Environment Agency

Evidence

# Derivation and use of soil screening values for assessing ecological risks

## Report – ShARE id26 (revised)

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**Revised Edition:**
This updated report corrects the evaluations for polychlorinated alkanes (medium chain-length), hexachlorobenzene, perfluorooctanoic acid, perfluorooctane sulphonate, and triclosan.

# Evidence at the Environment Agency

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Professor Doug Wilson
**Director, Research, Analysis and Evaluation**

# Executive summary

Recovery of waste and waste-derived materials to land is an important source of nutrients and soil improvers, reducing costs to both industry and land managers, while improving resource efficiency. Wherever possible, waste should be recognised as a resource, only being sent to landfill as a last resort. However, it is also important to ensure that the landspreading of waste-derived materials does not lead to unacceptable risks to human health, crops and livestock, and the wider environment.

The Environment Agency in England regulates the recovery of wastes to land under the Environmental Permitting Regulations 2010. These regulations ensure that potential agronomic and economic benefits are balanced against the broader health and environmental risks. Working together with the Irish Environmental Protection Agency, Natural Resources Wales, the Northern Ireland Environment Agency and the Scottish Environment Protection Agency through the Shared Agency Regulatory Evidence (ShARE) programme, the Environment Agency identified a need to further develop simple assessment criteria to help the technical review of the suitability of wastes and waste-derived materials for spreading on agricultural land. Such tools are commonly used in policy and regulation to screen out low risk activities to protect health and the wider environment.

Soil screening values (SSVs) were first proposed by the Environment Agency as part of a broader framework for ecological risk assessment (ERA) for historical soil contamination. SSVs were defined as:

> '... concentrations of chemical substances found in soils below which there [were] not expected to be any adverse effects on wildlife such as birds, mammals, plants and soil invertebrates, or on the microbial functioning of soils.'

SSVs are levels of chemicals in soil below which there is unlikely to be any risk to its health and functions.

This report adapts SSVs for use in a different purpose, setting out their use in the technical assessment of the recovery of waste and waste-derived materials to land. It updates their scientific basis, taking into account recent developments in international methods on assessing and characterising the terrestrial ecotoxicity of chemicals published by the European Chemicals Agency. It expands the coverage of chemicals for which an SSV is proposed to include a wider range of common trace elements and persistent organic pollutants that are relevant to wastes applied to land. SSVs cannot and should not be compared directly with the levels of chemicals in a waste or waste-derived material.

For this report, individual dossiers were prepared on the assessment of the direct terrestrial ecotoxicity and secondary poisoning of 38 chemical substances and mixtures (consisting of 23 trace elements and 15 organic pollutants). SSVs are recommended for 9 trace elements and 10 organic pollutants.

# Contents

# 1 Introduction

The recovery of waste and waste-derived materials to land is an important source of nutrients and soil improvers, reducing costs to both industry and land managers, while improving resource efficiency. Wherever possible, waste should be recognised as a resource, only being sent to landfill as a last resort. However, it is also important to ensure that the landspreading of waste-derived materials does not lead to unacceptable risks to human health, crops and livestock, and the wider environment.

The Environment Agency in England regulates the recovery of wastes to land under the Environmental Permitting Regulations 2010.[1] These regulations ensure that potential agronomic and economic benefits are balanced against the broader health and environmental risks (Environment Agency 2013). Working together with the Irish Environmental Protection Agency, Natural Resources Wales, the Northern Ireland Environment Agency and the Scottish Environment Protection Agency through the Shared Agency Regulatory Evidence (ShARE) programme, the Environment Agency identified a need to further develop simple assessment criteria to help the technical review of the suitability of wastes and waste-derived materials for spreading on agricultural land. Such tools are commonly used in policy and regulation to screen out low risk activities to protect health and the wider environment (Defra and Cranfield University 2011).

Healthy soils are vital to a sustainable environment (Environment Agency 2006a). They store carbon, produce food and timber, filter water, and support wildlife and landscapes. Soil quality depends on a number of complex and interacting factors including its structure, mineralogy, pH, organic matter and nutrient content, and the presence of diverse and abundant communities of micro- and macrofauna (Brady and Weil 1996, Kibblewhite et al. 2008, Defra 2012a). Recovery of waste and waste-derived materials to land can improve many of the beneficial aspects of soil such as structure, nutrient and organic matter content, and pH. However, they can also introduce or increase levels of chemicals in soil that may alter the physical properties and chemistry of soil, and affect the numbers, diversity and function of organisms.

Soil screening values (SSVs) were first proposed by the Environment Agency as part of a broader framework for ecological risk assessment (ERA) for historical soil contamination (Environment Agency 2008a).[2] This report adapts SSVs for use in a different purpose, setting out their use in the technical assessment of the recovery of waste and waste-derived materials to land. It updates their scientific basis, taking into account recent developments in international methods on assessing and characterising the terrestrial ecotoxicity of chemicals (ECHA 2008). It expands the coverage of chemicals for which an SSV is proposed to include a wider range of common trace elements and persistent organic pollutants that are relevant to wastes applied to land.

[1] Similar legislation exists in Ireland, Northern Ireland, Scotland and Wales, and is regulated in these countries by the appropriate regulatory body.

[2] The ERA framework is a tiered approach designed to be efficient in excluding sites with no potential to cause harm to ecosystems, while also gathering sufficient evidence for harm or the possibility of harm at sites where risk management may be required. An introduction to the framework can be found in ‘An ecological risk assessment framework for contaminants in soil’ (Environment Agency 2008a).

## 1.1 What are SSVs?

'Guidance on the use of soil screening values in ecological risk assessment' (Environment Agency 2008b) defined an SSV as:

> '... concentrations of chemical substances found in soils below which there [were] not expected to be any adverse effects on wildlife such as birds, mammals, plants and soil invertebrates, or on the microbial functioning of soils.'

This definition is still valid and is adopted throughout this report.

SSVs are 'trigger values' that can be used to simplify the initial assessment of risks to soil ecology and wildlife arising from the long-term presence of chemicals. In some circumstances, they can be used as part of a tiered ecological framework for the assessment and evaluation of risks to soil organisms and wildlife (see Section 4).

SSVs do not represent maximum permissible limits for chemicals in soil. They are indicators to an assessor that soil concentrations above this level may pose an unacceptable risk to soil health and dependant wildlife. The likelihood of an increased risk may depend on:

- the margin of exceedance
- the uncertainty in ecotoxicity data on direct toxicity and secondary poisoning
- the uncertainty in the measurement or estimate of the chemical level in soil including the natural variability of chemical concentration and soil properties
- the specifics of a soil ecosystem and the importance of its different soil functions (for example, a soil used for growing crops has different requirements from a soil used to restore land for recreational use)
- other site-specific factors such as organic matter content, soil texture and pH

## 1.2 Drivers for using SSVs

SSVs were originally developed to support the identification of land affected by historical soil contamination under Part 2A of the Environmental Protection Act 1990 (Environment Agency 2008a, 2008b).[3] While the updated SSVs presented in this report are still broadly relevant for this purpose, the drivers for their revision is the application of waste and waste-derived materials to land for agricultural and horticultural benefit, and site restoration. More detailed advice on the practical use of SSVs is provided in Section 4.

### 1.2.1 Environmental permitting

Many activities involving the recovery of waste to land for agricultural and horticultural benefit or site restoration are subject in England to standard rules under the

[3] Part 2A of the Environmental Protection Act 1990 places a duty on regulators to find and deal with unacceptable risks posed by historical land contamination (Defra 2012b). Specific ecological sites and species are protected under the Part 2A regime (for example, Sites of Special Scientific Interest, national and marine nature reserves, and areas for the special protection of birds).

Environmental Permitting Regulations 2010 (Environment Agency 2013).[4] These regulations transpose into English law a number of European Union Directives including the Integrated Pollution Prevention and Control (IPPC) Directive (2008/1/EC), the Waste Framework Directive (2008/98/EC), the Water Framework Directive (2000/60/EC) and the Groundwater Daughter Directive (2006/118/EC). They also implement government policies designed to protect people and the environment, and partially fulfil the environmental protection requirements contained in other legislation such as the Habitats Directive.

In setting standards for environmental protection within permits, the Environment Agency uses as a basis 2 common themes.

- Pollution must be prevented, including specifically meeting health and environmental quality standards.
- Going beyond meeting environmental quality standards is sometimes required, but this tends to be balanced by the need to compare costs with benefits.

In permitting waste management activities, including its recovery to land, the main requirements of the Waste Framework Directive must be met. These are the 'relevant objectives' set out in Article 13, which provide that waste management should be performed:

> '... without endangering human health and without harming the environment and in particular without:
>
> (i) risk to water, air, soil, plants or animals; or
>
> (ii) causing nuisance through noise or odours; or
>
> (iii) adversely affecting the countryside or places of special interest.'

Standard rules or bespoke mobile permits can be issued in England for landspreading for agricultural and horticultural improvement of soils and for site reclamation and restoration (Environment Agency 2013). Before spreading any waste on an area of land, the operator is required to submit a deployment form to the Environment Agency before the activity commences. Each deployment application is reviewed by the regulator to ensure that:

- any proposed landspreading is for recovery and not disposal in accordance with the requirements of the permit
- the relevant objectives in Article 13 will be met on a site-specific basis

SSVs may be used by the Environment Agency to identify and screen out low risk deployments from the need for further site-specific assessment and justification. Evidence presented with the deployment form will be used to compare the final chemical concentrations in soil[5] with the relevant SSV. In most circumstances, if the predicted soil concentrations are at or below the relevant SSV then the chemical pollution risks to soil and wildlife from the proposed activity will be low and acceptable. However, where the final soil level exceeds the SSV, it will be necessary for the applicant to provide further case-specific evidence to reassure the Environment Agency that no unacceptable impacts on soils remain.

