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DELIVERABLE D7b: Briefing Notes from The Second Thematic EUG Event

Part 1: Ionising Radiation and other Contaminants and Part 2: Contribution to Deliverable D4 on Risk Characterisation

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

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Foreword

This report (deliverable D7b) is a briefing note from the Second Thematic EUG Event. The report summarises presentations and group discussions that were held on two topics of interest:

- Part 1: "Ionising Radiation and other Contaminants"; and
- Part 2: "Contribution to Deliverable D4 on Risk Characterisation".

Summaries of some of the speaker's presentations were distributed prior to the meeting, together with an initial list of questions relevant to the themes to be discussed at the event.

During the meeting, a number of keynote speakers were invited to give presentations reflecting the state-of-the art on selected topics. This was followed by smaller group discussions with ERICA Consortium participants (representing each ERICA WPs), EUG members and invited speakers. A number of questions were distributed at each discussion sessions to help initiate the dialogues. All groups then reported in plenary sessions and further information was exchanged.

The deliverable D7b and well as all presentations for Part 1 have been placed on the public/results area of the ERICA website: www.erica-project.org. Presentations in Part 2 have been posted on the EUG protected area of the website, as the material is under development and discussion by ERICA participants.

We have endeavoured to ensure that all EUG comments and suggestions have been included and reproduced accurately in this document. Drafts have been sent to the EUG members present during discussion for comment. The report concludes with a summary of the main points raised by the EUG, together with the action to be taken by the ERICA Consortium.

The EUG organisations participating in the Event included:

International Union of Radioecology

World Wide Fund for Nature

World Nuclear Organisation

Belgium: Centre d'Étude de l'Énergie Nucléaire

Croatia: Institute for Medical Research and Occupational Health

Finland: Ministry of the Environment

France: Cogema, Commissariat à l'Énergie Atomique, Agence Nationale pour la Gestion des Déchets Radioactifs, Autorité de Sureté Nucléaire

Germany: Federal Office for Radiation Protection

UK: English Nature, The Centre for Environment Fisheries and Aquaculture Science

USA: Savannah River Ecology Laboratory

The external invited speakers belonged to:

Belgium: University of Anvers

France: Ministère de l'Écologie et du Développement Durable

Germany: University of Essen

UK: Environment Agency, The Institute for European Environmental Policy

Next Meeting	Location	Date
EUG Generic meeting	Freising (outside Munich), Germany	25-27 April 2005

Acknowledgements

The ERICA Consortium would like to thank the main contributors who have helped in generating the D7b text.

- Invited Keynote Speakers: Christian Streffer, Ronny Blust, Paul Whitehouse, Andrew Farmer and Eric Vindimian.
- ERICA Consortium Speakers: Philippe Ciffroy, Jacqueline Garnier-Laplace, Rodolfo Avila and David Copplestone.
- Group Chairs: Tom Hinton, Jill Sutcliffe, Bretannia Walker, Hildegarde Vandenhove, Miliza Malmelin, Ronny Blust, Paul Whitehouse, Eric Vindimian.
- Group and plenary discussion secretaries: Ingrid Bay, Astrid Liland, Turid Hertel-Aas, Kirsti-Liisa Sjoblom, Ulrik Kautsky, Rodolphe Gilbin, Rodolfo Avila.

Table of contents

1 Introduction

The ERICA co-ordinator, Carl-Magnus Larsson, welcomed all participants. He presented the ERICA project in broad terms, emphasising the role of the EUG members and the planned EUG event. Deborah Oughton then presented the aim of the second thematic EUG event and explained the procedures to be followed for the whole two-day event.

2 Overall Objectives

This second EUG event had two main objectives:

1. to provide a general discussion on risk assessment and management of ionising radiation and other environmental stressors (i.e. Day 1); and
2. to review a draft of the ERICA project Deliverable D4 on "Risk Characterisation Methodologies" (i.e. Day 2).

The event's agenda for Day 1 and Day 2 is shown in Appendix 1. This meeting, which was the second of a planned total of seven EUG events, consisted of EUG members, invited speakers and a limited number of ERICA Consortium participants, who represented all ERICA WPs. Those EUG members who previously expressed a wish to attend this meeting have been prioritised, but the meeting was also open to other EUG members, as space permitted.

EUG members were also requested to fill in an evaluation questionnaire at the end of the meeting to help the ERICA Consortium improve future events.

This report, D7b, which summarises both presentations and group discussions, will help the ERICA project in producing guidance on how decision-makers and authorities might approach the assessment and management of radiation contamination, i.e. Deliverable D8 on "Decision-Making Guidance".

Both D7b and related presentations on Part 1 have been placed on the public/results area of the ERICA website: www.erica-project.org. Presentations and background material related to Part 2 have been posted on the EUG protected area of the website, as the material is under development and discussion within the ERICA project. The final deliverable D4 will be publicly available in March 2005.

2.1 Day 1 - Ionising radiation and other environmental stressors

The purpose was to identify areas of consensus and dissent regarding the alleged similarities and differences in the assessment and management of ionising radiation and other stressors. The discussions on ionising radiation and other contaminants focused on a comparison of environmental stressors and their interactions, within three main themes.

1. Biological and toxicological effects:
   a. biological effects of radioactive substances and other chemical stressors in the low dose range;
   b. comparative environmental toxicology: towards an understanding of effects across levels of organization and complexity.
2. Dose-response models and risk characterisation:
   a. assessing the environmental risks of radioactive substances - a comparison with approaches for non-radioactive substances;
   b. the use of Species Sensitivity Distributions to derive predicted No-effect concentrations for stable chemicals. First applications to radionuclides and effects data from FRED;
   c. quantification of environmental risks.
3. Management and socio-economic issues:
   a. risk management: general comparison of regulation of environmental pollution; and

b. EC Chemicals Policy: from a European to a national point of view? Case study: the Water Framework Directive - is there an implication for radioactive contaminants?

A number of keynote speakers were selected to present introductions to these three themes. A draft briefing note was prepared based on the material received from the speakers and was distributed to participants prior to the meeting.

2.2 Day 2 - Contribution to deliverable D4 on risk characterisation

WP2 has been working on their first deliverable, D4: "Critical Review on Methodologies for Risk Characterization and for Effects Testing Strategies", due to be published in March 2005. The WP Leader was to present their efforts to date, which centres on three areas:

1. D4 overall structure and content;
2. proposed tiered approach to risk characterisation; and
3. overview of plans for experimental work at NLH/NRPA and IRSN institutions.

Some of the material related to the above was circulated prior to the event.

2.3 Procedure to follow during the discussion groups

In addition to keynote speakers, time was allocated to small, breakout group discussions, to enable a more focused dialogue between EUG and ERICA participants. A division of groups for Day 1 and Day 2 are shown in Appendix 2. The procedure was identical for both days.

Each group elected their own chairperson, and the Consortium provided a secretary and a referee. Comments provided during the group discussions were not to be attributed to individuals. Members had the choice of representing themselves or their organisations. Citation, or any other form of revelation, by one group member of another group member's opinion or assertion expressed during this part of the procedure would not be allowed. This was to be followed to enable free exchange of views.

2.3.1 Roles

- Chair/Rapporteur. A group elected EUG member to guide discussion, keep to time, sum up, and report in plenary session.
- Secretary. To take notes during discussion to provide any required support and assistance to the Chair in summing up and to assist in drafting the current report (ERICA consortium or EUG member).
- Referee (ERICA consortium member). To get the discussion started, aid the chair if necessary, ensure every person has an opportunity to speak and keep track of time.

A list of questions for each three themes was provided to help focus discussions, refer to Appendix 3.

Part 1: Ionising Radiation and other Contaminants

1 Theme 1: Biology and Ecotoxicology

1.1 Biological effects of radiation and chemical stressors

1.1.1 Summary of presentation

Ionising radiation is a genotoxin, capable of inducing chemical changes in DNA molecules and is an established carcinogen. At a cellular and organism level, radiation has the capability to produce similar effects as chemical stressors. However, there are also a number of important differences, both in the underlying mechanisms, reaction pathways, and dose-response relationships as well as the types of biological endpoints[1] associated with toxicant exposure. For example, important attributes of ionising radiation include the density with which ionising radiation can induce chemical changes in biological material (i.e., certain internal sources can induce a more in homogenous and localised damage than for chemical stressors), and the fact that external irradiation can induce harm without the need for contact, ingestion or inhalation of the substance by the organism (Table 1.1).

Table 1.1: Some Features of the Primary Events after Exposures to Ionising Radiation or Chemicals in the Low Dose Range [Streffer *et al.*, 2004]

	External Radiation	Internal Radionuclides	Chemicals
Biokinetic (Distribution)	No	Yes	Yes
Metabolism (Molecular Changes)	No	No (few)	Yes
Homogenity of Exposure			
• **Total Organism**	Mostly yes	Usually no	No
• **Tissue – Organ (Cellular Level)**	No	No	(Yes)
• **Exposed Cells**	Yes	Yes	No
Molecular Damage			
• **Breaks of Covalent Bonds**	Yes	Yes	Usually no
• **Clustered Damage**	Yes	Yes	Usually no
• **Single Sites**	Few	Few	Yes

Cancer represents one of the most studied endpoint of ionising radiation in humans, particularly in the low dose range. At high doses it is well established that, like chemicals, ionising radiation can produce a number of effects where the dose-response relationship shows a threshold. Biologically, the occurrence of a threshold requires a multicellular mechanism whereby damage to many cells—often cell death—is necessary for the effect to arise. These are often described as tissue or deterministic effects. Dose relationships without a threshold (stochastic effects) work via a unicellular mechanism,

[1] In chemical toxicology, *endpoint* is a general term referring to the biological state or disease (such as morbidity, fertility or cancer rate) against which toxicity is tested, whereas *effect* is used specifically to describe a *change* in a particular endpoint (e.g., increase in cancer rate, decrease in fertility) as compared to a control. In radiation biology, the two terms are often used synonymously – and even confused.

whereby a change in one cell—usually a mutation—can be sufficient to produce the effect. Induction of cancer and hereditary diseases are examples of such effects. Although induction can arise from a change in a single cell, carcinogenesis is a multistep process in which several mutations follow over a long time period. Some of these mutations occur in oncogenes (activation) and tumour suppressor genes (inactivation), and can stimulate cell proliferation. The proliferation processes following malignant cell transformation are very similar, or even identical, for exposure to genotoxic agents (Figure 1.1). Therefore these later processes of cancer promotion and progression are comparable for ionising radiation and certain genotoxic chemicals.

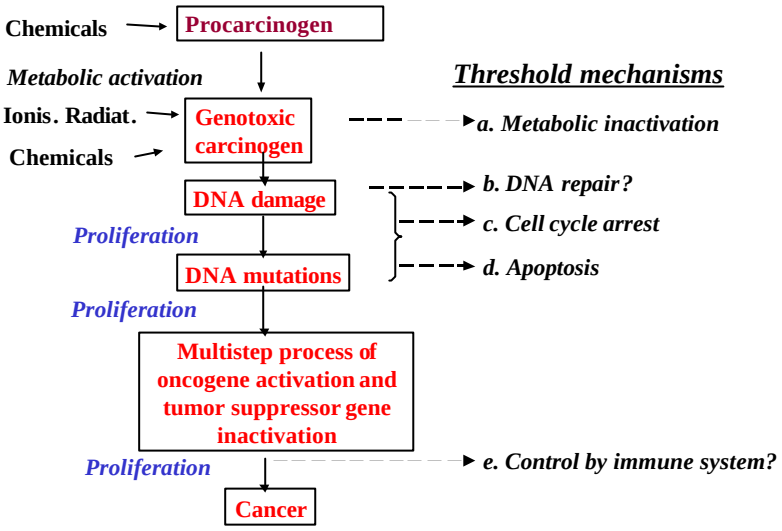

Figure 1.1: Mechanisms of carcinogenesis by toxic agents [Streffer *et al.*, 2004]

With respect to the primary events, the situation is often more complicated for genotoxic chemicals than for ionising radiation. While ionising radiation can always react directly on the genetic material (DNA) in cells a number of genotoxic chemicals have to be metabolically activated for interaction with DNA, or else other chemicals are inactivated. Therefore metabolic processes are frequently important for chemical carcinogens. On the basis of carcinogenic mechanisms, the toxic agents can be differentiated as shown in Table 2.1.

