Radiation protection of the environment

State of the art and IRSN recommendations

Report IRSN 2016-03
ABSTRACT

France has obligation to transpose into its national legislation no later than 2018 the new EURATOM basic Safety Standards Directive of the European Commission. In this context, pushed by the rapid international developments in the emerging field of radiological protection of the environment, discussions are underway at national level around existing knowledge and methodologies which are or could be used both by operators and by the authorities for assessing the radiological risk to ecosystems exposed to ionising radiation. The French Institute for Radioprotection and Nuclear Safety publishes herein its recommendations to guide the transposition work and to give practical guidance to implement the BSS requirements in the field of radiological protection of the environment.

IRSN’s recommendations listed below relate to exposure situations as defined in the revised EU BSS accordingly to the ICRP publication 103 (2007) - planned, existing and emergency. In this document, they are supported by the state of the art and a review of current international practices.

General position

(R1) IRSN considers that the explicit consideration of protection of the environment from radioactive substances within the existing corpus of international reference documents (e.g., basic safety standards, international conventions, special legislation in some member States) must lead to the adoption of a French position on protecting the environment per se from ionising radiation. Such a position will be useful to technical experts participating in current or future working groups in this field.

Recommendations for planned exposure situations

(R2) IRSN considers that the inclusion, in France, of the demonstration of protection of the environment from ionising radiation in any project that may impact the environment is perfectly in line with the French Environmental Code and, more specifically, the provisions of Article 91 of French decree No. 2007-1557 on basic nuclear installations.

(R3) IRSN considers that the demonstration of protection of the environment from radioactive substances must be integrated into the environmental impact assessment, to the same extent as with the assessment conducted for chemical substances. IRSN recommends that, in France, this demonstration be routinely requested from the licensees of any facility or activity involving controlled environmental releases of radioactive substances that may have an ecological impact. Such demonstration shall be commensurate with the environmental issues.

(R4) IRSN recommends using a graded approach consistent with the principle of proportionality to the issues set out in French legislation. Such an approach enables resources and means to be better allocated based on the expected risk and allows efforts to be focused on cases requiring a closer look.

(R5) IRSN considers that the tiered ERICA approach, which is compatible with and more operational than the ICRP approach, forms the basis to be followed to explicitly demonstrate protection of the environment during the assessment and control of radiological impacts associated with planned environmental exposure situations, in addition to the approach used for human radiation protection. This approach is used widely in Europe and was adopted a few years ago by a number of nuclear operators in France. It is similar in method and uses the concepts of the ICRP approach whilst providing a tool and associated databases that are regularly updated.

(R6) Regarding environmental radiological risk assessments, IRSN recommends having the assessor choose benchmark values that are best suited to the situation under assessment and provide evidence of the source of said values (as is the case with the practices used to assess ecological risk associated with chemical substances).

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1 This article indicates that the environmental impact assessment comprises an analysis of the facility’s direct and indirect, temporary and permanent effects on the environment and particularly on public health and safety, the climate, neighbourhood inconveniences due to noise, vibrations, odours or lighting, on sites, landscapes and natural environments, on fauna, on flora and biological equilibria, on crops and on the protection of property and cultural heritage.
(R7) IRSN proposes setting up a working group whose objective would be to draft a technical guide describing a standardised and optimum method of using the ERICA approach and tool. This working group shall take into account improvements in international methodologies expected from the ICRP and the IAEA and other such organisations. It is also recommended to train users in the methods and tools in order to coordinate their deployment.

Recommendation for existing exposure situations

(R8) IRSN considers that the tiered ERICA approach makes it possible to cover existing exposure situations, particularly through its tiered assessment method. To supplement the feedback for these situations, other cases of application similar to the case studies handled within the Mines Joint Expert Group (GEP Mines), may be necessary to reinforce this statement; while including international advances in this field.

Implications for environmental monitoring associated with planned and existing exposure situations

(R9) Regarding planned exposure situations, IRSN recommends that current environmental radioactivity monitoring practices be reviewed to assess whether the data acquired can be used as additional proof for radiation impact assessments for ecosystems. Additionally, such a review shall also cover the use, for the same purpose, of the results from monitoring practices currently used to monitor the quality of media and biodiversity (e.g., case of the WFD and the MSFD). Regarding existing exposure situations, IRSN recommends supplementing the approach of demonstrating via the environmental impact assessment by implementing a specific ecological monitoring strategy where warranted by the level of exposure to ionising radiation (i.e., accordingly to the conclusions of the radiation risk assessment).

Recommendation for emergencies and the post-accident phase

(R10) In the event of a major nuclear accident (i.e. Chernobyl- or Fukushima-type), IRSN considers that the priority of the emergency is to protect human populations. During the post-accident phase, protecting the environment may be considered as one aspect to take into account to better manage contaminated areas. This matter could be dealt with by a dedicated working group. In view of the state of the art, the radiological risk assessment method for non-human species must be adapted and the necessary data must be supplemented in order to be able to respond to such situations. The proposed group’s work will extend to environmental monitoring practices. In terms of smaller accidents, attention should also be given to emergencies where protecting the environment would be essential, particularly in cases of accidents/incidents that impact uninhabited conservation areas.

KEYWORDS
Radiation protection, Environment, Non-human species, Risk assessment, Environmental Impact Assessment, Regulation, Recommendations, France

LIST OF CONTRIBUTORS
Authors: K. Beaugelin-Seiller, J. Garnier-Laplace
LIST OF THE MOST COMMON ABBREVIATIONS USED IN THIS DOCUMENT

Where applicable, English abbreviations are followed by their French equivalents.

ASN: Autorité de Sûreté Nucléaire - French Nuclear Safety Authority
BSS: Basic Safety Standards
DCC: Dose Conversion Coefficient
DCRL: Derived Consideration Reference Level
EIA, EIE: Environmental Impact Assessment
EQRS: Évaluation Quantitative du Risque Sanitaire (Quantitative assessment of health risks)
ERA, ERE: Environmental Risk Assessment
FP: Framework Programme for Research and Technological Development
GEP-mines: Groupe d’Expertise Pluraliste sur les sites miniers d’uranium du Limousin (http://www.gep-nucleaire.org/gep)
GPRADE: Groupe permanent d’experts en radioprotection, pour les applications industrielles et de recherche des rayonnements ionisants, et en environnement (Permanent Group of experts in radiation protection for research and industry applications of ionising radiation, and in environment)
GRNC: Groupe Radioécologie Nord Cotentin (http://www.gep-nucleaire.org/norcot/gepnc/sections/actualites)
IAEA, AIEA: International Atomic Energy Agency (http://www.iaea.org/)
ICRP, CIPR: International Commission on Radiological Protection (http://www.icrp.org/)
NEA, AEN: Nuclear Energy Agency, a specialised agency within the OECD (http://www.oecd-nea.org/)
OECD, OCDE: Organisation for Economic Cooperation and Development (http://www.oecd.org/france/)
RAPs: Reference Animals and Plants
RO: Reference Organisms
TEC-DOC: TEChnical DOCuments series reports
TRS: Technical Report Series
UNEP, PNUE: United Nations Environment Programme (http://www.unep.org/)
TABLE OF CONTENT

FOREWORD AND ELEMENTS OF TERMINOLOGY ......................................................... 9

1 INTRODUCTION ........................................................................................................ 10
  1.1 BRIEF OVERVIEW OF INTERNATIONAL, EUROPEAN AND NATIONAL LEGISLATION .................. 10
  1.2 MAIN JUSTIFICATIONS FOR THE EMERGENCE OF THE FIELD ............................................ 11
  1.3 THE COORDINATION GROUP LED BY THE IAEA .............................................................. 13
  1.4 OBJECTIVES AND SCOPE OF THE REPORT .................................................................. 14

2 STATE OF THE ART ................................................................................................. 16
  2.1 SOME HISTORICAL CONTEXT .................................................................................... 16
  2.2 DEFINITIONS, PRINCIPLES AND STATE OF THE ART OF BASIC KNOWLEDGE ...................... 18
  2.3 INCLUSION OF ENVIRONMENTAL RADIATION PROTECTION IN REGULATIONS AND NATIONAL IMPLEMENTATION IN VARIOUS COUNTRIES .......................................................... 22

3 MAIN APPROACHES AND COMPARISON ............................................................ 30
  3.1 THE ICRP APPROACH ............................................................................................. 30
    3.1.1 Application of the concepts (Publication 124) .......................................................... 34
    3.1.2 Position of international organisations in relation to the ICRP approach for the environmental radiation protection system ............................................................. 37
  3.2 ERICA - THE APPROACH USED THE MOST IN EUROPE .................................................. 40
  3.3 COMPATIBILITY OF THE MAIN APPROACHES FOR ASSESSING RADIATION RISKS TO ECOSYSTEMS ................................................................................................. 41

4 APPLICATIONS AND FEEDBACK ............................................................................... 49
  4.1 AT AN INTERNATIONAL LEVEL .................................................................................. 49
  4.2 IRSN’S INVOLVEMENT ............................................................................................ 57
    4.2.1 Planned situations ................................................................................................ 58
    4.2.2 Existing situations .............................................................................................. 60
    4.2.3 Emergency situations ......................................................................................... 61

5 RECOMMENDATIONS - CONCLUSIONS ............................................................... 63

6 REFERENCE DOCUMENTS ..................................................................................... 65

7 LIST OF ILLUSTRATIONS ..................................................................................... 74

8 LIST OF TABLES ....................................................................................................... 76

9 APPENDICES ............................................................................................................. 77
  9.1 CALCULATION OF DOSE RATES FOR WILDLIFE ........................................................ 78
  9.2 BENCHMARK VALUES FOR EFFECTS ON NON-HUMAN SPECIES: COMPILATION OF THE DETERMINATION VALUES AND METHODS USED BY PROTECT ........................................... 80
  9.3 DETAILED ANALYSIS OF IRSN’S FEEDBACK FOR PLANNED/EXISTING SITUATIONS ........... 100
    9.3.1 Comparison of the results in relation to the benchmark values ................................. 100
    9.3.2 Contribution of internal exposure vs. external exposure ........................................ 102
    9.3.3 Contribution of radionuclides to internal exposure .............................................. 102
    9.3.4 Natural background radiation and benchmark values .......................................... 102
  9.4 DESCRIPTIONS OF THE ‘VALID’ APPROACHES, METHODS, TOOLS AND DATABASES ....... 106
  9.5 DESCRIPTIONS OF THE RELEVANT CONVENTIONS .................................................. 116
  9.6 DESCRIPTIONS OF CURRENT PROGRAMMES ........................................................ 122
9.7 DESCRIPTION OF THE ORGANISATION OF RADIATION PROTECTION RESEARCH IN EUROPE ........126
9.8 TABLE SUMMARISING THE MAIN DEMONSTRATION ELEMENTS UNDERPINNING EACH RECOMMENDATION ..........................................................128
FOREWORD AND ELEMENTS OF TERMINOLOGY

Environmental radiation protection is an emerging field where language and vocabulary have not yet been fully harmonised among the various stakeholders (regulators, radiological risk assessors and risk managers, experts, researchers, the general public). The terms used herein are therefore faithfully taken from the reference documents. For some very generic terms, such as ‘environment’, ‘biodiversity’ and ‘non-human species’, which are often incorrectly used as synonyms, IRSN proposes primarily using the following definitions:

- ‘Environmental radiation protection’ means the field related to protecting ecosystems from ionising radiation.

- ‘Environmental radiation protection system’ refers to the concepts, principles and approaches that establish the framework for assessing and managing radiological risk for ecosystems.

- ‘Environmental radiation risk assessment methods’ means the methods used to calculate a level of risk of damage to ecosystems in relation to their exposure to ionising radiation.

- When used in the context of assessing radiological risks to ecosystems, ‘benchmark values’ means the value(s) specifying an effect level expected in all or part of an ecosystem exposed to ionising radiation. The actual or estimated level of exposure of all or part an ecosystem is compared to these values to obtain a risk estimate (often as a first step, the risk is characterised by the ratio between the level of exposure and the no-effect value for all or part of the ecosystem).

- When adopted as ‘protection criteria’ in any piece of regulation used to manage environmental quality, ‘benchmark values’ correspond either to regulatory standard or guideline values for decision-making in managing ecosystems. In the specific field of protection of the environment, there are currently no normative values for ionising radiation.

- ‘Ecosystem health’ refers to the status of the structure and functioning of all ecosystems in which species live and interact in between each other and with the environmental compartments constituting their habitats.
1 INTRODUCTION

1.1 BRIEF OVERVIEW OF INTERNATIONAL, EUROPEAN AND NATIONAL LEGISLATION

(1) In 2006 the International Atomic Energy Agency (IAEA) anticipated the updating of the international basic safety standards in radiation protection in order to incorporate future recommendations issued by the International Commission on Radiological Protection (ICRP). In particular, Principle 7 of the Fundamental Safety Principles published in 2006 (IAEA, 2006) was added to include the protection of people and the environment from ionising radiation for present and future generations.

(2) ICRP Publication 103 (ICRP, 2007) compiles new recommendations on radiation protection and supersedes ICRP Publication 60 (ICRP, 1991). In a new chapter devoted to the environment, ICRP logically emphasizes the need for an environmental radiation protection system *per se* that is consistent, firstly, with the human radiation protection system and, secondly, with the system for protecting the environment from chemical substances $^2$.

(3) The recommendations of the ICRP (2007) include new objects to be protected from ionising radiation, *i.e.*, (i) biological diversity, which must be maintained; (ii) species, which must be conserved; (iii) the health and status of natural habitats, communities and ecosystems. The Commission “also recognises that these objectives may be met in different ways, that ionising radiation may be only a minor consideration - depending on the environmental exposure situation - and that a sense of proportion is necessary in trying to achieve them.”

(4) The updated international basic safety standards (IAEA, 2011a) supersede the 1996 version (IAEA, 1996), which did not explicitly mention protection of the environment. The updated version includes the latest recommendations of the ICRP (ICRP, 2007). The new basic standards on environmental radiation protection are part of the application of Principle 7 of the Fundamental Safety Principles (IAEA, 2006) and contain the objects of protection recommended by the ICRP (2007) and cited in item (3).

(5) The latest version of the international basic safety standards thus sets for environmental aspects a new vision that requires meeting two objectives: (i) ensure, for present and future generations of people, sustainable use of natural resources used for agriculture, forestry, fishing and tourism; and (ii) prevent the effects of ionising radiation on fauna and flora. It is by applying the principles of radiation protection justification and optimisation that aspects related to human health and environmental health $^3$ will become harmonised.

(6) Council Directive 2013/59/Euratom of 5 December 2013, which lays down the “basic safety standards for protection against the dangers arising from exposure to ionising radiation”, was published in the OJEU (Council of the European Union, 2014) on 17 January 2014. France has four years from the directive’s date of publication to transpose it into national law and adjust, where necessary, regulations set out in its

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$^2$ Item (360) of ICRP Publication 103: “Interest in the protection of the environment has greatly increased in recent years, in relation to all aspects of human activity. Such interest has been accompanied by the development and application of various means of assessing and managing the many forms of human impact upon it. The Commission is thus aware of the growing need for advice and guidance on such matters in relation to radiological protection even though such needs have not arisen from any new or specific concerns about the effects of radiation on the environment. The Commission also recognises that there is a current lack of consistency at international level with respect to addressing such issues in relation to radioactivity, and therefore believes that a more proactive approach is now necessary.”

$^3$ Dose limitation, the third basic principle of radiation protection, does not apply to environmental radiation protection. See Subsection 3.1.1
national health, labour and environmental codes. This directive updates, incorporates (and repeals) five Euratom directives that made no mention of environmental protection per se. It takes into account the new recommendations issued by the ICRP (ICRP, 2007) and brings European law into line with the latest international basic standards published by the IAEA (IAEA, 2011).

(7) The reference to the environment is incorporated in the latest European basic radiation protection standards in terms of long-term human health protection, which can be impacted by the state of the environment. Point (27) in the introduction to the directive thus states that the environment must be protected from the harmful effects of ionising radiation by enacting the appropriate regulations based on environmental criteria derived from internationally recognised scientific data.

(8) Article 2 of Directive 2013/59/Euratom specifies the scope for all planned, existing or emergency exposure situations involving “a risk from exposure to ionising radiation which cannot be disregarded ... with regard to the environment in view of long-term human health protection”. Of all the sections in the directive, only Chapter VIII on public exposures specifies an addition, which is described in Section 1 “Protection of members of the public and long-term health protection in normal circumstances”. Article 65 of Section 1 states that, at the discretion of each Member State, demonstration must be made that “environmental criteria for long-term human health protection are met”. As regards the other exposure situations (existing or emergency), no supplemental information is provided in addition to Article 2.

(9) Protection of the environment from ionising radiation is not explicitly mentioned per se in national French regulations. Nevertheless, some nuclear operators in France include the demonstration of radiation protection of non-human species in the Environmental Impact Assessments (EIA) requested by the French nuclear safety authority in the process of licence applications throughout the life cycle of their facilities.

(10) Such an initiative on the part of these licensees is due to two main reasons: (i) demonstrating environmental radiation protection is a regulatory requirement of the licence-granting procedure in other EU Member States (e.g., case of England and Wales); (ii) such demonstration, a regulatory requirement for assessing the environmental impact of chemical substances as part of EIAs, is extended, for reasons of consistency, to radioactive substances.

1.2 MAIN JUSTIFICATIONS FOR THE EMERGENCE OF THE FIELD

(11) EU legislation supports the implementation of the environmental policy in its entirety (i.e., protecting all living organisms for nature conservation - habitats, species and their genetic diversity) and using a non-sectorial approach. Environmental impact assessments (EIA) have been a tool for environmental protection since 1976 (French Nature Conservation Act No. 76-629). EIAs include assessing the direct,
indirect, temporary and permanent impacts of all projects that may significantly affect the environment as well as justifying any measures taken to offset these impacts.

(12) EIAs are a cornerstone of justification of the protection of natural resources in a broad sense of the term. In other terms, the body of regulations intended to fully protect the environment - i.e., regardless of the stressor(s) considered - requires that policy-makers and the public be made aware of the demonstration that the environment is protected at an expected or controlled level by means of (i) the environmental assessment filed by the petitioner through the appropriate administrative channel and (ii) the advisory opinion on this EIA issued by the French environmental authority and made publicly available.

(13) More and more regulations are being introduced in Europe to protect biodiversity and natural habitats. Examples include framework directives - such as the Water Framework Directive (WFD) and the Marine Strategy Framework Directive (MSFD), which aim to achieve good environmental status of aquatic environments by 2015 and 2010, respectively, and which include or refer to many instruments ((e.g., the Birds Directive 79/409/EEC and the Habitats Directive 92/43/EEC (accompanied by the creation of the Natura 2000 network)) - and conventions such as the Convention on Biological Diversity (CBD), and regional seas conventions such as OSPAR, HELCOM and the Barcelona Convention.

(14) Some of this legislation deals explicitly with radioactive substances (e.g., OSPAR, London Convention; Appendices p.117 and 119). As stated in item (10), transposition of this legislation into national law has led to differences regarding cases where this category of stressors is not explicitly mentioned (e.g., unlike in the other EU Member States, the Environment Agency of England and Wales requires that radiation risk assessments be included for Natura 2000 sites in all licence issuance or renewal applications involving controlled releases of radioactive substances to the environment).

(15) This situation has spurred the need for a method for explicitly demonstrating that the environment is protected from harmful effects related to the presence and/or release of radioactive substances. The method adopted is that of assessing the environmental risk posed by radionuclides in the same manner as for chemical substances.

(16) The environmental radiation protection approach currently recommended in ICRP publications is intended to be (i) consistent (and thus compliant) with regulatory applications filed nationally and even regionally; (ii) the same for all industries (nuclear or otherwise); and (iii) in line with current measures for controlling pollution and for reducing emissions of substances at their source. The ICRP recommends an approach and concepts and methods for demonstrations that fit easily into the EIA of any project.

(17) The new international basic safety standards (IAEA, 2011a) require considering environmental protection per se in the normal operating conditions of facilities (so-called planned environmental exposure situations) as part of the licence application procedure or to set release limits. In other situations (incidents/accidents or emergency exposure situations, existing situations), environmental protection is one of the factors to consider, in addition to human radiation protection and socioeconomic aspects, when applying the optimisation principle.
1.3 THE COORDINATION GROUP LED BY THE IAEA

Since the first International Conference on Protection of the Environment from the Effects of Ionising Radiation was held in Stockholm in 2003 (IAEA, 2003), the IAEA, in cooperation with the European Commission, IUR and UNSCEAR, developed an international action plan to address what was then an emerging issue (IAEA, 2005). The IAEA entrusted this plan to its IAEA’s Division of Radiation, Transport and Waste Safety. Together with key international organisations, such as the ICRP and UNSCEAR, the IAEA set up the Coordination Group on Radiation Protection of the Environment with the objective of internationally harmonising, in line with existing release regulations, the development of a regulatory framework, technical guides and normative criteria for environmental radiation protection. This regulatory framework and its body of methods and knowledge must be developed based on existing scientific data on exposure to ionising radiation and its potential effects on non-human species.

The Coordination Group on Radiation Protection of the Environment also includes a panel of various international and regional stakeholders (such as UNEP, OECD-NEA, IUR, WNA, WWF, Greenpeace and the European Commission) and Member States of the IAEA competent in the matter. After several years spent primarily sharing information amongst its members, the group convened for the fifth time in July 2013. The aim of this meeting was to review current work by the international organisations and to consider how to include in safety guidance in preparation (e.g., IAEA Draft Safety Standards DS427 “Radiological Environmental Impact Assessment for Facilities and Activities”) the requirements of new international basic standards for environmental radiation protection (IAEA, 2011a) as well as the ICRP’s latest recommendations, published in 2007 (Publication 103), 2008 (Publication 108) and 2009 (Publication 114), or in press (Publication 124).

The key international organisations involved in the development of basic knowledge and the environmental protection system voice their views within this coordination group. In accordance with the long-standing process behind the creation of basic radiation protection standards (Figure 1), by updating, in 2008, the summary of the effects of ionising radiation in non-human species (UNSCEAR, 2008); UNSCEAR consolidated the scientific basis of the ICRP’s recommendations on the matter (ICRP, 2008) and their implementation within basic radiation protection standards (IAEA, 2011a). The collaborative work of these organisations, particularly within the Coordination Group on Radiation Protection of the Environment, has since become much more interactive. Their participation in this group, alongside other entities such as the IUR, OECD-NEA and UNEP, suggests that, in coming years, the IAEA will support the ICRP’s developments remaining to be achieved during the current term of the Committee 5 (2013-2017) and the technical implementation of the ICRP approach. These points will be discussed in Chapter 3 herein.
OBJECTIVES AND SCOPE OF THE REPORT

Three reasons warrant the publication of IRSN’s recommendations on environmental radiation protection. Firstly, the GPRADE will, based on the recommendations submitted to ASN as part of the IRSN referral of 2 July 2013, be able to come to a decision on the inclusion in French regulations of technical methods and rules on assessing radiological risks to the environment. Secondly, this opinion and position of the GPRADE will be able to be used to transpose into French law the new Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (OJEU, 2014). Lastly, this opinion and position of the GPRADE will be able to take into account the latest developments of the ICRP on the application (Publication 124) of the new international basic radiation protection standards (IAEA, 2011a) and the elements derived from them, some of which could not be explicitly specified in the European version.

IRSN’s recommendations on environmental radiation protection, presented in the final chapter of this report, are based on the state of international scientific knowledge and methods currently available (Chapters 3 and 4) and on feedback regarding the implementation of radiation risk assessment methods in various exposure situations published in the scientific literature by IRSN and other organisations (Chapter 5). IRSN’s experience as a consultant to the competent authorities for assessments around France is also discussed.

The review of the information and documents that follows herein, and which is necessary for establishing IRSN recommendations, is not intended to be exhaustive. However, no available information was deliberately omitted. The data obtained from the reviews are provided for illustrative purposes only. The intention is to cover the widest possible spectrum without drowning the main subject in details. As a
result, these data were sought by focusing on the direct links between the subjects discussed and environmental radiation protection.
2 STATE OF THE ART

2.1 SOME HISTORICAL CONTEXT

(24) Until 1991, ecosystems were seen in terms of radiation protection only as vectors to human exposure pathways, with humans being the objects to be protected. Assuming that the human species is the most radiosensitive, its protection boils down to not endangering other species (ICRP, 1991). The last decade of the 20th century saw the emergency and proliferation of discussions on this matter, particularly in connection with the Rio Declaration (UN, 1992a) and the Convention on Biological Diversity (UN, 1992b). Based on literature reviews and expert opinions, the IAEA (1992) and UNSCEAR (1996) began proposing specific benchmark values for non-human organisms and expressed in exposure dose rates below which deleterious effects on pseudo-taxonomic groups would not be observed.

(25) The first benchmark values for the effects of ionising radiation on non-human species have since been published and can be used for comparison purposes or to assess the expected effects for actual exposure situations. In 2008, the update to the UNSCEAR review proposed, in line with various key publications on the matter, the following phrasing “...chronic dose rate of 100 µGy/h (2.4 mGy.d⁻¹) to the most highly exposed individuals unlikely to have significant effects on most terrestrial animal populations” or “the maximum dose rates of 400 µGy/h (9.6 mGy.d⁻¹) to a small proportion of the individuals in aquatic populations of organisms that would not have any detrimental effect at the population level” (UNSCEAR, 2008). These benchmark values are listed in Appendix 12.1.

(26) 1998 marked the first time that an international convention was signed by the contracting parties to the Oslo or Paris Conventions (Germany, Belgium, Denmark, Spain, Finland, France, Ireland, Iceland, Luxembourg, Norway, the Netherlands, Portugal, United Kingdom, Sweden, Switzerland, and European Union). It was agreed to explicitly take account of radioactive substances to protect an environment (OSPAR, see description in the Appendix). In the 2000s, the United Kingdom and Canada were the first States to integrate the issue of environmental radiation protection in their national legislation. An international consensus gradually began to appear on the need to set up a system to protect the environment from the effects of ionising radiation, prompting international bodies to establish specific discussions and working programmes with the objective of having a method of assessing the environmental risks associated with radionuclides. In parallel to the discussions and recommendations of these international bodies, research projects supported by EURATOM improved knowledge and led to the development of methods and tools. The key dates and achievements related to these developments are shown in “Milestones” box on the following page.

(27) The approach developed for human radiation protection and the well-established methodology for assessing environmental risks caused by chemical substances provided the basic elements for developing a specific approach for radionuclides and the environment consistent with the existing approaches and with the aim of a consistent protection approach (i.e. people-environment and chemical substances-radioactive substances).

For more detailed information on the state of the art, the reader is invited to refer to the IRSN documents on environmental radiation protection that are part of the collection of doctrine and summary documents published by the Institute (IRSN, 2005; 2006).
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<thead>
<tr>
<th>Date</th>
<th>International conference</th>
<th>Documents/recommendations issued by international organisations</th>
<th>Research projects (Euratom)</th>
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<tr>
<td>1996</td>
<td>Stockholm Conference (SSI and AECB, 1996)</td>
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<td>2001</td>
<td>IUR consensus conference in Oslo (Bréchignac et al., 2003)</td>
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<td>2005</td>
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<td>Creation of ICRP Committee 5</td>
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<td>Coordination Group on Radiation Protection of the Environment (and its activity plan) created by the IAEA</td>
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<td>2006</td>
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<td>Environmental protection incorporated in the fundamental safety principles by the IAEA (Principle 7 of the Fundamental Safety Standards) (IAEA, 2006)</td>
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<td>2007</td>
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<td>Publication of the revised edition of the ICRP on radiological protection (Publication 103) with a chapter specifically devoted to the environment (ICRP, 2007)</td>
<td>2007-2008 PROTECT project (Howard et al., 2010)</td>
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<td>2008</td>
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<td>Publication of the update to the 1996 document on the review of the effects of ionising radiation on non-human species by UNSCEAR (UNSCEAR, 2008)</td>
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<td>2009</td>
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<td>2011</td>
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<td>Revision by the IAEA of the international basic radiation protection standards, including environmental protection (IAEA, 2011a)</td>
<td>STAR network of excellence 2011-2015 (Appendix, p.123) (Hinton et al., 2013)</td>
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<td>2012</td>
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<td>Alliance European radioecology research platform (2012-)</td>
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2.2 DEFINITIONS, PRINCIPLES AND STATE OF THE ART OF BASIC KNOWLEDGE

The risk assessment methodology is now well codified. Although its vocabulary differs slightly depending on the area (people vs. the environment, conventional chemical substances vs. radionuclides), the principles that underlie it are common. It is underpinned by three key components - exposure analysis, effect analysis and risk characterisation. The main definitions to know are provided in the box below.