SSVs alone should not be used to assess the acceptability of any landspreading activity as it also necessary to take into account the benefits of recovery and other

[4] Other similar legislation applies in Ireland, Northern Ireland, Scotland and Wales.

[5] Levels estimated in soil **after** application of waste to land (see Section 4).

factors (including background soil levels) and receptors that may be affected (such as human health and controlled waters). The wider requirements on how to comply with a landspreading permit are set out in 'How to comply with your landspreading permit' (Environment Agency 2013) and SSVs should be used within the framework and scope of this guidance.

### 1.2.2 End-of-waste

The Waste Framework Directive (2008/98/EC) provides the definition for when a material is a waste and when it ceases to be a waste. Article 6 sets out the criteria that must be met by the end-of-waste test (Defra 2012c, Environment Agency 2014). These are as follows.

- The waste has been converted to a distinct and marketable product.
- The waste-derived product can be used in exactly the same way as a non-waste material.
- The waste-derived product can be stored and use with a 'no worse' environmental effect compared with the non-waste material it is intended to replace.

Environment Agency (2014) presents guidelines on how to conduct an environmental and human health risk assessment to support end-of-waste decisions. Consistent with government guidance (Defra and Cranfield University 2011), these guidelines recommend a tiered approach to the assessment:

- **Risk screening**. This step is concerned with the development of an outline conceptual model and establishing whether there is any potential for unacceptable risks and a need for further assessment based on the presence of chemicals that are hazardous to health or the environment.
- **Generic quantitative risk assessment (GQRA)**. This step uses generic assumptions about sources, pathways and receptors to quantify estimates of emissions to the environment and/or receptor exposures based on a fully developed conceptual model. Assumptions are usually protective of a broad range or reasonable worst case scenario.
- **Detailed quantitative risk assessment (DQRA)**. This step uses more scenario-specific data to refine the generic approach. It generally requires more intensive data collection and interpretation to characterise the sources, pathways and receptors to revise the generic conceptual model. Scenario assumptions may be refined based on measurements and other data to provide a more realistic and specific scenario.

SSVs may be used to demonstrate that the use of waste-derived materials presents a low risk to terrestrial ecology and wildlife from emissions to soil. Evidence presented at the GQRA or DQRA step may be used to compare predicted or measured chemical concentrations in soil[6] with the relevant SSV. Whether the emission scenario is generic or based on a more realistic set of assumptions (using a DQRA approach), the suitability of the SSV remains the same. Only where the DQRA invokes the more detailed methods of ERA, such as through undertaking field trials, may their usefulness be superseded (Environment Agency 2008a).

In most circumstances, if the predicted soil concentrations are at or below the relevant SSV then the chemical pollution risks to soil and wildlife from the proposed use of

[6] Levels estimated in soil **after** application of waste-derived materials to land (see Section 4).

waste-derived materials will be low and acceptable. However, where the final soil level exceeds the SSV, it will be necessary for the applicant to provide further evidence (such as moving from GQRA to DQRA) to reassure the Environment Agency that no unacceptable impacts on soils remain across a broad range of potential scenarios. For most end-of-waste assessments, Environment Agency (2014) concludes that a screening or GQRA approach is likely to be sufficient to determine whether a waste-derived material will satisfy the test.

SSVs alone should not be used to assess the acceptability of a waste-derived material to be used on agricultural land or in site restoration. 'End-of-waste and by-product hazard and risk assessment' (Environment Agency 2014) sets out the wider scope and requirements of an acceptable human health and environmental risk assessment.

## 1.3 About this report

This report explains the derivation of SSVs for a wide range of inorganic and organic chemicals that may be found in wastes to be applied to land for agricultural benefit and site restoration.

It is essential that SSVs are based on clear scientific methods and robust evidence, but they must also take into account the wider context and implications for their use. This is an important element in the derivation of SSVs and, in this report, is highlighted as a distinct step after a review of the scientific evidence.

Section 2 provides a brief commentary on the chemicals selected for study.

Section 3 explains how the data on the terrestrial ecotoxicity have been collected and assessed with the derivation of a Predicted No Effect Concentration (PNEC) for a chemical in soil and an SSV. It is intended to be used in conjunction with the relevant European Chemical Agency (ECHA) guidance (ECHA 2008, 2011, 2012, 2014a). These documents are signposted where appropriate.

Section 4 provides further advice and worked examples on the practical aspects of using SSVs for decisions related to the recovery of wastes and waste-derived materials to land.

Appendix A presents the SSVs for each chemical or trace element along with a short summary of the key data and decision points.

Appendix B presents a worked example of a literature search.

# 2 Selection and prioritisation of chemicals

## 2.1 Approach to selection and prioritisation

Wastes and waste-derived materials contain a wide range of existing and emerging chemicals. There is now a substantial and increasing volume of scientific literature on their terrestrial ecotoxicity. To derive this initial set of SSVs, potential chemicals of concern were prioritised on the basis of the following criteria:

- revision of existing SSVs and other soil limit values
- hazard characterisation
- presence in waste
- availability of data

### 2.1.1 Existing concerns and assessment criteria

Original SSVs were produced for 7 metals and 5 organic chemicals for the assessment of contaminated land (Environment Agency 2008b), although not all are considered a priority for recovery to land.[7] In this project, priority was given to revising these existing guidelines. A further 11 potentially toxic elements were identified in the widely used code of practice on the application of sewage sludge in agriculture (DoE 1996). Priority was also given to extending the range of SSVs to include these common trace elements in wastes and waste-derived materials.[8]

A small number of additional chemicals were also identified based on the operational experience of the environmental regulatory agencies. These experiences are supported by previous risk assessments and analytical exercises undertaken by the Environment Agency (for example, Environment Agency 2009b) and the Scottish Environment Protection Agency (SEPA) (for example, SEPA 2014) on wastes potentially being recovered to land.

### 2.1.2 Hazard characterisation

In discussion with the Environment Agency, the Food Standards Agency (FSA) had identified a range of emerging environmental chemicals of concern to the consumer food chain. This was supplemented by a further limited review of the published scientific and grey literature.

Hazard characterisation and prioritisation was made on the basis of:

- potential risk to human health via diet

[7] For example, toluene and tetrachloroethene are highly mobile and unlikely to persist in agricultural or manufactured soil-like materials.

[8] SSVs are not intended to replace the maximum permissible concentration of potentially toxic elements as set out in Tables 4 and 5 of the Code of Practice (DoE 1996). The limits given in the Code of Practice are based on the protection of crops, livestock and consumer health.

- ecotoxicological concerns
- persistence in soil and the environment

While existing soil guidelines focused mainly on common trace elements, a number of persistent organic pollutants are of increasing concern (Clarke and Smith 2011, EFSA 2012, FSA 2012, FSA 2013). Many of these compounds are found in wastes and waste-derived materials and pose a risk to human health via the food chain and to soil terrestrial ecology and wildlife (Environment Agency 2009c, Clarke and Smith 2011, Eggen et al. 2013, SEPA 2014, Suominen et al. 2014, Environment Agency 2015).

### 2.1.3 Presence in waste

In combination with the hazard characterisation, priority was given to those chemicals most likely to be found in wastes and waste-derived materials recovered to land. The materials covered by the limited literature review included sewage sludge, composts and compost-like outputs, anaerobic digestates, municipal solid wastes, ashes, minerals and animal manures (Brandli et al. 2007a, Brandli et al. 2007b, Environment Agency 2009c, Gawlik 2012, Jones et al. 2014, JRC 2014, SEPA 2014, Suominen et al. 2014, Umwelt Bundesamt 2015).

### 2.1.4 Availability of terrestrial ecological data

Although there are considerable amounts of data on the terrestrial ecotoxicity of a wide range of chemicals, studies on emerging chemicals of concern are likely to be more limited. An initial scoping review was carried out for a range of persistent organic pollutants to identify those substances where data were likely to be sparse or non-existent (Environment Agency 2015). Where data gaps were identified, the chemical was assigned a lower priority for derivation of an SSV at this time.

## 2.2 Prioritised chemicals

Taking into account the factors identified above, an initial list of 46 chemical substances and mixtures was compiled for review (Table 2.1). The list includes a large number of heavy metals and other inorganic substances such as fluorine and iodine as well as emerging organic chemicals including pesticides, flame retardants, personal care products, pharmaceuticals and veterinary medicines.

Detailed reviews of 38 chemical substances and mixtures were conducted using the method described in Section 3. SSVs are recommended for 19 (see Section 4).