Table 1.2: Classes of carcinogens and their dose-response relations [Streffer *et al.*, 2004]

	Classes of carcinogens	Examples
1	Genotoxic agents without a threshold dose; LNT (Linear No Threshold) supported by epidemiological and experimental data.	Ionising radiation, vinyl chloride, some heavy metals
2	Genotoxic agents without a threshold dose; there exist larger uncertainties in the low dose range. Precautionary principle suggests use of LNT.	4-aminobiphenyl, acrylamide
3	Genotoxic agents with scientific data for mechanisms, which suggest a threshold dose. Repeated exposures are necessary.	formaldehyde, vinylacetate (NOAEL and safety factors)
4	Non-genotoxic agents with a threshold dose supported by experimental data.	dioxines, hormones and analogous substances (NOEL, safety factors)

Phenomena modifying dose-effect relationships (ionising radiation)

Recent molecular and cellular investigations have demonstrated and highlighted a number of interesting biological phenomena, which can modify the dose-response relationships. These include DNA-repair, adaptive response, apoptosis, hyperradiosensitivity, induction of genomic instability, bystander effects, genetic disposition, and immune response. The significance of these phenomena and their possible implications on dose-effect relationships is a matter of intense debate within radiation protection, and many questions are open in this respect [Little, 2003; Lorimore and Wright, 2003]. These include questions concerning radiation quality, differences in individual response, genetic deposition and age or development stages [Streffer, EUG presentation]. Investigations of these molecular and cellular processes are important for evaluation of biological mechanisms, which are involved in the development of stochastic effects after exposures to chemicals as well as radioactive substances. For example, recent studies suggest that the bystander effect can be demonstrated with certain heavy metals [Mothersill *et al.*, 1998; Coen et al, 2001; Mothersill and Seymour, in press]. However, analyses of these studies suggest that the modification of dose responses by these new biological phenomena will not really lead to threshold doses for stochastic effects but the steepness of the dose-effect relationships in the very beginning (i.e. at the DNA level) will change [Streffer, EUG presentation].

1.1.2 Group discussions

Do we agree that radiation has, at a cellular and organism level, the capability to produce similar effects and endpoints as chemical stressors?

Group 1 agreed that at a cellular and organism level, radioactive substances had the capability to produce similar effects and endpoints as chemical stressors. They suggested that a unified system should be developed because there are more differences between the effects caused by various types of chemicals (e.g., heavy metals and PCB) than between certain types of genotoxic chemicals and radionuclides; and because effects caused by radionuclides are not uniform either (c.f. a-, ß-, and ?-emitters). The point was also made that while the mode of action may be different in its initial phase, there could be an overlap in effects as you move to higher levels (organ, individual). The role of background was discussed with respect to chemicals, and particularly EC approaches for heavy metals (Cd, Zn, Co, etc.). For example, that reference values for chemicals are based on added risk concept, so background is taken into account. Finally the question of mixed toxicity and synergism effects in chemicals and radionuclides was raised together with the issue of inhibitors and promoters, specifically how to handle uncertainties when there are so many possible combinations.

Group 2 assumed as a starting point that there were similar effects and endpoints between chemicals and ionising radiation. They suggested that, because mechanisms were different, maybe the effects and endpoints would also be different. For example, some chemicals, like endocrine disruptors, react through specific pathways. It was asked whether the ability to induce bystander effects was an attribute that was specific to ionising radiation (a question the group could not answer), and the issue of internal emitters was raised as an area of uncertainty. The group proposed that it would be fruitful to explore what was common and what was different between the two classes of toxicants (see Figure 1.2).

Group 3 also agreed with the statement in general, but noted that the range of mechanisms and modes of action and endpoints produced by chemicals were more complex than for ionising radiation. They concluded that while similarities undoubtedly exist (and a number of concrete examples of genotoxic chemicals were forwarded), there were also differences, and that a better understanding of the biological mechanisms and processes giving rise to these differences would be useful. Like Group 2, they also focused on categorising the specific criteria and attributes of radiation giving rise to biological effects. Examples of such criteria being DNA damage, the capability to produce double strand-breaks, and clusters. In common with Group 1 they also discussed the issue of background in depth; points raised included that life has evolved in a background of ionising radiation, that some

organisms have developed immunity to natural chemicals (e.g. heavy metals), and that for many chemicals background variation was greater than for ionising radiation. The relevance of radon and medical radiation was addressed; including whether there was any chemical used to treat the disease it caused?

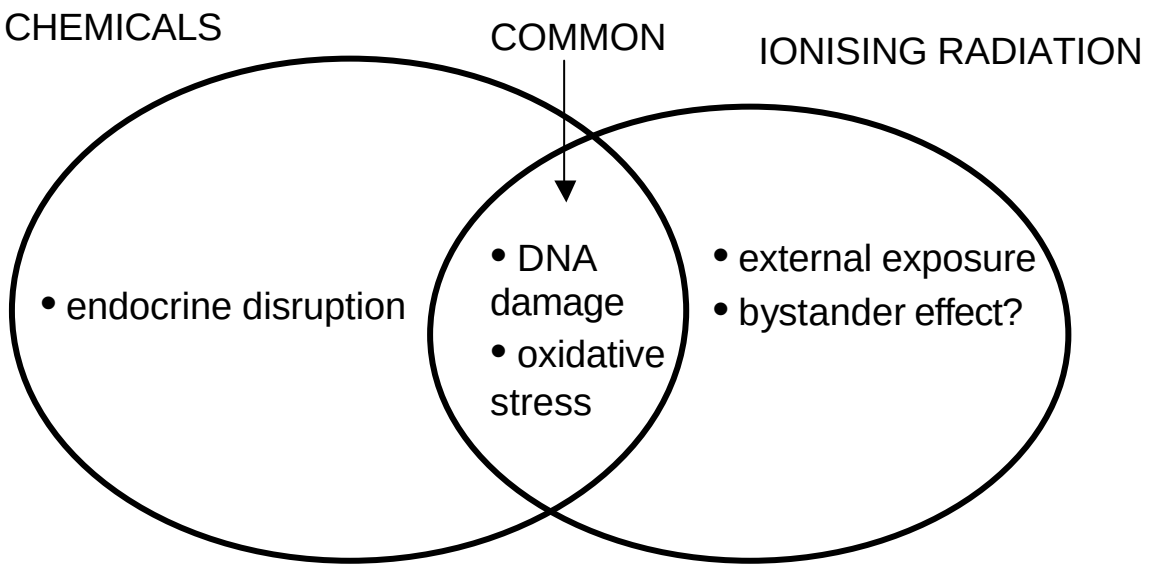

Figure 1.2: Main attributes of ionising radiation and chemical stressors

1.1.3 Summary and conclusions

All groups agreed that at the cellular and organism level, there were both similarities and differences in the biological mechanisms and biological effects arising from ionising radiation and chemical stressors. From considerations of the mechanisms for the induction of cancer by genotoxic agents it should be possible to build up a unified system of environmental standards and related regulations, although the differences of the primary processes and effects should not be overlooked. There was a general agreement on some of the criteria behind the similarity and differences for chemical stressors and radiation, although this is an area that could be expanded. For example, some of the dose-modifying phenomenon may be peculiar to ionising radiation, or may interact with other environmental stressors to produce a variety of complex synergistic , antagonistic or additive effects. Although most participants agreed these exist for ionising radiation, there was less understanding regarding chemical stressors. The problem of dose-modifying phenomena and synergistic effects was also raised during the plenary discussion, particularly regarding the associated implications for dose-response curves, thresholds and endpoints other than cancer and mortality.

1.2 Ecotoxicology

1.2.1 Summary of presentation

The presentation focused on three main areas: 1) the relationship between exposure and bioavailability of environmental toxicants, and effects on biota; 2) the role of biomarkers and 3) recent developments in the application of toxicogenomics, toxicoproteomics and toxicocellomics in understanding the mode of action of toxicants in biological systems. Overall, the presentation focused on a discussion of the

many chemical, environmental, biological and physiological factors that can influence the uptake and toxicity of pollutants in organisms (Figures 1.3 and 1.4). The increase in biological complexity as one goes from effects on a cellular and molecular level, through to the individual and ecosystem levels was stressed, together with possible methodologies for monitoring response.

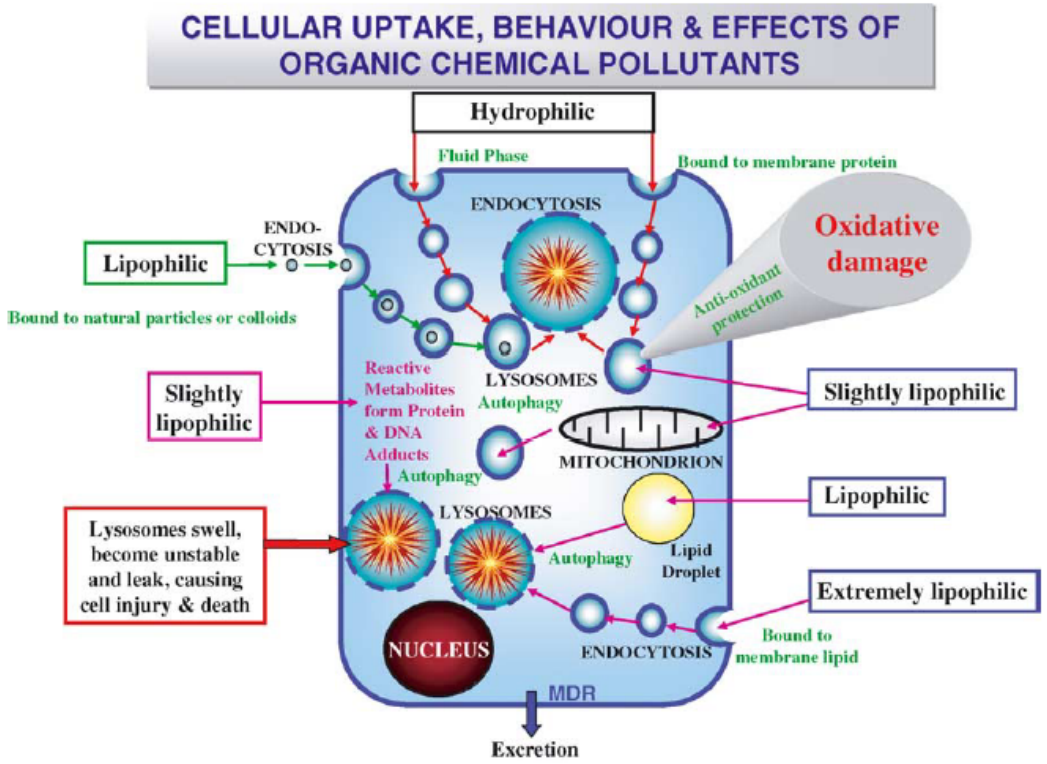

Figure 1.3. Uptake and effects of chemical pollutants [Blust, EUG presentation].

