:

- Risk assessment – quantitative based on science, without value judgement;
- Risk management – qualitative based on political and value based judgements.

The Canadian Nuclear Safety Commission has conducted work on uranium toxicity in wildlife, and has considered a number of organism types.

Dose conversion factors have been applied from Amiro (1997) with RBEs of 40 for alpha emitters and 3 for tritium, assuming a homogeneous tissue distribution. Geometric means have been applied in setting concentration factors.

A tiered approach to dose estimation is employed, from level I (conservative) to Level III (probabilistic/realistic). Critical threshold values are derived to

[12] Above ground from mouse (most exposed) to cattle (least exposed) a factor of three covers the dose commitment, whereas the dose variation from the energy of the source covers orders of magnitude. Below ground a similar argument applies from an earthworm to a mole. The depth of burrowing and the gamma energy dominates the dose variation, rather than the organism size.

[13] See http://www.ec.gc.ca/substances/ese/eng/psap/final/main

determine when more complex assessments are required, and to determine upper limits on acceptable dose exposures. Generally it is considered that the approach is adequate, but the following issues may require further attention, particularly for where more complex assessments are required:

- Spatial and temporal averaging of field data;
- Defining appropriate background values for interpretation of R(isk)Q(uotient) values;
- How to code limit of detection values;
- Bioavailability;
- Accumulation in specific organs (e.g. Po-210 in flesh, bone and kidney);
- Consideration of progeny nuclides (e.g. Rn-222 from uranium decay);
- What defines conservative and realistic assessments;
- When to use generic or site specific studies.

In answer to queries raised so far:

- Absorbed dose is a usable concept;
- Need far fewer than 31 reference organism types;
- Want more than look up tables to allow user specificity;
- An assumption of uniform body distribution is usually adequate.

Regulation requires a demonstration that the facility is making 'adequate provision for protection of the environment'. There needs to be a pragmatic realisation that everything cannot be covered. Regulators cannot review in detail large and complex safety submissions. Assessments need to retain credibility. A false impression of sophistication is counter-productive.

Questions and comments

How are population relevant endpoints defined to derived critical threshold values?

Generally as mortality, but determined also by extent and quality of literature. The intent is to provide protection on the basis of best available information, interpreted reasonably.

Max Wallis (FoE) queried how the approach (which is essentially generic, as described) deals with protected species requiring individual protection?

Steve Mihok believed that this is not generally a problem, because the facility is available simply switch to individual protection approach.

6.3.2 An operators view

Tim Parker, World Nuclear Association
Presentation Nº 14

Over the course of the meeting simplicity has been mentioned many times as a pragmatic means of moving forward. Operators support this because it means protection can be demonstrated.

Protection of biota is not a new concern nor are limits on discharges. Numerical limits on liquid discharges have applied since 1954 and atmospheric since 1986. Once limits are imposed, the industry works rigorously to achieve these limits consistently. However, given that across industry, and for BNFL at Sellafield in particular, the trend is for much lower discharges it is reasonable to question why, if the discharges in the 1970s were having no observable effect, is there any need for a new system to be introduced now that discharges are much lower?[14] Furthermore, a commitment has been made to further continuously reduce discharges out to 2020, in line with the OSPAR commitments[15] and these will be insignificant compared to historic (Magnox) discharges.

Looking at dosimetry endpoints for FASSET, there is a preference for:

- Weighted absorbed dose;
- A small set of reference organisms;
- A complementary set of reference ecosystems;
- Dose constraints linked to organisms type;
- Contextual information on background doses.

Regulation should be proportionate to effects. The system should be flexible to encompass effective cut-off points (screening levels) so that crude assessments only are required for small dischargers.

Industry objectives:

- Not a knee jerk response to perceived failing in ICRP ethics;
- Not so complicated that cost is disproportionate to benefit;
- Comparability between regulation of nuclear and other industries;
- ICRP has high credibility and should lead the introduction of a new system.

[14] The reference is to a x1 000 reduction in alpha discharges and x 100 reduction in beta discharges over the past two or three decades.

