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Guidance on the use of soil screening values in ecological risk assessment

Science report SC070009/SR2b

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Steve Killeen

Head of Science

Executive summary

Soil screening values (SSVs) are concentrations of chemical substances found in soils below which there are not expected to be any adverse effects on wildlife such as birds, mammals, plants and soil invertebrates, or on the microbial functioning of soils.

If concentrations of a chemical are found above an SSV, this should prompt further investigation to examine whether there are any ecological risks. SSVs are important tools in Tier 1 of the Environment Agency's Ecological Risk Assessment (ERA) framework for soil contamination, which can be used to support determinations under Part 2A of the Environmental Protection Act 1990 and impact assessments under the Habitats Directive.

The Environment Agency has used procedures set out in the European Commission's Technical Guidance Document for risk assessment to derive SSVs for 37 substances. But because toxicity data for soil organisms are generally sparse, equilibrium partitioning approaches had to be used for many of these substances to extrapolate from aquatic toxicity data to estimates of soil toxicity. Such extrapolations are insufficiently reliable to be used within the ERA framework, so this report proposes SSVs for only 12 substances commonly found at contaminated UK sites. Advice is provided on other sources for 'supplementary' SSVs used in North America and the Netherlands.

This report also provides guidance on how to use SSVs including how the availability and bioavailability of chemicals should be taken into account when assessing whether or not SSVs have been exceeded.

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1.1 The purpose of this document

Soil screening values (SSVs) are concentrations of chemical substances found in soils below which there are not expected to be any adverse effects on wildlife such as birds, mammals, plants and soil invertebrates, or on the microbial functioning of soils.

If concentrations of a chemical are found above an SSV, this should prompt further investigation to examine whether there are any ecological risks. This document provides guidance on the use of SSVs within a tiered framework when assessing ecological risks from contaminated soils.

SSVs are important tools in Tier 1 of the Ecological Risk Assessment (ERA) Framework for contaminants in soil (ERA 1, see Section 1.2 below). They are intended for use as an aid to decision-making when further, more extensive site investigations are being considered.

1.2 How this document fits into the Ecological Risk Assessment Framework

This document is one of six guidance documents that support the ERA framework.

The purpose of this guidance is to support activities in Tier 1 of the ERA – known as 'Site investigation and Quantitative Risk Assessment: Chemical'.

The position of this document (shown in red) within the overall ERA framework is summarised in the flow chart shown in Figure 1.1.

This report and the guidance documents in the series refer to each other in the following manner (full details can also be found in the reference list):

- This report is referred to as ERA 2b (Guidance on the use of SSVs).
- The overarching Ecological risk assessment framework for contaminants in soil is referred to as ERA 1 (Framework document).
- The Guidance on desk studies and Conceptual Site Models in Ecological Risk Assessment is referred to as ERA 2a (Guidance on desk studies and CSM).
- The Guidance on the use of Bioassays in Ecological Risk Assessment is referred to as ERA 2c (Guidance on the use of bioassays).
- The Guidance on the use of Ecological Surveys in Ecological Risk Assessment is referred to as ERA 2d (Guidance on the use of ecological surveys).
- The Guidance on the Attribution of Cause and Effect in Ecological Risk Assessment is referred to as ERA 2e (Guidance on the attribution of cause and effect).

- The Standard Operating Procedures for Bioassays is referred to as ERA 3 (SOPs for bioassays).

The tiered approach gives risk assessors early opportunities to eliminate benign sites from further investigation when they are confident that ecosystems are not being harmed. In Tier 1, a simple assessment is performed by comparing contaminant concentrations in soil against SSVs. This aims to determine which contaminants may to be posing a risk to receptors and to verify the plausibility of the potential pollutant linkages by demonstrating the presence of the contaminants in sufficiently high concentrations to potentially cause harm.

It is essential that generic screening values are protective of ecosystems but are not so stringent that a contaminant is never screened out of the assessment. This is the primary role (as a screening tool) and position (Tier 1) of an SSV.

The use of a weight-of-evidence approach, the likely complexity of the data generated and the importance of auditing and justifying decisions taken at every step mean that the ERA framework should be used only by experienced ecological risk assessors. It is intended primarily for use by local authorities and site owners with the help of experienced ERA practitioners.

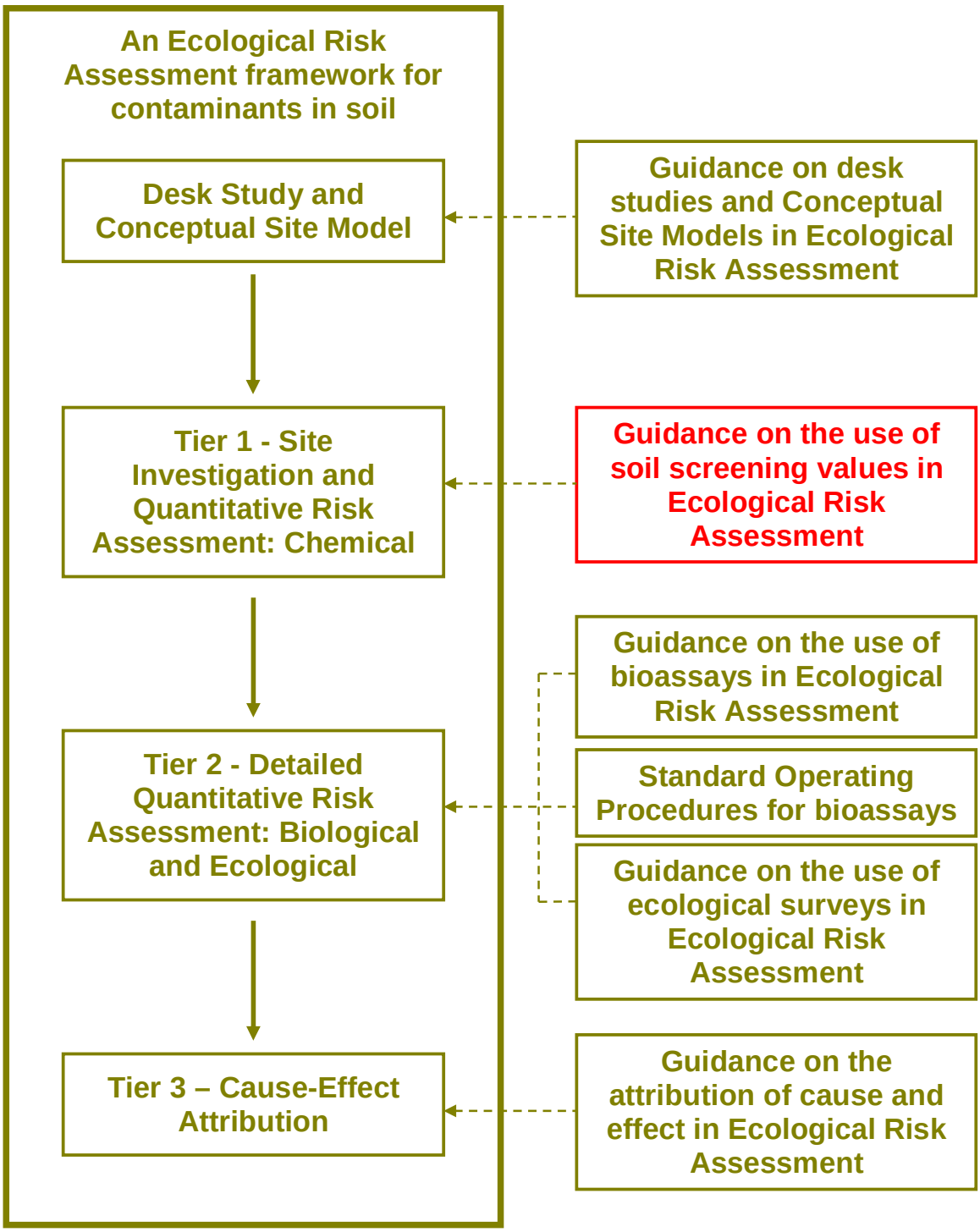

Figure 1.1 Position of this document within the overall ERA framework

1.3 Potential regulatory drivers for Ecological Risk Assessment

The primary driver is Part 2A of the Environmental Protection Act 1990. Other potential regulatory drivers include the Habitats Directive and the planning regime.