Key definitions in the field of environmental risk assessment

Ecological (or environmental) risk is the probability of occurrence and the severity of damage likely to occur in all or part of the ecosystem as a result of its actual exposure (existing situation) or planned exposure (planned situation) to the substances of interest.

Impact is the deterministic combination of a factor of exposure and an effect term (in the ecotoxicological sense of the term) characterised by a dose-response relationship. Risk is defined as a measurable impact.

Effect, in the ecotoxicological sense of the term, is the biological damage caused to an organism due to its exposure. In the effect term used in the impact or risk assessment, reference is made to a value representative of a meta-analysis of a sufficient number of studies that led to the establishment of dose-response relationships in several species and for several biological functions and for which the associated uncertainty is taken into account. The methods used to determine such benchmark values are described in item (90).

Object of protection is a combination (one or more species, effect endpoint at a biological or ecological organisation level) for which risk is assessed. For example, it could be protecting the reproduction of a given species, or the biomass of a population (assembly of individuals of the same species), or the structure and functioning of communities (assembly of people) or of ecosystems. Protecting a species at the level of each of its individuals is generally reserved for endangered species or species with a particular conservation value index. Regardless of the level of biological or ecological organisation in question, the huge diversity of species of flora and fauna requires simplification by adopting assumptions to be able to lead an environmental risk assessment. Indeed, having the necessary information at any stage of the assessment for each species of fauna and flora is inconceivable. This is why the radiation risk assessment calculation methods that have been developed so far use the concept of reference organisms (RO, RAP - see Glossary, items (57) to (60) and (83) to (87)). The purpose of these reference organisms is to simplify the approach using biological/taxonomic proximity assumptions to justify their representativeness of a wider range of species. Such an organism is a virtual entity represented by a model species whose anatomical, physiological and biological properties can be used to determine exposure/dose and dose/effect relationships that can be extrapolated to any organism that may be affiliated with it. In the case of environmental risk assessment methods based on field observations made during environmental monitoring campaigns, more structural and functional effect endpoints (e.g., decomposition rate of organic matter, specific richness of a community) are used. The underlying assumption is that these criteria are representative of the integrity of the structure and functioning of the ecosystem.
The assessment of an existing situation can be limited to the current state of the environment or characterise it over a past period, in which case it is referred to as retrospective. The assessment of a planned situation is necessarily prospective.

The approach used most in environmental impact or risk assessments (EIA or ERA) is a graded approach that leads to iteratively conducted assessments. There are generally three types of assessment: screening, a conservative approach based on generic data and assumptions aimed at being conservative for the impact assessment; generic assessments, which involve the use of generic data and less conservative assumptions (e.g., average values) and site-specific assessments, which require local information.

Chronic exposure, often associated with low continuous dose rates, corresponds to exposure occurring over a significant period compared to the lifespan of living organisms and effect endpoints which are objects of protection (typically under normal operating conditions of a facility). On the other hand, acute exposure, which is often associated with high punctual doses, occurs over a short period (typically under accidental situations). A chronic exposure phase may follow an acute exposure phase over the course of the same event (post-accident situations).

(29) The purpose of exposure analysis is to quantify, for each exposure pathway for the organisms to be protected, the levels at which they are exposed. In a retrospective assessment, the necessary data may be obtained from environmental measurements. By default, they may stem from models, as is always the case with prospective assessments.

(30) The purpose of effects analysis, which is based on characterisation of the relationships between exposure and ecotoxicological effects, is to determine appropriate benchmarks for assessment (e.g., values guaranteeing the protection of identified objects, known as no-effect values). These values are generally no-effect concentrations for the environment i.e. concentrations below which no adverse effects are expected for the object to be protected (these values are called Predicted No-Effect Concentrations (PNEC) for chemical substances and Predicted No-Effect Dose Rate (PNEDR) for radioactive substances).

(31) Risk characterisation combines the results of the exposure analysis and of the effects analysis in order to identify (and, where applicable, quantify) the existence of a risk for the objects of protection. The associated methods may be deterministic, semi-probabilistic or probabilistic (Figure 2).
Figure 2: Overview of the various methods of risk characterisation

Analysis of the exposure of non-human species to radioactive substances requires two types of data: (i) the concentration factors that quantify the transfer of radionuclides to organisms from various exposure routes, and (ii) dose coefficients. Work conducted as part of the IAEA EMRAS I Programme found that the variability of the dose coefficients used in the various environmental radiation protection approaches was insignificant in light of the uncertainties associated to the concentration factors (item (101); Vives i Batlle et al., 2007; AIEA, in press-a). These conclusions mirror those of the European PROTECT Project (Howard et al., 2010) and the IAEA Coordination Group (IAEA, 2011b). It was therefore decided to focus the efforts of a working group of the IAEA EMRAS II Programme on creating an as comprehensive as possible compendium of the concentration factors that quantify the transfer of the radionuclides studied from water or soil to non-human species (Howard et al., 2013). The resulting compendium contains the whole-organism concentration factor values for 40 taxonomic groups belonging to three ecosystems (terrestrial, freshwater and seawater, including brackish water), occasionally subdivided based on various criteria such as diet. They are available online in the Wildlife Transfer Database, http://www.wildlifetransferdatabase.org/, Appendix p.115) for around 70 elements for which the radionuclides are associated with NORM, routine discharges, accidents and waste disposal type sources. By February 2011, 520 references had been consulted, generating some 90,000 concentration factor values in the form of more than 800 combinations (element, taxon), available for the adult stage of the organisms. This seeming abundance nonetheless conceals a wide diversity in the volume of knowledge based on the ecosystem and the element (Figure 3). The number of values in the database thus varies from more than 100 for the concentration factor for sodium (Na) in brackish water to more than 7000 for that of caesium in the terrestrial environment. And even the last case - the best documented - reveals a wide disparity between taxonomic groups: mammals are characterised by nearly 2500 values versus a few more than 20 for annelids or arachnids (Figure 4). Furthermore, having a large number of values does not necessarily guarantee reduced uncertainty. For example, the caesium concentration in mammals varies by more than four orders of magnitude.
Lastly, although this database is currently the most comprehensive source of concentration factors for non-human species, it is affected by several limitations, the consequences of which on the associated uncertainty varies with the element, species and exposure route considered. These limitations are mainly (i) the lack of relevant data for many radionuclides (no data or extrapolation from the stable element); (ii) the limited geographic coverage of the data, limited primarily to the temperate zone; (iii) bias introduced in some average values by the dominance of some data sources; (iv) the dominance of the adult stage of life; (v) failure to take into account some transfers (root uptake in particular).

This understanding of concentration factors that has yet to be deepened remains the main source of uncertainty in the characterisation of the exposure of organisms and underscores the entire importance of having representative measurements on non-human species for this purpose (determination in correspondence of specific activities in organisms and their environments - water, soil/sediment), for the retrospective assessments at the very least.

(33) The vast majority of knowledge on the analysis of the effects of ionising radiation on non-human species is listed in the FREDERICA database (Copplestone et al., 2008; Appendix p.120). To date, this database contains 32,000 data points obtained from 1300 bibliographic references. The data points are listed by
ecosystem (marine and freshwater, terrestrial) and divided into 14 pseudo-taxonomic groups (bacteria, algae, plants, insects, molluscs, crustaceans, zooplankton, amphibians, birds, fish, mammals, terrestrial invertebrates, fungi, mosses and lichens). The biological endpoints are varied and described in specific terms. They are divided into four categories: mortality, morbidity, reproduction and mutation. These data points are pairs (dose or dose rate, effect) assembled by ‘test’ comprising a control group and a set of groups exposed at increasing levels and observed simultaneously, and associated with various information about the species and its life stage, the experimental conditions (laboratory or field), the exposure conditions (emitting radionuclide, type of radiation, exposure route, exposure time, etc.). These data points were used to reconstruct the relationships (dose (or dose rate) - effect intensity) according to a standardised procedure (Garnier-Laplace et al., 2010) for obtaining critical ecotoxicity values comparable from one species to another and from one exposure condition to another. In all, more than 1000 relationships (dose (or dose rate) - effect intensity) were reconstructed and used in a meta-analysis that resulted in the determination of benchmark values usable within ecosystem radiation risk assessment methods. The meta-analysis of these relationships (dose (or dose rate) - effect intensity) made it possible to derive the value of 10 µGy.h\(^{-1}\) to be used incrementally in background radiation in the case of chronic exposure to ionising radiation for the screening stage and generic stage of the tiered ERICA approach. The details of the primary data points and the derivation method applied are given in items (79) and (80). These associated relationships and data points are presented in the reports of the FASSET and ERICA projects and the associated publications (Garnier-Laplace et al., 2006; 2010; 2013). For information, 65% of these relationships relate to acute exposure (i.e. of short duration and at a high dose ranging from approx. 0.1 Gy to more than 1000 Gy). The vast majority of all the data points (acute and chronic) relate to external gamma radiation situations. During any risk assessment regarding effect analysis, knowledge gaps are managed by adopting a safety factor when determining benchmark values (see item (90)). Based on a critical literature review, Garnier-Laplace et al. (2004) proposed and supported operational recommendations for ecosystem radiation risk assessments by ranking the importance of the uncertainties associated with the necessary extrapolations related to knowledge gaps as follows: uncertainty introduced by the extrapolation of one species to another is greater than that generated by the extrapolation of an acute exposure to a chronic exposure, which itself is similar to that produced by the extrapolation of external irradiation to internal irradiation and to that associated with the extrapolation of an isolated radionuclide to a situation with multiple stressors. Next come uncertainty related to the extrapolation of knowledge acquired on the individual to the population and uncertainty from the extrapolation of the structure to the function of an ecosystem.

2.3 INCLUSION OF ENVIRONMENTAL RADIATION PROTECTION IN REGULATIONS AND NATIONAL IMPLEMENTATION IN VARIOUS COUNTRIES

(34) This section provides an illustration of the regulatory context and its origin in countries that have adopted provisions on environmental radiation protection in their regulations and focuses on the cases that prompted the development of dedicated methods and tools.

of the requirements for radioactive substances, but does not explicitly mention environmental protection. However, the associated government guidance (http://www.defra.gov.uk/publications/files/pb13632-ep-guidance-rsr-110909.pdf) states that one of the main objectives of the Radioactive Substances Regulation is to "ensure that the accumulation and disposal of radioactive wastes are managed effectively to limit the radiological impact on the general public and the environment."

(36) Under these regulations, it is the job of the UK Environment Agency (UK-EA) to check all existing permits, authorisations, agreements, licences and permissions of all types (including those for activities involving radioactive substances) that may affect Natura 2000 sites to ensure that they have no ecological impact on these sites. This regulatory requirement led to the development of the approach presented in R&D Publication 128 and the associated spreadsheets (Copplestone et al., 2002; Appendix p.108). The implementation of this approach, between 2000 and 2003, revealed that more than 100 of the 429 authorisations granted to nuclear facilities were likely to have a radiological impact on Natura 2000 sites and required a detailed assessment (site specific). In addition, nuclear operators are encouraged to provide, for all new projects and during the Generic Design Assessment, an assessment of the potential radiological impact of the future radioactive discharges of their facility on wildlife according to the approach implemented by EA.

(37) The purpose of the Canadian Nuclear Safety and Control Act of 1997 is "the limitation, to a reasonable level ... the risks to national security, the health and safety of persons and the environment that are associated with the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information." It established the Canadian Nuclear Safety Commission, whose purpose is to ensure that the risk level inherent to the aforementioned activities remains reasonable as regards the health and safety of persons and the environment, and to inform the public thereof. Regulations passed in the 2000s pursuant to the Nuclear Safety and Control Act of 1997 explicitly mention environmental protection, such as in the requirement imposed on licensees to provide "the proposed environmental protection policies and procedures" as well as "the proposed program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects on the environment" (Class I Nuclear Facilities Regulations, SOR/2000-204).

(38) In 1999, Canada passed the Environmental Protection Act (CEPA; Appendix p.113). This act requires the Ministers of the Environment and of Health to establish a Priority Substances List (PSL) identifying substances, in the broad sense of the term that may be hazardous to the environment or to human health. However, in 1995, the Ministers’ Expert Advisory Panel for the second Priority Substances List (PSL2) stated that (i) the assessment of risks posed by the discharge of radionuclides from nuclear facilities to non-human species contained ‘flaws’ and (ii) that, pursuant to CEPA, such risks warranted environmental assessment. The guide published in 1997 by the Canadian Government (Environmental Assessments of Priority Substances under the Canadian Environmental Protection Act: Guidance Manual, 1.0, Environment Canada) was thus implemented for radionuclide discharges from facilities associated with the nuclear fuel cycle or that used radioactivity for medical or research purposes, with a focus on the effects on non-human species. A draft of the assessment report was published for public comment in 2000. The comments received guided the drafting of the final version, which was published in 2006 (Environment Canada, 2006). The assessment’s findings indicate that releases of uranium and uranium compounds contained in effluent from uranium mines and mills are ‘toxic’ as defined in Section 64 of CEPA. Two recommendations were therefore made. The first was to consider investigations of options to reduce exposure to uranium from these sources a high priority and to manage the risks associated with
these sources under CEPA. The second related to the monitoring of radioactive releases from uranium mines and mills and stand-alone waste management facilities and the possibility of obliging the operators of such facilities to report, pursuant to Section 70 of CEPA 1999, any significant increases in radionuclide concentrations or loadings that they may learn of in the vicinity of said facilities.

(39) More than 100 power reactors are in operation in the United States. Of these, 10 are operated by the American government. The country also has three low-level waste repositories. The Yucca Mountain project to build the sole repository for high-level wastes in the US was jettisoned by the Obama administration without any alternative solution being identified. The need for environmental risk assessments arose in 1990 in the USA in the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), more commonly known as Superfund. It addresses the clean-up of abandoned sites containing hazardous wastes that may endanger human health and the environment. It relates to stressors of all types, and explicitly ionising radiation in particular. Standards on protecting the environment from radionuclides released into the biosphere, and which are generally applicable (40 CFR Part 190, Chapter I, Subchapter F - Radiation Protection Programs), fall under the authority granted to the US Environmental Protection Agency (USEPA) by the Atomic Energy Act of 1954. They are generally implemented by the Department of Energy (DOE) for activities within its jurisdiction and by the Nuclear Regulatory Commission (NRC) for commercial licenses.

(40) In 1990 the US Department of Energy (US DOE) enacted an order regulating the standards and obligations applicable to operations conducted by the US DOE itself and its subcontractors with respect to protecting the general public and the environment from the risks related to ionising radiation (DOE Order 5400.5; 8 February 1990). The order states that it is DOE’s specific objective to protect the environment from radioactive contamination to the extent practical. The Biota Dose Assessment Committee (BDAC; http://homer.ornl.gov/esa/environment/bdac/) was created within DOE in 1998. The BDAC has two objectives: (i) assist DOE in conceiving, developing, and promoting technical standards and guidance in assessing radiation doses to aquatic and terrestrial biota and (ii) serve as a major forum within DOE for obtaining technical assistance, discussing technical issues, and sharing lessons learned regarding biota dose standards and assessment methods.

(41) In 2002 DOE approved the technical approach to be implemented to demonstrate environmental radiation protection at its own facilities (A Graded Approach for Evaluating Radiation Doses to Aquatic and Terrestrial Biota; DOE-STD-1153-2002). This technical standard provides the methods that can be used to demonstrate the compliance of environmental situations in terms of biota dose rate guidelines with DOE requirements (Order 5400.5) and international recommendations. Implemented in the RESRAD-BIOTA code (Appendix, p.109), these methods also make it possible to assess radiological impacts on the environment. The dose limits referenced by DOE (expected safe exposure levels, presented as no observed adverse effect levels - NOAEL) are those proposed in report 109 (1991) of the National Council on Radiation Protection and Measurements (NCRP), the US counterpart of the ICRP. It should be noted that the term ‘dose limits’ can lead to confusion in that the corresponding values are not limits within the meaning of dose limits used in human radiation protection.

(42) The Nuclear Regulatory Commission (NRC) has authority over US regulations on civilian nuclear power. As a collegial body, the Commission formulates policies, develops regulations governing nuclear reactor and nuclear material safety, issues orders to licensees, and adjudicates legal matters. It is mandated by the US Congress to protect people and the environment from needless exposure to ionising radiation resulting
from the civilian use of nuclear materials. As such, the licensing process includes an environmental impact statement (EIS).

(43) Aimed primarily at human populations, radiation protection requirements laid down by NRC stipulate however that the absence of risk to human health and the environment, such as from residual contamination during dismantling operations, must be verified by implementing standards developed by the US EPA. NRC has also implemented procedures to take environmental justice into account in all documents required by regulations from operating organisations, particularly CERCLA, which classifies "radioactive emissions as harmful pollutants".

(44) Finland has four nuclear reactors in operation and a fifth under construction (EPR). A final disposal facility for spent fuel is under construction at the Olkiluoto nuclear power plant. Finnish regulations on nuclear power comprise three main pieces of legislation. The first, the Nuclear Energy Act, was enacted in 1987 and is designed to prevent the proliferation of nuclear weapons and ensure the safety of people and the environment (Section 26: "the use of nuclear energy must not damage the environment"). The second, the 1991 Radiation Act, covers all types of radiation but relates only to protection of people. The third, the Nuclear Liability Act, describes Finland’s obligations as a Party to the Conventions on Third-Party Liability in the Field of Nuclear Energy (Paris, 1960; Brussels, 1963). In the 1980s, Finland also ratified and implemented into Finnish law the 1974 Helsinki Convention (Protection of the Marine Environment of the Baltic Sea Area; Appendix p.118) and the 1972 London Convention (Prevention of Marine Pollution by Dumping of Wastes and Other Matter), thus restricting the sea dumping of radioactive waste.

(45) All licences to use nuclear energy (in the legal sense defined by the Nuclear Energy Act: possession, fabrication, production, transfer, treatment, use and storage of nuclear materials as defined by the IAEA) are issued under the authority of the Ministry of Trade and Industry or of the Radiation and Nuclear Safety Authority (STUK), which assesses measures taken by applicants, particularly in terms of protection of people and the environment. The consultation procedure for construction licences includes an assessment pursuant to the Environmental Impact Assessment Act of 1994 and information of the public on the environmental aspects of projects. An application for a new licence is filed for the operation of facilities. This process includes environmental protection criteria approved by STUK, the Finnish nuclear regulator. STUK publishes guidance documents in application of regulatory instruments. Published in 2001, document YVL 8.4 “Long-Term Safety of Disposal of Spent Nuclear Fuel” specified environmental protection objectives such as zero deleterious effects on flora and fauna from the disposal of spent fuel. Moreover, it stipulated that “rare animals and plants as well as domestic animals shall not be exposed detrimentally as individuals.” YVL 8.4 has since been replaced by guide YVL D.5, the 2010 draft version of which is mentioned biodiversity as a protection object, with the requirement of demonstrating that exposure (of the biota) “remain clearly below the doses that, on the basis of the best available scientific knowledge, would cause a drop in biodiversity or significant detriment to any living population” As these documents were available only in Finnish on STUK’s website, the final version of the guide, published in November 2013, could not be consulted.

(46) Sweden has 10 nuclear power reactors in operation. In 2008 it planned to expand its fleet. The Forsmark nuclear power plant is also the site of a final repository for low- and intermediate-level short-lived radioactive operational waste. Nuclear power in Sweden is regulated by five acts of legislation, two of which relate explicitly to radiological protection of the environment. The Environmental Code (1998) regulates the environmental aspects of nuclear activities and lists these activities as among "other
environmentally hazardous activities”. A 1999 amendment to the Nuclear Activities Act refers to this code. Ten years earlier, the Radiation Protection Act (1988) already included environmental protection in its objectives (“people and the environment must be protected from the hazardous effects of radiation”) and postulated that “final management of nuclear fuel must be carried out such that biodiversity and the sustainable use of biological resources … are protected”. Operating organisations must thus justify measures taken to prevent or compensate for harm caused to people, animals and the environment in relation to activities involving ionising radiation.

The Nuclear Activities Act requires that all operating organisations, when applying for a licence to build, possess or operate a nuclear power plant, must provide an environmental impact statement to assess the environmental effects of the planned operations and the management of natural resources. The procedure to be followed is described in Section 6 of the Environmental Code. Additionally, all nuclear facilities designed to produce energy or store waste or spent fuel must always be considered as having a significant impact on the environment (Section 3 of the Order on Environmental Impact Assessments). The Swedish nuclear regulator ensures that applications comply with regulations in parallel with the appropriate environmental court.

The only reactor in operation in Australia is a radiopharmaceutical research and production facility. Uranium mining began in the 1900s and remains extensive. The few nuclear actions authorised in Australia are governed by seven laws passed between 1986 and 2005. The main federal law on the protection of the environment in relation to ‘nuclear actions’ is the Environment Protection and Biodiversity Conservation Act 1999 (EBPC). It requires an environmental impact assessment for every action related to the seven matters of environmental significance, amongst which are nuclear actions. It should be known that Australian legislation prohibits all actions related to the construction or operation of fuel fabrication, enrichment or treatment plants as well as nuclear power reactors. The definition of a nuclear action encompasses the extraction and refinement of uranium ore; the transport of spent nuclear fuel; the establishment, significant modification, dismantling or rehabilitation of research reactors; or any other action exceeding the radioactivity threshold defined by the EBPC. Within the meaning of the EBPC, protection of the environment includes economic, social, cultural and biophysical aspects (sic).

In addition, each Australian state and territory has its own legislation in terms of environmental risk assessments. Reciprocal agreements for the approval of studies submitted to the authorities in each state or territory are in place to limit the number of duplicate assessments.

Fewer than 20 nuclear reactors produce energy in Germany, which also has a few research reactors. Plans to dispose of low- and medium-activity wastes began in 2013 (this repository is still under construction and has just successfully pass the stress tests imposed by the German federal government on all German nuclear facilities following the Fukushima-Daiichi accident). The site is not expected to begin receiving high-level wastes until after 2030.

Nuclear activities in Germany are governed by the Atomic Energy Act, which was promulgated in 1959 and revised in 2001. The Act has four purposes, the second of which has remained unchanged since 1959 and is to (i) protect life, health and property against the hazards of nuclear energy and the detrimental effects of ionising radiation; and (ii) provide compensation for damage and injuries caused by nuclear energy or ionising radiation. The Act does not specify whether these provisions apply only to people or to all forms of life. The protection of the environment against the effects of ionising radiation is embodied in the Environmental Risk Assessment Act of 1990. Environmental risk assessments must be included in the licensing procedure for nuclear facilities. Lastly, the Radiation Protection Ordinance of 2001 explicitly
states that people and the environment must be protected from all unnecessary exposure to radiation or contamination.

(52) In Europe, four other OECD Member Countries have nuclear facilities - Belgium, Spain, Italy and Switzerland. A brief overview of the regulated regulatory requirements is provided in Table 1.

(53) Lastly, one should bear in mind that, in some countries, regulations on protecting the environment from ionising radiation are enforced only through explicit requests to demonstrate the absence of risk of impact to all or part of ecosystems through an environmental risk/impact assessment for radioactive substances. The benchmark values used are sometimes included in the assessment method proposed by legislators and are sometimes left to the assessor to choose and justify. None of these benchmark values has been used as a standard, i.e., to impose measures through regulations in the event of exceedance. These are support values for assessing and managing risks.
### Table 1: Summary of environmental protection regulations regarding nuclear power in Belgium, Spain, Italy and Switzerland

(Taken from the OECD reviews, available online at [https://www.oecd-nea.org/law/legislation/](https://www.oecd-nea.org/law/legislation/))

<table>
<thead>
<tr>
<th>State</th>
<th>Area</th>
<th>National conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>Main nuclear facilities</td>
<td>7 nuclear power plants; 3 research reactors; Institute of radioelements (IRE); one fuel manufacturing plant; one waste repository in project, a second envisaged</td>
</tr>
<tr>
<td></td>
<td>Organisations in charge of text enforcement</td>
<td>Federal Agency for Nuclear Control (AFCN)</td>
</tr>
<tr>
<td></td>
<td>Licence processes</td>
<td>Environmental impact assessment required (art. 6.2 GRPIR), where the protection of the environment is seen through the definition both of limits for authorized releases and surveillance</td>
</tr>
<tr>
<td></td>
<td>Radioprotection</td>
<td>No text dealing explicitly with environmental protection per se</td>
</tr>
<tr>
<td>Spain</td>
<td>Main nuclear facilities</td>
<td>8 nuclear power plants; one fuel assembly plant; one operating waste repository; one research centre</td>
</tr>
<tr>
<td></td>
<td>Organisations in charge of text enforcement</td>
<td>Ministry for Industry, Tourism and Trade (MITYC) Nuclear Security Council (Consejo de Seguridad Nuclear - CSN) Autonomous Communities competent for the environment</td>
</tr>
<tr>
<td></td>
<td>Licence processes</td>
<td>Preliminary licences (authorization) and dismantling: environmental impact assessment required (art. 7 decree 1/2008; art. 51, 52 and 57 RPHIR), including elements expected in the impact assessment as defined by the French legislation. The licence owner has (i) to reach and maintain an optimal level of protection for the environment, (ii) to present an analytical radiological study assessing in theory the potential radiological impact of the installation on people and the environment.</td>
</tr>
<tr>
<td></td>
<td>Radioprotection</td>
<td>Protection of the environment against ionising radiation, centered on people (RPHIR, national declination of the directive Euratom 96/29))</td>
</tr>
<tr>
<td>Italy</td>
<td>Main nuclear facilities</td>
<td>No more operating reactor</td>
</tr>
<tr>
<td></td>
<td>Regulatory texts (protection of the environment)</td>
<td>No existing explicit text, some elements related to environmental impact assessment spread in several texts (mainly decree 377/88) ⇒ texts to come in the context of the expected nuclear revival, taking into account safety, security, human health and protection of the environment International Conventions (Espoo - appendix p.121, Aarhus)</td>
</tr>
<tr>
<td></td>
<td>Organisms in charge of text enforcement</td>
<td>ENEA (Ente per le Nuovo tecnology, l’Energia e l’Ambiente) ANPA (Agenzia Nazionale per la Protezione dell’Ambiente), created in 1994 with responsibilities in terms of control of the effects of ionizing radiation on the environment. Named APAT (National Agency for the</td>
</tr>
<tr>
<td>State</td>
<td>Area</td>
<td>National conditions</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Licence processes</td>
<td>Before site selection, presentation of a strategic environmental assessment (SEA) and an environmental impact assessment (EIA)</td>
</tr>
<tr>
<td></td>
<td>Radioprotection</td>
<td>Applicable texts (decree 230/95, decree 241/00) aim to the protection of the environment in order to protect people, based on the monitoring of contamination levels</td>
</tr>
<tr>
<td></td>
<td>Main nuclear facilities</td>
<td>5 nuclear power plants; 3 research reactors; 2 repository projects</td>
</tr>
</tbody>
</table>
Radiation Protection Act (RPA, 1991)  
Ordinance on radioprotection (Radiation Protection Ordinance - RPO- 1994)  
Swiss Environmental Protection Act (EPA, 1983)  
International Conventions (Espoo, Aarhus)                                                                                          |
|         | Organisations in charge of text enforcement | Federal Council and associated organisations (art 70 of the law on nuclear energy from 2003) : definition of measures in terms of human and environment protection, and follow up.  
Other stakeholders :  
* Federal Office of Public Health (FOPH)  
* IFSN  
* Swiss National Fund for Insurance in case of of accidents - CNA                                                                                   |
|         | Licence processes | General licensing (provisional decision regarding the authorization of creation) subordinated to a technical expertise realised by the federal inspection for nuclear safety (IFSN), especially on the aspects of people and environmental protection (Art. 7, 13, 16 and 20 of the law on nuclear energy)  
Évaluation de l’impact environnemental requise au titre de l’article 10 de l’EPA  
Protection of the environment against ionising radiation, centered on people (RPA, 1991).  
RPO based on ICRP recommendations, focusing on people protection.                                                                                      |
3 MAIN APPROACHES AND COMPARISON

3.1 THE ICRP APPROACH

(54) By creating a task group on the matter in 2000, then the Committee 5 for radiological protection of the environment, ICRP has taken a proactive approach to building and proposing an environmental radiation protection system in line with that in place for people and those relating to protecting the environment from chemical substances.