It was not possible to derive an SSV for all the chemicals listed in Table 2.1 because of:

- constraints on the project meant not all substances were reviewed
- limitations in the available data for each substance meant it was not possible to derive a robust and scientifically defensible PNEC
- other practical considerations that meant an SSV could not be recommended from the PNEC

**Table 2.1 List of chemicals prioritised for review of their soil ecotoxicity**

| Trace elements | Persistent organic pollutants |
|---|---|
| Aluminium (Al) | Benzo[a]pyrene[1] |
| Antimony (Sb) | Decabromodiphenyl ethane (DPDPE)[4] |
| Arsenic (As)[2] | Bis(2-ethylhexyl) phthalate (DEHP) |
| Barium (Ba) | Galaxolide (HHCB)[5] |
| Beryllium (Be) | Hexabromocyclododecane (HBCDD)[4] |
| Boron (B) | Hexachlorobenzene (HCB)[3,7] |
| Cadmium (Cd)[1,2] | Pentachlorobenzene[1,3] |
| Chromium (Cr)[1,2] | Pentachlorophenol (PCP)[1,7] |
| Cobalt (Co) | Perfluorooctanoic acid (PFOA)[5] |
| Copper (Cu)[1,2] | Perfluorooctane sulfonate (PFOS)[3,5] |
| Fluorine (F)[2] | Polybrominated diphenyl ethers (PBDE)[3,4] |
| Iodine (I) | Polybrominated dioxins and furans |
| Lead (Pb)[1,2] | Polychlorinated alkanes (short and medium chain length compounds) |
| Lithium (Li) | Polychlorinated biphenyls (PCBs)[3] |
| Mercury (Hg)[1,2] | Polychlorinated dioxins and furans (PCDDs/PCDFs)[3] |
| Molybdenum (Mo)[2] | Tonalide (AHTN)[5] |
| Nickel (Ni)[1,2] | Tributyl tin oxide[7] |
| Selenium (Se)[2] | Triclosan[5] |
| Silver (Ag) | Trimethoprim (TMP)[6] |
| Strontium (Sr) | Triphenyl tin oxide[7] |
| Thallium (Tl) | Tris(2-chloroethyl) phosphate (TCEP)[4] |
| Titanium (Ti) | Tris(2-chloro-1-methylethyl) phosphate (TCPP)[4] |
| Vanadium (V) | |
| Zinc (Zn)[1,2] | |

Notes: Not all substances were found to have sufficient and reliable data on which to derive a PNEC or to have sufficient regulatory certainty to recommend an SSV.
[1] Existing SSV recommended in Environment Agency (2008b)
[2] Potentially toxic elements identified in the 'Code of practice for agriculture use of sewage sludge' (DoE 1996)
[3] Persistent organic pollutants as listed under the Stockholm Convention
[4] Chemical used as a flame retardant
[5] Chemical used in personal care products
[6] Chemical used in veterinary and human medicines
[7] Chemical used as a pesticide

# 3 Methods of deriving SSVs

The description of the derivation of SSVs given in this section should be used in conjunction with the relevant ECHA guidance (ECHA 2008, 2011, 2012, 2014a). To assist the reader, this guidance is directly quoted or signposted[9] in the accompanying text so that the relevant documents can be more easily used together.

Soil ecotoxicology from chemical exposure and the interpretation of data from experimental studies is a specialist technical subject. Section 3.1 provides a brief introduction for those unfamiliar with the key concepts. However, while this report is supported by an extensive glossary, it is not intended to be used by non-specialists as an instruction manual for deriving SSVs.

## 3.1 Introduction

Ecotoxicology studies the effects of chemicals on organisms in the environment, with the aim of protecting the structure and functioning of ecosystems (van Gestel 2012). This aim is generally achieved by assessing effects on one or more single species of selected test organisms and trying to extrapolate the obtained (no) effect concentrations to 'safe levels' for the populations and communities that make up the wider ecosystem. In ecotoxicological risk assessment of chemicals, these 'safe levels' are then compared with predicted or measured exposure levels to assess the possible risk for an exposed ecosystem.

Soil ecotoxicology studies the effects of chemicals on the most important organisms in the soil environment such as bacteria, fungi, plants and invertebrates (for example, earthworms). Dating back to the 1960s, the first studies on soil ecotoxicology reported on the negative effects of pesticides on soil invertebrates (van Gestel 2012). While the available data on terrestrial organisms are generally more limited than for aquatic organisms, the number and range of studies has increased in recent years through the need to understand the environmental impact of existing and new chemicals (ECHA 2008, 2011, 2012, 2014a). Two approaches can be broadly distinguished (van Gestel 2012):

- a predictive approach that uses laboratory tests under standardised conditions to obtain toxicity data for targeted organisms and adverse effects to derive (no) effect levels
- a diagnostic approach that uses field studies to observe actual impacts on specific soil organisms and overall soil function and quality[10]

The predictive approach assumes that the risk of a chemical to soil ecosystems can be estimated from its toxicity to a number of surrogate test or indicator species exposed in standard laboratory tests (van Gestel 2012). Many of these tests are covered by international standards (OECD 1984, 2000, 2004) and express their results in terms of

[9] Relevant sections in the ECHA documents are given in the format 'R (section number) in (reference)'.

[10] Understanding the effects of chemicals on soil quality and function through observation has also been used with an increasing interest in chemical mixtures (van Gestel 2012). The long-term sludge trials sponsored by Defra are an example of the diagnostic approach (UK WIR 2007). These data are also used to support the predictive approach as weight of evidence for deciding on the assessment factor.

a dose–response relationship for selected endpoints such as mortality, growth and reproduction (ECHA 2008).[11] Toxicity is quantified by parameters such as:

- $LC_{10}$ and $LC_{50}$ (the concentrations killing 10% and 50% of the exposed test organisms, respectively)
- $EC_{10}$ and $EC_{50}$ (the concentrations causing 10% and 50% reduction in endpoints such as growth or number of offspring)
- NOEC and LOEC (no observable and lowest observable adverse effect concentration, respectively)

$LC_{50}$ and $EC_{50}$ values are usually obtained from short duration or acute toxicity tests, while $LC_{10}$, $EC_{10}$, NOEC and LOEC values are most frequently obtained from longer term tests. It is data from these studies that are primarily used in the derivation of SSVs.

Since there is no 'most sensitive species', a battery of tests is needed to obtain proper insight into the potential hazard of a chemical for the soil ecosystem (van Gestel 2012). R.10.6 in ECHA (2008) recommends that toxicity test data for soil organisms should preferably be representative of primary producers (such as plants), consumers (such as earthworms) and decomposers (as representative of microbial functions such as nitrification). Results on one or more specific organisms are extrapolated to predict the effect of a chemical on the wider ecosystem. It is assumed that, if there is enough information about the adverse effects of a chemical on the different parts of the ecosystem, the evidence can be assembled to predict the adverse effects on the whole community. However, it is essential to account for the difficulty and uncertainty in making such extrapolations in any subsequent assessment. In some circumstances, more complex multispecies tests may be used such as microcosms and mesocosms, or the diagnostic approach may be preferred.

In addition to their direct adverse effect on soil organisms, some chemicals can persist in the environment, accumulating in organisms over time and magnifying through the food chain. For example, persistent chemicals in soil may build up in earthworms which are then subsequently eaten by birds or mammals (R.16.6.7.2 in ECHA 2012). These animals at the end of the food chain may therefore be exposed to harmful levels of chemicals – an effect termed secondary poisoning. In some instances, secondary poisoning may be more significant than the direct action of the chemical on soil organisms. It may also be used in the derivation of SSVs.

## 3.2 General approach

SSVs are primarily derived from soil ecotoxicity data using the predictive approach. As explained above, this approach uses dose–response data for a range of key soil organisms to extrapolate to the potential impact of a chemical on the wider soil ecosystem. Figure 3.1 presents the 4 generalised steps in this approach, which are described in detail in Sections 3.3 to 3.8.

Steps 1 to 5 follow the standard technical approach to assessing terrestrial ecotoxicity recommended by ECHA (ECHA 2008, 2011, 2012, 2014a) to support the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No

[11] In recent years, there has been a move away from the use of mortality as an endpoint towards other adverse effects including biochemical and physiological effects such as enzyme synthesis or microbial respiration.

1907/2006 introduced in Europe in 2007.[12] The outcome at Step 4 is a PNEC in soil, which marks the environmental concentration below which no adverse ecotoxicological effects of exposure on soil organisms, ecosystems and function are expected.

Where a chemical is shown to be toxic to soil organisms and to bioaccumulate through the food chain, 2 PNEC values are possible. One applies to the direct toxicity of the chemical to soil organisms ($PNEC_{dt}$) and the other to secondary poisoning of birds and mammals ($PNEC_{sp}$). The final PNEC is the lower of the $PNEC_{dt}$ and $PNEC_{sp}$ values.[13]

Technical assessment of the data used to derive the PNEC is based on REACH guidance (ECHA 2008, 2011, 2012, 2014a) and from methods proposed by the Human and Veterinary Medicines Directives (VICH 2005, EMEA 2008). Data selection, screening for reliability and relevancy and extrapolation methods are all taken from the relevant ECHA guidance documents (for example, R.7.11 in ECHA 2014a). The explanation used in subsequent sections of this report should be used in conjunction with the more detailed guidance contained in these reports.

Step 5 introduces a formal decision point between the scientifically based PNEC and the proposed SSV. Not all PNECs are created equal, and their technical reliability and robustness will vary from chemical to chemical due to the size and quality of the available test data. Therefore, it cannot automatically be assumed that a PNEC will be a suitable candidate for regulatory decision-making. This step gives guidelines when making the judgement on whether there is sufficient regulatory confidence in the underlying data to recommend an SSV from a PNEC.