1.3.1 Part 2A of the Environmental Protection Act

Section 57 of Part 2A of the Environmental Protection Act 1990 (EPA 1990) introduced a new statutory regime for the identification and control of contaminated land in England and Wales (DEFRA 2006, WAG 2006 and Scottish Executive 2006). The Act states that:

> *'Contaminated land' is any land which appears to the local authority in whose area it is situated to be in such a condition, by reason of substances in, on or under the land, that –*
>
> *significant harm is being caused or there is a significant possibility of such harm being caused; or pollution of controlled waters is being, or is likely to be, caused…*

where 'harm' is defined as:

> *harm to the health of living organisms or other interference with the ecological systems of which they form a part, and in the case of man includes harm to his property.*

'Ecological harm' within Part 2A is confined to specified receptors as set out in Table A of the Statutory Guidance (DEFRA 2006, WAG 2006 and SE 2006). In summary, these are:

- any ecological system, or living organism forming part of such a system, within a location which is:
  - a site of special scientific interest (SSSI) notified under section 28 of the Wildlife and Countryside Act 1981;
  - a national nature reserve (declared under section 35 of the above act);
  - a marine nature reserve (designated under section 36 of the above act);
  - an area of special protection for birds (under section 3 of the above act);
  - any habitat or site afforded policy protection under paragraph 6 of Planning Policy Statement (PPS 9) on nature conservation;
  - any nature reserve established under section 21 of the National Parks and Access to the Countryside Act 1949;
  - any European site within the meaning of regulation 10 of the Conservation (Natural habitats etc) Regulations 1994;
  - any candidate Special Areas of Conservation or potential Special Areas of Conservation given equivalent protection.

1.3.2 Habitats Directive

Regulation 3 of the Conservation Regulations 1994 (commonly known as the Habitats Regulations) implements the requirements of the European Habitats Directive 92/43/EEC in Great Britain. It also secures the protection of areas classified under the Wild Birds Directive 79/409/EEC.

The Environment Agency is the competent authority (in England and Wales) for these regulations. As such, it applies the regulations when considering all applications for authorisations, permissions, permits, consents and environmental licences and for all relevant Environment Agency policy and operational activities.

A risk assessment process is initiated in situations where an application under the UK system of land use planning or a review of permits, licences, etc. is likely to impact on sites protected under the regulations. There are four stages to the risk assessment:

- identifying relevance;
- likely significant effect;
- identifying adverse impacts;
- implementing any changes.

The ERA framework will be a useful aid in this process.

1.3.3 Planning

Planning Policy Statement (PPS) 23: *Planning and Pollution Control* states that:

> *Land contamination, or the possibility of it, is a material planning consideration in the preparation of development plan documents and in taking decisions on individual planning applications* (ODPM 2004).

The remediation of contaminated land through the planning process should secure the removal of unacceptable risk and make the site suitable for its new use. Following redevelopment, the land should not be capable, as a minimum, of being determined as contaminated land under Part 2A of the Environmental Protection Act 1990.

Development plans and decisions on individual planning applications should take into account the potential sensitivity of the area to adverse effects from pollution, including nature conservation interests such as:

- SSSIs;
- National Parks;
- Areas of Outstanding Natural Beauty (AONBs);
- Special Areas of Conservation (SACs);
- Special Protection Areas (SPAs);
- wetlands of international importance (RAMSAR sites).

Where appropriate, soil screening values and the wider ERA framework can be used to assess the possible risks to nature conservation interests when potentially polluting activities are proposed. Where necessary, they can also be applied to the assessment and remediation of historic contamination.

1.3.4 Relation to human health risk assessments: Soil Guideline Values and Soil Screening Values

Soil guideline values (SGVs) are involved with the protection of human health, where Soil screening values (SSVs) are concerned only with ecological protection.

The Department for Environment, Food and Rural Affairs (Defra) and the Environment Agency have published a suite of Contaminated Land Reports, CLR7–10 (Defra 2002a, b,c,d), which set out a scientifically based procedure for assessing the risk to human health from land contamination using SGVs.

The ERA framework is for the assessment of the ecological risks posed by land contamination. Further investigation is indicated where concentrations of a particular contaminant in soil at a site exceed the SSV.

Where land contamination poses a potential risk to both human and ecological receptors, initial screening should employ both SGVs and SSVs. If either screening value is exceeded, there should be further investigation of the risks to the relevant receptors.

1.4 Report Structure

Section 2 describes how and why particular chemical substances were prioritised and selected for derivation of SSVs.

Section 3 explains the process followed to derive an SSV. Uncertainties and outstanding problems with SSV derivation are also highlighted.

These first three sections of the report provide the necessary background information to understand what SSVs are, why they are necessary for certain chemical substances, and how they are derived. The next two sections provide guidance on how to use SSVs.

Section 4 discusses the technical issues involved in using SSVs. This includes advice on how the availability and bioavailability of chemicals should be taken into account when assessing whether or not SSVs have been exceeded.

Section 5 provides succinct, step-by-step guidance on the use of SSVs.

2 Selection and prioritisation of chemicals

A list of priority contaminants was identified by the Environment Agency (Appendix 1).

The process of selection was to cross-reference published priority contaminant lists in UK contaminated land guidance documents with those of other international authorities (see Table 2.1). SSVs were initially derived for most of the substances selected but the greater proportion were then excluded due to the need to extrapolate them from aquatic toxicity data and / or the requirement to use large Assessment Factors (AF) where the data was sparse.

In these cases, the derivation was considered insufficiently reliable to propose SSVs at this stage (for a list of the excluded contaminants see Appendix 4). However, where further datasets are generated, the derivations can be reconsidered as appropriate.

Table 2.1 Sources examined when compiling the list of priority contaminants

Organisation	List
Environment Agency and Defra	Potential contaminants for the assessment of land listed in CLR8 (Defra 2002b)
Environment Agency	Pollution Inventory's top 40 releases to air*
European Commission	Priority list of existing chemicals for risk assessment (list of priority chemicals for European risk assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances; Commission Regulation (EC) No 1488/94 on risk assessment for existing substances; Directive 98/8EC of the European parliament and of the council concerning the placing of biocidal products on the market). The list is held by the European Chemicals Bureau (http://ecb.jrc.it/existing-chemicals/).
Canadian Council of Ministers for the Environment	Recommended Canadian Soil Quality Guidelines report (CCME 1997)
VROM (Netherlands Ministry for Housing, Spatial Planning and the Environment)	Circular on target values and intervention values for soil remediation (*The Netherlands Government Gazette*, 24 February 2000, No. 39, Table 1)
US Environmental Protection Agency (US EPA)	Ecological Soil Screening Level Guidance (draft, July 2000)
US Department of Energy (DOE)	List of substances with benchmark values for terrestrial plants, microbes and invertebrates sourced from the Risk Assessment Information System (RAIS) website (http://rais.ornl.gov/index.shtml).

* Complied in February 2003 by Dr Bogus Zaba of the Environment Agency's Pollution Inventory Team (Air and Chemicals Policy Function, Head Office).

3 SSV derivation

3.1 General approach

Derivation of SSVs in the UK is based on the methodology set out in the European Commission Technical Guidance Document (TGD; EC 2003) for generating a $PNEC_{soil}$ (Predicted No Effect Concentration for soil).

A stepwise procedure is used to gather data, select a suitable subset, apply the appropriate normalisation techniques, estimate the effects-based criteria, and determine a PNEC, which can then be used directly as an SSV. An overview of the general approach for the derivation of SSVs is presented in Figure 3.1.

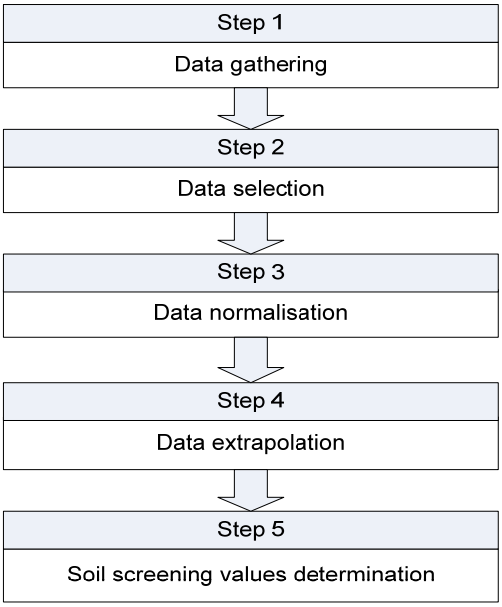

Figure 3.1 General approach for the derivation of SSVs

3.2 Data gathering

Data were gathered from international literature and databases such as the European Chemicals Bureau's International Uniform Chemical Information Database (IUCLID), and evaluated for adequacy and completeness.

