SOIL SCREENING VALUES FOR USE IN UK ECOLOGICAL RISK ASSESSMENT

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Statement of Use

This report reviews approaches to setting soil screening values or concentrations of contaminants, which if exceeded would prompt further risk assessment. The results will be used by the policy managers and advisors in the Agency (primarily Land Quality and Conservation departments) in recommending the most appropriate methods for developing screening values. The recommended approach will be used to develop soil screening values for use in Tier One (screening phase) of the Environment Agency's ecological risk assessment framework (R&D Technical Report P5-069/TR1, in preparation).

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EXECUTIVE SUMMARY

Statement of use

This report presents a review of leading international approaches to setting soil screening values that are used in environmental risk assessment. The recommendations will be used by the Agency's policy managers for land quality and by policy and process managers responsible for habitats regulation to advocate the most appropriate methodologies for deriving soil screening values. The recommended approach will be used to develop screening values primarily for use in Tier One (screening phase) of the Environment Agency's ecological risk assessment (ERA) framework (R&D Technical Report P5-069/TR1, in preparation).

Aim

The aim of this report is to review and recommend an approach for setting soil screening values for use in the Environment Agency's ERA framework.

What are soil screening values?

Screening values are concentrations of a contaminant in soil, which if exceeded may prompt further risk assessment. Screening values should afford a level of protection to terrestrial species and critical ecological functions, but also be reasonable and not so low that even at trivial concentrations no chemical is ever screened out from further risk assessment[1].

Why do we need screening values?

In the 1980's the UK was one of the first countries to propose criteria for concentrations in soil in the context of land used for redevelopment. These criteria related to the protection of human health and have since been withdrawn and superseded by soil guidelines values developed by Defra, its predecessor departments, and the Environment Agency. But, similar values do not yet exist for the protection of ecosystems. A draft framework for the risk assessment of ecosystems has already been developed by the Agency and research is currently underway to populate the framework with the tools required to perform ecological risk assessments, for example acute and chronic ecotoxicity tests, population and food web models. The contextual background to soil protection values for use in managing contaminated land is described in ***chapter 1***.

For assessing risks to ecological systems, the Agency's policy managers have recommended that criteria are developed for assessing potentially contaminated soils at the screening stage. As legislation to identify and remediate contaminated land is already in place, screening criteria are urgently needed. The only way to develop these quickly is to rapidly review existing approaches used in other countries and evaluate their suitability for use in the UK.

How are screening values developed?

In ***chapter 2*** the basic step-wise process of gathering data, selecting a subset of suitable data, estimating effects-based criteria, and determining final screening values is explained. This process is common to all international approaches when setting screening values.

Initial data gathering often reveals a paucity of terrestrial toxicity data compared to the quantity of data available on aquatic species. Lack of data is a real problem for regulatory authorities across the world and one which looks unlikely to be rectified quickly as the scientific community is unable to agree on a

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[1] *Ecological soil screening level guidance. Review of existing soil screening benchmarks - Exhibit 1.1*. Prepared for the American Petroleum Institute Biomonitoring Task Force, draft in July 2000.

standard set of ecotoxicological tests. Each authority sets its own criteria for data selection. Some authorities, for example the Netherlands and the European Commission, recommend normalising toxicity data. Soils are highly heterogeneous and confounding factors such as organic matter content or pH will influence whether a soil retains or releases a contaminant (for potential uptake by an organism). Normalising or adjusting toxicity data for a standard soil (as defined by each authority) allows each data set to be directly comparable.

An important part of reviewing standard-setting processes is to compare how toxicity data is extrapolated. This often highlights some of the main differences between the approaches used by regulatory authorities. Data is extrapolated to convert laboratory toxicity data to represent variable field situations and the inherent biodiversity represented there. The three main extrapolation methods are as follows;

- distribution-based methods which can include a statistical distribution or a ranked distribution and selects a particular percentile or cut-off point as the screening value,
- assessment factor methods select the lowest reported toxicity value and divides by an assessment (safety/uncertainty) factor,
- equilibrium partitioning method which converts aquatic toxicity data for use in the terrestrial compartment.

When viewing international approaches overall, there is an order of preference for using these methods based on their advantages and limitations and that is; distribution-based methods >> assessment factor >> equilibrium partitioning. Distribution-based methods take all selected data in to consideration and, in the case of species sensitivity distributions (SSDs), provide a statistical confidence in the chosen cut-off value. But distribution methods are data hungry and (depending on the authority) usually require at least ten data sets to be meaningful. Assessment factor methods are transparent, easy to use and can require only one toxicity test result. The drawbacks are that the size of assessment factor is rather crude and poorly justified. Assessment factors can be relatively large (≤1000) with the potential to make screening values too low to be useful in risk assessment. Finally, the equilibrium partitioning method is used as a last resort by some authorities when only aquatic data exists. This method may be unreliable as it is based on some major assumptions that terrestrial organisms are exposed to, taken up, and are affected by contaminants in soil in the same way as occurs in the aquatic environment.

Finally, authorities have an opportunity to refine toxicity-based criteria in the last stage of screening value development by adding or removing assessment factors where values are seen to be under- or over-protective (for example, when dealing with non-threshold effects like carcinogenicity).

International approaches to setting soil screening values

Some regulatory authorities have been leading on environmental standard development for many years and it is the well established approaches used by the Netherlands, European Commission, Canada, and the United States of America that are the focus of this review. ***Chapter 3*** considers the features and limitations of these approaches.

The Netherlands, European Commission Technical Guidance Document (EC TGD for the risk assessment of new and existing chemicals) and Canada all present flexible approaches to developing screening values. They use a range of extrapolation methods depending on data availability advocating the use of chronic toxicity data based on sublethal endpoints (for example, reproduction).

Canada offers an assessment procedure based on land use and aims for a level of ecological protection to ensure that land has the potential to support most activities likely to be associated with its land use. This land use based approach differs from the European and US policies where screening values are based on one or two levels of protection regardless of land use.

For most authorities the preferred level of protection offered by screening values is at the 20th percentile or lower. Only the US EPA exceeds this with a protection level selected at the geometric mean (50th percentile) of its distribution method.

In summary, although the same basic practice of developing values endures (chapter 2), final protection values differ primarily on how the literature is qualified for use, what measurement endpoints are acceptable, how interspecific differences are treated, and what type of assessment factors are applied (API, 2000).

Characteristics of screening values

Screening values are intended to be protective of terrestrial species and ecological functions yet also be practical for the assessment of potentially contaminated soil. That is, screening values that are below background levels or, in the case of essential elements, below levels required for healthy homeostatic functions are unusable.

In order to identify the most suitable screening value methodologies for the UK, we needed to identify existing contaminated land policies and establish the desired characteristics wanted in our screening values. For example, what level of protection should be afforded to ecosystems, how are varying soil parameters accounted for? These considerations are presented in ***chapter 4***. A 'wish list' was generated of the desired characteristics of screening values, which was used to compare with policies from existing international approaches. The result of the comparison and recommended approach for the Environment Agency is presented in ***chapter 5***.

From the list of desired characteristics of soil screening values we consider the most important to be:

- application of generic values at a screening level
- flexibility (using a range of data extrapolation methods)
- protection at the 95th percentile level (of a distribution)
- protection of sublethal endpoints, such as growth and reproduction
- protection of microorganisms, invertebrates, and plants as a minimum. And protecting higher organisms (birds and mammals) when contaminants are likely to bioaccumulate in the food chain.

Recommendations

As a result of comparing desired characteristics with international approaches to developing soil screening values there are two suitable options – the Netherlands and the European Commission TGD. Both approaches are similar and meet all of the characteristics listed above.

The recommendation of this review is to adopt the approach presented in the **European Commission TGD**. The deciding factors in simple terms are:

impartiality	European predicted no effect concentrations (PNECs) are scientifically based criteria and do not reflect any one country's policy or legislative requirements (and numerical adjustments)
easily adopted	the methods described in the TGD already have European imprimatur

Following the publication of this review, the Environment Agency will develop screening values for about 40 priority contaminants over the next two years. The methodology and values will be peer reviewed, undergo public consultation and 'road testing' using field trials and be finalised and published in 2005.

Key words: soil screening values, ecological risk assessment (ERA), land contamination, harm, Part IIA Environmental Protection Act 1990, Habitats Directive, predicted no effect concentrations (PNEC), European Commission Technical Guidance Document (EC TGD).

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1 INTRODUCTION

This chapter introduces the aims of the report, the contextual background to setting soil screening values in the UK and the framework in which values will be used.

1.1 Aim and outline of this report

The aim of the report is to review and recommend an approach for setting soil screening values for use in the Environment Agency's ecological risk assessment framework.

The Environment Agency is committed to developing a tiered ecological risk assessment (ERA) framework for use primarily in Part IIA of the Environmental Protection Act 1990, but also to support other regimes such as the Habitats Directive. *Assessing risk to ecosystems from land contamination* (R&D Technical Report P299), published in 2002, set out a proposed ERA framework and the tiers one and two of that framework are now being tested in R&D Project P5-069. This review complements this work by recommending a method for developing screening criteria for use in tier one of the ERA framework; in effect a set of concentrations which if exceeded, may prompt further risk assessment as set out in the framework.

Outline of this report

This review of existing soil screening values is divided in to 7 chapters.

Chapter 1 is an introduction to the drivers for developing soil screening values and the place they will have in the Agency's policies for assessing the risks of potentially contaminated land. The UK Government's Department for Environment, Food and Rural Affairs (Defra), its predecessor departments, and the Environment Agency are working together to develop and implement policy and guidance to meet the requirements of Part IIA of the Environmental Protection Act 1990 (from herein referred to as Part IIA EPA 1990). Current advice relates largely to protecting human health but regulatory effort is now being placed on protecting terrestrial ecosystems. The challenges of developing a robust and defensible risk assessment process for protecting human health has paved the way for ecosystems.

Chapter 2 describes a generic step-wise approach to developing soil screening values. Existing values may differ between regulatory authorities but the same basic process endures; gathering data, selecting a subset of suitable data, estimating effects-based criteria, and determining final screening values.

Chapter 3 considers the features and limitations of existing international soil screening values. The leading authorities of the Netherlands, European Commission, United States and Canada are reviewed. The chapter presents how the final values are developed and underlying policy requirements which determine their application.

Chapter 4 discusses the factors that influence the development of soil screening values. Screening values are intended to be protective of terrestrial species and ecological functions. This requires a mix of scientific understanding of the effects of contaminants to terrestrial ecosystems and policies for managing contaminated land. A list of influencing factors is presented, discussed and then summarised as a 'wish list' of characteristics that are then used to compare with international approaches.

Chapter 5 compares the desired characteristics from chapter 4 with the existing international approaches reviewed in chapter 3. Recommendations are made on the most suitable approach to develop screening values for use in the UK.

Chapter 6 provides an example soil screening value using the recommended method presented in chapter 5.

Chapter 7 lists the guidance documents from each of the main regulatory authorities reviewed and other references cited in this report.

1.2 Contextual background

1.2.1 History of screening values

The UK was one of the first countries to propose criteria for concentrations in soil in the context of land used for redevelopment. These values were based on the work of the Interdepartmental Committee on the Redevelopment of Contaminated Land[2] (ICRCL) in the 1980s. The values acted as trigger concentrations, which if exceeded, would prompt further investigation. The values were only applicable to protecting human health. The ICRCL trigger values are now technically out of date and their approach is not in line with the current statutory regime (Part IIA of the EPA 1990). They have now been withdrawn from use by Defra (December 2002) and superseded by soil guideline values designed specifically for use in Part IIA EPA 1990.

1.2.2 New soil guideline values

In 2002, Defra and the Environment Agency published a series of reports that, for the first time, provide a scientifically based framework for the assessment of risks to human health from land contamination. The framework is used to develop soil guideline values which represent 'intervention values' indicating to an assessor that soil concentrations above this level could pose an unacceptable risk to the health of site users and that further investigation and/or remediation is required. Soil guideline values are used to meet the formal requirements of the Part IIA EPA 1990 regime but may also be used where the effect of land contamination on human health is an issue.

The soil guideline values are designed to be protective of human health. Their development means that the Agency and Defra have agreed some scientific approaches and policy decisions, which for consistency, can be carried over to developing and applying screening values to ecosystems.

1.2.3 Current legislation

Part IIA of the Environmental Protection Act 1990

Part IIA EPA 1990 has created a new regime for the identification and remediation of contaminated land. A full description of the Part IIA regime, including procedural steps and statutory guidance can be found in DETR Circular 02/2000[3]. The main functions under the

[2] Interdepartmental Committee on the Redevelopment of Contaminated Land, ICRCL 59/83 (1987) *Guidance on the assessment and redevelopment of contaminated land 2nd edition*.

[3] Department of the Environment, Transport and the regions (2000) Environmental Protection Act 1990: Part IIA. Contaminated Land Circular 02/2000, Department of the Environment, Transport, and the Regions. Available from The Stationery Office, UK.

regime are exercised by local authorities and, in certain circumstances, the Environment Agency or the Scottish Environment Protection Agency. The advice of English Nature, Countryside Council for Wales and Scottish Natural Heritage, where relevant, is also sought in defining contaminated land. Part IIA is intended to complement other legislation, for example, the Town and Country Planning Acts, Pollution Prevention and Control regime, Groundwater Regulations, and the Habitats Directive.

In the context of Part IIA, action is necessary only where there are unacceptable risks to health or the environment, taking in to account the current use of the land and its environmental setting. This is the "suitable for use" approach. Action is decided on a risk assessment and management process.

Habitats Directive

Regulation 3 of the Conservation Regulations 1994, known commonly as the 'habitats regulations', implement in Great Britain the requirements of the European Habitats Directive (92/43/EEC) and 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 and as such will apply the regulations when considering all applications for authorisations, permissions, permits, consents and environmental licences and all relevant Agency policy and operational activities.

Where applications under the UK system of land use planning or review of permits, licences etc. are likely to impact on sites protected under the regulations, then a risk assessment process is initiated. Stage 2 of the process determines if a plan or project is likely to have a significant effect on a protected site.

Definitions of harm

Under Part IIA, land is only determined as contaminated land if there is a **significant pollution linkage** present. A linkage requires evidence of the direct or indirect contact between a receptor and a contaminant. In addition, the degree of harm that the receptor could suffer must meet the descriptions of "*significant*" contained in the statutory guidance.

The Part IIA (Table A) definition of significant harm is;

Harm which results in an **irreversible adverse change**, or in some other **substantial adverse change**, in the **functioning** of the **ecological system** within any part of that location

While this is a reasonable legal definition, it causes problems when attempting to derive quantitative criteria for harm. In addition, waiting until an effect is irreversible could result in significant consequences, particularly for rare or endangered species. The Agency is proposing that;

Significant harm is when growth, reproduction or mortality are adversely affected, such that the survival of a population/ community/ species is threatened.

There is a significant possibility of significant harm when the indicators of harm (as above) differ from reference or control values at an agreed statistical confidence level. This definition allows for the possibility that, in the case of a rare species, a less rigorous statistical test might be appropriate (for example at the 90 per cent confidence limit) than for a widespread species where a significant difference at the 95 per cent limit might be required.

The indicators for significant harm may be at the community, population or individual level.

The proposed quantitative criteria for harm are as follows;

For bioassays: when the mean value of a parameter measured in the test samples differs at the 95 per cent confidence limit from that in a relevant control sample (i.e. ideally, differing from the test sample only in the presence of contamination) there is an 'effect'. Consideration must then be given to the cause of the effect. Is it due to the suspected contamination? Or could it come from some other, unconnected factor, such as kids playing on the site etc. If other possible causes can reliably be eliminated, the cause is taken as harm.

For ecological surveys: if the measured parameter falls outside the 95 per cent confidence limits of a range expected from natural variation (temporal) or variability (spatial), there is an 'effect'. Again, consideration must be taken to the cause of the effect, and if other possible causes can reliably be eliminated, the cause is taken as harm.

It is important to note that for both these criteria, the statistical procedures to test for significant differences are identical to the mean value test employed in existing UK policies, CLR7 (Defra and Environment Agency, 2002a).

Under the habitats regulations, a likely significant effect is judged to be,

any effect that may reasonably be predicted as a consequence of a plan or project that may affect the conservation objectives of the features for which the site was designated, but excluding trivial or inconsequential effects.

The significant effect relates to,

possible impacts or effects on an interest feature or the supporting environment on which the feature depends.

Quantitative criteria for significant effects are not provided in the regulations.

1.3 A framework for protecting ecosystems

To meet the legislative requirements, the Environment Agency is committed to developing a tiered ecological risk assessment (ERA) framework for use primarily in Part IIA, but also to support other regimes such as the Habitats Directive. The report *Assessing Risks to Ecosystems from Land Contamination*[4], published in 2002, set out the Agency's proposed ERA framework and tiers one and two of that framework are now being tested in Environment Agency R&D Project P5-069. The proposed framework will be adapted in light of the results of this testing. One of the changes likely to be made to

[4] *Assessing risks to ecosystems from land contamination* (2002) Environment Agency R&D Technical Report P299

the existing framework is the insertion of a tier zero. A summary of the basic structure of the framework is provided in box 1.

The framework is tiered and iterative. The tiered approach gives assessors early opportunities to eliminate sites from further risk assessment where they are confident ecosystems are not being harmed. As the assessment proceeds more evidence is gathered at each tier giving assessors the opportunity to review and refine pollutant linkages and assessment objectives through iteration.

Box 1 Simple four tier ERA framework

Tier 0

- Limited site characterisation
- Setting objectives
- Site conceptual model

Tier 1

- Screening risk characterisation (Hazard Index = PEC/PNEC)

Tier 2

- Risk characterisation using ecological and toxicological tests

Tier 3

- Risk characterisation using further toxicity testing, ecological surveys, ecological modelling (populations, food webs)

The screening tiers of the framework are designed to sift out sites, which are not causing harm to terrestrial ecosystems, quickly and at minimal cost. These early tiers are intended for generic application. Tier zero assessment includes limited site characterisation and the setting of assessment objectives. At this initial screening level a simple site conceptual model is developed to confirm that pollutant linkages potentially exist between contaminants in the soil and receptors likely to be exposed to them. Tier one brings in a simple effects assessment by comparing contaminant concentrations in soil against toxicity-based screening values to determine which contaminants are likely to be posing a risk to receptors. It is essential that generic screening values are protective of ecosystems but not so stringent that a contaminant is never screened out of the assessment.

Tiers two and three are increasingly site specific and concentrate on reducing uncertainty around the measurement endpoints and assessment conclusions. Tier two introduces ecological and toxicological tests to help quantify effects of contaminants to receptors. These tests are reviewed in the Agency and SNIFFER report *Ecotoxicological and Biological Test Methods for the Assessment of Contaminated Land*[5] and the Agency and Centre for Ecology and Hydrology (Monks Wood) report *Review of Sublethal Ecotoxicological Tests for Measuring Harm in Terrestrial Ecosystems*[6]. Tier three aims to further reduce uncertainty in the evidence collected in previous tiers and really pinpoint the long-term effects of contamination. This final tier includes detailed methods, for example modelling receptor populations, food web analyses, and ecological surveys. These procedures can be time consuming and costly and generally will only be applied to large complex ERAs.

The framework embraces the concepts and ideals of the Government's *Guidelines for Environmental Risk Assessment and Management*[7]. Until the framework is finalised the Agency will continue to recommend the use of the Government's *Guidelines,* which describe general principles and provide case studies that demonstrate how environmental risk assessment and management processes can be applied across a diverse range of activities. Those involved in flood and coastal defence work will continue to use their own project appraisal guidance, which contains specific published information on assessing risk.

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[5] *Ecotoxicological and Biological Test Methods for the Assessment of Contaminated Land* (2002) Environment Agency R&D Technical Report P300

[6] *Sublethal Ecotoxicological Tests for Measuring Harm in Terrestrial Ecosystems* (2002) Environment Agency R&D Technical Report P5-063/TR1

[7] *Guidelines for Environmental Risk Assessment and Management – revised departmental guidance.* July 2000. The Stationery Office, ISBN 0 11 753551 6

1.4 Screening level assessment

Using the Government's *Guidelines for Environmental Risk Assessment and Management* to explain screening level assessment at tier 1, the aim is to determine which hazards or risks should be investigated in more detail and in what order of priority.

Hazard identification and magnitude of consequences

Characterising the nature of the hazard requires a consistent measure to be used and usually reflects the importance of the hazard in relation to others. Where the hazard is a chemical, its relative toxicity to the likely receptor organisms is an appropriate measure. This is the *effects assessment*.

This is where the soil screening values (developed as a result of this review) will be used to quantify the hazard in terms of toxicity to terrestrial organisms.

The exposure assessment will screen and prioritise the likely pathways linking sources and effects.

Probability of consequences

The likelihood of the hazard being realised can be roughly estimated using coarse indicators. This is the risk characterisation. One method is to generate a hazard index by comparing the actual or estimated environmental concentration of a contaminant (PEC) derived in the exposure assessment with soil screening values (PNEC) from the effects assessment.