[15] Magnox reprocessing is projected to cease in 2010, Thorp 'a few years' later.

6.3.3 'Ecodosimetry' and environmental protection

Norman Gentner, UNSCEAR
Presentation Nº 15

UNSCEAR has been addressing the need to set environmental dose standards.[16] There is a clear requirement to establish, and work within, an appropriate ethical framework. In addition, it is considered that any system introduced to regulate the nuclear industry should share features in common across industries and materials, addressing (for instance):

- Sustainability;
- Biodiversity;
- Environmental justice;
- Maintenance of human dignity.

In order to achieve this, we need to know

- What we are protecting (individuals, most sensitive species etc);
- Endpoints of concern (death, reproduction, induction of mutations).

Dose is the unifying quantity for radiation. It is a well established concept in radiation protection for man, with no equivalent in the chemical industry, but its use needs to be extended for environmental protection to derive an ecodosimetry weighting factor (e_R) similar to the radiation weighting factor (w_R) applied in human radiation protection practice to allow for the differential effects of equal absorbed doses of sparsely and densely ionising radiation. Weighting factors for organisms will also need to be cognisant of the relative radiobiological effectiveness (RBE) of different radiation types to induce harm.

RBE is not a simple concept. It varies with different endpoints, different organisms or tissues, different dose rates. Furthermore, RBE may vary with dose (especially for low LET). Moreover, there is a variety of biological considerations, including the occurrence of an adaptive response. Nonetheless, the concept of weighted absorbed doses appears to be necessary, both for simplicity and for enhanced realism, in determining environmental protection thresholds that can be applied across alpha, beta and gamma radiations.

e_R values must be linked to health effects. They will also be linked to RBE, but not limited to RBE considerations. Suggested e_R factors for alpha radiation:

Assessment endpoint	Level of protection	e_R
Survival, fitness (deterministic)	individual	5
Reproduction, fecundity (deterministic/stochastic)	population	10
Mutation, genomic instability	ecosystems and future generations	20

[16] See the UNSCEAR website at http://www.unscear.org

There are further questions to be addressed. Although it is reasonably well known how individuals are affected by exposure, it is not clear how this relates to population fitness. This issue cannot be discounted.

An international approach to protection of the environment is desirable. This may incorporate elements from the US, Canadian and FASSET approaches. The issue is more pragmatic than philosophical.

Questions and comments

The issue of teratogenic effects was raised, but considered to be of no great concern in most cases.

7. Effects analysis

7.1 Overview of work package on effects

Dennis Woodhead, CEFAS
Presentation Nº16

Four objectives have been set for this workshop:

- Identify the appropriate level in the biological hierarchy at which protective action should be focused;
- Identify the categories of effects which might be of concern;
- Identify target organisms;
- Summarise available information on radiation effects.

These are considered in turn below.

7.1.1 Biological hierarchy

Radiation acts at the atomic level, through energy transfer and the production of free radicals. These cause damage at the biomolecular level, through DNA breaks and biochemical pathway signalling. In turn this leads to scorable cytogenetic effects. Consequences may be cancer, cell death or impairment of organ function, with loss of vigour or reproductive performance, which in turn can reduce population density and lead to ecosystem imbalance.

Although the population may be considered the appropriate level at which to afford protection, this will automatically be provided for by focusing on individuals.[17]

7.1.2 Effects of concern

The objective is to preserve individual survival (avoid mortality), well-being (avoid morbidity) and reproductive capacity, and to avoid the accumulation of somatic or germ line mutations.

Generally, the primary targets are rapidly growing cells (such as meristematic cells in plants), the gonads and the developing embryo.

[17] In addition, a focus on individuals means that rare or endangered species are covered within the routine protection approach, and do not require special consideration.

7.1.3 Selection of reference organisms

With due consideration of the spatial and temporal distribution of radioactivity in the environment, chemical behaviour, uptake pathways etc., the range of potential reference organisms must cover the range of general radiosensitivity (through life cycle stages, trophic levels, phylogeny etc). This issue has been dealt with at length in WP 1, and the recommendations from that group have been published.