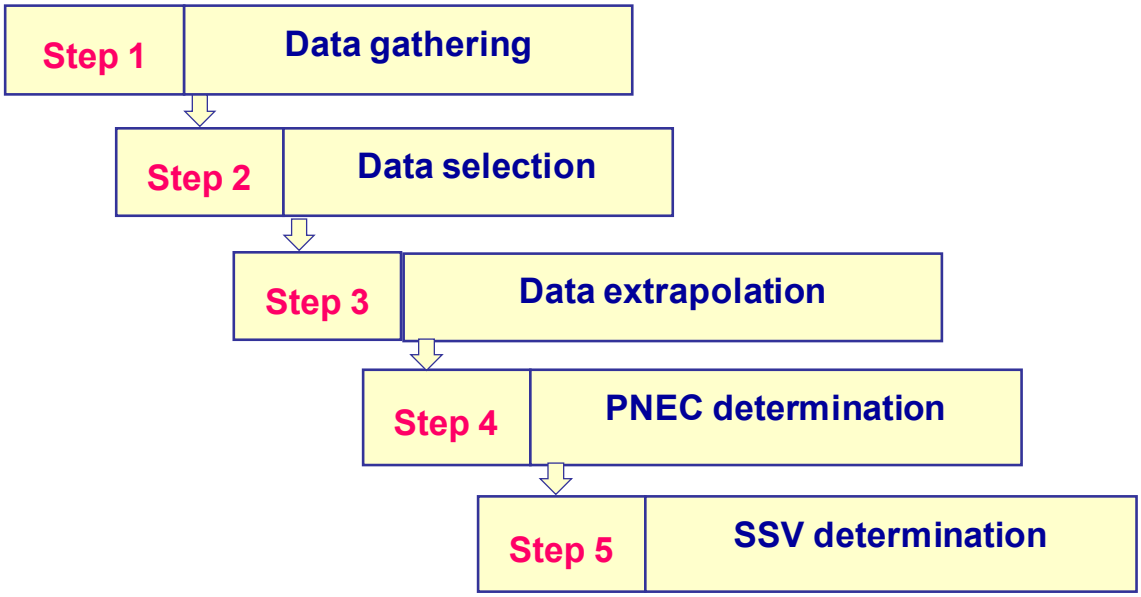


**Figure 3.1 Schematic showing the generalised steps in derivation of an SSV**

[12] 'Guidance on the use of soil screening values in ecological risk assessment' (Environment Agency 2008b) followed the older, and now superseded, technical guidance document on risk assessment (European Commission 2003) for the Existing Substances Regulation (EEC) No 793/93.

[13] Subscripts 'dt' for direct toxicity and 'sp' for secondary poisoning are used in this report to distinguish between the different PNEC values, but they are not used in the ECHA guidance.

## 3.3 Data gathering

Ecotoxicity test data for the most important soil organisms are available in the open and grey literature for a wide range of inorganic and organic chemicals. A relatively new and important source of terrestrial ecotoxicology data is the ECHA dissemination portal,[14,15] which provides summary dossiers of effects data for specific chemicals under REACH. However, only a limited number of the dossiers available from the portal have received regulatory review and they are not always complete. It is therefore necessary to use specialist expertise to carefully interpret the data. Chemicals may also be presented individually or within groups; if the latter is the case, it may not be easy to extract the data for a single substance without access to documentation outside the dissemination portal (such as the Chemical Safety Report and study reports).

Other regulatory jurisdictions in the USA, Canada, Australia and the Netherlands can also be reviewed for terrestrial assessment criteria (and the supporting effects data) used in national assessments, as these are often derived/performed to similar methods as those in the UK and Europe. For both Canada and the USA, however, soil microbial function data are not considered relevant.

Alongside test data on the direct toxicity of chemicals to soil organisms and wildlife, it is also important to understand their bioaccumulation and biomagnification potential (R.7.10.8 in ECHA 2014a). This is used to inform understanding of secondary poisoning (see also Sections 3.1 and 3.5.3).

The example search strategy presented in Appendix B illustrates a typical approach and should not be considered exhaustive.

## 3.4 Data selection

Having identified potentially useful soil ecotoxicity data, the next step is to assess them for reliability and relevance. Reliability considers the inherent quality of a test, that is, the way it has been performed and the results described. Relevance considers the extent to which a test is appropriate for PNEC derivation. ECHA guidance is available to make these assessments rapidly and consistently for soils' data (ECHA 2011).

Some testing may not be in the form of standardised test methods. This can often be the case for terrestrial testing where there are relatively few standard methods compared with the aquatic compartment (for example, R.7.11.4.1 in ECHA 2014a). Nevertheless, if these tests are judged to be reliable and relevant then they should be included with appropriate justification provided.

Where necessary, test data may need to be normalised to soil properties to allow direct comparison of collated results (see Section 3.6).

## 3.5 Data extrapolation methods for the PNEC

There are 2 methods for extrapolating from ecotoxicity tests performed with single terrestrial species or for single soil functions (such as nitrification or substrate-induced

[14] http://echa.europa.eu/information-on-chemicals/registered-substances

[15] Data are submitted and owned by the registrant. ECHA has a duty under REACH to make the registrants' data available to the general public in summary form.

respiration) in the laboratory to effects likely to be seen in field soils. These methods are described below and reflect those used within REACH.

Most commonly, the $PNEC_{dt}$ is estimated by division of the lowest (or derived) $EC_{10}$ or NOEC value from the collated soil ecotoxicity data by a relevant assessment factor (AF). AFs are primarily used to account for the uncertainty in extrapolating from the single species laboratory data to the wider soil ecosystem (R.10.2.4 in ECHA 2008). They are established by expert judgement from a review of the available data taking into account the number of species, the quality and number of tests, gaps in data, and other factors such as differences in acute and chronic toxicity. Because they are intended to be conservative, a larger AF is used if there is a greater uncertainty in the available data (for example, data are limited, contradicted and/or of poor quality).

The methodology for deriving the $PNEC_{sp}$ for secondary poisoning is outlined in Section 3.5.3. It is important to consider this in addition to the effects data for direct toxicity ($PNEC_{dt}$) as secondary poisoning may result in a lower PNEC.

### 3.5.1 Deterministic method

As noted above, the $PNEC_{dt}$ is most commonly derived from laboratory test data by using a deterministic AF. It is derived by applying the appropriate AF (Table 3.1) to the lowest reliable and relevant terrestrial effect concentration – usually the lowest NOEC or $EC_x$ dose observed from a critical study. See Equation 3.1.

**Equation 3.1**

$$PNEC_{dt} = \frac{Lowest\ NOEC\ or\ EC_x}{AF}$$

where:

| | |
|---|---|
| $PNEC_{dt}$ | = predicted no effect concentration for directly exposed soil organisms, mg $kg^{-1}$ dry weight (DW) |
| Lowest NOEC or $EC_x$ | = lowest credible datum in critical ecotoxicity study measured in soil across a range of tests and specific organisms, mg $kg^{-1}$ DW |
| AF | = assessment factor, unitless |

The AF reflects the uncertainty in extrapolating from laboratory ecotoxicity test data, often conducted on a single or small range of species, to the wider soil ecosystem (OECD 1992, European Commission 2003). Table 3.1 presents the guidelines recommended by ECHA to support the REACH regulation (Table R.10-10 in ECHA 2008). Where there are few terrestrial or only short-term (acute) effects data, an AF > 50 may need to be used.[16] Other factors determining the size of the AF include the type of data that are available (short-term or long-term toxicity tests) and the number of trophic levels tested across all of the collated data. The relative regulatory uncertainty of deriving a $PNEC_{dt}$ using an AF > 50 is discussed in Section 3.8.

The advantages of the deterministic approach to deriving a $PNEC_{dt}$ are that it is transparent, easy to use and simple to understand. It can be (and usually is) applied to small datasets. Its major drawback is that the choice of AF can be more 'art than

[16] For example, effects data from acute tests attract a larger AF due to greater uncertainty because potential toxic effects have only been assessed over a short part of the organism's lifecycle.

science' and depends on expert judgement and interpretation of the collated data. At the highest levels of uncertainty, the largest AF values can produce an extremely low (and possibly impractical) $PNEC_{dt}$ and subsequently the PNEC.

**Table 3.1 Recommended AFs for the derivation of $PNEC_{dt}$ based on Table R.10-10 in ECHA (2008)**

| Limits of available data | Assessment factor |
|---|---|
| $LC_{50}$ or $EC_{50}$ from short-term ecotoxicity test(s) (for example, plants, earthworms, microorganisms) | 1,000 |
| NOEC for long-term ecotoxicity (for example, plants) from only a single study | 100 |
| NOEC for long-term ecotoxicity from a number of studies that include 2 species at 2 trophic levels | 50 |
| NOEC for long-term ecotoxicity from a number of studies that include at least 3 species at 3 trophic levels | 10 |
| Species sensitivity distribution method (see Section 3.5.2) | 1–5 (fully justified on a case by case basis) |
| Field data or model ecosystem (see Section 3.5.2) | Reviewed on a case by case basis |

### 3.5.2 Probabilistic approach – statistical extrapolation

Where more test data are available for a particular chemical across a range of studies and test organisms, a species sensitivity distribution (SSD) can be derived. An SSD is a statistical distribution of the collated ecotoxicity data. It describes the differences in ecotoxicity of a chemical across a set of species and can be considered to represent a 'weight of evidence' on terrestrial effects data. The species set may comprise species from a particular taxon, a selected species assemblage or a natural community.

The true distribution of ecotoxicity endpoints is not known and so the SSD is estimated from a sample of ecotoxicity data; it is usually presented as a cumulative distribution function (see Figure 3.2) using standard software.[17] The curve follows the distribution of the sensitivity data obtained from ecotoxicity testing and plots the NOEC or $EC_{10}$ derived from chronic terrestrial toxicity tests.

For chemicals with sufficient effects data, SSDs are widely used in the derivation of PNECs for waters, sediments and soils across European regulatory regimes (for example, under the REACH regulation).

17 www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2005/februari/ETX_2_0_A_Program_to_Calculate_Hazardous_Concentrations_and_Fraction_Affected_Based_on_Normally_Distributed_Toxicity_Data

R.10.6.3 in ECHA (2008) provides an outline of what it considers to be sufficient data for the calculation of a PNEC using statistical extrapolation techniques.[18] Minimum data requirements include at least 10 and preferably more than 15 NOEC or LOEC values for different species, covering at least 8 taxonomic groups or soil functions. Where there are multiple data for one species or function, the NOEC or $EC_{10}$ from the most sensitive endpoint should be selected. Where multiple NOEC or $EC_{10}$ values for the **same** endpoint and species exist, the geometric mean of these effect values should be selected for the extrapolation.[19]

Ecotoxicity test results are often obtained using different soils that inevitably have different soil characteristics (such as pH, organic matter and clay content) and these may influence the NOEC or $EC_{10}$, despite being otherwise identical tests on the same soil organism. R.10.6 in ECHA (2008) recommends normalisation of the effects data to account for differences in soil characteristics and chemical bioavailability (see Section 3.6). However where such relationships do not exist between soil characteristics and chemical behaviour or have had limited validation, all the individual data should be used instead of geometric means. This will ensure there is no over-representation of certain species or soil functions.