1.5 International soil screening values

The recommendation in the report *Assessing Risks to Ecosystems from Land Contamination* to develop screening values for the ERA framework is in line with other authorities' risk assessment procedures. This report aims to recommend an appropriate method for developing soil screening values (usually based on PNECs) for use in the Agency's ERA framework. There is real urgency as legislation is already in place to risk assess potentially contaminated land. The quickest and simplest approach to developing soil screening values is to review how other countries have developed and are applying their soil protection values and assess whether any of these approaches are suitable for application in the UK. The following authorities have considerable experience of the development of soil protection values and the features and limitations of their approaches are reviewed in chapter 3:

- The Netherlands
- European Commission Technical Guidance Document for risk assessment of new and existing chemicals (EC TGD)
- Canadian Council of Ministers of the Environment (CCME)
- United States Department of Energy (US DoE)
- United States Environmental Protection Agency (US EPA)

1.6 Factors influencing soil screening values

So, why do methods differ between international countries and soil screening values vary for the same contaminants?

Essentially it comes down to our lack of understanding of how complex terrestrial ecosystems function, interspecies relationships and system interactions, the behaviour of chemicals in the environment with relation to contaminant bioavailability, and the [toxic] effect of contaminants to species including the

impacts on population biology. For instance, effects data is usually based on an individual chemical for an individual species established on individuals in a laboratory. Translating this to ecosystems is unclear. To compensate for our lack of understanding we have to make assumptions based on any data we have and assumptions are often conservative in order to be protective.

The American Petroleum Institute (API, 2000) concluded in their review of international soil protection values that generally values are drawn from the same worldwide body of scientific studies. Differences in final values are due to differences in policy, rather than technical rigour or quality in underlying data. Major issues that varied amongst authorities were level of protection, use of assessment factors, background levels and minimum data requirements.

These and other influencing factors, for example accounting for bioaccumulative contaminants, are discussed in chapter 4.

Finally, a comparison is made of the features of existing international approaches against desired influencing factors (science and policy). The chapter concludes with recommendations for an appropriate approach for the Agency.

A worked example of a soil screening value using the recommended approach is presented in chapter 6.

2 GENERAL APPROACHES TO DEVELOPING SCREENING VALUES

This chapter presents general approaches to selecting and extrapolating data in order to set soil screening values. Chapter 3 describes how these basic approaches have been taken up by The Netherlands, European Commission, United States and Canada and presents how they are used to meet differing policy requirements.

All authorities follow a similar stepwise approach (see figure 1) to developing screening values. These are as follows:

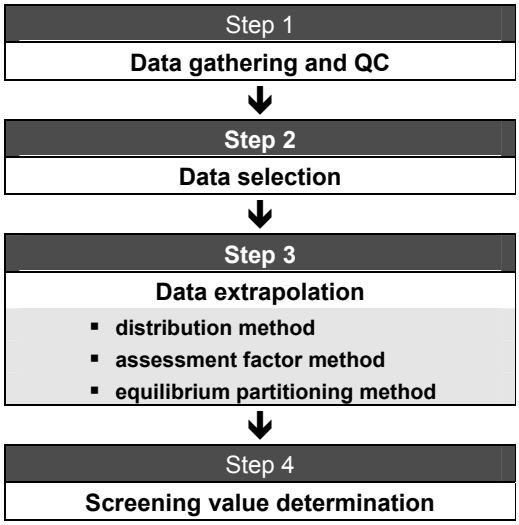

Figure 1 illustrates the basic step-wise approach to developing screening values

2.1 Data gathering (step 1)

When developing screening values, authorities interrogate the same databases and international literature for physico-chemical and ecotoxicological information on contaminants. Searches are usually performed on a contaminant specific basis. There are a number of public domain databases that contain acute and chronic ecotoxicity data for aquatic and terrestrial species, for example the European Chemicals Bureau's International Uniform Chemical Information Database (IUCLID). Some authorities also use physico-chemical information as an early screen for predicting the likelihood of a contaminant moving through food chains. For example, the Dutch suggest contaminants with a log Kow greater than 3 and molecular weight less than 700 are likely to accumulate in terrestrial biota and flag these contaminants as likely to cause harm to higher organisms early in the risk assessment process.

Qualitative information, for example lists of protected species, is also important and may be used to support risk decisions made at screening level but may not be incorporated directly in the derivation of a numerical screening value. This type of information is usually authority specific and can be sourced from the legislation and policies of national governments.

2.2 Data selection (step 2)

Once data has been gathered it is usually quality assured. For the purposes of setting screening values, data has to be comparable and there are reasons why toxicity data may be variable, for example, test methods change over time. Each authority uses its own criteria for sifting data but generally the same reasons for selection apply,

(i) data is suitable for use in preferred extrapolation methods,

(ii) to meet environmental policies, and

(iii) a preference for species that are representative of their national ecosystems.

The European Commission in their technical guidance recommends selecting data using quality criteria based on reliability, relevance and adequacy. These are defined by Klimisch *et al* (1997). Reliability

determines the robustness of ecotoxicological studies and is considered before relevancy and adequacy.

The US EPA in the development of their ecological soil screening levels (Eco-SSLs) evaluates toxicity data based on ten criteria and scores the quality of data to ensure only the most appropriate data is used in the derivation of Eco-SSLs. The scores are reported in the Eco-SSLs guidance document. Some other authorities use a less transparent approach by using expert judgement to select (or reject) data without reporting the criteria or judgements made in selecting final data sets.

The US and The Netherlands are more stringent than other authorities about data requirements and cite test methodologies, soil characteristics, measurement endpoints, species and contaminant details as being important parameters to select for.

At the data selection stage, data may also be treated so that it can meet selection criteria. For example, the most likely form of data treatment is normalising soil data. In the complex soil compartment various soil parameters (e.g. organic matter content) can influence the availability of a contaminant for uptake by organisms. This means that toxicity test results using different soil may not be directly comparable. To account for this, toxicity data can be normalised by converting results to a standard soil where data on the organic matter content of the test soil is provided (see chapter 4 for details on how this is done).

2.3 Data extrapolation (step 3)

For many potential contaminants there is a paucity of toxicity effects data for terrestrial organisms. In order to reflect the richness of species diversity and critical ecosystem functions in the real environment, toxicity data is extrapolated to deal with any uncertainties in laboratory tests. This means that flexible approaches are essential for making maximum use of information when it is plentiful and using alternative methods when little or no terrestrial toxicity data is available.

There are three widely recognised methods used to extrapolate laboratory toxicity data to reflect field situations. These have been developed, often independently and for other media, by leading international authorities but are adopted and used by many countries with risk assessment frameworks.

- Distribution-based methods that can include a statistical distribution or a ranked distribution and selects a particular percentile or cut-off point as the screening value.
- An assessment factor method selects the lowest reported toxicity value and divides by an assessment (safety/uncertainty) factor.
- Equilibrium partitioning method which converts aquatic toxicity data for use in the terrestrial compartment.

2.3.1 Distribution-based methods

There are different types of distribution-based extrapolation methods used amongst the national authorities. For example, the US DoE apply a ranked frequency distribution approach to toxicity data and then select an arbitrary cut-off point, the 10^{th} percentile. Other authorities use a statistical extrapolation. A statistical approach or species sensitivity distribution (SSD) was proposed two decades ago as an ecotoxicological tool that is useful for deriving environmental quality criteria and can also be used in ERA to quantify a proportion of species which might be affected by a particular concentration of a contaminant. The SSD method was developed in the US and in Europe simultaneously, but independently.

Ranked distribution

One of the simplest ways of making use of all the selected data is to do a ranked distribution (see figure 2). The US Department of Energy (US DOE) uses this approach, called Effects Range-Low (ER-L), first developed for the derivation of sediment quality standards. To derive the ER-L, the 10th percentile from ranked lowest observable effect concentrations (LOECs) is selected. For application to contaminated soil the LOEC toxicity data is drawn from soil invertebrates (earthworms), soil microbial processes, plants, wildlife, or birds.

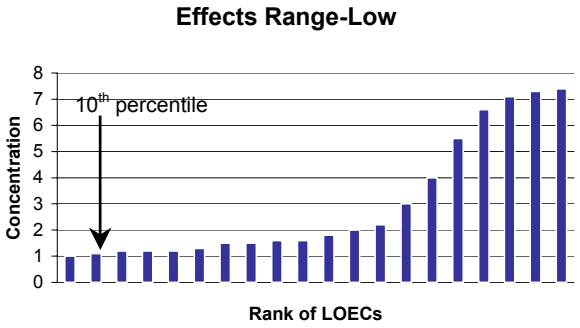

Figure 2 is an example of an effects range-low distribution with a cut-off point at the 10th percentile of the distribution

Species sensitivity distribution

A species sensitivity distribution (SSD) is a statistical distribution describing the variation among a set of species in toxicity of a certain contaminant or mixture (see figure 3). The species set may be composed of a species from a specific taxon, a selected species assemblage, or a natural community. Since the true distribution of toxicity endpoints is not known, the SSD is estimated from a sample of toxicity data and visualised as a cumulative distribution function (CDF). The CDF curve follows the distribution of the sensitivity data obtained from ecotoxicological testing, plotting effect concentrations derived from acute or chronic toxicity tests, e.g. LC_{50} or NOECs, respectively.

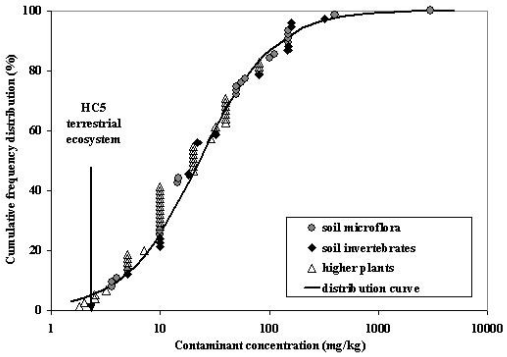

Figure 3 shows the basic appearance of species sensitivity distribution (SSDs). The dots are toxicity data. The line is a fitted SSD. The arrow on the x-axis represents the hazardous concentration at the 5th percentile of the distribution (HC_5).

The SSD concept can be used in a 'forward' as well as an 'inverse' way.

Inverse use – soil protection values

A cut-off percentage p is chosen (to protect 1-p percent of species, y-axis) and the desired 'safe' concentration (HCp) is calculated. The 5th percentile of a chronic toxicity distribution (HC_5) is chosen by The Netherlands and the EC TGD to be protective of most species in a community, but the value of p is a policy decision, not a scientific one.

Forward use – ecological risk assessment

The forward use, ecological risk assessment, requires estimation of the ambient concentration of a compound at a contaminated site or the concentration predicted to result from a proposed use (x-axis). The potentially affected fraction (PAF) at that concentration can then be estimated using the SSD. If a threshold for significant risk has been identified by policy (e.g. effects on more than 5% of species are unacceptable), any concentration higher than HC_5 can be considered to pose a risk. If variance or uncertainty is estimated, risk may be defined as the probability to harm more than p% of species. The type of harm is defined by the chosen ecotoxicological endpoint (e.g. reproduction) to construct the SSD.

Advantages and disadvantages

The greatest advantage of distribution-based methods generally is that they make use of all the available data. These methods make it easier for a risk assessor to see the distribution of species along the curve and make a judgement on the most sensitive groups of organisms.

The advantages of SSDs are multiple;

- they are more “scientific” than the use of basic assessment factors (see section 2.3.2),
- SSDs make use of a range of data not just the lowest toxicity value,
- major differences in the sensitivity of the tested species give rise to a lower precautionary cut-off value (e.g. HC_5),
- the use of statistics makes calculations of confidence intervals around the cut-off value possible.

Amongst the disadvantages are that the form of the distribution (log-logistic or log-normal) is rather unrefined. Statistical distribution methods are sensitive to variations in the data for the different test species. If the species represent a small part of the distribution curves only, the variance between species is underestimated and the protection concentration (HC_5) will be too high (Wagner and Løkke, 1991). These methods do not account for interactions between species or the modifying influence of non-biological components of the environment on the exposure and the biological effect. Furthermore, the toxicological endpoints used for calculations are heterogeneous, for example growth rate, reproduction. Neither is it justified to use large taxonomic distances ranging from microbes and plants to insects and vertebrates. A large variation of endpoints and taxa in combination with a limited number of test species may cause serious errors in the extrapolation procedure because of wrong assumptions in the distribution model or the lack of representativeness of the selected taxa. Reliable results are dependent upon the availability of sufficient data and its quality. Wagner and Løkke (1991) recommended the usage of short taxonomic distances and homogeneous endpoints. Additionally, that the distribution function of the test data should be controlled.

If NOEC values are the basis of the distribution, then these can form a poor basis for the distribution because of methodological problems of their derivation (see section 4.2) but also because laboratory species are not a random sample from the ecosystem to be protected. The ecological impact of a certain percentile remains unknown. Also, the use of persuasive statistics may suggest a larger degree of accuracy than is warranted.

On balance, a statistical extrapolation allows the estimate of expected effects and associated uncertainties rather than using worst-case assumptions or arbitrary safety factors (see section 2.3.2 for the discussion of assessment factors). But, the reliability of the results should be considered based on the quality and type of input data.

2.3.2 Assessment factor methods

A fixed assessment factor approach was suggested and further modified by the US EPA and is currently known as the (modified) EPA method (see tables 1 and 2). The EC TGD has also recommended the assessment factor approach for developing screening concentrations of no environmental concern (PNECs) for new and existing chemicals (see tables 3 and 4).

Assessment factors are applied to the lowest determined effect concentration usually from laboratory toxicity 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 (CEC 2003, OECD 1992) and the number of trophic levels represented in the data set. The factors are orders of magnitude and are derived by assuming constant differences between acute and chronic toxicity and between responses in laboratory single species and species under field conditions. Further assessment factors can be applied depending on the quantity and quality of data.

The assessment factor approach is simple to apply and is long established in setting screening values. Most international authorities use an assessment factor approach to derive screening values and may even apply additional assessment factors to values derived using other extrapolation methods when there is large uncertainty in the data.

Table 1 Modified US EPA assessment factors for terrestrial organisms

Available data	Assessment factor
L(E)C_{50} or QSAR estimate	1000
L(E)C_{50} or QSAR estimate for minimal three representatives of microbe-mediated processes, earthworms or arthropods and plants	100
NOEC or QSAR estimate**	100 or 1000 (based on L(E)C_{50})
	10 (based on NOEC)
NOEC or QSAR estimate for minimal three representatives of microbe-mediated processes, earthworms or arthropods and plants	10

** The value based on QSARs is compared to the extrapolated value based on acute L(E)C_{50} toxicity values. The assessment factor for L(E)C_{50}s is 100 for 3 L(E)C_{50}s, or 1000 for <3 L(E)C_{50}s.

Table 2 Modified US EPA assessment factors for bird and mammal toxicity data

Available data	Assessment factor
Less than 3 L(E)C_{50} values	1000
At least 3 L(E)C_{50} values	100
Less than 3 NOECs**	10
3 NOECs	10

** The value based on NOECs is compared to the extrapolated value based on acute L(E)C_{50} toxicity values. The assessment factor for L(E)C_{50}s is 100 for 3 L(E)C_{50}s, or 1000 for <3 L(E)C_{50}s.

Table 3 European assessment factors for soil compartment

Available information	Assessment factor
L(E)C_{50} short-term toxicity test(s) (e.g. plants, earthworms, or microorganisms)	1000
NOEC for one long-term toxicity test (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, to be fully justified on a case-by-case basis
Field data/data of model ecosystems	case-by-case

Table 4 European assessment factors for soil compartment (to consider secondary poisoning)

Available information	Assessment factor
LD50 for birds and mammals	Not acceptable for extrapolation
LC50 for birds	1000
NOEC (28-day repeated dose test)	100
NOEC (90-day repeated dose test)	30
NOEC for chronic studies	10

Advantages and disadvantages

The advantages to using this type of extrapolation are clear, for example, it is transparent, easy-to-use, a simple concept, and can be (and usually is) applied to small data sets.

The drawbacks are that the magnitude of an assessment factor is not usually developed on a thorough ecotoxicological understanding. Instead, it is often developed on precautionary principles and mathematical approaches. The assessment factors suggested for the terrestrial compartment are not based on comprehensive experience but are drawn directly from the factors used for the aquatic compartment. As already stated, information from tests with soil organisms will be limited and, in most cases, be from short-term tests with earthworms. This means that risk assessors need a deeper understanding of the difference between short- and long-term toxicity for several taxonomic groups representing terrestrial organisms. But more generally, risk assessors need to know more about the differences between laboratory and field tests for all environmental media. The choice of taxonomic groups for which toxicity data are necessary (comprising the base-set of algae, *Daphnia* and fish for the aquatic environment in the EC TGD), is also a point of discussion. A data set comprising toxicity data for primary producers, consumers and decomposers is preferred for the soil compartment. An internationally accepted set of standardised ecotoxicological tests for the hazard assessment of chemicals for the soil compartment is, though, not currently available. The EC TGD regards the assessment factors in table 3 as indicative and may have to be revised, as more information on the sensitivity of soil organisms becomes available.

Also, by applying an assessment factor to the lowest toxicity value, a risk assessor is assuming that even the most sensitive species and functions in the ecosystem will be protected.

2.3.3 Equilibrium partitioning methods

The equilibrium partitioning method (EqP-method) was originally developed to assess harmful effects to organisms living in the sediment compartment. The method uses aquatic toxicity data and the sediment/water partitioning coefficient. There are certain assumptions that have to be made when using this approach and for sediments these are:

- Sediment-dwelling organisms and water column organisms are equally sensitive to the chemical
- Concentration in sediment, interstitial water and benthic organisms are at thermodynamic equilibrium: the concentration in any of these phases can be predicted using the appropriate partition coefficients
- Sediment/water partition coefficients can either be measured or derived on the basis of a generic partition method from separately measurable characteristics of the sediment and the properties of the chemical.

The EqP-method only considers uptake via the water phase. For chemicals which are likely to adsorb to sediment (e.g. for chemicals with a log-Kow of greater than 3) then any uptake through the ingestion route will not be considered. This means that the total uptake for some substances may be underestimated and this is a major drawback of this particular method.

The same general approach is used for assessing harm to the terrestrial compartment as described for sediments. Terrestrial toxicity data is often very limited so using this approach means converting aquatic data to the soil environment by using the soil/water partition coefficient. For soil this assumes that bioavailability and therefore toxicity of chemicals to soil organisms is only determined by the concentration of a contaminant in the soil pore water. The same underestimation can occur when chemicals adsorb to soil particles and their uptake through ingestion by soil organisms is not considered.

To overcome the potential for underestimation when considering lipophilic compounds (log Kow > 5), the EC TGD recommends an additional factor of 10 is applied to the final predicted environmental concentration (PECsoil)/ predicted no effect concentration (PNECsoil) ratio. When only considering effect concentrations, it is reasonable to assume that the PNECsoil will be divided by a factor of 10.

The PNEC for soil is calculated using equation 1.

Equation 1

$$PNEC_{soil} = \frac{K_{soil\text{-}water} \times PNEC_{water} \times 1000}{RHO_{soil}}$$

Symbols

$PNEC_{water}$	predicted no effect concentration in water	[mg/l]
RHO_{soil}	bulk density of wet soil	[kg/m^3]
$K_{soil\text{-}water}$	partition coefficient soil water	[m^3/m^3]
$PNEC_{soil}$	predicted no effect concentration in soil	[mg/kg]

When considering risk assessment using the European TGD approach, if the $PEC_{soil}/PNEC_{soil}$ ratio is greater than 1 when using the EqP-method, then toxicity tests with soil organisms becomes a strict requirement.

In the Netherlands environmental risk limits (ERL) guidance document, the Eq-P method is modified for metals and metalloids in sediment and soil. The organic content normalisation of the sediment or soil uses empirically derived sediment/water or soil/water partition coefficients. These coefficients are then considered to be more representative of distribution processes in the Dutch environment. The sources of the Kp_{soil} and Kp_{sed} values can be found in Crommentuijn *et al* (1997, 2000).

Advantages and disadvantages

The Dutch have critically evaluated the validity of the EqP-method[8] by comparing aquatic with terrestrial toxicity data for twelve organic substances and eight metals. The EC_{50} or NOEC (in mg/l) values for water organisms were compared with EC_{50} or NOEC (in mg/kg) values for soil organisms or soil processes using selected sorption constants (in l/kg). The Dutch concluded that the EqP-method is not a scientifically valid method to derive environmental quality standards but can only be regarded as an estimation routine, which can give a significant over- or underestimation. In five percent of the cases there was more than a factor of 20 difference between the standard based on the EqP-method and the standard based on terrestrial toxicity data.

In very simple terms, the method emphasises the use of more abundant aquatic data but water organisms may not represent terrestrial life or soil exposure pathways. The methods only advantage is that it may be used for a screening estimation of a soil protection value when terrestrial toxicity data is scarce. But its use in the early tiers of risk assessment will lead on to the use of more sophisticated and relevant methods later on.

2.3.4 Quantitative Structure-Activity Relationships

Finally, it is important to introduce QSARs, or quantitative structure-activity relationships. This is a method of predicting toxicity, which can be used as input data in to the chosen method of extrapolation. QSAR is a set of methods that tries to find a mathematical relationship between a set of descriptors of molecules and their activity. The descriptors can reveal the shape, the electrostatic field, the hydrophobic propensity or other features of the molecules and can be experimentally or computationally derived. So far, QSARs have only been used to predict toxicity to species in the aquatic environment. This means that the method is unlikely to be used directly in predicting terrestrial toxicity. But QSAR-derived aquatic data may be included in the input data for the Eq-P method for extrapolation to the soil environment.