Few toxicity data are available for the soil compartment. Where such data exist, they usually only include test results from short-term toxicity tests. If soil test data are lacking, then toxicity data for aquatic species can be converted to values for the soil compartment using the equilibrium partitioning (EqP) method (Appendix 2). However, this approach is, at best, only indicative. Therefore SSVs derived on the basis of EqP alone are insufficiently reliable for use in the ERA framework.

3.2.1 Secondary poisoning

Contaminants with potential for bioaccumulation and biomagnification may pose an additional threat to organisms higher in the food chain such as top predators. This is

called secondary poisoning. If contaminants are likely to bioaccumulate (i.e. have a log Kow ≥3), the oral intake of the contaminant via earthworms is compared to a PNEC for worm-eating birds or mammals (Appendix 2).

In deriving the final SSV, account is taken of secondary poisoning and therefore no separate consideration is required, except in the case of cadmium where the SSV should be reduced from 1.15 to 0.9 mg/kg where secondary poisoning is suspected.

3.3 Data selection

The TGD presents general guidelines on the evaluation of ecotoxicity data for adequate reliability and relevance. 'Reliability' considers the inherent quality of a test, i.e. the way it has been performed and the results described. 'Relevance' considers the extent to which a test is appropriate for SSV derivation (Appendix 3).

Some toxicity results may not be from standardised International Standards Organization (ISO) and Organisation for Economic Co-operation and Development (OECD) tests, but are still allowable for use in the derivation of an SSV if there is adequate evidence to show that they are sufficiently reliable and relevant. For assessing effects on soil organisms, the TGD recommends that toxicity test data should represent:

- primary producers (plants);
- consumers (e.g. invertebrates that represent an important group in the soil compartment);
- decomposers (comprising micro-organisms that play an important role in food webs and nutrient cycling).

3.4 Data normalisation

Soil is a complex heterogeneous medium. Its characteristics include differences in organic matter and clay content, soil pH and soil moisture content. These can influence the availability of a contaminant for uptake by a soil organism and hence the observed toxicity.

The TGD recommends that toxicity tests are carried out in conditions where the test substance is bioavailable to the test organism. But it also recommends that, where possible, toxicity data are normalised by attempting to factor out confounding effects and make toxicity data generated in differing soil conditions directly comparable.

3.5 Data extrapolation

Following data selection and normalisation, relevant and adequate data are extrapolated from a range of single species laboratory toxicity data to estimate an SSV designed to protect organisms in the field and the inherent biodiversity found there.

The TGD identifies three scenarios when deriving a PNEC for soil:

- When no toxicity data are available for soil organisms, the equilibrium partitioning (EqP) method based on aquatic toxicity data can be applied. For the purposes of risk assessment under the Existing Substances Regulations (ESR), this method is regarded as a 'screening approach' and

further toxicity testing using terrestrial species may be required. There is evidence to suggest that EqP is insufficiently reliable for deriving SSVs (see Appendix 2), so this approach is not included in the ERA framework.

- When only one test result with soil dwelling organisms is available, a large assessment factor (AF) is usually applied, as the degree of protection afforded is not fully characterised. This may mean that the derived values are not based on sufficient data to be reliable and may be below the practical limits of analytical detection, so this approach is also excluded from the ERA framework.
- When toxicity data are available for a producer, a consumer and/or a decomposer, the PNEC is calculated using an appropriately low AF (less than or equal to 50). This approach is considered reliable for use within the ERA framework,
- When sufficient data are available, there is a fourth option of using statistical extrapolation techniques, or Species Sensitivity Distributions (SSDs). This is considered a very robust dataset from which to derive PNEC and usually require the use of AF less than or equal to 2.

All four options are discussed in more detail in Appendix 2.

3.6 SSVs determined to date

The Environment Agency uses PNECs derived from the process described above directly as SSVs. Some were previously derived by (or for, in the case of voluntary risk assessments) the European Union (cadmium, copper, lead, nickel, tetrachloroethene, toluene and zinc), and others were commissioned for use within the ERA framework (benzo(a)pyrene, chromium, mercury, pentachlorobenzene and pentachlorophenol).

For those substances that had previously undergone risk assessment, the PNEC derived were adopted as SSV except in the case of zinc, because the EU risk assessment makes use of a weak correlation in the microbial data between adaptation to background zinc levels and organism sensitivity. The proposed SSV differs from the PNEC in that it is more precautionary, because although it is based on the same overall dataset from the exposure of microbes, invertebrates and plants, it does not incorporate the potential for microbial adaptation to background zinc levels.

For those substances commissioned for use within the ERA framework, derivation reports on the proposed SSV are available from the Environment Agency on a CD[1]**.** Other substances for which SSV have been derived but have been excluded at this stage due to the use of the EqP method or high AF (>50) are listed in Appendix 4, and the derivation reports are also available on the CD.

Table 3.1 shows a summary of the proposed SSVs and their basis for derivation. SSVs for these substances are considered to be reliable as Tier 1 screening values because they were derived from a range of terrestrial toxicity data by means of an SSD or an AF of 50 or less. It should be noted that the process of deriving SSV is iterative, and values are subject to change with the appropriate consideration of new datasets. The Environment Agency will consult further both on these values, and on the selection, prioritisation and derivation of values for other chemicals on an on-going basis.

[1] The CD giving the SSV derived by the Environment Agency can be requested from the publishing department quoting the project reference; SC070009/SR4.

Table 3.1 Proposed SSVs and the basis for their derivation

Substance	Proposed SSV (mg/kg)	Basis for derivation
Benzo(a)pyrene	0.15[#]	AF of 10 on earthworm data
Cadmium[1]	1.15 (0.09[†])	SSD approach and an AF of 2
Chromium	21.1	SSD approach and an AF of 1
Copper[2]	88.4 (57.8)*	SSD approach and an AF of 1
Lead[3]	167.9	SSD approach and an AF of 2
Mercury	0.06	AF of 10 on springtail data
Nickel[4]	25.1 (20.3)*	SSD approach and an AF of 2
Pentachlorobenzene	0.029[#]	Secondary poisoning value based on mammal data and an AF of 30
Pentachlorophenol	0.6[#]	SSD approach and an AF of 1
Tetrachloroethene[5]	0.01[#]	AF of 10 on microbial nitrification data
Toluene[6]	0.3[#]	AF of 50 on earthworm data
Zinc[7]	90.1(72.5)*	SSD approach and an AF of 2

[1] Ref for derivation = EU 2007a

[2] Ref for derivation = EU 2007b

[3] Ref for derivation = EU 2007c

[4] Ref for derivation = EU 2007d

[5] Ref for derivation = EU 2005

[6] Ref for derivation = EU 2003

[7] Ref for derivation = EU 2004

[#] These SSVs were established for soil with 2% organic carbon (equating to 3.5% organic matter, assuming the latter contains 58% carbon). Therefore the PEC should be normalised according to the percentage of organic matter in the soil under assessment (see Section 4.2.1).

[†] The secondary poisoning SSV is based on renal thresholds of terrestrial mammals. The value in brackets should be used where secondary poisoning is suspected.

*The generic SSV are insufficiently protective for certain soils and should be adjusted to the site-specific conditions. The values in brackets are specific for a sandier soil with a pH of 6.5, an organic matter content of 2 per cent and a clay content of 10 per cent (see Section 4.2.2).

3.7 Contaminants of concern with no available SSV

Table 3.1 contains SSVs for only 12 substances. In many cases, it is likely that there will not be an SSV for at least some contaminants of concern found at a site. In these circumstances, it will be necessary to either accept that a risk is likely to be present or to find appropriate alternative values with which to compare measured concentrations in soil from a site.