7.1.4 Summary of information on radiation effects

There is a need to summarise available information on acute and chronic exposures, categorised by reference organism for potential impact. This part of the project is currently underway.

Questions and comments

Susan McCready-Shea (HSE) queried the omission of micro-organisms from the list of reference organism types.

Dennis Woodhead advised that these have not been ignored, but it was considered that the dosimetry would be dominated almost wholly by external pathways. Furthermore, as a group, they are very radioresistant and therefore effects would also be very limited.

Norman Gentner (UNSCEAR) noted that protecting individuals will protect populations. However, pragmatically, there may have to be an acceptance that some impact will be 'acceptable' and this will require transparent guidance. For instance, some level of cytogenetic mutation or scorable effects may be unavoidable if dose limits are to be set at workable levels.

Max Wallis (FoE) noted, by contrast, that there may be synergism between co-contaminants such that apparent protection of an individual from one contaminant will not protect a population or community from the range of contaminant exposures.

7.2 Guidance and critique

7.2.1 Involvement of the Nature Conservation Councils

Alastair Burn, English Nature
Presentation Nº 17

The EU Habitats Directive (1992), implemented under UK law in 1994, requires the assessment of all impacts on 'Natura 2000' sites. This includes the impact of radioactivity and requires that the polluter demonstrates no adverse effect on the integrity of the sites. Given the recent criticism of the ICRP Publication 60 approach, based on protection of humans, an interim approach was required

and has been published as EA R&D Publication 128. FASSET should seek to address many of the issues or approaches raised in this report.

A generally precautionary approach has been adopted in setting concentration ratios, calculating internal and external dose rates. However, assumptions of uniform radionuclide distributions within simple ellipsoids, and the omission of many radionuclides at this stage, may under-estimate doses. Consequently, as a further precaution, a 'trigger' level of dose estimate is set at 5 % of the IAEA guidance values, above which a more site specific demonstration of no adverse effects would be required.

Pointers for the FASSET programme

A risk assessment model is required which identifies particularly the issues for Natura 2000 sites, SSSIs and vulnerable species as well as the wider environment. Furthermore, FASSET cannot avoid the issue of risk management. Guidance is required to interpret and implement assessment data.

The use of 'reference organisms' (by which is currently meant 'reference ellipsoids') is laudable in the sense that it avoids toxicity testing on higher animals. However, for compatibility with other regulatory frameworks there needs to be a clear demonstration of the applicability of results on standard test organisms and the extrapolation to species of particular concern. Exceptional pathways (e.g. *Lophelia* corals) or exceptionally sensitive species (e.g. marine mammals) must be addressed explicitly.

The issue of background levels and the effects of co-contaminants[18] should be addressed. Furthermore, since FASSET deals with impacts post-release, dear guidance should be given on the requirement for monitoring to demonstrate no adverse effects. This appears to be an important omission from the current programme.

With respect to the effects of radiation, it may be useful to consider behavioural modifications. Population effects are agreed as the appropriate level to ensure protection, but for mammalian species this may require further guidance on sub-lethal effects and the accumulation and persistence of mutations in the population.

Finally, a move to a probabilistic means of expressing impacts would be valuable. This makes transparent the process by which some 'acceptable' impact levels are set.

[18] This includes the combined impact of radioactivity from all sources (including natural background) and other contaminants such as chemical compounds in the environment.

7.2.2 Difficulties in interpreting exposure-effect data

John Knowles, CEFAS
Presentation Nº 18

Fundamental questions on which effects are important can be raised. For instance, the loss of older animals, past reproduction or contributing negligibly to reproductive capability is of little environmental concern.[19] However, does FASSET have a role with respect to public concerns, in which case issues such as cancer induction may not be dismissed too lightly? Furthermore, the complexity of ecosystems may mean that protecting populations per se may not protect the whole ecosystem. Even non-reproductive individuals may have a role in community balances.

Extrapolation from laboratory experiments to field impacts is not always straightforward. Whole populations, let alone communities, are rarely raised in laboratory experiments. Perhaps FASSET should address this issue. Guidance on the type of information required could be used to influence research programmes.