The European TGD provides general principles for the selection and use of QSARs and recommends that they be used in a conservative manner in the development of PNECs. The Netherlands ERL guidance document only advocates the use of QSARs when no or few toxicity data are available and the contaminant of concern is exerting its toxicity via a non-specific mode of action.

In summary, QSAR-derived aquatic toxicity data should be used with caution so that only well validated data is accepted for extrapolation to the terrestrial environment.

[8] The evaluation of the equilibrium partitioning method using sensitivity distributions of species in water and soil or sediment. RIVM report 607220005. Beelen P van, Verbruggen EMJ, Peijnenburg WJGM. 2002.

2.4 Screening value determination (step 4)

Following the extrapolation of toxicity data, the final stage of screening value development is consideration by regulatory policy and, in most instances, peer review.

This final step allows policy makers an opportunity to refine screening values where they see the values being under-, or over-protective. In some instances soil protection values have been developed which fall below naturally occurring background levels or below analytical limits of detection. In these instances, policy makers have elected to revise values in order to make them useable in regulatory environmental risk assessment. This can work the other way when policy makers may want to reduce risk of harm from contaminants of concern and add additional safety factors in order to derive more stringent screening values (for example, non-threshold carcinogens).

Summary

In summary, this chapter has described a generic step-wise approach to developing soil screening values. Final values may differ between different regulatory authorities but the same basic step-wise process remains;

1. gathering data,
2. selecting a subset of suitable data,
3. estimating effects-based criteria,
4. determining final screening values.

In step 3, data can be extrapolated using three fundamental methods. There is an order of preference amongst the authorities reviewed in the methods used for extrapolating data for the development of soil protection values and this is;

- distribution-based method,
- assessment factor method,
- equilibrium partitioning method.

In the next chapter existing approaches to developing screening values are described for the Netherlands, European Commission, Canada and the United States. Chapter 3 reviews how the generic process described in this chapter has been modified to meet individual authorities own policy and legislative requirements.

3 INTERNATIONAL APPROACHES TO SETTING SOIL PROTECTION VALUES

This chapter summarises some of the features and limitations of the leading international approaches to setting soil screening values. Approaches developed by The Netherlands, Canada, European Commission, US Environmental Protection Agency, and the US Department of Energy are reviewed.

This chapter picks up the basic step-wise procedures for developing soil screening values explained in chapter 2 and reviews how these procedures are applied by international authorities to meet their own legislative and policy requirements.

By reviewing the features and limitations of these international approaches we can begin to see the similarities or differences with our own policies. This will set the scene for chapter 4, which explores the factors influencing soil screening values and evaluates the approaches that are most suitable for the UK.

To generalise, deriving soil screening values in Europe is still a national responsibility and not harmonised among Member States (CSTEE, 2000)[9]. In the United States of America individual States have traditionally developed their own approaches and standards although federal ecological screening values are in development. Canada's provinces have also traditionally developed their own approaches but recently Canada-wide standards have been introduced. In Australia national interim values exist as standards but new standards are in development which will be applied regionally.

The information in this chapter is mainly based on guidance documents from each authority. Also useful and recent reviews published by the American Petroleum Institute prior to the preparation of US EPA ecological soil screening level guidance and the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) opinion on assessment approaches have been invaluable sources. The review of each authority's guidance is presented as;

- the overall policy,
- application and method(s) for deriving screening values,
- main features of the approach,
- main limitations of the approach,
- a short summary.

[9] *The available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems*. Report of opinions expressed at the 19th plenary meeting of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) in November 2000.

3.1 THE NETHERLANDS

3.1.1 Overall policy

To undertake risk assessment at an ecosystem level by deriving soil protection values which predict to protect 95 percent of theoretical species in the ecosystem[10].

3.1.2 Summary of application

The Dutch regulator, RIVM[11] derives environmental risk limits (ERLs) which are used as scientific advisory values by the Dutch government, VROM[12] to set environmental quality standards (EQSs) for soil protection (see figure 4). ERLs are derived for different environmental compartments, based on observed or expected effects on species inhabiting these compartments, including effects from food chain exposure of predators (secondary poisoning). ERLs can also represent different levels of protection.

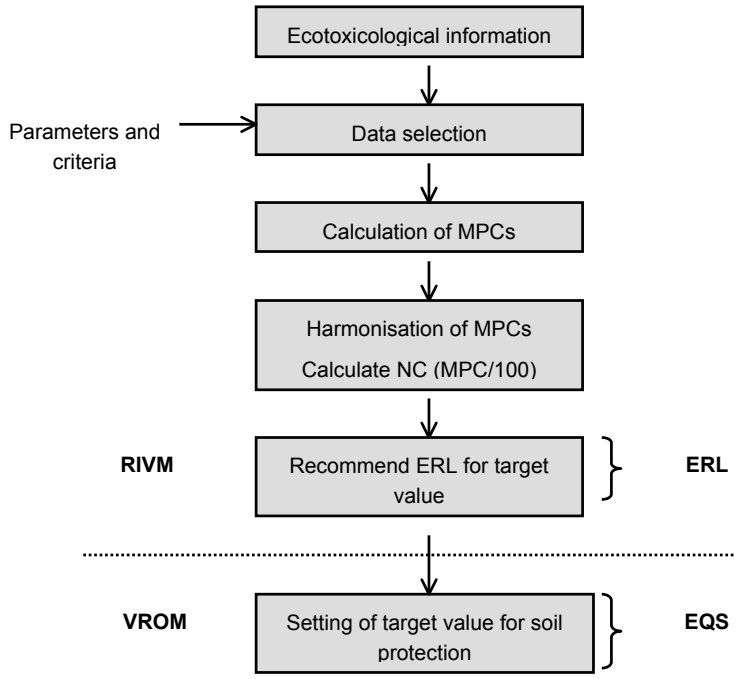

Figure 4 shows the process for deriving a target value where MPC is maximum permissible concentration, NC is negligible concentration, ERL is environmental risk limit and EQS is environmental quality standard

To manage historically contaminated land, the Dutch predict potential risk using intervention values (a type of EQS). These values are set at a 50th percentile protection level for terrestrial species. If contamination levels are above the intervention level then a site-specific assessment follows which aims to establish actual risks using target values. These EQSs are set at the 95th percentile protection level. The full definitions are given in table 5.

[10] Guidance Document on deriving Environmental Risk Limits (2002). RIVM Report 601501 012.

[11] RIVM is the National Institute of Public Health and the Environment

[12] VROM is the Ministry of Housing, Spatial Planning and the Environment

Table 5 The Netherlands soil protection values and their definitions

Description	ERL	EQS
A value causing negligible effects to ecosystems. It is the maximum permissible concentration divided by 100 (safety factor for combined effects)	**Negligible Concentration** (for air, water, soil, groundwater, and sediment)	**Target Value** (for air, water, soil, groundwater, and sediment)
A concentration that should protect all species in ecosystems from adverse effects of substances. A cut-off of the lower 5th percentile from species sensitivity distribution of NOECs is used. This is the HC^5_{NOEC}	**Maximum Permissible Concentration** (for air, water, soil, groundwater, and sediment)	**Maximum Permissible Concentration** (for air, water, sediment)
A concentration at which functions will be seriously affected or threatened to be negatively affected. This is assumed to occur when 50% of species and/or 50% microbial processes are possibly affected	**Serious Risk Concentration$_{ECO}$** (for water, soil, groundwater and sediment)	**Intervention Value** (for soil, sediment and groundwater)

3.1.3 Main features

Following the collation and selection of appropriate data, toxicity data is normalised prior to data extrapolation. Normalisation is when toxicity data is converted to represent a standard soil (which, for the Dutch represents their typical Netherlands soil; 10% organic matter, 25% clay). Normalisation means that all data is adjusted so it is comparable across data sets and suggests the same level of availability for uptake in the standard soil environment (refer to section 4.6 for more information on normalisation).

The Netherlands adopts a flexible approach to ERL development. Risk limits can be developed using any of the three different extrapolation methods of species sensitivity distribution, assessment factor or equilibrium partitioning (section 2.3). The preferred extrapolation method depends on the availability of toxicity data and the criteria are:

Data extrapolation method	Data availability
▪ Species sensitivity distributions	≥4 NOECs for soil organisms of different taxonomic groups and ≥4 NOECs for microbial processes, and/or enzymatic activity *
▪ Assessment factors	evaluate acute toxicity data when chronic data for <4 taxonomic groups is available
▪ Equilibrium partitioning	using aquatic toxicity data and soil/water partition coefficients

* Note: Data relating to microbial processes is treated separately from microbial species data.

Only one toxicity value for each substance and each species is extrapolated. Where there are many data sets for one species the following rules apply:

- 1 toxicological endpoint — use geometric mean
- different toxicological endpoints — use lowest value
- different life stages — use sensitive life stage

Considered in the development of target values, but not for intervention values, are the effects of secondary poisoning on predatory species. That is, the toxic effects on higher level organisms from consuming large concentrations of contaminants that have accumulated in organisms lower down the food chain. There are two possible approaches to developing values for the protection of predators - either by extrapolating direct toxicity data from higher organisms or by using a simple food chain model with bioconcentration factors. The values for predatory species are then compared with toxicity data for primary consumers to gauge the most sensitive organisms in the ecosystem (the lower of the two values). The final target value EQS is then considered to be protective of higher organisms by the inclusion of the secondary poisoning assessment.

Recent thinking in Dutch EQSs development has been applied to solving the problem of EQSs that fall below background levels for naturally occurring substances (mainly metals). Reports by Crommentujin (1997)[13] describe in detail how to deal with naturally occurring substance using the *added risk* approach. In simple terms, an average background concentration of a naturally occurring substance is summed to the no effects concentration derived through the usual ERL development. The policy underlying the added risk approach is that naturally occurring levels of essential elements are necessary for the biodiversity of ecosystems or serve to fulfil the need of micronutrients for species in the environment and are considered to be entirely unavailable for uptake by [and toxic effect to] an organism. The added risk approach is awaiting endorsement by the Dutch Government for application to EQSs for the soil compartment. A project due to report at the end of 2003 called 'VEM' - further research on essential metals – is aiming to improve some of the scientific assumptions behind the added risk approach for essential metals. Two improvements are expected to come out of the project; (i) differentiation of natural background levels, instead of the current assumption of a generic background level and, (ii) taking bioavailability into consideration and using a 'black box' approach rather than trying to establish causal relationships (pers. comm. Else Sneller, RIVM). The added risk approach is presented in more detail in section 4.7.

The Dutch regulator develops ERLs for the water, sediment, air and soil compartments and then harmonises ERLs to be protective of the most sensitive environmental compartment.

The development of environmental standards has been established for many years and the Netherlands benefits from a large number of compounds (almost 100) with ERLs and EQSs.

3.1.4 Limitations

Even though the Netherlands is one of the leaders in environmental standard development there are some limitations with their approach. However, many of the criticisms could be levelled at any country using species sensitivity distributions and stringent protection levels (the 95th percentile).

In particular, some scientists have criticised the adoption of the 95th percentile protection level[14] believing Dutch policy allows the loss of 5% of the species from the ecosystem. The inference being that protected species may be included in the 5 per cent. This criticism is just as valid for the assessment factor method. The statistical extrapolation method makes a policy statement that is consistent with the 5th percentile level but the level of protection afforded by the assessment factor approach is unknown. Laboratory data is more conservative than field conditions, for example tests are performed so that chemicals are highly available, so it is argued that the toxicity data underpinning Dutch ERLs is protective in field conditions.

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[13] Crommentuijn et al. *Maximum permissible concentrations and negligible concentrations for metals, taking background concentrations into account*. RIVM report 601501001 (October 1997).

[14] *Ecological implications of "95% protection levels"for metals in soil*. Hopkin, S.P. Oikos 66:137-141

There are uncertainties in the data extrapolation methods used. There is often too little toxicity data relating to soil organisms and the unsatisfactory equilibrium partitioning method is relied upon as the fall-back position. In the current list of target values (published in 1997), 9 metals and 100 organics were developed using the equilibrium partitioning approach. This represents 50% (metals) and 67% (organics) of target values were derived by this method.

The use of species sensitivity distributions in regulation has received some criticism (see Forbes and Calow, 2002). This method is seen as state-of-the-art and not yet validated or appropriate for widespread use in a legal framework. Others have suggested that the use of more than one data extrapolation method is cause for concern and that if scientists were in agreement with each other then there would be a single preferred approach.

Intervention values are designed to identify seriously contaminated sites, that is sites where there is a risk of losing 50 per cent of species in the ecosystem. A 50 per cent loss of species may not be considered to be protective enough for Agency screening values. Also, the intervention value approach does not consider biomagnification of contaminants up the food chain. For this reason, intervention values are not appropriate for areas with livestock or food crops.

Finally, when considering the adoption of any country's standards, it must be remembered that in the case of the Netherlands their EQSs represent their government's policy values and may not necessarily match UK requirements. This applies particularly to the limitations of intervention values.

The Dutch recognise the limitations of data paucity and have recommended the generation of more QSARs and combining ERLs for chemicals with the same toxic mode of action. Further research in these areas is ongoing.

3.1.5 Summary

The Netherlands approach offers flexibility of both data manipulation and adaptation to contaminated land policies using various types of risk limits. The Netherlands is a leading authority on environmental standard development and operates a rolling programme of review. The review of existing standards and the development of new standards also include validation studies. A summary of the types of data extrapolation are listed in table 6.

Table 6 List of data extrapolation methods used in the Netherlands

The Netherlands data extrapolation method	Type of data
Refined effect assessment	SSD approach using chronic data for 4 or more taxonomic groups
Preliminary effect assessment	Assessment Factor approach using chronic data for <4 taxonomic groups or only acute data
Added risk approach*	Accounts for background concentrations in naturally occurring substances
Secondary poisoning approach*	Combines direct toxicity with secondary poisoning for bioaccumulators
Equilibrium partitioning approach	Only used when soil data is absent. Based on aquatic toxicity data

* specific to target values

3.2 EUROPEAN COMMISSION TECHNICAL GUIDANCE DOCUMENT (EC TGD) ON RISK ASSESSMENT[15]

3.2.1 Overall policy

To risk assess new substances, priority existing substances and substances of concern in a biocidal product to derive a predicted no effect concentrations (PNEC). That is a concentration below which unacceptable effects on organisms will most likely not occur. In the case of distribution-based extrapolations the level of protection is at the 95th percentile level.

3.2.2 Summary of application

Commission Directive 93/67/EEC, Commission Regulation (EC) No. 1488/94 and Parliament and Council Directive 98/8/EC require that an environmental risk assessment be carried out on notified new substances, on priority existing substances and substances of concern in a biocidal product, respectively. This risk assessment should proceed in the following sequence:

- Hazard identification
- Dose (concentration) – response (effect) assessment
- Exposure assessment
- Risk characterisation

The TGD outlines a general environmental risk approach to address the concern for potential impact of individual substances on the environment by examining both exposures resulting from discharges and/or releases of chemicals and the effects of such emissions on the structure and function of the ecosystem. Three approaches are used:

- Quantitative PEC/PNEC estimation which compares compartmental concentration (PEC) with the concentration below which unacceptable effects on organisms will most likely not occur (PNEC). This includes also an assessment of food chain accumulation and secondary poisoning.
- Qualitative procedure for those cases where a quantitative assessment of the exposure and/or effects is not possible.
- PBT-assessment, which identifies the potential of a substance to persist in the environment, accumulate in biota and be toxic, combined with an evaluation of sources and major emissions. At present, this approach is applied to the marine compartment only.

EC TGD assessments aim to protect the following compartments;

- aquatic ecosystems (including sediment), terrestrial ecosystems, top predators, micro-organisms in sewage treatment systems, and the atmosphere. Marine ecosystems, including sediments and top predators are also considered.

Assessments are made for each protection goal but in this review we are interested only in the terrestrial compartment. Also, in considering soil protection values only the second step of the effects assessment of the TGD approach is relevant and this comprises:

- Hazard identification to identify the effects of concern and review the classification of an existing substance or propose a classification for a new substance.

[15] CEC (European Commission 2003). *Technical Guidance Document on 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 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market* (available at http://ecb.ei.jrc.it/).

- Dose (concentration) – response (effect) assessment to determine a predicted no effect concentration (PNEC). A PNEC is regarded as a concentration below which an unacceptable effect will most likely not occur.

The EC TGD proposes a strategy for assessing the effects of chemicals on soil organisms exposed directly via pore water and/or soil. There is also a procedure for assessing bioaccumulation and secondary poisoning of birds and mammals. The strategy for effects assessment of soil organisms is based on several documents: OECD (1989), Stavola (1990), Samsøe-Petersen & Pedersen (1994), Umweltbundesamt (1993) and Römbke et al (1993).

3.2.3 Features of PNECs for the soil compartment

The major advantages of the PNECs derived using the EC TGD are that they are broadly accepted by European Member States and as such, values are not slanted to any one countries' policies. The values are extensively peer reviewed by Member States and the methodologies are challenged and reviewed by Member States on an ongoing basis. Also, several PNECs have already been derived for new and existing chemicals which is useful when considering PNECs for potential adoption for UK soil screening values.

PNEC values are usually determined on the basis of results from single species laboratory tests, or in a few cases, established effect and/or no effect concentrations from model ecosystem tests, taking in to account adequate assessment factors. Toxicity data for existing substances is scarce and for most chemicals the data set is likely to be from short-term tests for earthworms and plants. For notified new substances, toxicity tests on terrestrial organisms are not yet included in base-set risk assessments (that is, the minimum data requirements on a new chemical submitted for assessment are short-term toxicity data for fish, daphnia and algae). Tests with plants and earthworms can be requested at a level 1 assessment.

The EC TGD suggests that results from tests using species representing different and significant ecological functions in the soil ecosystem be used for PNEC derivation. Ideally a suite of soil tests should relate to primary producers (plants), consumers (invertebrates) and decomposers (microorgansims). Also the TGD recommends soil data should be normalised, if possible, using relationships that describe the bioavailability of chemicals in soil. Results are converted to a standard soil which is defined as a soil with an organic matter content of 3.4% (see normalisation equation in section 4.6).

The PNECsoil can be derived in four ways:

- When no toxicity data is available for soil organisms, the equilibrium partitioning method is applied (as described in section 2.3.3)
- When toxicity data is available for a producer, a consumer and/or a decomposer the PNECsoil is calculated using assessment factors (as described in section 2.3.2).
- When only one test result with soil dwelling organisms is available the risk assessment is performed using assessment factors and the equilibrium partitioning method. From the PEC/PNEC ratios, the highest one is chosen for risk characterisation.
- Calculation of a PNECsoil can also be considered using statistical extrapolation techniques when sufficient data is available. For the aquatic environment, confidence can be associated with a PNEC derived by statistical extrapolation if the data contains at least 10 NOECs (preferably more than 15) for different species covering at least 8 taxonomic groups. Similar figures are not explicitly mentioned in the TGD for the soil compartment. The geometric mean is

calculated for data from the same species and endpoint. When results are available from different tests using different soils and it is likely that soil characteristics will influence the results, then effects data should be normalised. Alternatively, the lowest NOEC per endpoint and species should be used. Data on microbial processes and single species data should be considered separately (due to fundamental differences between these tests).

The TGD concludes that the approach of statistical extrapolation is still under debate and needs further validation although guidance is given as to its use in PNEC derivation.

3.2.4 Main limitations

The EC TGD methodology is similar to the Netherlands approach and as such the same limitations apply here.

The EC TGD recommends stringent protection at the 95th percentile level of a distribution. Despite the stringency this cut-off point has been criticised in the past as being under-protective of 5% of the most sensitive species in an ecosystem.

The flexibility offered by different methods of data extrapolation may also be viewed as a weakness as no one single method is agreeable to all Member States. At present the SSD method is used on a case-by-case basis with PNECs being compared to those derived using the assessment factor approach. The EC recommends further validation of the SSD method.

3.2.5 Summary

In summary the EC TGD method offers a flexible approach to PNEC development and is similar in thinking and design to the Netherlands approach. Its clear advantage over the Netherlands, for direct adoption to Agency policy, is that it doesn't carry any one country's policy refinements. The PNEC values are based on a solely scientific derivation whereas the final Dutch EQSs may carry a policy adjustment and preclude their direct adoption (although not the methods).

3.3 CANADIAN COUNCIL OF MINISTERS OF THE ENVIRONMENT (CCME)

3.3.1 Guiding principle

The CCME's guiding principle is to aim for a level of ecological protection that ensures that remediated land has the potential to support most activities likely to be associated with its land use.

3.3.2 Summary of application

The CCME in 1996 released *A protocol for the derivation of environmental and human health soil quality guidelines* followed by *Recommended Canadian soil quality guidelines* in 1997[16]. These Canada-wide standards have been published to improve consistency in soil protection across the country. Prior to this each Canadian Province managed land contamination in its own way. British Columbia Province is briefly discussed in section 3.3.6.