(55) Since 2003 and the release of Publication 91, in which ICRP discusses for the first time the need for a clear, common approach to assessing exposure-dose-effects relationships for non-human species, the Commission has embarked on a process to formalise the approach it developed by documenting the associated concepts as they are introduced.

(56) ICRP’s latest recommendations, described in Publication 103, released in 2007, effectively include an approach for developing the context of explicitly demonstrating radiological protection of the environment. Acknowledging the complexity of articulating the objectives of environmental protection, “The Commission does however subscribe to the global needs and efforts required to maintain biological diversity, to ensure the conservation of species, and to protect the health and status of natural habitats, communities, and ecosystems.”

(57) Considering the benefits provided by the reference anatomical and physiological models for use in human radiation protection (ICRP, 2002), the Commission has used this concept as the basis for its radiation protection system for other living species (Figure 5), defined as reference animals and plants (RAPs; ICRP, 2007).

![Diagram](image-url)

**Figure 5**: Schematic diagram of the key concepts used in systems to protect man and the environment from radiation, according to ICRP (Larsson, 2013)
Defined anatomically, physiologically and by their life-history properties, reference animals and plants (RAPs) are hypothetical entities that can be used to examine the dosimetry for each stage in the life cycle and for species with contrasting exposures (exposure scenario geometries in relation to their habitat and lifestyle). They can also be used to link doses and biological effects for this type of living organism. RAPs are described in terms of basic biological and ecological characteristics at the level of family (ICRP, 2007). At the taxonomic level, a RAP can be considered as the representative of species or group belonging to the same family (Table 2).

Table 2: The set of ICRP reference animals and plants (RAP) by environment. For each RAP, the stage of life taken into account is given between brackets and the family represented by the RAP is given in blue italics.

<table>
<thead>
<tr>
<th>Terrestrial</th>
<th>Freshwater</th>
<th>Marine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pine <em>pinaceae</em></td>
<td>Frog (egg, tadpole, adult) <em>ranidae</em></td>
<td>Flatfish (egg, adult) <em>pleuronectidae</em></td>
</tr>
<tr>
<td>Bee (adult, colony) <em>apidae</em></td>
<td>Trout (egg, adult) <em>salmonidae</em></td>
<td>Crab (egg, larvae, adult) <em>cancriidae</em></td>
</tr>
<tr>
<td>Earthworm (egg, adult) <em>lumbricidae</em></td>
<td>Duck (egg, adult) <em>anatidae</em></td>
<td>Brown seaweed <em>cyclosporeae</em></td>
</tr>
<tr>
<td>Grass (meristem, spike) <em>poaceae</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deer (young, adult) <em>cervidae</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rat <em>muridae</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

An intentionally limited number of these various types of animals and plants is used as a basis to generate points of reference linking exposure to dose and dose to various effect categories. Regarding environmental radiation protection, the biological effects of interest – be they deterministic or stochastic – are those with consequences for the population. The biological effects considered to be most relevant are early mortality, some forms of morbidity (which may impact the health of individuals), impairment of reproductive capacity and the induction of chromosome damage.

RAPs are not necessarily objects of protection as presented in item (28). The target of protection covers one or more actual species (the population or communities of which are to be protected), except in the case of endangered species (each individual of which is to be protected). The concept of representative organisms was thus introduced in Publication 124 (ICRP, 2014) by analogy with the representative person defined for human radiation protection (Figure 5). A representative organism (RO) is a particular species or group of organisms selected during a site-specific impact assessment and taking into account its geographic location in relation to the radiation source(s). In most cases, ROs are identical or very similar to RAPs. In other cases, recommendations will be given to establish links between ROs and RAPs, which are used during impact assessments on actual sites. The matter is on the agenda of ICRP’s 2013-2017 term. It is important to understand that RAPs are only ‘points of reference’ and are not necessarily objects of protection, hence the introduction in ICRP 124 of the concept of representative organism (RO).

ICRP deems it unsuitable to apply the dose limiting principle in the field of environmental radiation protection. It is the concept of DCRL (Derived Consideration Reference Levels) that was introduced (Figure 6). For each RAP, this is a band of dose rates, expressed in mGy.d$^{-1}$ and covering an order or magnitude, within which there is some chance of deleterious effects, briefly described, occurring to individuals of the same type as the RAP. These DCRLs, which are built on the opinion of experts based on existing knowledge on the effects of ionising radiation in non-human species, are used as guideline values or points of reference when demonstrating that the environment is protected and/or when applying the optimisation principle if necessary. Combined with other information, and for a given exposure situation,
DCRLs must make it possible to optimise the consented efforts and, where necessary, the environmental protection actions to be taken commensurate with the expected level of risk and using a management method that integrates all the challenges (including health and socioeconomic challenges). For example, if the exposure for a given organism is lower than the minimum bound of the associated DCRL, no demonstration/additional action is required (see 3.1.1. for cases of application).

The effect tables presented in ICRP Publication 108 (ICRP, 2007) cover a band of dose rates ranging from less than 0.1 to more than 100 mGy.d$^{-1}$, with a logarithmic progression. In each table, DCRLs are defined by the band of dose rates corresponding to a very low probability of effects, or the lack of data, if the known effects for the immediately higher band are significant (Figure 6).
Although numerical values are assigned by ICRP to DCRLs, the Commission states that other bands may be selected from the effects tables based on (i) the exposure situation (planned/emergency/existing); (ii) the spatial and temporal scale of the study; (iii) the assessment objectives (e.g., regulatory compliance); (iv) the targeted interests (fisheries, agriculture, habitat conservation, etc.); (v) the combination with other stressors; (vi) the need for considering some species individually; or (vi) the level of precaution adopted for the assessment. The selection of a band other than that of the DCRL must, however, be clearly outlined and justified. Furthermore, in its current term (2013-2017) Committee 5 is reviewing the possibility of expanding the concept of DCRL of a particular species - the RAP - to the class in which it
belongs (e.g., duck DCRL will be dropped but effect data will be reinterpreted to extend their applicability to birds).

3.1.1 APPLICATION OF THE CONCEPTS (PUBLICATION 124)

(64) The organisation of the component parts of the ICRP approach for environmental radiation protection, described in the previous section, is shown in Figure 7.

![Figure 7: Organisation of the various component parts of the ICRP approach for environmental radiation protection (adapted from Larsson, 2013).](image)

ICRP Publication 124 (2014) describes how to implement the previously described concepts when demonstrating environmental radiation protection and for the various environmental exposure situations (planned, emergency and existing). In an planned exposure situation, and considering the multiple possibilities of the sources of exposure of living organisms (possible cumulative impacts), the minimum bound of the interval of the DCRLs is what serves as the point of reference for optimising releases if necessary (Figure 8). Countermeasures can thus be considered if the dose rates estimated for the species are within the intervals of the DCRLs (e.g., change the requested quantities for releases). Below this interval, protection is appropriate; above it, actions are necessary. In emergency exposure situations, where the source or sources are not under control, protection of the environment is not the priority. Nonetheless, reference may be made for this secondary objective to a dose rate interval corresponding to a so-called severe effect level that is generally situated two orders of magnitude above the DCRLs. In such a situation the goal is to reduce the exposure of living organisms to a level within the range of the DCRLs by taking into account several criteria (e.g., cost-benefit ratio, technical feasibility of a remediation solution, public acceptability). In existing exposure situations, the exposure levels corresponding to the DCRLs are to be used as guides to assist in choosing environmental exposure mitigation actions. Lastly, whatever the exposure situation, the action is based on the optimisation principle (see Figure 8). Environmental protection is part of the objectives to which the principles of justification and optimisation apply, but there are no associated dose limits.
During its current term (2013-2017), Committee 5 will guide its work towards the demonstration of an integrated approach to human and environmental protection in planned exposure situations, based on the radionuclide concentrations in the environments. The future IAEA guide on radiological environmental impact analysis of facilities and activities (DS 427) follows this line. This approach has also just been approved by the Contracting Parties to the 1972 London Convention regarding materials that may be dumped at sea (see item (73) - Figure 9).
Figure 9: Flow chart of the procedure proposed by IAEA for implementing the 1972 Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter and its 1996 Protocol. (Top) General flow chart for the assessment to be conducted to define whether a radioactive material can be authorised for dumping at sea. (Bottom) Procedure for estimating doses to the public and flora and fauna (taken from Telleria et al., 2013)
3.1.2 POSITION OF INTERNATIONAL ORGANISATIONS IN RELATION TO THE ICRP APPROACH FOR THE ENVIRONMENTAL RADIATION PROTECTION SYSTEM

(67) The Coordination Group on Radiation Protection of the Environment led by the IAEA, which convened in July 2013 (IAEA, 2014b) considers that the ICRP approach described in Publications 91 (ICRP, 2003), 103 (ICRP, 2007), 108 (ICRP, 2008), 114 (ICRP, 2009) and 124 (ICRP, 2014) is conceptually and scientifically sound enough to be adopted into international radiation safety guidance. Such adoption must remain commensurate with the challenges.

(68) The group considers that, in targeting the protection of populations, communities, habitats and ecosystems, the ICRP approach is in line with IAEA’s Fundamental Safety Principles for protecting ecosystems against radiation exposure that would have consequences for populations of non-human species.

(69) The IAEA is going to develop international recommendations for technically assessing whether non-human species are protected in case of exposure to ionising radiation and, where applicable, propose measures to be taken based on the ICRP approach. These recommendations and the related guidance will take into account the particular conditions of environmental exposure situations as well as the objectives of impact assessments for non-human species.

(70) The coordination group considers that the ICRP approach is particularly straightforward with respect to the practical guidance necessary for the assessment and control of the radiological impact related to planned releases to the environment and that it is a complement to the approach used for human radiation protection. Such recommendations are necessary for the assessment and control of impacts due to routine discharges resulting from normal operations of nuclear facilities. Other radiological scenarios (e.g., other exposure situations, such as existing or emergency situations) may need additional analysis prior to defining detailed practical methods.

(71) The coordination group recognised the IAEA as the appropriate international organisation for coordinating studies on methodologies applicable to practical recommendations and technical guidance for the assessment and control of radiological impact to non-human species, in cooperation with international or regional organisations and those Member States more active in this field.

(72) In line with the safety objectives established in the IAEA’s Fundamental Safety Principles (IAEA, 2006) and incorporated in the international basic radiation protection standards (IAEA, 2011a), the IAEA is currently preparing a guide that follows the ICRP recommendations and approach for radiation protection of non-human species for scenarios related to planned exposure situations (IAEA, in preparation-a). This document is currently being discussed within the IAEA’s Safety Standards Advisory Committees (i.e., Waste Safety Standards Committee (WASSC) and Radiation Safety Standards Committee (RASSC)). Once it is endorsed by them, it will be submitted to the Member States. To support the implementation of this guide, the IAEA recently published a compendium of environmental transfer parameter values (IAEA, in press-b) and is working on updating (in three volumes) the guide describing the generic models for use in assessing the impact of radioactive discharges to the environment (SRS 19, IAEA, 2001), associated with additional data for assessing dosimetric impacts for the public and the environment (IAEA, in preparation-b).

(73) Two ad hoc groups of the IAEA are finalising two guides on the application of the ICRP approach on protection of non-human species for particular exposure scenarios to be assessed in terms of the
Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter 1972 (London Convention - see item (66)) and in terms of the application of the OSPAR Convention (see item (26)). The first was approved during the 35th Consultative Meeting of the Contracting Parties to the London Convention, held on 14-18 October 2013. It will be incorporated in the procedures of the Convention for the radiological assessment of candidate materials for dumping at sea. It will be published as a TECDOC entitled “Determining the Suitability of materials for Disposal at sea under the London Convention and Protocol”. The second document is being reviewed by the scientific groups of the OSPAR Convention.

At the last meeting of the coordination group led by the IAEA (IAEA, 2014b), the United Nations Environment Programme (UNEP) - a co-sponsor of the international basic standards for radiation protection published by the IAEA (2011) and for which it contributed to developing aspects related to radiation protection of the environment - expressed the view that the ICRP approach is too narrow. It suggested that the definitions given for 'environment' and 'protection of the environment' in the international basic radiation protection standards should have a wider scope beyond the considerations of radiological effects to flora and fauna. UNEP remarked that, when applying the radiation protection principles of 'justification' and 'optimisation' to control and manage radiological impacts to people and the environment, environmental issues such as sustainable protection of flora and fauna and maintenance of quality of media (air, water and soil) are key topics. UNEP expressed that it is willing to consider invitations for co-sponsoring IAEA safety guides currently under development or planned for the future on environmental protection topics. For UNEP, such sponsoring helps to broaden acceptance of international standards on environmental radiation protection, for example among ministries of environment around the world.

IUR suggests an ‘ecosystem approach’ for environmental radiation protection based on an ecological and theoretical perspective (IUR, 2012). This approach, in terms of its protection goals, is already embedded in many international initiatives, such as the OSPAR Convention (OSPAR, 1992), the Convention on Biological Diversity (CBD, 2000) and the EU Marine Strategy Framework Directive (EC, 2008). It directly targets environmental protection objectives and avoids extrapolations that are unavoidable when effects endpoints remain at the individual level, such as in the ICRP approach or the approach underpinning ecological risk assessment for chemical substances. The protection objects are natural biodiversity (including the diversity of species, the diversity of individuals [genetic diversity] and the diversity of environmental compartments) and ecosystem services. In other terms, the objective is to protect all living things by conserving all compartments, all species and their genetic diversity, and by valuating uses by people and the services rendered/expected from ecosystems. The environmental protection coordination group believes that this approach is complementary to the ICRP approach. It is often used in environmental impact studies to provide additional evidence based on data from environmental monitoring. Having justified this approach and its applicability to radiation protection of the environment by establishing a literature review on the topic, IUR is currently developing practical methods for implementing it in this context with the identification of more integrated ecological effects endpoints (Bradshaw et al., 2014). At this stage and in the light of the many challenges to be met, IUR does not suggest a practical approach. Instead, it is organising the next stages of its discussion as follows: (i) review environmental models and tools and obtain feedback on their application in various fields of environmental protection; (ii) use these theoretical foundations to identify configurations that make an ecosystem more radiosensitive at an integrated level rather than at a lower level of biological organisation; (iii) in keeping with this, explore the environmental effects for real cases based on standard scenarios; (iv) attempt to identify appropriate ‘ecosystem endpoints’ based on work conducted in other fields of environmental protection (Bradshaw et al., 2014).
In 2012, the European Commission organised, in cooperation with the group of experts established under Article 31 of the Euratom Treaty, a scientific seminar on protection of the environment from ionising radiation. The conclusions and recommendations made by the group of experts at the close of the seminar help the Commission to establish research programmes on radiation protection and/or revise or update European radiation protection regulations. Moreover, research in the whole field of radiation protection is now coordinated by four European associations that have signed a memorandum of understanding. Each association is dedicated to a specific sub-field of radiation protection: NERIS, for emergencies and post-accident situations; ALLIANCE, for radioecology; MELODI, for low doses; and EURADOS, for dosimetry issues. Each of these associations has produced a Strategic Research Agenda that serves as the basis for discussions among the parties to rank priority topics for the establishment of roadmaps and their funding through future European tenders. Regarding research to consolidate the environmental radiation protection system, priority R&D activities aim to understand (i) the mechanisms of action of ionising radiation at the various scales of living species, (ii) the role of genetic and epigenetic mechanisms in effects observed on reproduction, and (iii) the transgenerational effects (see Alliance description in Appendix 9.6).
3.2 ERICA - THE APPROACH USED THE MOST IN EUROPE

The so-called ‘ERICA’ approach is an integrated approach comprising aspects of risk assessment, management and communication (Figure 10).

The objective of the ERICA Integrated Approach is to aid environmental decision-making during the assessment and management of environmental risks from ionising radiation, so that appropriate weight is given to the environmental effects of radiation, for the purpose of protecting biota and ecosystems. In order to fulfil this objective, elements related to environmental management, risk characterisation and impact assessment have been integrated (hence the Integrated Approach) into one common structure, illustrated in Figure 1. Assessment here refers to the process of estimating exposure of biota, which involves estimation or input of activity concentrations in environmental media and organisms, definition of exposure conditions, and estimates of radiation dose (rates) to selected biota. Characterisation includes estimation of the probability and magnitude of the adverse effects in biota, together with identification of uncertainties. In the context of the ERICA Integrated Approach, such risk characterisation is performed on the basis of published effects data as an input to the assessment and is performed as an evaluation of output data from the assessment, combining both exposure and effects analyses. Management is in this context used as a general term for the process of taking decisions before, during, and after an assessment. The term covers such diverse aspects as decisions on specific technical issues associated with the execution of the assessment, general decisions relating to the interaction with stakeholders, and post-assessment decisions.

The use of this approach is briefly described below. Tier 1, which is based on the expression of the issue and the assessment objectives, corresponds to a screening exercise wherein each radionuclide and ecosystem component is reviewed to calculate the associated risk index. This index corresponds to the ratio between the radionuclide concentration measured or calculated in each exposure medium and its threshold concentration in it. This threshold limit value is obtained for each radionuclide by back-calculation from the PNEDR (Predicted No-Effect Dose Rate, equivalent to the PNEC\textsuperscript{12}, which is used for chemicals (EC, 2003)). The PNEDR is expressed in Gy or Gy per unit of time and is derived from knowledge on the effects of radionuclides on non-human organisms. Its default value in the ERICA tool is 10 µGy.h\textsuperscript{-1}, or 0.24 mGy.d\textsuperscript{-1} (see (79) and (80)). The back-calculation is performed for each radionuclide and each

\textsuperscript{12}Predicted-No-Effect Concentration. Defined as the concentration below which exposure to a substance has no effect on all or part of an ecosystem, within the meaning of the environmental risk assessment method described by the Technical Guidance Document (EC 2003) for chemical substances
reference organism. For a given radionuclide, the environmental value - or limit value (one per medium: water, soil, sediment) - corresponds to the minimum obtained from the results of the back calculations performed for all the organisms. Tier 2, which must be carried out if Tier 1 does not eliminate the risk, is a generic assessment identical to Tier 1 but offers a level of refinement required for analysis exposures. It also uses the concept of PNEDR, which is used directly and compared to the dose rates calculated for the set of reference organisms. In Tier 2, the risk index corresponds to the ratio between the calculated dose rate and the PNEDR. If the risk cannot be eliminated in Tier 2, Tier 3 proposes using specific site data and probabilistic methods to characterise the risk.

(79) The screening values of the tiered ERICA approach, used for Tiers 1 and 2, were determined according to the European recommendations for the estimation of PNECs for chemical substances (EC, 2003). The information in the FREDERICA database (Appendix, p.114) was processed by modelling to estimate the critical toxicity endpoints for various species and various effect endpoints (ED_{50} - doses giving 50% of the effect for acute exposure or EDR_{10} - dose rates giving 10% of the effect for chronic exposure). These critical ecotoxicity results were then used to construct Species Sensitivity Distributions (SSD) and estimate the doses (or dose rates) below which 95% of species in the ecosystem should be protected (HD_{5} or HDR_{5}) (ERICA, 2006).

(80) Applying this method made it possible to derive, in a transparent manner similar to that applied for chemical substances, a benchmark value set at a protection level of 95% of the species in an ecosystem during chronic exposure to external gamma radiation. This value (equal to 10 \mu Gy.h^{-1}, or 0.24 mGy.d^{-1}) is obtained by setting a safety factor at the 5th percentile of the Species Sensitivity Distribution (SSD) in order to take into account the uncertainty related to the use, expanded to the field of internal radiation from emitters of all types, of data obtained by external gamma radiation only. It can be compared to the benchmark values presented in Table 4.

3.3 COMPATIBILITY OF THE MAIN APPROACHES FOR ASSESSING RADIATION RISKS TO ECOSYSTEMS

(81) Initiated in the field of chemical risk assessments for the environment (Suter, 1999; Suter et al., 2000), the principle of a graded approach is now applied in most environmental risk assessment methods. Usually, three stages - the names of which vary with the scope - are suggested to assessors. The sequence of these stages corresponds to a qualitative and quantitative improvement in terms of data and representativeness for the case being studied (Figure 11). The first iteration is based on generic data, assumptions and conservative choices (i.e., which tend to maximise the impact and/or estimated risk) that are easily accessible and essentially make it possible to distinguish risk-free situations from those likely to cause environmental damage. This step is often referred to as 'screening' because of this sorting function. The following iterations involve data that are increasingly specific to the cases/sites being studied, generally in association with an uncertainty assessment and a probabilistic characterisation of the risk.
The screening step is implicit in the ICRP approach. It forms the basis of all applications to various environmental exposure situations through the use of reference organisms, which are then associated with the representative organisms. The approaches of the UK EA and the US DOE and the ERICA integrated approach are explicitly graded. The main tools used to implement them, at least for the last two (i.e., RESRAD-BIOTA and ERICA, respectively), explicitly describe the sequence of three successive stages. The possibility of continuing the assessment is present in each approach. The decision regarding this is always based on the identification of environmental risk in the previous stage.

Each stage in the assessment of the graded approach is organised into four phases (Figure 11). Articulating the issue sets the scope of the assessment through a series of inventories and various information (substances, receiving media and associated biological targets, transfer and exposure pathways, specific regulatory constraints, stakeholders, etc.) and determines how the assessment will be conducted (spatial and temporal scales, type of expected results and interpretation criteria, etc.). Next come the effect and exposure analysis phases. Their purpose is to technically assess data on measured or observed effects, based on dose-response relationships, and the measured or modelled exposure of the entities to be protected. The combination of the results thus obtained leads to the final phase of the process – risk characterisation.

Foreshadowed in conventional ecotoxicology (Suter, 1999), the concept of reference organisms was adopted and widely shared under various names in the field of environmental radiation protection. The concept appeared as such in the work of Pentreath and Woodhead (1988). The same year, IAEA used it for the London Convention. It is also a key concept in developments made in the European EPIC (Brown et
The international consensus is thus that the diversity of wildlife requires using a limited set of model organisms that authorises the standardisation of the models and associated data used, at the very least during first stage of an environmental radiation risk assessment. It is also recognised that, where necessary, this set may be completed or adapted to specific local conditions at the tiers 2 and 3 of the assessment.

Predicated on a shared vision of the necessity to simplify the diversity of species within the animal and plant kingdoms, the declination of the concept of reference organisms varies in quality and number (Table 3). The ICRP describes 12 hypothetical organisms at the level of their taxonomic family (Reference Animal and Plants - RAPs, at different stages in their life cycles), whereas the European consensus was for 31 taxa represented by a reference organism, in order to ensure the representativeness of the structure and function of ecosystems. It should be noted that, since the publication of the choices of the ICRP, the reference organisms selected in the ERICA approach and the ICRP RAPs have been partially standardised. The choices of the US DOE were limited to three categories of animal (aquatic animal, riparian animal, and terrestrial animal) and one category of plant (terrestrial plant). In contrast, the UK EA selected some forty organisms organised into different taxa depending on the ecosystem and group (e.g., freshwater mammals divided into seals and whales for the marine environment, and into carnivorous or herbivorous mammals for the terrestrial environment).

Lastly, RAPs and reference organisms are similar concepts that make it possible, when assessing the radiological impact/risk for ecosystems at the screening stage, to select a limited number of species whose varied shapes, lifestyles and habitats allow contrasting yet environmentally plausible exposure scenarios to be covered. If a potential risk is present at the end of the screening stage of a graded assessment approach, site-specific data must be used, in particular by considering the actual species. These actual species were introduced in the most recent ICRP publication (Publication 124) as ‘representative organisms’. The establishment of a correspondence with RAPs is currently being discussed.
Table 3: Illustration of the type of reference organisms and their correspondence for three of the approaches described

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Large terrestrial mammal / adult*</td>
<td>Reference deer</td>
<td>Mammal (deer)</td>
</tr>
<tr>
<td>Small terrestrial mammal / adult*</td>
<td>Reference rat</td>
<td>Mammal (rat)</td>
</tr>
<tr>
<td>Terrestrial insect / adult*</td>
<td>Reference bee</td>
<td>Flying insect</td>
</tr>
<tr>
<td>Terrestrial insect / colony</td>
<td>Reference bee</td>
<td></td>
</tr>
<tr>
<td>Terrestrial annelid / adult*</td>
<td>Reference earthworm</td>
<td>Soil invertebrate (worm)</td>
</tr>
<tr>
<td>Terrestrial annelid / egg</td>
<td>Reference earthworm</td>
<td>Detritivorous invertebrate</td>
</tr>
<tr>
<td>Large terrestrial plant / trunk*</td>
<td>Reference pine tree</td>
<td>Tree</td>
</tr>
<tr>
<td>Small terrestrial plant (spike)*</td>
<td>Reference wild grass</td>
<td>Grasses &amp; herbs / Shrub</td>
</tr>
<tr>
<td>Amphibian / adult*</td>
<td>Reference frog</td>
<td>Amphibian (freshwater and terrestrial)</td>
</tr>
<tr>
<td>Amphibian / egg</td>
<td>Reference frog</td>
<td></td>
</tr>
<tr>
<td>Amphibian / egg mass</td>
<td>Reference frog</td>
<td></td>
</tr>
<tr>
<td>Amphibian / tadpole</td>
<td>Reference frog</td>
<td></td>
</tr>
<tr>
<td>Aquatic bird / adult *</td>
<td>Reference duck</td>
<td>Bird (in each ecosystem)</td>
</tr>
<tr>
<td>Aquatic bird / egg *</td>
<td>Reference duck</td>
<td>Bird egg (in each ecosystem)</td>
</tr>
<tr>
<td>Mollusc (freshwater: bivalve, marine: benthic)</td>
<td></td>
<td>Phytoplankton (aquatic)</td>
</tr>
<tr>
<td>Gastropod (freshwater)</td>
<td></td>
<td>Insect larvae (freshwater)</td>
</tr>
<tr>
<td>Crustacean (freshwater)</td>
<td></td>
<td>Mollusc (freshwater: bivalve, marine: benthic)</td>
</tr>
<tr>
<td>Benthic fish (freshwater)</td>
<td></td>
<td>Gastropod (freshwater)</td>
</tr>
<tr>
<td>Mammal (freshwater and marine)</td>
<td></td>
<td>Crustacean (freshwater)</td>
</tr>
<tr>
<td>Polychete worm (marine)</td>
<td></td>
<td>Benthic fish (freshwater)</td>
</tr>
<tr>
<td>Lichens &amp; Bryophytes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Riparian animal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** Terrestrial animal
** Terrestrial plant
** Riparian animal
** Aquatic animal
In terms of points of comparison for assessing the potential effects of exposure to ionising radiation, the ICRP is the only organisation to use a range of dose rates. The other approaches use a single numerical criterion, generally applicable to all ecosystems (10 μGy·h⁻¹ - or 0.24 mGy·d⁻¹ - proposed in the ERICA tool at the screening stage and stage 2 and can be changed as needed by the user) or used for a category of organisms or environments (e.g., values presented in the relevant documents published by the IAEA (1992) and UNSCEAR (1996) and used by DOE - terrestrial plants and aquatic animals: 10 mGy·d⁻¹ / terrestrial animals: 1 mGy·d⁻¹). As an illustration, Table 4 shows the position of a few approaches in relation to the taxon to be protected and compared with the ICRP DCRLs. A more exhaustive summary is provided in Appendix (see section 9.1). These protection endpoints, defined for screening assessments, are not limits but benchmark values or thresholds below which the risk of the deleterious effects of ionising radiation for non-human species can be excluded.

The work conducted as part of the European PROTECT project (Protection of the Environment from Ionising Radiation in a Regulatory Context - Howard et al., 2010) made it possible to consolidate the benchmark value of the no-effect dose rate for all or part of an ecosystem chronically exposed to ionising radiation calculated within ERICA (i.e. 10 μGy·h⁻¹ - 0.24 mGy·d⁻¹; Garnier-Laplace et al., 2008; Larsson,
After a wide consultation with experts in the field of environmental risk assessment, it was concluded that this value could be used with a high degree of confidence in the screening stage of radiological risk assessments for ecosystems and must be considered incrementally in background radiation (Andersson et al., 2009). Other benchmark values specific to restricted taxonomic groups - such as plants, invertebrates and vertebrates - were suggested as temporary values pending more data for consolidation (Garnier-Laplace et al., 2010).