Ecotoxicology needs to combine two disciplines: ecology—the scientific study of interactions that determine the distribution and abundance of organisms, and toxicology—the study of injurious effects of substances on living organisms. Whereas in toxicology the organism sets the limit of the investigation, ecotoxicology aspires to assess the impact of pollutants not only on individuals, but also on populations and whole ecosystems. The biochemical, molecular and physiological disruption that toxicants may cause at an individual level need to be assessed in terms of the consequences for the structure and function of communities and ecosystems [Walker et al., 1996]. Examples of effects at a population may include changes in the numbers of individuals, changes in gene frequency (such as resistance of insects to insecticides, or changes in ecosystem function. This leap from individual to population, and the possible methods and usefulness of extrapolation, has been the source of much debate and controversy in ecotoxicology, particularly the use of single-species toxicity tests for pollutants [Forbes and Forbes, 1994].

Possible alternatives to single-species testing include experimental tests using more complex systems known as mesocosms or macrocosms, or studies using field trials. Such studies might address a number of effects and endpoints, from subcellular to population and community levels. Some use biomarkers as a measure of biological response to a chemical or pollutants. Biomarkers can be divided into those providing evidence of exposure and, more controversially, those indicating a toxic effect.

Finally a number of ecological and population dynamic models have been developed to aid understanding of the consequences of changes in ecosystem structure and interaction.

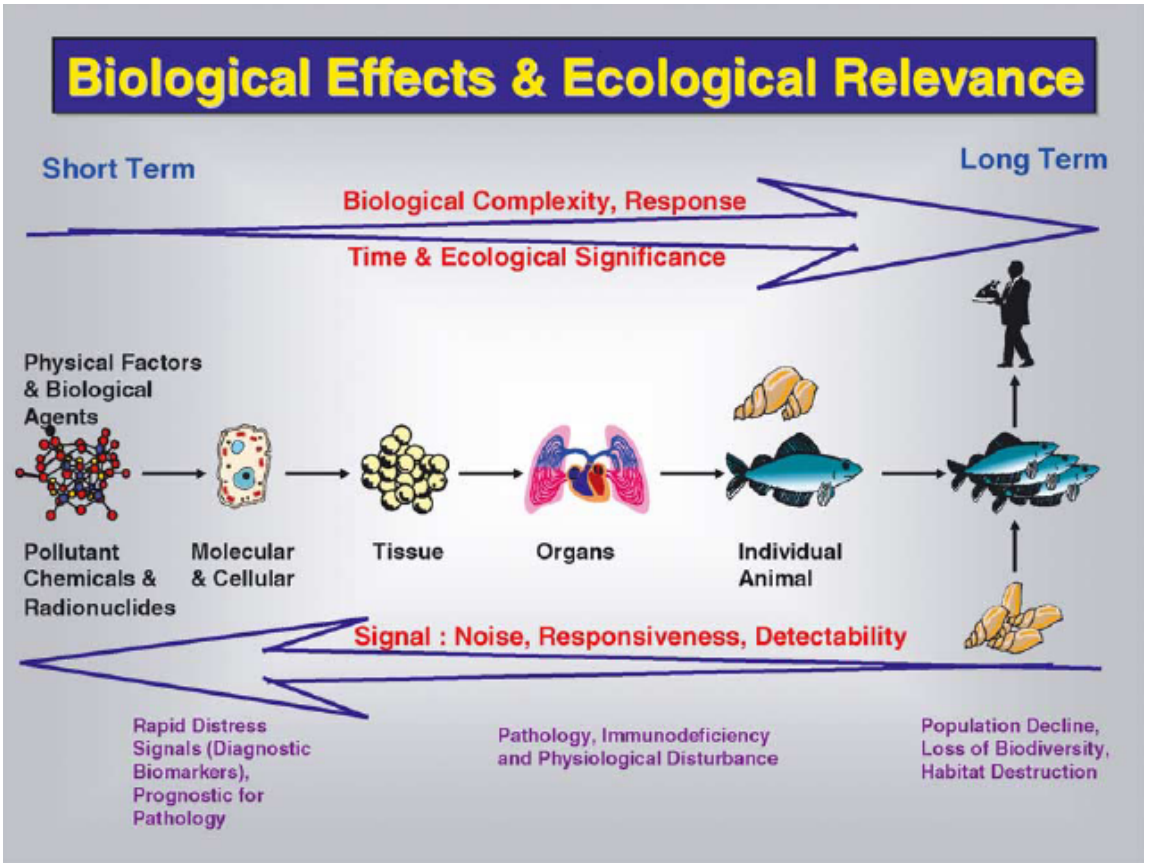

Figure 1.4. Overview of the relationship between biological effects and ecological relevance [Blust EUG presentation].

The main conclusions of the presentation were as follows.

- Environmental compartmentalisation and bioavailability are key considerations in exposure assessments.
- A direct relationship between tissue loading or uptake rate of toxicants may not exist, both within and among species, since toxicity relates to binding to specific receptors.
- A variety of biomarkers of exposure and effects have been shown to provide relevant information on the effects of toxicants both under laboratory and field conditions, but it remains difficult to separate background from effects.
- The advent of the omics has created totally new avenues to explore the effects of toxicant on biological systems. A lot will be learned concerning the mode of action of toxicants.
- The debate on how to apply this new information in risk assessment is just starting.

1.2.2 Group discussions

How do you extrapolate effects on an individual level up to population and ecosystem levels?

Group 1 did not come to any conclusive agreement, but the discussion focused on comparing the approaches used to derive regulations for chemicals and radioactive substances. For chemicals, two approaches are used: experiments and modelling. While laboratory experiments on individual species are common, at the ecosystem level experiments are very expensive and their relevance to the real natural ecosystem can be questioned. One modelling approach uses species sensitivity curves, but only for tropic events. Drug companies are using the modelling approach: experiments are carried out with rats and extrapolated to human species. It follows that modelling supported by experiments can be combined to then extrapolate to the real ecosystem. However, there is an assumption that the sum of the species being measured equals the ecosystem. For human radiation protection the objective is to prevent the occurrence of deterministic effects and limit the stochastic effects in individuals by applying the dose limit of 1 mSv/y. For non-human biota, the aim is to avoid deterministic effects on the population level Several studies suggest that at a dose rate of lower than 1 mGy/day for the most exposed individuals, there would be no detrimental effects at the population level Hence the system for man is more stringent than for non-human biota, which has some similarity for regulations of chemicals, where the criteria for drinking water (aimed at man) are much stricter than for surface water. A number of other factors were proposed that may have a greater impact than extrapolation. For example, food intake may be more important than exposure itself. The group concluded that a pragmatic approach would be to protect at the individual level, but build in a safety factor so that populations are protected too. Criteria (including the derivation of threshold levels) at the individual level should be such that the exposure of individuals is low enough not to affect reproduction.

Group 2 also considered what type of experiments could be used to aid in extrapolation, for example microcosom experiments, and concluded that there were only a few that had been applied successfully. They suggested that expert judgement, safety factors and modelling tools were more likely to be applied and noted that, at the present time, these approaches were being given much attention in chemical risk assessment. The role of biomarkers was debated, with concerns raised about their specificity including the claim that, even after 20 years experience of using chromosome aberrations within occupational medicine, their predictability was questionable. The general conclusion was that modelling tools were the best we have at present, but that they are far from perfect.

Group 3 focused more on the biological and ecological assumptions behind extrapolation rather than the tools available to approach the issue. They considered the problem of understanding cause and effect, which becomes far more complex as one goes from individual to population and ecosystem. Like Group 1 they also considered the difference between human and ecological risk type assessment, noting that there were many more endpoints that needed to be addressed when evaluating ecological systems. The use of biomarkers was also raised, including as a monitoring tool, but without agreement as to their usefulness for extrapolation. The main conclusion was that there was a basic need to understand both the biology and the ecology of the system.

1.2.3 Summary and conclusions

There was a general agreement among the groups that extrapolation was a matter of immense complexity, and that endpoints differ in human and ecological risk assessment. There was doubt as to the usefulness of the application of biomarkers as an extrapolation tool. In group and plenary discussions, modelling was proposed as the most feasible unified approach, both regarding chemicals and ionising radiation and for individual and ecosystem effects. There was some disagreement as to whether protecting at the individual level would be the most pragmatic approach.

2 Theme 2: Risk Assessment and Risk Characterisation

Risk, *environment* and *hazard* are all terms that are interpreted and conceptualised in different manners. For example, although most English-speaking scientists now define *hazard* and *risk* as being importantly distinct, in their French origins distinction is made, only partially if any, between "*hazarder*" and "*risquer*" [Rimington 1992]. Also the *environment* is a wide concept; does it include the living *and* non-living creatures in nature, or only the living organisms? In the context of risk assessment, Calow has pointed out that the environment sometimes has been intended to imply "for humans". Thus a narrow definition of *environmental risk assessment* would be taken to mean assessment of risk to human health only from exposures in the environment at large; whereas a broad definition may include both humans and non-human species. Alternatively, *ecological risk assessment* (ERA) is used exclusively for the assessment of risk to non-human communities and populations [Calow, 1997].

Calow gives the following definitions:

- *Hazard* – the potential to cause harm
- *Risk* – the likelihood of that potential being realized
- *Environmental* – the routes of exposure for both humans and wildlife.

It follows that ecological risk assessment –for ecological systems – is a subset of environmental risk assessment.

Environmental protection legislation is largely driven by scientific results. Tests are used to determine what level of a chemical is required to bring about a specific harmful effect, and account is taken of what might be described as potential exposure criteria (e.g., likelihood to persist in the environment and likelihood to bioaccumulate). Assessing the likelihood of harm requires a combination of an understanding of hazard, with an understanding of exposure to the target system. This is risk assessment [Calow 1998].

Determining the probability of an adverse effect depends upon the likelihood that exposure will exceed critical effect levels. However, an assessment of this probability need to address a number of issues, many of which may be overlooked..

- Stochasticity—we can define average population responses, but not the response of particular individuals.
- Ignorance—we rarely have full knowledge or understanding ("unknown unknowns" etc).
- You can never prove a negative—no effect in one group does not preclude effects at the same concentration in other groups of the same or different species.
- That an acute effect does not preclude an effect in another character at lower concentrations.
- Fallibility—we often make mistakes in our observations
- Time is not explicitly included, even though exposures and effects do change over time.
- In measuring the quality of ecological systems it is usually necessary to use comparison with supposed standardised systems. Predictions about impact are most often based on simplified tests.

2.1 Ecological risk assessment

2.1.1 Summary of presentation

For chemicals, there are two types of risk assessments, retrospective and prospective, both of which fit into a generic framework. The framework goes from problem formulation to determining exposure and effects to risk characterisation to risk management.

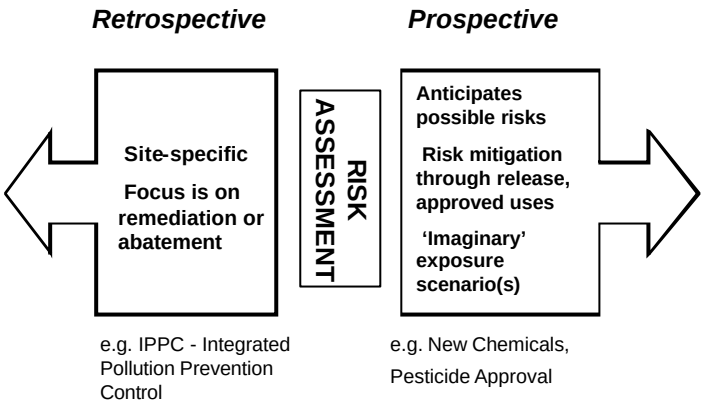

Figure 2.1: Types of risk assessment for chemicals [Whitehouse, EUG presentation]

As data will not always be available, extrapolations will be needed to account for uncertainties, whether it be from individual to population, laboratory to field, etc. The use of safety factors has also been widely used as a method of introducing conservatism into the estimates, whereby the size of the safety factor increased by increasing uncertainty.