[16] Recommended Canadian Soil Quality Guidelines (1997). Canadian Council of Ministers of the Environment (CCME) Documents, c/o Manitoba Statutory Publications, Manitoba, Canada.

The Canadian approach differs from the European approaches from the outset. CCME classifies potentially contaminated sites based on land use. There are four land use categories which are protected as follows; there should be “no appreciable effects” on agricultural, residential and parkland and “low level of effects” are acceptable at industrial or commercial sites. The CCME soil quality guidelines are derived to approximate a "no- to low-" effect level (or threshold level) based only on toxicological information and other scientific data. Non-scientific factors (socio-economic, technological, or political) are considered by site managers on a site-specific level as part of the risk management process.

The CCME risk assessment approach assumes exposure pathways, receptor arrays and exposure scenarios for each land use. Ecological receptors that sustain primary activities at each land use are identified and protected.

Soil quality guidelines (SQGs) are used at a generic screening level and also at a site-specific assessment level. A site can be remediated to meet SQG levels (generic approach) unless it triggers a site-specific approach. The triggers are the presence of;

- unusual or sensitive receptors,
- unusual or sensitive site conditions,
- unusual or sensitive exposure conditions,
- unacceptable data or knowledge gaps,
- complex mixtures of contaminants,
- or when SQGs do not exist for the contaminant of concern.

From the screening level there are three possible ways the risk assessment can proceed;

(i) meet SQGs without a risk assessment (i.e. absence of any triggers on site),

(ii) meet modified SQGs, or

(iii) a site-specific risk assessment route.

The Canadian approach offers a ‘middle ground’ between generic and site-specific risk assessment but does not recommend adjustment of SQGs on the basis of difficult-to-observe or unstable site conditions. SQGs may be modified on the basis of differences between assumed generic exposure scenarios and the site-specific conditions. SQGs are derived in a modular fashion so any differences can be identified and SQGs recalculated. An example of a modification may be the distance of a source of contamination from the groundwater table. This is a fixed variable in the SQG derivation but can be modified if the distance is different at the site of concern.

3.3.3 Main features

CCME’s soil quality 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 Canadians 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 it will apply. The methods are;

- weight of evidence method

- lowest observed effect concentration method
- median effects method
- nutrient and energy cycling check
- soil and food ingestion (secondary poisoning check)

The preferred method for SQG development for agricultural and residential/parkland land takes the 25th percentile of a frequency distribution of ranked effects (e.g. EC_{50}, LC_{50}) and no effects (NOEC) data. The 25th percentile is then divided by an uncertainty factor between 1 and 5, applied using the criteria presented in table 7. For commercial or industrial land, the 25th percentile of effects only data is used. CCME call this the *weight of evidence method*.

Table 7 Criteria for applying uncertainty factors to values derived by the weight of evidence method

Data	Uncertainty factor
3 studies minimum	5
>3 studies but < 3 taxonomic groups	3
>25% of data below 25th percentile are definitive effects data (i.e. not LOAECs)	1

When less data is available, a *lowest effect concentration method* is used to develop a SQG value. For agricultural or residential/parkland, the lowest LOEC value is divided by an uncertainty factor (1 to 5) depending on the criteria presented in table 8. For commercial or industrial land the geometric mean of the LOEC data is used.

Table 8 Criteria for applying uncertainty factors to values derived by the LOEC method

Data	Uncertainty factor
LOAEC is 'biologically significant' and not just statistically different from controls	5
LOAEC from an acute study	3
Only 3 studies and/or <3 taxonomic groups	1

When there is only acute toxicity data available, the Canadians apply their *median effects method*. This method is only applicable to agricultural and residential/parkland where the lowest EC_{50} or LC_{50} value is selected and divided by an uncertainty factor (5 to 10). The method is not recommended for guideline derivation for commercial and industrial land.

The values derived using the above methods are called soil contact SQGs (from data for microbes, plants and invertebrates, where available). These are then compared with guidelines derived from microbial nitrification and denitrification processes using *nutrient and energy cycling* data. If data is scarce then decomposition, soil respiration and nitrogen mineralisation rates are used. If the toxicity threshold based on soil contact is lower than the microbial value, the threshold concentration is adopted as the soil quality guideline (SQG). But, if the microbial process value is lower than the soil contact effects value then the geometric mean of the two values is adopted as the soil quality guideline (SQG).

The Canadians also develop soil quality guidelines to account for secondary poisoning of organisms higher up the terrestrial food chain – this is the *soil and food ingestion method*. But this is only developed for agricultural land use and only takes in to account the herbivore food chain. The $SQG_{ingestion}$ is primarily used to protect grazing livestock and wildlife. The threshold is derived by identifying the most threatened species by selecting the lowest LOAEL (from a minimum of 3 studies). This results in the daily threshold effect dose. This is converted to a $SQG_{ingestion}$ using data on;

- body weight,
- rate of soil ingestion,
- rate of food ingestion,
- bioavailability,
- bioconcentration of contaminants.

For agricultural land use, the soil quality guideline derived for soil contact is compared with the soil quality guideline for ingestion. The lowest value is chosen as the final soil quality guideline for agricultural land use.

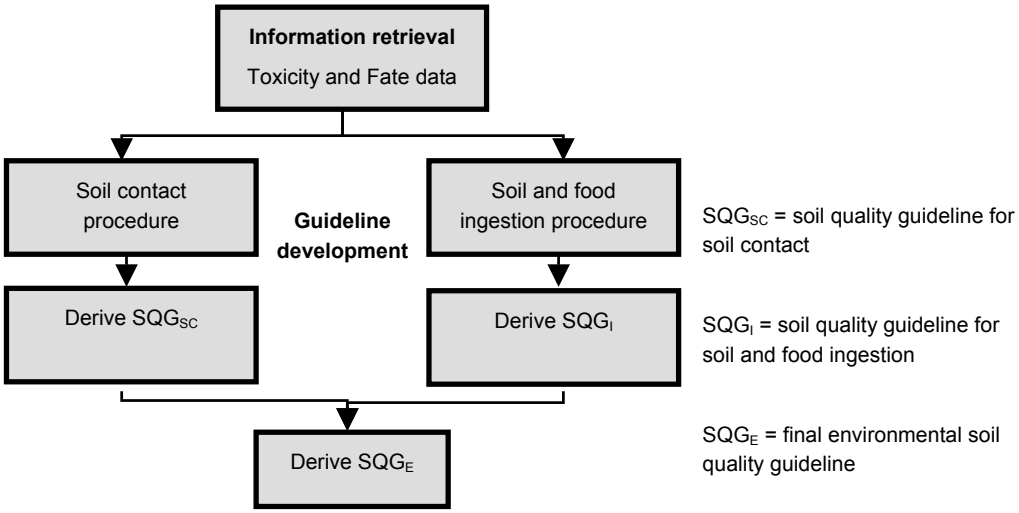
Final check

The final soil quality guideline for the environment is compared with the soil quality guideline for human health. The lower of the two values is selected as the final soil quality guideline. A final check is made to ensure the SQG_{final} for a particular contaminant is not lower than;

- plant nutritional requirements,
- naturally occurring background levels, and
- analytical limits of detection (LOD).

If the soil quality guideline falls below the concentration required for plant nutrition, background levels or analytical LOD, then the soil quality guideline will default to the lower value. A summary of the approach to derive environmental SQGs is provided in figure 5.

Figure 5 Summary of the CCME approach to deriving environmental soil quality guidelines



3.3.4 Main limitations

The CCME SQGs and ecological risk assessment protocol offer a different perspective to the European ecological risk assessment. For instance, the Canadians define levels of protection based on land use. Also, the adoption of SQGs as remediation objectives at a screening level offers a clear exit from further risk assessment at an early level. These may be viewed as advantages or disadvantages depending on the policy requirements of our contaminated land regime. A comparison of SQGs against our own policy is made in Chapter 5 but it has been clear from the outset of this study that values will be used for screening purposes only (that is, not as remediation targets).

One obvious limitation to the direct adoption of CCME's SQGs is the harmonisation step between SQGs derived for the protection of the environment and those for human health. The Agency's soil screening values will be developed to protect the terrestrial environment (excluding humans). But CCME does report the SQG$_{E}$ separately from the SQG$_{HH}$ prior to harmonisation so the environmental values can be traced back. However, SQGs are reported for each land use which could be a more serious limitation to direct adoption.

Finally, the CCME has opted to only protect herbivores from the effects of secondary poisoning and only on agricultural land. The issue of secondary poisoning is discussed in section 4.8 but only considering plants and plant-eaters is limiting.

3.3.5 Summary

The CCME protocol and guideline value derivation offers a flexible and clear approach to contaminated land assessment. The separation of land into four defined land types accepts that land in industrial or commercial usage may not require protection to the same level as residential or agricultural land.

Soil quality guidelines are protective of mortality, reproduction and growth in microbes, plants, invertebrates and, for agricultural land only, herbivores. CCME is also the least conservative with uncertainty factors of the authorities reviewed and recommends a maximum factor of ten arguing that data already contains conservative assumptions. The CCME guidelines have been

published since 1997 with new guidelines for contaminants being published since, for example, petroleum hydrocarbons. A wide range of contaminants has been considered so far.

3.3.6 British Columbia Province

The primary concerns in managing contaminated land in British Columbia (B.C.) are similar to those of the federal agencies. Environment Canada (2002) published *Compilation and review of Canadian remediation guidelines, standards and regulations* which examined how provinces and territories compared across Canada in their approaches to contaminated land regulation. Ontario, Quebec and British Columbia were found to have criteria or guideline-based values for the widest range of contaminants that generally cover most of the contaminants listed in the CCME environmental quality guidelines. The variations by B.C. Province from the federal CCME approach are summarised below.

Five land uses are described by B.C. Province as opposed to four land uses in the CCME guidelines. The primary land uses are:

(a) agricultural land use;

(b) commercial land use;

(c) industrial land use;

(d) urban park land use;

(e) residential land use.

B.C. Province uses a single method for deriving guideline values. Lethal and non-lethal data are combined in a regression line. The cut-off point for agricultural, residential land or parkland uses is the lesser of EC_{50} and LC_{20} values. For commercial or industrial lands the greater of EC_{50} and LC_{20} values is used as the threshold for guideline value derivation.

The B.C. Province guidelines do not address wildlife in their guideline derivation unlike the CCME guidelines which may represent effects of secondary poisoning for contaminants that are likely to bioaccumulate up the food chain (for agricultural land only).

3.4 UNITED STATES, DEPARTMENT OF ENERGY (US DOE)

3.4.1 Overall policy

These benchmarks are derived for screening purposes at waste sites in the United States. The screening threshold is based on the 10^{th} percentile of a 20 per cent reduction in growth, reproduction or activity in either soil invertebrates, soil microbial processes, plants, wildlife or birds.

3.4.2 Application

The benchmarks were originally derived by the Oak Ridge National Laboratory (ORNL) to evaluate chemical contamination on the Oak Ridge Reservation and other US DOE facilities where approved values from regulatory agencies were limited or absent. The benchmarks are a comprehensive set of ecotoxicological values used to screen chemical concentrations in environmental media to identify chemicals that are present at a sufficiently high concentration to present a potential risk to ecological receptors. These chemicals of potential concern (COPECs) require further risk assessment to determine whether they do pose a significant risk.

The US DOE asked the ORNL to develop a guide to DOE program managers and contractors to improve their understanding of what ORNL benchmarks are, for example describing their strengths and weakness[17]. The US EPA's interim final guidance for ecological risk assessment for Superfund sites (US EPA 1997) recommends the use of screening values and references the ORNL benchmarks. The benchmark values are accepted by various regulatory agencies but are not regulatory criteria. In the US, regulatory approval for the use of the ORNL benchmarks or other screening values should be obtained as part of the US Data Quality Objectives process (Bilyard et al., 1997).

3.4.3 Main features

One of the simplest ways of making use of all the available and relevant data is to do a ranked distribution. The US DOE uses this approach, called Effects Range-Low (ER-L), where the 10^{th} percentile from ranked lowest observable effect concentrations (LOECs) is selected. For application to contaminated soil the LOEC toxicity data is drawn from soil invertebrates (earthworms), soil microbial processes, plants, wildlife, or birds. See also section 2.3.1 for an example of ER-L.

The method overcomes the arguments against using the NOEC endpoint (see section 4.2), as toxicity data is in the range of effects on organisms usually at 20 per cent reduction in growth, reproduction or activity (significant effects at EC_{20}). If the 10^{th} percentile happens to be a toxicity value based on an equal or greater than 50 per cent effect on survivorship, for example an LC_{50}, then an additional safety factor is applied. An acute-to-chronic ratio of five is used and this is based on expert judgement.

The US benchmarks are based on the assumption that the toxicity of a chemical in soil is random but is of the same distribution across a site.

3.4.4 Main limitations

Many of the weaknesses listed in the ORNL review are applicable to all screening benchmarks, that is;

- benchmarks based on single chemicals do not account for mixtures of contaminants,
- generic ecotoxicological benchmarks lack consensus on what ecological entities and properties should be protected or what level of protection should be afforded,
- it is not possible to say which data extrapolation method leads to the best benchmarks,
- because benchmarks are based on laboratory toxicity data, their relationships to field exposure is uncertain. In particular, laboratory tests are generally designed to expose organisms to highly bioavailable and toxic forms of the test chemical, under conditions that maximise exposure. As a result this means that benchmarks are generally conservative.

[17] *A Guide to the ORNL Ecotoxicological Screening Benchmarks: Background, Development, and Application* (May 1998). Available to the public from the National Technical Information Service, U.S. Department of Commerce, Springfield, VA, United States.

3.4.5 Summary

The US DOE benchmarks are designed specifically for screening purposes and protect at the 10th percentile level of a 20 per cent reduction in growth, reproduction or activity in either soil invertebrates, soil microbial processes, plants, wildlife or birds. Conservative acute-to-chronic ratios are applied using an assessment factor of five.

The benchmarks are generic and not designed to meet particular regulatory policy goals, so they may be under-protective in some instances.

3.5 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (US EPA)

3.5.1 Overall policy

Ecological soil screening levels (Eco-SSLs) are protective of ecological receptors that commonly come in to contact with soil or ingest biota that live in or on soil. They are based on the geometric mean of selected chronic toxicity data.

3.5.2 Application and methods

The US EPA has published draft guidance[18] and risk-based screening values for many of the soil contaminants that are frequently of concern to terrestrial plants and animals at hazardous waste sites. These are called ecological soil screening levels (Eco-SSLs) and are designed to be used routinely to identify contaminants of potential concern (COPC) in soils requiring further evaluation in a baseline ecological risk assessment (ERA). They are intended to be applied in Step 2, following site visit and problem formulation, of the US Superfund ERA process.

Eco-SSLs are derived separately for four groups of ecological receptors, plants, soil invertebrates, birds and mammals. 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.

The US EPA clearly state that Eco-SSLs are not designed to be used as cleanup levels and the EPA emphasises that it would be inappropriate to adopt or modify these Eco-SSLs as national cleanup standards. The values are for use by EPA, federal agencies, states and private parties at all Superfund sites. Risk assessment processes are becoming more harmonised and the development of generic screening levels is another step towards consistency across the EPA regions.

3.5.3 Main features

Eco-SSLs have been derived using standardised procedures for literature review, toxicity data selection and data evaluation. Strict quality criteria are used to select data (ten in total) and only chronic toxicity data sets with an acceptance score of ten or more (of a possible eighteen) are used for Eco-SSL determination. Contaminant-specific Eco-SSL derivation is completed with a quality assurance review to ensure accuracy and appropriateness of the screening level.

[18] *Ecological Soil Screening Level Guidance*. July 2000. Office of Emergency and Remedial Response, United States Environmental Protection Agency.

There is a single approach to setting screening levels. On a contaminant-specific basis, Eco-SSLs for plants, invertebrates birds and mammals are derived by calculating a geometric mean from the highest quality data. A wildlife risk model incorporating exposure assessment is used for assessing risks to birds and mammals.

Three chronic toxicity values are the minimum requirement for Eco-SSL using the highest quality data (level A). If there are less than three values from the preferred data then data is used from the next preference level (i.e. acute) and adjusted with assessment factors. Table 9 shows the preference levels for data based on toxicity endpoint and bioavailability score with assessment factors below.

Table 9 presents the preference level assigned to data

Level	Toxicity endpoint	Bioavailability
A	EC20, EC10, MATC*	2
B	EC20, EC10, MATC	1 or 2
C	EC20, EC10, MATC	0, 1 or 2
D	EC20, EC10, MATC, EC50	0, 1, 2

* MATC is maximum acceptable threshold concentration or the geometric mean of the NOEC and LOEC.

The assessment factors available for converting toxicity data from acute to chronic:

- If an EC_{50} is greater than the MATC, then apply an assessment factor of 5
- If an EC_{50} is lower than the MATC, then apply an assessment factor of 2
- If only EC_{50}s are available, then apply an assessment factor of 5

Wildlife Eco-SSLs for birds and mammals are derived using a five-step process that includes selecting the wildlife risk model, selecting the surrogate species, parameterising the exposure dose model, deriving wildlife toxicity reference values (TRVs) and calculating the Eco-SSLs.

Generic screening levels have been drafted for 24 contaminants of concern. By way of examples, figures 6 and 7, show Eco-SSL derivations for cadmium and copper using invertebrate data. The black lines represent the geometric means (at 110 mg/kg for cadmium and 61 mg/kg dry wt for copper). For cadmium the spread of data ranges widely from 6 to 600 mg/kg whilst the copper data is much closer. This means the geometric mean for cadmium may not be protective of some sensitive species. The geometric mean for copper is more representative of toxicity and, as such, should be more protective of organisms sensitive to copper than for the comparative cadmium Eco-SSL.

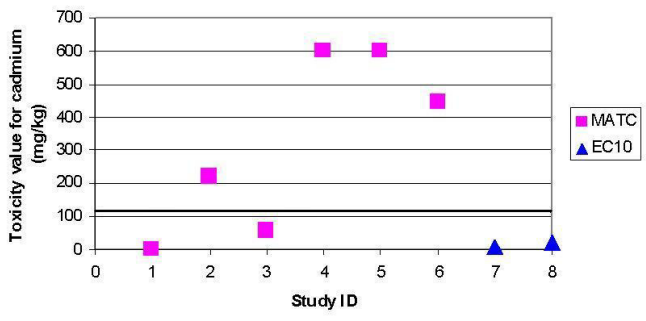


Figure 6 Data and geometric mean representing the Eco-SSL for cadmium (using invertebrate data)

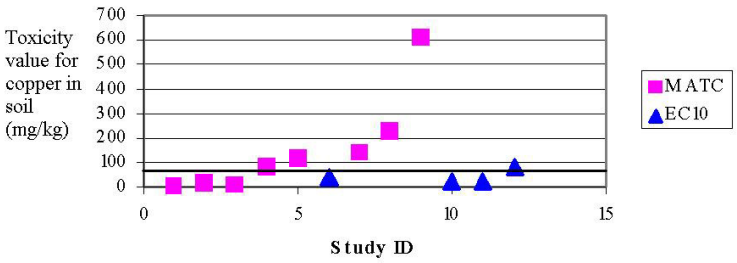


Figure 7 Data and geometric mean representing the Eco-SSL for copper (using invertebrate data)

3.5.4 Main limitations

The US EPA Eco-SSLs have some major limitations. Using the example of cadmium above, the figure shows that the use of the geometric mean of effects data may not be protective of sensitive species. Cadmium is one of the more data rich of potential contaminants and the limited data used in the US EPA calculation suggests some potentially useful studies may not have been selected. An Eco-SSL (for invertebrates) of 110 mg/kg seems very high compared with similar screening values of 20 mg/kg from ORNL (earthworms), 0.8 and 12 mg/kg from the Netherlands (target value and intervention value, respectively). Also related to this is the drawback that variation in the toxicity data is not reflected in the final screening level.

The Eco-SSLs do not account for microbial populations or processes – an essential part of soil ecosystems.

Eco-SSLs for all four receptor groups are not available for all the 24 contaminants (due to insufficient data). The Eco-SSLs are currently under development so this will improve over time.

3.5.5 Summary

In summary, the US EPA Eco-SSLs are designed purely for screening purposes. Strict data selection criteria are applied and preferred data is used in a single approach to setting screening levels. Screening levels are based on the geometric mean of chronic toxicity data for plants, invertebrates, mammals and birds. A wildlife risk model is used for assessing risks to birds and mammals. But, Eco-SSLs have two major drawbacks in their extrapolation method and there is a lack of consideration of microbial populations and functions.

3.6 Chapter summary

In this chapter the following authorities' approaches to deriving soil screening values have been summarised:

- The Netherlands
- European Commission (Technical Guidance Document)
- Canadian Council of Ministers for the Environment
- United States Department of Energy
- US EPA

These are the leading authorities in environmental standard setting and represent the range of data extrapolation methods available.

The Netherlands and the European Commission TGD approaches are very similar and offer flexible and scientifically progressive methodologies. These, with the US approaches, use a pragmatic policy to risk assessment where all land and the organisms in or above it are protected to the same level. The Canadian approach is also highly flexible but offers a different approach where land is characterised by its use and protection levels differ depending on that land use.