Extrapolation from acute exposures to chronic low-level doses should be avoided. Low dose response and repair mechanisms will be swamped at high level acute exposures and simple extrapolation may be highly misleading.

One specific example of a scorable cytogenetic effect, the comet assay for DNA damage, was presented to demonstrate the difficulties in: 1) extrapolating from short term to long term chronic exposure situations; and, 2) from this endpoint to other effects endpoints. Thus, for 1 hour and 24 hour exposures of zebra fish larvae at dose rates of 1 200 and 7 200 μGy h^{-1}, the degree of DNA damage was found to be dependent on dose rate, but not on the exposure period (and, therefore, the total accumulated dose). However, when exposure was prolonged to 1 year, the level of damage, in terms of reproductive output, even at 1 000 μGy h^{-1}, was indistinguishable from the controls (despite, presumably, the presence of similar levels of DNA damage). Both of these results suggest the importance of repair mechanisms in chronic exposure situations.

7.2.3 Establishing a radiation effects database

David Copplestone, ERC, University of Liverpool
Presentation Nº 19

A database derived from the experimental literature is being compiled, as part of the FASSET programme, to aid the reproducible definition of dose-response relations. The aim of the Radiation Effects database is to gather information to enable the systematic interrogation of data for dose/effect to cover a number of wildlife groups. Both high level acute doses and low-level chronic exposures are covered, but no judgements on the quality of data are incorporated.

[19] Thus, cancer induction, for instance, in organisms would be of limited concern.

Questions and comments

Max Wallis (FoE) considered that the lack of a quality check[20] on the data being entered appears to be a major concern. He contended that the nuclear industry has falsified data and continues to suppress publication of data that do not support its stance.

Carl-Magnus Larsson (SSI) responded that the data entered are those available in the scientific literature. It is not possible to judge the quality of data without introducing the potential for a significant bias on the part of the interpreter. Information must be used as it stands.

Paul Johnston (Greenpeace) supported the compilation of the database. There may be some drawbacks to individual data entries, but the overall compilation is a very worthwhile venture and much to be appreciated.

Jill Sutcliffe (EA) asked whether there would be an interface with data derived for human health effects (e.g. recording mice data used to determine effects on humans).

David Copplestone responded that all data for biota will be recorded, irrespective of the purpose for which it was originally obtained, but cross-reference to the implications for humans will not be recorded.

[20] That is, independent verification of the quality of the observational data, not of the data entry process.

8. Output from workshops and plenary sessions

Three parallel workshops were held, to address the elements of the FASSET framework. All Open Forum participants were requested to attend one workshop of their preferred topic. The outcome of the workshops is reported below and constitutes a consensus between participants within those three workshops.

8.1 Workshop on development of an assessment framework

Carol Robinson, chairperson

The following questions and responses were advanced in the open plenary session.

Has FASSET identified the correct elements for risk assessment?

- General agreement that it is useful to put all scientific information together, but a strong feeling from some contributors that risk assessment cannot be divorced from risk management and reference to socio-political aspirations.
- Need to incorporate the work of other organisations, such as the hazardous substances committee of the OSPAR Commission, SPRU[21] and CERRIE[22].
- May be useful if an independent international organisation were instituted to review information and recommendations.

Has FASSET addressed a relevant level of simplification through the introduction of reference organisms?

- Need to be cautious of over-simplification. Data need to be compared to 'reality'.
- Needs to be a balance between ecological requirements against the number of chosen reference organisms.

[21] SPRU is the Science Policy Research Unit, based at the campus of the University of Sussex.

[22] CERRIE is a Consultative Exercise on Radiation Risk from Internal Emitters.

Protecting the environment from other contaminants

- A consistent approach should be adopted across contaminants.

Protection of human health

- FASSET should be linked (or at least run in parallel to developments in human health protection).

What output is required from FASSET?

- Database.
- Method for environmental risk assessment.

What might be missing?

- Evaluation of data entered into the database (checking for areas of agreement as well as discrepancies).
- Consideration of dynamic fluxes and transfers within ecosystems.

