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Overview of international status of considering radiological protection of non-human biota in the context of deep geological disposal of radioactive waste

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Overview of international status of considering radiological protection of non-human biota in the context of deep geological disposal of radioactive waste

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ABSTRACT

There has relatively recently been considerable development of methodologies and recommendations by authoritative international organisations on the protection of the environment from detrimental effects of ionising radiation. This includes the change of paradigm from assuming the environment being protected when people are to acknowledging the need of demonstrate the protection of the environment for its own sake. There have been no particular concern over environmental radiation hazards, though, but the driver has rather been to fill a conceptual gap in the radiation protection system. The current Swiss regulatory requirements for geological disposal of radioactive waste (preparation work of which predates the final breakthrough of the paradigm change) address the environmental protection at the general level of conserving biodiversity. However, little practical means are provided or requirements stipulated at the moment, aside of a general reference to observing the development with the recommendations of the International Commission on Radiation Protection (ICRP).

After a brief summary of mechanisms of radiation effects on biota and their manifestation at various levels of biological organisation, and a concise evaluation of the level of their understanding in general, this report provides an up-to-date review of the current international framework for addressing radiological protection of the environment primarily in the context of disposal of radioactive waste and examples of current national requirements and practical approaches and tools to assess the exposures of and impacts on the 'non-human biota'. Some examples of their implementations in assessments of radioactive waste disposal, spent nuclear fuel encapsulation plants and other exposure situations are also provided.

The purpose of the current report is to support the Swiss regulator to develop their requirements and guidance if deemed necessary. Based on the discussion in the report, the authors' view is that there hardly is an argument related to the topics covered in this report against requiring more explicit demonstration of the protection of the environment also in Switzerland, even though such requirements should not be very prescriptive at this stage and rather aim at providing information to stakeholders than setting specific constraints.

Keywords: *disposal of radioactive waste; nuclear facilities; non-human biota; environmental radiation protection; environmental impacts; radioactivity; ionising radiation; current best practice; regulation.*

ZUSAMMENFASSUNG

In den letzten Jahren erarbeiteten die massgeblichen internationalen Organisationen wesentliche Entwicklungen bei der Methodik und den Empfehlungen zum Schutz der Umwelt vor nachteiligen Auswirkungen von ionisierender Strahlung. Dies umfasst den Paradigmenwechsel von der Annahme, die Umwelt würde geschützt, wenn die Menschen geschützt werden, hin zur Anerkennung, dass die Umwelt um ihrer selbst willen geschützt werden muss. Grund dafür waren keine konkreten Bedenken zu einer radiologischen Gefährdung für die Umwelt, vielmehr sollte eine konzeptuelle Lücke im Strahlenschutzsystem geschlossen werden. Die derzeitigen behördlichen Anforderungen in der Schweiz für die geologische Tiefenlagerung von radioaktivem Abfall (vorbereitende Arbeiten von vor dem Paradigmenwechsel) befassen sich mit Umweltschutz zur generellen Erhaltung der Biodiversität. Momentan gibt es jedoch nur wenige praktische Mittel oder Vorgaben, abgesehen vom generellen Hinweis, die Entwicklungen der Empfehlungen der Internationalen Strahlenschutzkommission (ICRP) im Blick zu behalten.

Der Bericht beginnt mit einer kurzen Zusammenfassung der Mechanismen der Auswirkungen von Strahlung auf Biota und ihre Manifestation auf unterschiedlichen Ebenen der biologischen Organisation und einer knappen Bewertung ihres Verständnisses im Allgemeinen. Weiterhin bietet dieser Bericht einen aktuellen Überblick über den derzeitigen internationalen Rahmen für den Schutz der Umwelt vor Strahlung vorrangig im Zusammenhang mit der geologischen Tiefenlagerung von radioaktivem Abfall und zeigt Beispiele für die derzeitigen nationalen Anforderungen und praktischen Herangehensweisen und Werkzeuge für die Beurteilung der Belastung von und der Auswirkungen auf 'nicht-menschliche Biota' auf. Einige Beispiele für ihre Anwendung im Rahmen von Begutachtung der nuklearen Entsorgung, der Verpackungsanlagen für abgebrannte Kernbrennstoffe und anderen Expositionssituationen werden ebenfalls genannt.

Das Ziel des vorliegenden Berichts ist die Unterstützung des Schweizerischen Regulators bei der Entwicklung seiner Anforderungen und Richtlinien bei Bedarf. Ausgehend von der Diskussion im Bericht vertreten die Autoren die Auffassung, dass es kaum ein Argument hinsichtlich der im vorliegenden Bericht abgedeckten Themen gibt, das gegen eine ausdrücklichere Darlegung des Schutzes der Umwelt auch in der Schweiz spräche, auch wenn solche Anforderungen in diesem Stadium nicht sehr präskriptiv sein sollten, sondern eher als Information für Interessensvertreter dienen sollten anstatt spezifische Beschränkungen vorzugeben.

Schlüsselwörter: *Entsorgung von radioaktivem Abfall; Kernanlagen; nicht-menschliche Biota; Schutz der Umwelt gegen Strahlung; Auswirkungen auf die Umwelt; Radioaktivität; ionisierende Strahlung; derzeit beste Vorgehensweise; Regulierung.*

TABLE OF CONTENTS

1 INTRODUCTION

In this introductory chapter, the current Swiss national requirements to addressing safety of geological disposal of radioactive waste are summarised. Thereafter the purpose, scope and arrangement of this report are explained at the end of the chapter.

Current Swiss national requirements

The Nuclear Energy Act (Federal Assembly 2003) and the Nuclear Energy Ordinance (Federal Council 2004) stipulate the top-level requirements for nuclear facilities in Switzerland. The key guideline for deep geological repositories is ENSI-G03 (ENSI 2009a, b) that also provides the radiological protection criteria for the post-closure phase. For the operational phase of a deep geological repository, the Radiological Protection Ordinance (Federal Council 2017) and the radiological protection criteria specified in other guidelines (ENSI 2010, 2015) shall be applied (ENSI 2009a[1]). Requirements relating to chemotoxic substances are set through environmental protection legislation (ENSI 2009a, b).

A safety case for the operational phase and the post-closure phase is required for the general, construction and operating licence applications (ENSI 2009a; Federal Assembly 2003), as well as for the application for the confirmation of final closure, and its level of detail has to be proportionate to the stage of the licensing procedure and it has to be updated periodically to represent the best knowledge (ENSI 2009a).

At the moment, there are no explicit requirements in Switzerland on the radiological protection of non-human biota applying to geological disposal of radioactive waste. However, whereas *"the geological disposal of radioactive waste may result in only low additional radiation exposure to individual members of the [human] population"* (ENSI 2009a), the environment is to be protected *"as the natural basis for the existence of humans and other living beings"* (ENSI 2009a) so that *"biodiversity may not be put at risk"* (ENSI 2009a). This corresponds to international aspirations for sustainable development (ENSI 2009b). Also, risks arising in the future may not be greater than those permissible today, and *"foreseeable future use of natural resources may not be unnecessarily restricted"* (ENSI 2009a).

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[1] The references to the other guidelines have been updated based on the information received from ENSI.

In a safety case, *"the possible radiological impacts of future evolutions have to be assessed using envelope variants"*, that is, *"variants for the waste, the engineered and natural barriers in and around a repository, the biosphere and human living habits"* so that the radiological impact is highly likely larger than that of actual future evolutions (ENSI 2009a). Also, *"the range of variation of possible releases of radioactive substances to the biosphere"* need to be reported for all scenarios (ENSI 2009a) in addition to the more direct radiological endpoints. Dose and risk calculations are to be performed *"up to the time of maximum radiological impact of the repository"* and *"for a period up to one million years, it has to be shown … that the* [radiological] *protection criteria can be met"* (ENSI 2009a). *"For longer time periods, the range of variation of possible regional radiological impacts from the repository has to be estimated taking into account inherent uncertainties"*, and *"these impacts may not be significantly higher than natural radiological exposure"* (ENSI 2009a). Even if human settlement can be ruled out for a time period, the presence of humans is to be assumed by means of applying a 'reference biosphere' (ENSI 2009a). Possible climate evolution variants and associated biosphere models shall be defined under the assumption of the living habits of people being realistic in a present-day perspective (ENSI 2009a).

Somewhat related to the present context in terms of potential exposure environments, a geological repository must be monitored at least in respect of *"springs and groundwater, soils, water bodies and the atmosphere in the area potentially influenced by the repository"* (ENSI 2009a).

However, although the efforts of the International Commission on Radiological Protection (ICRP 2007) for estimating radiation effects on biota have been acknowledged, it has been deemed that no specific recommendations regarding respective dose limits existed and that, on the other hand, the requirement to always postulate human presence in the safety analyses (*cf.* 'reference biosphere' above) should also provide sufficient protection to the other biota, in line with the standpoint of the IAEA safety requirements (IAEA 2006b [2]) in force at the time (ENSI 2009b). Since these Swiss regulatory requirements these international requirements and recommendations have been updated, though, which has been one of the motivations for the present study. The present international situation is described later in the report.

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[2] This Safety Standard has since been superseded by (IAEA 2011a).

This report

This report is intended for a review on addressing radiological protection of the environment (*i.e.*, non-human species) primarily in the context of disposal of radioactive waste with the purpose to support ENSI to develop the Swiss regulations if deemed necessary. Even though being a review, it is acknowledged that the amount of potentially relevant literature is exhaustive, and thus the underpinning material has been chosen somewhat selectively especially regarding more practical examples.

The subsequent chapter lays a foundation to the remainder of the report in terms of providing a brief summary on mechanisms of effects of ionising radiation on biological organisms. Thereafter, international policies and frameworks, as well as some examples of national requirements and current international developments, are presented in chapter 3. Then, further information is provided on the most commonly used biota assessment methodologies (chapter 4) and on the supporting material, tools and examples available to implement these (chapter 5). At the end, in chapter 6, key contents of the report is briefly summarised and some conclusions are drawn.

This report has been compiled and edited by Ari Ikonen and Ville Kangasniemi of EnviroCase, Ltd., and the work has been coordinated by Jürgen Hansmann (ENSI).

2 EFFECTS OF IONISING RADIATION ON NON-HUMAN BIOTA

This chapter briefly summarises mechanisms of radiation effects in biological organisms. As the intention here is to provide an introductory overview, and not a comprehensive account, the following text is for convenience largely adopted from (ICRP 2003), although there would be numerous other sources available as well[3]. For a more detailed summary, (UNSCEAR 2011, pp. 224–227) is recommended, with a wealth of further, yet summarised, information in their subsequent chapters. Even though there has been considerable research on the matter especially very recently, for example the UNSCEAR updates and white papers on the Fukushima situation (UNSCEAR 2014, 2015, 2016a, 2017) conclude that little has been changed the picture in fundamental context of radiobiology.

Even though there are differences in manifestation of the effects for exposure to different types of radiations in different types of plants

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[3] For example, for an elaboration within largely the same data basis, see (ICRP 2008, section 5.3).

and animals, and in humans, the mechanisms are similar. Basically, effects of ionising radiation on multicellular organisms occur on a number of levels of biological organisation, as a sequence (*e.g.*, ICRP 2003, fig. 3.1; UNSCEAR 2011) of

- radiation damage in the DNA;
- molecular mechanisms;
- effects on cells (cell lethality, transformation, mutation);
- effects on tissues;
- effects on individuals (mortality, morbidity, hereditary effects, reduced reproductive success);
- effects on the population;
- effects on the community; and
- effects on the ecosystem(s).

With the increasing level of organisation, not only a higher number of impacts from other stressors, but also an increasing number of corrective and compensating factors can be expected to play a role (including natural selection at the highest levels).

It has been evidenced from many studies using various types of cells from animals and plants, that DNA is the critical primary target for the induction of biological effects of ionising radiation in all living organisms. Thus, the wealth of data on initial radiation mechanisms of relevance for humans (*e.g.*, UNSCEAR 1986, 1996, 2000, 2001, 2008) are probably relevant to many other organisms as well. Ionising radiation induces many different kinds of DNA damage, and not all are equally important for the radiation protection. Also, although the cells of most mammals have roughly the same amount of DNA, they show considerable differences in radiosensitivity. (ICRP 2003). In general, according to a dogma in radiobiology, cells are radiosensitive if they are mitotically active, undergo many cell divisions and are functionally undifferentiated (Bergonié & Tribondeau 1906 referred to in ICRP 2003). Most cell production in mammals occurs in the bone marrow and the small intestine, and in their other tissues (*e.g.*, central nervous system), radiosensitivity is greatest during early development. The radiation response of these tissues in mammals, and possibly in all vertebrates, can be expected to be similar to that of humans. For other organisms, though, radiosensitive tissues may be quite different. In plants, the radiosensitive parts are usually the meristem tissues, which are located in the roots and shoot tips (and in trees, in an annulus around the trunk). (ICRP 2003).

The energy deposition in biological systems is well described by the concept of absorbed dose[4]. The difference arising from the heterogeneous spatial distribution of the energy deposited at low doses or dose rates, and subsequent difference in biological effects, can be quantified by applying a ‘relative biological effectiveness’ (RBE) factor that related to a defined biological endpoint in a specified organism or tissue. In the radiation protection of humans, related but different radiation-weighting factors are applied. Regarding the non-human biota, there has been much interest in proposing similar factors (*e.g.*, see references in ICRP 2003, para. 71)[5]. High radiation doses or dose rates may kill all large number of cells, thereby impairing the function of vital organs and tissues. This type of deterministic harm occurs above a certain threshold dose, and the severity of the effects increases with dose. Cancer or hereditary effects are examples of stochastic effects, for which the probability of induction (but not the severity) is assumed to be proportional to the dose in the low dose and dose rate regime. For the purpose of protection of species other than mammals, it has been considered premature to distinguish between deterministic and stochastic effects. Instead, broader categories such as early mortality (dying earlier than otherwise), morbidity (a reduction in general wellbeing, including effects on growth and behaviour) and reduced reproductive success (including effects on fertility and fecundity[6]) are commonly used. (ICRP 2003). Data on dose rates in natural background and on those causing chronic radiation effects on some broad categories of biota are exemplified in Tables 1 and 2.

Ionising radiation may also cause damage that is transmitted to subsequent generations, but particularly for non-human organisms, interpretation of its significance at the population level (*i.e.*, fitness and survival of the population) is difficult due to natural selection; only mutations conferring a selective advantage in particular environmental conditions will spread in the population and ‘neutral’ mutations may persist over many generations, but ‘deleterious’ mutations tend to be selected against in the population. Even though these categories collectively reflect the limitations of our current knowledge, they are nevertheless similar to the endpoints often used for risk assessments of other environmental stressors. Also therefore, they are considered

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[4] A physical dose quantity representing the mean energy imparted to matter per unit mass by ionising radiation. The unit of the absorbed dose is gray (Gy).

[5] Weighting factors proposed to account for the different cellular-level effect mechanisms of different kinds of radiation vary, for example, for alfa radiation in the range of 1–40 (*e.g.*, UNSCEAR 2011, pp. 249–251). However, such range of uncertainty can be argued to dwarf in comparison with overall uncertainties in safety assessments for geological disposal of radioactive waste.

[6] (Potential) ’reproduction rate’ of an organism or population (capacity to produce means of reproduction), the lack of fecundity being called sterility.

relevant to the needs of nature conservation and other forms of environmental protection. (ICRP 2003).

Table 1. Natural background dose rates to biota (ICRP 2008, pp. 85–86, and references therein). It is to be noted that there remains considerable data gaps, so these data should be considered only illustrative.

Biota category	Dose rate (µGy/h)		
	Total	External	Internal
Benthic fish (adult)	0.04 – 0.4		
Aquatic macrophytes (seaweed)	0.08 – 0.5		
Benthic crustacean (adult)	0.08 – 0.6		
Pelagic freshwater fish	0.5 – 0.8		
Terrestrial plants	0.08 – 0.8		
Deer		about 0.02	
Mice		about 0.03	
Earthworms		about 0.08	
Some mammals			1.7 – 3.3 (from Po-210) 8.3 – 290 (from radon)

Table 2. Summary of data on chronic effects of radiation exposure for plants, fish and mammals (UNSCEAR 2011, table 39 of annex E, and references therein).