If it is considered that a risk is likely to be present because the contaminant of concern has a relatively small ecotoxicity dataset and consequently a sufficiently reliable

protective value cannot be derived, then it will be necessary to move to Tier 2 of the ERA framework and to decide whether harm is occurring or likely to occur at the site.

However, if the contaminant has a ecotoxicity dataset that is reasonably comprehensive and any limitations are understood and accepted by the risk assessor, then an alternative value proposed by another jurisdiction may be used with the agreement of all the stakeholders (including the regulatory authority and the relevant conservation organisation).

It is essential that any alternative values are identified and agreed upon during the development of the Conceptual Site Model (refer to ERA 2a, Desk study and CSM development) and **before** any sampling takes place so that values are not seen to be chosen for convenience. Acceptable sources for alternative values are listed below.

3.7.1 Sources for alternative values

US EPA Ecological Soil Screening Levels

Ecological Soil Screening Levels (Eco-SSLs; http://www.epa.gov/ecotox/ecossl/) developed by the US EPA are protective of ecological receptors that commonly come into contact with soil, or ingest biota that live in or on soil.

Eco-SSLs are intentionally conservative to provide confidence to risk assessors that contaminants that could present an unacceptable risk are not screened out early in the ERA process. They are based on the geometric mean of selected chronic toxicity data for plants, invertebrates, mammals and birds. A wildlife risk model incorporating exposure assessment is used to determine risks to birds and mammals.

Eco-SSLs have two major drawbacks: the use of the geometric mean of effects data may not be protective of sensitive species and there is a lack of consideration of microbial populations and functions.

Values are currently available for:

- metals – aluminium, antimony, arsenic, barium, beryllium, cadmium, chromium, cobalt, copper, iron, lead, manganese, nickel, selenium, silver, vanadium and zinc;
- organics – DDT and metabolites, dieldrin, pentachlorophenol and total polycyclic aromatic hydrocarbons (PAHs).

There are Eco-SSLs for several substances for which SSVs are proposed in Table 3.1 (cadmium, chromium, copper, lead, nickel and pentachlorophenol). In these cases, the proposed SSVs in Table 3.1 take precedence and should be used in Tier 1 of the ERA framework.

Canadian Soil Quality Guidelines (SQGs)

Canadian soil quality guidelines (SQGs) are available at http://www.ec.gc.ca/CEQG-RCQE/English/Ceqg/Soil/default.cfm

The approach taken by the Canadian Council of Ministers of the Environment (CCME) to developing guideline values differs from the approach adopted by the UK in the following ways:

- CCME classifies potentially contaminated sites based on four different land use categories – agricultural, residential and parkland, industrial and commercial.
- The guidelines are based on effects data using mortality, reproduction and growth endpoints for soil-dependent organisms (microbes, plants, invertebrates).
- Soil and food ingestion pathways for consumers (i.e. livestock and wildlife) are considered for agricultural land use only.

The CCME have a total of five methods available for SQG development. The preferred method depends on the quantity and quality of data, and the land use to which the SQC will apply. A description of the different derivation methods is given in Environment Agency (2004).

The final soil quality guideline for the environment is compared with the soil quality guideline for human health. This is an obvious limitation to the direct adoption of CCME's SQGs as the Environment Agency's SSVs are developed to protect the terrestrial environment (excluding humans). However the final SQG for the environment is reported separately prior to this comparison, so can be identified.

Values are currently available for benzene, dioxins and furans, ethylbenzene, nonylphenol and its ethoxylates, polychlorinated biphenyls (PCBs), selenium, toluene and xylenes. If a Canadian SQG is available for a substance also found in Table 3.1 (e.g. toluene), the latter should be used in Tier 1 of the ERA Framework.

Oak Ridge National Laboratory screening benchmarks

These benchmarks from the Oak Ridge National Laboratory in Tennessee, USA (http://www.esd.ornl.gov/programs/ecorisk/benchmark_reports.html) are derived for screening purposes at waste sites in the USA. The screening threshold is based on the 10th percentile of a 20 per cent reduction in growth, reproduction or activity in either soil invertebrates, soil microbial processes, plants, wildlife or birds. The main features and limitations of these benchmarks are described in Environment Agency (2004).

The benchmarks are available for a large number of substances in separate reports for wildlife (mainly birds and mammals), terrestrial plants, soil invertebrates and microbial processes. If benchmarks are available for a substance also found in Table 3.1, the latter should be used in Tier 1 of the ERA framework.

RIVM Serious Risk Concentrations

RIVM (National Institute of Public Health and the Environment) in the Netherlands has developed Serious Risk Concentrations for ecosystems (SRCeco) (http://www.rivm.nl/bibliotheek/rapporten/711701023.pdf) for a large number of substances.

For soil ecosystems, aquatic sediment and groundwater compartments, the protection goal is set at the HC50, i.e. the concentration at which 50 per cent of the species or processes in an ecosystem may encounter adverse effects. The effects considered in the toxicity tests that form the basis of the HC50 are usually growth, reproduction and mortality.

The implication is that the more sensitive species are not protected at the level of SRCeco and thus these values are likely to be less protective than SSVs. For the

ecosystem, processes (e.g. microbial processes and enzymatic activity) and species are considered separately. The lower HC50 (species or processes) is the basis for SRCeco. If SRCeco values are available for a substance also found in Table 3.1, the latter should be used in Tier 1 of the ERA framework.

3.8 Uncertainties associated with SSV derivation

Even where a range of toxicity data for soil-dwelling organisms are available, some uncertainties remain in the derivation of SSVs, including:

- The behaviour of a chemical in a toxicity test does not necessarily reflect its behaviour in a natural system because of differences in physical and chemical parameters, and the effect of 'aging' on availability. The overall effect of this is likely to be that SSVs are conservative.
- AF are intended to ensure precaution where there is residual uncertainty in the toxicity data and the overall effect of this is also likely to be that SSVs are conservative.

SSVs should not be used to determine whether there are ecological risks from soil contamination. SSVs are intended as an early indication within the tiered framework of the **potential** for risks to exist. They are deliberately set at a conservative level so that false negatives (i.e. assessing a site as safe when in fact there are risks) are rare. It is therefore unavoidable that false positives (i.e. assessing a site as posing risks when it is in fact safe) will be relatively more common. Basing management decisions solely on the exceedance of one or more SSVs at a site could lead to unnecessary remediation.

This guidance describes the soil concentrations (SSVs) above which there may be concern that warrants further investigation and risk evaluation. These levels are a guide to help assessors estimate risk. They are non-statutory and as such do not provide a definitive test for telling when risks are significant, nor do they operate as a statutory licence, waiver, consent or approval from the Environment Agency.

4 Technical concerns involved in the use of SSVs

There are technical issues and potential modifications that need to be considered to ensure that an SSV is useful for identifying sites where there is a potential for risk and for eliminating sites of low or negligible risk. There are two main reasons that the SSV may not be appropriate:

- The substance is naturally occurring and the background concentration in soil is greater than the SSV.
- The fate and behaviour of the substance in the soil are affected by the physicochemical properties of the soil, so that comparing an SSV with the total soil concentration bears little relation to the potential ecological risk.

This section considers methods to address such issues in a technically sound and pragmatic way. Examples are provided to illustrate how these approaches might work in practice and their implications for the use of SSVs within the ERA framework.

4.1 Background concentrations

4.1.1 Added Risk Approach

The Added Risk Approach (ARA) is a Dutch policy solution to the issue of implementing single metal limit values when there are variable background metal concentrations (Crommentuijn et al. 1997). It assumes that the effects of naturally occurring background metal concentrations are desirable and that the ecosystem has developed because of the metals present. Therefore, only the metal 'added' to the background concentration is considered to contribute to the environmental effect (Environment Agency 2003).

However, ARA is not without flaws because added and background metal concentrations will behave as a single pool, and exposed organisms will not be able to distinguish between them. There is currently little scientific evidence to support the assumptions underlying this approach. Furthermore, an important practical requirement when using ARA is the need to derive a generic background soil metal concentration.

Methods are available for the estimation of ambient background metal concentrations in soils for a number of countries (VROM 1994, Ontwerp uitvoeringsbesluit 1995, Hamon et al. 2004, Zhao et al. 2007). However, these methods do not cover all the relevant metals and metalloids. In addition, it is not known how well these methods perform in urban areas and at brownfield sites. Because of these issues the use of ARA is not currently recommended for use in the ERA framework.