### Table 4: Position of a few benchmark values for the protection of various environmental objects with respect to the DCRLs defined by the ICRP (dose rate, mGy.d⁻¹)

<table>
<thead>
<tr>
<th>DCRL</th>
<th>0,1 to 1</th>
<th>1 to 10</th>
<th>10 to 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>(ICRP, 2008)</td>
<td>Pine Rat and deer Duke</td>
<td>Grass Frog Fish</td>
<td>Seaweed Earthworm, bee Crab</td>
</tr>
<tr>
<td>ERICA tool (Beresford et al., 2007; Larsson, 2008)</td>
<td>Ecosystem (0,24)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROTECT - * taxon: temporary value (Garnier-Laplace et al., 2010)</td>
<td>Ecosystem (0,24)</td>
<td>Vertebrates* (0,048)</td>
<td>Plants* (1,7) Invertebrates* (4,8)</td>
</tr>
<tr>
<td>RESRAD-Biota (US-DOE, 2002), from IAEA (1992) and UNSCEAR (1996)</td>
<td>Terrestrial animals (1)</td>
<td>Terrestrial plants (10) Aquatic animals (10)</td>
<td></td>
</tr>
<tr>
<td>Environment Canada (Bird et al., 2002)</td>
<td>Poissons (0,55)</td>
<td>Mammifères (2,7) Plantes terrestres (2,7) Amphibiens (2,7) Algues (2,7) Macrophytes (2,7) Invertébrés (5,5)</td>
<td></td>
</tr>
</tbody>
</table>

Whatever the approach used, the conclusions of the risk assessment rely heavily on the robustness of the selected benchmark value(s), which are used for the comparison of the level of real or estimated exposure. The several methods for deriving the benchmark values are described for chemical substances in the European technical guides supporting the regulations (e.g., REACH, Water Framework Directive) passed on environmental protection (EC, 2003a; 2011). These methods were entirely and transparently adapted to ecotoxicity data for ionising radiation during the European projects FASSET, ERICA then PROTECT. The selection of basic ecotoxicity values, as well as the main stages of derivation of benchmark values adapted to ionising radiation, including the method used to quantify the degree of confidence in their use, are described in detail by Garnier-Laplace et al. (2010). The corresponding extract from the PROTECT project deliverable (Andersson et al., 2008) is provided in Appendix (p.82).

It should be noted that the other benchmark values such as the ICRP DCRLs or the values published by the international organisations listed in Table 3 have all been determined from expert judgement based on a critical analysis of the literature.

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13 There are two: (i) the safety factors method, which consists in applying a safety factor to the lowest ecotoxicity value (this factor varies from 10 to 1000 based on the quality and quantity of the ecotoxicity data set selected) and (ii) the statistical extrapolation method, which consists in using the 5th percentile of the Species Sensitivity Distribution (SSD) and applying to it a safety factor from 1 to 5 depending on the remaining uncertainties. For more information, refer to EC (2003, 2011).
In order to provide a concise overview of the advantages and drawbacks of the various approaches and methods presented above, their respective characteristics and strengths and weaknesses are listed in Table 5.

The so-called 'ecosystem' approach suggested by IUR - see item (75)- is not listed here because its development is at the first stage of discussion based on a review of the literature. As presented by IUR (Bradshaw et al., 2014), it is not able to be implemented at the same practical level as the other approaches/methods for which there is already feedback in terms of their application to various studies. Furthermore, this approach is often used as additional proof in impact study demonstrations by means of relevant environmental monitoring of the quality of environments and the diversity of flora and fauna, which may be impacted.
### Table 5: Comparative summary of the characteristics of the main approaches for assessing radiation risks to ecosystems

<table>
<thead>
<tr>
<th>Approach/method</th>
<th>Environment Agency UK</th>
<th>Environment Canada</th>
<th>US DOE</th>
<th>ERICA</th>
<th>ICRP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dedicated appendix</strong></td>
<td>p.108 See appendix</td>
<td>p.113 See appendix</td>
<td>See appendix</td>
<td>No (cf. §.3.2)</td>
<td>No (cf. §.3.1)</td>
</tr>
<tr>
<td>Tier number</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Implicite dans l’application</td>
</tr>
<tr>
<td>Number of reference organisms</td>
<td>42 (dose coefficients and transfer parameters non modifiable)</td>
<td>Not defined</td>
<td>4 (dose coefficients non modifiable, transfer parameters changeable)</td>
<td>31 (all parameters modifiable)</td>
<td>12 (dose coefficients and transfer parameters non modifiable)</td>
</tr>
<tr>
<td>Considered radionuclides</td>
<td>16 to 17 depending on the ecosystem, for a total of 21</td>
<td>Not defined</td>
<td>44</td>
<td>63 per default</td>
<td>75</td>
</tr>
<tr>
<td>Number of benchmarks</td>
<td>1</td>
<td>7 (1 per taxon)</td>
<td>4 (1 per taxon)</td>
<td>1 (user modifiable) at tiers 1 and 2; to define at tier 3</td>
<td>12 (range min-max, 1 band -DCRL- per reference organism -RAP)</td>
</tr>
<tr>
<td><strong>Strength</strong></td>
<td>• Noble gases included</td>
<td>• Fit for purpose when deployed in Canada</td>
<td>• Tier 3 probabilist</td>
<td>• Tier 3 probabilist</td>
<td>• Consistent with the system of human radioprotection</td>
</tr>
<tr>
<td></td>
<td>• Excel files</td>
<td>• Allometry for transfers</td>
<td>• Possibility to add elements (radionuclides, organisms)</td>
<td>• Traceability</td>
<td>International consensus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• tool (RESRAD-Biota)</td>
<td>• Operational capability</td>
<td>• European scientific consensus</td>
<td>Demonstration in progress regarding the integration « Man-Environment » and of its applicability to the three exposure situations (2013-2017 term of Committy 5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>maintained and updated</td>
<td>• Easy to use</td>
<td>• Tool maintained and updated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• European scientific consensus</td>
<td>• Link with effect database</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Tool maintained and updated</td>
<td>• FREDERICA</td>
<td></td>
</tr>
<tr>
<td><strong>Weakness</strong></td>
<td>• Inhomogeneous level of description of organisms</td>
<td>• Approach very incomplete and not updated</td>
<td>• 4 taxonomic groups (3 animals, 1 plant)</td>
<td>• No consideration of noble gases</td>
<td>• Operational character not felt for the situations other than planned</td>
</tr>
<tr>
<td></td>
<td>• Few radionuclides</td>
<td></td>
<td>• Few radionuclides</td>
<td>• Some radionuclides not in the ICRP 38</td>
<td>• Traceability of benchmarks (DCRL = expert judgement)</td>
</tr>
<tr>
<td></td>
<td>• Little flexibility</td>
<td></td>
<td></td>
<td>• Tier 3 requires an expert</td>
<td>• Limited representativeness of RAPs</td>
</tr>
<tr>
<td></td>
<td>• No more maintained</td>
<td></td>
<td></td>
<td>• Not well adapted to accidental releases (no dynamic modelling of transfer)</td>
<td>• Number of radionuclides (no addition)</td>
</tr>
</tbody>
</table>

*Date of the last update of the tools
4 APPLICATIONS AND FEEDBACK

4.1 AT AN INTERNATIONAL LEVEL

(94) The EU-funded MARINA I project (1985-1990) focused on estimating the radiological exposure of people in relation to contamination levels in Northern European marine waters. The MARINA II study (1999-2002) built on the MARINA I project, making the results as useful as possible for implementing the OSPAR strategy with regard to radioactive substances. The study covered environmental protection as protecting and conserving the ecosystems and biological diversity of the maritime area are recognised in Annex 5 of the OSPAR Convention. In order to contribute to the strategy's aspects related to environmental impact assessments, the objectives of the MARINA II study explicitly include (i) exposure of human populations and marine ecosystems to ionising radiation; (ii) the effects on marine ecosystems from existing and future releases and from the presence of radioactive substances.

(95) An environmental radiation impact assessment was thus conducted for MARINA II for the years 1986-2001 based on existing developments referred to as preliminary (EC, 2003b). The range of variation in the dose rates estimated for marine organisms spans five orders of magnitude across the OSPAR region, up to 0.1 mGy per day. This study concluded that, based on the available knowledge, there was no impact on populations of marine organisms and that the methodology used was still under development and would be improved in the future.

(96) Starting in 2000, the UK EA began conducting the regulatory assessment of radiological risks affecting Natura 2000 sites in England and Wales exposed to authorised releases of radioactive substances. The assessment was conducted in three stages. The first consisted in determining which activities, based on their type and location, could affect the sites. Screening was then conducted for the corresponding authorisations. The threshold below which there would be no adverse effects on Natura 2000 sites was set at 1 mGy.d$^{-1}$ (i.e., the lowest value recommended by the IAEA (1992) and UNSCEAR (1996)). In the case of ten authorisations, the exposure analysis for non-human organisms resulted in dose rate estimations of between 0.5 and 1 mGy.d$^{-1}$. In two cases the estimated dose rates exceeded 12 mGy.d$^{-1}$. The third and final step consisted in reconducting the radiological risk assessments for the sites that exceeded the protection criteria after lowering the corresponding authorisations. The radiological risk to the environment was then estimated using the ERICA tool. The newly estimated dose rates were below the 1 mGy.d$^{-1}$ threshold adopted by the agency.

(97) The application associated with R&D Publication 128 (UK EA, 2001) was created merely as a screening tool to allow the UK EA to meet its regulatory deadlines pending the release of the ERICA tool. The application was thus not developed beyond the design stage, as UK EA intended to use the ERICA tool once it was ready. However, the ERICA tool cannot process noble gases or radon. This resulted in the creation of a radon module and usage of the spreadsheet that continues on cases requiring it.

(98) During the years 2000-2004, the European EPIC Project (Environmental Protection from Ionising Contaminants, European Commission Inco-Copernicus Programme) was conducted to examine the protection of Arctic environments against the effects of ionising radiation. It made it possible to (i) collate information relating to the behaviour of the radionuclides in these environments; (ii) suggest reference Arctic organisms; (iii) develop a set of dose models for these organisms; (iv) compile data on dose-effect relationships and assessments of potential radiological consequences for reference Arctic organisms. Two environmental impact assessments - one on the marine environment and one on the
terrestrial environment - were conducted and positioned the estimated impact (on the order of $10^{-2}$ to $10^{-1}$ mGy over a 20-year period for marine organisms and $10^{-1}$ to $10^2$ mGy over a one-year period for terrestrial organisms) in relation to background radiation (Brown et al., 2003). The authors found this impact to be low. The conclusions emphasised the need for continuing the development of methodologies for environmental radiation impact assessments and for acquiring additional information to close gaps in knowledge on both transfers and effects.

At the same time, and in close consultation with the EPIC Project, the FASSET Project (Framework for Assessment of Environmental ImpacT, Larsson et al., 2004) initiated the development of the methodology known today as ERICA. Five months before the eponymous tool was released, this approach was tested using five case study sites to assess its applicability and compare predictions and observations, both in terms of activities and induced effects, in order to guide further developments of the tool (Beresford and Howard, 2005). The scenarios were selected to test all of the components of all types of ecosystem and all application situations of the method: (i) sites contaminated by technologically enhanced natural radionuclides (e.g., mining sites, production of phosphate fertilisers, etc.); (ii) regulated sites; (iii) contaminated areas where potential radiation-induced effects had been observed. A number of recommendations were made, including (i) the need to clearly set out the scope of the methodology; (ii) full user guidance should be provided to assist the assessor at every step; (iii) clear, consistent terminology should be used between the tools and the related documents; (iv) the organisms considered by the tool should be revised; and (v) the list of radionuclides in the tool should be extended and the radionuclides in it prioritised.


Two exercises were conducted during the EMRAS I Programme (IAEA, 2012: detailed description on the CD-ROM available online at http://www-pub.iaea.org/MTCD/Publications/PDF/TE_1678_CD/Start.pdf). The first compared the basic elements of the environmental radiation risk assessment, i.e., the dosimetric model and transfer parameters for a limited number of radionuclides and organisms (Vives i Batlle et al., 2007). The second compared models and measured values (Yankovich et al., 2010). The conclusions on dosimetry indicate good agreement for internal exposure – provided explicit indications of how the daughter products are taken into consideration are given – and greater variations for external exposure (less than one order of magnitude) particularly regarding $\alpha$ and $\beta$ emitters. However, the group concluded that these differences were of little importance given that external exposure of the biota to such emitters was of little biological significance in view of their limited transfer through the matter. The intercomparison of the dose rates calculated for non-human organisms was extended in the EMRAS II Programme to 74 radionuclides and 10 dosimetric approaches (Vives i Batlle et al., 2011). The conclusions of this exercise are similar to those of the previous exercise (agreement of the results, with a variation of approx. 30% in the internal dose rates for one order of magnitude for external exposure). Four factors that can create dose-rate variations were highlighted: (i) whether or not daughter products (and the selection criteria to be applied to them) are taken into account; (ii) differences in the choice of reference organism describing an actual species; (iii) differences in the description of environments; and (iv) the source of the nuclear data used (variations in energies emitted by a radionuclide according to the source). In contrast, comparisons of radionuclide transfer have shown differences of three orders of magnitude or more between the various approaches tested. Consistent with the previous results, the differences observed during the model-measured value comparison were generally of one order of
magnitude, and sometimes two or more because of transfer. In the end, the estimated dose rates are in a range of less than a factor of 10, with the total of all the radionuclides smoothing out the over- and underestimates for each.

(102) In the light of the conclusions of the aforementioned programmes, comparisons are ongoing in the IAEA MODARIA Programme, with a focus on implementing dynamic approaches for marine environments, in relation to the Fukushima-Daiichi accident.

(103) In addition to the information from the intercomparison exercises, the two IAEA’s most recent radioecology programmes also use feedback on the implementation and derivation of benchmark values for environmental radiation protection. In order to establish yet more robust dose-effect relationships between exposure of flora and fauna to ionising radiation and the resulting effects, the FREDERICA database was updated (see Appendices) then reused during the EMRAS II Project based on a new statistical analysis of constructible dose-effect relationships. At the same time, a comparison of radiotoxicity data obtained in field or controlled conditions was made (Garnier-Laplace et al., 2013). The comparison revealed a greater radiosensitivity (by a factor of 4 to 6) of organisms in the field vs in the laboratory. Several explanations are given (duration of exposure - e.g. one vs several generations -, species tested, effect endpoints measured, etc.) and led the authors to recommend the adoption of more robust field sampling strategies to deal with confounding factors.

(104) The issue of individual-population extrapolations, indicated in particular by Garnier-Laplace et al. (2013), was discussed as part of EMRAS II and continues to be explored in MODARIA. Population dynamics models were proposed to help derive, using individual radiotoxicity data, a valid radiation protection criterion for a population (IAEA, 2014a) in the ultimate objective of integrating such models in the analysis of the effects of ionising radiation to increase the robustness of the environmental radiation protection criteria derived from it. Although this approach appears promising, it suffers from a lack of data that makes it difficult to extend it to a sufficiently large number of organisms. The work under way in MODARIA is therefore organised to meet this need for extension.

(105) The BIOPROTA international forum for environmental collaboration brings together European regulators and operators responsible for safe and acceptable radioactive waste management. It deals with key uncertainties in assessing the long-term impacts of releases to the environment of contaminants from radioactive waste management practices. The objective is to make the best sources of information available to justify the inherent modelling assumptions. When common needs are identified among several assessment projects in different countries, a common effort is made to meet these needs. The group looked at the demonstration of the compliance of post-closure safety cases for radioactive waste repositories with protection objectives for non-human organisms (Smith et al., 2012). The data thus collated are presented as a transitional approach, pending the establishment of principles for governing post-closure safety cases, in the absence of fully formulated and accepted international recommendations.

(106) The desired simplicity of screening assessments resulting in the creation of a single criterion of protection, which is not a limit but a threshold below which the protection of non-human organisms requires no further demonstration. However, the members of BIOPROTA consider necessary to develop a more structured approach to manage situations in which these current screening level protection criteria are exceeded. To contribute to ongoing international discussions on the issue, also raised in PROTECT and other projects, as well as provide a standby solution to its members who could use it, the BIOPROTA forum proposed a two-step/three zone approach (Figure 12). This approach was presented as the most
relevant for long-term assessments of the potential impact of deep geological repositories for radioactive waste. The underlying idea is to promote a risk-based approach commensurate with the level of effort required to conduct and interpret assessments. It is here that BIOPROTA parallels ICRP, as shown by how ICRP presents the implementation of DCRLs (see 3.1.1, ICRP 2014).

![Structured approach proposed by the BIOPROTA forum for long-term assessments of the impact of deep geological repositories (Smith et al., 2012)](image)

In 1999, a screening-level assessment of dose rates absorbed by a variety of aquatic organisms (plants, fish, molluscs and fish-eating birds) was conducted jointly by the SENES Consultants Ltd., COGEMA and a university upstream of the Marcoule nuclear facility on the river Rhône (Saint-Pierre et al., 1999). The results obtained were used to qualitatively determine the magnitude of the potential impacts of exposure to artificial and natural radionuclides in the aquatic environment on the health of these organisms. The estimated dose rates span three orders of magnitude, with the highest values ranging from $4.8 \times 10^{-4}$ to $5.8 \times 10^{-3}$ mGy.d$^{-1}$. According to the paper (Saint-Pierre et al., 1999), when one considers that these levels are much lower than the international guideline values recommended for the protection of aquatic organisms, the radioactivity levels routinely measured in the organisms studied were not considered to be likely to affect the health of the local fauna and flora. It was not deemed necessary to conduct any additional assessments.

Three years later, COGEMA commissioned SENES to conduct a similar study to assess the doses received by marine organisms from exposure to radioactive liquid effluents released by the reprocessing fuel plant at La Hague (Chambers et al., 2005), along the Nord-Cotentin coast in Normandy. The dose rates for the selection of representative organisms were estimated from radionuclide concentrations in the environment collated by the Nord-Cotentin Radioecology Group (GRNC). The impact was assessed by comparing the exposure dose rates to the benchmark values in terms of effect. The values proposed by UNSCEAR and the IAEA were used (see Appendix 9.1). They were supplemented by those established by SENES from the FRED database created during the FASSET Project, the predecessor to FREDERICA (Copplestone et al., 2005). The authors of the study concluded that the dose rates attributable to radioactive discharges into the sea from the La Hague plant are low (less than $10^{-3}$ mGy.d$^{-1}$) and generally well below the comparison guideline values. Their conclusions are in agreement with those of the MARINA II Project for the La Hague plant (EC, 2003b).
Following the studies conducted at the Marcoule and La Hague nuclear power plants, SENES was contacted in 2006 by the World Nuclear Association to draw up an overview of representative ecological risk assessments to date (Chambers et al., 2008). The studies selected for the overview are representative of the entire nuclear cycle, from mining to power generation to waste disposal. Sites involving enhanced levels of naturally occurring radioactive materials (NORM) and the impact of fallout from the Chernobyl accident were also considered. The general conclusion of the overview is that, for normal operations of nuclear fuel cycle facilities of all types, the resulting level of exposure of non-human organisms is low and below (by 2 to 5 orders of magnitude) the reference dose rates used by the assessors and at which adverse health effects to non-human populations might be anticipated. For those few situations where these reference dose rates are exceeded, the areal extent of these sites is limited to the sites themselves or to areas in close proximity (waste storage sites and repositories). Even in the event flora and fauna receive very high doses and dose rates, such as those experienced following the Chernobyl accident (of the order of 700 mGy in three months, according to the authors), Chambers et al. (2008) consider that the affected populations recovered within a reasonably short period once the radiation dose rates dropped. For the authors, the radiation protection system in place at the time provided an adequate level of protection to populations of non-human organisms exposed to authorised releases of radioactive substances.

Following these various studies, SENES Consultants Ltd. compared, in 2010, three ‘popular’ radiological risk assessment approaches/tools (Garisto et al., 2010): the RESRAD-BIOTA tool, the ERICA tool and their own model (SENES Risk Model). Using a case study, the underlying methodologies of these models, as well as the default parameters used in the corresponding software, were compared. From this exercise, Garisto et al. (2010) conclude in the absence of a real methodological difference among the three approaches. However, they show a great variability in the default parameters of as much as five orders of magnitude (solid-liquid \(^{14}\) distribution coefficient of polonium). They also point out a few conceptual differences that, according to them, impact the uncertainty of the results and the degree of confidence that can be given to them. For example, RESRAD-BIOTA and the ERICA tool are based on the use of aggregated transfer factors, unlike the SENES model, which differentiates the various pathways of radionuclide uptake by organism. Likewise, RESRAD-BIOTA considers very broad animal categories, such as ‘aquatic animal’. For Garisto et al., these aggregations are detrimental to the transparency of the assessment and increase its uncertainties. They thus make a case for minimalist use of aggregate parameters and ‘black box’ tools.

In addition to the review conducted by Chambers et al. the review of the international literature reveals that, over the past five years, more than 30 scientific papers have presented the results of environmental radiation risk assessments (Table 6). Generally speaking, the authors conclude that applying the methods used to assess radiological risks to the environment leads to excluding these risks, with a few exceptions. The assessments made within the vicinity of the stricken Chernobyl plant as well as at its cooling pond reveal, under certain conditions, dose rates higher than the internationally proposed protection criteria. The same is true for some uranium mine studies (e.g., Slovenia, Russia, Central Asia), as well as for waterways the most impacted by radioactive contamination in the former USSR. Among the documents consulted, the last case leading to a situation of environmental risk from exposure to ionising radiation is the theoretical accident of a nuclear submarine in the Barents Sea (Iosjpe and Liland, 2012).

\(^{14}\) Ratio of the concentration of plutonium in the solid phase to its concentration in the liquid phase
<table>
<thead>
<tr>
<th>Year</th>
<th>Geographical area</th>
<th>Exposure situation</th>
<th>Origin</th>
<th>Approach/method/tool</th>
<th>Ecosystem</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>Russia (Komi /</td>
<td>existing</td>
<td>Uranium mines / radium production</td>
<td>ERICA</td>
<td>Terrestrial (plants)</td>
<td>Evseeva et al., 2009</td>
</tr>
<tr>
<td></td>
<td>Vodny)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>Ukraine</td>
<td>existing</td>
<td>Cooling pond (Chernobyl accident)</td>
<td>ERICA</td>
<td>Interface freshwater/terrestrial</td>
<td>Oskolkov et al., 2010</td>
</tr>
<tr>
<td></td>
<td>(Chernobyl)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UK (generic)</td>
<td>planned</td>
<td>Geological repository</td>
<td>ERICA</td>
<td>Freshwater Terrestrial</td>
<td>Robinson et al., 2010</td>
</tr>
<tr>
<td>2011</td>
<td>Boreal/arctic</td>
<td>existing</td>
<td>NORM</td>
<td>Adaptation de FASSET/ERICA au contexte boréal</td>
<td>Freshwater Terrestrial</td>
<td>Hosseini et al., 2011a</td>
</tr>
<tr>
<td></td>
<td>Russia (Komi)</td>
<td></td>
<td>Uranium/radium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Norway (Sove)</td>
<td>existing</td>
<td>NORM</td>
<td>ERICA</td>
<td>Terrestrial</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Poland (Wislinka, Kaniow)</td>
<td>existing</td>
<td>NORM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ukraine</td>
<td>existing</td>
<td>Chernobyl accident- 25 years after</td>
<td>ERICA + autres approches</td>
<td>Terrestrial</td>
<td>Gaschak et al., 2011</td>
</tr>
<tr>
<td></td>
<td>(Chernobyl)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Japan</td>
<td>Accident</td>
<td>Fukushima accident</td>
<td>ERICA</td>
<td>Tout écosystème</td>
<td>Garnier-Laplace et al., 2011</td>
</tr>
<tr>
<td></td>
<td>Australia</td>
<td>existing</td>
<td>Water treatment plant (131I nuclear medicine)</td>
<td>ERICA</td>
<td>Marin</td>
<td>Veliscek Carolan et al., 2011</td>
</tr>
<tr>
<td></td>
<td>Lithuania</td>
<td>existing</td>
<td>Cooling pond (normal operation)</td>
<td>ERICA</td>
<td>Freshwater</td>
<td>Nedveckaite et al., 2011</td>
</tr>
<tr>
<td>Year</td>
<td>Geographical area</td>
<td>Exposure situation</td>
<td>Origin</td>
<td>Approach/method/tool</td>
<td>Ecosystem</td>
<td>Reference</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------</td>
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<td>------------------------------------------------------------------------</td>
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<td>-----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Brasil</td>
<td>existing Uranium mines (²³⁸U, ²³²Th, ²²⁶Ra, ²²⁸Ra and ²¹⁰Pb)</td>
<td></td>
<td>???</td>
<td>ERICA</td>
<td>Freshwater</td>
<td>Pereira et al., 2011</td>
</tr>
<tr>
<td>2012</td>
<td>Belgium (Doel, Tihange)</td>
<td>existing</td>
<td>Liquid effluents NPP (authorization)</td>
<td>ERICA</td>
<td>Freshwater</td>
<td>Vandenhover et al., 2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Terrestrial</td>
<td>Vandenhover et al., 2013</td>
</tr>
<tr>
<td></td>
<td>Lithuania (Ignalinia/lake Druksiai)</td>
<td>existing</td>
<td>Cooling pond (normal operation)</td>
<td>ERICA</td>
<td>Freshwater</td>
<td>Vandenhove et al., 2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prokopciuk et al., 2012</td>
</tr>
<tr>
<td></td>
<td>India (Mannar gulf)</td>
<td>existing</td>
<td>Background ²¹⁰Po / ²¹⁰Pb</td>
<td>ERICA</td>
<td>Marine</td>
<td>Feroz Khan and Godwin Wesley, 2012</td>
</tr>
<tr>
<td></td>
<td>Norway (Barents sea)</td>
<td>existing</td>
<td>Anthropogenic</td>
<td>ERICA</td>
<td>Marine</td>
<td>Gwynn et al., 2012</td>
</tr>
<tr>
<td></td>
<td>Norway (Barents sea)</td>
<td>planned</td>
<td>Accident on nuclear submarine</td>
<td>NRPA</td>
<td>Marine</td>
<td>Iosjpe and Liland, 2012</td>
</tr>
<tr>
<td></td>
<td>Ex-USSR (Chernobyl, radioactive trace in East Ural, rivers Techa and Yenisei)</td>
<td>existing</td>
<td>Anthropogenic (notably accidents)</td>
<td>Propre à la publication</td>
<td>Freshwater</td>
<td>Kryshev and Sazykina, 2012</td>
</tr>
<tr>
<td></td>
<td>Slovenia (Zirovski)</td>
<td>existing</td>
<td>Mines (²³⁸U, ²³⁴U, ²²⁶Ra, ²²⁸Ra)</td>
<td>ERICA</td>
<td>Freshwater</td>
<td>Cerne et al., 2011</td>
</tr>
<tr>
<td>Year</td>
<td>Geographical area</td>
<td>Exposure situation</td>
<td>Origin</td>
<td>Approach/method/tool</td>
<td>Ecosystem</td>
<td>Reference</td>
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<td>--------</td>
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<td>----------------------</td>
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<td>----------------------</td>
</tr>
<tr>
<td>2013</td>
<td>Lithuania</td>
<td>existing</td>
<td>Subsurface waste repository</td>
<td>RESRAD-Biota</td>
<td>Terrestrial</td>
<td>Nedveckaite et al., 2013</td>
</tr>
<tr>
<td></td>
<td>Central asia</td>
<td>existing</td>
<td>Uranium mines</td>
<td>ERICA</td>
<td>Freshwater</td>
<td>Oughton et al., 2013</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Terrestrial</td>
<td>Skipperud et al., 2013</td>
</tr>
<tr>
<td></td>
<td>Sweden</td>
<td>planned (Forksmark)</td>
<td>repository (licensing process)</td>
<td>ERICA</td>
<td>Freshwater</td>
<td>Torudd and Saetre, 2013</td>
</tr>
<tr>
<td></td>
<td>Finland</td>
<td>existing</td>
<td>Chernobyl fallout</td>
<td>ERICA</td>
<td>Terrestrial (game)</td>
<td>Vetikko and Kostiainen, 2013</td>
</tr>
<tr>
<td></td>
<td>Japan/USA</td>
<td>existing</td>
<td>Fukushima fallout during April 2011</td>
<td>EDEN</td>
<td>Marine</td>
<td>Fischer et al., 2013</td>
</tr>
<tr>
<td></td>
<td>South Korea</td>
<td>existing</td>
<td>Fukushima fallout in March-April 2011</td>
<td>K-BIOTA (appendix p.110)</td>
<td>Freshwater</td>
<td>Keum et al., 2013</td>
</tr>
<tr>
<td>2014</td>
<td>Slovenia (Zirovski vrh)</td>
<td>existing</td>
<td>Mines (^{238}\text{U}, ^{234}\text{U}, ^{226}\text{Ra}, ^{230}\text{Th})</td>
<td>ERICA</td>
<td>Wetlands</td>
<td>Smodis et al., 2014</td>
</tr>
<tr>
<td></td>
<td>Japan</td>
<td>existing</td>
<td>Fukushima fallout during 100 days after the accident</td>
<td>K-BIOTA</td>
<td>Marine</td>
<td>Keum et al., 2014</td>
</tr>
</tbody>
</table>
In 2011, UNSCEAR created an international group of experts to analyse the dosimetric impact of the Fukushima-Daiichi disaster, and implications for health, workers, the public and non-human species. In terms of the impact on ecosystems, this work is the first international assessment of the radiological risk for wildlife exposed after the accident. This study, part of the report published in April 2014 (UNSCEAR, 2014), was conducted by applying the ICRP approach combined with (i) the use of the ERICA tool for the medium- and long-term assessment (i.e. after June 2011, when exposure to radionuclides may be considered chronic), supplemented by kinetic models for assessing radionuclide bioaccumulation in various species to estimate the evolution of doses and dose rates over time during the 2-3 months immediately following the accident (when exposure to radionuclides can be considered to be acute); (ii) the use of nearly 10,000 monitoring results for the environmental compartments of interest for such evaluation (radionuclide concentrations in soils, seawater, various species) (Strand et al., 2014). Using the calculated doses and dose rates, the effects on various non-human species were inferred from the comparison with the existing benchmark values. The study concluded that, for terrestrial species, the acute effects (in the short-term period occurring within a few weeks after the accident) are unlikely and the chronic effects (in the medium-term period occurring in the months and years after the accident) may affect the most radiosensitive species (mammals) located in a restricted geographical area characterised by high levels of fallout (i.e., north-western cloud extending as much as approx. 100 km beyond the crippled plant). For marine species, the doses calculated for the short-term phase after the radioactive releases does not indicate the possibility of acute effects for people except for macroalgae near the discharge point. In the medium and long terms, the exposure levels of freshwater and marine species are well below those characteristic of significant effects. In addition to the conclusions of this assessment of the risk to wildlife, its methodological lessons have been learned and shared internationally: (i) this study is the first case of application of the ICRP approach in an emergency and post-accident situation; (ii) it is proof of the compatibility of the developments and tools made in Europe and internationally; (iii) it demonstrates how to use environmental monitoring data to supplement and validate dose and dose estimates for non-human species. Furthermore, the study’s conclusions are in disagreement with the few field observations that reported significant adverse effects on the abundance of populations of various species of bird (Moller et al., 2012). Nonetheless, these studies, like various identical studies conducted in the Chernobyl exclusion zone, are the subject of scientific disagreement (e.g., Beresford et al., 2012).