The presentation described the overall risk assessment process, from problem formulation to risk characterisation, and compared methodologies for chemicals and radioactive substances. The main similarities and differences are summarised in Table 2.1. It was concluded that generic frameworks for chemical and ionising radiation risk assessments have much in common. However, two significant, and probably unavoidable, differences with the risk assessment methodology for radioactive substances were:

- the emphasis on dosimetry; and
- the domination of exposure and effects assessments.

2.1.2 Group discussions

What are the differences between the use of test species in the chemical approaches compared to "reference organisms" in the radiation field. What alternatives exist?

Group 1 defined test species as real organisms for use in the laboratory. Chosen organisms are simple, easy to handle and can be used to test a wide range of pollutants. Reproduction is an important endpoint, dose-effect relationships can be derived, and responses can be used to derive benchmark values. Reference organisms were defined as virtual entities used for dosimetry purposes, and representative of the ecosystem being studied. The concept of reference organism has existed for the last 50 years within radiation protection for humans. Thus the model had been proved to be practical and had been demonstrated to work. It is also used in some occasions for chemicals, using models

Table 2.1: A comparison of risk assessment (RA) methodologies for chemicals and radionuclides [Whitehouse, EUG presentation]

	Chemical RA	Radionuclide RA
Problem Formulation	• Potentially vast range of contaminants • Simplified compartments at risk defined • Implicit focus on population protection • Assumed that structural (species) protection will afford functional protection • Prioritisation of risks	• Defined range of radionuclides • Ecosystems defined • Explicit focus on population protection • Reference organism types defined – based on availability of information about radiation effects, relevance to selected ecosystems and dosimetric, considerations • Prioritisation of risks
Exposure Assessment	• Ambient concentrations (PEC) estimated, based on expected releases and fate in the environment • Local or regional with standardised or site-specific exposure scenarios • Backgrounds usually only considered for metals and soils	• Radionuclide transfer estimated, based on expected releases and fate in the environment • Additional focus on external and internal radiation doses experienced by reference organisms • Background radiation accounted for
Dosimetry	• Does not feature at all; chemical doses and uptake pathways rarely known • Decision-making based on ambient concentrations • Effectively one step; exposure - effect	• Significant feature of radionuclide RA • Absorbed dose estimated on basis of organism geometry and radiation quality (RBE) • Requires understanding of toxicokinetics • Two steps; exposure – dose and dose – effect
Effects Assessment	• Based on adverse effects at individual level • Emphasis on demographic endpoints (mortality, morbidity, reproduction) • Empirical approach to species of interest (but guidance on trophic levels, diversity) • PNEC based on most sensitive species/endpoint or distribution of species sensitivities • Extrapolation to account for biological uncertainties – to cover all conceivable species/ecosystems at risk • Effects data expressed in terms of ambient concentration	• Based on adverse effects at individual level • Emphasis on demographic endpoints (mortality, morbidity, reproduction) • Effects data extracted from species represented in FRED database • Relevant species are those most likely to receive highest radiation dose by virtue of geometry, habitat, feeding characteristics, bioaccumulation potential • Extrapolation to population-level effects (Deliverable 5) • Effects data expressed in terms of absorbed dose
Risk Characterisation	• Deterministic (PEC:PNEC ratio) to judge acceptability or requirement for refinement (reduce uncertainty through additional data) • Probabilistic approaches also possible where data sufficient	• To be resolved

from water concentrations to exposure. The group concluded that absorbed dose was an adequate unit for quantification. In both fields, however, the main objective is to reduce the level of complexity to something that is more manageable in risk management. Similarities between the two approaches include age of the individual and species sensitivity. However, the group wondered how good are we at representing the real world using this method. They suggested that one might consider the use of test species for radionuclide screening, but agreed that although the system is not perfect, no practical alternatives can compete at the present.

Group 2 described test species as indicator species such as earthworms, chosen both because of exposure and ease of maintenance in laboratory experiments, as well as the availability of standardised test methods (e.g. OECD). They noted that the range of established and internationally recognised test species, and endpoints is expanding. The group defined reference organisms as being primarily derived for dose assessment, and also noted that radiation protection does not define test species as such—asking whether it should? The question of whether one should work with dose or concentration was also raised, and it was proposed that dose was a method of "standardising" between radionuclides. Finally, it was thought that scientific consensus would be vital.

Group 3 highlighted the difference between use of dose (energy/mass) for reference organisms as compared to concentration or body burden (µg/kg) for chemicals and test species. They described reference organisms as unreal models as compared to the real and specific test species, noting also that test species were derived for assessment of a complex array of chemicals, including new chemicals. The group submitted that, in general, the concept of dose, and the dose approach, was more advanced and developed than the concentration approach used for chemical toxicants, and questioned the logic of trying to squeeze the ionising radiation approach into the chemical approach. They also discussed whether effect (rather than dose or concentration) could function as the common standard. But this raised the question of "effect as compared to what?" The group asked what the role of the most sensitive species in an ecosystem might be, and wondered what endpoints were important at the population level, including to what extent carcinogenity was relevant to ecotoxicology. It was suggested that genotoxicity was the relevant link, but that ecological risk would need to be regulated with as many endpoints as possible. Finally the group enquired if mammals were the most sensitive organism and we wanted to protect the most sensitive 5% of species, then would these be mammals?

2.1.3 Summary and conclusions

In discussion of the two approaches, all groups tended to define test species as real organisms selected to test specific chemicals, medium and endpoints with standardised internationally accepted methods (e.g. OECD). In contrast, reference organisms were generally perceived as something "lacking reality". These were portrayed as entities primarily designed for dose assessment, being described as "virtual entities", "hypothetical models" and "not real animals" by the groups. In the plenary session, the suggestion that test species were good for predicting effects while reference organisms were good models for determining doses was discussed further, and the point was also made that chemicals were regulated in the basis of effects not dose. It was proposed that one might use dose or concentration for regulatory issues, but effects for communication. But the question was also raised, without answer, that if effect were taken as the criterion, would we then be pushing the system further for animals than for humans?

2.2 Risk Quantification and Characterisation

2.2.1 Summary of presentations

Deterministic vs probabilistic approaches to estimating risk

In any practical risk assessment we have to deal with uncertainties associated with possible outcomes. One way of dealing with uncertainties is to be conservative in the assessments. For example, we may compare the maximal exposure to a radionuclide with a conservatively chosen reference value. In this

case, if the exposure is below the reference value, then it is possible to assure that the risk is low. This approach is commonly called "deterministic". Its main advantage lies in the simplicity and in that it requires minimum information. However, problems arise when the reference values are actually exceeded or might be exceeded, as in the case of potential exposures, and when the costs for realising the reference values are high. In those cases, the lack of knowledge on the degree of conservatism involved impairs a rational weighing of the risks against other interests.

An alternative approach for dealing with uncertainties that is more consistent than the deterministic one is called "fully probabilistic risk assessment" (Avilia and Larsson, 2001). The essence of this approach consists in measuring the risk in terms of probabilities, where the latter are obtained from comparing two probabilistic distributions, one reflecting the uncertainties in the outcomes and the other the uncertainties in the reference value (standard) used for defining adverse outcomes.

There are a number of advantages and disadvantages in applying the "fully probabilistic approach", with its main disadvantage being that time and effort are required to document the rationale for the chosen probability density functions (Stark *et al.*, in press). However, some of its many advantages include:

- it provides a more complete quantitative characterisation of the uncertainties, and is less likely to include a bias than the more simple deterministic approach;
- when combined with sensitivity analyses, the probabilistic approach allows a more informative "what-if" assessment of the impact of a change in a variable, or a group of variables, on the risk estimates, thus providing a cost-effective tool for making risk management decisions;
- it permits more constructive comparisons of remedial alternatives, when diverse attributes must be compared to systematically reduce the baseline risk; and
- it facilitates the derivation of standards, e.g. , standards in terms of concentrations may be derived from standards in term of doses, even when there is variability and uncertainty in the relationship between the doses and the concentrations.

Overall, it appears that the "fully probabilistic risk assessment" approach is most appropriate when the risks are not trivial, for example, in situations where the risk might be above or slightly below the acceptable level of risk or hazard, and where the costs for risk reduction are potentially high.

Species sensitivity distributions to derive predicted no-effect concentrations

Environmental risk for chemicals is commonly assessed relative to the Predicted No-Effect Concentration (PNEC), wherein the risk can be expressed as:

$$\text{Risk} = \frac{\text{PEC – predicted environmental concentration (by measurements or models)}}{\text{PNEC – predicted non effect concentration (by ecotoxicological tests, e.g. EC50)}}$$

EC50s can be experimentally determined using single organisms. However when data is lacking, PNEC can be derived by analysis of species sensitivity distribution (SSD), which brings together data from a range of species to represent the ecosystem under study. The end result can be expressed as HC values, e.g. HC_5 signifies that 95 % species are protected, see Figure 2.1.

It has been proposed that this is a transparent process allowing the maximum use of available information [Forbes & Calow, HERA, 2002]. Calculations can be carried out with the help of dedicated software, and include consideration of the following aspects:

- intraspecies variability;
- repartition of data among taxonomic groups; and

- statistical methods and confidence interval.

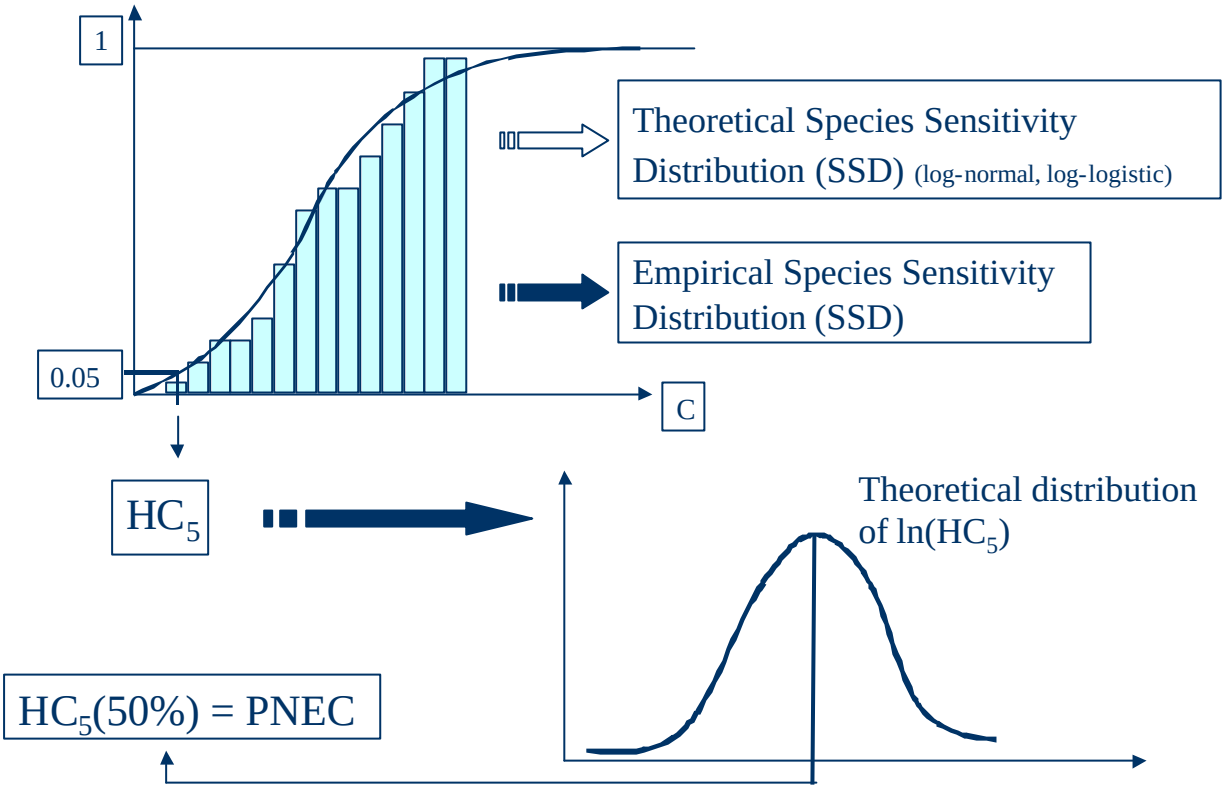

Figure 2.1: Statistical approach for PNEC (predicted non effect concentration) determination [Philippe Ciffroy, EUG presentation]