4.1.2 Comparison with local background concentrations

When an SSV is exceeded, it may be of value to make an assessment of the local background concentrations. This will depend on the degree and frequency of exceedance in the samples taken. If both the number (in proportion to the total samples analysed) and extent of the exceedances are low, then further soil samples

can be taken from areas close to the site under investigation but away from the source of contamination. These soil samples should be of similar composition and deriving from the same bedrock as those samples that are exceeding the SSV.

Where similar concentrations of the contaminant are measured at the site under investigation and at the uncontaminated sites around it, the risk assessor may conclude that the samples are exceeding the SSV due to the background levels in that location. This will always be a judgement made on the part of the risk assessor, and care should be taken to ensure that all of the stakeholders are in agreement that the additional samples are from areas that can properly be considered as uncontaminated.

4.2 Correction for availability and bioavailability

The fate, behaviour and subsequent ecological impact of metals and organic micropollutants are not governed solely by their total soil concentrations. Factors such as soil pH, clay content, organic carbon, redox and salinity may all have a bearing on contaminant behaviour. There are also different routes of contaminant uptake and assimilation for different organisms.

Availability can be defined as the total amount of a specific contaminant in soil that is in equilibrium with the contaminant in soil solution. This is also sometimes described as the 'labile pool', which is generally considered to provide a better estimate of the fraction of contaminant potentially available to ecological receptors than the total soil concentration.

The bioavailable concentration of a contaminant is the organism-specific concentration taken up or assimilated by that organism. For example, what is bioavailable to a wheat plant is not necessarily bioavailable to an earthworm. Bioavailability can be considered as a combination of the soil factors governing organic micropollutant or metal behaviour **and** the biological receptor with its specific pathophysiological characteristics (e.g. route of entry, duration and frequency of exposure; Drexler et al. 2003).

By correcting a total soil contaminant concentration for availability and, if possible, bioavailability, the most environmentally relevant metric is provided by which to assess ecological risk.

4.2.1 Availability refinements for organic micropollutants in soils

The availability of most non-ionic organic micropollutants is strongly determined by the soil organic matter fraction. Therefore it is necessary to normalise the measured concentration in the samples from the site under investigation by means of a ratio of the percentage organic matter (%OM) that is present in those samples with the %OM that was present in the soils used to determine the PNEC. Many laboratories measure the percentage organic carbon (%OC) rather than %OM, because they use a dry combustion method, but the standard conversion between the two expressions is:

%OM = %OC x (100/58)

Generally the %OC in soils used to determine the PNEC is 2% (OM = 3.45%).

This commonly used approach provides a more ecologically relevant metric than total contaminant load for the risk assessment. Box 4.1 illustrates the approach assessing the risk of the organic micropollutant pentachlorophenol in soil with an OM = 6%.

Box 4.1 Availability correction for an organic micropollutant

An SSV of 0.6 mg/kg dry weight has been derived for pentachlorophenol (PCP) from a soil containing 3.45% organic matter (OM).

If the soil at the site of interest has 6 per cent OM, a normalisation step is required to enable an appropriate comparison to be made.

The following calculation can be performed on the measured field concentration of PCP (e.g. 4 mg/kg) in the soil with 6 per cent OM to normalise this concentration to a soil of only 3.45 per cent OM.

Effective PCP concentration in the field soil if it had 3.45 per cent OM

$$= \text{PCP concentration at the site} \times \left(\frac{\text{OM for the SSV}}{\text{OM for the soil at the site}} \right)$$

$= 4 \times (3.45/6) = 2.3$ mg/kg

The risk quotient (RQ) is the measured field concentration of PCP divided by the SSV. If this is >1, (as in this case) there is a potential ecological risk associated with PCP.

RQ = 2.3 / (SSV for PCP = 0.6) = 3.83

4.2.2 Availability and bioavailability refinements for metals

The most scientifically and technically robust approach to assessing ecological risk for metals in soils is to account for availability and bioavailability. This approach reduces the need to estimate metal background concentrations in the soil.

There is a significant amount of data on the fate, behaviour and ecotoxicity for the metals copper (Cu), lead (Pb), nickel (Ni) and zinc (Zn). Most of these data have been developed under the auspices of the Existing Substances Regulations (Directive 793/93EC) and have been subject to significant Member State peer review.

Two types of refinement to the use of total soil metal concentrations to incorporate (bio)availability have been proposed (ICMM 2007). The first accounts for differences in effects found in soils tested in the laboratory, where metals are more available, and the same soils contaminated to similar levels in the field.

In laboratory toxicity tests, the soils are often freshly spiked with soluble metal salts (e.g. chlorides or nitrates) and are used soon after spiking, allowing limited time for metal equilibration. The metals present in field soils tend not to be from such soluble sources and have often equilibrated over a significant period, resulting in reduced availability. Experiments (e.g. Pedersen and van Gestel 2001, Smolders et al. 2003, Waegeneers et al. 2005) have estimated a ‘leaching/aging factors’ for each of these metals. These factors have already been incorporated into the deriviation of the SSV given in Table 3.1.

The second type of refinement aims to more fully account for bioavailability, although it can only be applied at present to Cu, Ni and Zn. This is because there are significantly more chronic terrestrial ecotoxicity, fate and behaviour data available for these metals in soils relative to that for Pb.

Experimental programmes with several different soil types (representing a range of physicochemical conditions) have undertaken chronic toxicity tests to examine the relationships between various soil factors and the toxicity of these three metals. Linear regression models were then constructed and certain soil parameters (e.g. pH, percentage organic matter, percentage clay content) had significant relationships with metal toxicity to plants and invertebrates and/or microbial soil functions, though the relationships with these parameters were different for each metal.

The slopes from these significant relationships are used to adjust the toxicity database from which the SSV for these metals are derived to the specific site conditions (i.e. the site under assessment). This enables a site-specific Species Sensitivity Distribution (SSD) to be estimated, from which a site-specific SSV can be derived.

With support from the European metal industries, the Environment Agency has developed a spreadsheet based SSV Decision Tool which can be used to make this site-specific adjustment where the soil parameters are known, or to make an estimate based on these parameters for a representative soil type (e.g.sandy or clayey) where these data are not available. An example of how this is executed in the tool is given in Box 4.2 for Cu, and the spreadsheet is available on the ERA webpage of the Environment Agency website.

Box 4.2 Refinement for the assessment of Cu risks

An experimental programme with 19 different soil types, representing a range of physicochemical conditions, was undertaken in which seven types of chronic ecotoxicity test were carried out on each soil (ECI 2007). Significant relationships were observed between Cu toxicity and soil cation exchange capacity (CEC), organic matter and also, to a lesser extent, with clay content and pH. These data are required as input parameters for a site-specific assessment for Cu., although the CEC can be approximated from data for the other parameters.

This understanding of the influence of specific soil properties on Cu toxicity allows a Species Sensitivity Distribution to be plotted for the soil at the site of interest. From this, a site-specific SSV is calculated for bioavailable Cu against which the measured Cu concentration in the soil can be compared. The SSV Decision Tool calculates a site-specific SSV for the site under investigation, and makes this comparison.

For example, if the soil is sandy, as described by the parameters used in Table 3.1 (pH = 6.5, %OM = 2 and % clay content = 10), then the SSV is calculated as 57.9. Therefore, if the measured concentration in the soil sample is 75 mg/kg, then RQ = 1.3 and it is concluded that there is a potential for risk. Similarly, if the soil is simply described as ‘sandy’, then a (slightly more precautionary) SSV of 46.6 is calculated and the RQ becomes 1.6.

However, if the soil has a higher clay content (e.g. pH = 6.5, %OM = 8 and % clay content = 44), then the SSV is calculated as 176 and a sample with the same measured concentration of Cu (75 mg/kg) will give an RQ = 0.43 and it is concluded that there is no risk. Similarly, if the soil is simply described as ‘clayey’, then a (slightly more precautionary) SSV of 138 is calculated and the RQ becomes 0.55 (also no risk).