There are many factors which influence the process for developing, and the outcome of, soil screening values. In the next chapter these factors are the focus of discussion. There are already policies for contaminated land management in the Agency which were developed for the protection of human health. Some of these can carry over to ecological risk assessment. Agency policy and preferences based on scientific factors will determine which of the international approaches featured in this chapter will be most appropriate for use by the Agency.

4 WHAT FACTORS INFLUENCE SCREENING VALUES?

This chapter considers the many factors that influence soil screening values. Terrestrial ecosystems are complex and developing screening values that are protective, yet practical, means identifying the relevant influencing factors. The chapter concludes with a recommended list of attributes. These are then compared in Chapter 5 against the international approaches reviewed in Chapter 3.

Screening values are intended to be protective of terrestrial species and critical ecological functions, but also be reasonable and not so low that even at trivial concentrations no chemical is ever screened out from further risk assessment (US EPA 2000). A mix of scientific understanding and policy pragmatism is needed to reconcile protectiveness and practicality. The list of influencing factors to be considered in this chapter is presented in box 2. By reviewing these factors we can agree on a 'wish list' of attributes for screening value development and compare these with the international approaches reviewed in the previous chapter.

Box 2 A list of considerations for screening value development

- How are the values applied?
- What are the appropriate toxicity endpoints?
- Are the species;
  - representative of UK ecosystems and soil processes?
  - range across all levels of biological organisation?
  - of societal relevance?
- What type of data extrapolation is preferred?
  - distribution methods
  - assessment factors
  - equilibrium partitioning
- Have bioavailability adjustments been made?
- Do values consider background concentrations?
- Is secondary poisoning considered?
- Are the screening values validated?
- Have they been peer reviewed?

4.1 How are the values applied?

The aim is to develop screening values that can be inserted in to Tier One of the Agency's draft ERA framework and meet the requirements of contaminated land legislation (as outlined in Chapter 1) and regulatory policies.

A number of international authorities have developed soil protection values to meet their own legislative requirements. Understanding the similarities and differences in their application is an important factor in deciding whether it is appropriate to directly adopt others' published values. For instance, in Denmark environmental quality criteria are often near or below naturally occurring background concentrations of substances. The stringency of the Danish values reflects their policy of protecting all soil systems to the same optimum level of a "*natural habitat land*". Denmark has very little historically contaminated land so their soil policies protect land against potential future contamination. In contrast, other authorities such as Canada, develop guideline values based on land use and recognise that land under ongoing industrial use needn't warrant the same level of protection as land in domestic, parkland or agricultural use.

There is growing consensus amongst international authorities that soil protection values make useful screening tools. The Dutch intervention values, the US EPA and the US Department of Energy's soil protection values are designed for screening purposes only. The Dutch target values and the Canadian soil quality guidelines may be used in screening and/or as clean-up remediation goals. The Dutch are unique in being the only authority that has developed different values specifically for screening or remediation. Intervention values are used to screen sites for serious contamination. The values are

based on concentrations set at 50 per cent lethal concentrations. Target values are used as clean-up goals where levels of contaminants are set at very low no-effect levels.

There are differences in the way the soil protection values are applied in risk assessment. The Dutch, US EPA and US Department of Energy's intervention or screening values are all explicitly generic. But, the Canadian soil quality guidelines can be applied generically and site-specifically.

Recommendations for the Environment Agency

The Agency's draft ERA framework uses a generic approach to problem formulation and screening in the early tiers. The Agency's contaminated land policy team advocates the use of generic soil protection values to be used for screening purposes only (i.e. not as remediation targets). The Agency's policy on ecological risk assessment takes a pragmatic approach to land use under the Part IIA EPA 1990 legislation. To be consistent with the ERA framework it is recommended that the screening values will not be developed for specific land uses (e.g. agricultural vs. industrial).

The impetus at screening level is to quickly screen out sites that are unlikely to be causing harm to terrestrial organisms. When considering what level of protection to apply, the Agency has existing policy[19] in the protection of human health which can read across to terrestrial ecosystems:

"In deriving a soil guideline value for human health, the protection level advocated by Defra and the Environment Agency is the 95th percentile of the distribution of average daily exposures. This value is consistent with policy objectives behind soil guideline values namely their application as generic assessment criteria, and is consistent with other approaches to environmental risk assessment where a reasonable worst case is required. By selecting at the 95th percentile level, the most likely exposure scenarios are excluded but a wide range of more likely situations is included."

To be consistent with existing policies, the protection level for ecological systems is recommended at the 95th percentile of an ecotoxicity-based distribution.

4.2 What are the appropriate measurement endpoints?

Soil screening values are required to meet the Part IIA EPA 1990 definition of harm and the Agency's guidance on harm. This is, *"significant harm is when growth, reproduction or mortality are adversely affected, such that the survival of a population/ community/ species is threatened"* (section 1.1.3). Most authorities prefer to use sublethal or chronic toxicity data, where possible, and select NO(A)EC or LO(A)EC measurement endpoints. But, the paucity of toxicity data relating to soil organisms means that many authorities review all available data, i.e. lethal and sublethal effects from chronic and acute studies, and apply their preferred extrapolation method according to the quantity and type of data available. Only screening values derived in Canada's British Columbia differ by excluding no-effect data and preferring to select EC_{20} and LC_{50} concentrations from acute toxicity studies. The Netherlands maintains a flexible approach by including other endpoints where appropriate. For example, when a specific toxic mode of action (e.g. endocrine disruption) is known about a substance (e.g. phthalates), then expert judgement is used to select for other endpoints (e.g. (anti-) oestrogenic effects) to verify and support environmental risk limits derived from preferred endpoints.

The preference for no- or lowest-effect concentrations shows that screening level values are conservative and aim to be protective of sublethal effects. But, there is considerable and justified

[19] *The contaminated land exposure assessment model (CLEA): Technical basis and algorithms*. R&D Publication CLR10. Department of the Environment, Food and Rural Affairs and the Environment Agency (2002).

criticism in the scientific press of the widespread use of NOECs/NOAELs as the basis for screening value derivation.

No effects concentrations (NOECs)

Laskowski (1995) writes a compelling argument against using NOECs and LOECs. To illustrate the flaw in the NOEC approach, Laskowski presents a measured characteristic of a control versus a treated population (as normal distributions) with sample sizes ranging from 5 to 50. The probability of rejecting the null hypothesis (no effect) when using four different sample sizes changes dramatically. When using a sample size of 11 the null hypothesis is accepted at 0.1 (10%) but when the sample size is reduced to 5, then the probability of accepting the null hypothesis rises to 0.39 (39%). And, as the author suggests, nobody would like to be treated with a substance for which there is a 39% chance of it being harmful!

In simple terms, the NOEC depends strongly on the selected test concentrations, as the NOEC has to be a tested concentration. The less accurate the test (small sample sizes, high variation), then the higher are the resulting NOECs. The NOEC becomes an artefact of test and statistical design. These are properties that are undesirable in screening value derivation.

The CSTEE recognises these disadvantages and encourages efforts to consider the replacement of the NOEC/NOAEL. There is a general shift in the European Commission towards the use of EC_{10}s[20] but for the moment the NOEC is firmly anchored in existing test protocols and regulatory frameworks.

Effect concentrations

If effect concentrations are selected, for example EC_{10}s or EC_{20}s, from a well characterised dose-response relationship, then statistical confidence can be fitted to the resulting curve. In this situation, a risk assessor uses the entire dose-response function and can see the slope of the curve. If the relationship produces a shallow curve, relatively large amounts of a contaminant will be required before a response is seen, or alternatively, a steep curve means a small dose will produce a harmful effect to a substantially greater proportion of the population. This adds greater confidence to a risk assessors understanding of the likely toxicity and the resulting sensitivity of a species with changing concentration.

Recommendations for the Environment Agency

When screening values focus exclusively on one compartment and its organisms to the exclusion of other organisms and their interactions the procedure basically comprises the initial decision on the risk acceptability and an effect assessment exercise determining the best assessment endpoints according to the available information and the ecological relevance (CSTEE, 2000). Effects of secondary poisoning to above-soil organisms is considered in section 4.8.

To be protective of growth and reproductive lifecycle traits, we should aim to select appropriate sublethal toxicity data. The read across with existing human health regulation under Part IIA EPA 1990, shows that the toxicologically-based tolerable daily intakes (TDIs) used in the development of [human health] soil guideline values are based upon NOAELs and LOAELs for critical health effects from toxicological or epidemiological studies[21]. Despite the obvious drawbacks, NOECs are so entrenched in international

[20] Personal communication from Steve Dungey (Chemicals Assessment Unit, Environment Agency)

[21] *Contaminants in soil: Collation of toxicological data and intake values for humans*. R&D Publication CLR 9 (2002). ISBN 1 857 05734 1.

screening value development that if we chose to adopt an existing international set of values and/or methods, we will be using values based on NOECs. Using data at no- or lowest-effect levels also maintains consistency with human health protection and is recommended as the preferred measurement endpoint for our soil screening values.

4.3 Are the screening values ecologically relevant?

For screening values to be applicable to sites of potentially contaminated land in the UK, it is desirable that the values are based on species which are representative of the biodiversity in the UK. Generally adverse effects on the terrestrial environment will include (taken from CSTEE, 2000):

- ***effects on soil functions***, particularly on the capacity of soil to act as a substrate for plants including effects on seed germination and on those organisms (invertebrates, microbes) important for proper soil function and nutrient cycling.
- ***effects on plant biomass production***, related to contamination of soil or air including deposition to plant surfaces. Plants are the source of food for the whole system (including humans) and have additional roles in terms of land protection, nutrient cycles, equilibrium of gases in the atmosphere, etc.
- ***effects on soil, ground and foliar invertebrates***, which represents food for other organisms, and covers essential roles as pollinators, detritivores, saprophages, pest controllers, etc.
- ***effects on terrestrial vertebrates***, domestic and wild species, exposed to contaminated food, soil, air, water or surfaces, with obvious economic and/or social consequences. Poisoned birds and mammals probably constitute the highest social concern, while reproductive effects, although less evident, represent a higher ecological hazard.
- ***accumulation of toxic substances through the food chain*** is a typical exposure route for animals within the contaminated ecosystem and represents an additional concern related to the consumption of this food by humans and domestic animals.

All authorities recognise the importance of having relevant soil protection values but when any of the above effects will dramatically alter the whole system, the lack of knowledge and data on these effects becomes very constraining. Currently the knowledge about the biology of soil organisms, their interdependencies at ecosystem level and their dependency on certain soil properties is not very well studied. The Agency's SOILPACS[22] study looked at the feasibility of identifying soil communities that live on a contaminated site with a view to comparing them with communities likely to be found there if the site was uncontaminated. The SOILPACS study concluded that this approach is unfeasible at the present time because of the lack of information on reference communities.

We are also constrained by the lack of toxicity effects data for protected and endangered species (for obvious reasons). So, soil protection values rely on a few key receptors that act as predictive surrogates for species in the field. The paucity of data for representative species and soil processes for each site, each region, each country in the world is one of the main reasons why universal soil protection values cannot be agreed upon. But surrogate species should be representative of the species of interest on site and as such should be within the same class (mammalian or avian) with similar diets (US EPA, 2000). The types of surrogate organisms used in standardised tests (e.g. OECD and ISO) are reviewed in *Ecotoxicological and biological test methods for the assessment of contaminated land* (Environment Agency R&D Technical Report P300).

[22] *A demonstration of the feasibility of SOILPACS*. Weeks J.M., Hopkin S.P., Wright J.F., Black H., Eversham B.C., Roy D., Svendsen C. (1998). Environment Agency R&D Technical Report P213

One of the main conclusions of the US EPA review of soil protection values was that all authorities use the same base set of toxicity data but vary their approaches to data selection. One important criteria is selecting data from studies using species that are representative of an authority's own country and this affects the outcome of soil protection values. Most authorities consider soil microorganisms, invertebrates and plants, and develop either individual soil protection values for each trophic level (for example, the US Department of Energy) or compare all data sets and select the value that reflects the most sensitive species from three trophic levels. The Canadians base their soil guidelines on plants and invertebrates and run a quick check against effects on soil microbial processes. The US EPA is one of the few exceptions, as their screening values do not consider microbial populations or processes at all.

Recommendations for the Environment Agency

Most authorities agree on the need to protect organisms at three trophic levels, that is microorganisms, plants and invertebrates and accept that much of the world-wide species used in toxicity studies are surrogates representative of their biodiversity.

The recommendation for the Agency is that we should also aim to protect terrestrial organisms to at least three trophic levels and should advise risk assessors where screening values may not be protective of UK biodiversity. Higher organisms are discussed under 'secondary poisoning' in section 4.8.

4.4 Considering value judgements in soil screening levels

An important part of the screening stage of ecological risk assessment is identifying the receptor(s) and any significant values attributed to them. Defining unacceptable harm to ecosystems is difficult and ultimately depends on the values society places on ecosystems (DETR, 2000). Values may be considered as being of societal, ecological and economic importance. The Royal Commission on Environmental Pollution's 21st report (RCEP 1998) reviewed environmental standard setting and recommended that in order to achieve sustainable development, standard setting processes must consider social and economic consequences, as well as environmental impacts.

But, agreement on the relevance or importance of values will not always converge. Value judgements will vary from person to person and area to area. For example, the plight of threatened mammals and birds is always more emotive to the public than soil invertebrates and microorganisms due to the 'cuddliness' factor. Also, values assigned to particular species and habitats will change over time as we increase our understanding of them or new threats appear.

Ecological values

The UK Government has set out its priorities and strategies for conservation in the UK Biodiversity Action Plan (BAP). Some habitats and species are considered to be of particularly high value for conservation as a result of judgements made on the basis of rarity, attractiveness, fragility and other values. The UK BAP is reinforced by national statute implementing the EC Wild Birds Directive and the EC Habitats Directive.

Societal values

As mentioned above, society tends to place greater expectations on protecting species with direct human interest, although increasingly society is demanding high standards of protection for the environment as a whole. When considering potentially contaminated sites of importance to the local community, then it is important to engage with the community in identifying

ecological values together (for further reading see Environment Agency (in press)[23], ILGRA[24] and SNIFFER[25] reports).

Economic values

Consideration of the economic value of receptors should be discussed with the appropriate authorities and site owners and should be balanced with any costs of maintaining biota. For example, protected species and unique habitats may contribute to a local tourist industry.

Most international authorities refer to the importance of societal values in their guidance documents for ecological risk assessment. The CCME are clear about protecting economic values in their soil quality guidelines for agricultural land uses. This is the only CCME land use category where guidelines are developed to protect mammals (other than humans).

For authorities not using a land use based framework, the pragmatic approach is taken to treat all species and ecosystem functions as equally important and deserving of protection.

Recommendations for the Environment Agency

It is recommended that the Agency takes the pragmatic approach to protecting ecological, societal and economic values and recognises that species and ecosystem functions are equally important. UK BAP species living, breeding and/or foraging on potentially contaminated sites should be recognised in the early tiers of the risk assessment. The toxicity data underpinning soil screening values is unlikely to include protected and rare species so at all tiers of the risk assessment, links between highly valued species and surrogate species - the basis of screening values and ecotoxicity tests – must be clearly explained.

Risk assessment decisions are made on scientific and value judgements and as such societal and economic values should be reflected at screening level. Changing values over time must also be considered in the risk assessment framework and the impact these have on risk significance should always be borne in mind.

4.5 What type of data extrapolation method is preferred?

Our aim is to adopt robust and defensible methods of data extrapolation that are flexible enough to deal with varying quantities and quality of ecotoxicity data. A review of methods of data extrapolation is presented in Chapter 2.

In summary, there are three main types of extrapolation used widely in the derivation of soil protection values. These are distribution methods, assessment factors, and equilibrium partitioning methods. Distribution methods are generally applied when terrestrial data is plentiful and reflects three or four trophic levels. Assessment factors are used widely in Europe, Canada and the US when terrestrial

[23] Environment Agency (in press) *Participatory Risk Assessment: Involving Lay Audiences in Decisions on Environmental Risk. Literature Review and Stakeholder Interviews.* R&D Technical Report E2-043/TR/01. And, *Participatory Risk Assessment: Characterising Environment Agency Decisions on Risk.* R&D Technical Report E2-043/TR/02

[24] *Risk assessment and risk management – Improving policy and practice within Government departments* (1998). Interdepartmental Liaison Group on Risk Assessment.

[25] *Communicating understanding of contaminated land risk* (1999). Scotland & Northern Ireland Forum For Environmental Research

toxicity data is limited. The size of assessment factor varies with the amount and type of data available. The European TGD recommends applying factors ranging from 1000 to 10 depending on whether the data is from acute $L(E)C_{50}$ studies or no-effect data representing a range of organisms at various trophic levels. An assessment factor of less than 10 may be used when mesocosm data is available. The modified US EPA method applies a similar range of assessment factors. But, the Canadians apply much less stringent assessment factors of between 5 to 10 for the lowest $L(E)C_{50}$. Finally, the equilibrium partitioning method is only advocated when there is no terrestrial toxicity data and aquatic data is converted to represent the soil compartment.

The European Commission considers that statistical distribution methods are still developmental and require validating. When deriving PNECs, the EC TGD recommends that PNECs are derived using both SSDs (with additional assessment factors) and assessment factor approaches for comparison. The Netherlands preferred extrapolation method is the SSD approach (without additional assessment factors). The Canadian and US authorities agree that distribution approaches are their preferred methods.

Recommendations for the Environment Agency

A statistical distribution approach offers risk assessors a method that uses all the selected toxicity data and can be used to calculate confidence limits around the variation in the data. Where data is provided, the assessor can quickly see from the distribution the species or processes represented and the most sensitive groups of organisms. For the aquatic environment, the European TGD suggests confidence in a PNEC can be ascribed when the statistical extrapolation of the data contains at least 10 NOECs (preferably more than 15) for different species covering at least 8 taxonomic groups. Similar criteria are not given for soil data. The assessment factor approach is very transparent and has been used for many years but is a crude approach and uses only one toxicity data point as the basis for a soil protection value. The equilibrium partitioning approach is considered a last resort when only aquatic toxicity data exists.

It is recommended that a flexible approach is adopted for soil screening values development. This means that improved methodologies, technical understanding and new data can easily be incorporated in to a flexible system. The following extrapolation methods are recommended in order of preference; SSDs > assessment factors > equilibrium partitioning methods. This order of preference allows a more rigorous extrapolation method to be used when data is plentiful.

The Agency's Chemicals Assessment Unit is also keen to work on validating the extrapolation methods and improve confidence in the PNECs and subsequent screening values (pers. comm. Steve Dungey).

4.6 Have bioavailability adjustments been made?

The characteristics of soils vary enormously. They depend on the kind of rocks the soils came from, the conditions under which they were formed and the length of time that has subsequently elapsed. Soils differ in depth, in physical structure (bulk density, permeability, stability), in water content, in the proportion of organic material they contain and in their chemistry. These differences affect a soil's fertility, its properties – such as whether it retains or releases particular substances – and the specific flora and fauna that live in it. The physical and chemical characteristics of soils are heterogeneous, even at micro level (RCEP, 1996).

The underlying rationale for normalising toxicity data for soil organisms is to attempt to account for those physico-chemical factors that influence the availability of a contaminant.

Toxicity test data for soil organisms may not reflect simply the intrinsic toxicity of a particular contaminant to a particular organism. Instead, they account for both the contaminant's intrinsic toxicity *and* its bioavailability, in a combination that is specific to that test medium and that organism. The normalisation of toxicity data is an attempt to define more clearly the dose-response relationship by taking into account factors that affect the availability of the contaminant. Recent proposals to revise the OECD plant toxicity tests highlight the potential for future problems. The proposals recommend using an artificial substrate with a sand content of between 50 and 85 per cent. Such variation in the composition of soil could have a significant effect on its indigenous buffering capacity and sorption properties. This is likely to be particularly relevant in the case of ionisable contaminants.

For metals and organics in soil, the pore water concentration is likely to give a more accurate indication of the toxic fraction of a contaminant than the whole soil concentration. The same amount of metal or organic added to different soil produces different pore water concentrations. This is primarily because of differences in cation exchange capacity (in the case of metals) and organic matter levels (in the case of organics). Normalising toxicity concentrations in soil could factor out the confounding effects of differing sorption. This could be achieved by correcting whole soil concentrations to pore water concentrations.