As an example of the way one might deal with limited data on a large number of organisms, the above methodology has been applied to radionuclides in the aquatic environment. Data were extracted from the FRED database, and a Species Sensitivity Weighted Distribution (SSWD) was built from derived critical toxicity values ED_{50} for acute exposure or EDR_{10} for chronic exposure, and finally, dose-response curves were constructed. The exercise demonstrated that the approach was possible, and that it permitted a quantification of uncertainties and explanation of the implied assumptions. Further work is planned to:

- apply the whole methodology to terrestrial wildlife groups/terrestrial ecosystems;
- develop methods to apply SSWD techniques to small sets of data; and
- develop methods to extrapolate acute-to-chronic SSD.

2.2.2 Group discussions

When it comes to quantifying risk, the methods can be complex and appear non-transparent, so how much effort should be directed at educating decision-makers? Is a probabilistic approach to risk estimation easy to implement by decision-makers?

Group 1 suggested that the term "decision-makers" be replaced by "stakeholders" and focused on the notion of risk and the perception of risk by stakeholders. Discussions focused on the choice of using a single number for comparison purposes versus a probabilistic distribution, which requires a greater understanding of mathematics. The group suggested that deterministic risk assessment was good for the first stage of ERA, as it is relatively easy and well known and also "cost-effective", but that complex issues may need the probabilistic approach. The group thought that the probabilistic approach

was not currently used for chemicals or protection of man, but that there were moves towards such an approach. There was a query as to whether the Species Sensitivity Distributions were derived from so few data, and whether this met with EC guidance. On this issue, the question of variation due to genetic diversity, environmental conditions and biodiversity was raised.

Group 2 suggested that the capacity of decision-makers to understand is greater than specialists sometimes imagine. The group thought that deterministic standards were easier to explain than probabilistic, and agreed with Group 1 that the probabilistic approach may be better suited to more difficult cases (or "higher up" a tiered approach). They forwarded the EU Technical Guidance Document (TGD) as a tool promoting consistency and fairly good practice, and proposed that scientific consensus would be vital for acceptance of any method. It was also noted that different groups (and end-users) had different needs and views, and that the approach would need to provide clear options to fit these different needs. Finally, it was proposed that some stakeholders might need educating on the necessity of protecting the environment from ionising radiation.

Group 3 concluded that many decision-makers already understood quite a lot about probabilistic risk assessment. In fact the group wondered who should be educating whom, and contemplated whether the scientists themselves actually understood probabilistic risk assessment! It was noted that the need to encompass data on both size of effect and probability made risk a difficult concept. After asking the decision-makers present, it appeared that the majority preferred to have probabilistic answers rather than black and white; they wanted information on uncertainties, as well as some background on why choices were made. There was a certain amount of debate as to whom, exactly, the decision-makers were, and a general agreement that communication between scientists, decision-makers and the public would be vital.

2.2.3 Summary and conclusions

There appeared to be consensus amongst the participants that using probabilistic approach is a good solution to estimating risk, but that perhaps the use of deterministic standards may still be used as a first stage . However the point was made that whatever approach is to be used (e.g. deterministic, probabilistic, species sensitivity distributions) some consensus amongst stakeholders should be sought. The selected approach should provide clear options to fit with the different stakeholder needs.

3 Theme 3: Risk Management and Socio-economic Issues

It is often assumed that risk assessment should be separated from management decisions [Calow, 1998]. The assessment part is deemed to be scientific and objective, whereas the decision-making is influenced by political or social views. Deciding how much harm might be (or is being) caused is a matter for science; it can be done by reference to critical analyses and carefully controlled observations. The argument is that this part should be separated from the more subjective decision about whether or not the harm is important and what should be done about it. Yet the distinction is not always so clear-cut. For example, protecting the environment presupposes that we have targets that we aim to protect, that we agree how much damage we are expected to tolerate and how much proof of protection is enough. Sometimes we do not have particular target systems or end-points in mind, particularly when it comes to new commercial chemicals and genetically modified organisms. Furthermore, these are issues are not easily defined, especially for ecosystems, and a number of prior decisions need to be addressed before the "scientific" stage of risk assessment can be carried out:

1. Decisions have to be made about what to protect prior to an assessment;
2. Decisions have to be made about to what level protection should be exerted so that appropriate threshold levels can be defined; and
3. Management decisions often involve balancing the advantages to environment and human health of different options with their consequences for other social benefits.

These decisions determine how management criteria can, or indeed should, influence assessment criteria. Thus the question of what we want to protect and why, will have both a social and scientific dimension. Society needs to understand what ecological services it receives and prioritise them; science needs to explore what factors affect those services and how they can be operationalised for measuring and predicting relevant effects.

3.1 Summary of presentations

3.1.1 EU legislation on chemicals

Chemicals entering the environment are subject to a variety of legislative control, for example the Water Framework Directives (WFD), but this is not always to the EU's satisfaction. Theoretically, to control chemicals one needs to (Fig. 3.1):

- know their physical, chemical and toxicological properties;
- know the life cycle of chemicals and their route to the environment;
- assess *a priori* their fate and effects in the environment: risk assessment;
- monitor and report their concentration in the different media; and
- take sound decisions in a precaution/prevention context.

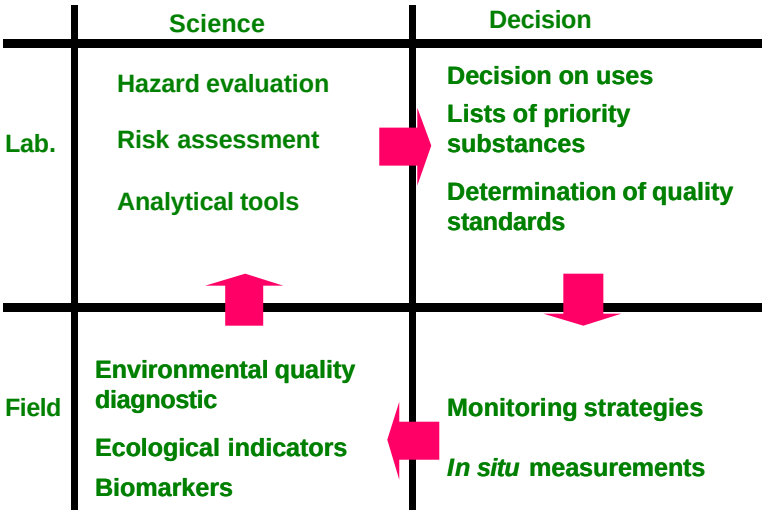

Figure 3.1 Theoretical scheme for the control of chemicals [Vindimian, EUG presentation]

Between 1930 and 2004, production of chemicals rose from 1MT in 1930 to 100MT. At present, 2700 new chemicals are evaluated each year. Under present regulations, a comprehensive risk assessment is required if the production is above 10 kg/year. Public authorities pay for the evaluation of existing chemicals, but most of the information on toxic properties is lacking. The situation varies for radionuclides, as their production is much more controlled and the industry is much more concentrated. Whilst radioactive properties allow a better tracking in the environment, toxicological properties are still controversial.

The EU has launched a new innovative project of regulation called REACH – Registration Evaluation and Authorisation of Chemicals – which will have as a basic principle: no data, no access to the market. As the burden of proof is to fall on the producer to provide the necessary data, REACH has been strongly opposed by the European industry due to the derived heavy costs.

Monitoring

The Water Framework Directive (WFD) is based on ecological concepts: direct measurement of community composition; monitoring of water body characteristics; comparison with reference zones; and risk based control of chemicals. The aim is to establish the environmental quality of surface waters as regards chemical status, which needs to be reached by 2015: "good chemical surface water status". The aim is also to establish measures at Community level to help reach this quality status and other environmental objectives of the Water Framework Directive (Article 4, Directive 2000/60/EC).

The Directive identifies a list of substances of concern (priority substances) that present a significant risk to or via the aquatic environment. Water quality standards are thus set, via toxicity data, and monitoring plans established.

In comparison to chemicals, the Commission: "Towards a strategy to protect and conserve the marine environment", i.e. COM(02) 539, prevents pollution from ionising radiation through progressive reductions in discharges. Its aim is to reach, by 2020, concentrations near background values for naturally occurring radioactive substances and close to zero for artificial substances.

Public acceptance is different when it comes to radioactivity. Attention to radioactive substances is high in the population, and in the past a "culture of secrecy" has been dominant. Although levels seem to be well below concentrations of concern, effects on ecosystems are not documented.

It is noted that whilst radionuclides are absent from chemical policies and monitoring strategies, synergies could be gained by adopting a similar system, e.g.:

- tracers to predict fate of chemicals;
- use of common surveys;
- more comprehensive knowledge of variables used in epidemiology;
- build better models that fits both needs.

3.1.2 Regulation of environmental pollution

The presentation focussed on how regulations need to address information on environmental impacts of pollution to create legal conditions, mainly at the EU level. It also made use of examples to illustrate the points.

Translating risk assessment into regulation requires management of uncertainties. Risk characterisation also needs to be translated into regulation, which can be done via prescriptive standards (not flexible), command and control on industrial activities (flexible or not) or through alternative measures (e.g. voluntary agreements). The resulting regulation can then be strict ('must do') or advisory ('should do'). If strict, then the regulation will need to rely on conditions that are required, for example an environmental quality standard (EQS).

Standards are a crucial part of the policy process. A number of standards are employed to manage pollution risk, including: obligatory EQS limit values; EQS objectives; obligatory emission limit values; emission limit values determined case by case according to criteria; controls on marketing products, shipping, etc.; and EQSs set as environmental goals. The setting of the EQSs or criteria depends on the purpose of the aim of the compliance.

Regulation can be aimed at single pollutants but can also extend to multiple sources, e.g. waste incineration or Water Framework Directives. These largely seek to control new pollution, but can also be applied to the management of extensive historic pollution. There is a move away from setting a "single number value", taking account of the complexities of risks of pollution impacts and providing a better representation of the environment that might be potentially affected.

Regulation must also deal with other factors, such as gaps in knowledge and public participation. As a result, new regulations will need to explicitly address these issues, and demonstrate inclusion of public participation, address uncertainties, and develop risk communication strategies.