8.2 Workshop on exposure and dosimetry

Norman Gentner, chairperson

The object set for the session was to provide helpful inputs to guide the future FASSET programme. Where possible broad agreement was sought on each issue.

A number of topics were raised, and the highlighted issues were broadly considered to identify the priority areas for FASSET to address:

- The use of reference organisms – numbers (too many or too few), how representative, representative of what, how have they been selected, do they over-simplify the issue;
- Extrapolation from protection of individuals to populations and to ecosystems, definition of pathways, transfer mechanisms and community inter-actions;
- Monitoring and compliance, what environmental measurements are required to demonstrate compliance, what screening levels might be introduced;
- What weighting factors are to be applied, and how are they to be derived;

- Interface between exposure pathways and choice of reference organisms – does this imply a set of 'reference models';
- Consideration of the dynamics of ecosystems (i.e. non-equilibrium conditions), there may be too much reliance on simple K_ds and concentration ratios as a basis for deriving dose conversion factors and the appropriateness of the methodology as a flexible tool needs to be addressed;
- How is the information used – unless it is clear how the tool is to be used, the appropriate assessment method cannot be determined;
- More fundamental review of radiobiology (as opposed to a health physics approach) to identify mechanisms of impact;
- Identification of *key* problems and recommendations to prioritise future research needs (reduction of uncertainty on the basis of where it matters);
- Further weight to be given to effects on reproduction;
- Further emphasis on variability (spatial and temporal variability);
- Transparency of the method to be applied (clear tabulation of data with caveats on use, ability to deal with site specific scenarios).

More detailed consideration was then given to the prioritised topics.

Reference organisms

In general, the approach adopted by FASSET is supported, but issues arise over the appropriate set of parameters to define a reference organism and how to extrapolate this to organisms of real concern. This requires knowledge of exposure pathways, habitats and impacts and will lead to a list of 'candidate species' for monitoring purposes.

The question almost needs reversing. Defining the system to be protected will define the appropriate types of reference organisms. Defining the effects to be avoided will determine the characteristics of the reference organisms to be addressed.

How far should reference organisms be generic (fish, tree, herbivorous mammal), which are therefore ubiquitous within the chosen ecosystem types? Should reference organisms be identifiable with representative organisms (which define both geometry and biology/radiobiology)? Can this be linked to the use of indicator species for monitoring? Even closely related species can evidence high variability between uptakes and impacts (sensitivity).

Protection of individuals, communities and ecosystems

Issues include spatial and temporal variability of concentrations, doses incurred and effects on individuals. Late onset detriment (e.g. cancer induction), which

reduces longevity (assumed to remove predominantly post-reproductive individuals) may imply that stochastic as well as deterministic effects need to be considered.

Behavioural modifications may also affect community structures, although laboratory trials may not evidence any population effect.

Other factors of relevance may include the effect of co-stressors on broader community groupings, immune response suppression etc.

The general feeling is that whilst public perceptions may require addressing such issues, from a scientific view it is of little real consequence.

One important, and so far unresolved, question is how to apply risk quotients or individual based risk coefficients to population protection. The suggestion is that FASSET provide guidance on the application of dose factors in the demonstration of environmental protection (i.e. to provide risk management guidance).

Radiation weighting factors

General support that weighted absorbed dose is a useful concept. The derived radiation weighting factors need to be linked to radionuclide (energy transfer), reference organisms and endpoints of concern. RWFs will not always be the same as RBEs derived for stochastic effects.

RWFs need to be identified for all alpha and beta emitters.

Can a single RWF be defined applicable to all exposure scenarios (acute, chronic, dose rate) and all endpoints of concern? Should a distinction be made between realistic and conservative derived RWF? Should a probability distribution function be used to describe RWFs?

Monitoring, surveillance and demonstration of compliance

General support was given to developing a screening approach, e.g. based on concentrations in the environment (analogous to a GDL approach) or in organisms (defining appropriate indicator species). The setting of levels requires an understanding of the dose response relationships and the levels set to avoid unacceptable detriment. The simple assumption of uniform radionuclide distributions (either in the environment or in organisms) may require further consideration, since variability has been raised on many occasions, but a simple measure for monitoring compliance is required. This should be based on whole organism data where possible.