4.2 IRSN’S INVOLVEMENT

As a public expert on research and expertise in nuclear and radiological risks, IRSN possesses feedback on environmental radiation protection acquired through its role as a support for authorities and through its research activities.

IRSN conducts prospective assessments (planned exposure situation) of radiological risks for ecosystems around France as part of the review, for ASN, of licence applications required throughout the lives of nuclear facilities. IRSN also works on retrospective assessments (existing exposure situations) in the same vein as the work conducted for the joint expert group at the uranium mines in France’s Limousin region (GEP Mines) (Garnier-Laplace and Beaugelin-Seiller, 2006; Beaugelin-Seiller and Garnier-Laplace, 2007; Beaugelin-Seiller et al., 2008, 2009a, 2009b). This work continued as part of the agreement between IRSN and the French Ministry of the Environment (Directorate-General for Risk Prevention, or DGPR) in order to propose a method, values and approach for assessing and managing environmental risks associated with uranium (and its daughter products) at former uranium mines throughout France that is consistent with existing practices for managing the quality of water masses under the Water Framework Directive.
IRSN’s expertise is regularly sought by international bodies in various fields, including environmental radiation protection. For example, the Institute supports the Directorate General for Energy and Climate (DGEC) at the OSPAR Committee in the adoption of the strategy for the protection of marine environments from ionising radiation (existing exposure situations). The Institute’s members participated in assessing the impact of the Fukushima-Daiichi accident on ecosystems as part of UNSCEAR (UNSCEAR, 2014) and served as consultants or represented IRSN in the work of the IAEA. Some are members of various ICRP committees, including Committee 5, and lead and/or participate in various working groups of the IAEA’s MODARIA Programme.

4.2.1 PLANNED SITUATIONS

Nuclear operators are beginning to address the issue of environmental radiation protection in the EIAs they submit to ASN with their licence applications (see item (9) to (12)). For example, EDF now systematically includes it in the impact study associated with each stage in the life cycles of its NPPs based on the European consensual approach formalised by the ERICA tool.

IRSN generally conducts its own assessment of these applications using the most suitable and most up-to-date tools and data. The main approach used is that derived from the ERICA Project and which is predicated on the most conservative assumptions, particularly in terms of source term completeness. For example, noble gases and radionuclides absent from the default configuration of the associated tool can be released to the environment during the normal operation of a nuclear facility. IRSN thus begins its assessments directly at stage 2 of the approach (see the description of the ERICA tool in Section 12.2). This makes it possible to add missing radionuclides, by inputting the associated parameters required for the calculations. Noble gases are taken into account whenever necessary using the spreadsheet associated with the R&D Publication 128 approach (Copplestone et al., 2002). Combining the results produced by both tools generally means that radionuclides present in authorised discharges from nuclear facilities are taken into account in the most comprehensive manner possible.

IRSN has always estimated exposures of ecosystems receiving radioactive releases produced during the normal operations of NPPs to be several orders of magnitude less than the adopted protection criterion (0.24 mGy.d⁻¹, no-effect dose rate ensuring protection from chronic exposure to ionising radiation for 95% of the species of any ecosystem, determined during the ERICA Project), in accordance with the assumptions behind developments in European methodologies (Table 7).
Table 7: Summary of the radiological risk assessments conducted by IRSN to support the analysis of operators’ applications

<table>
<thead>
<tr>
<th>Object</th>
<th>Kind of targeted operation</th>
<th>Qualitative source-term</th>
<th>Range of assessed dose rates (minimum - maximum, mGy.j⁻¹)</th>
<th>Expected effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Terrestrial</td>
<td>Aquatic</td>
</tr>
<tr>
<td>Power generation</td>
<td>Renewal of discharge authorization</td>
<td></td>
<td>4.3 10⁻⁵ - 1.0 10⁻⁴ (reptile)*</td>
<td>1.4 10⁻⁵ - 1.9 10⁻² (insect larvae)</td>
</tr>
<tr>
<td></td>
<td>Discharge prescriptions for a waste storage</td>
<td></td>
<td>7.8 10⁻⁶ - 2.1 10⁻⁵ (reptile)</td>
<td>2.0 10⁻⁶ - 2.9 10⁻³ (insect larvae)</td>
</tr>
<tr>
<td></td>
<td>Renewal of discharge authorization</td>
<td></td>
<td>7.2 10⁻⁶ - 1.9 10⁻⁵ (reptile)</td>
<td>2.2 10⁻⁷ - 6.5 10⁻⁴ (insect larvae)</td>
</tr>
<tr>
<td>Upstream of the fuel cycle</td>
<td>Authorization of creation for a storage of settling muds</td>
<td></td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Upstream of the fuel cycle</td>
<td>Modification of discharge authorization</td>
<td></td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Upstream of the fuel cycle</td>
<td>Follow-up of a storage of residues of ore processing</td>
<td></td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

*most-exposed reference organism
4.2.2 EXISTING SITUATIONS

(119) Created in 2006 by the ministers of the environment, industry, and health, the joint expert group (GEP) for uranium mines presented its conclusions in 2010. Its purpose was to propose to the government, based on a critical inventory of the situation of former mines in France’s Limousin region, ways of improving long-term monitoring and management conditions at all former mining sites and, where necessary, identify actions to reduce current and future impacts.

(120) For its work on the environmental impact of the former uranium mines, the GEP relied heavily on IRSN’s scientific and technical expertise on the subject. This contribution resulted in the publication of a series of reports (Garnier-Laplace and Beaugelin-Seiller, 2006; Beaugelin-Seiller and Garnier-Laplace, 2007; Beaugelin-Seiller et al., 2008, 2009a, 2009b) that fuelled the discussions of both the group and the public authorities. The work explores, using the catchment basin of the river Ritord as an example, the assessment of risks to ecosystems through the lens of uranium chemotoxicity and radiotoxicity. Consistency between the two parts was ensured by basing the radiation risk assessment method on the concepts and principles underlying the ERICA approach, which was then still in development.

(121) The results of the assessment provided answers regarding the assessment of the environmental risk related to uranium discharges in the catchment basin of the river Ritord. However, a number of questions remain unanswered, primarily regarding the issue’s chemical aspect. The risk of radiotoxicity for wildlife was ultimately excluded by a probabilistic approach (in 90% of exposure cases, fewer than 10% of species would be affected, with an effect intensity of 10%, through exposure to the radionuclides considered). The study’s conclusions formed the basis of part of the recommendations made by the joint expert group (GEP, 2010), including the need for characterising background radiation, for determining the equilibrium state of uranium isotope decay chains, for understanding of local flora and fauna, and for acquiring the data needed to model the metal speciation.

(122) Under the OSPAR Convention, a regular assessment is made of the health state of the North-East Atlantic Ocean. In the run-up to preparing the general assessment of 2010, four thematic assessments were conducted in relation to the OSPAR strategy for radioactive substances, one of which was devoted to the impact of past and present anthropogenic sources of radioactive substances on living marine biota (OSPAR, 2009). To this end, IRSN published a three-part study (Garnier-Laplace and Beaugelin-Seiller, 2007). Using a state of the art of the assessment of the environmental risks and impact of radioactive substances, the Institute proposed a method for demonstrating the potential consequences of advances made by the Contracting Parties, in terms of reducing their anthropogenic inputs of radioactive substances, on dose rates to marine organisms. Lastly, the method was implemented across the maritime regions defined in the OSPAR Convention for which the necessary data were available.

(123) The ERICA approach was used because it represents the only European reference for integrated assessments of doses absorbed by wildlife. Nevertheless, an intercomparison was conducted selectively with the RESRAD-BIOTA tools and the spreadsheets associated with R&D Publication 128 of the UK Environment Agency. Ultimately, the flexibility of the ERICA approach in terms of radionuclides and organisms was found to be better adapted to the needs of OSPAR and was the deciding factor in its selection.
In the light of the limited list of radionuclides considered by OSPAR (\(^1\)H, \(^{99}\)Tc, \(^{239,240}\)Pu, \(^{210}\)Po, \(^{226}\)Ra, \(^{228}\)Ra, \(^{210}\)Pb), the conclusions of the application of the method are only partial in terms of potential biological damage from ionising radiation. Indeed, the results of such an environmental radiation risk assessment are robust only if the radionuclide inventory is exhaustive, on account of the recognised additivity of the effects of the different isotopes present. For the period 1995-2001, the interval used for the study, the dose rates partially calculated for the series of organisms of interest are low and below the lowest levels likely to result in harmful consequences for wildlife.

### 4.2.3 EMERGENCY SITUATIONS

In addition to serving as a support for the public authorities, IRSN expands its experience through research, studies and assessments it conducts on its own behalf. For example, in the months following the Fukushima-Daiichi accident, IRSN published one of the first assessments of the environmental consequences for the areas affected by the resulting fallout (Garnier-Laplace et al., 2011). Using the limited partial information available on contamination of Japan’s forest and marine environments, the dose rates received by representative organisms of the various taxonomic groups 30 days after the accident were generically assessed with the ERICA tool. The comparison of the results obtained with the highly conservative approach used and the ICRP DCRLs showed a risk for the marine ecosystem and for some groups of terrestrial animals or plants (Figure 13). IRSN concluded that it was necessary to implement, as soon as practicable, long-term monitoring of these environments in order to conduct research on the transgenerational effects of the low doses, a subject that is still controversial 25 years after the Chernobyl accident.

If a radiological risk to non-human species is identified following an incident or accident, the types of concrete action to be implemented depend on the measures already in place to conserve certain species (e.g., definition of specific protection areas) and environmentally monitor the demography of at-risk species or communities of species. The strategy for implementing these measures will vary on a case-by-case basis. These actions must be compared to the issues. It must be recalled that environmental protection is only a facet of radiation protection optimisation in cases of exposure incidents or accidents. In the case of the Chernobyl and Fukushima accidents, protecting people from radiation was the logical priority of the emergency phase and its management.
Figure 13: Potential effects of exposure to ionising radiation for the representative RAPs of various taxonomic groups of marine and forest ecosystems and comparison with the dose rates absorbed during the first few months after the Fukushima-Daiichi accident from exposure to $^{131}$I, $^{134}$Cs, $^{137}$Cs (according to Garnier-Laplace et al., 2011).

As an example to help in reading this figure, the maximum dose rate estimated for rodents lies within the range of doses likely to impair reproduction and which is only slightly lower than that in which the life span can be decreased.
5 **RECOMMENDATIONS - CONCLUSIONS**

Based on this state of the art, IRSN issues ten recommendations, which are listed below. The main demonstration elements associated with each recommendation are restated in the table in Appendix 9.8.

**General position**

(R1) IRSN considers that the explicit consideration of protection of the environment from radioactive substances within the existing corpus of international reference documents (e.g., basic radiation protection standards, international conventions, special legislation in some member States) must lead to the adoption of a French position on protecting the environment per se from ionising radiation. Such a position will be useful to technical experts participating in current or future working groups in this field.

**Recommendations for planned exposure situations**

(R2) IRSN considers that the inclusion, in France, of the demonstration of protection of the environment from ionising radiation in any project that may impact the environment is perfectly in line with the French Environmental Code and, more specifically, the provisions of Article 9 of French decree No. 2007-1557 on basic nuclear installations.

(R3) IRSN considers that the demonstration of protection of the environment from radioactive substances must be integrated into the environmental impact assessment, to the same extent as with the assessment conducted for chemical substances. IRSN recommends that, in France, this demonstration be routinely requested from the licensees of any facility or activity involving controlled environmental releases of radioactive substances that may have an ecological impact. Such demonstration shall be commensurate with the environmental issues.

(R4) IRSN recommends using a graded approach consistent with the principle of proportionality to the issues set out in French legislation. Such an approach enables resources and means to be better allocated based on the expected risk and allows efforts to be focused on cases requiring a closer look.

(R5) IRSN considers that the tiered ERICA approach, which is compatible with and more operational than the ICRP approach, forms the basis to be followed to explicitly demonstrate protection of the environment during the assessment and control of radiological impacts associated with planned environmental exposure situations, in addition to the approach used for human radiation protection. This approach is used widely in Europe and was adopted a few years ago by a number of nuclear operators in France. It is similar in method and uses the concepts of the ICRP approach whilst providing a tool and associated databases that are regularly updated.

(R6) Regarding environmental radiation risk assessments, IRSN recommends having the assessor choose benchmark values that are best suited to the situation under assessment and provide evidence of the source of said values (as is the case with the practices used to assess ecological risks associated with chemical substances).

---

15 "The environmental impact assessment comprises an analysis of the facility’s direct and indirect, temporary and permanent effects on the environment and particularly on public health and safety, the climate, neighbourhood inconveniences due to noise, vibrations, odours or lighting, on sites, landscapes and natural environments, on fauna, on flora and biological equilibria, on crops and on the protection of property and cultural heritage."
(R7) IRSN proposes setting up a working group whose objective would be to draft a technical guide describing a standardised and optimum method of using the ERICA approach and tool. This working group shall take into account improvements in international methodologies expected from the ICRP and IAEA and other such organisations. It is also recommended to train users in the methods and tools in order to coordinate their deployment.

**Recommendation for existing exposure situations**

(R8) IRSN considers that the tiered ERICA approach makes it possible to cover existing exposure situations, particularly through its tiered assessment method. To supplement the feedback for these situations, other cases of application similar to the case studies handled within the Mines Joint Expert Group (GEP Mines), may be necessary to reinforce this statement; while including international advances in the field.

**Implications for environmental monitoring associated with planned and existing exposure situations**

(R9) Regarding planned exposure situations, IRSN recommends that current environmental radioactivity monitoring practices be reviewed to assess whether the data acquired can be used as additional proof for radiation impact assessments for ecosystems. Additionally, such a review shall also cover the use, for the same purpose, of the results from monitoring practices currently used to monitor the quality of media and biodiversity (e.g., case of the WFD and the MSFD). Regarding existing exposure situations, IRSN recommends supplementing the approach of demonstrating via the environmental impact assessment by implementing a specific ecological monitoring strategy where warranted by the level of exposure to ionising radiation (i.e., accordingly to the conclusions of the radiation risk assessment).

**Recommendation for emergencies and the post-accident phase**

(R10) In the event of a major nuclear accident (i.e. Chernobyl -or Fukushima-type), IRSN considers that the priority of the emergency is to protect human populations. During the post-accident phase, protecting the environment may be considered as one aspect to take into account to better manage contaminated areas. This matter could be dealt with by a dedicated working group. In view of the state of the art, the radiological risk assessment method for non-human species must be adapted and the necessary data must be supplemented in order to be able to respond to such situations. The proposed group’s work will extend to environmental monitoring practices. In terms of smaller accidents, attention should also be given to emergencies where protecting the environment would be essential, particularly in cases of accidents/incidents that impact uninhabited conservation areas.
6 REFERENCE DOCUMENTS


7 LIST OF ILLUSTRATIONS

Figure 1: Long-standing process behind the creation of basic radiation protection standards through collaboration amongst the three main international bodies involved .......................................................... 14
Figure 2: Overview of the various methods of risk characterisation ................................................ 20
Figure 3: Number of data points for the 10 best-documented elements in each ecosystem (Wildlife Transfer Database, adapted from Howard et al., 2013) ............................................................... 21
Figure 4: Variability in the concentration factor of caesium in the terrestrial environment (Extracted from the Wildlife Transfer Database, 2011. The figure in parentheses after the taxon name is the number of data points minus the arithmetic mean and outliers) ................................................................................ 21
Figure 5: Schematic diagram of the key concepts used in systems to protect man and the environment from radiation, according to ICRP (Larsson, 2013) ................................................................. 30
Figure 6: (Top) Example of the tables published in ICRP 108 and showing the range of DCRLs (in white boxes) per reference organism in relation to the entire body of knowledge on the effects of ionising radiation for two reference organisms. (Bottom) Set of reference organisms (RAPs) and associated benchmark values (DCRLs) forming the basis of the ICRP approach .................................................................................................. 33
Figure 7: Organisation of the various component parts of the ICRP approach for environmental radiation protection (adapted from Larsson, 2013). .......................................................................................... 34
Figure 8: Application of the ICRP concepts and methodology for the three types of exposure situation. Diagram adapted from ICRP Publication 124 (2014). ...................................................................................... 35
Figure 9: Flow chart of the procedure proposed by IAEA for implementing the 1972 Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter and its 1996 Protocol. (Top) General flow chart for the assessment to be conducted to define whether a radioactive material can be authorised for dumping at sea. (Bottom) Procedure for estimating doses to the public and flora and fauna (taken from Telleria et al., 2013) .... 36
Figure 10: Overview of the ERICA Integrated Approach (Larsson et al., 2009) .................................. 40
Figure 11: Flow chart showing the organised, graded approach to environmental risk assessments .......................... 42
Figure 12: Structured approach proposed by the BIOPROTA forum for long-term assessments of the impact of deep geological repositories (Smith et al., 2012) ...................................................... 52
Figure 13: Potential effects of exposure to ionising radiation for the representative RAPs of various taxonomic groups of marine and forest ecosystems and comparison with the dose rates absorbed during the first few months after the Fukushima-Daiichi accident from exposure to $^{131}$I, $^{134}$Cs, $^{137}$Cs (according to Garnier-Laplace et al., 2011). ............................................................................................................... 62
Figure 14: Comparison of the dose rates estimated for the aquatic reference organisms to the release threshold limit values at the NPP site with the PNEDR from the ERICA tool and the applicable DCRLs. .............................. 101
Figure 15: Comparison of the dose rates estimated for the aquatic reference organisms for estimated releases from the storage facility with the PNEDR from the ERICA tool and the applicable DCRLs. .................................. 101
Figure 16: Contribution of internal and external exposure to the total dose rates estimated for the aquatic reference organisms (NPP site) .................................................................................................. 103
Figure 17: Contribution of internal and external exposure to the total dose rates estimated for the aquatic reference organisms (storage facility) .................................................................................. 103
Figure 18: Contribution of the various radionuclides present in the source term to internal exposure of the aquatic reference organisms (NPP site) ................................................................. 104

Figure 19: Contribution of the various radionuclides present in the source term to internal exposure of the aquatic reference organisms (storage facility) ................................................................. 104

Figure 20: Dose rates received by the terrestrial reference organisms due to their exposure to natural radioactivity (diamond: typical value; green bar; range of variation; source: ERICA tool) and applicable DCRLs ...................... 105

Figure 21: Dose rates received by the aquatic reference organisms due to their exposure to natural radioactivity (diamond: typical value; green bar; range of variation; source: ERICA tool) and applicable DCRLs ...................... 105
8 LIST OF TABLES

Table 1: Summary of environmental protection regulations regarding nuclear power in Belgium, Spain, Italy and Switzerland ........................................................................................................................................................................28
Table 2: The set of ICRP reference animals and plants (RAP) by environment. For each RAP, the stage of life taken into account is given between brackets and the family represented by the RAP is given in blue italics. ..................................................31
Table 3: Illustration of the type of reference organisms and their correspondence for three of the approaches described ..................................................................................................................................................44
Table 4: Position of a few benchmark values for the protection of various environmental objects with respect to the DCRLs defined by the ICRP (dose rate, mGy.d⁻¹) ..................................................................................................................46
Table 5: Comparative summary of the characteristics of the main approaches for assessing radiation risks to ecosystems ..............................................................................................................................................48
Table 6: Overview of the international literature published over the last 5 years and presenting environmental radiation risk assessments and various case studies ..................................................................54
Table 7: Summary of the radiological risk assessments conducted by IRSN to support the analysis of operators’ applications ............................................................................................................................................59
9 APPENDICES
9.1 CALCULATION OF DOSE RATES FOR WILDLIFE

Notations

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>m</td>
<td>Subscript symbol for exposure medium</td>
<td>[w.d.]*</td>
</tr>
<tr>
<td>o</td>
<td>Subscript symbol for exposed organism</td>
<td>[w.d.]</td>
</tr>
<tr>
<td>r</td>
<td>Subscript symbol for the radionuclide that the organism in question is exposed to</td>
<td>[w.d.]</td>
</tr>
<tr>
<td>int</td>
<td>Subscript symbol for internal exposure</td>
<td>[w.d.]</td>
</tr>
<tr>
<td>ext</td>
<td>Subscript symbol for external exposure</td>
<td>[w.d.]</td>
</tr>
<tr>
<td>TDR</td>
<td>Total dose rate</td>
<td>[mGy.d⁻¹]</td>
</tr>
<tr>
<td>EDR</td>
<td>External dose rate</td>
<td>[mGy.d⁻¹]</td>
</tr>
<tr>
<td>IDR</td>
<td>Internal dose rate</td>
<td>[mGy.d⁻¹]</td>
</tr>
<tr>
<td>DCC</td>
<td>Dose conversion coefficient</td>
<td>[mGy.h⁻¹ per Bq.kg⁻¹]</td>
</tr>
<tr>
<td>[r]₀</td>
<td>Concentration of radionuclide r in organism o</td>
<td>[Bq.kg⁻¹]</td>
</tr>
<tr>
<td>[r]ₘ</td>
<td>Concentration of radionuclide r in medium m</td>
<td>[Bq.kg⁻¹]</td>
</tr>
<tr>
<td>CF</td>
<td>Concentration factor</td>
<td>[kg medium per kg organism]</td>
</tr>
<tr>
<td>OF</td>
<td>Occupancy factor (fraction of time spent in medium by organism)</td>
<td>[w.d]</td>
</tr>
</tbody>
</table>

* w.d. Without dimension

**Concentration factor**

The concentration factor is determined empirically using the ratio between the whole-body concentration of a radionuclide measured in an organism and the concentration measured in the medium, expressed in fresh weight. This sets it apart from the concentration factor used to assess transfers along the human food chain and which relates only to edible parts and is usually expressed in dry weight.

The concentration factor provides assessors with an integrated view of all the transfer pathways that contribute to an organism’s contamination. In particular, exposure via air (inhalation, cloud exposure) is implicitly taken into account by the concentration factor regardless of whether this factor is expressed in relation to soil or air (case of hydrogen, carbon, and sulphur or phosphorous in the ERICA tool).

**Dose conversion coefficient**

The dose conversion coefficient is an operational parameter that, when applied to the radionuclide concentration of an exposure source, is used to assess the dose rate received by a receptor organism. It is calculated by simulating the transport of particles in a geometry that represents, in a simplified way, a three-dimensional scene in order to collect energy deposits in the receptor organism. In general, the receptor organism is represented by an ellipsoid homogeneous in composition and contamination when the media are described as by semi-infinite layers also with homogeneous characteristics.