3.2 Group discussions

The groups were asked to consider four questions. Since not all groups addressed all questions, and merged some of them together, the discussion sessions have been summarised under the general themes of standards, background and regulation.

3.2.1 Standards

If standards are to be applied, should they be based on environmental concentrations, as for chemicals, or on dose rates to organisms? Should decision-makers (implementers and regulators) base their decision on a single standard, or on a "band of concern" approach?

Group 1 thought that dose was preferred, and better than concentrations, and suggested that chemicals should be regulated as for radionuclides, not the other way round. However, it was thought that stakeholders appeared to accept the way that chemicals were regulated but not radionuclides. They noted that the reason for much of the differences in regulations comes from the fact that they are derived from different sources. The group thought that dose should be the basis for regulation and concentrations for monitoring, but overall they did not see the relevance of the question, as in dose based standards the demonstration of compliance can also be expressed using concentrations, through back calculations. Group 2 thought that dose should be the basis for standards, but that concentration of total Bq was needed for discharge limits. Chemical toxicity was highlighted as being important for some radionuclides (e.g. U). Group 3 started by noting that concentrations were something that could be measured, whereas dose (at least in this context) was a unit that required calculation. They suggested that for radionuclides most of the effluent data were tied to doses, but that concentrations were used in monitoring and to demonstrate compliance. It was agreed that the issues of chemical toxicity of some radionuclides and problems of mixed contaminants were important, but it was not clear how to resolve them. It was suggested that a scientifically-based derivation of standards required well-defined dose-response relationships, and that these needed to be tied to observable harm. The group concluded that data were still lacking in this respect.

Both Group 1 and Group 2 were in favour of bands of concerns, particularly for regulation of radioactive substances. However, Group 1 pointed out that single values are usually used for chemicals, with ranges being the exception rather than the rule (e.g. CO_2 where the goal is to go as low as possible), and that single values are used to set limits. They also suggested that a single value could be used as the first level of a tiered approach, and bands in higher levels. Group 2 thought people were generally comfortable with bands of concern, providing a number of examples from both radiation and chemicals where the system was already in use, including: reporting and action levels in radiation protection; the IAEA banding system; bathing water quality; Canadian sediment guidelines; HSE (UK) "tolerability of risk". Group 3 did not get time to discuss this issue.

3.2.2 Background and past activities

How to treat in decision-making natural background radiation levels and those originating from past activities?

The general conclusion from Group 1 was that fluctuations in background should be taken into account. Group 2 discussed the IAEA's banding approach from past NORM activities as well as the added risk concept for chemicals (i.e. that biota have evolved in a high background of lead and can tolerate it). It was suggested that a similar assumption existed in radiation protection. Group 3 focused on radon, but also noted that the specificity of different radionuclides should be taken into account in evaluating background doses. It was also suggested that background was in a sense already included in radiation protection, since the additive risk concept was applied.

3.2.3 Regulation

Should radionuclides be regulated differently from other hazardous substances in risk management?

All groups agreed that, in principle, radionuclides should not be regulated differently from other hazardous substances. But the responses differed according to whether this referred to what was actually happening in practice (historically, they are regulated by different bodies and different laws) or what the best approach might be. Questions were raised as to whether regulation should refer only to acceptable risk, and on the general relevance of background and thresholds. Group 1 raised the issue of "polluter pays"; Group 2 replied only "no"; and a strong claim was forwarded in Group 3 that the case for additional pollution control of radionuclides had not been made. There was also some disagreement within Group 3 as to whether chemicals were regulated more or less strictly than radioactive substances, although there seemed to be consensus that this varied from country to country. Mechanisms, modes of action and thresholds were also raised as an important criterion that might support differences in regulation. However, since the uncertainty is large for low doses both for chemicals and radionuclides, one might wonder why they should be treated differently.

3.3 Summary and conclusions

For this discussion there seemed to be less agreement between the three groups. There was some disagreement between the groups as to what the best basis for regulation was, particularly with regard to dose versus concentrations. For example, while one group thought the dose concept was easy to convey, another said that, despite 50 years of use in radiation protection, the concept was still a matter of contention among some scientists. Regarding the question of bands of concern, it was interesting to note that an alternative view was forwarded in the next day's discussion on benchmark values, where a number of participants expressed preference for a single value over a range (read Part 2 - Section 2). The question of thresholds was raised in the plenary discussion, where it was pointed out that it is very difficult to set thresholds for new chemicals before a large population group is exposed, and that water systems may occasionally be awarded a good chemical status, simply because of a lack in knowledge on links between cause and effect. Finally, a member repeated the point made in group discussions (3.2.3) that although there was international agreement that an *assessment framework* for radionuclides was needed (e.g., IAEA Action Plan), the case for the *subsequent steps* to assessment (i.e., control/standards) had not been made.

4 Summary of Day 1

Work on Day 1 generated a number of ideas, which could be investigated further. Some of the main points made by the EUG have been summarised in Table 4.1.

Table 4.1: Ideas and suggestions derived from the various discussions held on Day 1.

	EUG COMMENTS
Biology and ecotoxicology	• Summarise criteria for similarities and differences between chemicals and radioactive substances from cell to individual levels. • Revisit and examine in more detail the issue of dose modifying phenomena and synergistic effects. • Use of experiments and modelling as tools for extrapolation. • Use of other tools for extrapolation, e.g. biomarkers.
Risk assessment and risk characterisation	• Which main parameter, e.g. effects, doses, concentrations, should be used to set standards? • Is there a difference between reference organisms and ICRP's reference animals and plants? • Are mammals the most sensitive species for all biological and/or ecological endpoints? • What criteria would form the basis for derivation of test species for radionuclides? • Select an approach to estimate risk that satisfy different stakeholder needs.
Risk management and socio-economic issues	• Discuss whether the case has been made for regulation and control of radionuclides, and the role of ERICA within the risk management rather than risk assessment (i.e., scientific) aspects part of ERA. • Discuss socio-economic aspects, e.g. OECD report, which was due to be discussed in Aix, but speaker couldn't attend. • Decide on whether dose or/and concentration should be used as a basis for regulation (also stated above in risk assessment and risk characterisation). • Decide on how to treat background in the ERICA integrated approach. • Debate the advantages and disadvantages of relying on a single value vs a range/band of values.
Additional considerations	• Agree on terminology, e.g. effect, endpoint, risk, harm.

The Consortium needs to review the above items and consider which ones can be taken forward. The next EUG event in Germany, scheduled for April 2005, will be an important forum to either discuss or prioritise items.

The Consortium's decisions on whether to address each of the above suggestions will be compiled in the progress report, which follows the inputs of the EUG and actions taken by the ERICA Consortium. The progress report, updated regularly, is available to EUG members, on the EUG protected area of the ERICA website www.erica-project.org .

5 Reading Material

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Part 2: Contribution to D4 on Risk Characterisation

1 Summary of Presentations

1.1 General structure of the D4 structure

The WP2 Leader, Jacqueline Garnier-Laplace gave a brief overview of WP2 work and introduced the deliverable, D4, on risk characterisation methodologies. The structure to the report is to be as follows.

- Background
- Review Methods
- Ecological Risk Characterisation – general concepts
- Risk Characterisation – approaches and methods
- Uncertainties (including data requirements)
- Interpretation and weighing of evidence
- Conclusion
- Annex on experimental protocols

Draft material and the presentation related to D4 can be found on the EUG protected area of the ERICA website. The final deliverable D4 is due out in March 2005, and will be further discussed at the next EUG event, in April 2005 in Germany.

1.2 Interim ERICA tier-approach

The interim tiered approach has been developed to guide the risk characterisation process. The purpose of the tiers is to make the assessment procedure more cost-effective, as it allows for situations of negligible or minor environmental significance to be excluded from detailed and costly assessments. This is accomplished through application of conservative and, in some cases, qualitative assumptions or criteria in the lowest tier. Such criteria could be that even inhalation of undiluted exhaust from an industrial stack would only cause negligible doses, or that the source term is too small to, in any circumstance, create an environmental effect of managerial concern. For the cases where these criteria do not apply, the assessment detail gradually increases with higher tiers.

From this it follows that, by definition, a tiered approach is primarily directed towards providing sufficient and relevant information for judging compliance and for management decisions – whereas from a strict scientific viewpoint only the higher tiers provide information of substance for the characterisation of risk. However, this trade-off between scientific and managerial needs is practical, and allows for cost-effective decision making on rational grounds.

The interim approach currently explored within ERICA has four tiers; these are schematically illustrated in Figure 1.1, followed by a brief description of main features.

Tier 0:

- Uses expert judgement, extreme assumptions or other qualitative or semi-quantitative arguments to reject the need for further assessment for cases that are of no concern, and consequently allows for identification of cases that do cause concern. It needs to be ensured that sources of potential concern (e.g. accidents) are not screened out because their normal operation may be below concern.

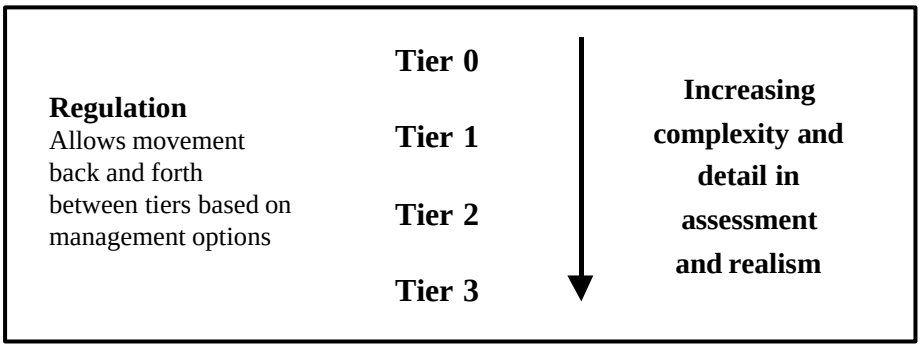


Figure 1.1: ERICA Interim Risk Characterisation Approach

Tier 1:

- Use of assessment tool.
    - Use measurement data to compare predicted environmental/biota concentrations (sanity check).
- Against screening benchmark. The identification of such a "benchmark" is not trivial and may possibly be controversial and lead to considerable debate. Two major options are at hand:
    - a 'simplified single' benchmark based on all effects data available, or
    - application of a safety factor drawing on experience from other frameworks.

Tier 2:

Key point in tier 2 is to reduce the level of conservatism. Suggestions might be to:

- introduce probabilistic techniques;
- introduce currently available site-specific environmental concentrations;
- distribute both exposure and effects information amongst reference organisms;
- quantity assessment of 'risk'; or
- re-evaluate the benchmark on the basis of probability plus more site-specific factors (e.g. social, economic and ecological).

Stakeholders must be involved in the assessment process leading to a decision on the acceptability of the output.

Tier 3:

- Retrospective assessment:
    - additional site-specific data collection.
- Prospective assessment:
    - site-specific modelling for all ecosystems potentially affected;
    - derive additional transfer data (lab or field studies);
    - alternative scenarios to assess, e.g. ALARA, BPEO.
- Both types of assessment:
    - possible evaluation/experiments of more effects data, etc.

2 Group Discussions

The interim tier approach, described in Section 1.2 was distributed to each group and became the focal point of the discussions.

2.1 Group 1

Group 1 structured its discussions around the tiered approach handouts rather than the specific questions.