The collated dataset is fitted to a specific statistical distribution using standard models such as log-logistic or log-normal. The choice of model used should be described in the supporting documentation. For pragmatic reasons, the concentration corresponding to the modelled or extrapolated point on the SSD below which 5% of the species occur (the Hazardous Concentration calculated for 5% of species, or $HC_5$) is used to determine the $PNEC_{dt}$. This should always be accompanied by a percentile confidence interval to illustrate the uncertainty in the calculation.

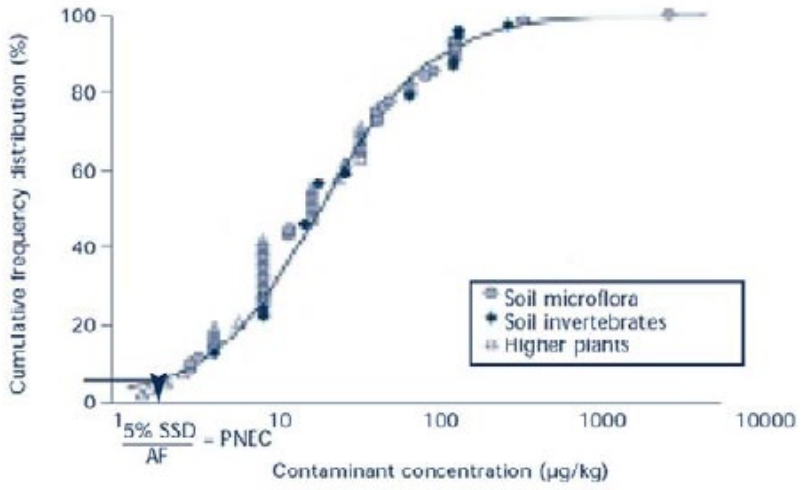


**Figure 3.2 Example of a SSD and estimation of an $HC_5$ for a fictitious chemical (reproduced from Environment Agency 2008b)**

[18] ECHA guidance redirects this discussion to R.10.3.1.3, which is explicit recognition that the terrestrial framework for probabilistic approaches reads across directly from the aquatic framework.

[19] Different laboratory studies may have exposed organisms to varied concentrations of a chemical, resulting in a different NOEC or LOEC at the lowest environmental concentration used.

As shown in Figure 3.2, the $PNEC_{dt}$ is calculated from Equation 3.1 using the $HC_5$ and an AF between 1 and 5 (see Table 3.1). The size of the AF is considered to reflect further uncertainties in the derivation process such as:

- overall quality of the database and number of endpoints covered
- diversity and representation of the taxonomic groups, for example, differences in the life forms, feeding strategies and trophic levels of the organisms represented
- knowledge of presumed modes of action of the chemical
- statistical uncertainties around the $HC_5$
- comparisons between the $HC_5$ and field or mesocosm studies (where available), although these data are not often available for terrestrial effects assessment[20]

### 3.5.3 Secondary poisoning

As noted in Section 3.1, some chemicals through accumulation and biomagnification have the potential to pose a threat to wildlife such as birds and mammals higher up the food chain. This is known as secondary poisoning, which forms the basis of a separate $PNEC_{sp}$.

Uptake of a chemical by a soil-dwelling organism is a complex process determined by the chemical properties, soil characteristics, climate and the biology of the organism (ECHA 2014a). For risk assessment, this complexity tends to be ignored and the process is expressed in terms of simple ratios. Equation 3.2 illustrates the calculation based on soil and earthworm concentrations.[21]

Bioaccumulation can be estimated by a standard earthworm test, but in many cases a reasonable worst case value can be obtained by using estimation methods based on chemical and soil properties (R.7.10.8, R.7.10.9 and R.7.10.10 in ECHA 2014a). For example, the potential for bioaccumulation in many hydrophobic organic chemicals can be predicted from their octanol–water partition coefficients ($K_{ow}$).

**Equation 3.2**

$$BAF_{worm} = \frac{C_0}{C_s}$$

where:

$BAF_{worm}$ = Soil to worm bioaccumulation factor, kg DW soil $kg^{-1}$ WW worm

$C_0$ = Chemical concentration in the whole organism, mg $kg^{-1}$ WW

$C_s$ = Chemical concentration in soil, mg $kg^{-1}$ DW

Secondary poisoning is concerned with toxic effects in the higher members of the food chain, either living in the aquatic or terrestrial environment, which results from ingestion of organisms from lower trophic levels that contain accumulated substances (R.10.8 in

[20] Data-rich trace elements such as copper, nickel, and zinc are the exception. Long-term field trials can provide information that can be used in weight-of-evidence approaches to provide regulatory certainty around the choice of AF.

[21] Alternatively, this calculation can be based on soil pore water (R.7.10.8 in ECHA 2014a).

ECHA 2008). Biomagnification between trophic levels in a food chain follows many different pathways and is difficult to measure and predict. Secondary poisoning should, in principle, be assessed by comparing the measured or estimated concentrations in tissues and organs of the top predators with no-effect concentrations for these animals, expressed as the internal dose. In practice, however, such measurements are rarely available and most ecotoxicity data for higher predators are expressed as the chemical concentration in their diet (for example, R.7.10.14 in ECHA 2014a).

Risk assessments are therefore normally based on a comparison of the (predicted) concentration in the food of the top predator and the (predicted) no-effect concentration for ecotoxicity in the predator from dietary exposure studies (for example, standard laboratory tests using rat or quail). Results from these studies may be expressed as a chemical concentration in food (mg $kg^{-1}$ food) or a dietary intake causing no effect, that is, a No Observed Adverse Effect Level (NOAEL) expressed in mg $kg^{-1}$ body weight $day^{-1}$). Long-term chronic studies with endpoints including mortality, growth and reproduction are preferred (for example, R.7.10.16 in ECHA 2014a). If adequate data are not available, a $PNEC_{oral}$, and subsequently a $PNEC_{sp}$, cannot be derived.

R.16.6.7 in ECHA (2012) presents guidelines for deriving a $PNEC_{oral}$ based on secondary poisoning. For soil (R.16.6.7.2 in ECHA 2012), the terrestrial food chain considered is soil → earthworm → worm-eating bird or mammal. The $PNEC_{oral}$ is calculated as shown in Equation 3.3. Since the $PNEC_{oral}$ is always expressed on a food concentration basis (using a conversion factor that is the ratio of body weight to the assumed quantity of food consumed per day), any no-effect predator data based on dietary intake must be converted from a NOAEL to a NOEC (R.10.8.2 in ECHA 2008).

**Equation 3.3**

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

where:

$PNEC_{oral}$ = Predicted no-effect concentration for chemical secondary poisoning of birds and mammals, mg $kg^{-1}$ FW food

$TOX_{oral}$ = Relevant no-effect concentration from adverse effects via the diet (for example, $LC50_{bird}$, $NOEC_{bird}$ or $NOEC_{mammal}$), mg $kg^{-1}$ FW food

$AF_{oral}$ = Assessment factor applied in extrapolation of PNEC, dimensionless

In this case, the $AF_{oral}$ takes into account:

- interspecies variation
- any extrapolation from acute/subchronic to chronic ecotoxicity studies
- extrapolation from laboratory data to field impact

Table 3.2 presents the guidelines recommended by ECHA to support the REACH regulation (Table R.10-13 in ECHA 2008). These AF values consider the differences between:

- the ratio of body weight and daily food ingestion rates between laboratory species and wildlife species (the ratio can differ up to a factor of 8 for birds and 10 for mammals)
- intrinsic species sensitivities

- varying metabolic stages in the lifecycle of predators (for example, extra sensitivity during migration or hibernation)

**Table 3.2 AFs for extrapolation of bird and mammalian toxicity data (Table R.10-13 in ECHA 2008)**

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

The $PNEC_{oral}$ cannot be used directly as a $PNEC_{sp}$ because it is based on the concentration of a chemical in the predator's food and not soil. To derive a comparable $PNEC_{sp}$, it is necessary to make a back-calculation that relates the chemical concentration in food (normally assumed to be an earthworm) to the chemical concentration in soil. This can be straightforward if the bioaccumulation factor for earthworms ($BAF_{worm}$) has been determined from relevant studies, in which case the $PNEC_{sp}$ can be calculated using Equation 3.4. Where $BAF_{worm}$ is not known then R.16.6.7.2 in ECHA (2012) provides guidance on estimating the chemical concentration in an earthworm ($C_{worm}$) to known soil and soil pore water levels using experimental data, predictive modelling of gut loading and tissue concentration, and/or an empirically derived bioconcentration factor (BCF) for an earthworm.