Some international authorities have set precedents. The EC TGD and The Netherlands recommend normalising toxicity data, where bioavailability data is provided, to convert results to a standard soil. The EC TGD defines a standard soil with an organic matter content of 3.4%. For non-ionic compounds it is assumed that bioavailability is determined by the organic matter content only. NOECs and L(E)C_{50}s are corrected according to the following formula:

Equation 2

$$NOEC\ or\ L(E)C_{50(standard)} = NOEC\ or\ L(E)C_{50(\exp)} \bullet \frac{Fom_{soil(standard)}}{Fom_{soil(\exp)}}$$

Symbols

NOEC or L(E)$C_{50(standard)}$	NOEC or L(E)C_{50} in standard soil	[mg/kg]
NOEC or L(E)$C_{50(exp)}$	NOEC or L(E)C_{50} in experiment	[mg/kg]
Fomsoil(standard)	fraction of organic matter in standard soil	kg/kg]
Fomsoil(exp)	fraction of organic matter in experimental soil	[kg/kg]

The Netherlands normalise soil data to represent their standard soil with 10% organic matter and 25% clay content. The following equation is used in the normalisation of studies with metals:

Equation 3

$$ECx_{(ssoil)} = ECx_{(\exp)} \frac{R_{(ssoil)}}{R_{(\exp)}}$$

Symbols

$EC_{x(ssoil)}$	Effect concentration; normalised NOEC or EC_{50} for standard soil	[mg/kg dw]
$EC_{x(exp)}$	Effect concentration; normalised NOEC or EC_{50} for soil used in the experiment	[mg/kg dw]
$R_{(ssoil)}$	Reference value for standard soil (10% OM, 25% clay)	[mg/kg dw]
$R_{(exp)}$	Reference value for soil used in the experiment soil (y% OM, z% clay)	[mg/kg dw]

The reference values for metals in soil are based on so-called reference lines. These reference lines were derived from a regression analysis on 90th percentiles of ambient background concentrations from various, relatively unpolluted sites in The Netherlands with percentage clay and organic matter content of these soils. The reference values are listed in the Dutch ERL guidance document.

For organic substances, the toxicity data is normalised for organic matter content:

Equation 4

$$ECx_{(ssoil)} = ECx_{(\exp)} \frac{H_{(ssoil)}}{H_{(\exp)}}$$

Symbols

$EC_{x(ssoil)}$	Effect concentration; normalised NOEC or EC_{50} for standard soil	[mg/kg dw]
$EC_{x(exp)}$	Effect concentration; normalised NOEC or EC_{50} for soil used in the experiment	[mg/kg dw]
$H_{(ssoil)}$	Organic matter content for standard soil (H = 5 or 10%)	[mg/kg dw]
$H_{(exp)}$	Organic matter content for soil used in the experiment soil (H = y%)	[mg/kg dw]

The organic matter content for standard soils in ERL development is usually 10%, but this is amended to 4.7% in the context of plant protection products. The organic matter content for a standard soil can also be changed where specific soil conditions prevail, for example soils with low organic matter content (H < 2%) the H value is set at 2%; soils with high organic matter content (H > 30%) the H value is set at 30%. The Netherlands is currently studying the physico-chemical and biological aspects of bioavailability and their interaction. The Dutch are hoping to refine models for partitioning, bioaccumulation and toxicity based on critical tissue concentrations. The models could then be used with current toxicity data for developing their ERLs so that they are corrected for bioavailability.

Other international authorities define acceptable ranges for soil parameters and use these criteria in their data selection. Soil parameter data supporting the development of the US EPA Eco-SSLs is scored for environmental relevance and then likely availability depending on the contaminant type, for example, pH ranges between 4.0 and 8.5 are acceptable. But this range is further divided in to three sub-ranges which are scored high, medium or low depending on whether the contaminant is a metal cation, nonionic organic or anionic species.

In data extrapolation procedures, following any data treatment such as normalisation, authorities usually assume bioavailability of a contaminant in soil to be 100%, i.e. a worst case scenario. This complies with the precautionary principle in risk assessment.

Recommendations for the Environment Agency

In order to recommend a way forward for the Agency, we must consider if we can afford to ignore normalisation? The following three questions should be contemplated before implementing a policy on normalising toxicity data for the soil compartment.

Q: Are we introducing further unnecessary uncertainties?

A reason for not normalising toxicity data could be that the effects of physico-chemical properties on the availability of a particular contaminant are very limited. Standardised OECD test guidelines suggest that if replicates are within 20 per cent confidence limits, then that is acceptable reproducibility. So, if the spread of toxicity data (for the same endpoints) is within a factor of two or three, then there appears little scientific justification for normalising data. In fact, simply undertaking a further iteration may introduce further uncertainty to the data.

Q: Is there a policy precedent for normalisation?

As described above, the European TGD and The Netherlands recommend that data should be normalised. The Environment Agency's Chemicals Assessment Unit, on behalf of the UK Government, reviews substances to meet European requirements under the Existing Substances Regulations. Normalisation of toxicity data for organic chemicals has been undertaken in UK risk assessment as per

the European TGD. Further assessments have also been carried out when a range of organic carbon coefficients (Koc) is given for the same chemical. Then, for comparative purposes, both the extremes and a median are used in the calculation of the PEC/PNEC ratio. Some European Member States do not support normalising toxicity data, possibly because test conditions represent a range of realistic soil toxicity conditions or worst-case scenarios.

Q: Do we understand the influence of soil properties for all contaminants?

The relationship between the soil's physico-chemical properties and its effect upon sorption may not be well developed or understood. So to normalise for contaminants with low Kows (ionisable not neutral) and inorganics may be particularly onerous. But contaminants with a high Kow often show excellent relationships with soil organic matter content, and our understanding of these is much better.

The application of data normalisation is currently being debated at European Member States' technical meetings for the review of risk assessments under the Existing Substances Regulations. As this is still 'work-in-progress' at a European level, we are unable to offer a firm recommendation for policy makers at the moment. A number of interim solutions will be offered to risk assessors in the Environment Agency's consultation on the draft ERA framework. These solutions will include correcting whole soil concentrations to pore water concentrations or a pragmatic approach of applying an additional assessment factor to toxicity data accounting for differences in laboratory and field soil.

4.7 Do values consider background concentrations?

Most current methods for setting soil protection values do not take the natural background concentrations of a substance into account. As a result, values may be lower than the concentrations that, for a number of substances, are naturally present in the environment. Consequently, many substances will always fail the screening values, because the levels at which they occur in the field will never fall below the toxicity-based screening value, though adverse effects may not be observed.

Screening values are normally derived from laboratory toxicity studies. Many of the authorities reviewed here identify the lowest contaminant concentration causing no observable adverse effect (NOEC). Translating NOECs from the laboratory to the field produces the predicted no effect concentration (PNEC) and final screening value. In recent years, it has become apparent that for many potential contaminants, the PNECs derived from laboratory experiments are lower than ambient concentrations in a number of environmental concentrations. The PNEC for nickel in soil, for example, is ~1mg/kg but the average concentration of nickel in UK soils is 20 mg/kg. Ambient and background concentrations are defined in box 3.

Box 3

Ambient concentration – the average concentration measured in an environmental compartment. Ambient may further be categorised into 'rural' and 'urban'

Background concentration – the concentration of an element or compound in an environmental compartment before significant anthropogenic additions. For practical purposes, it is taken to equal pre-industrial revolution concentrations

If derived correctly, screening values should focus resources by identifying sites where a *genuine* risk exists, while eliminating sites of low or negligible risk. So, is it appropriate to translate PNECs, derived in 'pristine' laboratory experiments (i.e., minimal concentration of contaminant in control samples) to environments which may have been adapting to increasing ambient concentrations for two to three thousand years – assuming that most anthropogenic additions occurred during and after the industrial revolution?

Also, to what degree are PNECs realistic? Are they too stringent, since ecosystems exposed to concentrations greater than the PNEC appear still to be functioning? Or, alternatively, have these ecosystems already suffered significant harm and what we are observing are systems that have already changed due to damage?

Devised by The Netherlands the *added risk* approach is a pragmatic policy which takes background concentrations into account when calculating environmental standards for naturally occurring substances. Toxicity tests in the laboratory calculate a hazardous concentration at the 5th percentile (HC_5) of a statistical extrapolation. (This is the maximum concentration that it is considered can be added to the background concentration without harming an ecosystem.) The environmental standard is then calculated by adding the HC_5 to a background concentration for a particular substance.

The added risk approach was developed in The Netherlands for deriving their maximum permissible concentrations (similar to PNECs) and, ultimately, environmental risk limits for naturally occurring substances. The Netherlands policy position is that concentrations of naturally occurring substances in the environment at background levels are necessary for biodiversity and micronutrients in ecosystems. The added risk method is described in the latest Dutch environmental risk limits guidance (RIVM, 2002). To date this has been applied only to metals.

But why should we consider the background concentration? Taking background concentrations of substances in the environment into consideration is important in developing soil screening values for several reasons:

- ***screening values below background concentrations are not practical***

Screening values must be practical and useful. This will not be the case if screening values consistently fall below the background concentrations likely to be found in uncontaminated environments. As a result, large parts of the country will be classed as contaminated. Also, values should be set above chemical analytical limits of detection.

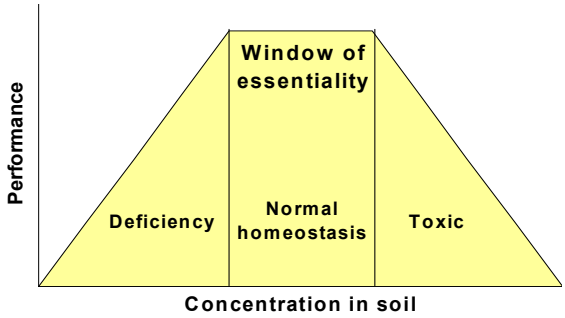
- ***background concentrations establish baseline or reference data***

Controls or reference samples are always recommended for even the simplest laboratory experiments. By the same token, it is of fundamental importance to know or estimate the likely concentration of a substance on a site before the source of contamination arrived. This knowledge will help link toxic effects to the contaminants.

- ***some naturally occurring substances are essential for health***

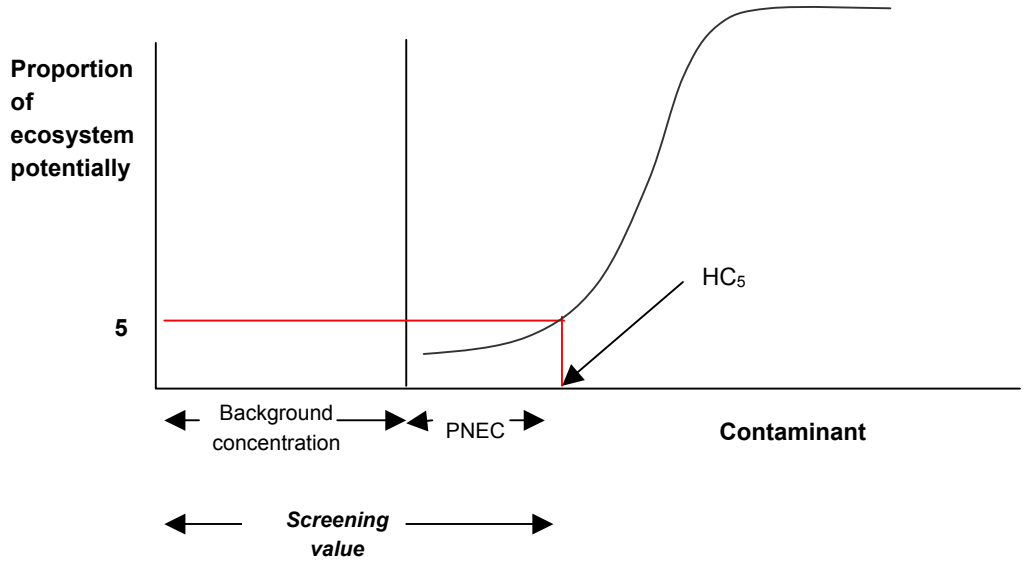
Major essential elements are carbon, hydrogen, oxygen, nitrogen, sulphur, calcium, phosphorus, potassium, sodium, chlorine and magnesium. Other elements, for example zinc, are essential, but to a lesser extent. Non-essential elements include cadmium, lead and mercury. There is an optimum concentration of each essential element to enable healthy performance in individual organisms. This is called the 'window of essentiality'. Too little of an essential element can cause symptoms of deficiency – for example, calcium deficiency is linked to brittle bones/ teeth/ eggshells. Conversely, an organism's capacity to regulate essential elements may be exceeded in environments of high external concentrations beyond which the element will accumulate and become toxic. This is illustrated in figure 8. Soil screening values should fall within the window of essentiality for naturally occurring substances. A constraint to risk assessment methodologies is that there is a lack of readily available information on the optimum levels of essential elements to all organisms.

Figure 8 The window of essentiality when a concentration of an essential element enables optimum performance in an organism



The added risk approach offers a potential solution for determining practical and useable soil screening values. To accept the approach is to accept that the naturally occurring background concentration of a substance does not have an adverse effect on the ecosystem and to regulate the anthropogenically 'added' concentration. This is a pragmatic, policy-based approach. But no viable alternative has, as yet, been suggested.

Figure 9 An example of the added risk approach using a statistical extrapolation of effects data (SSD)



Equation 5 soil screening value = HC_5 + background concentration

Using a statistical extrapolation technique (figure 9) and a protection level at the 95th percentile of the species in an ecosystem, the HC_5 is calculated from the SSD. A suitable background concentration is then added to the HC_5 to derive the screening value (equation 5). The background is assumed to be entirely unavailable and, therefore, ineffective in terms of toxicity. This tends to give the lowest screening values numerically. It is consistent with the precautionary principle. But, if the background concentration already has an adverse effect, this method may not be protective.

The European Commission TGD describes a general approach to assessing metals using the methods available for risk assessing new and existing organic chemicals. But Appendix IX of the TGD acknowledges that there are fundamental differences between metals and organic chemicals, and that these must be taken into account when performing a risk assessment. The availability of metals for uptake by organisms in field conditions, for example, is limited. It will vary from site to site and is highly dependent on the speciation of the metal. The TGD suggests applying the standard method (as described here in section 3.2). But it advises that care be taken when extrapolating short-term toxicity data using standard assessment factors. This is because of the specific mode of action that some metals may have for some species. For the soil compartment, the EC TGD recommends that soil type correction be applied to correct for differences among soil types, i.e. normalisation (as described in section 4.6). Also, that information on deficiency levels be taken in to account. Though the TGD does not explicitly mention the added risk approach, the method has been applied to the PNEC derivation for hydrogen peroxide and chromates (and the draft zinc risk assessment report, awaiting finalisation).

Other countries, for example Canada, run a final cross check of their soil protection value against appropriate geochemical background concentrations. If the background concentration is higher, then this is adopted as the final soil protection value. The Canadians also run a check against plant nutritional

requirements for their agricultural, parkland and residential land use categories. Again, if the soil guideline value is below nutritional requirements critical to sustaining plants, then the plant nutritional requirement concentration is adopted instead.

National or regional background levels are generally provided in authorities' guidance documents.

Recommendations for the Environment Agency

It is recommended that background levels be considered in the derivation of soil screening values. The policy decision to adopt or reject the added risk approach as a means to accounting for background concentrations will be asked in the Agency's ERA consultation.

If the added risk approach is to be adopted then consideration needs to be given to the reference concentrations as background and to what we might define as a naturally occurring substance. Ambient concentrations of a number of contaminants have increased since the industrial revolution and, in some cases, earlier (for example, PAH concentrations will have risen due to wood-burning for centuries prior to 1850). The ecosystems we observe today have evolved and adapted to a fraction or all of this change. For them, the concept of the original pre-anthropogenic activity 'background' concentration may be meaningless. That part of the ambient concentration that can now be considered to be ecologically ineffective (in toxicity terms) is the part of the ecosystem that has adapted and is now the relevant background. So, what is a representative background concentration?

Secondly, what is a naturally occurring substance? The question of which substances this method will apply to is crucial. The philosophy is that the substances are naturally occurring and therefore essential for the health of the ecosystem. But does this apply only to metals or also to some organics? The Netherlands has applied the method only to metals so far. But the European Member States, in their risk assessments of existing substances, have applied added risk to hydrogen peroxide.

Whatever the outcome of the consultation, it is recommended that the Agency includes references to background concentrations in guidance on the use of screening values.

4.8 Is secondary poisoning considered?

Standard ecotoxicological effects data usually provides information on direct toxic effects of a contaminant. But contaminants that are likely to bioaccumulate may pose a threat to organisms higher in the food chain, e.g. predatory birds and mammals. This is termed secondary poisoning. Some countries use criteria based on physico-chemical properties of contaminants (e.g. high log Kow) to judge if they are likely to bioaccumulate and are therefore a threat to top predators.

All international authorities reviewed consider invertebrates and plants. One exception was found in the literature for Australian regulators where their interim ecologically-based investigation levels (EILs) are based on phytotoxicity and soil survey data. Most authorities also consider microbes (in-soil biota) in their soil protection values. But many authorities differ on how they protect terrestrial birds and mammals at a screening level. There are four basic options available;

- not accounting for secondary poisoning,
- developing soil protection values for in-soil biota, and separate values for terrestrial vertebrates using direct toxicity data,
- developing soil protection values that protect microbes, invertebrates, plants, birds and mammals using direct toxicity data but as a harmonised single value,

- developing an uptake model for defined food chain(s) and comparing the results to direct toxicity data, usually selecting the lower of the two values as the final soil protection value.

The US DOE benchmarks for wildlife are equivalent to NOAELs or LOAELs for avian and mammalian wildlife species. They are derived by extrapolating oral dose (mg/kg/d) for test species to an oral dose for wildlife species using body weight or allometric scaling models. These estimated NOAELs and LOAELs are combined with species-specific food and water consumption rates to generate food and water benchmarks. For wildlife species that feed primarily on aquatic organisms, a piscivore benchmark is also calculated. The US DOE benchmark values do not take secondary poisoning in to account but the US DOE does recommend the use of soil-to-biota uptake factors or other bioaccumulation models where secondary poisoning may be a concern. Uptake models for plants, earthworms, and small mammals can be referenced in Baes et al (1984), Sample et al (1997) and Sample et al (1998a and 1998b).

The CCME calculates soil quality guidelines for organisms in contact with soil (microbes, invertebrates, plants) for all land uses. For agricultural land use only, CCME calculates soil quality guidelines for wildlife and livestock that ingest soil and food by grazing. The food chain is only relevant to herbivores so chemicals that bioaccumulate in the tissues of plants and can be transferred in the food chain are of primary importance. Once a direct toxicity threshold has been calculated for the most sensitive species, information is gathered on body weight, rate of soil and food ingestion of the most sensitive species, and bioavailability and bioconcentration factors specific to the contaminant. The lower value between the soil quality guideline for soil contact and soil ingestion is taken as the final soil quality guideline (for agricultural land use).

The US EPA Eco-SSLs includes values for wildlife, which are calculated for six generic surrogate receptors and exposure pathways. These are herbivore, ground insectivore and carnivore and are calculated for avian and mammalian surrogate species (depending on data availability). The lowest of the three avian Eco-SSLs and three mammalian Eco-SSLs are selected as the final wildlife Eco-SSLs. The calculations are made using the wildlife risk model for Eco-SSLs which relates the contaminant soil concentration to an acceptable threshold based on a food-chain exposure model.

In the Netherlands, contaminants with a log Kow greater than 3 and a molecular weight less than 700 are considered likely to bioaccumulate through a food chain and may have toxic effects on higher organisms (birds and mammals). Metals are considered on a case-by-case basis but generally for soil contaminants likely to bioaccumulate ecotoxicological data for birds and mammals and bioconcentration factors (BCFs) for earthworms is gathered. One terrestrial food chain 'soil – earthworm – worm-eating predators' is considered. All individual NOECs for birds and mammals are divided by a BCF to obtain concentrations in soil. Together with the $L(E)C_{50}$ or NOEC values for soil organisms, these values are used as input data for the data extrapolation method (e.g. species sensitivity distribution). The combined data set is used to derive the Dutch environmental risk level (ERL). The Dutch also recalculate the ERL by keeping the direct toxicity data and the secondary poisoning data separate to gain an insight in to the relative sensitivity of vertebrates compared to that of other species. This is done for comparative purposes only.

The Dutch[26], have studied this comparison using a general algorithm developed to compare mean concentration factors (BCFs) in prey (earthworms) with critical food concentrations of the predator (birds or mammals). Romijn *et al.* (1994), concluded that the algorithms are only valid in defined situations but

[26] *Presentation of a general algorithm to include effect assessment on secondary poisoning in the derivation of environmental quality criteria. Part 2. Terrestrial Food Chain*s. Romijn et al., 1994. Ecotoxicology & Environmental Safety. 27:107-127.

by comparing the calculation of MPCs for secondary poisoning with MPCs for direct poisoning, they found that secondary poisoning could be a critical pathway for cadmium and methyl mercury.

The EC TGD recommends the terrestrial food chain model 'soil – earthworm – worm-eating birds or mammals' as described by the Dutch. The EC TGD recommends criteria for recognising potential bioaccumulating chemicals and these are:

- log Kow ≥ 3; or,
- is highly adsorptive; or,
- belongs to a class of substances known to have a potential to accumulate in living organisms; or,
- there are indications from structural features;
- and there is no mitigating property such as hydrolysis (half-life less than 12 hours).

Recommendations for the Environment Agency

It is recommended that secondary poisoning is considered for substances likely to bioaccumulate through the terrestrial food chain. A standard uptake model is the simplest method for deriving screening values, such as the one described by the Dutch and in the European TGD. This is appropriate at a screening level risk assessment. However, if the risk assessor is uncertain if the uptake model is relevant to the food chain scenario on a particular site and bioaccumulating contaminants are present, then the risk assessment should proceed to the next tier where a more detailed (and species specific) assessment can be performed. An example of this might be where a receptor is a fish-eating bird or mammal.