Tier 0 – the group thought that expert judgement was not in itself a robust argument; therefore the group agreed that using well-defined assumptions were more convincing. The wording of "tier 0" within a 4-tier approach was questioned, as it is not used in other EU documentation. It was also felt that stakeholders, who were more used to a 3-tier approach, might become confused. It was explained that it is important to show the public that decision-makers are doing something, for example in the UK industry accepts a Tier 0 before the classical 3-tiered approach is carried out. The use of a tier 0 shows this tier is different than classical tier 1. The group concluded that the terminology was not important, as long as it was communicated properly.

Tier 1 – the group suggested that the wording "use measurement data" be changed to "historical data". They felt that Tier 1 should be more realistic than Tier 0 but also conservative in its approach; it should be flexible and rapid. The use of a screening benchmark, as a "simplified single benchmark" (one value, e.g. Bq/mass…) should be explained so that it can be defended and believed. The justification for the number must be made, which includes the source of the information, e.g. values from UNSCEAR, which are not guidelines but most people refer to them. The justification for the choice of conservative safety factor(s) must also be given, e.g. in the EU TGD they are quite justified, and accepted. The focus appears to be for contaminated sites, with the use of measured concentration in the environment and compare with effects and the use of reference organisms (generic) to calculate exposure for each level of organisms. The group queried whether it would also be able to do predictions. There was a discussion to whether SSD and HC5 should be used. In TGD you have the choice to derive benchmark according to available data (safety factors or SSD and HC5). The group believed that the derivation has to be explained, and that the approach should evolve with scientific knowledge.

Tier 2 - the group felt that the objective of this tier was to reduce uncertainty. It appeared that the decision would be based on less conservative/more realistic data. They suggested that the benchmark should not change (conservative). Instead, different safety factors could be used as you move between tiers, becoming more realistic and less conservative. Deterministic tools should be used in the first instance, with probabilistic techniques moved to Tier 3, where a lot of data is required. The group queried what site-specific data should be measured preferentially, i.e. concentrations vs biology data (generally based on environmental concentrations excluding biota). The group was not sure as to when stakeholder involvement should be introduced in the tier process, and did not have time to discuss which criteria should be used to move from Tier 2 to Tier 3.

Tier 3 - the group agreed that for both types of assessments there would be a need to go and acquire more data (e.g. in the laboratory or field) at this tier, and that extra costs would be incurred to prove that benchmark was too conservative. There should also be a choice to be made between the degree of "refinement" in function of time/cost. More site-specific modelling, using the best available datasets, should be used in retrospective assessments. For prospective assessments, there was a discussion on whether there would be a need for differentiating between specific contamination compared to the background. A generic question arose, but could not be answered by the group, on how to define in this tier that an ecosystem is or not affected.

2.2 Group 2

Group 2 structured the discussion around the questions forwarded for discussion.

Is this tiered approach appropriate?

The group thought that a tiered approach is favourable, but whether this one is the best can be discussed. It was suggested that a tiered approach would limit effort by screening out trivial issues. Participants asked what other examples of the approach were used, and the OECD and EU TGD for chemicals were forwarded as examples. It was suggested that as one went up the tiers, it was important to make sure that this is not perceived as the industry tuning the model to get below a given level. Thus decision-makers will need guidance to select appropriate tier level needed, and one should be clear that the way the tiered approach is used could differ according to the user, e.g. an industry or a nature preservation group. The need for proper documentation at each level was pointed out, specifically the way results have been derived at each particular level and what uncertainties exist. The importance of documentation was strongly linked to the transparency of the approach. The group had difficulty seeing whether, in real life, Tiers 2 and 3 would separate out. They also wondered whether it was necessary to go through each step proposed for each tier. From experience in other fields, there are usually clear criteria for when to stop or move on going up the tiers. For the ERICA approach, the exits are not indicated, and need to be addressed, including documentation for why one has exited the process and identification of "safety nets". A number of participants stated that there should be room for common sense, in principles are followed but that they should be flexible in their application. The process should be transparent for stakeholders, and uncertainty and sensitivity analysis should be included. In conclusion, the group was in favour of the tiered approach in principle, but the actual performance needs to be refined (flexible, not too limiting, room for common sense).

Should stakeholders be involved in the process, and if so how?

Yes. But there are different groups of stakeholders and they might come in at different tiers during the assessment. Should be room for the approach to develop according to the different inputs.

Any suggestions for the methods to use for derivation of the benchmark (for Tier One)?

The group first asked for a clarification of what a benchmark value is. It was explained that this is a value against which you compare something. For example, the IAEA TecDoc 332 gives some numbers on dose limits to biota that have been subsequently used as benchmarks for the scientific communities (even though one should be aware that this was not the original intention of the IAEA working group). The benchmark is often a conservative value, so if your screening gives an answer below that value, you are pretty sure that you do not need to go further in your assessment. A suggestion was made to send a draft document on benchmarks to stakeholders for comments in relation to decision making situations. This has been done in France within the “Groupe Radioécologie Nord Cotentin”. The group thought that a range of benchmark values (band, or overlapping bands, of concern) was more appropriate than single benchmark values. But it was also noted that as soon as one made any decision on numbers, be they single values or ranges, these would be open to criticism from the whole community.

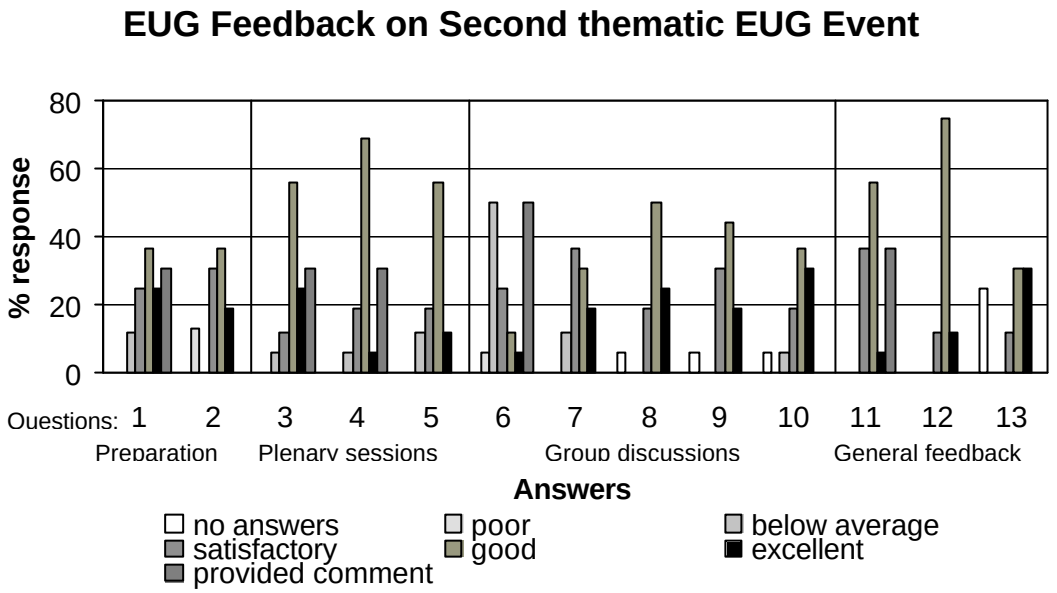
3 Summary and Conclusions

In the plenary session, it appeared that one group was interested in having a single benchmark (with variable safety factors), whereas the other group wanted a range of different benchmarks. A question was raised about whether it might be easier to explain to stakeholders/end-users why one has chosen a range of values or a single value. Neither group rejected the idea of using a tiered approach.

4 Feedback Questionnaire

EUG members were also requested to fill in a feedback questionnaire at the end of the second event to help the ERICA Consortium improve future events. The results of the survey are summarised in Appendix 4.

4.1 Summary of feedback



4.2 Response from ERICA consortium to EUG feedback

It was overall a good meeting, but there is room for improvements, as listed below.

- There is a need to make more use of the ERICA website to improve visits and disseminate material prior to the events.
- Distribute material prior to event in good time.
- Increase discussion times.
- More focus presentations and topics to be addressed by the groups.
- Improve questions to better focus discussion times.

These improvements will be addressed in the future events.

Although some presentation summaries and questions were circulated prior to the meeting, it was only 10 days before the event. Not all speakers provided the necessary information, which contributed to the delay in distribution.

5 Summary of Day 2

Work on Day 2 generated a number of ideas, which could be investigated further. Some of the main points made by the EUG have been summarised in Table 5.1.

Table 5.1: Ideas and suggestions derived from the various discussions held on Day 2.

	EUG COMMENTS
Interim ERICA tiered approach	• Define benchmark • Draft a document related to benchmarks in relation to decision making situations for stakeholders to comment • Further develop the tiered-approach.

The Consortium needs to consider the suggestions related to the use of a tiered approach. The next EUG event in Germany, scheduled for April 2005, may be an important forum to develop further the approach.

The feedback from the questionnaire will already be implemented in the next EUG event. A number of actios have been identified.

	EUG COMMENTS	ACTION FOR ERICA
Feedback questionnaire	There is a need to make more use of the ERICA website to improve visits and disseminate material prior to the events.	Structure of the website will be re-visited to make information more obvious.
	Distribute material prior to event in time for people to read.	All documents to be posted on the website in advance of events. ERICA e-newsletter will remind EUG members and link to where documents are on the website.
	Increase time for discussion .	Forthcoming events will make more time for discussion.
	More focused presentations and topics to be addressed by the groups.	Number of topics to be covered in forthcoming events will be reduced.
	Improve questions to better focus discussion	Be clear on what the ERICA Consortium wants to get out of the EUG.

As stated in Part 1, the Consortium's decisions to address, or not, specific issues will be compiled in the progress report, which follows the inputs of the EUG and actions taken by the ERICA Consortium. The progress report, updated regularly, is available to EUG members on the EUG protected area of the ERICA website www.erica-project.org .

Appendix 1: Final Agenda for the Two-day Event

2nd Thematic EUG Meeting: Ionising Radiation and other Contaminants

Day1 *Monday 13th September:* ***Ionising Radiation and other Contaminants***

09:00-09:10 Welcome

Biology and Ecotoxicology

09:10-09:50 Keynote speakers

Christian Streffer (University of Essen, Germany) – "Biological effects of radiation and other chemical stressors in the low dose range"

Ronny Blust (Laboratory for Ecophysiology, Biochemistry and Toxicology Department of Biology, University of Antwerp, Belgium) – "Comparative environmental toxicology: towards an understanding of effects across levels of organization and complexity."

09:50-11:00 Breakout group discussion (including coffee break)

11:00-11:30 Plenary presentations and discussion

Risk Assessment: Dose-Response Relationships and Risk Characterisation

11:30-12:30 Keynote speakers

Paul Whitehouse (Environment Agency, UK) – "Assessing the environmental risks of radioactive chemicals - a comparison with approaches for non-radioactive substances"

Philippe Ciffroy (EDF, France) and Jacqueline Garnier-Laplace (IRSN, France) – "The use of Species Sensitivity Distributions use to derive predicted No-effect concentrations for stable chemicals. First applications to radionuclides and effects data from FRED"

Rodolfo Avila (Facilia, Sweden) – "Quantification of environmental risks"

12:30-13:30 Breakout group discussion

13:30-14:30 Lunch

14:30-15:00 Plenary presentation and discussion

Risk Management and Socio-economic Issues

15:00-15:40 Keynote speakers

Andrew Farmer (Institute for European Environment Policy, London, UK) – Risk management: general comparison of regulation of environmental pollution.

Eric Vindimian (Ministère de l'écologie et du développement durable, France) – "EC Chemicals Policy: from a European to a national point of view? Case study: the Water Framework Directive - is there implication for radioactive contaminants?"