8.3 Workshop on effects analysis

David Copplestone, chairperson

Concentrate on three issues:

- RBE;
- Extrapolation from acute to chronic exposure-effect responses;
- Cytogenetics.

Safety factors and probabilistic queries – agreed that this had been discussed suitably in the plenary sessions but there should be guidance given from FASSET on the application of safety factors

RBEs

- RBE required – but 'radiation weighting factors' terminology;
- Simplification issue;
- One or many RBEs?
- In order to simplify you need to understand the data, and gaps in the data;
- RBE is always dependent upon endpoint;
- Need to consider all four 'umbrella' endpoints and need to consider RBEs for the reference organisms;
- *Then*, if necessary, you can simplify if required (i.e. do not do this *a priori*);
- Degrees of discomfort?
- Data gaps quantity and quality is of most concern – require some management decisions (e.g. RBE use one or more values?);
- Learn from the Canadians.

Extrapolation of data

- Rule of thumb to extrapolate from acute to chronic – a total dose of approximately 10 times the LD_{50} can be accumulated at chronic dose rates;
- Ward Whicker (IAEA 1992) approach – where data sets exist that can be used in this way – *caution* (may need safety factors, precautionary);
- Recommend FASSET try to 'replicate' the Ward Whicker approach;
- Will not be able to do for all reference organisms and all endpoints;
- Will only be for low LET as there is not enough information on high LET;
- Will identify data gaps, are there any numbers and are they realistic?

Cytogenetic effects

- Acceptability of cytogenetic in terms of an endpoint – it is an endpoint in itself and hence potentially not that useful in its own right *but* FASSET could use towards RBE assessment;
- FASSET explore and advise on where concerns are between the no effect and no adverse effect levels for cytogenetics and this should justified for management purposes;
- Extrapolate cytogenetic effects to populations but FASSET should look at the cytogenetics to the individual level;
- Good biomarker;
- Good testing (screening) tool;
- Utility for cross comparison with other contaminants (using a *retrospective* approach) could be used for validation;
- However, watch the sensitivity and background variation.

Conclusion

Future studies of the effects of chronic radiation exposure on the umbrella endpoints of reproduction, morbidity and mortality should also include parallel studies of appropriate biomarkers.

9. General discussions following the workshop session

9.1 Philosophy of protection

FASSET seeks to address scientific principles of risk assessment, without entering into risk management principles and application, and seeks to avoid value-based judgement. Thus organisms are considered only as types. The issue of whether one species, population or ecosystem merits greater protection than another is not addressed. However, it is contended that all science is socio-economically shaped and therefore value judgements cannot be avoided and should not be avoided. This raises a fundamental issue: can a single dose limitation system be supported?

A 'pragmatic approach' is widely referred to. We do not live in a no risk environment. Natural radioactivity is ubiquitous and dose limitation frameworks must be set within this context. The purpose is to protect the environment. Therefore, need to relate dose to biological endpoints.

Risk based or zero discharge (ultimate precautionary principle). Protection of the environment implies an inherent value judgement.

Individual *vs* population effects. It may not be true that *appearing* to protect individuals adequately protects populations?

A tiered approach is generally favoured. This may need to be built into the risk assessment framework. For instance, screening levels may be set to protect reproduction (population fitness) or mortality (individual fitness), or may be set at levels of probabilistic risk.

9.2 Scope of FASSET

Is it reasonable to duck the issues of risk management (e.g. the application of risk assessment information within a regulatory framework)? Although the consensus is that FASSET should restrict itself to the problem formulation and risk assessment stages, some views were expressed that assessment and management are linked inextricably.

The programme should include recommendations regarding monitoring and field work to demonstrate compliance against limits.

9.3 Determination of doses and effects (endpoints)

Treatment of uncertainty. Deterministic *vs* probabilistic approaches to dose estimation and limitation.

The use of scorable cytogenetic effects is questioned closely.