Biota category	Dose rate (µGy/h)	Effects	Endpoint
Plant	100 – 1000	Reduced trunk growth of pine trees	Morbidity
	400 – 700	Reduced numbers of herbaceous plants	Morbidity
Fish	100 – 1000	Reduction in testis mass and sperm production, lower fecundity, delayed spawning	Reproduction
	200 – 499	Reduced undifferentiated male germ cells and sperm in tissues	Reproduction
Mammals	<100	No detrimental endpoints have been described	Morbidity, mortality, reproduction
Generic (terrestrial and aquatic ecosystems)	about 80	Statistical species sensitivity distribution approach (SSD; see section 3.2.5), the dose rate at which 95% of the species in the ecosystem are protected	Morbidity, mortality, reproduction

Effects on populations, biota communities and ecosystems occur, in principle, only if individual organisms are affected. Also empirical data on the effects are generally obtained, largely for practical reasons and the need of controlled conditions to draw conclusions, for individuals rather than for higher levels of organisation. However, caution should be made for situations where the effects on individuals might not be easily recognisable, but the effects on a population might be manifested. Depending on the circumstances, assessments of radiation effects may have to be made at the level of the individual, population, community, or ecosystem. This will depend upon many factors, including the number of individuals affected within a population, the nature and role of the different types of populations within a community, and so on. In natural environment, the situation can become very complex because of the interaction between each individual (and population) and their surroundings; a change in one ecological factor may have a drastic effect on another. The effects can also be modified by the presence of other environmental stressors or by combined effects of them and the radiation; compensatory, additive, or synergistic effects of radiation and other environmental factors can be expected. In the long run, the resulting effect of ionising radiation on an ecosystem, especially on one comprising of several exposed communities of plants and animals, is likely to be determined by a balance between damaging and recovery processes at various levels of the biological organisation. (ICRP 2003).

However, based on theoretical models of ecosystem functioning developed for a limited number of ecosystems, species and life stages of interest, also the ecosystem integrity is protected, if the most sensitive species or life stage is protected. Further, although most of the information is based on studies on individuals, some field observations on populations, ecosystems, and communities have been made under controlled laboratory and experimental field conditions, and some observations are available from studies made regarding the accidental releases of high levels of radionuclides into the environment (*i.e.*, prominently at Chernobyl and Fukushima). Such studies have shown that reproduction is likely the most limiting endpoint regarding survival at the population level, depending of definitions of a population and its survival. (ICRP 2003). Also other evidence points towards the most important populations-level effects arising through those on reproduction and reproductive success of the individuals (*e.g.*, UNSCEAR 1996, 2011). However, interpolation further at a community level and beyond is more complicated (*e.g.*, ICRP 2003; Garnier-Laplace *et al.* 2004; UNSCEAR 2011, 2014, 2015, 2016a, 2017) and still under debate (*e.g.*, Barnett *et al.* 2016). In addition, taking into account of the combined effects of radiation and other environmental stressors (*e.g.*, chemicals or temperature) may have a different combined effect than that from each stressor in isolation (*e.g.*, UNSCEAR 2014, 2015, 2016a, 2017).

Also in a reasonably recent COMET workshop on radiation effects on biota the divergent results on radiation effects that have been reported for a range of species and endpoints from field studies from Chernobyl and Fukushima regions, it was concluded that *"some of these field studies are not compatible with the outcomes of laboratory studies"* (Barnett *et al.* 2016). More practically, it was concluded that in a large number of field studies, results seem improbable in the light of laboratory experiments with similar species and higher dose rates prevailing from natural background in many countries, but also that these data should not be dismissed and, quite the opposite, further efforts should be made to explain the 'photographic evidence' reported. In examining these and further field studies, attention should be based, among other issues, on appropriate determination of the external exposure (dose/dose rate), heterogeneity of the contamination, reliable estimation of internal exposure (that has rarely been accounted for in field studies so far), consideration of actual or potential exposure history and the history of the site (including involvement of other stressors), sufficient control data, sufficiently rigorous statistical treatment and, all in all, recognition of the limitations of the work. It was agreed also that also no-effect results should be published and that all data should be openly and freely available to promote wide re-evaluation and collective efforts to address these important issues. (Barnett *et al.* 2016).

3 INTERNATIONAL FRAMEWORK AND EXAMPLES

To systematically and quantitatively assess radiation effects on biota, shared objectives and principles (including aims to protect individuals or populations), quantities and units, biological endpoints, target organisms selection, reference dose models, dose–effects relationship and means to assess compliance need to be agreed upon (*e.g.*, Pentreath 1999). In this chapter, present views of key international bodies regarding the matter of radiation protection of the environment and examples from national requirements are presented. At the end, a summary of benchmark values adopted is dawn and current development efforts are discussed about.

As international bodies, the United Nations Scientific Committee on Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA) are considered. In addition, the views promoted through the OSPAR conventions are briefly presented and the European Union (EU) is addressed as a valid regional multinational entity of relevance through proximity. Typically, the path from scientific observations to radiation protection regulations follows the sequence of (*e.g.*, ICRP 2003):

- radiological and epidemiological studies assessed by the UNSCEAR;
- recommendations of the ICRP, formed in consultation with ICRU and IRPA);
- discussions in the IAEA, the OECD/NEA, and other organisations;

- international (*e.g.*, IAEA, ILO, WHO, PAHO, FAO, NEA) and regional standards (*e.g.*, EU directives) and international conventions (*e.g.*, OSPAR); and
- national legislation for radiological protection.

For the radiological protection *per se*, the ICRP maintains the international system of radiological protection used world-wide as the common basis for radiological protection standards, legislation, guidelines, programmes, and practice – adopted in general also by the IAEA and many others.

3.1 Radiation protection principles

In brief, the IAEA Safety Fundamentals (IAEA 2006a) present ten safety principles, with explanations, to meet the fundamental safety objective of protecting people and the environment from harmful effects of ionising radiation. These regard the responsibility for safety; role of government; leadership and management for safety; justification of facilities and activities; optimisation of protection (to provide the highest level of safety that can reasonably be achieved); limitation of risks to individuals; protection of present and future generations; prevention of accidents; emergency preparedness and response; and protective actions to reduce existing or unregulated radiation risks.

The fundamental principles of the ICRP correspondingly emphasise justification, optimisation of protection, and application of dose limits (ICRP 2007). These have been developed in terms of protecting humans, but the ICRP considers that it is necessary to provide advice also with regard to all exposure situation ‘irrespective of any human connection’ with them (ICRP 2007), as discussed further below (particularly sections 3.2.2 and 4.5).

3.2 Radiological protection of the environment

Overall, there has been a considerable change in the paradigm in respect of the radiation protection of the environment. Traditionally, the premise of the ICRP 1977 recommendations (ICRP 2008) — if people are appropriately protected, also the *“other living things are also likely to be sufficiently protected”* although *“not necessarily individual members of those species”* — has been keenly adopted globally. Still in their 1990 recommendations (ICRP 1991), the ICRP essentially kept the ground, albeit through slightly different wording (*“are not put at risk”*).

However, impacts of the long development for sustainable development that culminated at the Rio Convention and Declaration of 1992 (UN 1992; ICRP 2003, 2008; UNSCEAR 2011) were seen also in the field of radiation protection and, for example, the UNSCEAR explicitly addressed the topic in their 1996 review report (UNSCEAR 1996), the IAEA laid an ethical basis and a plan (IAEA 2002, 2005), and the ICRP set up a Task Group and later a Committee dedicated to the matter (see section 3.2.2). Parallel, assessment methodologies (see chapter 4) were developed for example in the UK (Copplestone et al. 2001), in the US (USDOE 2002) and in Europe (for the several projects, see below), proceeded by a number of earlier efforts to assess the effects of exposure of plants and animals to ionising radiation (*e.g.*, Davey & Jeffree 1988; IAEA 1976, 1988, 1992; NEA 2002, 2003, 2004; Pentreath 1996; Thompson 1988; Whicker & Hinton 1996). Such development has propagated, most prominently, to the present ICRP recommendations (ICRP 2007; section 3.2.2) and other regulations.

Even though the view of the protection of the environment shifted from the long-held anthropocentric view on one expressly considering biota (ICRP 1977 *vs.* ICRP 2007; *e.g.*, Jaeschke *et al.* 2016), the need to explicitly demonstrate that the environment can and will be protected from the effects of ionising radiation should not be taken to have been driven by any particular concern over environmental radiation hazards, but rather developed to fill a conceptual gap in radiological protection (ICRP 2003, 2007; also, *e.g.*, Jaeschke *et al.* 2016).

To assess the significance of the exposure of biota, a range of benchmarks have been used, notably those from reviews undertaken by UNSCEAR (UNSCEAR 1996) and IAEA (IAEA 1992). With the mutual development, current approaches usually depend on ‘reference organisms’, generally proposed in the paper by Pentreath (1999). However, it is generally considered that the objectives of environmental protection relate to ‘ecosystem health’ and are thus related to populations, communities or ecosystems rather than individuals, with the possible exceptions of protected or threatened species warranting individual-level considerations (*e.g.*, Hingston *et al.* 2007, Robinson *et al.* 2010).

In the following, the main views and approaches of international bodies are described in the order of typical propagation of scientific findings into regulations. At the end of this section, their most prominent commonalities are then briefly described.

3.2.1 United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

In their reports to the United Nations General Assembly, the UNSCEAR started with fundamental radiobiology (UNSCEAR 1958, particularly annexes F–H). There was an increasing focus on the radiation effects on humans (UNSCEAR 1962, 1966, 1969, 1972, 1977, 1982, 1986, 1988, 1993, 1994, 2000, 2001), albeit largely based on animal or cellular experiments. As described in the following, special recognition of non-human biota has been included in the 1996, 2010 and 2014 reports (UNSCEAR 1996, 2010[7], 2011, 2014). However, the latest report to the General Assembly (UNSCEAR 2016b) does not again directly address exposures of non-human biota.

Prior to the 1996 report (UNSCEAR 1996), the Committee considered the non-human biota *“primarily as part of the environment in which radionuclides of natural or artificial origin may be presented and contribute to the internal exposure of humans via the food chain”*, but eventually this position was challenged (*e.g.*, Davey & Jeffree 1988, Thompson 1988), and the 1996 report summarised and independently reviewed information on the actual and potential exposures of various organisms resulting from various sources and on the responses of plant and animal individuals and populations to acute and chronic irradiation (UNSCEAR 2011). The 2011 report (UNSCEAR 2011) then built on the earlier report with new data on the effects of exposure to ionising radiation on non-human biota (regarding the impacts of the Chernobyl accident, particularly observations in field conditions, in addition to other literature and international developments) and concluded that there is no need to change the previous conclusions of the values of nominal chronic dose rats below which direct effects on non-human species are unlikely at the population level, but that there is a need to better understand the effects particularly regarding scaling from molecular and cellular levels to higher levels of ecological organisation, the role of multi-generational effects and chronic effects from multiple stressors; however, *“where data of suitable scientific quality are available for a specific species endpoints and/or other level of biological organisations, the Committee would encourage their use in assessments of the potential effects of radiation exposure”* (UNSCEAR 2011). Further information has since been added in terms of a report dedicated to the effects of the Fukushima Daiichi nuclear accident (UNSCEAR 2014[8]) and its update reports (UNSCEAR

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[7] An overview from the 1996 report (UNSCEAR 1996) to the year 2008 on their page 18.

[8] This report includes also a summary of assessments for non-human biota through utilisation various equilibrium and dynamic models (UNSCEAR 2014, app. F of annex A).

2015, 2016a, 2017) that consider also the impacts on non-human biota. On the general level, the earlier conclusions on the radiation effects remain, although there is on-going debate on interpretation of some of observations especially from field conditions.

3.2.2 International Committee on Radiological Protection (ICRP)

As outlined above, the ICRP gives out recommendations and guidance regarding the radiological protection of people and the environment, and they have updated their radiation protection system to explicitly consider also non-human biota. In this sub-section, first a brief outline on the present ICRP recommendations and their basis is presented, followed by rather chronological description of their further advice regarding the principles. More technical details of the ICRP assessment approach are discussed, however, later in section 4.5.

Outline

Arising from the international efforts for sustainable development, the ICRP concluded in 2000 that environmental protection is a global matter and established a Task Group (ICRP 2003, 2008; UNSCEAR 2011). A key recommendation of the group was that the approach to environmental protection, need of which was clear, *"should relate as closely as possible to the current system for human radiological protection, and these joint objectives could therefore best be met by the development of a limited number of Reference Animals and Plants*[9]*"* (ICRP 2003). The development work was continued through ICRP Committee 5 (ICRP 2008) further specifying that *"as radiation effects at the population level — or higher — are mediated via effects on individuals of that population, it seems appropriate to focus on radiation effects on the individual for the purpose of developing a framework of radiological assessment that can be generally applied to environmental issues"* (ICRP 2008).

The highly versatile nature of non-human biota presents a major challenge in environmental radiation protection, and therefore, the ICRP ended up to propose (ICRP 2003, 2007) the use of a limited set of Reference Animals and Plants (RAPs) to focus on a few 'representative' target areas. The RAPs were subsequently defined as *"a hypothetical entity, with the assumed basic biological characteristics of a particular type of animal or plant, as described to the generality of*

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[9] For an explanation, see the following paragraphs.

the taxonomic level of Family, with defined anatomical, physiological, and life-history properties, that can be used for the purposes of relating exposure to dose, and dose to effects, for that type of living organism" (ICRP 2008). They are intended, as a set, to mutually cover the range of both radiation exposures and radiosensitivities which may arise within contaminated ecosystems (ICRP 2008).

The most recent ICRP overall recommendations (ICRP 2007) maintain from earlier both the three fundamental principles of radiation protection (justification, optimisation, and application of dose limits) and individual dose limits in planned exposure situations, and include an approach to demonstrate radiological protection of the environment (ICRP 2008). The ICRP has also specifically addressed the radiological protection in geological disposal of radioactive waste (ICRP 2013), especially from the perspective how to apply the overall recommendations for the protection of future generations over the long time scales associated with the geological disposal. These considerations also emphasise the basic principle (ICRP 2000) that *"individuals and populations in the future should be afforded at least the same level of protection as the current generation"* and 'watchful care' throughout the decisions and implementation of the waste management and disposal (ICRP 2013, p. 6).

These specific recommendations regarding geological disposal of long-lived solid radioactive waste (ICRP 2013) update and consolidate previous general recommendations that still remain valid (particularly, for near-surface disposal, also (ICRP 2000) shall be followed). Now it is clearly advised that *"consideration of environmental protection, where appropriate, should be part of the risk-informed decision-making"* and that also the 2007 recommendations (ICRP 2007) incorporate the RAP approach for non-human biota should be followed.

ICRP framework to assess radiation protection of the environment

The first ICRP recommendations on how to explicitly address the protection of the environment were developed as a result of the Task Force (ICRP 2003). A key driver was rather the lack of policy and technical basis endorsed at an international level to determine or demonstrate whether or not the environment is adequately protected than any particular concern over environmental radiation hazards. It was considered that the IAEA 'ethical considerations' (IAEA 2002) provided a sound basis, but needed to be harmonised with the approach for the protection of humans. For this, it was foreseen that an agreed set of quantities and units, reference dose models, dose-per-unit-intake data and reference organisms need to be developed. As a first step, the idea of a limited number of reference flora and fauna (to be developed by the ICRP, parallel to the Reference Man concept for people; Figure 1) was adopted to provide a high-level advice and guidance and to provide a primary point of reference, so that others can then develop more specific approaches based on *"more locally relevant information"*. Another goal recognised was to identify a set of dose rate magnitudes set out in a 'banded' fashion, similarly to the levels of concern considered for humans. The main objectives proposed were to safeguard the environment by *"preventing or reducing the frequency of effects likely to cause early mortality or reduced reproductive success in individual fauna and flora to a level where they would have a negligible impact on conservation of species, maintenance of biodiversity, or the health and status of natural habitats or communities"*. (ICRP 2003).

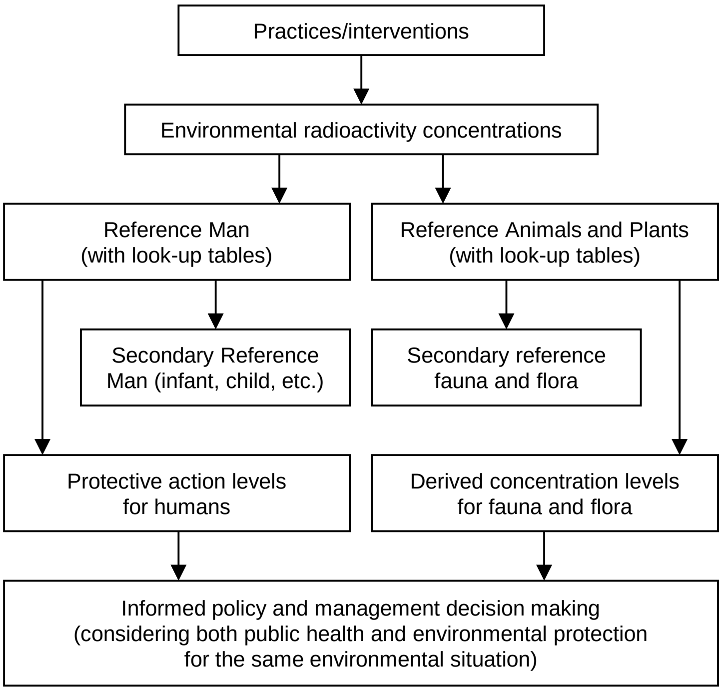

Figure 1. Parallelism in the radiological protection approaches for humans and non-human organisms (modified from Pentreath 2002b; ICRP 2003, 2008; NEA 2003).