The dose conversion coefficient is the equivalent for wildlife of the dose coefficient used in human radiation protection.
Dose rate received by the receptor organism

Total dose rate received by the organism \( o \) due to the presence of the radionuclide \( r \) in the medium \( m \)

\[
TDR_m(o,r) = EDR_m(o,r) + IDR_m(o,r)
\]

\[
EDR_m(o,r) = DCC_{ext}(o,r) \times OF(o,m) \times [r]_m
\]

\[
IDR_m(o,r) = DCC_{int}(o,r) \times CF_m(o,r) \times [r]_o
\]

Total dose rate received by the organism \( o \) due to the presence of \( n \) radionuclides in the medium \( m \)

\[
TDR_m(o) = \sum_{r=1}^{n} TDR_m(o,r)
\]

Total dose rate received by the organism due to the presence of \( n \) radionuclides in \( t \) media

\[
TDR(o) = \sum_{m=1}^{t} TDR_m(o)
\]
### 9.2 BENCHMARK VALUES FOR EFFECTS ON NON-HUMAN SPECIES: COMPILATION OF THE DETERMINATION VALUES AND METHODS USED BY PROTECT

(1) Compilation of the dose rates (in µGy/h) proposed by various organisations or project consortia in support of the analysis of the effects on whole or partial ecosystems during chronic exposure to radioactive substances (adapted and updated from Garnier-Laplace *et al.*, 2008)

<table>
<thead>
<tr>
<th>Targeted protected level as described in the source</th>
<th>Method/justification of the value¹</th>
<th>Dose rate (µGy/h)</th>
<th>Reference²</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Terrestrial ecosystems</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generic ecosystems - No effect value</td>
<td>SSD-95% species protected plus SF of 5</td>
<td>10</td>
<td>ERICA (2006), confirmed by PROTECT (Garnier-Laplace <em>et al.</em>, 2010)</td>
</tr>
<tr>
<td>Plants - Transitional No effect value</td>
<td>Lowest EDR₁₀ value plus SF of 10</td>
<td>70</td>
<td>PROTECT in (Garnier-laplace <em>et al.</em>, 2010)</td>
</tr>
<tr>
<td>Plants - Effects unlikely</td>
<td>Review, SF on the lowest critical radiotoxicity value</td>
<td>110</td>
<td>Environment Canada (1997) and Bird <em>et al.</em> (2002)</td>
</tr>
<tr>
<td>Plants - No effect</td>
<td>Critical review for screening purpose from IAEA 1992</td>
<td>400</td>
<td>Environment agency UK (2003)</td>
</tr>
<tr>
<td>Invertebrates</td>
<td>Review, SF on the lowest critical radiotoxicity value</td>
<td>220</td>
<td>Environment Canada (1997) and Bird <em>et al.</em> (2002)</td>
</tr>
<tr>
<td>Invertebrates - Transitional No effect value</td>
<td>SSD-95% species protected plus SF of 3</td>
<td>200</td>
<td>PROTECT in (Garnier-laplace <em>et al.</em>, 2010)</td>
</tr>
<tr>
<td>Vertebrates - Transitional No effect value</td>
<td>SSD-95% species protected plus SF of 1</td>
<td>2</td>
<td>PROTECT in (Garnier-laplace <em>et al.</em>, 2010)</td>
</tr>
<tr>
<td>Small mammals</td>
<td>Review, SF on the lowest critical radiotoxicity value</td>
<td>110</td>
<td>Environment Canada (1997) and Bird <em>et al.</em> (2002)</td>
</tr>
<tr>
<td>Vertebrates and cytogenetic effects</td>
<td>Review Contaminated environments</td>
<td>4 - 20</td>
<td>Sazykina (2005)</td>
</tr>
<tr>
<td>Vertebrates and effects on morbidity</td>
<td>Review Contaminated environments</td>
<td>20 - 80</td>
<td>Sazykina (2005)</td>
</tr>
<tr>
<td>Vertebrates and effects on reproduction</td>
<td>Review Contaminated environments</td>
<td>80 - 200</td>
<td>Sazykina (2005)</td>
</tr>
</tbody>
</table>

**Aquatic ecosystems**

<table>
<thead>
<tr>
<th>Targeted protected level as described in the source</th>
<th>Method/justification of the value&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Dose rate (µGy/h)</th>
<th>Reference&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic marine ecosystems</td>
<td>SSD-95% species protected plus SF of 5</td>
<td>10</td>
<td>ERICA (2006) and Garnier-Laplace et al. (2006)</td>
</tr>
<tr>
<td>Aquatic algae/macrophytes</td>
<td>Review, SF on the lowest critical radiotoxicity value</td>
<td>110</td>
<td>Environment Canada (1997) and Bird et al. (2002)</td>
</tr>
<tr>
<td>Amphibians/Reptiles</td>
<td>Review, SF on the lowest critical radiotoxicity value</td>
<td>110</td>
<td>Environment Canada (1997) and Bird et al. (2002)</td>
</tr>
<tr>
<td>Benthic invertebrates</td>
<td>Review, SF on the lowest critical radiotoxicity value</td>
<td>220</td>
<td>Environment Canada (1997) and Bird et al. (2002)</td>
</tr>
<tr>
<td>Fish</td>
<td>Review, SF on the lowest critical radiotoxicity value</td>
<td>20</td>
<td>Environment Canada (1997) and Bird et al. (2002)</td>
</tr>
<tr>
<td>Flora and fauna</td>
<td>Review concluded that few indications for readily observable effects at chronic dose rates below</td>
<td>&lt;100</td>
<td>FASSET (2003)</td>
</tr>
</tbody>
</table>

<sup>1</sup> Abbreviation used: SF Safety Factor; SSD Species Sensitivity Distribution; EDR10 Dose rate giving 10% effect on the effect endpoint examined

<sup>2</sup> References:


(2) Methods for determining the benchmark values used by the PROTECT consortium using the data in the FREDERICA database: Extracted from “Numerical benchmarks for protecting biota from radiation in the environment: proposed levels, underlying reasoning and recommendations”, Deliverable 5, October 2008. Protect Contract No. 036425 (Fl6R)
4.3 Methodology to derive the screening value(s)

4.3.1 Overview of methods

Within chemical risk assessment, three main methodologies are commonly used for deriving environmental benchmarks:

- Deterministic, based on the application of Assessment (or Safety) Factors to a single species sensitivity value (for the most sensitive species observed).
- Probabilistic, based on Species Sensitivity Distribution (SSD) modelling.
- A weight of evidence approach, typically using data from field exposures.

The two first approaches are currently used for chemicals under the European recommendations from the Technical Guidance Document (TGD) (EC, 2003). The aim of these two methods is to derive the Predicted No-Effect Concentration (PNEC). Within the TGD, this is based on critical ecotoxicity values (e.g., stressor level in a given medium representing the no observed effect concentration (NOEC) or a 10% effect in the exposed group in comparison to the control group (EC10) for chronic exposure, or 50% effect (EC50) for acute exposure conditions). Such ecotoxicity values are derived from individual experiments for as many species as possible for the contaminant under concern (for chemical assessments, a common set of test species and experimental methodologies are often used, see e.g., requirements in EC regulation 1907/2006 (EC, 2006)). The difference between the methods is in the extrapolation from the results for a single species in individual experiments to a PNEC for an ecosystem. Whereas the deterministic method simply takes the lowest significant ecotoxicity value found for any species and divides it by a predefined (depending on availability of data) assessment factor, the probabilistic method uses the distribution of all available ecotoxicity data and applies a cut-off value for this distribution, normally the 5th percentile (HC5), in the derivation of the PNEC. Both of these extrapolation methods seek to account for uncertainties arising from the available data by applying an assessment factor (AF).

These two approaches were critically reviewed and compared with respect to deriving predicted no-effect dose rates (PNEDR) for radioactive substances within the ERICA project (Garnier-Laplace et al., 2006; Garnier-Laplace and Gilbin, 2006). The assessment factor approach has also been used within Canada to derive radiological benchmark values (Environment Canada, 2003). Detailed discussions on advantages and disadvantages of applying these methods can be found in Garnier-Laplace and Gilbin (2006). Further critical discussion of the SSD methodology can be found in Forbes and Carlow (2002) and Posthuma et al. (2002). Within the PROTECT project, we have tried to be as consistent as possible with current European chemicals regulation and the TGD methodologies are further described in the next section as they have formed the basis of much of our work.

Alternative approaches to estimating risk include field observations and population or ecosystem modelling all of which have associated assumptions and uncertainties. The weight of evidence approach evaluates each separate line of evidence and organises these coherently to assess risk according to relevance to the exposure scenario of interest; relevance to the assessment endpoint; and degree of confidence in the evidence (Environment Canada, 1997). The weight of evidence approach has been used for radioactive substances by Thompson et al. (2005). However, a consideration of the available evidence is also used as part of the process of deriving benchmarks by deterministic and probabilistic methods. For example, if the derived...
benchmark was below the range of typical background (e.g., metal) concentrations then weight of evidence would suggest that it is not fit for purpose.

4.3.2 Brief description of the EC guidance to derive “no-effect” values for chemical substances

Deterministic method

According to the TGD (EC, 2003), the PNEC can be calculated using the deterministic assessment factor method by dividing the lowest short-term (acute) EC50 or long-term (chronic) EC10 or No Observed Effect Concentration (NOEC) values by an appropriate assessment factor. The extrapolations include two underlying assumptions: (i) the ecosystem response depends on the most sensitive species and (ii) protecting ecosystem structure protects community function (EC, 2003). In reality, when a limited set of toxicity data are available, a constant assessment factor is used to extrapolate from the NOEC, EC50 or EC10 concentration to the PNEC for an ecosystem according to a number of well-defined rules as shown in Table 3. Because of the limited data usually available, this is the most commonly used approach to derive chemical PNECs.

Probabilistic method

Providing sufficient data points are available, PNECs can also be calculated using a probabilistic statistical extrapolation model in the form of a species sensitivity distribution (SSD). The SSD model is based on the assumptions (EC, 2003) that: (i) the variability in the sensitivity of the laboratory-tested species is similar to the variability among the species in the field; (ii) the endpoint measured in laboratory tests is indicative of effects on populations in the field (e.g., Van Straalen and Dennenman, 1989; Aldenberg and Slob, 1993); and (iii) input data are drawn at random from the distribution of possible species sensitivities. Thus, an extrapolation is made from a standard test endpoint (or a mixture of ecologically relevant endpoints) for a set of test species to the same endpoint (or mixture of endpoints) in the full set of potentially exposed species. The input to the SSD can include the NOEC, EC50 or EC10 (see below) depending upon the protection goal. The output is the concentration which is hazardous for only a small fraction of the species in the ecosystem. For chemicals, the TGD recommends that the Hazardous Concentration 5% (HC5) is estimated, where HC5 is the predicted concentration at which 5% of species will be affected by less than, for instance, the 10% level if EC50 values are used as the input (i.e., 5% of species may demonstrate a 10% or higher effect - see Figure 1). Whilst the selection of HC5 has been described as ‘arbitrary and the result of political compromise’ (Suter et al., 2002) it has been independently adopted by regulators in a number of countries worldwide and is that recommended in the TGD (EC, 2003).

The TGD also recommends the application of an assessment factor ranging from 1-5 to the estimated HC5 value to determine the PNEC. The magnitude of the assessment factor should be assessed on a case by case basis depending upon a number of factors including quality of the database, diversity of the taxonomic groups and statistical uncertainties in the HC5 estimate.
Table 3. Assessment factors applied to derive PNECs depending on the quantity and quality of the available toxicity data and the extrapolation method used. Illustration for freshwaters adapted from the TGD (EC, 2003). For information on other ecosystems, see the TGD.

<table>
<thead>
<tr>
<th>Available toxicity data</th>
<th>Assessment factor</th>
<th>Extrapolation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute or Chronic to single species in ecosystem</td>
<td>1000</td>
<td></td>
</tr>
<tr>
<td>At least one short-term 1/E[C]? from each of three trophic levels of the base-set (fish, Daphnia and algae)</td>
<td>1000</td>
<td>Acute to Chronic and single species to ecosystem</td>
</tr>
<tr>
<td>At least one long-term NOEC (either fish or Daphnia)</td>
<td>1000</td>
<td>Acute to Chronic and single species to ecosystem</td>
</tr>
<tr>
<td>Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)</td>
<td>100</td>
<td>Single species to ecosystem</td>
</tr>
<tr>
<td>Long-term NOECs from at least three species (normally fish, Daphnia, algae) representing three trophic levels</td>
<td>10</td>
<td>Single species to ecosystem</td>
</tr>
</tbody>
</table>

1. \(1/E[C]\) is the Low or Effect Concentration is defined as the concentration associated with 50% change in the (target) level of the endpoint considered.

2. The NOECs are effects concentrations in the tested concentration just below the LOEC. The Lower Observed Effect Concentration is the lowest concentration out of the tested concentrations at which a statistically significant difference from the control group is observed. They are both estimated by experimental observation and extrapolation.

However, the TGD presents no defined rules on how to select the assessment factor. In section 4.3.4 PROTECT has outlined rules for determining an appropriate assessment factor to apply with the decisions recorded in a transparent manner. Whilst a NOEC or lowest observed effect concentration (LOEC) may be reported for a given study, this endpoint can be influenced by the test design, for instance, the level of replication and choice of test concentrations. The reported NOEC or LOEC may be well below or above the true no effects concentration depending upon the number and range of experimental concentrations used. An accepted alternative is to estimate the no effects concentration by determining the concentration corresponding to the 10% effect compared with a control group (i.e. the EC10) by statistical extrapolation of the response data for an individual study. Whilst the TGD recommends the use of the EC10 for this purpose, it has been suggested that this will not always be significantly different to the control treatment and some alternative guidance documentation suggest the use of EC20 as a compromise (USEPA, 2001; MERAG, 2005).

The main advantage of the SSD method over the deterministic AF method is that it uses all the appropriate available data, whereas the deterministic method uses only the lowest relevant value. The SSD method, therefore, also more likely to result in a revised value as additional data become available; the deterministic approach is only influenced if the new data are lower than existing toxicity values, unless the additional data triggers the use of a different AF value (e.g. see Table 3). The main criticisms of the SSD methodology have been on the implicit assumption of equal relevance for all endpoints for all species (Stark, 2004), and concerns that there may be foundational or keystone species among the 5% that are “unprotected” (Forbes and Forbes, 1993; Hopkins, 1993). However, it has also been stressed that ecosystems possess a varying degree of resilience, and that any risk assessment philosophy should acknowledge that environmental protection cannot eliminate all possible risks but should reduce them to an acceptable level (Van Stralen and Denneman, 1989; Van Stralen, 2002). Finally, in practice,
there may be disagreements over which data and endpoints to include, and how to treat those data mathematically. These issues are discussed in more detail in the following sections.

As evident from the above description the SSD approach does require some degree of expert judgment (e.g. in selection of AF and EC₃ values). However, there is precedence for some of these judgements from the application of SSD within chemicals (e.g. the use of HC₅ in the derivation of PNEC) and all the judgements which are required can be transparently documented in a stepwise manner.

4.3.3 Methodologies for small datasets
The TGD (EC, 2003) recommends that an SSD is based on at least 10 data points, although deviation from this recommendation could be made on a case by case basis under certain conditions. In many cases this amount of data is not available, and methodologies to utilise smaller datasets (4-10 input values) in a probabilistic approach have been developed (e.g. Aldenberg and Luttik (2002), van Vlaardingen et al. (2004)). The approach utilises a standard deviation from a larger appropriate dataset making the assumption that this standard deviation is representative of that for the smaller dataset. As an example, van Vlaardingen et al. (2004) present standard deviation values estimated from pooled toxicity data for 55 pesticides in birds for application to small toxicity datasets of individual pesticides under assessment. However, the method is dependent upon having an appropriate standard deviation which is applicable to the data under assessment.

4.3.4 PROTECT derivation method for screening values
The SSD methodology has previously been used to successfully derive radiological benchmarks by Garner-Laplace et al. (2006) and it was selected as the favoured approach for use in the derivation of numeric benchmarks by the PROTECT consortium for the following reasons:

- it provides a framework for transparent derivation
- it is broadly endorsed by consulted experts (Andersson et al., 2008; Beresford et al., 2008a)
- it is consistent with approach used within chemical assessments in the EC
- it imposes a high level of quality control for data selection
- it makes most use of all available data

Below, we document the data selection and application of SSD as used by PROTECT. Where data were insufficient for the application of an SSD, the deterministic method was used instead following the recommendations given in the TGD (although other approaches were considered).
The derivation of benchmark values for ionising radiation consists of three steps as shown in Figure 1.

**Compiling quality assessed exposure-effect data (step 1):**

The primary source of effects data used was the FREDERICA database (available online at http://www.fredERICA-online.org; Copplestone et al., 2008). The robustness and the scientific credibility of the derived numerical thresholds are strongly linked to the relevance and quality of the critical ecotoxicity data set selected. In contrast to chemical substances, for radioactive substances there are no standardised ecotoxicity test exists. Therefore, we have to make best use of the available data which, especially in the case of data for mammals, may not have been produced for the purposes of environmental protection.

When input into the database, each reference in FREDERICA was assessed against three criteria (dosimetry, experimental design and statistical details) which were then aggregated into a total score with a maximum value of 80 (Copplestone et al., 2008). Only data from papers considering chronic exposures and with medium to high scores (>35) were used in the analysis described below. Moreover, the papers needed to present sufficient data to enable an EDR_{10} to be derived (e.g. data-set includes a dose rate giving rise to at least a 10% effect); the rules to select data suitable for deriving an EDR_{10} value are illustrated in Figure 2. All potential useful source references identified were reviewed by members of the PROTECT consortium with expertise in chemical risk assessment before the data were accepted for subsequent use.

This process is similar to how data were extracted by Garner-Laplace et al. (2006; 2008) the difference being that more data are now included within the FREDERICA database. Additionally, dose rate-effect relationships showing a hormetic pattern have now been accepted, providing they met the criteria specified in Table 4.

Having applied the above criteria, data suitable for inclusion in the SSD were available only from chronic, external, gamma-irradiation studies.

**Estimation of critical ecotoxicity values (step 2):**

The dose rate-effect relationships were then analysed to give the EDR_{10} that has been adopted here, in accordance with European guidance (i.e. the TGD).

A number of assumptions were made concerning the quality of the data submitted to the mathematical treatment. For example, data from FREDERICA were assumed to be representative of the mean of a sufficient number of replicates, although the actual number of replicates was often not presented in the source reference. Depending upon the nature of the data, one of two curve types was fitted (Figure 3) as described below.

Before the calculated EDR_{10} values were accepted for further use in the process of benchmark derivation, they were checked against rules 3-5 in Figure 2 to ensure the spread of experimental dose rates was sufficient to determine a robust EDR_{10} value. The data and the fitted models for all data sets that were accepted for inclusion in the SSD are presented graphically in Appendix 1.
Figure 1. The methodology applied to the FREDERICA database to reconstruct chronic exposure dose-effect relationships and derive benchmark values (see subsequent text for definitions) from SSD.
Logistic dose rate-effects relationships:

Typical dose rate-response curves (Figure 3) were modelled using the commonly used logistic model:

\[ y(x) = c + \frac{d - c}{1 + \exp[b(ln(x) - ln(c))] \]  

Where \( d \) denotes the control response, and \( c \) is the response at infinite dose. The parameter \( e \) is the dose rate at which the value of \( (d - c) \) is reduced by 50% \( (EDR_{50}) \), and \( b \) is proportional to the slope around \( EDR_{50} \). Depending on whether the response or the effect is being assessed, the logistic functions are either decreasing from a maximal control response at zero dose rate to a lower limit at infinite dose or increasing from no effect at zero dose rate to maximum effect at infinite dose rate.

Data set for one test

A test is defined as a consistent group of dose rate versus effect data points from a given species and a given effect, examined under defined exposure conditions (duration, irradiation pathway).

<table>
<thead>
<tr>
<th>Rule 1</th>
<th>The data set is made up of</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>At least 3 different data points including one control (no dose rate)</td>
</tr>
<tr>
<td>NO</td>
<td>At least 3 different data points if the effect is analysed relative to the control</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 2</th>
<th>The pattern is consistent with the state of the art on the tested effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td>data set rejected</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 3</th>
<th>The maximum effect value was not reached during the test but can be calculated on a theoretical basis if knowledge on the effect is sufficient to do so</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>data set accepted</td>
</tr>
<tr>
<td>NO</td>
<td>data set rejected</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 4</th>
<th>At least one data point is located within 10 to 90% of the variation in the observed effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>data set accepted</td>
</tr>
<tr>
<td>NO</td>
<td>data set rejected</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rule 5</th>
<th>The estimated ( EDR_{50} ) is between two experimental doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>data set accepted</td>
</tr>
<tr>
<td>NO</td>
<td>data set rejected</td>
</tr>
</tbody>
</table>

The estimated \( EDR_{50} \) can be used within the SDD analysis.

Figure 1. Rules applied on each data set from FREDERICA to reconstruct dose-effect relationships.
Table 4. Data selection criteria for datasets exhibiting a hormetic pattern.

<table>
<thead>
<tr>
<th>Curve shape</th>
<th>NOEC definition</th>
<th>Selection criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inverted U-shaped</td>
<td>the highest dose with a response &gt; 90% of the control</td>
<td>- at least 5 dose-response data points (the minimal number to fit a hormetic model with 4 parameters, requires the lower limit to 0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 1 control data point</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- at least 2 doses ≤ NOEC with a response numerically higher than the control</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 1 NOEC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- at least 1 dose &gt; NOEC with a response &lt; 90% of the control</td>
</tr>
<tr>
<td>U-shaped curve</td>
<td>the highest dose with a response ≤ 110% of the control</td>
<td>- at least 6 dose-response data points (the minimal number to fit a hormetic model with 5 parameters, lower and upper limit are different to 0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 1 control point</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- at least 3 doses ≤ NOEC with a response numerically lower than the control</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 1 NOEC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- at least 1 dose &gt; NOEC with a response &lt; 110% of the control</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>(1) The absence of a relevant control;</td>
<td>(2) The incapacity to achieve responses greater than (or less than, depending on endpoint) the control response (e.g. studies where the end point was survival and the control response was 100% or where the end point was tumour incidence and the control response was zero);</td>
</tr>
<tr>
<td></td>
<td>(3) at least two doses below the NOEC,</td>
<td>(4) at least one dose showing a priori criteria-based inhibition.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The curve fitting is based on the Levenberg-Marquardt algorithm and enables the \( EDR_{10} \) (or other \( EDR_k \)) to be calculated together with corresponding uncertainty. The extreme effect values, i.e. those obtained for the control group exposed only to the dose rate corresponding to the natural background \( d \), and a hypothetical group exposed to infinite dose rate \( c \) need to be determined in a systematic and robust way as their values greatly influence the resulting curve fit. A rule to initiate the fitting process was defined as follows: if the control effect value is 0 (continuous data), 0% or 100% (percentage data), this value is imposed on the model. Otherwise, the control value can be adjusted. The value for the maximum effect used is always imposed on the model to avoid irrational estimates (i.e. >100% or <0% or <0).

Hormetic dose rate-effects relationships:
The logistic functions previously described cannot be used to model dose responses that exhibit an initial response stimulation or effect minimisation. Some data sets from FREDERICA visually exhibit a hormetic pattern (i.e. a stimulation effect in low dose rates zone, Figure 3). These were processed through data selection criteria described in Table 4. Non-linear regression was applied to the hormetic data sets using the Braun-Cousens model:

\[
y(x) = c + \frac{d-c+fx}{1+\exp[b(ln(x) - ln(c))]}\]
where interpretation of $c$ and $d$ is the same as that for the logistic model, whereas $a$ and $b$ have no specific interpretation except the fit. The statistical test for the presence of hormesis is the test of $f=0$. For more detail, see Cedergreen et al. (2005).

The hormesis effect in the selected data is assessed statistically using the lack of fit test to compare the logistic and Brain-Cousens model fits with the DRC package (Ritz and Streibig, 2005) and R Software (R Development core team, 2005). For the effective hormesis data (for which the lack of fit test would be significant), the hormesis effect is described by means of the shape of the curve ($U$ or inverted $U$), the size of induction regarding control, the estimation of the dose rate corresponding to the maximal response and to the $ED_{50}$. Both data sets showing hormetic response relationships included in the SSD for derivation of benchmarks are presented in Appendix 1.

![Logistic model](image1.png)

![Hormetic model](image2.png)

Figure 3. Examples of the two dose rate – effect models used to estimate $ED_{50}$ value; the $y$-axis represents a measure of response relative to the control treatment (where the control is shown as the data point marked on the $y$-axis).
Derivation of screening values (step 3):

The last step of the methodology uses the EDR values calculated in step 2 to derive the HDRs (i.e. dose rate at which 95% of species will be affected below a 10% level) by applying the SSD method. The predicted no effect dose rate (PNEDR) is then obtained by applying a relevant assessment factor to the HDR to account for any residual uncertainties (e.g. lack of data for certain taxa or endpoints). The PNEDR is equivalent to the screening value referred to above.

There are several considerations that need to be addressed during this third step which have a direct and potentially considerable influence on the final benchmark value. These include the selection of data to include in the SSD, the precise methodology of fitting a distribution to these data, and the value of the assessment factor applied to the HDR. We discuss these issues in relation to the derivation of the PROTECT benchmark values below.

Selection of data

The work of Garnier-Laplace and Gibbin (2006) suggested that SSD for radiological effects can be created by using data across both terrestrial and aquatic ecosystems as resultant HDRs estimates were similar for species in both ecosystem types. Consequently, for the purposes of defining screening levels we have considered the available EDR values as one combined generic dataset. All 105 of the EDR values derived from references meeting the above criteria within the FREDERICA database are presented in Appendix 2.

As our protection goal is to protect populations from ionising radiation, the selection of which EDR should be included in the SSD needs to consider each endpoint's relevance for population sustainability. In an earlier approach, Garnier-Laplace et al. (2006; 2008) estimated the geometric mean EDR for a given species and a given category of endpoints among reproduction, morbidity and mortality. This approach has been challenged within PROTECT as it may produce an EDR which is not the most protective as it mixes endpoints of differing sensitivity within the SSD.

The approach used within PROTECT was to select the most sensitive (lowest EDR) endpoint for any given species. Genetic endpoints were not considered to be relevant to population sustainability, although these may be more sensitive. Reproduction endpoints were most often amongst the more sensitive and these are generally accepted as being population relevant (IAEA, 1992; UNSCEAR, 1999) (see Appendix 2). The approach of Environment Canada (2003) used the most sensitive reproductive endpoint for each wildlife group in a deterministic assessment factor approach. This selection required expert judgement of the ecological relevance of each individual endpoint.

The EDR values used in the final derivation of PNEDR values are identified in Appendix 2. The total number of EDR values was 20 comprised of 4 plants, 2 nematodes, 3 crustaceans, 2 molluscs, 2 birds, 4 fish and 3 mammals. There is considerable statistical uncertainty associated with some of the EDR estimates (as may be inferred by consideration of the figures presented in Appendix 1). An alternative dataset comprising EDR values with the lowest uncertainty for each species was therefore also compiled (Appendix 2).

To evaluate the robustness of the HDR resulting from this data selection, HDR values were also derived using slightly differing data selection approaches. These include the EDR with
the lowest uncertainty rather than the EDR\textsubscript{10} with the lowest value, or substituting the EDR\textsubscript{10} with an available HNEDR (Highest No Effect Dose Rate) value if this was lower (thus using results from experiments that did not fulfill the requirements to derive an EDR\textsubscript{10} value). The database was also investigated to determine whether HNEDR or LOEDR values from studies that did not allow determination of EDR\textsubscript{10} values could be used to increase the number of species included in the SSD. However, no suitable data were found.

Methodology of fitting a distribution to the selected data

The SSDs were constructed using a log-normal distribution by the approach of Dubouzin et al. (2003). The Direct Weighted Bootstrap method (DWB) was used to build SSDs and their confidence intervals. The bootstrapping was run for 1000 samples. The goodness of fit was tested by a Kolmogorov-Smirnov test with a Dallal-Wilkinson approach and by the multiple R-square coefficient between theoretical and empirical distributions.

A basic assumption of the SSD approach is that the species tested are representative of all species. Depending upon the proportions of test species from different trophic levels or taxonomic groups the validity of this assumption could be questioned. Dubouzin et al. (2004) and Forbes and Calow (2002) investigate an approach to weight data within an SSD for different taxonomic groupings although such data manipulation is not common practice in ecological risk assessments. The DWB method was used to enable the construction of samples in which the effect of different proportions of data among species and among taxonomic groups could be investigated. For instance, the analysis could be weighted to let the influence of species from dominating taxonomic groups (in terms of number of species) reflect this dominance even if they are not prevalent within the test species.

Within PROTECT, results from unweighted SSDs have been compared with those using a weighting based on taxonomic group. For the generic screening value, which is based on values from all species from all types of ecosystems, the weighting was based on proportion of species within three taxonomic groups (the small dataset available precluded further division): plants, invertebrates and vertebrates. As an example, the same weight was given to each taxonomic group, meaning that species in underrepresented groups (i.e. less species than the average number of species per group) were allocated a higher weight and species from over-represented groups were allocated a lower weight. Dubouzin et al. (2004) discuss other approaches to taxonomic weighting.

Furthermore, SSDs were also produced for which the data were weighted according to the uncertainty in the individual EDR\textsubscript{10} values. The weighting factors for uncertainty were given by dividing the values into three groups based on the coefficient of variance for each estimated EDR\textsubscript{10} value where 0-10\% was classed as low (L) uncertainty, 10-100\% as medium (M), and >100\% as high (H) uncertainty. Arbitrary weightings of L:M:H of 3:2:1 and 100:10:1 were applied and compared.

Choosing an appropriate assessment factor to apply to the generic HDR

As described above, whilst the TGD (EC, 2003) suggests that an assessment factor between 1 and 5 should be applied to the HC\textsubscript{3} value (equivalent to our HDR\textsubscript{3} value), it gives no clear guidance on how these assessment factors should be chosen.
<table>
<thead>
<tr>
<th>(AF = 1)</th>
<th>(AF = 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Many data</td>
<td>Few data</td>
</tr>
<tr>
<td>Predominantly field data</td>
<td>Predominantly laboratory data</td>
</tr>
<tr>
<td>Sensitive endpoints</td>
<td>Non-sensitive endpoints</td>
</tr>
<tr>
<td>Supporting evidence</td>
<td>Lack of evidence</td>
</tr>
<tr>
<td>Wide data spread</td>
<td>Poor data spread</td>
</tr>
</tbody>
</table>

Within PROTECT we have applied scores between one and three stars to the factors contributing to uncertainty given in Table 5 (where three *** denotes the least uncertainty). On this basis, the justification for selection of an appropriate AF for the generic screening value is outlined below.

**Amount and quality of data***: The data have been through a rigorous selection process from being quality controlled when first entered into FREDERICA through to the consideration of endpoint relevance. Quality and robustness of the data are further strengthened by the evaluation of the effects of weighting data according to taxonomic groups or \(EDR_{10}\) uncertainty and effect of using different input data (i.e. HNEDR if lower than \(EDR_{10}\)). The amount of data was above the minimum required according to the TGD.

**Field-lab data***: Although most of the data are from laboratory studies, the vast majority of available field observations (not included as not suitable for input to SSD) suggest that population relevant effects would not be observed at dose rates below the derived HDR₅ (17 \(\mu\)Gy h⁻¹).

**Sensitivity of endpoints***: We have selected the lowest \(EDR_{10}\) value for each species for observations of ecologically relevant endpoints.