**Equation 3.4**

$$PNEC_{sp} = \frac{PNEC_{oral}}{BAF_{worm}}$$

where:

$PNEC_{sp}$ = Predicted no-effect concentration for chemical secondary poisoning of birds and mammals, mg $kg^{-1}$ DW soil

$PNEC_{oral}$ = Predicted no-effect concentration for chemical secondary poisoning of birds and mammals, mg $kg^{-1}$ FW food

$BAF_{worm}$ = Bioaccumulation factor for earthworms on a wet weight basis from empirical studies, kg DW soil $kg^{-1}$ WW earthworm

The latter approach is illustrated in Equations 3.5 and 3.6. It requires the chemical levels in bulk soil ($C_{soil}$) and soil pore water ($C_{pw}$) to be used as input values. In order to calculate $C_{soil}$ using Equation 3.5, the $PNEC_{oral}$ is assumed to be equal to $C_{worm}$. Because $C_{pw}$ and $C_{soil}$ are dependent variables, Equations 3.5 and 3.6 must be solved simultaneously by iteration (Environment Agency 2009c). The $PNEC_{sp}$ can be calculated by multiplying $C_{soil}$ by the wet weight to dry weight conversion factor ($CONV_{soil}$).

In calculating the $PNEC_{sp}$, it is important to state clearly the additional uncertainties from chemical bioaccumulation and soil partitioning introduced by this method.

**Equation 3.5 (based on R.16-75 in ECHA 2012)**

$$C_{worm} = \frac{\left(BCF_{worm} \times C_{pw}\right) + \left(C_{soil} \times F_{gut} \times CONV_{soil}\right)}{1 + \left(F_{gut} \times CONV_{soil}\right)}$$

where:

$C_{worm}$ = Chemical concentration in a whole worm on a wet weight basis, mg $kg^{-1}$ wet weight (WW). The chemical specific value is assumed to be equal to the $PNEC_{oral}$ value.

$BCF_{worm}$ = Bioconcentration factor for earthworms on a wet weight basis, L $kg^{-1}$ WW. The chemical specific value is obtained from review of empirical evidence.

$C_{pw}$ = Chemical concentration in pore water, mg $L^{-1}$ (found by iteration using Equation 3.6)

$C_{soil}$ = Chemical concentration in soil, mg $kg^{-1}$ WW

$F_{gut}$ = Fraction of gut loading in worm, kg DW per kg WW **[0.1]**

$CONV_{soil}$ = Conversion factor for soil concentration from wet to dry weight, kg WW per kg DW **[1.133]**. Calculated using the default values in Table R. 16-9 in ECHA (2012).

Default values are given in bold.

**Equation 3.6 (based on R.16-57 in ECHA 2012)**

$$C_{pw} = \frac{C_{soil} \times \rho_{soil}}{K_{sw} \times 1000}$$

where:

$C_{pw}$ = Chemical concentration in pore water, mg $L^{-1}$

$C_{soil}$ = Chemical concentration in soil, mg $kg^{-1}$ WW (found by iteration using Equation 3.5)

$\rho_{soil}$ = Bulk density of weigh soil, kg WW $m^{-3}$ **[1,700]** Default value in ECHA (2012)

$K_{sw}$ = Soil–water partition coefficient, $m^3$ per $m^3$. The chemical specific value is derived from review of empirical evidence.

Default values are given in bold.

## 3.6 Availability and normalisation of the PNEC

Soil is a complex heterogeneous medium. Its characteristics include differences in organic matter and clay content, soil pH and soil moisture content. These can influence the availability of a chemical for uptake by soil organisms and hence the observed toxicity. Availability in this context is the chemical availability, that is, what concentration of a chemical might be labile in the soil and available for potential uptake by an organism (though it may not be taken up). The bioavailable concentration of a chemical is the exposure concentration the organism actually experiences, so it reflects both the chemical reactions in the soil that determine the labile component of a chemical and the interactions at the biological surfaces of the organism.

Generally, terrestrial ecotoxicity tests are conducted using the most available forms of a chemical (for example, the most soluble salts of trace elements). Some terrestrial test guidelines recommend the use of a standard artificial soil (for example, ECHA 2008), but natural soils can also be used. Natural soils comprise a broad range of soil types with differing physical and chemical properties including organic matter content, clay content, soil pH, cation exchange capacity (CEC) and soil moisture content. These characteristics can strongly influence chemical availability, meaning that test data on the same organism cannot always be directly compared.

To reduce this inherent variability, R.10.6 in ECHA (2008) recommends that the terrestrial ecotoxicity test data are 'normalised' to a standard soil. This is done using relationships that describe the availability of chemicals in soil, that is, by attempting to account for confounding effects and make test data directly comparable. Normalisation is usually to a specific soil type with fixed properties – for example, a soil organic matter (SOM) content of 3.4%. This is equivalent to all the testing being carried out in the same soil and so allows direct comparison of results across the collated dataset.

Normalisation for most non-ionic organic chemicals is based only on SOM content (R.10.6 in ECHA 2008). The PNEC values for non-ionic chemicals given in Appendix A, and therefore the corresponding SSVs, are normalised to a SOM content of 3.4% by weight.[22] It is assumed that chemical availability in soil depends primarily on the amount of organic matter present. No observed effect concentrations for different tests can be corrected using Equation 3.7.

**Equation 3.7**

$$NOEC\ or\ EC_x or\ LC_{x_{normalised}} = NOEC\ or\ EC_x or\ LC_{x_{test}} \times \frac{0.034}{F_{om,test}}$$

where:

NOEC or $EC_x$ or $LC_x$ [normalised] = NOEC, $LC_{50}$ or $EC_{50}$ from a specific ecotoxicity test normalised to a standard soil containing 3.4% SOM, mg $kg^{-1}$ DW

NOEC or $EC_x$ or $LC_x$ [test] = NOEC, $LC_{50}$ or $EC_{50}$ from a specific ecotoxicity test measured in a test soil containing a measured % SOM, mg $kg^{-1}$ DW

$F_{om,test}$ = Fraction of organic matter in soil tested, kg $kg^{-1}$

The mobility of metals and other trace elements in soil is typically much more complex and influenced by multiple soil characteristics, chemical ageing in soil, and differences in speciation between field soils and laboratory tests. Extensive long-term research programmes have increased our knowledge of these factors on the availability of metals and other trace elements in soil systems and their bioavailability to specific soil organisms (Smolders et al. 2009).[23] This evidence has led to the development of empirical relationships that enable no-effect concentration results from different ecotoxicity tests to be normalised for soil properties and the influence of ageing on chemical fate and behaviour.

Outlined below are the steps taken in deriving generic PNEC values for trace elements, which apply bioavailability correction models in a consistent and transparent way. In

[22] Normalisation can also be adjusted, allowing the PNEC or SSV to be corrected for the soil organic matter content of specific soils (see further discussion in Section 4).

[23] Among all commonly assessed soil properties (including pH, organic matter content, clay content), the effective CEC has been observed to provide the most consistent measure of soil influence on ecotoxicity (Smolders et al. 2009).

principle these steps can be followed for each trace element found in Appendix A. However, in reality they are applied only to relatively data-rich trace elements for which a probabilistic approach can be utilised to derive an $HC_5$ (see Section 3.5.2). The outcome from this process is a generic PNEC, which is precautionary for a wide range of soil types and to which corrections for site-specific soil properties can subsequently be made.

The 3 steps in the process are as follows.

1. Establish whether to use an 'added risk' or total approach based on the $HC_5$ from the Chemical Safety Report or its summary on the ECHA dissemination portal. Specifically, make a brief separate comparison of the range of ambient background concentrations for relevant UK soils with both the $HC_5$ and the ecotoxicity data driving that value (see Section 4.3.1).
2. Calculate an $HC_5$ based on species/process individual data, but without making any corrections for leaching–ageing (L/A) or any bioavailability normalisation to account for different soil properties between tests. Apply an AF to the $HC_5$, choosing the AF using a weight of evidence approach to derive the PNEC (see Section 3.5.2; ECHA 2008).
3. Where appropriate to do so, modify the generic PNEC from the previous step to correct the data for differences in toxicity between laboratory-spiked and field-contaminated soils by application of an L/A factor. Empirical data and observations have shown that in many cases the fresh addition of metal solutions to test soils over predicts the long-term toxicity observed in aged or field soils. The L/A factor refers to the combined effect of leaching (due to changing ionic strength) and ageing (due to long-term reactions in the soil) on trace element bioavailability and toxicity in soil, and is experimentally derived (see, for example, Smolders et al. 2009).

Ecotoxicity test data can also be normalised for some trace elements to take into account empirical evidence of soil properties on toxicity (see, for example, Smolders et al. 2009). Common properties considered include soil pH, clay content, SOM content, and effective CEC. Unlike non-ionic organic chemicals, these adjustments are complex and highly metal specific, and require the use of a spreadsheet tool (Environment Agency 2017) (see also Section 4). The generic PNEC derived by using the steps above can subsequently be adjusted to take account of differences in site-specific soil properties based on species/process normalised geometric mean data and the L/A factor.

Where appropriate, the SSVs for trace elements, presented in Appendix A, are based on the generic PNEC values derived above. They are therefore **not** normalised to a standard set of soil properties. However, where such potential soil adjustments are supported by sufficient evidence, an example of the effect of leaching–ageing and important soil properties on the SSV is provided.

## 3.7 Uncertainties in derivation of the PNEC

Throughout the derivation of the PNEC values in this report, areas of uncertainty have been identified including, but not limited to:

- the extrapolation of test data from single organisms to complex ecosystems
- gaps in data and understanding
- inherent variability in the persistence, accumulation, mobility and ecotoxicity of chemicals

AF values have been used to account for some of this uncertainty. However, they are only indicative and a significant source of technical and regulatory uncertainty (ECHA 2008).

As in all risk-based frameworks, high levels of uncertainty can be acceptable provided the sources of uncertainty are clearly documented along with a statement of how the uncertainty has been taken into account. However, an overly precautionary approach should be tempered with the recognition that the outcome may not be fit for purpose and possibly environmentally irrelevant.

Taking this into account, PNEC values will not be recommended where they are based solely on either aquatic toxicity data or where the AF > 50 (see Section 3.8). Although ECHA (2008) permits terrestrial PNEC values to be extrapolated from aquatic ecotoxicity data, the uncertainties are considered here to be unacceptably high.