As outlined in chapter 2, there can be many and complex linkages between molecular effects at the individual level to potential population- and ecosystem-level effects combining the ionising radiation and possibly other environmental stressors. However, these effects manifest themselves at the population level, or higher in the biological organisation, through effects on individuals of that population. Therefore, it is considered *"appropriate to focus on the individual as the purpose of developing a framework of radiological assessments that can be generally applied to environmental issues"*. (ICRP 2003).

ICRP 2007 general recommendations

With the framework established (ICRP 2003), the ICRP 2007 recommendations (ICRP 2007) incorporated also that as an approach to address radiation protection of the environment *"to maintain biological diversity, to ensure the conservation of species, and protect the health and status of natural habitats, communities and ecosystems"* (ICRP 2007). To reach this goal, the ICRP *"suggests that the aim should be a negligible effect on the maintenance of biological diversity, the conservation of species and the health and status of natural habitats, communities and ecosystems"* (ICRP 2007).

The ICRP also reaffirmed the view that *"it is necessary to consider a wider range of environmental situations, irrespective of any human connection with them"*. For this, the Reference Animals and Plants (RAPs) should be used, but not necessarily as the direct objects of protection themselves. Instead, they should be considered as points of reference that can provide a basis for management decisions. For this reason, the Commission did not propose *"any form of 'dose limits' with respect to environmental protection"*, but rather merely *"offer more practical advice than in the past"* through setting out transparently derived data for the application of the RAPs. (ICRP 2007).

Concept and use of the Reference Animals and Plants

As a high-level ambition, the approach to environmental protection should be commensurate with the overall level of risk, and the ICRP believes its system meets this need through the provision of 'numerical guidance' for the use of the Reference Animals and Plants (ICRP 2008). In the key publication (ICRP 2008) the concept of RAPs is introduced in depth and a small set of RAPs[10] is defined, including their

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[10] For a list of the RAPs, see Table 4 in section 4.1.

exposure pathways and dosimetry. Also a tabulated set of dose conversion factors[11] that allow the dose (rate) to be calculated for 75 radionuclides that may be within or external to each RAP is provided, as well as a summary of data on radiation effects on non-human biota. These data are further amended in another publication (ICRP 2009) with recommended values of environmental media-to-RAP concentration ratios, with data gaps readily filled in a systematic manner

Similarly to the Reference Man being a substitute of the representative person in theoretical calculations, the Reference Animals and Plants can be used as the representative non-human organisms especially in sufficiently generic circumstances and to provide a point of reference (ICRP 2008). As the classification of animals and plants is primarily a reflection of their morphological characteristics and physiological and biochemical features, and because there are no internationally accepted 'rules' on classification on higher taxonomic levels, family has been suggested as the most suitable level of generalisation (Pentreath 2002a, 2005; Pentreath & Woodhead 2001) for types of animals and plants (ICRP 2008).

It was considered that a mixture of animals and plants are needed to reflect the variety of exposure situations and conditions, but that the set should be reasonably limited but flexible to be pragmatic. However, it is emphasised that *"there is nothing sacrosanct about the set; other biotic types could have been chosen"*. (ICRP 2008).

To further avoid the 'expenditure of unnecessary effort', it was considered *"not appropriate to set generalised dose 'limits'"*, even though some numerical guidance is needed. Optimally the natural background radiation dose rate normally experienced by animals and plants would work as such a 'comparator' (Pentreath 1999, 2002b); additional doses of small multiples of the normal background would be 'unlikely to be the cause of any environmental managerial concern'. However, there is still a considerable lack of data in such normal background conditions experienced by the variety of non-human biota, and thus 'such a precise simplification' was not attempted. Therefore, bands of dose rates within certain radiation effects could be expected were identified from the existing database, to serve as 'derived consideration reference levels' (DCRLs). Also here, the underlying thought was that *"these bands can then be put into perspective by, at one extreme, noting the effects of very high levels of dose that are unlikely to be encountered in the environment and, at the*

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[11] In terms of (µGy/d)/(Bq/kg).

other, by noting what might be expected in terms of natural background." (ICRP 2008).

The current numerical values of the DCRLs are specific to the type of a Reference Animal or Plant, with the lower ends of the range lying at 4–400 µGy/h and the upper ends at 40–4000 µGy/h (ICRP 2008, 2014; these are presented in more detail in section 3.4). However, it is emphasised that *"this first step towards the derivation of DCRLs is essentially that – a first step"* and further efforts to fill knowledge gaps are expected. It is also expected that the approach will be revised with new knowledge made available. Also, when applying the DCRLs, it needs to be borne in mind that the underlying data relates to animal and plant individuals. Even if it can be supposed that any impacts at the population level will arise from responses by the constituent individuals, there has been little analysis to link these two endpoints (ICRP 2008 referring to Woodhead 2005). Therefore, measures to protect individual organisms do not necessarily ensure protection of the population. (ICRP 2008).

Consideration of different exposure situations of non-human biota

For the application of ICRP's Reference Animals and Plants approach to meet various environmental protection criteria, Copplestone (2012a) discusses their use in the context of various environmental protection goals identified in international treaties and national legislation. Whilst the initial set includes twelve RAPs, it is anticipated that this initial list will be extended by the ICRP as further data become available. Already as outlined in the ICRP recommendations summarised above, the RAP approach does not exclude the use of more specific data and organisms. (Copplestone 2012a).

The ICRP view on the matter is consolidated in their publication number 124 (ICRP 2014). There, also further advice is given to apply the approach in various situations, also throughout the life span of nuclear installations. At the planning stage, the approach supports decisions to minimise the possibility of potential exposures. During normal operations, explicit demonstration of the level of radiological protection of flora and fauna can be included in the routine surveillance and assessment. (ICRP 2014).

The appropriate representative organisms of concern in a specific situation may be among the ICRP RAPs, and data on DCRLs can be used without further consideration. However, in some circumstances, the representative organisms may not be well represented by any of the RAPs, and the differences should be assessed. In any case, the location of the representative organisms needs to be defined carefully. (ICRP 2014).

The ICRP recommends that the derived consideration reference levels (DCRLs) are used under all circumstance of a (potential) incremental exposure significantly above the local natural background level. In planned exposure situations[12], the lower boundary of the relevant DCRL band should be used as the reference point. However, due to the possibility of multiple current or past sources affecting the same biota, also possible cumulative effects should be appropriately considered. (ICRP 2014).

It is also recommended, that protection of the environment should complement the protection of the public and not to add unnecessary complexity. It is foreseen that, at least for planned normal operation situations, the demonstration of protection of both humans and the environment could be integrated ‘in a relatively simple manner’. However, the ICRP also expects future revisions based on the experiences of using the approach. (ICRP 2014).

3.2.3 International Atomic Energy Agency (IAEA)

Similarly to the international situation in general, despite of some early publications indicating raising awareness (*e.g.*, IAEA 1987, 1992), earlier views of the IAEA were rather anthropocentric, reflecting those of the ICRP. As referred to above, eventually the IAEA published an ‘ethical basis’ document (IAEA 2002) and an action plan on protection of the environment (IAEA 2005) concluding that whilst there were significant knowledge gaps, time was ripe for launching international initiatives to consolidate the approach. This change in the paradigm, along with international progress with the topic, can be seen also in the current editions of IAEA’s safety standards.

Of the safety standards, the IAEA General Safety Requirements (GSR) apply to all facilities and cover regulatory framework, management, radiation protection, safety assessment, waste management, decommissioning and emergency preparedness. The Specific Safety Requirements (SSR) are then focused on site evaluation, safety of different type of facilities and safe transport of radioactive material.

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[12] They are, here, ”situations involving the discharge and disposal of radioactive waste, decommissioning of installations, and the activities related to eventual remediation and decontamination work of resulting contaminated sites” (ICRP 2014).

Of the latter group, the SSR most important to the present context is the one addressing the disposal of radioactive waste (IAEA 2011a).

The general safety requirements (IAEA 2009) stipulate that a graded approach shall be used in safety assessments, *"consistent with the magnitude of the possible radiation risks arising from the facility or activity"*. Regarding the protection of the environment, also the possible release of radioactive material to the environment shall be taken into account when identifying and assessing the possible radiation risks. Also, it shall be determined that *"adequate measures are in place to protect people and the environment from harmful effects of ionising radiation"* (IAEA 2009).

The specific safety requirements for disposal of radioactive waste (IAEA 2011a) expect ICRP recommendations (ICRP 1997, 2000, 2007) to be taken as the 'prime consideration'. However, it is still assumed in these requirements that if the exposed groups are appropriately defined, *"the protection of people against the radiological hazards associated with a disposal facility will also apply the principle of protecting the environment"*. International developments have been acknowledged, though, but in a rather vague manner. Additional indicators, for example in terms of comparing concentrations and fluxes of radionuclides from the facility with those of natural origin, are considered to provide also indications of overall environmental protection. The specific safety requirements for geological disposal and safety case of radioactive waste disposal (IAEA 2011b, 2012c) add little to this in the context of the present review.

In addition, the IAEA General Safety Guides (GSG) address mostly the regulation and management of nuclear installations indeed in a rather general level. Within the Specific Safety Guides (SSG), however, a few apply directly to the nuclear waste disposal – namely, those regarding the geological disposal as a whole (IAEA 2011b), the safety case and safety assessment for the disposal (IAEA 2012c), and the monitoring and surveillance of disposal facilities (IAEA 2014c). However, these provide little further guidance regarding the radiation protection of the environment.

For screening evaluations of facilities and activities with radioactive releases in the environment, the earlier models and data (IAEA 2001) are currently under revision. Whereas earlier the focus was solely on radiation protection of people, now also environmental protection per se is to be addressed. (IAEA 2016b). Also, the earlier methodology for biosphere assessments of geological disposal of solid radioactive waste (IAEA 2003) is currently being updated, and explicit advice to address the protection of non-human biota shall be added there as well (Smith 2018).

3.2.4 OSPAR

Within the OSPAR mechanisms, fifteen governments and the European Union co-operate to protect the marine environment of the northeast Atlantic. The mandate originates from the 1972 Oslo Convention against sea dumping and its extension (the Paris Convention of 1974) to cover land-based sources and offshore industry conventions/agreements/recommendations, and from the unification, update and extension of these two conventions in the 1992 OSPAR Convention. (OSPAR 2016b). Regarding radioactivity, the agreements cover (OSPAR 2016b):

- *"a complete and permanent ban on all dumping of radioactive waste and other matter"*; and
- *"a strategy to guide the future work of the OSPAR Commission on protecting the marine environment of the North-East Atlantic against radioactive substances arising from human activities"*.

Under an implementation programme, the OSPAR contracting parties shall each prepare a national plan and monitor and report (*e.g.*, ENSI 2014) on the progress; in addition, periodic evaluations are produced by the OSPAR Radioactive Substances Committee (RSC) (OSPAR 2016b). The evaluation of radioactive substances has been prepared (*e.g.*, Fievet & Beaugelin 2009, Shah *et al.* 2009, OSPAR 2016a), but not yet implemented[13]. However, there is an agreement on using a methodology developed by the IAEA in 2013 (OSPAR 2016a). The methodology (OSPAR 2016a, annex 1) assesses the *"radiological impact on humans and non-humans in an integrated manner"* that for the non-human biota essentially follows the ICRP Reference Animals and Plants approach. Documents on testing and demonstration of the methodology also have been annexed to the agreement (OSPAR 2016, annexes 2 and 3). For the context of the present review, it needs to be noted, though, that these evaluations are for the marine environment.

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[13] Environmental concentrations of radionuclides and doses to humans and biota were not included in the latest evaluation, but will be assessed in the next one that will also contribute to OSPAR's overall Intermediate Assessment 2017 (OSPAR 2016). However, radionuclide discharge limits, discharges and concentrations have been reported in a number of OSPAR publications.

3.2.5 European Union (EU)

In the newly revised Basic Safety Standards of the European Union (EC 2014), in force from the 6th February 2018, it is stipulated that the ICRP 2007 recommendations (ICRP 2007) shall be followed, thus bringing in also dose assessment for the biota. Otherwise, the radiation protection of the environment is addressed only through the general statement of *“while the state of the environment can impact long-term human health, this calls for a policy protecting the environment against the harmful effects of ionising radiation”*, in addition to requiring to base the environmental criteria long-term human health protection on internationally recognised scientific data, such as those published by the European Commission, ICRP, UNSCEAR and IAEA.

Before this revision of the radiation protection directives, there have been several EU research projects developing approaches to the radiation protection of the environment, outcome of which has become nearly a practical standard in the member states. Further technical details are presented in section 4.4, but here the overall strategy is outlined.

The overall approach was finalised in the ERICA project (Beresford *et al.* 2007b) building upon the earlier FASSET (Larsson *et al.* 2004) and EPIC (Brown *et al.* 2003b) projects that run parallel, EPIC focusing on Arctic environments. In addition, the application of ERICA outcome in regulatory context has since been addressed in the PROTECT project (*e.g.*, Copplestone *et al.* 2010, Howard *et al.* 2010).

Similarly to the ICRP approach, the FASSET–ERICA approach is based on a reference organism approach and the specification and development of related parameter values, including radionuclide transfer factors and dose conversion coefficients based on representative geometries and occupancies (*e.g.*, Robinson *et al.* 2010). The approach is also implemented in a specific assessment tool (Brown *et al.* 2008; see section 5.2.3).

The reference organisms selected in the ERICA project are *“a series of entities that provide a basis for the estimation of radiation dose rate to a range of organisms which are typical, or representative, of a contaminated environment”* in the European context (Beresford *et al.* 2007b). Similarly to the ICRP, also the ERICA approach provides with default radionuclide transfer data (Beresford *et al.* 2008b, Hosseini *et al.* 2008) that have since been updated (Brown *et al.* 2016).

To derive dose rate benchmark values for screening purposes, the ERICA method follows the European Commission recommendations (EC 2003b) for the estimation of predicted no-effect concentration (PNEC) for chemicals (UNSCEAR 2011): First, coherent data on endpoints related to mortality, morbidity and reproduction were collated from individual experiments (through the FREDERICA database; section 5.2.5), and dose-rate–effect relationships were systematically reconstructed to estimate critical toxicity endpoints (an effect dose rate EDR_{10}, the dose rate giving a 10% rise in the observed effect, was used here). Then, a species sensitivity distribution (SSD, Figure 2) was constructed from the critical toxicity data to determine the hazardous dose rate HDR_5, the dose rate at which 95% of the species in the aquatic/terrestrial ecosystem are protected (resulting here in 82 µGy/h, with 95th percentile confidence intervals of 24 and 336 µGy/h). To derive the final dose rate for screening purposes (*i.e.*, PNEDR, corresponding the PNEC for chemicals), a safety factor of 5 was used and the resultant figure was rounded down to the nearest one significant digit (yielding the screening value of 10 µGy/h). In the ERICA project, this value was also shown (Garnier-Laplace *et al.* 2006a, b, 2008) to be similar to those derived using alternative methods to the SSD. (UNSCEAR 2011).

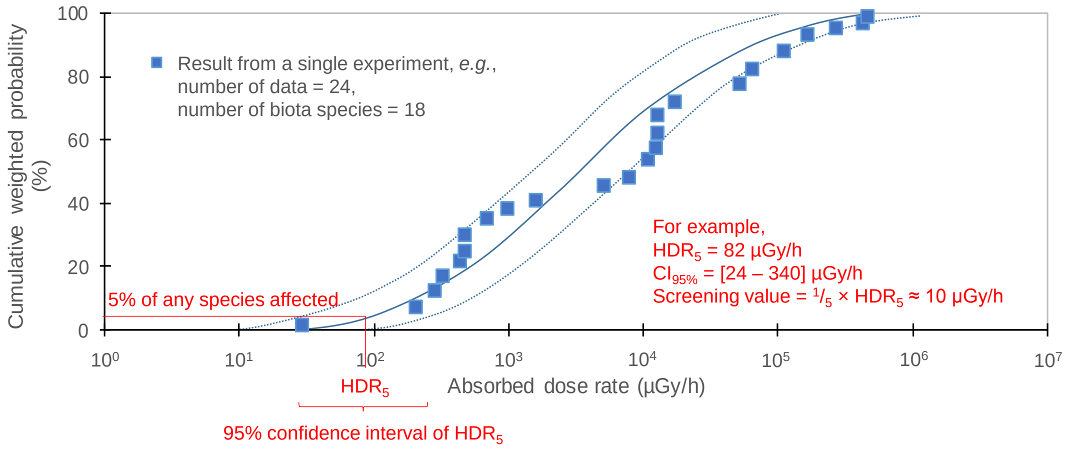

Figure 2. Schematic presentation of a species sensitivity distribution: a log-normal distribution with its associated 95% confidence interval is fitted to geometric means per effect category for each species calculated from critical ecotoxicity data (see the text) (modified from Garnier-Laplace *et al.* 2006a, UNSCEAR 2001).