**Data spread***: The overall data spread of the 20 data entries is fairly good covering plants, crustaceans, molluscs, annelids, fish, birds and mammals.

**Supporting indications***: The derived HDR₅ is comparable to, or lower than, the recommendations of ICRP, UNSCEAR, NCRP and IAEA (see Table 1). It is also comparable to the upper range of estimated background dose rates (1-30 \(\mu\)Gy h⁻¹) as given in the ERICA Tool (Brown et al., 2008). Available laboratory and field effects data for appropriate endpoints, as discussed below, are above the HDR₅ value.

On the basis of the above, we consider the application of an assessment factor of 2 to be justified. To avoid the application of an assessment factor (thus minimising expert judgements) and still address uncertainty in the data Twining et al. (2005) used the lower end of a confidence interval around the HDR₅. However, as PROTECT has followed the recommendations of the TGD (EC, 2005) we have applied an AF.
Table 6. Derived HDR₅₀ values (µGy h⁻¹) with 95% confidence interval within brackets using the standard methodology (EDR₁₀₀; lowest value and no weighting) as well as alternative input data and weighting options. See text for explanation of the different options.

<table>
<thead>
<tr>
<th>Data used</th>
<th>No weight</th>
<th>Weighting for uncertainty (100:10:1)</th>
<th>Weighting for uncertainty (2:1)</th>
<th>Weighting for organism group (1:1:1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDR₁₀₀; lowest value</td>
<td>17 (2-211)</td>
<td>28 (3-1-364)</td>
<td>21 (2-4-212)</td>
<td>34 (3-7-307)</td>
</tr>
<tr>
<td>EDR₁₀₀; lowest uncertainty</td>
<td>37 (5-9-322)</td>
<td>24 (4-6-188)</td>
<td>37 (5-6-288)</td>
<td>63 (13-240)</td>
</tr>
</tbody>
</table>

4.4 Resulting benchmark values

4.4.1 Generic Screening level estimates

The resulting generic HDR₅₀ when all 20 EDR₁₀₀ values are used to produce a generic SSD as described above, is 17 µGy h⁻¹ (Table 6). Table 6 also shows the resulting HDR₅₀ values when the alternative derivation methods were used as described above (weighting for organism group or uncertainty in individual EDR₁₀₀ values, or using alternative data, i.e. the EDR₁₀₀ value for each species with the lowest uncertainty rather than the lowest value or substituting EDR₁₀₀ with HNEDR if lower). As can be seen from Table 6, the median values derived by the different approaches to analysing the available data are similar especially when considering the uncertainty around the estimates (as indicated by the 95% confidence limits).

There were three instances when an available HNEDR was lower than the EDR₁₀₀ for a given species. However, use of these values resulted in a poor fit to the modelled distribution and this option was therefore rejected. Using the other alternative data or weighting options gave similar results as the unweighted approach using the lowest EDR₁₀₀ value for each species. This suggests that the derivation is robust and that high uncertainty in some of the individual EDR₁₀₀ values do not influence the results unduly. As weighting makes little difference to estimated HDR₅₀, and as it is not common practice and requires additional expert judgement, PROTECT has favoured the use of unweighted SSD. The robustness of the methodology is further supported by the similarity to the HDR₅₀ values previously determined by: (i) Garnier-Laplace et al. (2008) of 82 µGy h⁻¹ based upon a different data input selection which included some less sensitive endpoints in the SSD (see above); (ii) Twining et al. (2005) of 15 µGy h⁻¹ for aquatic organisms using HNEDR and LOEDR values as inputs into an SSD.

Applying the selected assessment factor of 2 results in a generic screening level of 10 µGy h⁻¹.

4.4.2 Organism group specific screening level estimates

As discussed above the application of a generic screening value to all organism types raises some problems when used in assessments as the most exposed organism identified may not necessarily be the organism most at risk. Ultimately, it would be desirable to have screening values for as many relevant groups as justifiable (probably taxonomically at the family or class level), however, currently we do not have enough data to achieve this. Consideration was therefore given to deriving values for three broad groups, namely plants, vertebrates and invertebrates recognising that these groupings each contain organism which are likely to have a range of radiosensitivities.
Table 7. Proposed organism group screening values (µGy h⁻¹), deterministically derived estimated PNEDR and HDR₃ values estimated using SSD or ‘small dataset’ methodologies (see text for explanations of these alternatives).

<table>
<thead>
<tr>
<th>Proposed PNEDR</th>
<th>n</th>
<th>Lowest EDR₁₀</th>
<th>Deterministically estimated PNEDR</th>
<th>HDR₃ generated using SSD**</th>
<th>HDR₃ estimated using ‘small dataset’ approach***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertebrates</td>
<td>2</td>
<td>9</td>
<td>3.6</td>
<td>0.4</td>
<td>2.1 (0.3-62)</td>
</tr>
<tr>
<td>Invertebrates</td>
<td>200</td>
<td>7</td>
<td>1030</td>
<td>100</td>
<td>505 (55-4447)</td>
</tr>
<tr>
<td>Plants</td>
<td>70</td>
<td>4</td>
<td>710</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**Estimated using SSD=10
***95% confidence limits presented in parenthesis
****Estimated using software of Vlaardingen et al. (2004); 90% confidence limits presented in parenthesis

The numbers of data points for each of these groups were: vertebrates (n=9), invertebrates (n=7) and plants (n=4). Even for vertebrates and invertebrates, the available data were therefore below the ideal requirements to enable a SSD to be generated according to the TGD. To derive organism specific screening levels three approaches were compared: (i) generate an unweighted SSD as above for both vertebrates and invertebrates; (ii) apply the small sample method within the EXT² programme (Vlaardingen et al., 2004) to generate HDR₃ values for each group; (iii) estimate a PNEDR for each group deterministically.

No attempt to generate an SSD was made for plants as the available dataset was too small. The EXT² programme has a function enabling HDR₃ values to be generated from small datasets (n=10) implementing the methodology described by Aldenberg and Luttik (2002). The method requires a suitably standard deviation (SD), for assessment of chemicals the assumption is made that a SD derived for similar chemicals/organisms (e.g. the programme contains predefined SD of pesticide toxicity values in birds – pooled across different pesticides) is available and can be applied to the chemical being assessed. However, for radioactivity we do not have alternative datasets from which to derive SD values. Therefore, we assumed that all three groups had the same SD value as the overall dataset of 20 values; an assumption which we acknowledge is unlikely to be valid. To estimate PNEDR values deterministically, an AF of 10 was applied to the lowest EDR₁₀ value within the dataset for each organism group, justified on the basis that for each group data, were available from more than 3 species (see Table 3 for guidance on selection of deterministic AF values from the TGD). Results from each of the three approaches are compared in Table 7; confidence intervals are also shown where appropriate.

The SSD and small dataset methods give broadly comparable results for vertebrates and invertebrates. Given our application of the small dataset method is limited by the lack of suitable SD values, we favour the SSD approach whilst acknowledging that the datasets are sub-optimal according to the TGD (which recommends n≥10). Statistically acceptable fits are achieved for the two SSD and the comparison with the small dataset method implementation (accepting the limitations of this) is encouraging. Therefore, for invertebrates and vertebrates we recommend using the SSD derived HDR₃ values to estimate organism specific PNEDRs. The arguments put forward above for the selection of an AF for calculation of the generic
screening level remain valid for the organism specific screening values with the exception that
the datasets are smaller (although coverage within each group is the same as for the generic
screening level derivation). Taking into account the smaller dataset, an AF value of 3 is
suggested. The resultant PNEDR for invertebrates is then 200 μGy h\(^{-1}\) (rounded to one
significant number). The resultant PNEDR for vertebrates would be approximately 0.7 μGy h\(^{-1}\)
which is similar to the value estimated deterministically (Table 7); this value is considerably
below any relevant observed effects measured in field studies. For example, Szakánska (2005)
reported only minor cytogenetic effects for mammals in the dose rate range 4-20 μGy h\(^{-1}\) from a
review of data from contaminated sites in former Soviet Union countries. The value is also
similar to background dose rates for many vertebrates (Beresford et al., 2008b; Brown et al.,
2004) and considerably lower than some reported values for aquatic organisms and estimates
for burrowing animals, both of which are of the order of 10^3 μGy h\(^{-1}\). A screening value <1
μGy h\(^{-1}\) for vertebrates would not be fit for purpose and therefore pragmatically we propose that
the actual HDR\(_{50}\) value of 2 μGy h\(^{-1}\) is currently our best estimate as the vertebrate screening
value. Environment Canada (2003) used an assessment factor of 1 in deriving radiological
benchmarks for a similar reason (see also Hingston et al., 2007b).

Given the lack of data for plants, the deterministic option has to be used to derive a suggested
PNEDR of 70 μGy h\(^{-1}\)

Taking into account the uncertainty associated with these estimates they should be considered
as indicative of the order of magnitude of values, rather than definitive numbers. These
illustrative organism group values were derived because we recognised that there would be
differences in radiosensitivity depending upon taxa. As discussed above, it would be desirable
to derive screening values for as many relevant groups as justifiable and this should probably
be at the taxonomic levels of family or class. The groupings selected for derivation of organism
group screening values in this report represent what could be practically achieved with the
current data. The PROTECT consortium considers that, whilst currently there may be less
confidence in the organism specific values we have derived compared to the generic screening
value (which appears to be fairly robust), that the derivation of more robust organism group
values should be pursued in the future. Table 8 compares the advantages and disadvantages of
the two types of screening value (with some comments being based upon current data
availability). The conceptual difference between the two approaches is that the generic value
should protect 95 % of all species whereas the organism specific values should protect 95 % of
species within each organism group. However, if organism group screening values are to be
derived, then all groups should be considered in an assessment; in the examples presented here,
use of just the lowest value, for vertebrates, could result in components of the vertebrate
foodchain not being adequately considered possibly resulting in indirect effects on vertebrates.
Accepting that there are differences in radiosensitivity between groups, it should be
acknowledged that the generic screening value will over protect some groups and under protect
others. For instance, on the basis of the currently available data we estimate that 83 % of
vertebrate species are protected at 10 μGy h\(^{-1}\). Obviously, some organism group screening
values will be higher than the generic screening value (plants and invertebrates in the examples
presented here) whilst others will be lower (vertebrates in the examples presented here).
Appendix 1. Graphs showing the fitted distributions and the derived $EDR_{10}$ values for the 20 datasets showing the lowest $EDR_{10}$ value for each species which have been used for derivation of the screening values presented within the report.
9.3 DETAILED ANALYSIS OF IRSN’S FEEDBACK FOR PLANNED/EXISTING SITUATIONS

To help the reader better understand the results of the environmental radiation risk assessments conducted by IRSN, two cases relating to contrasting facilities were analysed more in detail. The first case relates to the assessment conducted at a NPP, which has nuclear reactors that are in operation or are being dismantled as well as a waste repository. This study was conducted using the threshold limit values requested by the plant’s licensee to obtain authorisation to release radioactive effluents into the environment. The second case relates to a storage facility for residues of ore conversion. The assessment was conducted using the release estimates provided by the licensee.

In both studies, the assessment reported herein relates to aquatic environments for comparative purposes. All the figures are shown on the same page to facilitate this comparison. Lastly, the knowledge in the ERICA tool regarding the dose rates received by terrestrial and freshwater reference organisms due to exposure to natural radiation is provided in the last section. It, too, is compared to the benchmark values in the tool and of the ICRP. This information can be viewed in the tool’s Tier 2 assessment by clicking the Background tab on the Results page.

Illustrations shown

- Comparison of the estimated dose rates in relation to the benchmark values p.101
- Contribution of internal exposure vs. external exposure p.103
- Contribution of radionuclides to internal exposure p.104
- Comparison of the ‘background noise’ dose rates in relation to the benchmark values p.105

9.3.1 COMPARISON OF THE RESULTS IN RELATION TO THE BENCHMARK VALUES

The total dose rates estimated for each reference organism are compared first to the PNEDR proposed by default in the ERICA tool and then to any applicable DCRLs (Figure 14: NPP; Figure 15: storage facility). In both cases, the estimated dose rates are, overall, at least one order of magnitude lower than the lowest benchmark value presented. The most significant difference is for the storage facility and is due to the qualitative composition of the source term (alpha-emitters).
Figure 14: Comparison of the dose rates estimated for the aquatic reference organisms to the release threshold limit values at the NPP site with the PNEDR from the ERICA tool and the applicable DCRLs.

Figure 15: Comparison of the dose rates estimated for the aquatic reference organisms for estimated releases from the storage facility with the PNEDR from the ERICA tool and the applicable DCRLs.
9.3.2 CONTRIBUTION OF INTERNAL EXPOSURE VS. EXTERNAL EXPOSURE

The contribution of internal exposure and external exposure is presented for each reference organism in both studies (Figure 16: NPP site; Figure 17: storage facility). Depending on the organisms and their exposure medium (water surface, water/sediment interface, sediment) and the type of source term (gamma or alpha-dominant emission), the prevalent contribution is related to either route of exposure. The contribution of external exposure is significant only for organisms exposed to sediment.

9.3.3 CONTRIBUTION OF RADIONUCLIDES TO INTERNAL EXPOSURE

For example, the contribution of the various radionuclides to the dose rate received by the aquatic reference organisms due to their internal exposure, often predominant, was analysed (Figure 18: NPP plant; Figure 19: storage facility).

For the normal operation of nuclear power reactors, coupled with the releases associated with the dismantling of gas-cooled reactors and those of the future waste storage facility at the NPP site, $^{14}$C is the main contributor in terms of internal exposure for all or nearly all the reference organisms. $^{110m}$Sa is second main contributor, particularly for some sediment-dwelling organisms. The distribution for phytoplankton is completely different, with a major contribution of $^{123m}$Te, followed by $^{55}$Fe.

As the radionuclide spectrum for the storage facility is totally different, the contributions are also distributed in another way. For this facility, the main contributor to internal exposure of aquatic organisms is generally $^{230}$Th (except for sediment-dwelling organisms) along with uranium-238 and uranium-234. The other radionuclides play an insignificant role in the scenarios studied.

9.3.4 NATURAL BACKGROUND RADIATION AND BENCHMARK VALUES

The interface of the ERICA tool allows the user to access the characterisation of exposure of reference organisms to natural radiation by presenting a ‘typical’ dose rate and range of variation. These data, and the corresponding benchmark values, are listed for the freshwater and the terrestrial environments.
Figure 16: Contribution of internal and external exposure to the total dose rates estimated for the aquatic reference organisms (NPP site)

Figure 17: Contribution of internal and external exposure to the total dose rates estimated for the aquatic reference organisms (storage facility)
Figure 18: Contribution of the various radionuclides present in the source term to internal exposure of the aquatic reference organisms (NPP site)

Figure 19: Contribution of the various radionuclides present in the source term to internal exposure of the aquatic reference organisms (storage facility)
Figure 20: Dose rates received by the terrestrial reference organisms due to their exposure to natural radioactivity (diamond: typical value; green bar; range of variation; source: ERICA tool) and applicable DCRLs.

Figure 21: Dose rates received by the aquatic reference organisms due to their exposure to natural radioactivity (diamond: typical value; green bar; range of variation; source: ERICA tool) and applicable DCRLs.
9.4 DESCRIPTIONS OF THE ‘VALID’ APPROACHES, METHODS, TOOLS AND DATABASES

In this document, the term ‘validity’ means:

- For the approach and method: the latest version released, considered by their promoters as still being current and not replace by another version;
- For the tools and databases: maintained and available.

<table>
<thead>
<tr>
<th>Name</th>
<th>Level</th>
<th>Category</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERICA assessment tool</td>
<td>Europe</td>
<td>Tool</td>
<td>107</td>
</tr>
<tr>
<td>R&amp;D Publication 128 approach</td>
<td>Great Britain</td>
<td>Approach and tool</td>
<td>108</td>
</tr>
<tr>
<td>RESRAD-BIOTA</td>
<td>USA</td>
<td>Tool</td>
<td>109</td>
</tr>
<tr>
<td>K-BIOTA</td>
<td>South Korea</td>
<td>Approach and tool</td>
<td>110</td>
</tr>
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<td>Doses3D</td>
<td>Europe</td>
<td>Tool</td>
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<td>Approach</td>
<td>113</td>
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<td>Europe</td>
<td>Database</td>
<td>114</td>
</tr>
<tr>
<td>Wildlife Transfer Database</td>
<td>International</td>
<td>Database</td>
<td>115</td>
</tr>
</tbody>
</table>
What is the ERICA assessment tool?

The ERICA tool is a software system for assessing radiological risks for aquatic and terrestrial organisms. It is based on the integrated tiered approach developed during the European FASSET (FP5) and ERICA (FP6) projects.

Tier 1 assessments are conducted by comparing as risk quotients radionuclide concentrations in the environment and limits tabulated in ERICA.

Tier 2 assessments calculate dose rates that are compared to benchmark values proposed by the software or selected by the user. At this stage, the user can view and edit the parameters used in the calculation - concentration factors, solid-liquid distribution coefficients, dose coefficients and their weighting factors, and occupancy factors. New organisms and radionuclides (based on ICRP publication 107) can also be added provided the relevant information - particularly in terms of transport parameters - is available.

Tier 3 assessments allow the option to run probabilistic calculations provided the parameter probability distribution functions are defined.

The tool contains simple transport models, derived from IAEA SRS-19 that can be used if only the amounts of discharged radionuclides are known.

The ERICA tool can connect to the FREDERICA database to put into perspective the dose rates calculated based on exposure with effects listed in the literature.

Scope and limits

Chronic releases from nuclear facilities, excluding noble gases.

Fixed range of organism size and weight.

Radionuclides present in the ICRP database (ICRP 107).

Tool availability

The ERICA tool can be downloaded for free on the website of the same name.

Tool maintenance

The ERICA tool is maintained by six partners (NRPA, UK EA, CEH, Swedish Radiation Safety Authority, IRSN, CIEMAT), all of whom are involved in several ongoing projects (MODARIA, STAR, COMET). The results from these projects are integrated into the tool, as and when they become available, to improve the assessments made with it. Since being made available in 2007, the ERICA tool is in its 5th version, which was released in November 2012.
What is the approach of R&D Publication 128?
The United Kingdom included radiological risk in assessments of the impact of authorisations affecting Natura 2000 sites, under the 1994 Habitats Directive. As there was no international consensus, the UK Environment Agency and English Nature initiated, in 2001, an R&D project to develop a robust approach for assessing the environmental impact of radioactive releases authorised in the UK (17 radionuclides, without the possibility of adding others). This approach was applied to develop in correspondence three Excel® spreadsheets, one for each type of ecosystem likely to be impacted (freshwater, estuarine/marine and terrestrial).

The aim of the approach is to calculate the dose rates received by a defined series of organisms for which the dose coefficients have been predetermined based on their use of the environments exposed to radioactive discharges. These dose rates can then be compared with guideline values given in the report describing the approach (R&D Publication 128) and which contains effects tables for assessing any biological damage. The spreadsheets allow doses to wildlife to be calculating using generic or site-specific characteristics. The user can use default concentration factor values (taken from the literature review) to determine concentrations in the various organisms from those modelled or measured in the ecosystem compartments (water, soil, etc.). The user can also directly enter concentration values in the organisms.

Scope
Authorised radioactive releases, noble gases included.

Tool availability
Provided on a CD initially attached to R&D Publication 128, the spreadsheets are now freely accessible at the following links:
- Coastal model
- Terrestrial model
- Freshwater model

Tool maintenance
No changes have been made to the tool’s approach since the ERICA tool has been made available. Nevertheless, it is still available and is used in conjunction with other approaches, including the ERICA tool, due to its complementary aspects (inclusion of noble gases).
RESRAD-BIOTA

What is RESRAD-BIOTA?
RESRAD-BIOTA is the computer code in the RESRAD series of tools developed by the Oak Ridge National Laboratory for the US Department of Energy (US DOE) that calculates doses for non-human organisms. It implements US DOE’s graded approach methodology, described in DOE Technical Standard A Graded Approach for Evaluating Radiation Doses to Aquatic and Terrestrial Biota also known as the BIOTA manual (US DOE, 2002).

It is described as a user-friendly tool that provides a full spectrum of analysis capabilities, from practical, cost-effective screening to realistic dose estimates for plants and animals. At Level 1, radionuclide concentrations in environmental media are compared with guidelines (Biota Concentration Guides, BCG) that were determined by back calculation from protection endpoints proposed by the IAEA (1992) and UNSCEAR (1996). As the user progresses to Levels 2 and 3, fewer assumptions are made a priori but more site- or receptor-specific input data are required. Greater user flexibility is offered, particularly in the selection or creation of organisms. The tool contains allometric models that allow terrestrial or riparian mammals, birds and even simple trophic chains to be added.


Scope
Terrestrial and aquatic environments are covered via a series of organisms categorised into four groups: terrestrial animals and plants, riparian animals and aquatic animals. The tool’s nuclear database contains 45 radionuclides.

Tool availability
The RESRAD-BIOTA code can be downloaded for free on the RESRAD website (http://web.ead.anl.gov/resrad/).

Tool maintenance
Code maintaining and version control are currently done by DOE through Argonne. The predecessor to RESRAD-BIOTA is the BCG Calculator. Although the BCG Calculator will be replaced by RESRAD-BIOTA and is no longer maintained, it is still available on some US government sites.

The latest release of RESRAD-BIOTA (V.1.5, December 2009) features probabilistic functions for analysing uncertainty on most of the input parameters.
What is K-BIOTA?

K-BIOTA is a computer code for calculating doses for non-human organisms. It was developed by the Korea Atomic Energy Research Institute (KAERI) in South Korea. Developed to assess the radiological impact on endemic organisms of Korea, its main objective is to implement an integrated methodology for addressing the recent issue of protecting Korea’s ecosystems from ionising radiation (Keum et al., 2011). K-BIOTA is not regulatory in scope. Its purpose is to serve as a basis for future research on dosimetric assessments for non-human species in Korea.

K-BIOTA calculates a whole-body absorbed dose rate. Internal and external dose conversion factors are predetermined for selected organisms according to the ICRP reference approach and used in combination with concentration factors specific to the endemic organisms of Korea, measured in the laboratory or taken from the literature.

Scope

Pursuant to the ICRP reference approach, one plant and seven animals were selected from the RAPs (ICRP 2008). Their size was taken from the corresponding endemic species of Korea.

A set of 25 radionuclides was used based on the programme for monitoring low- and intermediate-level waste at the Gyeongju disposal facility.

Tool availability

No information available.

Tool maintenance

No information available.
DOSES3D

What is Doses3D?

Doses3D is the environmental dosimetry tool developed under the European EPIC Project (Environmental Protection from Ionising Radiation, Inco-Copernicus Programme). Dedicated to the Arctic environment, EPIC had four objectives: (i) collate information on the transfer and fate of radionuclides in Arctic ecosystems; (ii) suggest adapted reference organisms; (iii) jointly develop dosimetric models; and (iv) compile knowledge on effects for the selected organisms.

Doses3D offers a probabilistic calculation of the dose conversion factors for phantom organisms (Golikov and Brown, 2003). If the necessary data are not available, a simplified geometric approximation is made from ellipsoids, cylinders, etc. Any organism can therefore be considered.

Scope

A list of nine terrestrial organisms and eight aquatic organisms was defined as part of EPIC. A simplified geometric representation was adopted for each.

Initially applicable to 25 radionuclides, the tool has been expanded to cover 42 radionuclides by default.

Tool availability

No information available.

Tool maintenance

Many outputs from the EPIC project have been replaced by equivalent elements from the ERICA project. The Doses3D tool is no longer used in this context. There is no publicly accessible information about its maintenance.
What is SADA?

Developed by the US Environmental Protection Agency (US EPA) and the Nuclear Regulatory Commission (NRC), the tools included in the SADA platform include integrated modules for visualisation, geospatial analysis, statistical analysis, human health risk assessment, ecological risk assessment, cost/benefit analysis, sampling design, and decision analysis. The capabilities of SADA can be used independently or collectively to address site-specific concerns when characterising a contaminated site, assessing risk, defining a sampling strategy, and when designing remedial action.

Designed initially for non-radioactive contaminants, SADA can be applied to radionuclides for screening assessments based on Biota Concentration Guides (BCG) defined by US DOE (see RESRAD-BIOTA). SADA can thus be used for assessments equivalent to those produced by RESRAD-BIOTA Level 1, but with an additional feature that allows data to be considered spatially, not just as points.

Scope

See RESRAD-BIOTA.

Tool availability

SADA is an open-source program that is available for free on the website of the Institute for Environmental Modelling at the University of Tennessee, which develops it.

Tool maintenance

Version 5.0.78 is the latest version available for download. The previous version (V.4) is still maintained.

The Oak Ridge National Laboratory (ORNL, www.ornl.gov) has now joined the group of developers and will contribute to upcoming versions of SADA.
What is in the Canadian Environmental Protection Act?

The Canadian Environmental Protection Act of 1999 (CEPA) requires the publication of a Priority Substances List (PSL) identifying substances to be assessed to determine whether they are toxic to the environment or human health. The Canadian government must then determine the toxicity of these substances as defined in Section 64 of CEPA, i.e. whether they (i) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (ii) constitute or may constitute a danger to the environment on which life depends; (iii) constitute or may constitute a danger in Canada to human life or health. Substances that are thus recognised as toxic may be included in the Act and be the subject of the risk management measures described in the legal instruments. Releases of radionuclides from nuclear facilities have thus been identified as requiring environmental assessment pursuant to CEPA (http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2A379917-1), which was finalised in 2003 (Environment Canada, 2003).

The relevant data for assessing the possible effects on the environment were obtained from annual reports filed by licensees, environmental status reports, environmental impact statements and harmful concentrations of radiation doses. Critical Toxicity Values (CTVs) determined for aquatic and terrestrial organisms, by taxon (fish, benthic invertebrates, algae, macrophytes, mammals, terrestrial plants, terrestrial invertebrates) have been converted to Estimated No-Effects Values (ENEVs) using an application factor. The radiological risk is then assessed using the quotient method, by comparing the irradiation doses calculated for the organisms of interest to the adapted ENEVs.

ENEVs were used to determine the radiological toxicity, as defined in CEPA, of radionuclide releases from nuclear facilities. They indicated a limited potential of these releases for harmful effects on the environment, which nevertheless requires regular monitoring of these releases to evaluate whether risk management initiatives may be needed for ionising radiation in the future.

Scope

Chronic exposure at low doses arising from normal operations.
Increment compared to the background noise.

ENEV availability

A copy of the Environment Canada publication presenting ENEVs can be obtained from the Environment Canada electronic library.

Maintenance/evolution

There are no planned revisions of the ENEVs published in 2003.
**What is FREDERICA?**

The FRED database was originally created as part of the EC 5th Framework Programme FASSET (Framework for the Assessment of Environmental Impact). Its main use was to gather literature data to help summarise dose-effect relationships between exposures to ionising radiation and their effects on non-human organisms.

FRED became FREDERICA, an expanded, improved and more user-friendly database during the European ERICA project (Environmental Risk from Ionising Contaminants: Assessment and Management, 6th Framework Programme). It is available for use on its own or in conjunction with the ERICA assessment tool for undertaking risk assessments for the impact of ionising radiation on non-human species.

FREDERICA contains more than 1300 references for a total of around 32,000 data entries. The information in it spans various groups of organism for various effect categories - primarily mutation, morbidity, reproduction and mortality. Three categories (stimulation, adaptation and ecology) were added following the merging of FREDERICA with EPIC, a database containing only 1350 entries, primarily from Russian-language literature.

**Scope**

More than half the data relates to external exposure of terrestrial organisms in acute conditions. Chronic exposure corresponds to around one-fourth of the information collected.

**Database availability**

You must first register to access FREDERICA. Registration and access are free of charge. FREDERICA should be accessed using Internet Explorer only.

**Database maintenance**

FREDERICA was last updated during the IAEA EMRAS II Programme (WG6, 2009-2011). Accessibility to FREDERICA is guaranteed as part of maintenance of the ERICA tool.
What is the Wildlife Transfer Database?

Most analyses of existing approaches to assessing exposure of wildlife to ionising radiation find that the main source of uncertainty regarding dose rates thus estimated is related to the determination through modelling of radionuclide concentrations in exposed organisms, which are to assess at the whole body scale rather than for organs.

The purpose of the database is to gather firstly data collected during the EMRAS II Programme (WG5, 2009-2011) on radionuclide transfer to wildlife. This data also form the basis of a manual in IAEA’s Technical Reports Series that was written in collaboration with IUR and an ICRP working group (http://www-.pub.iaea.org/books/IAEABooks/10514/Handbook-of-Parameter-Values-for-the-Prediction-of-Radionuclide-Transfer-to-Wildlife).