5 Checklist for the use of SSVs

The checklist given in Table 5.1 takes a risk assessor through the steps required in order to use SSVs appropriately within the ERA framework. Assessors should not proceed to the next step unless all earlier activities have been completed.

Table 5.1 Checklist for ERA Tier 1

Step	Activity	Check box
1	Identify the Contaminants of Potential Concern from an appropriate desk study and the development of a Conceptual Site Model. • See ERA 2a (Guidance on desk studies and CSM).	[ ]
2	Determine whether all of the Contaminants of Potential Concern have SSV available. • If YES, go to step 3 • If NO, either consider whether alternative values agreeable to all stakeholders are available from other jurisdictions (see Section 3.7 of this guidance) or move to Tier 2 of the ERA framework.	[ ]
3	Collect appropriate soil samples and analyse the contaminant concentrations. Also, record the relevant physico-chemical parameters for the contaminant of concern. • For organic contaminants, record the % organic carbon • For copper, nickel and zinc, record the pH, % organic carbon and % clay content (plus the soil cation exchange capacity where possible).	[ ]
4	Use the SSV Decision Tool to refine the risk assessment to the specific soil conditions of the site under investigation • For organic contaminants, normalise the measured concentration against the % organic matter in the soil • For copper, nickel and zinc, adjust the SSV according to the relevant physico-chemical parameters	[ ]
5	Review the Risk Quotients (RQ) generated and determine whether there are any exceedances of the SSV (RQ>1). • If NO, exit the ERA framework, document the decision and inform the appropriate conservation organisations. • If Yes, go to step 6.	[ ]

Step	Activity	Check box
6	Review the degree and extent (in terms of proportion of the number of samples taken) of the SSV exceedances. • If there are large exceedances or the SSV is exceeded in many samples over a wide area, move to Tier 2 of the ERA framework. • If the degree of exceedance is small and in a low proportion of samples, consider analysing further samples from uncontaminated areas with similar soil characteristics to assess whether the exceedances are due to background concentrations (ensure all stakeholders are in agreement prior to undertaking this step).	[ ]
7	Decide whether the SSV exceedances are due to the presence of background concentrations of the potential contaminants. • If YES, exit the ERA framework, document the decision and inform the appropriate conservation organisations. • If NO, move to Tier 2 of the ERA framework.	[ ]

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List of abbreviations

AF	Assessment Factor
AONB	Area of Outstanding Natural Beauty
ARA	Added Risk Approach
BCF	Bioconcentration Factor
CCME	Canadian Council of Ministers of the Environment
CEC	Cation Exchange Capacity
CSM	Conceptual Site Model
ECx	Effective Concentration that causes a given degree of response (x percent) in a toxicity test
Eco-SSL	Ecological Soil Screening Level [USA]
EPA	Environmental Protection Act [1990]
ESR	Existing Substances Regulations [European]
EqP	Equilibrium Partitioning
EQS	Environmental Quality Standard
ERA	Ecological Risk Assessment
HC_5	Hazardous Concentration for 5 per cent of organisms
ISO	International Standards Organization
IUCLID	International Uniform Chemical Database
MNR	Marine Nature Reserve
NNR	National Nature Reserve
NOEC	No Observed Effect Concentration
OC	Organic Carbon
OECD	Organisation for Economic Co-operation and Development
OM	Organic Matter
PAH	Polycyclic Aromatic Hydrocarbon
PNEC	Predicted No Effect Concentration
RQ	Risk Quotient
SAC	Special Area of Conservation
SE	Scottish Executive
SGV	Soil Guideline Value
SPA	Special Protection Area

SQG	Soil Quality Guideline [Canada]
SRC	Serious Risk Concentration [The Netherlands]
SSD	Species Sensitivity Distribution
SSSI	Site of Special Scientific Interest
SSV	Soil Screening Value
TGD	Technical Guidance Document
TLM	Target Lipid Model
TPH	total petroleum hydrocarbons
US EPA	US Environmental Protection Agency
WAG	Welsh Assembly Government

Glossary

Acute test	A comparative study in which organisms, subjected to different treatments, are observed for a short period – usually a small portion of their lifespan.
Adverse effect	An impairment of biological functions or description of ecological processes that results in unfavourable changes in an ecological system.
Availability	The total amount of a specific contaminant in soil that is in equilibrium with the contaminant in soil solution.
Bioaccumulation	Net uptake of a chemical into the tissues of an organism, either as a result of direct contact with a medium such as soil or through the diet.
Bioassay	A laboratory test in which the toxicity of a contaminant or environmental sample is measured by exposing a specific organism and measuring a life-cycle parameter (e.g. survival, reproduction, development, growth).
Bioavailability	The degree to which a chemical can be taken into the tissues of an exposed organism.
Bioconcentration factor (BCF)	The degree to which a chemical can be concentrated in an organism after exposure to the chemical in water. The BCF is the concentration in the organism divided by the concentration in the environment.
Biodegradation	The decomposition of a chemical substance by natural biological processes.
Biomagnification	The degree of increase in the tissue concentration of a chemical with each trophic step in a food chain. For example, a biomagnification factor of 5.0 indicates that the concentration of a given chemical in the tissues of a predator is five times the concentration of that chemical in the tissues of its primary prey species.
Contaminant	In general terms, a substance that is in, on or under the land and that has the potential to cause harm or cause pollution of controlled waters. Within ecological risk assessment the specific emphasis will be on contaminants that have the potential to cause harm to ecological receptors.
Chronic Test	A comparative study in which organisms, subjected to different treatments, are observed for a period representing a substantial portion of a lifespan of an organism.
Dose	The amount of chemical taken into an organism per unit of time.

Dose-response relationship	The relationship between the dose of a contaminant administered or received and the incidence of adverse effects in the exposed population. From the quantitative dose-response relationship, values are derived that can be used to estimate the likelihood of adverse effects occurring at different exposure levels.
ECx	A statistically or graphically estimated concentration that is expected to cause one or more specified effects in x per cent (e.g. 50 per cent) of a group of organisms under specified conditions.
Ecological Risk Assessment	Evaluation of the likelihood of adverse effects on organisms, populations and communities from chemicals present in the environment.
Ecosystem	An ecological community of plants and animals together with its physical environment or habitat, regarded as a unit.
ED/EC50	A statistically or graphically estimated dose/concentration that is expected to cause one or more specified effects in 50 per cent of a group of organisms under specified conditions.
Effect	A change in the state of an organism or other ecological component, resulting from exposure to a chemical or other stressor.
Endpoint	The biological or ecological entity or variable being measured or assessed.
Exposure	The amount of a chemical that is available for intake by a target population at a particular site. Exposure is quantified as the concentration of the chemical in the medium (e.g. air, water, food) integrated over the duration of exposure. It is expressed in terms of mass of substance per kg of soil, unit volume of air or litre of water (e.g. mg/kg, mg/m^3 or mg/l).
Hazard	The intrinsic danger of a substance or process.
Lethal concentration (LCx)	The concentration of a substance at which a lethal effect of magnitude x occurs. The x is usually 50 per cent of the exposed population, in which case LC50 is known as the median lethal concentration.
Life stage	A developmental stage of an organism (e.g. juvenile, adult, egg, pupa, larva).
LOEC	Lowest Observed Effect Concentration. The lowest concentration of a material used in a bioassay or toxicity test that has a statistically significant adverse effect on the exposed population of test organisms compared with the controls.
Medium (plural: media)	The substance in which a chemical may exist such as air, soil, sediments and water.