The PROTECT project (Hington *et al.* 2007; Andersson *et al.* 2008, 2009; Copplestone *et al.* 2010; Howard *et al.* 2010) aimed at developing criteria and evaluating approaches for use in regulation by considering the suitability of the different approaches available and to develop dose rate thresholds for wildlife on the basis of consultation (including the ICRP, IAEA, European Commission, regulators, industry, non-governmental organisations and chemical risk assessment experts). By revising and amending the data used in the ERICA project and reapplying the species sensitivity distribution approach, PROTECT independently derived a benchmark screening dose rate of 10 µGy/h which can be used to identify situations which are below regulatory concern (Andersson *et al.* 2008, 2009; Howard *et al.* 2010). Different data treatment methods were tested, but all the options gave a reasonably similar result (Andersson *et al.* 2008).

As a generic screening value is applied to all species, and the most exposed organism type may not necessarily be the most sensitive, screening values specific to organism groups can be considered desirable. However, there were serious limitations with data availability, so such values were derived only for three broad groups; these values were for vertebrates 2 µGy/h, for plants 70 µGy/h, and for invertebrates 200 µGy/h. It needs to be borne in mind, though, that the confidence in these more specific values is lower than in the generic screening value, and that in any case the screening values should be applied to the total incremental exposure. (Andersson *et al.* 2008).

3.2.6 Common features

The radiation exposure of non-human biota is highly variable and depends, for example, on the contamination level in the environment, the radionuclides present, the geometrical settings of the radiation source and the exposed organism, size of the organism, shielding properties of the medium and the exposure time (*e.g.*, Hansen *et al.* 2016). All the frameworks addressed above use a number of simplifications that are of practical necessity to carry on a quantitative assessment (*e.g.*, UNSCEAR 2011). Common key elements in the assessment frameworks address (modified from UNSCEAR 2011, table 1):

- exposure of biota – spatial and temporal patterns of radionuclide concentrations in environmental media, uptake by organism, and distribution within organism (typically non-uniform, but homogeneity approximations are commonly used);
- reference or representative biota – not possible to evaluate all types and species, but a selection of reference biota or indicator species appropriate for the area of interest and assessment context is necessary (although in case of endangered species or species of other high interest it may be necessary to consider the individual types/species *per se*);

- dosimetry model – often a stylised geometry is assumed, or geometry corrections are made, to calculate the absorbed dose (usually to the whole body, in some approaches to tissues/organs) taking into account effects of the different qualities of radiation;
- assessment endpoints – selection of appropriate population-level (deterministic) ‘umbrella’ effects such as mortality or reproductive capacity, and of corresponding benchmark values;
- effects assessment – connection between radiation effects on the endpoints in individual and consequent possible effects on population (most conveniently demonstrating dose rates below an well-established screening value readily denoting low probability of population-level effects), and considerations of the role of background radiation levels and natural population variability.

The selection of target organisms (reference organisms or species, Reference Animals and Plants, *etc.*) need to be justified. The selection criteria may include (*e.g.*, Copplestone 2012b, UNSCEAR 2011):

- ecological niche;
- intrinsic radiosensitivity;
- radioecological sensitivity;
- distribution (*e.g.*, typically those species that are present year-round are preferred for the higher exposure to the local contamination);
- amenability to research and monitoring;
- protected status.

After the target organisms have been selected, the dosimetry to derive estimates of the absorbed dose rates is relatively straightforward (and is, thus, left here for the more technical details in chapter 4).

In derivation of benchmark values, some of the approaches rely on expert judgement and some use formal methods of employing species sensitivity distributions with safety factors. However, even though the general aim is to protect biota populations, the benchmarks are based on individual-level effects data that needs to be borne in mind in the decision making.

3.3 Examples of national requirements

This section provides examples of national requirements regarding the radiation protection of the environment in the context of nuclear facilities, and particularly disposal of radioactive waste. It is to be noted that in addition to the requirements discussed above, there are also requirements on the safety assessments and safety cases in general that have not been reported here. For the present context, for example those regarding assessing uncertainties may be of relevance, but as such requirements are generic in nature, they have not been incorporated here. The focus has been to provide relevant reasonably recent examples, since summaries of earlier status of regulatory requirements can be found for example in (Hington *et al.* 2007).

In the following, regulations and regulatory guidance chosen as examples are presented alphabetically for the geographical regions in question. Concerning Germany, however, little explicit requirements regarding the protection of the environment from radiation effects were found except in general terms of limiting and monitoring radioactive releases (*e.g.*, BfS 2015, 2016), and thus no further summary was developed.

Canada

In Canada, the main regulatory document REGDOC 2.9.1 (CNSC 2017) provides with guiding principles for environmental protection, requirements and guidance to applicants and licenses for developing environmental protection measures for both new and existing facilities and activities. Basically, environmental protection measures need to be demonstrated for all activities when licencing decisions are made. Such environmental assessment (EA) is conducted either under the Nuclear Safety and Control Act (NCSA) or, for designated projects, under the Canadian Environmental Assessment Act (CEAA). The assessments shall be *"commensurate with the scale and complexity of the environmental risks associated with the facility or activity"*. An environmental risk assessment (ERA) is to be performed as a part of EA when required. The ERA *"is a systematic process that identifies, quantifies and characterises the risk posed by contaminants (nuclear or hazardous substances) and physical stressors in the environment. It is a practice or methodology that provides science-based information to support decision-making and to prioritize the implementation of mitigation measures"*. This includes assessments of exposure and effects on representative biota and changes in habitat and effects on species that rely on that habitat, and for ‘Class I’ facilities and uranium mines and mills, this shall be conducted in accordance with a specific standard (CSA 2017). (CNSC 2017).

Somewhat older regulatory guidance (CNSC 2006) on long-term safety of management of radioactive waste, including uranium mine waste rock and mill tailings, is to be applied to a degree that depends on the nature and purpose of the assessment, the hazard of the radioactive waste and the consequences of making an incorrect decision. However, as stipulated in the general nuclear regulations (Canadian Minister of Justice 2015), the licensee shall anyway take all reasonable precautions to protect the environment. Regarding non-human biota, it is recognised that *“because exposures of each of the various receptor organisms used as representative of the biosphere will occur by different pathways, and will be judged by different acceptance criteria than those applied to humans or to each other, multiple approaches may be needed to estimate the exposures and impacts, even when all receptors are present in the same environment at the same time”*. The safety assessments shall, also for the non-human biota, encompass the time period of predicted maximum impact. However, *“the demonstration of safety will rely less on quantitative predictions and more on qualitative arguments as the timescale increases. Long term quantitative predictions should therefore not be considered as guaranteed impacts, but rather as safety indicators”* [14]. (CNSC 2006).

To identify the exposed groups, explicit exposure pathway analysis for example in terms of an analysis of features, events and processes (FEPs) or assessment of valued ecosystem components (VECs) is required for both humans and ‘environmental receptors’. These may be specific to each assessment scenario. For the environmental protection purposes, the protection should be based on protection of populations, communities and ecosystems, not necessarily individual organisms (*i.e.*, the ‘predicted impact’ to individuals in the assessments needs to be evaluated for the significance to populations). (CNSC 2006).

For assessment endpoints, there are four categories of protection criteria to be established: both protection of persons and protection of the environment further split into radiological protection and protection from hazardous substances. For the protection of non-human biota from radiation exposure, the primary concern is the total radiation dose to the organisms resulting in deterministic effects. Regarding quantitative benchmark values, the immaturity of the knowledge

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[14] It is to be noted that similar views are shared in most of the regulations reviewed, although not nearly always so clearly stipulated.

is recognised and some proposals available at the time (NRCP 1991, IAEA 1992, EC & HC 2003) are referred to. Interestingly, it is clearly required that *"development of criteria for ensuring radiological protection of the environment should follow the protocols established for hazardous substances"*. For the non-radiological protection of the environment from hazardous substances, Canadian Environmental Quality Guidelines (CCME 2002) are referred to, for developing safety criteria such as expected no-effects values (ENEV) in terms of, for example, 25%-response effect concentration (EC_{25}), lowest observable adverse effects level (LOAEL) or no observable effects level (NOAEL) for most sensitive species, derived from critical toxicity values using appropriate safety factors. (CNSC 2006).

England and Wales

In England and Wales, there are relatively strict national regulations implemented in 1994 to comply with the EU Birds and Habitats Directives (79/409/EEC and 92/43/EEC) especially in respect of protecting the related 'Natura 2000' conservation area network from any direct or indirect adverse effects by activities under existing or new environmental permits (Allott *et al.* 2009). High-level guidance (EA 2010) has been established under the Environmental Permitting Regulations of 2010, providing a standardised framework for technical assessments and regulatory judgements. However, there are also constraints that release limits should not be further reduced, provided that the operator applies and continues to apply best available technology, where the prospective dose to the most exposed group of members of the public is below 10 µSv/y from the overall discharges of an authorised site.

In assessments of the potential impact of radioactive discharges on the EU Natura 2000 protection sites (Allott *et al.* 2009), a screening level of 40 µGy/h was applied to demonstrate that the *"integrity of Natura 2000 habitat sites"* is not affected. When assessing such environmental permits, the Environment Agency calculates, if deemed necessary, dose rates to organisms in coastal, freshwater and terrestrial environments, taking account of the combined impact of discharges from multiple authorised releases and cautiously assuming that discharges occur at the authorisation limits (Allott *et al.* 2009). The Environment Agency, Natural England and the Countryside Council of Wales have agreed that below the threshold screening dose rate (40 µGy/h) there would be no adverse effect to the integrity of a Natura 2000 site (Allott *et al.* 2009).

The high-level guidance (EA 2010) arising from the Environmental Permitting Regulations of 2010 provides an overall hierarchy and topic framework for radioactive substances management that includes also waste disposal. The basic principles include sustainable development, best available technology and best scientific knowledge, the precautionary principle and the ALARA principle (as low as reasonably achievable), but their application depends on the nature of the facility and the issues under consideration. The *"non-human species should be adequately protected from exposure to ionising radiation"* in terms of populations rather than 'every individual organism', except where specified by legislation. However, key species needing protection and habitat features should be identified. (EA 2010).

The technical approach to be used should be that of (Copplestone *et al.* 2001, 2003; see section 4.2). The current guideline value for the dose rate 40 µGy/h. (EA 2010). More specific principles for disposal of solid radioactive waste are given separately (EA *et al.* 2009), including further details on an environmental safety case that is required from such facilities. The standpoint is that *"although there is no specific evidence that there might be a threat to populations of non-human species from the authorised release of radioactive substances if people are protected, there may be times when there are no people near a disposal facility. Environmental damage might also occur to areas and habitats that are not extensively exploited by people. Furthermore, there is a specific need to be able to demonstrate that non-human species are protected under legislation related to conservation, for example that derived from the EC Habitats Directive"*. Also, in any case, *"the developer/operator of a disposal facility for solid radioactive waste should demonstrate that the disposal system provides adequate protection against non-radiological hazards"*. (EA *et al.* 2009).

Finland

In Finland, the regulations for nuclear power plants and interim storage of spent nuclear fuel stipulate that the releases of radioactive substances to the environment shall be controlled and monitored, and the activity concentrations in the environment monitored (STUK 2015d). Also, operational release limits shall be defined for the various release pathways, and monitoring shall also be used to ensure that the radiation exposure of the public is kept as low as reasonably achievable (STUK 2015e). Seemingly, based on the other examples, this is thought to keep also the effects on the environment inconsequently low.

For long-term safety in geological disposal of radioactive waste, the regulatory guide (STUK 2013) provides principles of protecting the non-human biota, although omitting any specific guidance. Firstly, there may not be detrimental effects on plant and animal species. Secondly, this shall be demonstrated through an assessment of 'typical radiation exposures' of terrestrial populations assumed similar to the present kind. These exposures shall remain clearly below levels indicating 'significant detriment to any living population', judged based on best available knowledge. For humans, dose constraints for the most exposed individuals and for other exposed population apply for a period of at least several millennia after the closure, and for periods thereafter constraints for radioactive releases to the biosphere are applied. For the earlier period, assumptions regarding the biosphere conditions and exposure pathways are prescribed by the regulator to an extent. (STUK 2013).

Newer higher-level regulation on the disposal (STUK 2015a), however, seems to prompt some future revision of the guideline document: The long-term safety assessment shall cover the post-closure period that is deemed necessary for ensuring the safety of the disposal (*i.e.*, as far into the future as the disposed waste can be seen to constitute a risk to humans and the environment) and the 'possible impacts on flora and fauna' shall be analysed so that these analyses can largely be based on the ICRP and IAEA recommendations. For periods beyond first several millennia, stylised biosphere models (such as 'reference biospheres') shall be used, but the focus is on the exposure of people. (STUK 2015a, b).

Similarly to the nuclear power plants, discharges of radioactive substances from a nuclear waste facility shall be monitored during its operation, and operational release limits shall be defined for the various release pathways. With the releases as low exposure of the public as reasonably achievable shall be strived for. (STUK 2015a, b).

For mining and milling aiming at producing uranium or thorium, including the disposal of the production waste, the focus is on limiting the radiation exposure of workers and members of public, and on limiting the releases of radioactive substances practically similarly to nuclear power plants and nuclear waste facilities, but recognising the difference in the conditions (*e.g.*, dusting) and measures being proportionate to the potential risk. As with other nuclear activities, also here environmental baseline survey and monitoring are obligatory. (STUK 2015c, d).

In addition to the nuclear regulations, also the environmental impact assessment (EIA) procedure, including international hearing, applies to all nuclear facilities (Ministry of Environment 2017a, b). However, there are no specific requirements or guidance regarding the radiological protection in terms of the EIA.

France

According to the review of (IAEA 2016a), French regulatory requirements for geological disposal conclude that it is not possible to predict the local biosphere evolution for very long periods of time and introduces the concept of biosphere types, representative of the different biosphere states that could pertain during a long time period (ASN 2008). Such states shall consider also glaciation and deglaciation periods and other situations within relevant climatic cycles. (IAEA 2016a). However, there seems to be no specific requirements on the non-human biota.

The Institute for Radiological Protection and Nuclear Safety (IRSN) has recently given their recommendations (Beaugelin-Seiller *et al.* 2016) based on their experience as ‘national public expert’ conducting various types of assessments. They have found that nuclear operators need to address the radiation protection of the environment as a part of their environmental impact assessment as a part of the licencing process, but regulatory requirements are not clear and an official position is warranted. IRSN currently uses mostly an approach derived from the ERICA assessment (Tiers 2 and 3; see section 4.4) as the ‘most suitable and most up-to-date tool’ (*e.g.*, assessment of radioactive noble gases has been added by adopting the methods of Copplestone *et al.* (2001)). They consider 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, by using a graded approach. IRSN also considers the ERICA approach as a suitable basis for such assessments, due to its compatibility and being ‘more operational’ than the ICRP approach. Regarding the benchmark values, IRSN recommends they to be set through case-by-case considerations. (Beaugelin-Seiller *et al.* 2016).

Sweden

Regarding the Swedish requirements on the post-closure safety of geological disposal of nuclear waste[15], human health and the environment shall be protected from detrimental effects of ionising radiation, and the disposal shall be implemented so that biodiversity and sustainable use of biological resources are protected against the harmful effects of ionising radiation (SSM 2009a). More practically, biological effects of the radiation in habitats and ecosystems concerned shall be described based on available knowledge, for example on the basis of ICRP general guidance (ICRP 2003)[16], and by taking *"particular account of the existence of genetically distinctive populations such as isolated populations, endemic species and species threatened with extinction and in general any organisms worth protecting*[17]*"* (SSM 2009a). Regarding also both human and biota populations, *"a realistic set of biosphere conditions"* are to be associated with each climate evolution that should be selected to mutually *"illustrate the most important and reasonably foreseeable sequences of future climate states and their impact on the protective capability of the repository and their environmental consequences"*; however, unless it is clearly inconsistent with the climate state, 'today's biosphere conditions' should be assumed (SSM 2009a). For the time period of one thousand years after the closure of the repository, *"available measurement data and other knowledge of the initial conditions should be used for a detailed analysis and description of the protective capability of the repository and the evolution of its surroundings"* (SSM 2009a). For a time period covering expected large climate changes, for example a glaciation cycle, a quantitative risk analysis is required, but for the even further time periods (up to a million years in case of spent nuclear fuel or other long-lived nuclear waste) the dose calculations should be made in a simplified way (SSM 2009a).