An Environment Agency project[27] is underway to investigate alternative secondary poisoning models as the EC TGD and Netherlands simplified food chain model has been shown to be under-protective in instances where birds do not eat worms, for example the detection of decaBDE in birds eggs. The results of the project will inform the recommendations here.

Regardless of the extrapolation method used to derive soil protection values, effects due to secondary poisoning are likely to be important when considering cadmium, lead, mercury and persistent organic pollutants (e.g. organochlorines)[28].

4.9 Are soil screening values validated?

Validation of protectiveness and reasonableness are seen as essential steps in establishing soil protection values. But, very little published work exists on validating soil protection values. Most international authorities check that values do not fall below background concentration for naturally occurring substances (see earlier discussion) or are below analytical detection limits for xenobiotics.

More published studies are needed to improve the validity of soil protection values by reporting comparisons with background levels and with regulatory decisions taken in risk assessments (in effect, ground truthing screening values).

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[27] Environment Agency R&D Project P6-020/U: *An umbrella project on environmental and human health standards for chemicals*

[22] *Critical loads for lead, cadmium and mercury in Denmark* (1998). Ministry of Environment National Environmental Research Institute

Recommendations for the Environment Agency

It is recommended that the Environment Agency validate the screening values it develops or adopts. It is unlikely that validation studies will exist in published literature but validation of screening value applicability for use in UK soil and ecosystems and compliance with Agency policy will be needed anyway.

4.10 Peer review

Some authorities require peer review and public comment on all policy and regulatory requirements prior to implementation, for example the US EPA. The CCME and British Columbia soil guidelines have undergone considerable review prior to adoption. The PNECs derived using the European TGD are reviewed and challenged by Member States during the EC risk assessment of chemicals. The US DOE benchmark values have not received public and scientific review.

Recommendations for the Environment Agency

There is no statutory requirement for the Agency to undertake peer review of any screening values but it is recommended that screening values derived as a result of this report are peer reviewed and undergo public consultation (in accordance with Cabinet Office guidelines[29]).

4.11 Summary

In summary, a list of desired features can be compiled for the development of the Agency's soil screening values (see box 4). These attributes are consistent with Part IIA EPA 1990 and Agency contaminated land policy, although some will be finalised through public consultation.

In chapter 5 the international approaches to setting soil protection values are compared with these desired characteristics to see which is the most suitable approach for the Environment Agency.

Box 4 ***A list of preferred scientific and policy features for soil screening values***

♦ Application	used for screening purposes with a 95th percentile protection level
♦ Measurement endpoints	preference for sublethal endpoints from chronic toxicity studies
♦ Species	relevant species and soil processes for UK environment representing at least three trophic levels
♦ Extrapolation method	flexible approach in order of preference; distribution-based > assessment factor >equilibrium partitioning
♦ Bioavailability	the approach will be agreed following public consultation
♦ Background concentrations	the approach will be agreed following public consultation
♦ Secondary poisoning	birds and mammals protected using appropriate uptake models for contaminants likely to bioaccumulate
♦ Validation	validate our own screening values in the absence of relevant information
♦ Peer review	peer reviewed values are desirable

[29] Cabinet Office *Code of Practice on Written Consultation* (November 2000) is available from the Cabinet Office website (cabinet-office.gov.uk)

5 SUMMARY AND RECOMMENDATIONS

This chapter summarises how the leading international approaches to setting soil protection values (chapter 3) meet our policy needs (chapter 4). It also acts as a note of the first meeting hosted by the Agency (on 13 December 2002) to discuss how we should develop soil screening values, plus follow-up meetings to agree our chosen approach.

Chapters 1 and 4 explain why we need to develop soil screening values summarising the contextual background and the factors considered in choosing the most appropriate approach for the UK. Chapter 2 summarised the general step-wise approach to setting soil screening values. Chapter 3 presented the approaches developed by the leading international authorities, highlighting the features and limitations of these approaches; The Netherlands, Canadian Council of Ministers for the Environment, European Commission Technical Guidance Document, US Environmental Protection Agency, and the US Department of Energy.

The information in these preceding chapters was presented to a mix of representatives from the Agency and other interested parties (listing is in Appendix 1) at a discussion meeting in December 2002. The presentation highlighted the features and limitations of the leading international approaches. This was followed by a theoretical screening assessment in which soil contamination data from a former gas works, two operational chemical plants and a rural “pristine” site was screened against toxicity data extrapolated by assessment factor and statistical distributions. Both approaches correctly identified those sites requiring further risk assessment and the rural pristine site exited the ERA framework at the screening stage.

The discussions following the presentation and screening exercise raised a number of important points and the follow-up meetings led to a recommended way forward for developing soil screening values.

5.1 Summary of meeting and screening exercise

At the December meeting a number of conclusions were drawn based on the information presented. These were:

- ecotoxicological data is in short supply; all the approaches are exploiting essentially the same data set
- species sensitivity distributions (SSDs) were acknowledged as scientifically the most robust and defensible approach to deriving screening values *provided the data comprising the distribution were relevant and sufficient.* The point was made repeatedly that much of the data in published SSDs was not soil relevant and that to generate a robust SSD required a minimum data set
- Because the data were patchy and often sparse, it was not possible to identify any one data extrapolation method (SSD or assessment factor) that was ideal. Where the data were available, SSD should be the preferred option; otherwise it was better to apply assessment factors
- This more flexible approach to deriving screening values is already embodied in EC Technical Guidance Document that already has a European imprimatur
- The example screening exercise undertaken at the meeting showed that when comparing site experimental data with screening values, the mean value test

described in the Agency's and Defra's CLR7 guidance should be used. CLR7 suggests comparing the mean of a number of determinations with the Soil Guideline Value (or soil screening value in this instance). The treatment in CLR takes account of the uncertainty in the measured mean value as a function of the number of samples and the consequent standard deviation of the mean. The variability in the sample means that there is uncertainty as to the measured mean but the CLR identifies the 95 per cent confidence limit of the mean and compares the upper limit of this with the Soil Guideline Value. The more samples that are taken the narrower the 95 per used to compare concentrations in field soils with screening values and continue consistency with the approach for human health risk assessment under Part IIA EPA 1990.

5.2 Summary of approaches versus recommended features

All international authorities use the same base of toxicological and exposure information to derive their soil protection values. Final numbers differ primarily in how the literature is qualified for use, what measurement endpoints are acceptable, how interspecific differences are treated, and what type of assessment factors are applied (API, 2000).

The Agency is committed to developing an ERA framework for use in Part IIA EPA 1990 and with other legislative regimes in the wider context of environmental protection. The development of soil screening values must be compliant with these legislative requirements and with the level of protection required by contaminated land policy.

Table 10 presents these policy requirements and corresponding features from the leading international regimes to determine which is the most appropriate for use in the UK.

Table 10 Matrix of features, contaminated land policy and international approaches to setting soil screening values

Feature	Contaminated land policy	International approaches	The contenders
❖ Application			
– Screening level	Previous research and regulatory policy has recommended that soil protection values are used in the early tiers of the ERA framework only, i.e. not to be used as remediation or cleanup goals.	The Dutch intervention values and both US approaches are designed for screening purposes only. The EC TGD-derived PNECs are designed for risk assessment of chemicals at a screening level. The Dutch target values and the Canadian soil quality guidelines may be used in screening and/or as clean-up remediation goals.	The Netherlands US DoE US EPA EC TGD Canada
– Generic or site-specific	Risk assessment for the protection of human health under Part IIA EPA 1990 is generic at a screening level. For consistency, the same rule is applied to ecological risk assessment.	The Dutch environmental quality standards, the US EPA's Eco-SSLs, US Dept. of Energy's benchmarks and EC risk assessment PNECs are all explicitly generic. The Canadian soil quality guidelines can be applied generically and site-specifically.	The Netherlands US DoE US EPA EC TGD Canada
– 95th percentile protection level	Existing contaminated land policy recommends that biota is protected at the 95th percentile protection level.	Only the Netherlands and EC TGD choose to protect at the 95th percentile level of a toxicity distribution.	EC TGD The Netherlands
❖ Measurement endpoint	The Agency's guidance on defining harm calls for protection at a sublethal level. Data from chronic toxicity studies is preferred to acute toxicity data for application to historically contaminated land.	All the leading international authorities prefer to use chronic toxicity data (with the exception of Canada's British Columbia province) and aim to protect species at a sublethal level.	The Netherlands US DoE US EPA EC TGD Canada (but not BC Province)
❖ Species	Species should be relevant to the UK terrestrial environment.	All authorities rely on using the same basic ecotoxicological information. The Netherlands and EC TGD consider microbes, invertebrates and plants in their soil protection values. CCME use microbial data as a	The Netherlands EC TGD

	Screening values should aim to represent at least three trophic levels.	checking mechanism against plant and invertebrate toxicity data. US DoE benchmarks are derived separately for plants, invertebrates, microbial processes, and wildlife. The US EPA Eco-SSLs do not consider microbes.	
❖ Extrapolation method	A flexible approach to data extrapolation in order of preference, SSD > assessment factor > equilibrium partitioning		The Netherlands EC TGD
- Distribution-based approach		The species sensitivity distribution method is the Dutch preferred extrapolation approach The Canadians preferred approach is to rank effect and no effect (NOEC) toxicological data. The screening concentration is then based on the 20th percentile of the distribution The US Department of Energy ranks toxicological data based on a 20% reduction in growth, reproduction or activity (EC_{20}). The screening concentration is then the lowest 10th percentile of this ranked distribution The US EPA preferred approach is to calculate the geometric mean from reliable EC_{10}s and maximum allowable threshold concentrations (MATC) as the screening concentration (PNEC) The European Commission risk assessment reports use the SSD method when data allows but recommends an assessment factor method is used for comparative purposes.	
- Assessment factor approach		This approach uses toxicological data for individual contaminants (and usually individual receptors) together with a safety factor usually based on the modified US EPA method or the European factorial application	

		method. These methods are used by most European countries, Australia (National Ecological Investigation Levels) and the US EPA (prior to the development of Eco-SSLs). But, all authorities use safety factors of one kind or another in the development of protection values.	
❖ Bioavailability	It is likely that the complex problem of judging the availability of contaminants for uptake by soil organisms will be raised for public consultation (in the context of the ERA framework). It is not possible to recommend an approach at present, but it is clear that soil properties can influence bioavailability and should be considered when deriving screening values.	Only the Netherlands and the EC TGD recommend normalising toxicity data for a standard soil. Most other authorities recommend ranges for soil parameters. These criteria are used to select acceptable toxicity data. The US DoE for their benchmarks assume that the bioavailability of chemicals in conventional laboratory toxicity data is higher than in the field so all their benchmarks are conservative.	
❖ Background	It is recommended in this report to consider background levels in the derivation of soil screening values.	All authorities, as a minimum, check their soil protection values against background levels. It is common practice to default to the background concentrations where soil protection values are lower. Only the Netherlands routinely apply the added risk approach to naturally occurring substances. The added risk approach has been used to derive PNECs (using the EC TGD) but this has been done on a case-by-case basis.	
❖ Secondary poisoning	It is recommended in this report to consider secondary poisoning for substances likely to bioaccumulate through the terrestrial food chain	The US EPA, The Netherlands and the EC TGD all recommend considering secondary poisoning for substance likely to bioaccumulate through the food chain. These authorities have developed generic food chain models for calculating soil protection values for higher organisms. CCME regard secondary poisoning for agricultural land use and only consider exposure to herbivores.	The Netherlands EC TGD US EPA

❖ Validation	It is recommended in this report to validate the soil screening values developed as a result of this report	Only the Netherlands has studied the validity of their soil protection values in Dutch soils. Their research is ongoing.	The Netherlands
❖ Peer review	It is recommended in this report to subject soil screening values to peer review	Most authorities undertake peer review of their soil protection values, with the exception of the US DoE benchmarks.	The Netherlands EC TGD US EPA Canada

5.3 Recommendations

Using the information in table 10 and the conclusions drawn from discussions at the December meeting, plus two further meetings, there is a clear way forward.

5.3.1 The recommended approach

The recommended approach for the Environment Agency to develop soil screening values is the ***EC TGD methodology*** for deriving predicted no-effect concentrations (PNECs) for the soil compartment. The EC TGD is accepted by European Member States and meets the Agency's key criteria of

- flexible (using a range of data extrapolation methods)
- protection at the 95th percentile level (of a distribution)
- protection at a sublethal level
- generic values applied at a screening level

5.3.2 Recommended science and policy factors

Having recommended the EC TGD methodology it is important to relate this to the Agency's policy perspectives and reaffirm the influence certain principles will exert on screening value development and implementation. These are listed below.

Application	▪ Use the values at a screening level only in Tier One of the ERA framework ▪ The values should not be used as clean-up targets ▪ The values are designed for generic application but should not be automatically adopted as thresholds of significant risk. A risk assessor should consider the relevance of screening values to species and conditions at the site of concern ▪ Values aim to protect at the 95th percentile level (where the SSD method is used)
Measurement endpoints	▪ Protecting sublethal endpoints using chronic toxicity data, where available
Species	▪ Toxicity data should aim to characterise species and soil processes for the UK terrestrial environment and represent at least three trophic levels (that is microbes, invertebrates and plants). Microbial process and species data should be treated separately where appropriate.
Extrapolation method	▪ The EC TGD offers the flexibility of different methods to be used in order of preference where quality and quantity of data allow; ▪ SSD > assessment factor > equilibrium partitioning ▪ Minimum data requirements for the SSD for the aquatic environment include at least 10 NOECs (preferably more than 15) for different species covering at least eight taxonomic groups. Similar criteria and rigour should be applied to the terrestrial environment.
Bioavailability	▪ The policy of whether to normalise toxicity data for a standard soil will be agreed following public consultation ▪ At a screening level assume the contaminant is 100% bioavailable to the receptor ('worst case' scenario)

Background concentrations	▪ The policy of whether to use the added risk approach to account for background concentrations will be agreed following public consultation ▪ Final screening values should not fall below background concentrations for naturally occurring substances or below analytical limits of detection ▪ Background concentrations for potential contaminants in UK soils will be published with soil screening values. For basic information on background concentrations refer to *Information on land quality in the UK* (Environment Agency R&D Technical Reports P291-294)
Secondary poisoning	▪ Birds and mammals will be protected using appropriate uptake models for contaminants likely to bioaccumulate
Validation	▪ Aim to validate our own screening values for sites of potentially contaminated land in the UK.
Peer review	▪ All screening values and revisions will be peer reviewed and endorsement sought from Defra and NAW. If the screening values will be adopted UK-wide, then consultation with Scotland and Northern Ireland is recommended also.

5.3.3 List of priority substances

A list of contaminants likely to be found at potentially contaminated sites in the UK has been prepared (see Appendix 2). Soil screening values will be prepared for these contaminants in a phased programme of work ending in 2005. This list will also be open for public consultation and additional contaminants may be added as a result.

The list of priority contaminants was identified by Agency staff from the Science Group, Land Quality Policy, and Air and Chemicals Policy. The starting point for drawing up the list was to cross-reference published priority contaminant lists in our own contaminated land regulation and that of other authorities;

- The Agency and Defra's *Potential contaminants for the assessment of land* (CLR8)
- The Agency's Pollution Inventory Top 40 releases to air
- EC priority list of existing chemicals for risk assessment (under Existing Substances Regulations)
- Canadian Council of Ministers for the Environment
- The Netherlands
- US EPA
- US DOE

5.4 What's next?

The decision to proceed with the EC TGD approach will enable the development of soil screening values to begin. A sub-set of the contaminants listed in Appendix 2 will have soil screening values developed for them by Agency scientists in the summer 2003. The remainder will follow on in 2004/05. In parallel, the Agency is seeking to further develop the ERA framework, tests and preliminary screening values [the sub-set] in partnership with our contaminated land stakeholders. This is mapped out in the following sections and concludes with an outline of how the ERA framework, tests and screening values will be implemented.

5.4.1 Consultation exercise

The Environment Agency will consult owners of potentially contaminated land and their advisors, other regulators and Government (herein referred to as “stakeholders”) on the usefulness of the soil screening values that are developed as a result of this report. The aim of the consultation exercise is to agree practical and protective soil screening values in partnership with the assessors who will be using them.

Draft soil screening values will be developed for a sub-set of the priority list of contaminants by Agency scientists and agreed by policy managers by September 2003. The format will look like the example soil screening value for toluene in chapter 6. The remaining screening values will be developed during 2004/05 under Environment Agency R&D Project P6-020/U: *An Umbrella Project on Environmental and Human Health Standards for chemicals*.

Soil screening values will be one component of the consultation exercise. The consultation will comprise the results of a trial of the draft ecological risk assessment (ERA) framework and ecotoxicological tests at two sites with potentially contaminated land and the proposed soil screening values. The overall aim is to agree and finalise an ERA framework, series of tests and soil screening values, in partnership with our contaminated land stakeholders, which will be practical and useful in the UK.

The consultation exercise will run from December 2003 to February 2005.

5.4.2 Final agreement and publication

The final ERA framework, series of ecotoxicological tests and soil screening values will be agreed during the consultation exercise. This will include strategic stakeholders such as Defra, NAW, English Nature, Countryside Council for Wales and local authorities. Final endorsement of future iterations of screening values will be sought from Defra and NAW.

Final publication will be in Spring 2005 when reports will be available in the public domain.

5.4.3 Training

At the time of writing, Agency Process teams have identified two training courses for Agency staff to learn about ecological risk assessment. The first is a brief introduction to ecotoxicology, including basic concepts and terminology, and will be inserted in to a one-day course on land contamination for novice regulatory staff. The second is a half-day module on ecological risk assessment – the framework, tests and screening values – for staff who are technical specialists in the regulation of land contamination.

External stakeholders will be targeted in the consultation process and subsequent implementation of the ERA framework.

6 AN EXAMPLE OF A SOIL SCREENING VALUE (PNEC) USING TOLUENE

European Members States have derived a predicted no-effect concentration (PNEC) for toluene in the soil compartment for risk assessment purposes under the Existing Substances Regulations. The EC Technical Guidance Document methodology is applied and the final risk assessment report can be downloaded from the European Chemical Bureau's website, ecb.jrc.it/existing-chemicals.

6.1 PNEC derivation

Two extrapolation methods are applied separately to toluene data for comparative purposes due to the limited availability of toxicity data for terrestrial species,

- assessment factor method,
- equilibrium partitioning method.

Assessment factor method

For the terrestrial compartment, toxicity data represents acute earthworm EC_{50} >150 but <280 mg/kg soil, with NOEC values for mortality and cocoon production of ≤150 and <280 mg/kg, respectively, whereas a NOEC based on visual inspection is between 15 and 50 mg/kg soil. For plants, a yield decrease is observed in *Lactuca sativa* at 1000 mg/kg. For soil microorganisms, NOEC for nitrification is <26 mg/kg soil (dry weight).

The $PNEC_{soil}$ is based on the lowest NOEC from the earthworm study of 15 mg/kg. An assessment factor of 50 is applied, as there is long-term toxicity data for two trophic levels (see below). The $PNEC_{soil}$ is 0.3 mg/kg (wet weight).

Assessment factors for deriving PNECs in the soil compartment

Available information	Assessment factor
L(E)C_{50} short-term toxicity test(s) (e.g. plants, earthworms, or microorganisms)	1000
NOEC for one long-term toxicity test (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, to be fully justified on a case-by-case basis
Field data/data of model ecosystems	case-by-case

Equilibrium partitioning method

For comparison the $PNEC_{water}$ is converted to the terrestrial compartment using partitioning theory.

$$\mathrm{PNEC}_{\mathrm{soil}} = \frac{\mathrm{PNEC}_{\mathrm{aqua}} \cdot K_{soil-water} \cdot 1000}{\mathrm{RHO}_{\mathrm{soil}}}$$

The $PNEC_{soil}$ using the above equation is 0.26 mg/kg, which compares closely with the PNEC derived using the assessment factor method.

6.2 Final $PNEC_{soil}$

The two $PNEC_{soil}$s compare closely. The derivation using the assessment factor approach is preferred as it is based on long-term experimental data for a terrestrial organism. The final $PNEC_{soil}$ is 0.3 mg/kg.

The potential for secondary poisoning is considered to be negligible for toluene so a PNEC is not derived for food chain effects.

6.3 Proposed soil screening value

The $PNEC_{soil}$ has been developed, peer reviewed, agreed and published at a European level. The EC TGD methodology is the recommended approach for developing soil screeening values and is consistent with Environment Agency policies. The proposal is to adopt the $PNEC_{soil}$ as the Agency's soil screening value for toluene. ***The proposed soil screening value is 0.3 mg toluene per kg soil.***

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APPENDIX 1

List of attendees at the Environment Agency discussion meeting on 13 December 2002 and subsequent meetings to agree on an approach for setting soil screening values.