NOEC	No Observed Effect Concentration. In test organisms, the highest concentration at which no significant adverse effects, such as growth or reproduction, were observed.
PEC	Predicted Environmental Concentration. The predicted concentration of a chemical in an environmental compartment. The PEC can represent a calculated or a measured concentration.
PNEC	Predicted No Effect Concentration. The lowest environmental concentration at which the absence of any adverse effect is expected.
Population	A group of individuals of the same species interacting within a given habitat.
Ecological Receptor	In general terms, [a receptor is] something that could be adversely affected by a contaminant, such as people, an ecological system, property or a water body. Within ecological risk assessment, an ecological receptor will be an organism, population or community that might be affected by exposure to a contaminant of concern.
Relevant	The ability of the assay to provide data that are either in themselves ecologically meaningful or that can be related directly – preferably in a mechanistic way – to effects at higher levels of organisation (population, community, ecosystem).
Representative	The ability of the assay to be used at a range of potentially contaminated sites to facilitate comparisons between separate locations. In this respect, the ecological compartment, community or species used for the test should be present at each site.
Risk Quotient	An expression of ecological risk described by the ratio between the measured concentration of a contaminant in soils and the Soil Screening Value.
Soil Screening Value (SSV)	Concentrations of chemical substances found in soils below which there are not expected to be any adverse effects on wildlife such as birds, mammels, plants or soil invertebrates, or on the microbial functioning of soils.
Speciation	Refers to the various forms in which chemicals occur (e.g. metals, ions, complexes).
Sublethal	Effects at concentrations below those that cause death. Focuses on endpoints other than mortality.
Terrestrial	Living or growing on land.
Toxicity	The property of a chemical substance manifested as its ability to cause a harmful effect (e.g. death, disease, reduced growth, modified behaviour) on an organism.

Appendix 1 List of priority contaminants likely to be found at potentially contaminated sites in the UK

Metals	Arsenic	**Polycyclic aromatic hydrocarbons (PAHs)**	Polycyclic aromatic hydrocarbons (PAHs)
	Beryllium		Benzo(a)pyrene
	Cadmium		Anthracene
	Copper		Naphthalene
	Lead	**Chlorinated hydrocarbons**	1,2,4-trichlorobenzene
	Mercury		Tetrachlorobenzene
	Nickel		Pentachlorobenzene
	Selenium		1,2-Dichloroethane
	Zinc		1,1,1,-Trichloroethane
Organometals	Organolead compounds		Trichloroethene
	Organotin compounds, e.g. tributyltin		Tetrachloroethene
Inorganics	Cyanides		Pentachlorophenol
Aromatics	Total petroleum hydrocarbons (TPH)		Chlorotoluenes
	Benzene		Vinyl chloride
	Toluene		Chloroform
	Ethylbenzene		Hexachlorobuta-1,3-diene
	Xylene(s)		Polychlorinated biphenyls (total)
	Phenol		Dioxins and furans
Pesticides	Dieldrin		
	DDT (total)		
	HCH (total)		

Appendix 2 Extrapolation methods used to calculate SSVs

EqP method

The EqP method converts toxicity data for aquatic species to the terrestrial environment using the soil/water partition coefficient.

For soil, this assumes that bioavailability (and therefore toxicity of contaminants to soil organisms) is determined only by the concentration of a contaminant in the soil pore water. This means that the EqP method may not be suitable for:

- lipophilic compounds or substances with a specific mode of action;
- species that are exposed primarily through their food;
- exposure from contaminants adsorbed to soil particles and taken up by ingestion.

To account for this potential underestimation of exposure, contaminants with a logKow >5, the PEC/PNEC ratio is increased by a factor of 10. This also applies to compounds with a corresponding adsorption or binding behaviour (e.g. ionisable substances).

Scientists in the Netherlands have critically evaluated the EqP method (van Beelen et al. 2003). They compared aquatic and terrestrial toxicity data for 12 organic substances and eight metals. They concluded that the EqP method:

- is not a scientifically valid method to derive screening values;
- be regarded only as an estimation routine, which can give a significant over- or under-estimation.

In five per cent of the cases, there was a factor of more than 20 in the difference between the standards based on the EqP method and the standards based on terrestrial toxicity data.

In simple terms, the method emphasises the use of more abundant aquatic data. However, water organisms may not represent terrestrial life or terrestrial exposure pathways.

Assessment factor method

Assessment factors are intended to set a level below which a contaminant is unlikely to cause an unacceptable effect.

In the TGD, the European Commission recognises that the assessment factors proposed in Table A1 must be regarded as indicative. As more information on the sensitivity of soil organisms becomes available, these factors may have to be revised.

Table A1 Assessment factors to derive a $PNEC_{soil}$

Available data	Assessment factor
L(E)C50 short-term toxicity test(s) (e.g. plants, earthworms, microorganisms)	1,000
NOEC for one long-term toxicity (e.g. plants)	100
NOEC for additional long-term toxicity tests of two trophic levels	50
NOEC for additional long-term toxicity tests for three species of three trophic levels	10
Species sensitivity distribution (SSD) method	5-1 (fully justified case-by-case)
Field data or model ecosystem	reviewed on a case-by-case basis

The assessment factors recommended by the TGD are order of magnitude estimates that can be used for:

- screening and prompting a move to another stage in an iterative risk assessment,
- predicting a level at or above which the balance of probabilities suggest an environmental effect will occur;
- identifying which experimental data will most reduce uncertainty or prompt the revisiting of existing data.

The size of the assessment factor reflects the uncertainty in extrapolating from laboratory toxicity test data, often on single species, to multi-species ecosystems (OECD 1992, EC 2003). Other factors include the type of data that are available (short-term or long-term toxicity tests) and the number of trophic levels tested.

The assessment factors suggested for the soil compartment are not based on comprehensive experience and, as already stated, information from tests with soil organisms will be available for some compounds only.

The advantages of this type of extrapolation for developing SSVs are that:

- it is transparent and easy-to-use;
- it is a simple concept;
- it can be (and usually is) applied to small datasets.

Statistical extrapolation techniques

A species sensitivity distribution (SSD) is a statistical distribution. It describes the differences in toxicity of a contaminant across a set of species. The species set may comprise species from a particular taxon, a selected species assemblage or a natural community.

The true distribution of toxicity endpoints is not known so the SSD is estimated from a sample of toxicity data. It is usually visualised as a cumulative distribution function. The curve follows the distribution of the sensitivity data obtained from toxicity testing. It plots

no-effect concentrations derived from chronic toxicity tests (see Figure A1 for an example).

One of the advantages of the SSD approach is that the distribution makes use of the range of selected data and not just the lowest value. A risk assessor can make a judgement on the most sensitive groups of organisms based on their position on the curve.

When sufficient data are available, calculation of a PNEC using statistical extrapolation techniques can be considered. Minimum data requirements in the TGD include at least 10, and preferably more than 15, no observed effect concentrations (NOECs) for different species covering at least eight taxonomic groups.

- Where there are multiple data for one species, the most sensitive endpoint should be taken as representative for the species.
- Where multiple values for the same endpoint and species exist, the geometric mean should be used as the input value for the extrapolation.

When results are available from tests using different soils and soil characteristics are likely to influence the results, the TGD recommends that the effect data are normalised before further processing (see Section 4).

Data on microbial mediated processes and single species tests should usually be considered separately due to fundamental differences between these tests (e.g. functional vs. structural test, multi-species vs. single species, adapted indigenous microbe community vs. laboratory test species, variability of test design and different endpoints, etc.). The results should be compared and evaluated on a case-by-case basis when deciding on a final PNEC for the soil compartment.

Different distributions such as log-logistic, log-normal or others may be used to extrapolate toxicity data. The TGD encourages a discussion of the fit of the data to the selected distribution.

For pragmatic reasons, the concentration corresponding with the point on the SSD below which five per cent of the species occur (HC5) is used to determine the PNEC. A 50 confidence interval (CI) associated with this concentration should also be derived.

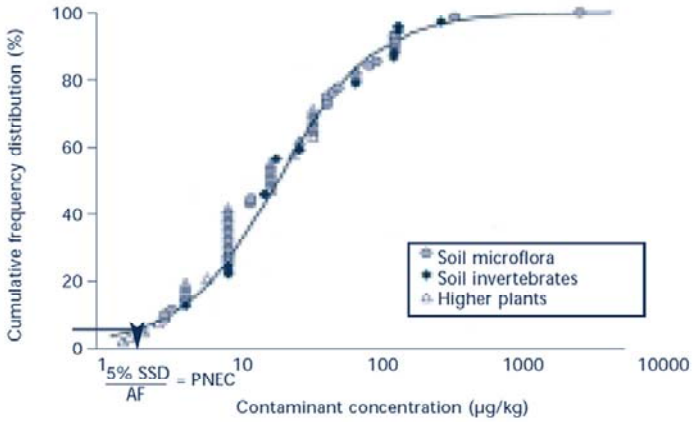

Figure A1 Example of a species sensitivity distribution and estimation of an HC5

An appropriate assessment factor (AF) between 5 and 1 is applied to the HC5 to determine the PNEC. The size of the assessment factor reflects further uncertainties, including:

- overall quality of the database and endpoints covered;

- diversity and representation of the taxonomic groups, e.g. differences in the life forms, feeding strategies and trophic levels of the organisms represented;
- knowledge of presumed modes of action of the contaminant;
- statistical uncertainties around the HC5;
- comparisons between the HC5 and field and mesocosm studies (where available).