9.4 Demonstration of protection

Identification of the most sensitive species, which seems common sense, raised a number of objections.

All processes need to be transparent.

9.5 Specific suggestions

Use a smaller, not a larger, set of reference organisms.

10. Concluding remarks

The External Forum highlighted major discussion points on the choice of reference organisms and the use of RBE/RWFs. Broadly, the meeting agreed that the current programme is formulating an appropriate response, but with some reservations continuing to be expressed relating to the core concept of the usefulness of weighted absorbed dose.

Appendix 1

External Forum Programme

Monday, 8 April, 2002

Introductions

10:00 – 10:20	Opening Addresses	*Joe McHugh,* *Ernst-Hermann Schulte*
10:20 – 11:05	Project overview, objective of the meeting	*Carl-Magnus Larsson*
11:05 – 11:30	Structure of plenary discussions	*Irene Gize*
11:30 – 12:15	Structure of workshops by the Chairpersons	*Carol Robinson* *Norman Gentner* *David Copplestone*
12:15 – 13:30	Lunch	

Framework elements

13:30 – 15:30	**Assembling a Framework** Guidance and Critique	*Carl-Magnus Larsson* *Paul Johnston* *Lars-Erik Holm* *Carol Robinson*
15:30 – 16:00	Coffee/Tea	
16:00 – 18:00	**Exposure and Dosimetry** Guidance and Critique	*Gerhard Pröhl* *Per Strand* *Steven Mihok* *Tim Parker* *Norman Gentner*

Tuesday, 9 April, 2002

Framework elements (cont'd)

09:00 – 11:00	**Effects Analysis** Guidance and Critique	*Dennis Woodhead* *Alastair Burn* *John Knowles* *David Copplestone*
11:00 – 11:30	Coffee/tea	

Workshop

11:30 – 13:00	Group Recommendations on	
	1. Framework	*Carol Robinson*
	2. Exposure and Dosimetry	*Norman Gentner*
	3. Effects	*David Copplestone*
13:00 – 14:00	Lunch	
14:30 – 16:00	Writing Group Recommendations	
14:30 – 16:30	Reports by the Chairpersons, General Discussion and Closing	*Carol Robinson* *Norman Gentner* *David Copplestone* *Carl-Magnus Larsson*

Appendix 2

List of participants attending the External Forum

International Organisations

European Commission	Ernst-Hermann Schulte
Environmental Protection from Ionising Contaminants, EPIC (EC project)	Brenda Howard
Friends of the Earth, FoE	Max Wallis
Greenpeace	Paul Johnston
International Atomic Energy Agency, IAEA	Carol Robinson
International Commission on Radiological Protection, ICRP	Lars-Erik Holm
International Union of Radioecology	Deborah Oughton
Nuclear World Association	Tim Parker Sylvain Saint-Pierre
OSPAR Commission	Reiner Goud
United Nations Scientific Committee on the Effects of Atomic Radiation, UNSCEAR	Norman Gentner

Canada

Canadian Nuclear Safety Commission, CSNC	Glen Bird Steve Mihok

Finland

Posiva Oy	Ari Ikonen
Radiation and Nuclear Safety Authority, STUK	Erkki Ilus Ritva Saxén

France

Institute of Radiological Protection and Nuclear Safety, IRSN (former IPSN)	Francois Brechignac Jacqueline Garnier-Laplace Pascal Santucci

Germany

Institute for Radiation Protection, GSF	Gerhard Pröhl
Federal German Radiation Protection Office, BfS	Frank Bruchertseifer Wolfgang Donhärl

Norway

Norwegian Radiation Protection Authority, NRPA	Justin Brown Mikhail Iosjpe Helene Stensrud Per Strand

Appendix 2

List of participants attending the External Forum

Spain

CIEMAT – Environmental Institute	David Cancio José Maria Gomez-Ros Almudena Real Beatriz Robles

Sweden

Kemakta	Celia Jones Sara Södergren
SKB	Ulrik Kautsky
Stockholm University	Michael Gilek Linda Kumblad
Swedish Radiation Protection Authority, SSI	Rodolfo Avila Synnöve Sundell-Bergman Carl-Magnus Larsson