Name	Organisation
Dr Danielle Ashton	Environment Agency
Dr Declan Barraclough	Environment Agency
Steve Dungey	Environment Agency
Samantha Fishwick	Environment Agency
Tim Gannicliffe	English Nature
Dr Gordon Lethbridge	Shell Global Solutions (UK)
Heather Lewis	Environment Agency
Dr Graham Merrington	Environment Agency
Dr Beth Power	Azimuth Consulting Group Inc., Canada
Dr Steve Robertson	Environment Agency
Suze Southern	Environment Agency
Dr David Spurgeon	Centre for Ecology and Hydrology, Monks Wood
Dr Jason Weeks	WRc-NSF Ltd

APPENDIX 2

List of priority contaminants likely to be found at potentially contaminated sites in the UK. Soil screening values will be developed for these contaminants in 2004/05.

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

APPENDIX 3

Appendix 3 presents the lists of priority contaminants developed by the Netherlands, Canada, US EPA, US DOE, Existing Substances Regulations priority chemicals for risk assessment (Europe), Environment Agency and Defra contaminated land reports, and the Agency Pollution Inventory Top 40 releases to air.

Environment Agency and Defra

The list below presents the priority contaminants for the assessment of land. The contaminants listed are those which are indicated as most likely to be risk to vegetation and ecosystems. The list is published in the report, *Potential contaminants for the assessment of land*. R&D Publication CLR8 (2002) Environment Agency and Defra.

- Beryllium
- Cadmium
- Chromium
- Copper
- Lead
- Mercury
- Nickel
- Zinc
- Boron
- Selenium
- Sulphur
- Cyanide (complex)
- Cyanide (free)
- Sulphate
- Sulphide
- pH
- Oil/fuel hydrocarbons
- Benzene
- Chlorophenols
- Ethylbenzene
- Phenol
- Toluene
- Xylene (o,m,p isomers)
- Chloroform
- Carbon tetrachloride
- 1,2-dichloroethane
- 1,1,1-trichloroethane
- Trichloroethene
- Tetrachloroethene
- Hexachlorobuta-1,3-diene
- Hexachlorocyclohexanes
- Dieldrin
- Chlorobenzenes
- Chlorotoluenes
- Pentachlorophenol
- Polychlorinated biphenyls
- Dioxins and furans
- Organolead compounds

Environment Agency

This list is compiled from the Environment Agency's Pollution Inventory Top 40 permitted pollutants released by volume (in kilograms). The list was compiled in February 2003. The Pollution Inventory list was gathered by Dr Bogus Zaba of the Environment Agency's Pollution Inventory Team (Air and Chemicals Policy Function, Head Office, Environment Agency, Bristol, UK).

- **Top 40 (in order of kgs released)**
- Carbon dioxide
- Sulphur dioxide
- Carbon monoxide
- Nitrogen oxides (except N_2O)(reported as NO_2)
- Total volatile organic compounds (as C)
- Hydrogen chloride
- Particulates - total
- PM10s (particulates <10 micron)
- Dinitrogen oxide (nitrous oxide)
- Methane
- Propene (propylene)
- Carbon disulphide
- Ethylene
- Ammonia
- Dichloromethane (methylene chloride or dichloride)
- Xylene (all isomers)
- Benzene
- 1,2-dichloroethane (ethylene dichloride)
- Trichloroethene
- Chloromethane
- Butene (all isomers)
- Boron
- Dimethylformamide
- Acrylonitrile
- Chloroethene (chloroethylene, vinyl chloride)
- Pentene (all isomers)
- 1,3-butadiene
- Tetrachloroethene(tetrachlorethylene, perchloroet)
- Styrene
- Zinc
- Methyl bromide
- Acetaldehyde (ethanal)
- Lead
- HCFCs (hydrochlorofluorocarbons)
- Ethylene oxide
- Propylene oxide (methyloxirane)
- PAHs – total (as benzo(a)pyrene)
- Chromium
- Formaldehyde
- Chloroform (trichloromethane)

US Environmental Protection Agency

The list of priority contaminants below is taken from the US EPA Ecological Soil Screening Level Guidance (draft, July 2000). US EPA, Office of Emergency and Remedial Response, Washington DC, United States and represents priority contaminants with Eco-SSLs.

Metals

- Aluminium
- Antimony
- Arsenic
- Barium
- Beryllium
- Cadmium
- Chromium
- Cobalt
- Copper
- Iron
- Lead
- Manganese
- Nickel
- Selenium
- Silver
- Vanadium
- Zinc

Organics

- Dieldrin
- Total polychlorinated biphenyls
- Trinitrotoluene (TNT)
- Pentachlorophenol
- Polycyclic aromatic hydrocarbons (PAHs)
- 1,1,1-Trichloro-2,2-bis(p-chlorophenyl)ethane (DDT)
- Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)

The Netherlands

The Netherlands have compiled a list of substances for which target values and intervention values have been developed. The list is sourced from the English translation of the Circular on target values and intervention values for soil remediation as published in the Netherlands Government Gazette of the 24th February 2000, No. 39, Table 1 (VROM, 2000).

Metals	**Inorganics**
▪ Antimony	▪ Cyanides – free
▪ Arsenic	▪ Cyanides – complex
▪ Barium	▪ Thiocyanates
▪ Cadmium	▪ Bromide
▪ Chromium	▪ Chloride
▪ Cobalt	▪ Fluoride
▪ Copper	
▪ Mercury	
▪ Lead	
▪ Molybdenum	
▪ Nickel	
▪ Zinc	

Polycyclic aromatic hydrocarbons	**Aromatics**
▪ PAH (sum of 10)	▪ Benzene
▪ Naphthalene	▪ Ethyl benzene
▪ Anthracene	▪ Toluene
▪ Phenatrene	▪ Xylenes
▪ Fluoranthene	▪ Styrene
▪ Benzo(a)anthracene	▪ Phenol
▪ Chrysene	▪ Cresols (sum)
▪ Benzo(a)pyrene	▪ Catechol
▪ Benzo(ghi)perylene	▪ Resorcinol
▪ Benzo(k)fluoranthene	▪ Hydroquinone
▪ indeno(1,2,3-cd)pyrene	

Chlorinated hydrocarbons

- vinyl chloride
- dichloromethane
- 1,1-dichlroethane
- 1,2-dichlroethane
- 1,1-dichlroethene
- 1,2-dichlroethene
- dichloropropane
- trichloromethane
- 1,1,1-trichloroethane
- 1,1,2-trichloroethane
- trichloroethene
- tetrachloromethane
- tetrachloroethene
- chlorobenzenes (sum)
- monochlorobenzene
- dichlorobenzenes
- trichlorobenzenes
- tetrachlorobenzenes
- pentachlorobenzenes
- hexachlorobenzenes
- Chlorophenols (sum)
- Monochlorophenols
- Dichlorophenols
- Trichlorophenols
- Tetrachlorophenols
- pentachlorophenols
- Chloronaphthalene
- Monochloroaniline
- Polychlorobiphenyls (sum)
- EOX

Pesticides

- DDT/DDE/DDD
- drins
- aldrin
- dieldrin
- endrin
- HCH-compounds
- a-HCH
- b-HCH
- g-HCH
- atrazine
- carbaryl
- carbofuran
- chlorodane
- endosulphan
- heptachloro
- heptachloro-epoxide
- maneb
- MCPA
- organotin compounds

Other contaminants

- cyclohexanone
- phthalates
- mineral oil
- Pyridine
- Tetrahydrofuran
- Tetrahydrothiophene
- Tribromomethane

Canadian Council of Ministers for the Environment (CCME)

This priority list is taken from the substances listed in the Recommended Canadian Soil Quality Guidelines report (CCME, 1997).

- Arsenic
- Benzene
- Benzo(a)pyrene
- Cadmium
- Chromium
- Copper
- Cyanide
- Ethylbenzene
- Ethylene glycol
- Lead
- Mercury
- Naphthalene
- Pentachlorophenol
- Phenol
- Tetrachloroethene
- Toluene
- Trichloroethene
- Vandaium
- Xylene
- Zinc

US Department of Energy

This priority list is taken from the list of substances with benchmark values for terrestrial plants, microbes and invertebrates sourced from Risk Assessment Tools and Information (website http://risk.lsd.ornl.gov/rap_hp.shtml). The tools are designed for use at all DOE sites and also includes information, guidance, and risk results applicable to the Oak Ridge Reservation.

- Aluminium
- Antimony
- Arsenic
- Barium
- Beryllium
- Boron
- Bromine
- Cadmium
- Chromium
- Chromium VI
- Cobalt
- Copper
- Fluorine
- Iodine
- Iron
- Lanthanum
- Lead
- Lithium
- Manganese
- Mercury
- Molybdenum
- Nickel
- Selenium
- Silver
- Technetium
- Thallium
- Tin
- Titanium
- Tungsten
- Uranium
- Vanadium
- Zinc
- 1,2,3,4-Tetrachlorobenzene
- 1,2,3-Trichlorobenzene
- 1,2,4-Trichlorobenzene
- 1,2-Dichloropropane
- 1,4-Dichlorobenzene
- 2,3,4,5-Tetrachlorophenol
- 2,3,5,6-Tetrachloroaniline
- 2,4,5-Trichloroaniline
- 2,4,5-Trichlorophenol
- 2,4,6-Trichlorophenol
- 2,4-Dichloroaniline
- 2,4-Dinitrophenol
- 3,4-Dichloroaniline
- 3,4-Dichlorophenol
- 3-Chlorophenol
- 3-chloroaniline
- 4-Nitrophenol
- Acenaphthene
- Acrylonitrile
- Biphenyl
- Carbon tetrachloride
- Chloroacetamide
- Chlorobenzene
- Dibutyl phthalate
- Diethyl phthalate
- Dimethyl phthalate
- Fluorene
- Formaldehyde
- Furan
- Hexachlorobenzene
- Hexachlorocyclopentadiene
- Mercury (methyl)
- N-Nitrosodiphenylamine
- Nitrobenzene
- PCB-1254
- PCBs (total)
- Pentachloroaniline
- Pentachlorobenzene
- Pentachlorophenol
- Phenol
- Styrene
- Toluene
- cis-1,4-Dichloro-2-butene
- trans-1,4-dichloro-2-butene

European Existing Substances Regulations priority list

This is the 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. European Chemicals Bureau. European Commission Joint Research Centre EUR 20418 EN/2.

- (3-chloro-2-hydropropyl) trimethylammonium chloride
- (Z)-octadec-9-enylamine
- 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one
- 1,2,4-trichlorobenzene
- 1,2-benzenedicarboxylic acid, di-C8-C10- branched alkyl esters, C9-rich
- 1,2-benzenedicarboxylic acid, di-C9-C11- branched alkyl esters, C10-rich
- 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran
- 1,4-diclorobenzene
- 1,4-dioxane
- 1-methoxypropan-2-ol
- 1-vinyl-2-pyrrolidone
- 2-(2-butoxyethoxy)ethanol
- 2-(2-methoxyethoxy)ethanol
- 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA)
- 2,2-bis(chloromethyl)trimethylene bis(bis(2-chloroethyl)phosphate)
- 2,3-epoxypropyltrimethylammonium chloride
- 2,4,4-trimethylpentene
- 2,4-dinitrotoluene
- 2-butoxyethanol
- 2-butoxyethyl acetate
- 2-ethoxyethanol
- 2-ethoxyethyl acetate
- 2-ethylhexyl acrylate
- 2-furaldehyde
- 2-methoxy-1-methylethyl acetate
- 2-methoxy-2-methylbutane
- 2-methoxyethyl acetate
- 2-nitrotoluene
- 3,4-dichloroaniline
- 4,4'-isopropylidenediphenol (bisphenol-A)
- 4,4'-methylenedianiline
- 4-chloro-o-cresol
- 4-methyl-m-phenylenediamine
- 4'-tert-butyl-2',6'-dimethy-3',5'-dinitroacetophenone (musk ketone)
- 4-tert-butylbenzoic acid
- 4-tert-butylphenol
- 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)
- acetonitrile
- acrylaldehyde
- acrylamide
- acrylic acid
- acrylonitrile
- alkanes, C10-13, chloro (SCCPs)
- alkanes, C14-17, chloro (MCCPs)
- aluminium fluoride
- amines, coco alkyl
- amines, hydrogenated tallow alkyl
- amines, tallow alkyl
- ammonium dichromate
- aniline
- anthracene
- benzene
- benzene, C10-13 -alkyl derivs.
- benzyl butyl phthalate
- bis(2-ethylhexyl) phthalate
- bis(hydroxylammonium) sulphate
- bis(pentabromophenyl)ether
- boric acid
- boric acid, crude natural
- but-2-yne-1,4-diol
- buta-1,3-diene
- cadmium
- cadmium oxide
- calcium fluoride
- chlorine
- chloroacetic acid
- chlorodifluoromethane
- chloroform
- chromium trioxide
- cumene
- cyclohexane
- di-"isodecyl" phthalate
- di-"isononyl" phthalate
- diantimony trioxide
- dibutyl phthalate
- dimethydioctadecylammonium chloride
- dimethyl sulphate
- dioctyl phthalate
- diphenyl ether, octabromo derivative
- diphenyl ether, pentabromo derivative
- diphenylamine
- disodium tetraborate, anhydrous
- distllates (coal tar)
- editic acid
- ethyl acetoacetate
- ethylbenzene
- hexabromocyclododecane
- hexachlorocyclopentadiene
- hydrogen fluoride
- hydrogen peroxide

European Existing Substances Regulations priority list (contd.)

- LCCPs
- methacrylic acid
- methenamine
- methyl acetate
- methyl methacrylate
- methylenediphenyl diisocyanate
- methyloxirane
- naphthalene
- N-cyclohexylbenzothiazole-2-sulphenamide
- nickel
- nickel carbonate
- nickel dichloride
- nickel dinitrate
- nickel sulphate
- nitrobenzene
- nonylphenol
- o-anisidine
- octadecylamine
- pentane
- pentanol
- perboric acid, sodium salt
- phenol
- phenol, 4-nonyl-, branched
- piperazine
- pitch, coal tar, high-temp.
- potassium dichromate
- propan-1-ol
- sodium chromate
- sodium dichromate
- sodium hydroxide
- sodium hypochlorite
- styrene
- tert-butyl hydroperoxide
- tert-butyl methyl ether
- tetrachloroethylene
- tetrasodium ethylenediaminetetraacetate
- toluene
- trichloroethylene
- tris(2-chloro-1-methylethyl) phosphate
- tris(2-chloroethyl) phosphate
- tris(nonylphenol) phosphite
- tris[2-chloro-1-(chloromethyl)ethyl] phosphate
- trisodium hexafluoroaluminate
- trisodium hexafluoroaluminate
- trisodium nitrilotriacetate
- trizinc bis(orthophosphate)
- vinyl acetate
- zinc
- zinc chloride
- zinc distearate
- zinc oxide
- zinc sulphate

ABBREVIATIONS AND THEIR MEANING

Abbreviation	Meaning
BCF	Bioconcentration factor
CCME	Canadian Council of Ministers for the Environment
COPC or COPEC	Contaminants of potential [environmental] concern
CSTEE	Scientific committee on toxicity, ecotoxicity and the environment (European Commission)
Defra	Department of the Environment, Food and Rural Affairs
EC50 or ECx	50 or x percent effect concentration
EQS	Environmental quality standard
ERA	Ecological risk assessment
ERL	Environmental risk limit
ER-L	Effects-range low
EC TGD	European Commission Technical Guidance Document
EqP	Equilibrium partitioning method
FAME	Factorial application method
HI	Hazard index
ICRCL	Interdepartmental Committee on the Redevelopment of Contaminated Land
ISO	International Organisation for Standardisation
LC50 or LCx	50 or x percent lethal concentration
LOD	Limit of detection
LOEC	Lowest observable effect concentration
MATC	Maximum allowable threshold concentration
MPC	Maximum permissible concentration
NAW	National Assembly of Wales
NOEC	No observable effect concentration
OECD	Organisation for Economic Cooperation and Development
ORNL	Oak Ridge National Laboratory
Part IIA EPA 1990	Part IIA Environmental Protection Act 1990
PEC	Predicted exposure concentration
PNEC	Predicted no effect concentration
QSAR	Quantitative structure activity relationship
RIVM	National Institute of Public Health and the Environment (Netherlands)
SNIFFER	Scotland & Northern Ireland Forum for Environmental Research
SOILPACS	Soil invertebrate prediction and classification system
SQC	Soil quality guideline (relates to CCME)
SSD	Species sensitivity distribution
UK BAP	United Kingdom biodiversity action plan
US DOE	United States Department of Energy
US EPA	Untied States Environmental Protection Agency
VROM	National Institute of Public Health and the Environment

GLOSSARY

Acute effect	One having a sudden onset or lasting a short time. Often associated with lethal responses.
Acute test	A comparative study in which organisms, that are subjected to different treatments, are observed for a short period usually not constituting a substantial portion of their life span.
Adverse effect	An impairment of biological functions or description of ecological processes that results in unfavourable changes in an ecological system.
Benchmark value	A benchmark value or concentration is the concentration of chemical in ambient media that is believed to represent an acceptable concentration with respect to a selected ecological receptor.
Bioaccumulation	Net uptake of a chemical into the tissues of an organism as a result of direct contact with a medium, such as soil or through the diet.
Bioassay	A test in which the toxicity of a contaminant or environmental sample is measured by exposing a specific organism and measuring a life-cycle (e.g. survival, reproduction, development, growth) parameter.
Bioavailability	The degree to which a chemical can be taken into the tissues of an exposed organism.
Bioconcentration factor	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.
Chronic	Characterised by a time period that represents a substantial portion of a life span of an organism (e.g., chronic toxicity is the characteristic of a chemical to produce a toxic response when an organism is exposed over a long period of time).
Community	Interacting populations of species (plants or animals) living in the same habitat.
Concentration	The amount of a chemical substance expressed relative to the amount of environmental medium (e.g. ug/g micrograms of chemical per gram of soil).
Consumer	An organism that consumes another organism as food as a mean of energy.
Decomposer	Organisms that feed on dead plant and animal matter, breaking it down physically and chemically and recycling elements and organic compounds to the environment, and which include chiefly microorganisms and small animals.

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, toxicity values are derived that are used in the risk characterisation step to estimate the likelihood of adverse effects occurring in humans at different exposure levels.
ECx	A statistically or graphically estimated concentration that is expected to cause one or more specified effects in x% (e.g. 50%) 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.
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 (*see* measurement endpoint and assessment endpoint).
Exposure	Contact between a human or ecological receptor and a chemical in the environment.
Exposure assessment	The portion of the risk assessment that describes the frequency, magnitude and duration of exposure of human or ecological receptors to contaminants of concern.
Intervention value	A value or soil concentration representing the lower limit of an unacceptable soil quality. Specifically, the concentration of a contaminant in soil at which some remedial action is warranted.
LC_{50}	A statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions.
Lethal Concentration (LCx)	The concentration of a substance at which a lethal effect of magnitude x occurs. The x is usually 50% of the exposed population, in which case EC_{50} is known as the median lethal concentration.
Life stage	A developmental stage of an organism (e.g., juvenile, adult, egg, pupa, larva).
LOAEL	Lowest Observed Adverse Effect Level. The lowest concentration or dose at which significant adverse effects were observed in experimental trials. Also referred to as LOEL.

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.
Measurement endpoint	The phenomenon measured in a toxicity test (e.g., survival, growth or reproduction) that is subsequently related to an assessment endpoint by a risk assessor.
Medium (plural: media)	The substance in which a chemical may exist, such as air, soil, sediments, and water.
Mineralisation	The process of the breakdown of complex compounds containing the element of interest (e.g. Carbon and Nitrogen) enabling the release of this element to the rest of the soil community. Usually carried out by microorganisms, this is a fundamental process in healthy soils.
NOAEL	No-Observed-Adverse-Effect Level. The highest concentration or dose at which no significant adverse, such as growth or reproduction, effects were observed in experimental trials.
NOEC	No Observed Effect Concentration. The highest concentration at which no significant adverse effects such as growth or reproduction, were observed in test organisms. NEL, NOAEL, NEC and NOEC are essentially equivalent terms, where the 'L' refers to Level and relates to the exposure dose rather than exposure concentration.
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.
Producer	Any organism capable of creating organic materials which can be used by other members of the environment by feeding on the producer.
QSAR	Quantitative Structure Activity Relationship. Technique for relating the structure of chemicals to their toxicological properties.
Receptor	The organism, population, or community that might be affected by exposure to a contaminant of concern.
Reference area	An area that has similar physical characteristics to a site being evaluated, but is unaffected by contaminants of concern. The reference area is compared to the site to assess the effects of contaminants of concern.

Reference toxicant	A chemical used as a positive control in a bioassay or toxicity test to demonstrate that biological effects can be measured consistently in the test.
Risk assessment	An assessment of the probability of a hazard being realised.
Screening level	A process or criterion that separates sites that are deemed to represent no apparent risk from those for which further analysis is desirable. Screening criteria are usually based upon conservative assumptions in order to be generally protective.
Soil	Upper layer of earth's crust, composed of minerals, organic substances, water, air and living matter.
Sublethal	Effects at concentrations below those that cause death. Thus a Sublethal test focuses on endpoints other than mortality.
Terrestrial	Living or growing on land.
Threshold	The chemical concentration (or dose) at which physical or biological effects begin to be produced.
Toxicity assessment	The stage of a risk assessment that describes the potential effects of a chemical on organisms and the quantitative exposure-response relationship.