## 3.8 When can a PNEC be considered as an SSV?

PNEC values can be derived for the vast majority of chemicals either through data considered under the REACH regulation or by using the scientific literature along with the ECHA guidance (ECHA 2008, 2011, 2012, 2014a). However, not all PNEC values are sufficiently robust to be used in regulatory decision-making. As noted above, the scientific uncertainty may be too high leading to an over-precautionary AF that makes the PNEC environmentally irrelevant (for example, it could be less than practical detection limits or existing widespread natural background). Other non-scientific factors can also lend a practical and socioeconomic dimension to their suitability for use.

The decision to recommend an SSV from a PNEC has therefore been made an explicit step in this report. Scientific and non-scientific factors that are considered at this stage include the following.

- Scientific uncertainty and a lack of sufficient evidence. As noted above, it is possible to derive a PNEC in the absence of data across a range of key organisms such as a base set of primary producers, consumers and decomposers. This uncertainty is reflected in the use of a high AF, often >50. No SSVs will normally be recommended from a PNEC where the underlying evaluation uses an AF > 50 (see point below for possible exceptions).
- Where the toxicological mode of action is known and understood, it might be reasonably justified to consider that the level of uncertainty is akin to that where additional data are available if the most sensitive group has been tested (see, for example, European Commission 2011, Section 2.9.1). For example, if the chemical is a cholinesterase inhibitor, it is unlikely that plants will be the most sensitive taxa. Therefore, expert consideration needs to be made on a case by case basis as to whether an AF > 50 is appropriate. Under circumstances where the specific mode of action is understood a lower AF may be justified.[24] For industrial chemicals, however, the specific mode of action is not often known.
- Where chemical contamination is relatively widespread, either from diffuse anthropogenic pollution or existing natural sources, the practicality of an SSV should be carefully considered. It may be difficult for an SSV to be used to screen out low risk activities where the PNEC is at or below

[24] For example, a chemical with only two chronic effect data points would have an AF of 50 (see Table 3.1). But if the missing effect data point was for plants and the chemical had a specific insect related mode of action, it could be argued an AF of 10 would be more reasonable.

existing widespread concentrations. In addition, ambient background levels may vary over many orders of magnitude, but where no normalisation or bioavailable correction is possible, the relevance and usefulness of an SSV would be compromised.

- Where an SSV conflicts with existing regulatory frameworks (now and in future), its implementation will need to be carefully considered by decision-makers. Existing guidance and frameworks include the Sludge (Use in Agriculture) Regulations 1989, the Fertiliser Regulations, Quality Protocols and other sources such as National Risk Assessments. In such instances, it may be considered disproportionate to use a stricter guideline.[25]

A brief section in the individual substance dossiers prepared during this project addresses these potential uncertainties and recommends whether an SSV should be recommended from the scientific perspective. Only those PNEC values were then taken forward for additional consideration as an SSV and their findings are summarised in Appendix A.

[25] The individual summary sheets in Appendix A provide a useful overview of the evaluation of current evidence on the ecotoxicity of a wide range of chemicals. They may be used as a starting point for a wider consideration of the existing guidance on the application of materials to land.

# 4 Using SSVs

This section provides practical advice on the use and interpretation of SSVs. See Section 1.1 for an explanation of what SSVs are.

## 4.1 Introduction

SSVs require quantified measurements of chemical concentrations in soil and/or robust estimates of changes in chemical levels after activities such as landspreading have been completed. Although their calculation does consider the ecological food chain risks to wildlife, they do not take into account risks to livestock[26,27] or human health, either directly or indirectly through agricultural food chain transfer. SSVs do not consider the risks to soil productivity (the ability to grow commercial crops) or controlled waters, or take into account biological pathogens or adverse changes to either soil chemistry or texture and physical structure.

SSVs have been derived as a screening tool to support the assessment of risks to soil quality and wildlife from the presence of chemicals. They should be used only within the wider context of guidance and regulations on the recovery of wastes and waste-derived products to land for agricultural and horticultural benefit, or for site restoration purposes.

## 4.2 SSVs for common trace elements and persistent organic pollutants

Using the methodology set out in Section 3, the available ecotoxicity data for many of the prioritised trace elements and organic pollutants set out in Section 2 were reviewed. Individual dossiers were prepared for 38 chemical substances and mixtures (consisting of 23 common trace elements and 15 persistent organic pollutants), summarising the available data and its evaluation.[28] Whether or not a PNEC was recommended as an SSV depends on the factors outlined in Section 3.8. Apart from technical uncertainties within the existing dataset or evaluation methodology, the most common reason for rejecting a PNEC as an SSV was an unfavourable comparison with background soil concentrations.

Where a PNEC was found to be significantly lower than typical rural soil concentrations, its likely usefulness as a screening value was considered too limited. However, where it is based on a low level of technical uncertainty, and the environmental behaviour and fate are fully understood, it is possible that ecological effects may sometimes occur at existing ambient levels. Although an SSV was not proposed, decision-makers may still wish to manage inputs of these substances from waste applications to land by other mechanisms. The individual dossiers prepared during this review will be an important technical element in any such deliberations.

[26] Livestock may be affected differently by exposure to soil chemicals compared to wildlife such as birds and small mammals. Potential adverse effects include not only their health but also reductions in produce quality and yield. Livestock are also exposed to soil chemicals via additional pathways (for example, direct ingestion of soil attached to grass) that are not taken into account by the framework for developing SSVs for ecological risk assessment.

[27] With the exception of molybdenum (see Appendix A).

[28] Individual dossiers are available on request from the Environment Agency.

Tables 4.1 summarises the recommended SSVs for 19 substances (9 trace elements and 10 organic pollutants). Section 4.3 provides further essential advice to explain their basis and use. It is recommended that SSVs are used only in conjunction with this advice and any wider guidance on the landspreading of waste materials. A summary sheet with key details for each substance for which an SSV is recommended is provided in Appendix A. Table 4.2 gives details of the 19 substances for which an SSV has not been proposed and the reasons why.

**Table 4.1 SSVs for common trace elements and persistent organic pollutants**

| Substance | SSV (mg per kg DW) | Added risk | Site-specific adjustment | Driver |
|---|---|---|---|---|
| **Trace elements** | | | | |
| Antimony | 37 | No | No | Direct toxicity |
| Cadmium | 0.6 | No | No | Direct toxicity |
| Cobalt | 4.2 | No | Yes | Direct toxicity |
| Copper | 35.1 | No | Yes | Direct toxicity |
| Molybdenum | 5.1 | No | Yes | Direct toxicity |
| Nickel | 28.2 | No | Yes | Direct toxicity |
| Silver | 0.3 | No | Yes | Direct toxicity |
| Vanadium | 2.0 | Yes | No | Direct toxicity |
| Zinc | 35.6 | Yes | Yes | Direct toxicity |
| **Organic pollutants** | | | | |
| Benzo[a]pyrene | 0.15 | No | Yes | Direct toxicity |
| Bis(2-ethylhexyl) phthalate | 13 | No | No | Direct toxicity |
| Hexachlorobenzene | 0.002 | No | Yes | Secondary poisoning |
| Pentachlorophenol | 0.6 | No | Yes | Direct toxicity |
| Perfluorooctanoic acid | 0.019 | No | No | Secondary poisoning |
| Perfluorooctane sulfonate | 0.013 | No | No | Secondary poisoning |
| Polychlorinated alkanes (medium chain) | 2.2 | No | Yes | Secondary poisoning |
| Triclosan | 0.13 | No | Yes | Direct toxicity |
| Tris(2-chloroethyl) phosphate | 1.1 | No | Yes | Direct toxicity |
| Tris(2-chloro-1-methylethyl) phosphate | 1.8 | No | Yes | Direct toxicity |

Notes: See Appendix A for further details on the derivation of these SSVs and Section 4.3 for additional explanation and advice on their use.

**Table 4.2 Substances reviewed for which SSVs were not recommended**

| Substance | PNEC | Driver | Uncertainty | PNEC below typical ambient levels |
|---|---|---|---|---|
| Aluminium | No | Insufficient ecotoxicity data to complete assessment | | |
| Arsenic | Yes | Direct toxicity | Low | Yes |
| Barium | Yes | Direct toxicity | High | Yes |
| Beryllium | Yes | Direct toxicity | High | No |
| Boron | Yes | Direct toxicity | Low | Yes |
| Chromium | Yes | Direct toxicity | Low | Yes |
| Dioxins and furans | No | Insufficient ecotoxicity data to complete assessment | | |
| Fluoride (available) | Yes | Direct toxicity | High | – |
| Iodine | Yes | Direct toxicity | High | Yes |
| Lead | Yes | Secondary poisoning | High | No |
| Mercury | Yes | Secondary poisoning | High | Yes |
| Pentachlorobenzene | Yes | Direct toxicity | High | – |
| Polychlorinated alkanes (short chain) | Yes | Sec. poisoning | High | No |
| Polychlorinated biphenyls | No | Insufficient ecotoxicity data to complete assessment | | |
| Selenium | Yes | Secondary poisoning | High | Yes |
| Strontium | No | Insufficient ecotoxicity data to complete assessment | | |
| Thallium | Yes | Direct toxicity | High | Yes |
| Titanium | No | Insufficient ecotoxicity data to complete assessment | | |
| Trimethoprim | Yes | Direct toxicity | High | – |

## 4.3 Advice on using SSVs

As noted in Section 1.2, the principal drivers for the revision of SSVs is the application of waste and waste-derived materials to land for agricultural and horticultural benefit, and site restoration. SSVs are used primarily to screen waste recovery operations to help decide whether these activities pose a low or acceptable risk to soil ecosystems and function, and dependant wildlife. They are levels of chemicals in soil below which there is unlikely to be any risk to its health and functions. They cannot and should not be compared directly with the levels of chemicals in a waste or waste-derived material.