UK

Centre for Ecology & Hydrology, CEH	Nicholas Beresford
Centre for Environment, Fisheries and Aquaculture Science, CEFAS	John Knowles Dennis Woodhead
Department of Environment, Food and Rural Affairs, DEFRA	Martin Hum
English Nature	Alastair Burn Jill Sutcliffe
Environment Agency	Irene Gize Joe McHugh Clive Williams
Enviros Quantisci	Duncan Jackson
ERC, University of Liverpool	David Copplestone
Health and Safety Executive	Susan McCready-Shea
Scotland and Northern Ireland Forum for Environmental Research, SNIFFER	Ken Ledgerwood Julie Tooley
Westlakes Scientific Consulting	Paul Daniel Steve Jones Jordi Vives

Appendix 3

Condensed list of recommendations and responses

Responses to issues raised and recommendations made during the FASSET External Forum

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 FASSET Consortium welcomes feedback from all invited organisations to the Forum, as well as other interested parties. Please send comments to carl-magnus.larsson@ssi.se

Exposure and Dosimetry

Issue/Recommendation	**FASSET Response**
An 'equivalent dose for fauna and flora' will have to be developed and the concept of a 'weighted absorbed dose (rate)' could be useful. 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.	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.
We need to know how to do a much more realistic job in estimating dose. A uniformly distributed dose is not too simplistic, given the tremendous diversity of organisms and ecology in the real word, and given the data collected to meet regulatory requirements.	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.

Exposure and Dosimetry (continued)

Issue/Recommendation	FASSET Response
We need to know effect 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

Issue/Recommendation	FASSET Response
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)

Issue/Recommendation	**FASSET Response**
Information on responses to acute exposures is insufficient to extrapolate to low chronic exposures. Recommend FASSET to try to extrapolate from acute to chronic with available datasets. We need to know how to convert what are essentially dose data to dose-rate criteria.	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.
Consider the credibility (public acceptance) of providing results for many species.	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.
Use of standard test organisms, as in other jurisdictions.	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 defendable than performing substantial testing on, e.g., mammals. It is possible that review of effects data may lead to suggestions of possible tests 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.
Provide guidance to interpret data. Limited QA on database entry.	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.

Appendix 3

Condensed list of recommendations and responses

Framework structure

Issue/Recommendation	FASSET Response
The framework should be applicable to various assessment situations. Need to consider effects of radiation from all point sources into a given receiving environment. Will FASSET consider the impact of different disposal routes?	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.
For practical application the following are important: • a structured approach to problem formulation and assessment, • transparency of assumptions included in the framework, • compatibility with established assessment procedures. Industry would wish to see FASSET providing output compatible with developing ICRP thinking. The FASSET approach should learn from other chemical approaches.	The Consortium has agreed to restructure Deliverable 2 into a main report which systematically analyses the FASSET assessment context, reviews different choices, and justifies the approaches taken by FASSET. This Deliverable will be backed up by an Appendix 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.
Use tiered risk assessment approach: use of thresholds for triggering higher tier testing, or for regulatory action. Consider thresholds for judging acceptability of effects at each stage. Need to develop guidelines to determine acceptability of effect (how to incorporate/interpret 'close to zero' emissions.	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.

Appendix 3

Condensed list of recommendations and responses

Framework structure (continued)

Issue/Recommendation	FASSET Response
There is a need for a primary set of reference organisms (< 10) and then secondary reference organisms as necessary. 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. The concept of reference organisms is not universally agreed.	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.
What tools? Look-up tables? 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.	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. FASSET will adapt the BIOMASS methodology and come up with checklists to help guide decision makers in carrying out assessments.
Risk concept premature.	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.
Avoid academic 'overkill'. Consider the ability of regulators to review QA-complex, detailed submissions. Consider the ability of licensees to use the information wisely, for the intended purpose. Consider management issues when designing a framework.	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.
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.

Framework structure (continued)

Issue/Recommendation	FASSET Response
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 analysis, 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.