For the radioactive releases from nuclear facilities during their normal operating conditions (SSM 2009b), *"human health and the environment shall be protected from the harmful effects of ionising radiation while a nuclear facility is in operation as well as in the future"*.

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[15] The requirements apply not only to the repository alone, but also to relevant auxiliary installations and measures undertaken before the disposal that can have an impact on the protective capability of the repository and its environmental consequences (SSM 2009a).

[16] In addition to this, it is specifically required that "the applicability of the knowledge and databases used" shall be assessed and reported (SSM 2009a).

[17] It is further specified (SSM 2009a) that this latter criterion refers to, for example, to cultural history and to economic criteria in respect of providing livelihood (for example, through hunting and fishing). Also, the conservation criteria "refer to possible protection by current legislation or local regulations" (SSM 2009a).

The limitation of the discharges shall be based on optimisation of radiation protection, use of best available technology and consideration of all facilities located within the same geographical area. A dose criterion for humans is stipulated, and corresponding reference values for the discharges shall be derived by the licence holder. In addition there shall be discharge and environmental monitoring in place. However, there are no direct requirements regarding the exposure of the non-human biota, except for the general principle cited above. (SSM 2009b).

United States

In the United States, there are rather elaborate requirements set by the Nuclear Regulatory Commission (NRC 1999, 2007, 2013). However, it seems that for addressing the radiological protection of the environment, the standard (USDOE 2013) and graded approach (USDOE 2002) of the Department of Energy are more illustrative and often referred to as such.

Objectives of the DOE order (USDOE 2013) are, among others, *"to conduct DOE radiological activities so that exposure to members of the public is maintained within the dose limits established"*, *"to ensure that potential radiation exposures to members of the public are as low as is reasonably achievable"*, and *"to provide protection of the environment from the effects of radiation and radioactive material"*. Regarding the latter, the protection target is specified to be at populations of aquatic animals and terrestrial plants and animals. If the protection of the non-human biota cannot be demonstrated through assessment of actions taken to protect humans, the compliance can be demonstrated by using the graded approach implemented in RESRAD-BIOTA (see section 5.2.1), by using an equivalent method and demonstrating that the same dose rate criteria are met, or by employing an ecological risk assessment on the population level. (USDOE 2013).

3.4 Summary of benchmark values adopted

Above the principles of setting appropriate benchmark values were discussed, and here the actual values adopted in the international assessment frameworks and in national regulations are collated here (Table 3) for convenience of later reference.

Table 3. A compilation of benchmark values of dose rates to plants and animals for screening purposes.

Biota category (and endpoint)	Dose rate (µGy/h)	Reference
Invertebrates (bee, crab, worm)	400 – 4000 *	ICRP 2008, 2014
Aquatic organisms	400 *	NCRP 1991, UNSCEAR 1996, USDOE 2002
Aquatic organisms	400	Copplestone *et al.* 2001
Terrestrial plants	400 *	IAEA 1992, UNSCEAR 1996, USDOE 2002
Terrestrial animals (mortality)	400 *	UNSCEAR 1996
Benthic invertebrates	250 *	SENES 2009
Invertebrates	200 **	Andersson *et al.* 2009
Algae, macrophytes, amphibians	125 *	SENES 2009
Plants	70 **	Andersson *et al.* 2009
Grass, seaweed ***	40 – 400 *	ICRP 2008, 2014
Poikilothermic vertebrates (frog, trout, flatfish)	40 – 400 *	ICRP 2008, 2014
Terrestrial animals	40 *	IAEA 1992, USDOE 2002
Terrestrial birds and mammals	40 *	SENES 2009
Terrestrial animals	40	Copplestone *et al.* 2001
Terrestrial animals (reproduction)	40 *	UNSCEAR 1996
General screening value	40	Allott *et al.* 2009
Fish	25 *	SENES 2009
Generic reference organism	10 **	Beresford *et al.* 2007b, Andersson *et al.* 2009
Pine tree	4 – 40 *	ICRP 2008, 2014
Higher vertebrates (deer, rat, duck)	4 – 40 *	ICRP 2008, 2014
Vertebrates	2 **	Andersson *et al.* 2009

* Converted from original units of mGy/d and rounded downwards.

** Derived by employing a probabilistic species sensitivity distribution method.

*** ICRP (2008, para. 203) states that the DCRL for seaweed is the same as grass, which is inconsistent with the data presented in the DCRL tables.

3.6 Current development efforts

As has been brought up in the discussion above, there are considerable data gaps still remaining even though it is commonly seen that the time is ripe to proceed with quantitative assessment methods. This section provides a brief summary on most prominent recent and current international developments.

International Atomic Energy Agency (IAEA)

Since the BIOMASS-6 biosphere assessment methodology for disposal of solid radioactive waste (IAEA 2003), there has been a long series of IAEA programmes on improving environmental modelling for radiation safety: EMRAS in 2003–2007 (IAEA 2012a, b), EMRAS II in 2009–2011 (*e.g.*, IAEA 2014b, 2016b; Lindborg *et al.* 2018) and in MODARIA[18] in 2012–2015, all of which have included one or several working groups addressing biota assessments. In the currently ongoing MODARIA II, started in 2016, there are working groups for

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[18] Reporting yet pending; http://www-ns.iaea.org/projects/modaria/default.asp?s=8&l=116 (accessed 26 February 2018).

further development of transfer and exposure models for biota assessments as well as of assessing radiation effects on wildlife populations[19]. The MODARIA II programme hosts also a working group to update the BIOMASS-6 methodology (IAEA 2003) into a common framework for addressing environmental change in long-term assessments of radioactive waste disposal, now also explicitly considering non-human biota aspects (*e.g.*, Smith 2018).

International Union of Radioecology (IUR)

The International Union of Radioecology (IUR) is an independent society with members from 58 countries[20]. Currently, they also promote the ’ecological approach’ that aims to reconcile radiation impact understanding developed essentially in the laboratory with observations in the real environment (IUR 2015). As the need and relative immaturity to embrace all levels from effects on individuals to ecosystem impacts has been recognised also a consensus workshop was arranged, agreeing on a statement that *“reference organism approaches represent an important first step … but they have significant limitations”*, warranting further multidisciplinary effort to understanding mechanisms and processes of manifestation of radiation effects in natural ecosystems (IUR 2015, Bréchignac *et al.* 2016). These views will likely be advanced through IUR Task Groups, which include[21] for example ‘Protection of the environment’, ‘Radioecology in a multiple stressor environment’ and ‘Joint IUR/CERAD ecosystem approach task group’.

European Union (EU)

The research programmes of the European Union, there are a number of recent and current projects and frameworks related to developing radioecological knowledge and biota assessments.

STAR (Roelofs *et al.* 2015) relatively recently established strategic research agenda (Hinton *et al.* 2014) which is further implemented by, for example, COMET and ALLIANCE (Ikäheimonen *et al.* 2015, Muikku *et al.* 2017, Vandenhove *et al.* 2017a). These frameworks incorporate, for example, plans for laboratory studies (including specification of candidate organisms) (Alonzo *et al.* 2011), methodologies to extrapolate up to population dynamics (Alonzo *et al.* 2012, Oughton *et al.* 2013) and apply

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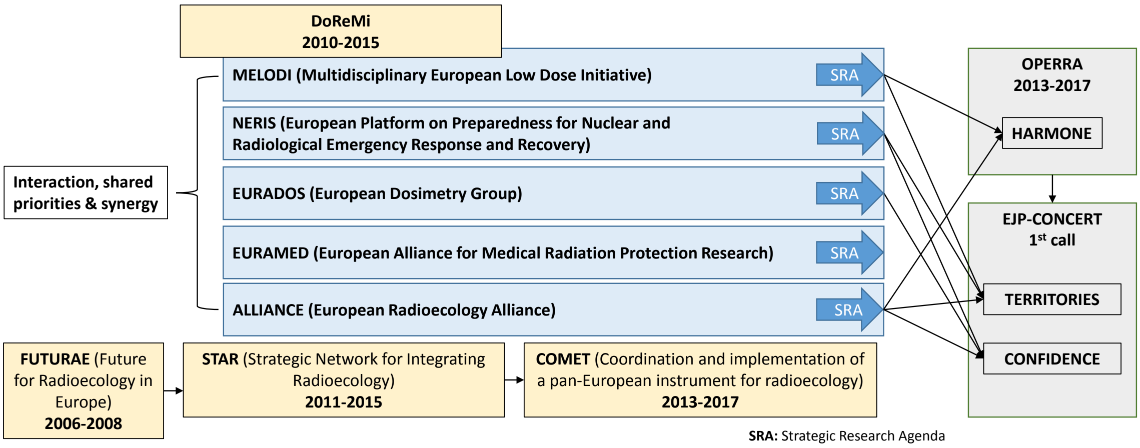
[19] http://www-ns.iaea.org/projects/modaria/modaria2.asp?s=8&l=129 (accessed 26 February 2018).

[20] http://www.iur-uir.org/upload/About%20IUR/brochure-iur-2017.pdf (accessed 26 February 2018).

[21] http://www.iur-uir.org/en/task-groups (accessed 26 February 2018).

ecotoxicological methods developed for non-radioactive contaminants (Vandenhove *et al.* 2012), and to provide general support to fill radionuclide transport data gaps by various extrapolation methods, for example alternative parameterisation, allometric scaling and ecological stoichiometry (Beresford *et al.* 2014) and to improve radioecological models (Urso *et al.* 2015). Further, COMET included further developments in understanding biological effects (*e.g.*, Adam-Guillermin *et al.* 2013, Spurgeon *et al.* 2015) and in model parameterisation and data (*e.g.*, Skipperud *et al.* 2016, 2017). Before the end of the project, COMET also outlined continuation plans (Vandenhove *et al.* 2017b) including a summary of remaining challenges and a roadmap for the CONCERT joint programme[22] to carry on. The current system of European research programming related to radioecology and radiobiology is illustrated in Figure 3.



DoReMi: Low Dose Research towards Multidisciplinary Integration
OPERRA: Open Project for European Radiation Research Area
EJP: European Joint Programme Co-fund Action
HARMONE: Harmonising Modelling Strategies of European Decision Support Systems for Nuclear Emergencies
CONCERT: The European joint programme for the integration of radiation protection research
TERRITORIES: To Enhance unceRtainties Reduction and stakeholders Involvement TOwards integrated and graded Risk management of humans and wildlife In long-lasting radiological Exposure Situations
CONFIDENCE: COping with uNcertainties For Improved modelling and DEcision making in Nuclear emergenCiEs

Figure 3. Current European Commission joint programming structure related to radiobiological and radioecological research (based on Salomaa *et al.* 2015, ALLIANCE 2017, Kreuzer *et al.* 2018, Thorne 2018).

Also the European Radioecology ALLIANCE (ALLIANCE 2017, Muikku *et al.* 2017) is continuing to implement STAR's strategic research agenda as "progress is still needed to gain fundamental knowledge and the validated tools and methods one of the outcome

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[22] Currently, majority of European radiation protection research are being organised within the CONCERT European Joint Programme Co-fund Action (EJP). The programme aims to integrate European radiation protection research and launches research calls in radiation protection on behalf of the European Commission. OPERRA (Open Project for European Radiation Research Area, 2013–2017) was an important planning project for the establishment of the CONCERT programme. (Kreuzer *et al.* 2018).

being to perform realistic, integrated and graded impact and risk assessments for humans and wildlife, across all ecosystems and exposure scenarios" (ALLIANCE 2017).

Similarly to CONCERT, MELODI improves radiation protection of humans (*e.g.*, Kreuzer *et al.* 2018). It is "a European research platform with a focus on health risk assessment after exposures to low-dose ionising radiation and its application for radiation protection, aiming for a progressive integration of national and European activities" especially regarding priority objectives in low-dose risk research through a long-term strategic research agenda[23].

Nationally in the United Kingdom, the relatively large consortium 'TREE' (TRansfer-Exposure- Effects) is supporting science to support radioactivity assessments for humans and wildlife[24]. It is funded by the Natural Environment Research Council (NERC), the Environment Agency (EA) and Radioactive Waste Management Limited (RWM) under the Radioactivity and the Environment (RATE) programme. The overall objective of the TREE project is to reduce uncertainty in estimating the risk to humans and wildlife associated with exposure to radioactivity and to reduce unnecessary conservatism in risk calculations through four interlinked science components beginning with improving our understanding of the biogeochemical behaviour of radionuclides in soils through to studying the transgenerational effects of ionising radiation exposure on wildlife. Both controlled laboratory experiments with fieldwork are included, and studies in the Chernobyl Exclusion Zone are in a major role. (CEH 2018).

In addition, a modelling tool called MERLIN-Expo (Ciffroy *et al.* 2016) has been developed within the recent EU project 4FUN for state-of-the-art exposure assessment for environment, biota and humans, but rather from the viewpoint of chemical contaminants. It is *"composed of a library of fate models dedicated to non-biological receptor media (surface waters, soils, outdoor air), biological media of concern for humans (several cultivated crops, mammals, milk, fish), as well as wildlife biota (primary producers in rivers, invertebrates, fish) and humans. These models can be linked together to create flexible scenarios relevant for both human and wildlife biota exposure."* (Ciffroy *et al.* 2016).

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[23] The European Network of Excellence DoReMi (2010–2016) served as an important initial operational tool for establishing MELODI (Salomaa *et al.* 2015), similarly to the role of OPERRA for CONCERT.

[24] When compiling the present report, a wide selection of the programme results were available as individual journal articles listed at the website (http://tree.ceh.ac.uk/), but no summary report was identified.

Voxel models

Similar to those used to complement the Reference Man (*cf.* Figure 1), anatomically more accurate voxel models have been developed also for non-human biota (*e.g.*, Stabin *et al.* 2006, Bitar *et al.* 2007, Dogdas *et al.* 2007, Taschereau & Chatziioannou 2007, Kinase *et al.* 2008). Studies with some recent voxel models (Mohammadi *et al.* 2011, 2012; Caffrey & Higley 2013; Ruedig *et al.* 2014, 2015; Caffrey *et al.* 2016) have concluded mainly that the present general approaches employing simplified geometries are, in most cases, in a reasonable agreement with the more accurate voxel models. Also some new geometries have been explored (*e.g.*, Jia 2017). However, these are yet individual examples of specific types of biota.

4 BIOTA ASSESSMENT METHODOLOGIES

In this chapter, brief summaries of leading assessment methodologies are provided after a concise description of the assessment process in general, due to the amount of similarities within the four approaches presented here.

Before the introduction of ICRP's Reference Animals and Plants approach in its completeness, *"the three most comprehensive approaches which are freely available for use, and which are being used by organisations other than their developers"* were the 'EA R&D 128' developed for use in England and Wales, the US Graded Approach (implemented in RESRAD-BIOTA), and the European ERICA approach (Beresford *et al.* 2008c). These have been chosen to be presented also here.

4.1 General assessment process

As outlined above, before getting to the stage of assessing the compliance against appropriate benchmarks, the process of biota assessment includes selection of the target organisms, simplification of the geometry, position and/or occupancy, radionuclide transfer modelling and dose calculations.

For the reference organisms readily chosen in the assessment approaches, there is considerable variability (Table 4). The US Graded Approach (USDOE 2002) considers only aquatic and riparian animals and terrestrial biota in screening assessments. However, usually the geometry of each reference organism is heavily simplified to aid the dosimetric calculations (an ellipsoid located as close to the radiation source as reasonable is commonly assumed). Also, usually the distribution in the body is assumed homogeneous regardless of the radionuclide. If dose rates were found high due to a non-homogeneously distributed nuclide and further studies are thus warranted, consultation with a more explicit approach may be necessary. An example of such situations is assessing exposure of rodents to bone-seeking Sr-90 by using a biokinetic model (Malinovsky *et al.* 2014).