Secondary poisoning

Assessment of the potential impact of substances on top predators is based on the accumulation of hydrophobic chemicals through food chains. This accumulation may follow many different pathways along different trophic levels. In predatory birds and mammals, it may result in toxic concentrations.

This 'secondary poisoning' should, in principle, be assessed by comparisons between the measured or estimated concentrations in the tissues and organs of the top predators and no-effect concentrations for these predators expressed as the internal dose.

In practice, however, data on internal concentrations in wildlife are hardly ever available. Most no-effect levels are expressed in terms of concentrations in the food that the organisms consume (i.e. in mg/kg food). Therefore, the actual determination in a risk assessment is normally based on a comparison of the (predicted) concentration in the food of the top predator and the (predicted) no-effect concentration for the predator, which is based on studies with laboratory animals (e.g. rats or quail).

A distinction is made between the methods used to assess the effects of substances whose effects can be related directly to bioconcentration (direct uptake via water) and those where indirect uptake via food may also contribute significantly to bioaccumulation.

The TGD methodology for bioaccumulative substances is used when deriving SSVs. For a terrestrial food chain, this is as follows:

Soil → earthworm → worm-eating bird or mammal

The PNEC relating to ingestion by the predator ($PNEC_{oral}$) is derived in the same way as for the aquatic route. It predicts a no-effect concentration in birds and mammals from studies reporting on dietary and oral exposure. Data such as NOECs for mortality, growth and reproduction from long-term chronic studies are preferred. If adequate data are not available, a PNEC for oral exposure cannot be estimated.

The $PNEC_{oral}$ is expressed as a concentration in the food (prey item) as mg/kg food or a dose as mg/kg body weight per day.

The calculation is as follows:

$$PNEC_{oral} = \frac{TOX_{oral}}{AF_{oral}}$$

where:

$PNEC_{oral}$ = PNEC for secondary poisoning of birds and mammals (in kg/kg food)

TOX_{oral} = $LC50_{bird}$ or $NOEC_{bird}$ or $NOEC_{mammal,\ food,\ chronic}$ (in kg/kg food)

AF_{oral} = assessment factor applied in extrapolation of PNEC (unitless).

The assessment factor takes into account:

- interspecies variation;
- acute/sub-chronic to chronic extrapolation;
- extrapolation from laboratory data to field impact.

Table A2 shows the TGD assessment factors for extrapolating mammalian and bird data. These consider the differences between:

- the ratio of body weight and daily food ingestion rates between laboratory species and wildlife species (the ratio can differ up to a factor of eight for birds and 10 for mammals);
- intrinsic species sensitivities;
- varying metabolic stages in the lifecycle of predators (e.g. extra sensitivity during migration or hibernation).

Table A2 Assessment factors for extrapolation of bird and mammalian toxicity data

TOX_{oral}	Duration of test	AF_{oral}
$LC50_{bird}$	5 days	3,000
$NOEC_{bird}$	Chronic	30
$NOEC_{mammal, food, chronic}$	28 days	300
	90 days	90
	Chronic	30

Using the $PNEC_{oral}$, a back calculation is made to a concentration in the soil using either a predictive model of gut loading in the earthworm and concentration in the tissue, or an empirically derived bioconcentration factor (BCF) for the earthworm.

When a substance is likely to accumulate and two soil-related toxicity values have been derived – one as a PNEC (for microbes, plants, inverts) and the other relating to secondary poisoning – both are available for use as SSVs in Tier 1 of the ERA framework.

Appendix 3 Checklist of criteria for the reliability evaluation of ecotoxicity studies used for SSV derivation

Type of test

- Standard test or relevant non-standard test.
- Ecotoxicity endpoints are reported.
- Test duration is reported.
- Static or flow-through design is reported (if test is aquatic).

Description of test material and methods

- Test set-up and measuring chamber/device are reported.
- Test material (including purity), solutions used and dilution water (if applicable) are reported, and whether there are indications that these factors influence the outcome of the test. If no information on impurities/solutions/dilution water is reported but there are no indications that impurities/solutions/dilution water might influence the results, this criterion is considered to be met.
- Test organism type including size (age), origin and number of organisms per replicate are reported.
- Test design, including number of replicates, is reported.
- Feeding regime is reported for long-term tests.

Description of physicochemical test conditions

Description and control of physicochemical conditions that may influence the outcome of a test are reported. For soil toxicity tests, this should include temperature, particle size distribution, organic carbon, pH and clay content. For water toxicity tests, this should include temperature, oxygen, hardness, salinity (if applicable) and pH.

Chemical analysis (particularly important in case of volatile/degradable substances)

- Test concentrations during the test are measured and reported.
- Test concentrations are not measured, but an indication is provided that the nominal concentrations are close to actual concentrations.
- Evidence is provided that concentrations were maintained during the test (<30 per cent variation), no evidence of precipitation of test substance or exceedance of its solubility.

Concentration-effect relationship

- Acceptable control mortality, reproduction or growth is reported; if this is not reported but there are no indications of unacceptable effects in controls, this criterion is considered met.
- Reliable statistics are used: 95 per cent confidence limits are reported or data are provided that allow further analysis to derive a suitable L(E)Cx value (Lethal or Effective Concentration for x per cent of test organisms) or No Observed Effect Concentration (NOEC).
- Test concentration range is reported.
- A concentration-related response is clear with a progressively increasing effect observed as a function of the dose. However, hormesis is sometimes observed in toxicity tests (e.g. increased performance for growth or reproduction) at low doses. In such cases, statistical models other than the conventional log-logistic dose-response model can be used to fit the toxicity data. For example, the linear-logistic model of Brain and Cousens (1989) has been extended to allow EC50 and EC10 calculations when hormesis occurs (van Ewijk and Hoekstra 1993, Schabenberger et al. 1999, Cedergreen et al. 2005).

Appendix 4 Substances for which derived SSVs are currently insufficiently reliable

Substance	Proposed SSV (mg/kg)	Basis for derivation
Arsenic	0.04	Only an ARA value derived
1,1,1-trichloroethane	0.015	EqP based on algal data, plus AF of 50.
1,2,4-trichlorobenzene	0.05	AF of 1,000 on terrestrial plant data.
1,2-dichloroethane	1.37	EqP based on waterflea data, plus AF of 10.
Anthracene	0.02	AF of 1,000 on terrestrial plant data.
Benzene	0.2	EqP based on fish data, plus an AF of 10.
Chloroform	0.496	EqP based on fish data, plus an AF of 10.
2-chlorotoluene	0.024	EqP based on waterflea data, plus an AF of 50.
4-chlorotoluene	0.281	EqP based on waterflea data, plus an AF of 10.
alpha-chlorotoluene	0.01	EqP based on waterflea data, plus an AF of 50.
Cyanides	0.0057	AF of 1,000 on terrestrial plant data.
Ethylbenzene	0.879	EqP based on waterflea data, plus an AF of 50.
Hexachlorobutadiene	0.032	EqP based on fish data, plus an AF of 100.
Naphthalene	0.0533	EqP based on fish data, plus an AF of 50.
Organolead compounds	0.068 (tetramethyl lead) 0.196 (tetraethyl lead)	EqP based on fish data, plus an AF of 1000.
Organotin compounds	0.034	AF of 100 on earthworm data
Phenol	0.136	AF of 1,000 on earthworm data.
Tetrachlorobenzene	0.024	AF of 100 on terrestrial plant data.
Thiocyanates	7.18	AF of 1,000 data on wire worm data.
Total petroleum hydrocarbons (TPH)	Depends on different hydrocarbon blocks present at site	EqP and hydrocarbon blocking approach used.
Trichloroethylene	1.71	EqP based on fish data, plus an AF of 10.
Xylenes	0.34	EqP based on waterflea data, plus an AF of 10.

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