15:40-17:00 Breakout group discussion (including coffee)

17:00-17:30 Plenary presentation, general discussion and recommendations for ERICA

Day2 *Tuesday 14th September:* ***D4 Risk Characterisation***

09:00-09:30 EUG matters and Feedback questionnaire

09:30-10:00 ***Change in programme arising from the ERICA workshop that preceded the event.***

Presentation of D4 draft deliverable and suggested topics for discussion

Jacqueline Garnier-Laplace - General presentation and articulation of the work planned within D4

David Copplestone – Proposed interim ERICA tier-approach to risk assessment and management

10:00-10:15 Coffee

10:15-11:30 Group discussions on previous topics

11:30-12:30 Plenary presentations, discussion and recommendations for ERICA

Deborah Oughton - Presentation of guidelines for the design of daphnids and earthworms experiments planned within WP2

12:30- Lunch

Appendix 2: Division of Groups on Day 1 and Day 2

Day 1

	Group 1	Group 2	Group 3
EUG members	Patrick Delvin [A] Francois Brechignac [B] Valerie Moulin [C] Jill Sutcliffe [D,#]	Hildegarde Vandenhove [E] Marie-Odile Gallerand [F] Brettania Walker [G,#] Kins Leonard [H] Sanja Milkovic-Kraus [I] Frank Bruchertseifer [J]	Marianne Calvez [C] Miliza Malmelin [K] Andre Jouve [L] Tom Hinton [M,#] Ivica Prlic [I] Sylvain Saint Pierre [N]
External invited speakers	Ronny Blust [O,#] Eric Vindimian [P,#]	Paul Whitehouse [Q,#]	Andrew Farmer [R] Christian Streffer [S]
Consortium participants **(*also speaker)**	Rodolfo Avila [a] * Ulrik Kautsky [b] David Copplestone [c] Gerhard Pröhl [d] Kirsti-Liisa Sjoblom [e]	Jacqueline Garnier-Laplace [g] * Carl-Magnus Larsson [f] David Cancio [h] Steve Jones [i] Astrid Liland [j]	Philippe Ciffroy [l] * Rodolphe Gilbin [g] Michael Gilek [m] Peer Børretzen [j] Turid Hertel-Aas [k]
Consortium Referees	Irene Zinger [f]	Ingrid Bay [k]	Deborah Oughton [k]

[#] **- Chair**

EUG: **A**, Cogema, France; **B**, International Union of Radioecology; **C**, Commissariat à l'Énergie Atomique, France; **D**, English Nature, UK; **E**, Centre d'Étude de l'Énergie Nucléaire, Belgium; **F**, Agence Nationale pour la Gestion des Déchets Radioactifs, France; **G**, World Wide Fund for Nature – Artic Branch; **H**, The Centre for Environment Fisheries and Aquaculture Science, UK; **I**, Institute for Medical Research and Occupational Health, Croatia; **J**, German Federal Office for Radiation Protection; **K**, Ministry of the Environment, Finland; **L**, Autorité de Sureté Nucléaire, France; **M**, Savannah River Ecology Laboratory, USA; **N**, World Nuclear Organisation.

Speakers: **O**, University of Anvers; **P**, Ministère de l'Écologie et du Dévelopement Durable; **Q**, Environemnt Agency; **R**, The Institute for European Environmental Policy; **S**, University of Essen.

Consortium: **a**, Facilia; **b**, SBK; **c**, EA; **d**, GSF; **e**, STUK; **f**, SSI; **g**, IRSN; **h**, CIEMAT; **i**, WSC; **j**, NRPA; **k**, NLH; **l**, EDF; **m**, SUC.

Day 2

	Group 1	Group 2
EUG members	Patrick Delvin [A] Francois Brechignac [B] Valerie Moulin [C] Hildegarde Vandenhove [E,#] Brettania Walker [G] Kins Leonard [H] Tom Hinton [M]	Marianne Calvez [C] Jill Sutcliffe [D] Marie-Odile Gallerand [F] Ivica Prlic [I] Sanja Milkovic-Kraus [I] Frank Bruchertseifer [J] Miliza Malmelin [K,#] Andre Jouve [L]
External invited speakers	Ronny Blust [N] Eric Vindimain [O]	Paul Whitehouse [P] Andrew Farmer [Q]
Consortium participants (*also speaker)	David Copplestone [c]* Jacqueline Garnier-Laplace [f]* Rodolphe Gilbin [f] David Cancio [g] Peer Børretzen [h] Turid Hertel-Aas [i]	Rodolfo Avila [a] Ulrik Kautsky [b] Kirsti-Liisa Sjoblom [d] Carl-Magnus Larsson [e] Astrid Liland [h] Ingrid Bay [i] Philippe Ciffroy [j]
Consortium Referees	Irene Zinger [e]	Deborah Oughton [i]*

[#] **- Chair**

EUG: **A**, Cogema, France; **B**, International Union of Radioecology; **C**, Commissariat à l'Énergie Atomique, France; **D**, English Nature, UK; **E**, Centre d'Étude de l'Énergie Nucléaire, Belgium; **F**, Agence Nationale pour la Gestion des Déchets Radioactifs, France; **G**, World Wide Fund for Nature – Artic Branch; **H**, The Centre for Environment Fisheries and Aquaculture Science, UK; **I**, Institute for Medical Research and Occupational Health, Croatia; **J**, German Federal Office for Radiation Protection; **K**, Ministry of the Environment, Finland; **L**, Autorité de Sureté Nucléaire, France; **M**, Savannah River Ecology Laboratory, USA.

Speakers: **N**, University of Anvers; **O**, Ministère de l'Écologie et du Dévelopement Durable; **P**, Environemnt Agency; **Q**, The Institute for European Environmental Policy.

Consortium: **a**, Facilia; **b**, SBK; **c**, EA; **d**, STUK; **e**, SSI; **f**, IRSN; **g**, CIEMAT; **h**, NRPA; **i**, NLH; **j**, EDF.

Appendix 3: List of Questions for Each Group Discussion

Day 1: Ionising Radiation and Other Contaminants

Session 1: Biology and Ecotoxicology

- Do we agree that radiation has, at a cellular and organism level, the capability to produce similar effects and endpoints as chemical stressors? If not, what are the main attributes of radiation that need to be addressed?
- How do you extrapolate effects on an individual level up to population and ecosystem levels?

Session 2: Risk Assessment and Risk Characterisation

- What are the differences between the use of test species in the 'chemical approaches' compared to the use of "reference organisms" in the radiation field? What alternatives exist?
- When it comes to quantifying risk, the methods can be complex and appear not too transparent, so how much effort should be directed at educating decision-makers?
- Is a probabilistic approach to risk estimation easy to implement by decision-makers and will it require a lot of guidance?

Session 3: Risk Management and Socio-economic Issues

- Should radionuclides be regulated differently from other hazardous substances in risk management? What criteria exist to support their being/not being treated differently?
- If standards are to be applied, should they be based on environmental concentrations, as for chemicals, or on dose rates to organisms?
- How to treat in decision-making natural background radiation levels and those originating from past activities?
- Should decision-makers (implementers and regulators) base their decision on a single-value standard, or on "band of concern" approach, e.g. ranges of radiation doses or environmental concentrations?

Day 2: D4 - Risk Characterisiation

Session 1: Interim tiered approach

- Is this tiered approach appropriate? Should stakeholders be involved in the process, and if so how?
- Any suggestions for the methods to use for derivation of the benchmark (for Tier One)?

Appendix 4: Questionnaire Results from EUG Members

2nd Thematic EUG Meeting: Ionising Radiation and other Contaminants

75 % of the questionnaires were filled, i.e. 16 out of 21 EUG members and external speakers.

93 % of the questionnaires were returned anonymously.

% response **1. poor** **2. below average** **3. satisfactory** **4. good** **5. excellent** **x. no answer**

Preparations	1	2	3	4	5
Q1: Did you find the background material provided for this event useful?	0	12	25	**37**	25
Q2: Was the material distributed in a timely manner?	13	0	31	**37**	19

Other comments or suggestions **– 31 %**

- Slide presentations could be distributed ahead of presentation so that the audience is able to write comments for themselves on the slides
- Didn't get any material before the meeting
- Send background questions before the meeting
- It was on time for we to prepare, but not on time for us to organise a small meeting in Croatia in order to familiarise colleagues with the ERICA interpreted approach
- It would have been nice to have the group questions in advance

Plenary sessions	1	2	3	4	5
Q3: Did the find the presentations interesting?	0	6	12	**56**	25
Q4: Were the presentations at an appropriate level?	0	6	19	**69**	6
Q5: Did the presentations adequately cover the identified topics?	0	12	19	**56**	12

Were there any particular issues that were missed **– 31 %**

- Not enough discussion time
- Presentations in general were not focused enough on the main ideas to convey
- Generation of effects data for RNs and chemicals – how is this done? How do they differ?
- Need to clarify between "assessment" frameworks and "control" frameworks. There is a consensus to develop the former but the case for the need of the later is not yet made
- An interpreted (approach) was not really pointed in some presentations

Other comments or suggestions **– 31 %**

- Longer discussion time
- A clearer brief to external speakers would have been helpful, to make the presentations more focused
- Ask invited speakers to address specific questions rather than providing general rather open overviews
- All speakers had o cu their presentations. Would have liked to get copies before the meeting to speed discussions, or as they spoke.
- Need more time for discussions bout the key items

% response **1. poor** **2. below average** **3. satisfactory** **4. good** **5. excellent** **x. no answer**

Group discussions – some gaps	x	1	2	3	4	5
Q6: Was there enough time allocated for discussions?	0	6	**50**	25	12	6
Q7: Did you get the opportunity to raise your issues?	0	0	12	**37**	31	19
Q8: Was the level of facilitation appropriate?	6	0	0	19	**50**	25
Q9: Were the group discussions fruitful?	6	0	0	31	**44**	19
Q10: Did the background questions prompt interest in the discussions?	6	0	6	19	**37**	31

Other comments or suggestions **– 50 %**

- Interesting to come back to these questions in one year or at the end of the project
- Didn't receive background questions prior to the meeting
- Questions were sometimes ambiguous, hence answers sometimes out of scope
- Less presentations; cover less issues at one meeting; more time for group discussions – takes time to warm-up
- Good discussions but didn't always do the subjects justice – lack of time
- Questions not always relevant for EUG -> scientific questions to be treated by scientists
- It was excellent to have such a cross section of expertise present and would have like some time to hear from those present
- Need more time for discussions bout the key items

General feedback	x	1	2	3	4	5
Q11: Did the meeting fulfil your expectations?	0	0	0	37	**56**	6
Q12: Was there consistency between what was announced and what was carried out?	0	0	0	12	**75**	12
Q13: Is the ERICA website informative?	25	0	0	12	**31**	**31**

Other comments or suggestions **– 37 %**

- Fruitful meeting, interesting and stimulating ideas for the future
- I'll confirm that when I will have the password
- Not yet visited website
- How useful did the Consortium find the EUG inputs? Not easy to hear speakers. Very useful to have Consortium members there in the discussions – could helpfully inform and help clarify things.
- Program too heavy, so timing as difficult to follow. WNA to respond by the end of the year to ICRP proposal on the protection of non-human species. Happy to present information as an input to ERICA.
- I think it was pretty obvious that the careful terminology (background radiation) is to be introduced clearly (if possible for chemicals too group of chemicals). The background(radioactive) varies up to (5 standard deviation) under ozone holes (gamma rays); it is not "contaminant" but brings stress to environment (habitat) affected.