Common ways to perform the dose calculations have been presented, for example, in (UNSCEAR 2011, pp. 242–253 (section E; in particular, p. 253)). In the simplest case, that also seems to be the most common one, the organism is assumed to be in an infinite homogeneous medium and to have a uniform activity concentration throughout its body. In addition, the densities of the medium and the organism's body are assumed to be identical. By further assuming a conveniently symmetrical (spherical) shape, it becomes reasonably straightforward to calculate the absorbed doses from the internal and the external radiation. The doses depend somewhat on the size of the organism in relation to the radiation type and energy; at an extreme, the internal exposure from incorporated alpha emitters is independent of the shape of the organisms due to the short range of the alpha particles. With re-scaling and interpolation techniques, dose calculations made for spherical organisms can be extended to ellipsoidal ones ('non-sphericity parameters') and to the internal exposure of non-aquatic organisms (*e.g.*, Ulanovsky & Pröhl 2006). However, the estimation of external exposures of terrestrial organisms is more complex due to the intrinsically different density and composition of soil, air and organic matter, and it cannot, in general, be adequately handled with analytical solutions. In such cases, a key factor is the geometric relationship between the radiation source and the exposed organism, yielding an infinite number of configurations that need to be stylised into representative exposure situations (*e.g.*, Brown *et al.* 2003a, Taranenko *et al.* 2004). For animals, the fur and outer layers of skin can be considered to form a shielding layer. For plants, attention can be paid to the meristem and buds that are generally of a conveniently simple shape. However, to take into account of the distribution of radionuclides in the plant canopy, certain simplifying conceptualisations are needed for the different types of radiation (for further details, see Taranenko *et al.* 2004). As the elemental composition and density of the materials involved importantly impacts the radiation transport calculations, all organisms can be assumed to be composed of a skeletal muscle (ICRU 1991) alone. Then, dose conversion coefficients (*i.e.*, absorbed dose (rate) per unit radioactivity concentration) are derived using Monte Carlo techniques for a suite of radiation energies, allowing data for other energies to be interpolated from the results.

Essentially, these calculations are similar to those performed for the Reference Man.

Table 4. Comparison of reference organisms defined in various assessment approaches and methodologies (not in a complete chronological order to fit on a single page).

R&D128 (Copplestone *et al.* 2001)			**UNSCEAR** (2011)
Freshwater ecosystems	*Estuarine/marine ecos.*	*Terrestrial ecosystems*	
Bacteria	Bacteria	Bacteria	Deer/herbivorous mammal
Macrophyte	Macrophyte	Lichen	Rat/burrowing mammal
Phytoplankton	Phytoplankton	Tree	Duck/bird
Zooplankton	Zooplankton	Shrub	Frog/amphibian
Benthic mollusc	Benthic mollusc	Herb	Trout/pelagic fish
Small benthic crustacean	Small benthic crustacean	Seed	Flatfish/benthic fish
Large benthic crustacean	Large benthic crustacean	Fungus	Bee/above-ground invertebrate
Pelagic fish	Pelagic fish	Caterpillar	Crab/crustacean
Benthic fish	Benthic fish	Ant	Earthworm/soil invertebrate
Amphibian	Fish egg	Bee	Pine tree/tree
Duck	Seabird	Woodlouse	Wild grass/'grass' *
Aquatic mammal	Seal	Earthworm	Brown seaweed /macroalga
	Whale	Herbivorous mammal	
		Carnivorous mammal	
		Rodent	
		Bird	
		Bird egg	
		Reptile	

FASSET (Larsson *et al.* 2004)		**EPIC** (Brown *et al.* 2003b; specific to the Arctic)	
Terrestrial ecosystems	*Aquatic ecosystems*	*Terrestrial ecosystems*	*Aquatic ecosystems*
Soil microorganism	Benthic bacteria	Soil invertebrate (*Collembola*)	Pelagic planktotrophic fish
Soil invertebrates	Benthic invertebrates	Soil invertebrate (mite)	Pelagic carnivorous fish
Plants and fungi	Molluscs	Herbivorous mammal (lemming)	Benthic crustacean
Bryophytes	Crustaceans	Herbivorous mammal (vole)	Benthic fish
Grasses, herbs and crops	Vascular plants	Herbivorous mammal (reindeer)	Bivalve mollusc
Shrubs	Amphibians	Herbivorous bird	Sea bird
Above-ground invertebrates	Fish	Bird egg	Pelagic crustacean
Burrowing mammals	Fish eggs	Carnivorous mammal	Carnivorous mammal
Herbivorous mammals	Wading birds	Plant roots	
Carnivorous mammals	Sea mammals		
Reptiles	Phytoplankton		
Vertebrate eggs	Zooplankton		
Amphibians	Macroalgae		
Birds			
Trees			

ERICA (Beresford *et al.* 2007b)			**ICRP** (ICRP 2008) **
Terrestrial ecosystems	*Freshwater ecosystems*	*Marine ecosystems*	Deer
Amphibian	Amphibian	(Wading) bird	Rat
Bird	Benthic fish	Benthic fish	Duck
Bird egg	Bird	Bivalve mollusc	Frog
Detritivorous invertebrate	Bivalve mollusc	Crustacean	Trout
Flying insect	Crustacean	Macroalgae	Flatfish
Gastropod	Gastropod	Mammal	Bee
Grass/herb	Insect larva	Pelagic fish	Crab
Lichen/bryophyte	Mammal	Phytoplankton	Earthworm
Mammal	Pelagic fish	Polychaete worm	Pine tree
Reptile	Phytoplankton	Reptile	Wild grass
Shrub	Vascular plant	Sea anemone/true coral	Brown seaweed
Soil invertebrate (worm)	Zooplankton	Vascular plant	
Tree		Zooplankton	

* Grass, herb or crop.

** Representatives of a large (deer) and small (rat) terrestrial mammal, an aquatic bird (duck), an amphibian (frog), a freshwater fish (trout), a marine fish (flatfish), a terrestrial insect (bee), a marine crustacean (crab), a terrestrial annelid (earthworm), a large (pine tree) and small (wild grass) terrestrial plant, and a seaweed (brown seaweed) (ICRP 2008).

The R&D 128 (or, R&D128/Sp1a) assessment tool (Copplestone *et al.* 2001, 2003) was developed for the Environmental Agency of England and Wales to assist them in fulfilling their regulatory obligations, particularly related to the EU Habitats Directives. Its use has been largely been replaced by the ERICA tool due to the limitations. However, it still remains the only one of the freely available models that allows modelling noble gases. (Smith *et al.* 2016).

The approach was actually considered an interim means before publication of the results of the EU FASSET project, which it was also feeding with an example (Copplestone *et al.* 2001). The basis of the approach is the calculation of doses to wildlife based on their size, dietary uptake of radionuclides and external exposure in the environment, by using either literature data or measurements (Copplestone *et al.* 2001):

- each organism is presented as an ellipsoid to aid dosimetric calculations;
- selection of the organisms for the assessment shall be based on their radioecological significance and radiosensitivity, and endpoints of importance (*e.g.*, morbidity, mortality, reproductive capacity, mutation rate) – however, they are not a direct representation of any identifiable animal or plant species;
- concentration ratios are used to evaluate internal contamination of each organism;
- positioning relative to soil, sediment or water is used to evaluate the external exposure;
- dose per unit concentration (DPUC) is evaluated for each radionuclide from the abovementioned information;
- the average dose throughout the volume of the organism is calculated for both internal and external irradiation.

The default reference organisms are presented in Table 4 above. In the main documentation of the approach, it is acknowledged that there is no international consensus on the benchmark values, but based on a review and evaluation (Woodhead 1998) the Environmental Agency shall use the following benchmarks for chronic exposures (Copplestone *et al.* 2001):

- 40 µGy/h for terrestrial animal populations;
- 400 µGy/h for terrestrial plant populations;

- 400 µGy/h for populations of freshwater and coastal organisms; and
- 1000 µGy/h for populations of organisms in the deep ocean.

4.3 DoE Graded Approach

As outlined in section 3.3 above, in the United States an order of the Department of Energy (USDOE 2013) essentially requires the Graded Approach (USDOE 2002) to be used for biota assessments. For practical use, the approach has been implemented in the RESRAD family of codes (see section 5.2.1). The intent of the graded approach *"is to protect populations of aquatic animals, terrestrial animals, and terrestrial plants from the effects of exposure to anthropogenic ionising radiation"* (USDOE 2002).

The Graded Approach for evaluating radiation doses to aquatic and terrestrial biota consists of three steps that guide the user from an initial conservative screening to a more rigorous site-specific analysis where needed. The steps are (USDOE 2002):

- collation of radionuclide concentration data and knowledge of sources, receptors, and routes of exposure for the area to be evaluated;
- applying an easy-to-use general screening methodology that provides limiting radionuclide concentration values ('Biota Concentration Guides', BCGs) in soil, sediment, and water; and
- if needed, conducting an analysis through site-specific screening, site-specific analysis, or an actual site-specific biota dose assessment through incorporation of relevant elements of ecological risk assessment procedures.

The following benchmark values are to be used within a Graded Approach *"to demonstrate that populations of plants and animals are adequately protected"* (USDOE 2002):

- 1 rad/d (10 mGy/d) for aquatic animals or for terrestrial plants; and
- 0.1 rad/d (1 mGy/d) for terrestrial animals.

For the application of the Graded Approach, it is emphasised that care must be taken if potential radiological impacts to "endangered, threatened, rare, or otherwise sensitive species" or commercially or culturally valued species are to be evaluated, since then the general screening methodology may not provide correct answers to the question being addressed (USDOE 2002).

4.4 European Commission

The background and general principles in the FASSET, EPIC, ERICA and PROTECT projects are provided above (section 3.2.5). Here, the overall workflow of the ERICA, or FASSET/ERICA, approach is summarised. For clarity, the following text is mostly adapted from the main description of the ERICA approach, the 'D-ERICA' document (Beresford *et al.* 2007b).

The purpose of the ERICA Integrated Approach is to ensure that decisions on environmental issues give appropriate weight to the environmental exposure, effects and risks from ionising radiation with emphasis on ensuring the structure and function of ecosystems. To fulfil this objective, elements related to environmental management, risk characterisation and impact assessment have been integrated into one common structure. This includes also components of problem formulation and stakeholder involvement that are not usually explicitly presented in the other frameworks.

The assessment element of the ERICA Integrated Approach is organised in three separate tiers, where satisfying certain criteria in Tiers 1 and 2 allows the user to exit the assessment process while being confident that the effects on biota are low or negligible, and that the situation requires no further action. Where the effects are not shown to be negligible, the assessment should continue to Tiers 2 and 3. Situations of concern should be assessed further in Tier 3, by making full use of all relevant information available through the Integrated Approach or elsewhere. The Tiers are further described as follows:

- Tier 1 is a simple and conservative screening, requiring a minimum of input data. Here, the screening value is applied to all ecosystems and organisms, and it is used to calculate Environmental Media Concentration Limits (EMCLs) against which the input concentrations are compared to check for compliance.
- Tier 2 is more interactive, meaning that the user can modify the parameter values and select specific reference organisms. A 'traffic light' system is used when comparing the calculated dose rates with the screening value, indicating (i) negligible concern with a high degree of confidence; (ii) potential concern prompting qualified judgements, improvement of

Tier 2 assessment or continuing to Tier 3; or (iii) concern prompting improvements or continuation to Tier 3.

- Tier 3 assessments are typically complex and case-specific, and simple yes/no answers cannot be formulated beforehand. Typically the FREDERICA effects database (see section 5.2.5) should be consulted. Tier 3 also involves a probabilistic risk assessment, in which uncertainties within the results may be determined using sensitivity analysis.

If data on all environmental concentrations are not available (through measurement or an external model), the IAEA screening models (IAEA 2003) are used to estimate the radionuclide distributions in the environment. The internal contamination of the organisms is estimated anyway by means of environmental media-to-organism concentration ratios. To calculate the external irradiation, ten different positions (Figure 4) can be assigned to each reference organism through an occupancy fraction parameter (fraction of the time spent in the position).

The reference organisms used in the ERICA approach are listed in Table 4 above. They are used to calculate the EMCLs in Tier 1, and they can be selected individually for Tier 2 assessments. They also form a basis in Tier 3.

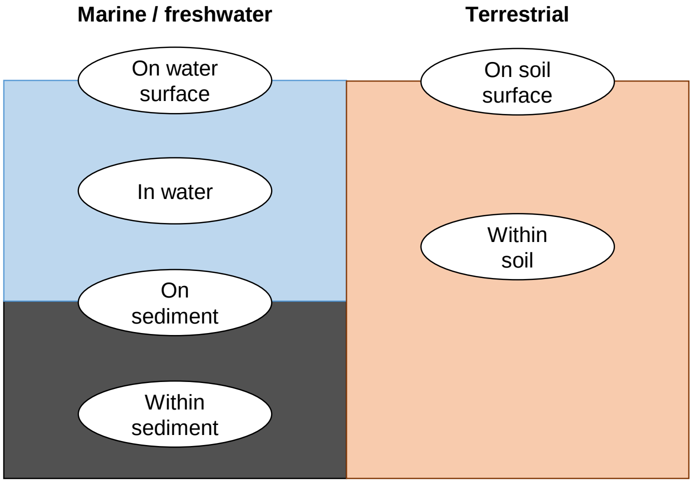

Figure 4. The 'habitats' available for the reference organisms in the ERICA approach in respect of the radioactivity in the water, sediment or soil of the three ecosystems (modified from Beresford *et al.* 2007b).

It is also to be noted that the ERICA Integrated Approach is consistent with the ICRP Reference Animals and Plants approach (*e.g.*, Brown *et al.* 2016).

4.5 ICRP Reference Animals and Plants

The ICRP system has largely been described above in section 3.2.2, and thus the description here consists rather of further details stipulated in the recommendations. However, a degree of flexibility seems to be allowed, especially regarding details of the representative organisms assessed (ICRP 2008, 2014; Copplestone 2012a).

Even though it is not possible to provide a comprehensive biological background to all of the Reference Animals and Plants (RAPs), some additional general information is provided in (ICRP 2008, annex A), together with a more general discussion on their populations, basic characteristics of which are given in (ICRP 2008, table 2.1). The population characteristics and the geographic area of relevance need to be borne in mind when considering the potential effects on the level of populations (ICRP 2008).

Although each RAP is generalised to the taxonomic level of family, they are labelled by a more common name to help the general reader (ICRP 2008). However, *"it is envisaged that a set of biota would be chosen as a basis for assessing the actual or potential impact upon them. These are the 'representative organisms', the equivalent of the human 'representative individual'. The actual choice of such organisms will depend upon the purpose of the assessment, and may be specific and predetermined … or they may be selected on purely practical grounds."* (ICRP 2008).

For the dose calculations, the most recent Monte Carlo-based models used within the EPIC project (Golikov *et al.* 2003), the RESRAD-BIOTA computer code (USDOE 2002), the French EDEN code (Beaugelin-Seiller *et al.* 2006), and codes used within the FASSET and ERICA projects (Taranenko *et al.* 2004, Ulanovsky & Pröhl 2006) were compared (ICRP 2008, annex B). Of these models, the largest set of geometries and exposure situations was that of the FASSET/ERICA programme, based on its flexible dosimetry method. This model allowed calculations for a sufficiently wide range of organisms to include the specific dimensions of the Reference Animals and Plants. It was therefore used to calculate a comprehensive set of values for all of the Reference Animals and Plants. (ICRP 2008). Furthermore, information on extrapolation and interpolation in terms of basic dosimetry assumptions into other shapes and sizes of animals and plants could be compiled (ICRP 2008, annex E).

In the dose calculations, a few definitions regarding the RAPs were used (ICRP 2008):

- The body composition is assumed to be equivalent to the four-component composition defined by ICRU (ICRU 1989)[25], and a body density of 1.0 g/cm³. The organisms are assumed to be in an infinite water medium to ensure that there is sufficient medium for secondary photon transport.
- It should be noted that the underlying basic calculations for the absorbed fractions are made for organisms immersed in water. These values are also applied for organisms living in other media, such as soil or air, or at the soil/air interface, although they are slightly different due to the different backscattering of photons, which is more pronounced when the density of the surrounding medium is higher.

Finally, after the dose rate calculations, there are matters to consider when comparing with the DCRLs (ICRP 2008), particularly those that relate to the reason for the assessment being made, to factors that are essentially related to the sciences of radiobiology and radio-ecology, or to more basic issues relating to ecology and environmental science generally. Such factors could include but not limit to the following (ICRP 2008):

- the nature of the exposure situation (normal, existing or emergency);
- the size of the impacted geographical area;
- the duration of such dose rates;
- the presence, or expected presence, of additional stressors (*e.g.*, chemicals, heat, or other forms of environmental stress) in the same area;
- whether or not the assessment is related to actual species, or simply to generalised animal or plant types; and
- the degree of precaution considered necessary in the specific circumstances.

5 IMPLEMENTATION OF BIOTA ASSESSMENTS

In this chapter, first the supportive material that provides advice specific to geological disposal and has been produced through the BIOPROTA collaborative forum is summarised. In the subsequent

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[25] Such four-component composition eludes the reader in the document referred to. However, for example a composition of hydrogen (10%), carbon (14.89%), oxygen (71.39%), nitrogen (3.47%), chlorine (0.1%) and sodium (0.15%) has been reported for some corresponding uses (*e.g.*, Stabin & Konijnenberg 2000, Mohammadi *et al.* 2012).

sections, key tools available for practical implementation of a biota assessment are briefly presented, followed by examples of such assessments in various contexts of radiation exposure of the environment.