The parameter values reported in the database are to be used in environmental radiological assessments to estimate the transfer of radioactivity to non-human biota, i.e., wildlife (defined here as including all non-domesticated animals and plants as well as self-sufficient allochthonous populations). Transport parameter values applicable to ICRP reference animals and plants (RAPs, ICPR 2008) are derived from it.

Scope

All ecosystems, all organisms (adult life stage if no other specifications), all radionuclides for which data are available.

Concentration factors are expressed in terms of whole organisms without distinction as to parts or organs and in terms of fresh weight.

Database availability

You must first register to access the Wildlife Transfer Database. Registration and access are free of charge.

The Wildlife Transfer Database should be accessed using Internet Explorer only.

Database maintenance

The aim was to provide a ‘living resource’ that is regularly updated on a voluntary basis by anyone who adds to it, the idea being to update it once a year.

The database is maintained by the consortium that created it.
### 9.5 DESCRIPTIONS OF THE RELEVANT CONVENTIONS

<table>
<thead>
<tr>
<th>Name</th>
<th>Level</th>
<th>Category</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSPAR</td>
<td>European</td>
<td>Environmental protection</td>
<td>117</td>
</tr>
<tr>
<td>Helsinki</td>
<td>European</td>
<td>Protection of the Baltic Sea</td>
<td>118</td>
</tr>
<tr>
<td>London</td>
<td>European</td>
<td>Dumping of anthropogenic wastes at sea</td>
<td>119</td>
</tr>
<tr>
<td>Aarhus</td>
<td>Europe and beyond</td>
<td>Public information on environmental matters</td>
<td>120</td>
</tr>
<tr>
<td>Espoo</td>
<td>European</td>
<td>Transboundary environmental impact</td>
<td>121</td>
</tr>
</tbody>
</table>
What is the OSPAR Convention?

The Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) was signed and ratified by the contracting parties to the original Oslo (1972) or Paris (1974) Conventions, which it replaces. Adopted in 1992, together with a final declaration and an action plan, OSPAR entered into force on the 25th of March 1998. Recommendations and agreements adopted under the aforementioned Conventions continue to be applicable, unaltered in their legal nature, unless they are terminated by new measures adopted under OSPAR.

The OSPAR Convention deals with the following five areas:

- Prevention and elimination of pollution from land-based sources (Annex I);
- Prevention and elimination of pollution by dumping or incineration (Annex II);
- Prevention and elimination of pollution from offshore sources (Annex III);
- Assessment of the quality of the marine environment (Annex IV);
- Biodiversity and ecosystems (Annex V).

The Contracting Nations and the Commission

The European Union and 15 nations (Germany, Belgium, Denmark, Spain, Finland, France, Iceland, Ireland, Luxembourg, Norway, the Netherlands, Portugal, United Kingdom, Sweden, and Switzerland) cooperate within the OSPAR Convention via a commission made up of five committees, each of which is dedicated to a specific strategy.

OSPAR strategies

Work related to six strategies (biodiversity and ecosystems, eutrophication, hazardous substances, offshore industry, radioactive substances, joint assessment and monitoring programme) is undertaken in relation to the monitoring and assessment of the status of the marine environment, the results of which are used to follow up implementation of the strategies and the resulting benefits to the marine environment. The six strategies fit together to underpin the ecosystem approach.

Radioactive Substances Committee

The objective is that, by the year 2020, discharges, emissions and losses of radioactive substances will be reduced to levels where the additional concentrations in the marine environment above historic levels are close to zero. The Committee must therefore identify pressures and their impacts on the marine environment and deal with radionuclide concentrations and the resulting doses for human and non-human organisms (Assessment on Impact of Anthropogenic Sources of Radioactive Substances on Marine Biota).
What is the Helsinki Convention?
Signed on the 22d of March 1974, the Helsinki Convention aims to help reduce pollution in the Baltic Sea Area from discharges from waterways, estuaries, canals, dumping and ships, as well as from atmospheric pollutants. The Convention sets up a Baltic Marine Environment Protection Commission (HELCOM), whose responsibility is to monitor implementation of the Convention and issue recommendations. One of its objectives is to achieve good environmental status of the Baltic Sea by 2021.

The Contracting Parties to the Convention
The Helsinki Convention was signed by all the countries with shorelines along the Baltic Sea (Denmark, Germany, Sweden, Estonia, Finland, Latvia, Lithuania, Poland, and the Russian Federation). The first Convention entered into force in 1980. A new Convention was signed in 1992.

Obligations of the Contracting Parties
The objectives of the Convention are similar to those of the OSPAR Convention for the North-East Atlantic, a regular partner. The Contracting Parties agree to not use groups of substances (DDT and its derivatives, PCB’s and PCT’s) in the Baltic Sea Area. They also decide on all appropriate measures and collaborate together to control and reduce to a minimum telluric-based pollution (mercury and cadmium, chromium, copper, lead, hydrocarbons, pesticides, radioactive materials, acids, oils and petrochemical wastes, substances that may float, etc.).
The Contracting Parties take a series of measures to prevent the discharge of harmful substances and wastewater by ships, the dumping of wastes (dredged material excepted, subject to prior authorisation, and cases were the safety of human life, a ship or an aircraft is endangered) and pollution from exploration and exploitation of the seabed or its subsoil.
The Convention also addresses the specific case of nuclear wastes and weapons dumped in the Baltic Sea during World War II. These wastes are possible aggravating causes of the appearance of dead zones in the Baltic sea, which is highly fragile due to the fact that it is enclosed.
Lastly, the Contracting Parties cooperate together in the field of scientific and technological research and agree to jointly adopt rules concerning responsibility for damage resulting from acts or omissions in contravention of the Convention.

Case of radioactive substances
The Baltic Sea has the world’s highest average $^{137}$Cs concentrations in surface water. Radioactive fallout from the Chernobyl accident is the dominating source for artificial radionuclides in the Baltic Sea. Specific targets to reduce $^{137}$Cs pollution have been set to bring concentrations back to pre-Chernobyl levels (average concentrations measured in 1984-1985) in fish (2.5 to 2.9 Bq.kg$^{-1}$ fresh muscles), water (15 Bq.m$^{-3}$) and sediment (1640 Bq.m$^{-2}$). Other artificial radionuclides are also the subject of voluntary monitoring by the Contracting Parties.
What is the London Convention?

The “Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter 1972” - the “London Convention” for short - was called for by the United Nations Conference on the Human Environment, held in Stockholm in 1972. In force since 1975, it is one of the first global conventions to protect the marine environment from human activities. Its objective is to promote the effective control of all sources of marine pollution and to encourage the Contracting Parties to take all practicable steps to prevent pollution of the sea by dumping of wastes and other matter. Currently, 82 States are Parties to this Convention.

What is the London Protocol?

In 1996, the “London Protocol” was agreed to further modernize the Convention and, eventually, replace it. Under the Protocol all dumping is prohibited, except for possibly acceptable wastes on the so-called “reverse list”. This list includes the following wastes and other materials:

1. dredged material;
2. sewage sludge;
3. fish wastes;
4. vessels and platforms;
5. inert, inorganic geological material (e.g., mining wastes);
6. organic matter of natural origin;
7. bulky items primarily comprising iron, steel and concrete; and
8. carbon dioxide streams from carbon dioxide capture processes for sequestration.

The London Protocol entered into force on 24 March 2006. There are currently 32 Parties to the Protocol.

Exemption from radiological monitoring

In 1972, the London Convention prohibited the sea dumping of radioactive wastes and other radioactive material. However, the Contracting Parties acknowledged that wastes may contain ‘background’ radiation (natural radionuclides, fallout from testing, etc.). Directives enforcing the ‘de minimis’ concept were developed based on work by the IAEA to provide guidelines for deciding whether materials to be dumped at sea may be exempted from radiological monitoring (and thus be dumped provided they are not otherwise prohibited from disposal).
What is the Aarhus Convention?

The Convention, whose premises date back to the Rio Declaration (Principle 10), was signed by 39 Member States of the UNECE (United Nations Economic Commission for Europe) on 25 June 1998 and entered into force on 30 October 2001. It grants the public rights to access to information, participation in government decision-making processes and justice in environmental matters. By offering the public involvement in environmental discussions, it meets the requirements of transparency and proximity, synonymous with good public governance.

The Contracting Parties to the Convention

The Convention was established as part of the UNECE. It has been signed and ratified by every country in Europe, some countries in Asia Minor and Central Asia, Israel, Canada and the United States (http://www.unece.org/env/pp/ratification.html).

Pillars of the Convention

The Convention grants three basic rights to citizens and the associations that represent them:

- **access to information**: right of any actual or legal person to gain access to information on the environment that is in the possession of the public authorities, such as (a) the state of components of the environment (air, water, soil, biological diversity, etc.); (b) factors (substances, energy, noise, radiation, wastes, emissions, discharges and other releases to the environment, etc.); decisions and activities likely to affect the environment; and (c) the state of human health and safety, conditions of human life, and the state of cultural sites and buildings.

- **public participation in the decisions** on the issuing of licences for some activities or facilities, the development of plans, programmes and policies relating to the environment, and regulations. In France, public participation occurs primarily via public debate, public inquiry, availability to the public and concertation procedure.

- **access to justice**, which ensures proper enforcement of the aforementioned two rights. It grants the public the right to have access to legal procedures and remedies for violations committed by the public authorities regarding access to information and public participation, as well as the possibility to challenge any violation of environmental legislation.

The Convention also specifically addresses two major issues in terms of transparency (GMOs and information on pollutant release and transfer registers (PRTR), the inventory of which contains 86 stable priority pollutants). France has transposed into national law the Community directives adopted in application of the Convention, most particularly in its 2005 Environmental Charter and related articles of law. In France, access to justice has been ensured by the Commission d’Accès aux Documents Administratifs (CADA) since 1978.
Espoo: Convention on Environmental Impact Assessment in a Transboundary Context

http://www.unece.org/env/eia/welcome.html

What is the Espoo Convention?
The official name of the Espoo Convention (or EIA Convention) is the Convention on Environmental Impact Assessment in a Transboundary Context. It gets its name from the city of Espoo, in Finland, where the Convention was adopted and opened for signature in 1991, before entering into force six years later, on the 10th of September 1997.

Scope of the Convention (items directly or indirectly related to radiation protection)
The Convention contains a list of 17 examples of actions or projects that must be addressed by the signatory parties to the Convention. Three of these 17 items are listed below, directly or indirectly related to radiation protection:

2. Thermal power stations and other combustion installations with a heat output of more than 300 megawatts (except research installations for the production and conversion of fissionable and fertile materials, whose maximum power does not exceed 1 kilowatt continuous thermal load);
3. Installations designed for the production and/or enrichment of nuclear fuels, for the reprocessing of irradiated nuclear fuels or for the storage, disposal and processing of radioactive waste;
14. Major mining, on-site extraction and processing of metal ores or coal.

Principles established by the Convention
In Article 2 on its general provisions, the Espoo Convention states that the parties shall “take all appropriate and effective measures to prevent, reduce and control significant adverse transboundary environmental impact from proposed activities” as well as take the necessary legal, administrative or other measures to this end.

This general obligation is built around two principles:
- Notification of neighbouring countries of any project likely to cause a significant adverse transboundary impact.
- Assessment of the environmental impact of such projects as part of procedures allowing the public in neighbouring countries to be informed and be provided with possibilities for making objections.

Other provisions are besides planned to strengthen cooperation on transboundary environmental issues.
### 9.6 DESCRIPTIONS OF CURRENT PROGRAMMES

<table>
<thead>
<tr>
<th>Name</th>
<th>Level</th>
<th>Category</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAR</td>
<td>European</td>
<td>Network of excellence (6th Framework Programme)</td>
<td>123</td>
</tr>
<tr>
<td>COMET</td>
<td>European</td>
<td>Project (7th Framework Programme)</td>
<td>124</td>
</tr>
<tr>
<td>MODARIA</td>
<td>International</td>
<td>IAEA Programme</td>
<td>125</td>
</tr>
</tbody>
</table>
What is STAR?

STAR is the result of discussions that began with FUTURAE (Future for Radioecology in Europe - coordination action of the 6th Framework Programme Euratom 2007-2009) to review research and expertise in radioecology in Europe and to assess the feasibility of creating a network of excellence. The alarming diagnostic regarding cuts in funding, the risk of facilities closing, the fragmentation of research teams and the lack of replacement of senior experts prompted the creation, in June 2009, of the European Radioecology Alliance (Era, http://www.er-alliance.org, see p.126). The STrategy for Allied Radioecology (STAR) network of excellence, created in February 2011 under the Euratom 7th Framework Programme, is the Alliance’s first accomplishment and will last for a period of 4.5 years. Coordinated by IRSN, STAR brings together seven of the initial partners of the Era (BfS, CIEMAT, STUK, CEH, SCK•CEN, NRPA, IRSN), as well as the University of Stockholm, Sweden, and the Norwegian University of Life Sciences.

What are its objectives?

The objective is to pool the knowledge, infrastructure and research efforts of each partner to create a genuine “European research area in radioecology” whose activity will be guided by a 15-year Strategic Research Agenda (SRA) that also includes needs expressed outside the consortium. This agenda is one of the key results expected of STAR (https://wiki.ceh.ac.uk/display/star/Strategic+Research+Agenda?atl_token=b7af5b8a2738a7a7e67fc1001dc06a509af7cce3).

The key aim of STAR is the integration - i.e., the pooling - of human, financial and infrastructure resources in order to optimise radioecological research at the European scale.

Organisation of the STAR Programme

STAR is organised into seven Work Packages (WP). Besides the coordination of the project (WP1), three WPs are specifically devoted to integration - the creation of radioecology observatories (WP2), radioecology training throughout Europe (WP6) and the dissemination of knowledge and data (WP7). Three WPs are specifically reserved for research on priority themes relating to environmental radiation protection:

- Development and proposal of an integrated approach for assessing the radiological risk for humans and the environment (WP3).
- Examination of the relevance of taking into account the context of multi-pollution, which could modify the risk estimated for pollutants taken in isolation on account of interactions between contaminants (WP4).
- Determination of relevant ecological effects for situations of exposure to low doses and proposals for associated environmental protection criteria (WP5).

IRSN is participating in all of this work and coordinates the entire project (WP1) in addition to WP5.
What is COMET?

COMET (COordination and iMplementation of a pan-Europe instrumenT for radioecology) is a consortium (2013-2017) funded by the European Union under the 7th Framework Programme and coordinated by the SCK•CEN (Belgium).

The COMET consortium brings together 13 organisations (from 9 European countries as well as Ukraine and Japan), including IRSN. Its aim is to strengthen integration of research in radioecology, the discipline of studying the transport and transfer of radionuclides in the environment as well as their potential impact on people and ecosystems. To do this, COMET relies heavily on work conducted by the European Radioecology Alliance, whose eight founding members are part of the consortium.

Organisation of the COMET Programme

The programming tools proposed as part of COMET are developed jointly, based on after those developed under the Open Project for the European Radiation Research Area (OPERRA). One of the key deliverables of the COMET project is the updating of the Strategic Research Agenda for radioecology, prepared under the aegis of STAR and the Alliance, and its conversion into a roadmap.

A call for projects was opened in December 2013 regarding three areas, two of which are likely to relate to environmental radiation protection:

- Marine modelling, including marine biotope exposure predictions;
- Particle behaviour, including wildlife exposure predictions;
- Modelling of the human food chain.

In addition to these tools, the COMET project will include research on the effects of low doses of ionising radiation on ecosystems and on improvements to and validation of risk assessment models in emergency and post-accident situations. IRSN is involved in all of this work and coordinates research on the effects of low doses.
What is the MODARIA Programme?


MODARIA will also facilitate implementation of the revised version of the Basic Safety Standard. Lastly, it provides an international focal point for radioecology and helps Member States to develop and maintain knowledge and competence in this area as well as that of environmental assessments.

Organisation of the MODARIA Programme

The overarching principle is to test, compare and, where appropriate, develop models and their application guidelines for assessing the exposure of populations and the radiological impacts on the environment by sharing experience, ideas and information about current international research. Special attention is given to models for particular environments as well as the establishment of consensus on data sets that are generally applicable in environmental transfer models.

Working groups involved in environmental radiation protection

Environmental radiation protection is addressed within two themes by three complementary working groups.

*Exposure and Effects on Biota*

WG8 - Biota modelling: Further development of transfer and exposure models and application to scenarios

WG9 - Models for assessing radiation effects on populations of wildlife species

*Uncertainties and variability*

WG4 - Analysis of radioecological data in IAEA Technical Reports Series publications to identify key radionuclides and associated parameter values for human and wildlife exposure assessment
9.7 DESCRIPTION OF THE ORGANISATION OF RADIATION PROTECTION RESEARCH IN EUROPE

European Radioecology Alliance

http://www.er-alliance.org

What is the European Radioecology Alliance?

The Alliance is a transnational organisation that aims to integrate the research programmes of partners involved in radioecology, specifically in the field of assessing the impact of radioactive substances on humans and the environment. The Alliance was created following the findings of the FUTURAE Project (Future for Radioecology in Europe) as part of the 6th Framework Programme, which mapped the state of radioecological research in Europe between 2007 and 2009.

FUTURAE reported that technical facilities were being closed for a number of reasons - significant cuts in funding, a lack of strategic coordination between R&D programmes in the field, the dispersal of research teams and a strong tendency to not replace outgoing experts.

The members of the Alliance

In mid-2009, eight European organisations (BfS, Germany; CIEMAT, Spain; STUK, Finland; SSM, Sweden; CEH, United Kingdom; SCK•CEN, Belgium; NRPA, Norway; IRSN, France) signed the memorandum of understanding that created the European Radioecology Alliance. The Alliance’s partners intend to eventually integrate all their research programmes in assessing the impact of radioactive substances on humans and the environment. The aim is also to maintain and enhance skills and experimental infrastructure in Europe.

STAR and the Alliance

Funded in part by the European Commission, the Strategy for Allied Radioecology project (STAR, see p.123) is the Alliance’s first achievement. This led to the initiation of a Strategic Research Agenda (SRA), which aims to define and prioritise the areas of research for the coming 15 years and which the Alliance will support. The network’s objective is also to contribute to setting up the technical and organisational infrastructure needed to pool together research programmes diagonally with the Alliance, which is gradually taking over.

The Alliance and the other European radiation protection platforms

The first roadmap derived from the SRA was established in September 2013 as part of COMET and last for 5 years (see p.124). It initiates the organisation and strengthening of ties between the Alliance and the European research platforms NERIS (emergency response and post-accident phase) and MELODI (low doses), which are summarised in the figure on the following page. Subjects of common interest among the three entities have been identified and are discussed in documents that will soon be published on the Alliance’s website.
The ALLIANCE SRA build around the three major components of the Risk Assessment for man and environment.

Common interests with NERIS, MELODI and EURADOS are visualised schematically.

**Human and wildlife exposure**
- Flows and Concentrations in compartments (biotic, abiotic), including human food chain
- Spatial scale (local, regional, global)
- Timescale
- Ecosystem types
- Climate
- Key environmental descriptors
- Other stressors
- Resource use type

**Scientific Challenge 1**
- Doses to human and wildlife

**Radiation effects on living organisms**
- Interactions with biomolecules
  - Cellular responses
  - Tissue/organ responses
  - Organism responses (reproduction, growth, survival, behaviour, cancer)

**Scientific challenge 2**
- Population responses
- Community and Ecosystems
  - Structure, function, services

**Risk characterization and management**
- Exposure - effects profiles
- Sensitivity analysis
- Uncertainty analysis
- Multi-criteria analysis
- Decision support tools
- Communication with stakeholders

**Scientific challenge 3**
- Cross-cutting extrapolation issues

**Research Lines 1 to 4**

**Research Lines 5 to 9**

**Research Lines 10 to 15**

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**Challenge 1**
1. Identify and mathematically represent key processes that make significant contributions to the environmental transfer of radionuclides and resultant exposures of humans and wildlife.
2. Acquire the data necessary for parameterisation of the key processes controlling the transfer of radionuclides.
3. Develop transfer and exposure models that incorporate physical, chemical and biological interactions, and enable predictions to be made spatially and temporally.
4. Represent radionuclide transfer and exposure at a landscape or global environmental level with an indication of the associated uncertainty.

**Challenge 2**
5. Mechanistically understand how processes link radiation induced effects in wildlife from molecular to individual levels of biological complexity.
6. Understand what causes intra-species and inter-species differences in radioactivity (e.g., among cell types, tissues, life stages, among contrasted life histories, influence of ecological characteristics including habitats, behaviour, feeding regime...).
7. In a broader exposure context, understand the interactions between ionising radiation effects and other co-stressors.
8. In a broader ecological context, understand the mechanisms underlying multi-generational responses to long-term ecologically relevant exposures (e.g., maternal effects, hereditary effects, adaptive responses, genomic instability, and epigenetic processes).
9. Understand how radiation effects combine in a broader ecological context at higher levels of biological organisation (population dynamics, trophic interactions, indirect effects at the community level, and consequences for ecosystem functioning).

**Challenge 3**
10. Integrate uncertainty and variability from transfer modelling, exposure assessment, and effects characterisation into risk characterisation.
11. Integrate human and environmental protection frameworks.
12. Integrate the risk assessment frameworks for ionising radiation and chemicals.
13. Provide a multi-criteria perspective in support of optimised decision-making.
14. Integrate ecosystem services, ecological economics and ecosystem approaches within radioecology.
### 9.8 Table Summarising the Main Demonstration Elements Underpinning Each Recommendation

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Main Elements of Justification and Item(s) Underlying the Demonstration</th>
</tr>
</thead>
</table>
| **(R1)** IRSN considers that the explicit consideration of protection of the environment from radioactive substances within the existing corpus of international reference documents (e.g., basic radiation protection standards, international conventions, special legislation in some member States) must lead to the adoption of a French position on protecting the environment per se from ionising radiation. Such a position will be useful to technical experts participating in current or future working groups in this field. | - Change in the international radiation protection system (international BSS)  
- Introduction in the European basic radiation protection standards (Euratom BSS)  
- Taken into account in the regulations of some neighbouring countries (United Kingdom, Finland)  
- Subject discussed in international bodies  
   Items 1; 4; 6; 7; 17; 20; 26; 36; 37; 38; 53 |
| **(R2)** IRSN considers that the inclusion, in France, of the demonstration of protection of the environment from ionising radiation in any project that may impact the environment is perfectly in line with the French Environmental Code and, more specifically, the provisions of Article 916 of French decree No. 2007-1557 on basic nuclear installations. | - Demonstration made for other stressors (chemical/thermal)  
- Current content of the EIA  
   Items 8; 11 |
| **(R3)** IRSN considers that the demonstration of protection of the environment from radioactive substances must be integrated into the environmental impact assessment, to the same extent as with the assessment conducted for chemical substances. IRSN recommends that, in France, this demonstration be routinely requested from the licensees of any facility or activity involving controlled environmental releases of radioactive substances that may have an ecological impact. Such demonstration shall be commensurate with the environmental issues. | - Consistency in the EIA approach (= consider all source of interference in the same way; => treat people and the environment in parallel)  
- Demonstration made in other European countries  
- EIA, a regulatory element for the authorisation of discharges  
- Principle of proportionality to the environmental challenges set out in regulatory texts  
   Items 8; 9; 10; 11; 12; 70 |
| **(R4)** IRSN recommends using a graded approach consistent with the principle of proportionality to the issues set out in French legislation. Such an approach enables resources and means to be better allocated based on the expected risk and allows efforts to be focused on cases requiring a closer look. | - Recommended graded approach used widely for all environmental risk assessment  
- Approach adopted for environmental radiation protection (RESRAD-BIOTA, ERICA tool and implicitly ICRP)  
- In line with the principle of proportionality with the environmental issues  
   Items 12; 15; 16; 116; 117; 118 |
| **(R5)** IRSN considers that the tiered ERICA approach, which is compatible with and more operational than the ICRP approach, forms the basis to be followed to explicitly demonstrate protection of the environment during the assessment and control of radiological impacts associated with planned environmental exposure situations, in addition to the approach used for human radiation protection. This approach is used widely in Europe and was adopted a few years ago by a number of nuclear operators in France. It is | - Analysis of the strengths and weaknesses of the various approaches: Consistent with the others and more operational  
- European consensus  
- The approach used most  
- Already used by operators  
- Supported/used by some international organisations in the field (UNSCEAR, IUR)  
   Items 77; 78; 79; 80; 103; 104 |

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16 “The environmental impact assessment comprises an analysis of the facility’s direct and indirect, temporary and permanent effects on the environment and particularly on public health and safety, the climate, neighbourhood inconveniences due to noise, vibrations, odours or lighting, on sites, landscapes and natural environments, on fauna, on flora and biological equilibria, on crops and on the protection of property and cultural heritage.”
similar in method and uses the concepts of the ICRP approach whilst providing a tool and associated databases that are regularly updated.

(R6) Regarding environmental radiation risk assessments, IRSN recommends having the assessor choose benchmark values that are best suited to the situation under assessment and provide evidence of the source of said values (as is the case with the practices used to assess ecological risks associated with chemical substances).

- Some benchmark values based on expert judgement
- Various, yet consistent values (between organisations, according to taxonomic level, etc.)
- Work under way to strengthen/supplement the set of values
- Choice and justification of choice: integral part of the demonstration; responsibility of the assessor

Items 88; 89; 90; 91; 92

(R7) IRSN proposes setting up a working group whose objective would be to draft a technical guide describing a standardised and optimum method of using the ERICA approach and tool. This working group shall take into account improvements in international methodologies expected from the ICRP and IAEA and other such organisations. It is also recommended to train users in the methods and tools in order to coordinate their deployment.

- Lack of international harmonisation
- International work under way for technical guides
- ‘User’ effects highlighted (project/programme test cases - FASSET, ERICA / EMRAS 1 and 2)
- Some applications have wrinkles that still need to be ironed out (storage - BIOPROTA) – uncertainties, long term

Items 66; 72; 73; 101; 102; 105; 106

(R8) IRSN considers that the tiered ERICA approach makes it possible to cover existing exposure situations, particularly through its tiered assessment method. To supplement the feedback for these situations, other cases of application similar to the case studies handled within the Mines Joint Expert Group (GEP Mines), may be necessary to reinforce this statement; while including international advances in the field.

GEP-mines feedback, with:
- Effectiveness of screening (number of at-risk situations identified?)
- Difficulty in sharing/communicating probabilistic approaches (level 3)
- Difficulty in using monitoring data

Items 119; 120; 121;

(R9) Regarding planned exposure situations, IRSN recommends that current environmental radioactivity monitoring practices be reviewed to assess whether the data acquired can be used as additional proof for radiation impact assessments for ecosystems. Additionally, such a review shall also cover the use, for the same purpose, of the results from monitoring practices currently used to monitor the quality of media and biodiversity (e.g., case of the WFD and the MSFD). Regarding existing exposure situations, IRSN recommends supplementing the approach of demonstrating via the environmental impact assessment by implementing a specific ecological monitoring strategy where warranted by the level of exposure to ionising radiation (i.e., accordingly to the conclusions of the radiation risk assessment).

- Monitoring = one of the ‘regulatory elements’ of environmental protection
- Correspondence with what is referred to as the integrated ‘ecosystem approach’ (i.e., non-stressor-specific)

Items 28; 75; 93; 119

(R10) In the event of a major nuclear accident (i.e. Chernobyl - or Fukushima-type), IRSN considers that the priority of the emergency is to protect human populations. During the post-accident phase, protecting the environment may be considered as one aspect to take into account to better manage contaminated areas. This matter could be dealt with by a dedicated working group. In view of the state of the art, the radiological risk assessment method for non-human species must be adapted and the necessary data must be supplemented in order to be able to respond to such situations. The proposed group’s

UNSCAR feedback - assessment of the health and environmental impacts following the Fukushima-Daiichi accident
- Consideration of the post-release phase for a correct dosimetric estimate – need for kinetic models - and benchmark values adapted to ‘acute’ effects
- Use of ‘typical’ monitoring data
- Communication
- Need for agreeing on the main principles to be adopted (extension of the scope of the CODIRPA?)

Items
work will extend to environmental monitoring practices. In terms of smaller accidents, attention should also be given to emergencies where protecting the environment would be essential, particularly in cases of accidents/incidents that impact uninhabited conservation areas.