5.1 BIOPROTA supportive material for geological disposal

BIOPROTA is a collaborative forum bringing together operators and regulators with responsibility for achieving safe and acceptable radioactive waste management[26]. This section summarises their projects addressing assessments of radiation protection of the environment in the context of geological disposal of radioactive waste. These draw from the existing international frameworks (chapter 3), but are open for choosing between the tool options (from those presented later in section 5.2, or otherwise).

It is characteristic for geological disposal facilities that the releases potentially occur from deep underground (in the geosphere) and radionuclides are commonly assumed to be carried to the surface environment (biosphere) with the movement of groundwater over very long time periods. The time periods under consideration are of such an extent that the effects of climate change and its impact on the nature and structure of the ecosystems cannot be fully defined. (Robinson *et al.* 2010, Lindborg *et al.* 2018, among others). Over these time periods, the biota populations change naturally in size and otherwise, and also the species composition will fluctuate and evolve. Thus, instead of explicitly protecting present populations, it seems more appropriate to target the protection towards ensuring that the environment remains productive and capable of supporting high biodiversity and sustainable use of biological resources. Such protection of environment, also promoted by the ICRP (*e.g.*, ICRP 2007), is still achieved by ensuring that biota are not impacted significantly, but the focus is taken from protecting the present populations to protecting any populations that may naturally occur at the site, both now and in the future. However, effects on the ecosystem must be extrapolated for example over climatic fluctuations from presently available knowledge. Thus, the organisms and populations currently found at the site may therefore represent future assemblages in terms of the range of biological complexity. (Jaeschke *et al.* 2016).

A workshop was held in 2007 (BIOPROTA 2007), coinciding with the developments in the ERICA and PROTECT projects (see above) to

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[26] http://www.bioprota.org/ (accessed 26 February 2018).

summarise the international developments in, for example, ICRP Committee 5, ERICA and PROTECT, and discuss experiences with applying these and other methods in assessment case studies.

In a subsequent BIOPROTA project (Smith *et al.* 2010), conceptual uncertainties associated with the application of the ERICA assessment method to post-closure assessments of geological disposal of radioactive waste were addressed through sensitivity and knowledge quality assessments based on the default assessment parameters within the ERICA assessment approach. The sensitivity analysis of the models was run for both generic and test cases. The knowledge quality assessment part involved development of a questionnaire around the ERICA assessment approach, which was distributed to a range of experts in the fields of non-human biota dose assessment and radioactive waste disposal assessments. When the results were combined, these assessments enabled identification of critical model features and parameters that are both sensitive (*i.e.*, have a large influence on model output) and of low knowledge quality to be identified for each of the three test cases. (Smith *et al.* 2010).

In the following project (Smith *et al.* 2012, Jackson *et al.* 2014), demonstration of compliance with the environmental protection targets was discussed in the same context based on comments received to an interim report and in a workshop. Advice was provided on how non-human biota assessments may be undertaken within performance assessments for disposal facilities for long-lived radioactive waste. A particular focus was to provide an outline concept which forms one possible approach to the demonstration of compliance with environmental protection objectives for radioactivity in the environment where available screening values are exceeded. Table 5 summarises the main outcome, a two-tier general concept to demonstrate compliance partly following the approach to tolerability of varying levels of risk and usage of the ALARP (as low as reasonably practicable) principle in radiation protection of humans (HSE 1992).

Fourth BIOPROTA project on the biota assessments, SPACE (Smith *et al.* 2016), aimed at improving the understanding of temporal and spatial scales for populations of non-human biota and their commensurability with current approaches to human spatial and temporal averaging since the averaging based on assessment of human exposure, typically used in past assessments, has been considered as inappropriate in many situations. Based on a review of life-history parameters, a range of representative species were defined for the purpose of the project. It was concluded that temporal averaging resolution is unlikely to be a significant issue in the long-term assessments. Thus, only spatial averaging was explicitly explored through modelling in which the commensurability of the biota and human spatial scales was evaluated using typical averaging scale for humans (use of an agricultural system) and by overlaying distributions of biota populations per the specifications of the representative species. At the end, it was concluded that *“although the scope of the scales assessment has been limited in this study to biota of temperate terrestrial ecosystem, … there may be merit in giving further consideration to the utilisation of the biosphere by populations of plants and animals that may be exposed due to their possible occupancy in areas potentially affected by discharge zones concurrently to the consideration of human utilisation of the system”* (Smith *et al.* 2016).

Table 5. Generalised two-tier concept for compliance demonstration in respect of radiological protection of the environment from geological disposal of radioactive waste (rearranged and amended from Smith *et al.* 2012, Jackson *et al.* 2014).

Dose rate range	Level of protection	Implications to assessment	Further measures
Above Tier 2	Potential effects anticipated	Improve assessment knowledge base	Need to justify exposure and/or demonstrate off-setting measures
Tier-2 criteria dependent on the biota type (taxa) *			
Between Tier 1 and Tier 2	Confident of acceptable [or no] impacts	Improve assessment using available knowledge	Use ‘best endeavours’ to reduce dose **
Tier-1 generic screening value independent of the biota type (taxa)			
Below Tier 1	All biota types (taxa) protected at an acceptable level	Simple screening assessment ***	No further measures required

* Corresponding to limited [*i.e.*, at most, acceptable degree of] effects.
** Consistent with maintaining ALARA for people.
*** [For example, corresponding to tiers 1 or 2 in the ERICA approach, augmented with site-specific information where appropriate.]

Currently, BIOPROTA is supporting the update of IAEA BIOMASS methodology (IAEA 2003) for biosphere assessments of solid radioactive waste disposal. Lessons learned from experiences with non-human biota assessments will be incorporated in the work (*e.g.*, Smith 2018).

5.2 Assessment tools

This section provides brief summaries of practical tools available for conducting biota assessments. The tools presented in this section are publically available. They are also the most widely used for the purposes of biota assessments internationally (Smith *et al.* 2016).

However, all these tools are poor for conducting temporal and/or spatial assessments. For spatial assessments, the USEPA SADA model[27] enables screening tier assessments to be conducted spatially by using parameters from the RESRAD-BIOTA tool, and the calculation routines of the ERICA Tool have been implemented in geographical information systems. Similarly, more advanced dosimetric models require the use of other software not generally available. (Beresford *et al.* 2008c).

5.2.1 RESRAD-BIOTA

RESRAD-BIOTA (USDOE 2004) is a tool belonging to the RESRAD family of model codes that implement the Graded Approach (USDOE 2002; see also section 4.3) established in the United States. It is an evolution of the Biological Concentration Guide (BCG) calculator that was originally developed to support the Graded Approach. RESRAD-BIOTA enables the application of a kinetic-allometric approach to modelling transfer (Higley *et al.* 2003b) from the diet of animals, rather than relying solely on the use of equilibrium concentration ratios (Smith *et al.* 2016). The current version incorporates probabilistic calculation mode, enabling sensitivity analysis for most of the modelling parameters. However, the tool still has the rather common limitation of not hosting a functionality to easily address spatial or temporal variability (Smith *et al.* 2016), except through multiple model runs and pre- and post-processing.

5.2.2 CROM (CROMERICA)

CROM (Robles *et al.* 2007) is a generic environmental model code developed by the CIEMAT in collaboration with the Polytechnic University of Madrid based on IAEA screening models (IAEA 2003) with some variations from (Simmonds *et al.* 1995). Thus, it uses generic models for dispersion and dilution to simulate radionuclide concentrations in atmospheric dispersion/deposition, surface waters, terrestrial environment ('farm') and in foodstuff. After independent quality control, the IAEA has adopted the code for a worldwide distribution as the reference for the screening models. (Barnett *et al.* 2013, Mora *et al.* 2015).

The tool allows use of local parameter values, and version 7 implements capabilities for propagating uncertainties by using Monte

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[27] For example, "Spatial Analysis and Decision Assistance": ecological risk assessment, https://www.sadaproject.net/ecological_risk.html (accessed 31 March 2018).

Carlo methods. CROM version 8, also known as ‘CROMERICA’, integrates approaches for radiation protection of both the humans and the biota. (Mora *et al.* 2015).

5.2.3 ERICA Assessment Tool

The ERICA Assessment Tool (Brown *et al.* 2008) has been developed in an EU project to implement the ERICA integrated assessment (see section 4.4), but has since been updated a few times (Brown *et al.* 2016; Smith *et al.* 2016).

The tool guides the user through the assessment process, recording information and decisions and allowing the necessary calculations to be performed to estimate risks to selected animals and plants. Tier 1 assessments are based on the radionuclide concentration in environmental media and use pre-calculated environmental media concentration limits (EMCLs) to estimate risk quotients. Tier 2 calculates dose rates, but allows the user to examine and edit most of the parameters used in the calculation including the specifications of the reference organisms and concentration ratios. Tier 3 allows further the option to run the assessment probabilistically, if the underling parameter probability distribution functions are defined. Results from the tool can be put into context using the dose–effect data from the incorporated FREDERICA database (see section 5.2.5 below). The tool also readily incorporates the ICRP Reference Animals and Plants as reference organisms available for the analyses. Also customised reference organisms can be added, and the software interpolates or extrapolates then the needed dose coefficients. (Brown *et al.* 2008). As with RESRAD-BIOTA, however, the ERICA tool does not readily support spatial or temporal analysis (Smith *et al.* 2016).

5.2.4 Wildlife Transfer Database

The Wildlife Transfer Database (WTD; Wood *et al.* 2013) is an international online database for environmental media-to-wildlife concentration ratio values, originated to help the data compilation of the IAEA (IAEA 2014a, Howard *et al.* 2013) and the ICRP (ICRP 2009), and envisaged to be further improved. In addition to the categorisation used in the abovementioned publications, the database allows various groupings of the data, for example by different wildlife groups, and keeps track on references to the underpinning publications[28].

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[28] http://www.wildlifetransferdatabase.org/ (accessed 26 February 2018).

5.2.5 FREDERICA effects database

Within the FASSET and ERICA projects, an online radiation effects database ‘FREDERICA’[29] (Copplestone *et al.* 2008, Garnier-Laplace *et al.* 2008) was developed that includes effects data for 16 wildlife groups, which are broadly comparable with the chosen reference organisms (*e.g.*, Robinson *et al.* 2010). Essentially, the database contains quality-assured information about biological effects associated with absorbed dose rates (Copplestone *et al.* 2008).

The origins of the database are in the FASSET Radiation Effects Database (FRED) that was later expanded with the database from the EPIC project and augmented within the ERICA project, thus the current name (Woodhead *et al.* 2003, Beresford *et al.* 2007b, Copplestone *et al.* 2008, Garnier-Laplace *et al.* 2008). The effects data are arranged by ‘umbrella endpoints’ of mutation, morbidity, reproductive capacity, mortality, stimulation, adaptation and (non-direct) ecological effects. The source data have also been evaluated in terms of a grading scheme of the underlying peer-reviewed papers. (Copplestone *et al.* 2008).

Even though the database was originally a companion of the ERICA tool (and is still accessible directly through it), it has become important also in other projects, especially in those deriving or updating species sensitivity distributions (*e.g.*, Andersson *et al.* 2008, 2009). It has been used also to assess the effects from dose rate levels otherwise (*e.g.*, UNSCEAR 2011).

5.3 Examples of biota assessments

This section provides an overall view of key points in the selected applications of biota assessment methodologies applied and provides references for further study. The topic areas aim to cover various situations with a focus on the about last ten years, excluding the impacts of nuclear accidents (Chernobyl and Fukushima) due to generally high levels of exposure. For earlier national developments in biota assessments of particularly geological disposal, see for example (Smith & Robinson 2008, app. 2). Also several case studies, testing the FASSET/ERICA approach, have been reported within the ERICA project (Beresford & Howard 2005).

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[29] http://www.frederica-online.org/ (accessed 26 February 2018).

5.3.1 Deep geological radioactive waste disposal (post-closure)

Regarding deep geological disposal of radioactive waste, key examples here are for generic repositories (Canada and the UK) and for repositories at specific sites (Finland and Sweden).

Canada

Biota assessments have been developed for the Canadian deep repository concept for considerably long. For example, selection of representative organisms (Sheppard 2002) has displays criteria similar to those adopted later in the major other approaches. The assessment of Garisto *et al.* (2008) used undefined geometries absorbing the entire radiation energy the organism is exposed to (Garisto *et al.* 2008 referring to Amiro 1997, USDOE 2002) or dose conversion factors derived in the FASSET project (Larsson *et al.* 2004) if they were higher. As benchmark values, they used no-effect concentrations (NEC) that represent levels for which there was confidence that at lower concentrations there would be “no significant ecological effects on non-human biota”. (Garisto *et al.* 2008). The concentrations in the biota were then calculated based on relatively simple pathways and use of both transfer factors based on the intake rate of a mammal or bird and media-to-organism concentration ratios for the other organisms[30] (Medri & Bird 2015).

An update to that earlier methodology (Medri & Bird 2015) was based on experiences of using particularly the ERICA approach and its assessment tool, together with a Canadian environmental risk assessment approach (CSA 2012). The reference organisms (Table 6) were selected to be *“representative of the main taxonomic groups found in ecosystems that represent a range of Canadian conditions: southern Canadian deciduous forest (SCDF), boreal forest (BF) and inland tundra (IT) (a potential far-future climate condition during glaciations)”* based on taxonomic categories of the FASSET (Brown *et al.* 2003a), ICRP (2008) and ERICA (Brown *et al.* 2008) approaches, with certain categories excluded through rationales.

Results of an assessment for a site-selection process based on the same, or similar, methodology were presented in a BIOPROTA meeting (Smith 2017, pp. 23–27). Hypothetical illustrative sites both in areas of granite crystalline bedrock and on sedimentary bedrock were assessed with two scenarios, a normal evolution scenario and a

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[30] For example in the ERICA and ICRP approaches, environmental media-to-organism concentration ratios are used for all organisms.

bounding disruptive scenario, were analysed in the biota assessment. Three ecosystems were representative of a range of Canadian conditions were considered: boreal forest, inland tundra and southern Canadian deciduous forest. A temperate climate was assumed with the species present in these three ecosystems being used to define a representative species list for assessment. For the benchmark values, a two-tier approach was adopted, with the ERICA/PROTECT screening value of 10 µGy/h being applied as a lower generic screening value and the upper end of the ICRP derived consideration reference levels (DCRL) being applied as upper species-dependent acceptance criteria (further investigation being triggered if exceeded). These criteria may be revised later based on feedback from regulators or changes in ICRP or other recommendations. Generally, the calculated dose rates were below the criteria, but dose rates to some representative species in the disruption scenario fell between the general and species-dependent values. As such scenario has been deemed highly unlikely, it was concluded that there is no radiological concern.

Table 6. Representative biota applied in the present NWMO non-human biota assessment methodology (Medri & Bird 2015).

Aquatic (inland) ecosystems		**Terrestrial ecosystems**	
Category	**Selected representative species**	**Category**	**Selected representative species**
Amphibian	Northern leopard frog	Reptile	Common garter snake
Aquatic bird, omnivorous	Canada goose * Mallard	Terrestrial bird, carnivorous	Great horned owl
Aquatic bird, piscivorous	Red-throated loon Common loon	Terrestrial bird, herbivorous	Willow ptarmigan Ruffed grouse
Aquatic mammal	Mink * Beaver * Muskrat *	Terrestrial invertebrate	Earthworm
Aquatic plant	Pondweeds Water sedge	Terrestrial mammal, small carnivorous	Red fox Arctic fox
Benthic invertebrate	Chironomid larvae	Terrestrial mammal, small herbivorous	Arctic hare Eastern cottontail rabbit Snowshoe hare
Fish, benthic	Lake whitefish	Terrestrial mammal, rodent	Meadow vole Brown lemming
Fish, pelagic	Lake trout	Terrestrial mammal, small burrowing	Groundhog Arctic ground squirrel
		Terrestrial mammal, large carnivorous	Brush wolf Grey wolf Arctic wolf
		Terrestrial mammal, large herbivorous	White-tailed deer Moose * Barren-ground caribou
		Terrestrial plant, tree	White cedar Dwarf (Arctic) willow
		Terrestrial plant, berries	Berries
		Terrestrial plant, grasses and herbs	Sedges
		Terrestrial plant, lichen	Lichens

* Considered to be both aquatic and terrestrial organism.

Finland

In the Finnish spent nuclear fuel repository programme, there has been development of biota assessment methodology from a phase of confirming site investigations (Smith & Robinson 2006, Smith *et al.* 2007) to a safety case supporting the construction licence application. The basic concept has remained the same, though, but with increasing degree of sophistication along the rest of the assessment. Where initial studies were about reviewing and development of a potential methodology, Broed *et al.* (2008) used the generic ERICA Tier 1 environmental media concentration limits (EMCL) applied to a large number of calculation cases varying mainly the magnitude and location of the release to the biosphere according to postulated scenarios of the behaviour of the repository system, with all the results meeting the EMCL criteria. Hjerpe *et al.* (2010) focused then on fewer calculation cases and introduced explicit use of ERICA Tier 1 and 2 for screening out radionuclides, and Tier 3 with site-specific data and representative species for main analysis (for the ERICA Tiers, see section 4.4).

In the latest assessment (Posiva 2013b, 2014), the default ERICA reference organisms were placed with representative species (Posiva 2013a, section 4.1) selected based on species common in ecosystem types expected to prevail at the site in the future, importance in the food web (taking into account for example community structure, ecological niche, ecosystem functioning and identified keystone species[31]), likelihood of maximal exposure due to ecological traits or habits (through, *e.g.*, food sources, typical location in the environment, presence in the area throughout the year, or sub-soil hibernation), species of public interest, and availability of context-relevant information on the species[32]. Also site-specific data were used for the size and weight of the organisms, as well as for concentration ratios where available. Summarised briefly, in all the scenarios and calculation cases the dose rates remained several orders of magnitude below the ERICA screening value.

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[31] “Keystone species are those that have a disproportionate effect on their environment relative to their abundance (or biomass). Such species play a critical role in maintaining community structure, determining the type and number of other species in a community. By removing keystone species, a large shift in community structure may occur (for example, a population explosion of a prey species may occur where a predator is removed with commensurate effects on species that share the niche of, or provide a source of nutrition to, the prey species” (Posiva 2013a).

[32] Based on the list of the selected species and other material presented, the aim has clearly been to sufficiently cover the food web representative of each ecosystem type, but data limitations have somewhat constrained the final set.

Sweden

In Sweden, the long-term safety of a spent nuclear fuel repository has been evaluated in the SR-Site assessment that included also non-human biota considerations (Jaeschke *et al.* 2016; SKB 2010, Torudd 2010, Torudd & Saetre 2013). The ERICA assessment approach and the tool were employed. The representative species were identified based on legislation, site information and through mapping to ERICA reference organisms (freshwater, marine and terrestrial); it was required that also particularly vulnerable or important species and 'average organisms' were included. In addition, the results for the site-specific representative species were compared with the default ERICA reference organisms. Impacts to non-human biota were assessed in different scenarios (corrosion base case, pulse-release and change in climate conditions) and compared with the ERICA screening dose rate. The ICRP derived consideration levels were used as secondary indicators. All the results obtained were "lower than the screening dose rate of 10 µGy/h, indicating that no significant effects at population are predicted and no deeper investigation is necessary" (Jaeschke *et al.* 2016).

Independent comparisons of the biota assessment in SR-Site were made for the regulator by using RESRAD-BIOTA (Stark 2015). Also in this case the *"results suggest the calculated dose rates will not exceed the screening level values of 10 µGy/h"*. It was also concluded that, here, using RESRAD-BIOTA instead of the ERICA tool would not lead to different conclusions. However, it was observed that dose rates calculated with the default settings of these two tools sometimes differ even two orders of magnitude. The differences could be explained, for example, by differences in plant geometry, biomass and position in respect of the soil surface, and by differences in occupancies of representatives of animals in the various locations in the environment. Also, Np-237 was not readily available for the RESRAD-BIOTA simulations. More fundamentally, the choice of reference organisms by different assessors to represent site-specific species may influence the results (*e.g.*, Johansen *et al.* 2012 referred to by Stark 2015), but this was not studied in detail.

Another assessment for geological disposal of radioactive waste in Sweden, for an extension of low-level nuclear waste repository SFL (the SR-PSU project, SKB 2014), addressed the potential exposures of non-human biota as well, although largely scaling the earlier results from SR-Site (Torudd 2010, Jaeschke *et al.* 2016) and discussing on the interpretation. In addition to the ERICA/PROTECT screening value, also the ICRP derived consideration reference levels (DCRLs; ICRP

2014) were considered, especially in cases where they are more restrictive than the ERICA/PROTECT screening value (see Table 3 in section 3.4). However, the conclusions of the assessment were similar to those in the SR-Site assessment described above.

United Kingdom

A biota assessment for a generic deep geological repository in the UK has been developed by Smith & Robinson (2008), and it predates the regulations of England and Wales summarised above. The ERICA approach and assessment tool (Tier 2) were used also here, but in general also the ICRP recommendations available at the date were considered. The ERICA screening value of 10 µGy/h was retained here, and in all cases, the dose rates were below that value.

5.3.2 Near-surface disposal of radioactive waste

As an example of near-surface disposal of radioactive waste, the case of the Low Level Waste Repository (LLWR) is presented here. It is the principal facility for the disposal of solid low-level radioactive waste in the United Kingdom, located on the West Cumbrian coastal plain[33], about 0.5 km inland, near the Sellafield site. The biota assessment (LLWR 2011) has been implemented as a part of an environmental safety case for estimating the radiological effects of the LLWR on the accessible environment for all pathways of exposure, both during the period of authorisation and afterwards. Similarly to many examples, a limited number of reference organisms were identified to avoid the impossibility of developing "*ecological, bioaccumulation or dosimetric models for all types of organisms and all relevant stages of their life cycles*". Whole-body dose rates were calculated for these reference organisms with the ERICA tool and compared with threshold dose rate of 10 µGy/h, following an advice from the Environment Agency (this screening threshold being more restrictive than the previous value used in the UK, 40 µGy/h). In essence, the ERICA reference organisms were used, added with further ones appropriate to estuarine and beach/foreshore environments (Thorne & Schneider 2011) relevant in this assessment. Taking all radionuclide sources into account, the dose rates were generally below 1 µGy/h and very unlikely to exceed the screening value of 10 µGy/h. For the specific case of gaseous releases and particularly C-14, the dose rates in the range of 3–9 µGy/h were

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[33] To the west and south the site is adjacent or close to the Drigg Coast Special Site of Scientific Interest (SSSI), which is designated also as a Natura 2000 Special Area of Conservation (SAC) (LLWR 2011).

calculated, and for a scenario of a repository collapse event on the storm beach area, dose rates up to about 100 µGy/h were calculated for invertebrates inhabiting and gaining sustenance from the very area, but such organisms are generally considered ‘relatively insensitive to radiation’ (LLWR 2011).

5.3.3 Operational safety of nuclear waste facilities

Potential radiological impacts of spent nuclear fuel encapsulation plant also on non-human biota have been studied at least in Finland and Sweden.

In the Finnish case, the safety analysis of normal operational conditions and postulated incidents and accidents in the encapsulation plant (Rossi & Suolanen 2012) considered also dose rates to terrestrial biota calculated with the ERICA approach. Also the FREDERICA effects database was used to interpret the results, since in the worst accident scenario, highest doses to terrestrial reference organisms were about 20 µGy/h at the distance of 200 m from the ventilation stack (release source to the environment), but below the 10 µGy/h generic screening value at 1 km from the facility. It was concluded that such high release is relatively momentary, so the dose rate would not describe well the chronic exposure to most species. For both normal operational conditions and incident scenarios the dose rates were estimated to be at least more than two orders or magnitude smaller than in the worst accident scenario. In addition, possibilities to monitor radiation effects per se have been reviewed in a separate study (Smith 2016), although concluding them being impractically minor at the expected exposure levels.

Another corresponding facility in Sweden has been analysed relatively similarly. The potential releases from Clink, a facility combining the existing underground central interim storage facility for spent nuclear fuel (‘Clab’) and the spent nuclear fuel encapsulation plant (‘Ink.’) (Edelborg *et al.* 2014), have been modelled with the ERICA tool (Hallberg *et al.* 2011). Dose rates resulting from releases to the sea and from atmospheric dispersion and deposition into soil and water were estimated for both normal operation and accidents. Despite of the cautious assumptions made, the dose rates remained below or much below the screening value of 10 µGy/h. The highest dose rates were simulated to occur in the aquatic environment due to the combined effect of direct marine releases and deposition from the atmospheric releases (sea covers a large part of the surroundings of the facility).

5.3.4 Releases from nuclear power plants and other nuclear facilities

For the Pickering Nuclear Generating Station on Lake Ontario, Canada, a screening level ecological risk assessment has been performed for regulatory compliance. A range of radionuclides in the receiving aquatic, atmospheric and terrestrial environments were assessed based on measured and predicted concentration. The methodology followed generally those of the IAEA and NCRP (IAEA 1976, 1992, 2001; NCRP 1992, 1996). For trumpeter swan, a species identified for special protection, a lower benchmark was derived and used for protection of this species. The screening value was exceeded for earthworms in a very conservative upper bound scenario based on the localized maximum concentration of tritium in on site groundwater. Similar case was found for trumpeter swan from intake of radionuclides through aquatic plants in the discharge plume. No other potential effects were identified. More detailed studies have demonstrated that there is no potential for ecological effects even in those two cases. (Chambers *et al.* 2010).

For approval process for new nuclear units at an existing site at Darlington, Ontario, Canada, an assessment (SENES 2009) has been carried out following the requirements of the Canadian Environmental Assessment Act (Canadian Minister of Justice 2018). Here, a review of potential dose rate benchmarks was made based on materials published by the CNSC, IAEA, UNSCEAR and US DOE, and the ERICA, FASSET and PROTECT projects. For aquatic organisms the lowest benchmark values prescribed by the CNSC (0.6–6 mGy/d) were chosen, and for terrestrial birds and mammals correspondingly those reported by the IAEA (1 mGy/d). The dose calculations were made based on measured maximum radioactivity concentrations. At maximum concentrations across the site, all results were well below the benchmark value, and thus it was concluded that there are no ecological risks identified for the existing conditions and there is also a wide margin for new developments. (SENES 2009).

In France, 14 nuclear power reactors were commissioned at five different sites on the Loire River and its tributaries in France between 1963 and 1999. The FASSET approach was used to assess the radiological situation at two locations, the Loire River downstream of the Chinon nuclear power plant and the estuary some 350 km downstream. All the estimated dose rates to freshwater organisms in the river and the estuary were at least five orders of magnitude lower than those at which effects were reported in the FRED databased, and thus and it was concluded that effects are unlikely. (Chambers *et al.* 2010).

A considerably more elaborate ecological risk assessment of mixtures of radiological and chemical stressors in the Rhone River, France, has been recently carried out by employing an ‘msPAF’ approach (Beaumelle *et al.* 2017). Also there, several nuclear power plants are discharging their liquid effluents into the river. In the assessment, species sensitivity distributions (SSD) were combined with chemical mixture models (concentration addition, CA, and independent action, IA) to derive an integrated proxy of the ecological impact of combined radiological and chemical stressors. The SSD of ionising radiation was significantly flatter than the SSD of eight stable chemicals (Cr, Cu, Ni, Pb, Zn, B, chlorides and sulphates). *“This difference in shape had strong implications for the selection of the appropriate mixture model: contrarily to the general expectations the IA model gave more conservative results than the CA model. The msPAF approach was further used to rank the relative potential impact of radiological versus chemical stressors.”* It was concluded that there are no conceptual or practical limitations of applying such multiple stressor models also for radiological purposes, except for the limitations of data availability in some cases. (Beaumelle *et al.* 2017).

5.3.5 Other planned releases of radioactive substances

Cumulative impacts of radioactive discharges to sewer by the non-nuclear industry has been assessed in Scotland (SEPA 2010), with an objective to carry out a prioritisation and monitoring, sampling and assessment campaign around a number of waste water and sludge treatment sites in Scotland. Radionuclides in treated sewage effluent discharged to rivers and sea and in sludge and sewage solids that may be applied to land or utilised for energy recovery as waste derived fuel (WDF) via incineration were considered to provide estimates of radiological exposure of members of the public and fauna and flora. For the biota, the ERICA approach was employed. The maximum dose rate calculated for reference organisms exposed to discharges was 399 µGy/h to insect larvae. This is at the IAEA–UNSCEAR benchmark of 400 µGy/h for aquatic organisms, and thus further evaluation was found warranted, for example in terms of better determination of activity concentrations, identification of sensitive species present and comparison of the exposure received to organism-specific-effects data. (SEPA 2010).

In assessments for MacArthur River and McClean Lake uranium mines in northern Saskatchewan, Canada, IAEA/NCRP methods have been used. At the former location, some exceedance of the benchmark dose rate was estimated for a duck, primarily from ingestion of Po-210 in a small area near the discharge location. At the latter site, it was assessed that there is some potential for exceedance of benchmark values within the treated effluent management system. Otherwise, all dose rates were below the screening values. (Chambers *et al.* 2010).

Further examples include, for example, an assessment of radioecological impacts of tin mining in Nigeria, employing the ERICA assessment tool (Aliyu *et al.* 2015). Also, Hansen *et al.* (2016) have rather recently reviewed past and current environmental practices of uranium facilities in a number of countries worldwide.

5.3.6 Radioactivity in the general environment

Background dose rates to terrestrial organisms in England and Wales arising from naturally occurring radionuclides have been assessed for the IAEA Reference Animals and Plants using the ERICA tool (Beresford *et al.* 2007a, 2008a, c; Jones *et al.* 2008).

The ERICA assessment tool has been used also in retrospective studies on the effects of the Chernobyl fallout in Finland. Historical and present measurement data gathered around the country were used to estimate doses during the early and late phases of the deposition. All the estimated dose rates were found to lie below the ERICA screening value for lake fish and plants (Vetikko & Saxén 2010), as well as for game animals (moose, hare and wildfowl) (Vetikko & Kostiainen 2013). However, it was concluded that the case of the highest dose rates (3.7 µGy/h) for arctic hare in 1986 “cannot be considered negligible given the uncertainties involved” (Vetikko & Kostiainen 2013).

A study in Norway (Mrdakovic Popic *et al.* 2010) used the ERICA assessment tool based on measured activity concentrations in a closed mining area at a fen complex with magmatic, carbonatite rocks rich in naturally occurring radioactive materials, prominently thorium and uranium, but also in iron and rare earth elements. Even though all mining activities were finished in 1960s, technologically enhanced naturally occurring radioactive materials (TENORM) are still important sources of environmental pollution there.

As brought up in the beginning of the report, there seems to have been little new in recent years in fundamental radiobiology especially in the level of effects on individuals. However, extrapolation to populations (not to mention communities or ecosystems) is found, rather expectedly, very difficult due to the multitude of interactions. In addition, there is some ongoing debate on interpretation of some field studies, particularly some from Chernobyl and Fukushima.

Even though there are gaps in the detailed knowledge, time has been seen ripe by a number of international organisations — foremost the ICRP — to establish radiation protection framework also for non-human biota. Although often not very detailed, there are also national regulations as well pointing to the same direction. Whereas there is consensus that the protection target should be on the population level, or higher in the biological organisation, it is acknowledged that it is anyway worthwhile to establish the quantitative basis in terms of dose rates and (no-)effects on individuals. There are also supporting material also to address the protection of the environment in the specific context of geological disposal, as well as reasonably well-established, readily available modelling tools and examples of their application in such biota assessments.

For benchmark values indicating dose rate levels under which certain radiation effects are not likely there is some variety. However, it seems that in many cases the dose rates from planned exposures and especially from geological disposal are anyway clearly below even the lower end.

The long time frames inherent to geological disposal systems can be seen to provide additional challenges, though. On the other hand, choosing appropriate representatives for the variety of species and populations[34] is a common problem in nearly all contexts. With the general aim to protect rather the ecosystems and their functions instead of specific populations, as has readily been proposed, this should not become an obstacle; such assessment choices are anyway necessary elsewhere in the safety case and can be reasoned out, reviewed and settled.

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[34] This is exemplified by a recent study on the need to include fungi into a standard set of reference organisms that concluded that there seems to be no great need especially for the fruiting bodies, but for the mycelium further research and subsequent development of dosimetric models corresponding to the geometry might be of use (Guillén *et al.* 2017).

To wrap up, it seems that even though debate on effects of radiation and their manifestation in population level continues and there is no final consensus on single quantitative criteria yet, at least the assessment methodology seems mature enough (albeit still developing in details). Thus, there hardly is an argument related to the topics covered in this report against following the example of a few of other countries and requiring biota assessments also in Switzerland, at least in the sense of providing information on the potential radiological impacts on the environment. On the other hand, it seems that such requirements should not be too prescriptive, though, to allow flexibility to follow the international developments and to apply best available knowledge. If regardless some benchmarks were to be adopted, the two-level example of BIOPROTA and NWMO, reflected to an extent also in the ICRP 'bands', seems practical as not being overly constrictive but providing information for stakeholder discussions.

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