Using SSVs to assess the risk from a landspreading or restoration activity generally involves an estimate of the change in soil levels after the proposed recovery to land has taken place. To make this assessment the following information is usually required:

- pre-existing soil concentration **before** the recovery activity

- other relevant characteristics in receiving soils, wastes and waste-derived materials including SOM content, CEC and pH
- good characterisation data including concentration levels of the chemicals in the wastes or waste-derived materials
- application rates and/or mixing rates of all materials to be spread or used in site restoration

Additional advice relating to using an SSV is given below.

### 4.3.1 Ambient soil concentrations and added risk

Soils contain a wide variety of chemicals from natural and anthropogenic sources (Environment Agency 2007, Defra 2009). Metals and other trace elements in soil are derived partly from weathering and mineralisation (geogenic processes) and partly from additions resulting from human activity (anthropogenic sources). Organic chemicals occur naturally in soils from the combustion and/or breakdown of organic matter, but many chemicals are man-made. Anthropogenic sources include atmospheric deposition, livestock (including manures) and crops, and agricultural chemicals including fertilisers and pesticides. Ambient soil concentrations vary from field to field because of differences in local and regional background levels and farming practices.

An accurate and representative soil analysis is essential to assess the impacts of spreading wastes to land (Environment Agency 2013). Soil samples should be collected and analysed before their deployment and should be representative of the fields on which the wastes will be spread. A widely used sampling strategy is to walk a 'W' shaped path over the field taking between 20 and 25 samples, which are bulked and subsampled for analysis (Rowell 1994). The sampling depth for the assessment of soil quality varies according to land use, with recommended depths of 7.5cm and 15cm for grassland and arable fields, respectively (DoE 1996). Recent research by the US Environmental Protection Agency (US EPA) suggests that the zone of highest biological activity for soil-dwelling organisms extends to the bottom of the plough layer in many soils (between 25cm and 30cm) (US EPA 2015).

Generic risk assessment for waste-derived materials does not rely on site-specific field measurements but on representative regional or national data that are typical of reasonable worst case conditions (Environment Agency 2014). Example datasets include:

- Geochemical Baseline Survey for the Environment (GBASE) published by the British Geological Survey (Ander et al. 2013)
- National Soil Inventory for England and Wales (Environment Agency 2006b)
- Geochemical Mapping of Agricultural and Grazing Land Soil in Europe (GEMAS) published by the Geochemistry Expert Group of EuroGeoSurveys and Eurometaux (Reimann et al. 2014)
- UK Soil and Herbage Survey (Environment Agency 2007)

When making a comparison between the results of various surveys, it is important to consider differences in sampling methods (such as depth) and the procedures for sample extraction, digestion and analysis.

Representative chemical levels in the receiving soil are required to estimate the concentration in soils after landspreading (see Section 4.3.3) for comparison with SSVs. Typical values from site-specific measurements may include the median or

upper bound mean concentration (UCL95), while reasonable worst case for regional or national datasets may include the 90th or the 95th percentile value. Representative soil data may also be required to vary the SSV itself where the added risk approach applies through its derivation (for example, see the SSV for zinc in Appendix A).

The concept of 'added risk' was developed by the Dutch government in the late 1990s (Crommentuijn et al. 2000). It assumes that:

- natural levels of trace elements have contributed to existing soil biodiversity and function
- adverse effects are attributable only to additional chemical loadings from anthropogenic sources

This approach is not without its flaws because an exposed organism will not always be able to distinguish between natural and anthropogenic sources of contamination, and there is little scientific evidence to support it (Environment Agency 2008b). For some metals, however, a clear discrepancy in bioavailability has been observed between the natural background concentration and the added anthropogenic fraction, and the approach has been accepted for some common and widespread trace elements (European Commission 2010).

An SSV based on added risk is therefore the sum of the natural chemical level in soil and the additional component related to adverse effects (see Equation 4.1). In this respect, a reasonable worst case scenario minimises the background soil contribution (such as using a 10th percentile value from a regional or national dataset or site-specific data, when available). It is clearly stated in Appendix A where added risk should be applied to an SSV.

**Equation 4.1**

$$SSV_{ARA} = C_{amb} + SSV$$

where:

$SSV_{ARA}$ = Soil screening value for a trace element taking into account added risk, mg $kg^{-1}$ DW

$C_{amb}$ = Representative chemical concentration in natural background soil (usually the 10th percentile from a regional or national dataset), mg $kg^{-1}$ DW

SSV = Soil screening value for a trace element derived from dose–response effects data for specific organisms (see Section 3), mg $kg^{-1}$ DW

### 4.3.2 Soil characterisation and adjusting an SSV

Soil is a complex and heterogeneous medium, which strongly influences the mobility and availability of chemicals in soil. As described in Section 3.6, the results from terrestrial ecotoxicity tests are normalised to remove the inherent variability introduced by soil properties to enable comparison of the data generated. Almost all PNEC values for non-ionic organic chemicals in Appendix A, and therefore the corresponding SSV, have been corrected to a SOM content of 3.4% (ECHA 2008).

Applying an SSV requires a correction from the standard soil to site-specific conditions. Soil properties are typically determined by field measurements and should be representative of the land on which the wastes are to be spread (Rowell 1994). In some circumstances, however, it may also be appropriate to consider the predicted changes to soil properties as a result of landspreading (for example, where there is likely to be a significant adjustment to soil pH or organic matter content).

SSVs for non-ionic organic chemicals are normally corrected only for differences in SOM content, which can be performed using Equation 4.2. Generally speaking, where the site organic matter content is greater than standard soil conditions then the adjusted SSVs will be higher (because predicted chemical mobility and availability will be lower). Care should be taken not to extrapolate results too far from the original test data; for example, some peat soils can have organic matter contents more than 10 times higher than tested soils.

Where necessary, measurements of total organic carbon should be converted to organic matter content using Equation 4.3 (Environment Agency 2008b).

**Equation 4.2**

$$SSV^* = SSV \times \frac{SOM^*}{SOM}$$

where:

SSV* = Soil screening value for organic chemical taking into account site-specific SOM content, mg $kg^{-1}$ DW

SSV = Soil screening value for organic chemical under standard soil conditions, mg $kg^{-1}$ DW

SOM* = Representative measured or predicted soil organic matter content, % weight basis

SOM = Soil organic matter content for standard soil conditions, % weight basis

**Equation 4.3**

$$SOM = OC \times \frac{100}{58}$$

where:

SOM = Soil organic matter content, % weight basis

OC = Soil organic carbon content, % weight basis

Multiple soil properties influence the mobility and availability of trace metals in soils, making the normalisation process more complex (see Section 3.6). Smolders et al. (2009) and others have developed a number of empirical relationships to enable normalisation of dose–response data to soil properties including pH, organic matter content, clay content and eCEC. A Microsoft® Excel spreadsheet tool has been developed to help adjust PNEC values to different soil conditions for a range of common metals including copper, nickel, lead, cadmium, molybdenum, zinc and cobalt (Environment Agency 2017). Adjustments can normally be made based on total metal content or added risk.

### 4.3.3 Waste characterisation and spreading scenarios

It is vital that wastes and waste-derived materials are appropriately characterised. The general principles and basic requirements for waste analysis are set out in ‘How to comply with your landspreading permit’ (Environment Agency 2013). When submitting data on waste soils, the Environment Agency only accepts data from methods that have been approved under its Monitoring and Certification Scheme (MCERTS).

Although Environment Agency (2013) sets out a typical analytical suite, this list is not prescriptive, exhaustive or a minimum requirement for what should be tested for. Many of the chemicals for which an SSV has been recommended (see Appendix A) are not listed in current advice on landspreading deployments. It is therefore important that the operator understands the origins of any waste and the potential biological, chemical and physical hazards that it may contain (Environment Agency 2015).

SSVs apply to the receiving soil and therefore it is necessary to predict the impact of landspreading of waste and waste-derived materials on the final chemical levels in soil. For cases involving a standard rules permit, this calculation should be made as part of the deployment assessment. In the case of waste-derived materials, the applicant will be required to demonstrate the risks to health and the environment through a generic risk assessment. Useful guidance on developing a ‘use scenario’ for land applications is available in ‘End-of-waste and by-product hazard and risk assessment’ (Environment Agency 2014). Predicted chemical concentrations in the receiving soil can be compared with an SSV and levels lower than the SSV can be considered a low risk to soil health and function.

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# Abbreviations

| | |
|---|---|
| BAF | bioaccumulation factor |
| BSAF | biota to soil accumulation factor |
| BCF | bioconcentration factor |
| DW | dry weight |
| CEC | cation exchange capacity |
| CF | conversion factor |
| DQRA | detailed quantitative risk assessment |
| $EC_x$ | Effect concentration affecting x% of the test population |
| ECHA | European Chemicals Agency |
| ERA | ecological risk assessment |
| FW | fresh weight |
| GQRA | generic quantitative risk assessment |
| L/A | leaching–ageing |
| $LC_x$ | Lethal Concentration killing x% of the test population |
| LOEC | Lowest Observed Effect Concentration |
| NOAEL | No Observed Adverse Effect Level |
| NOEC | No Observed Effect Concentration |
| PNEC | Predicted No Effect Concentration in soil |
| $PNEC_{dt}$ | PNEC in soil based on direct toxicity to invertebrates, plants and soil microbiology |
| $PNEC_{oral}$ | PNEC in wildlife diet based on secondary poisoning to birds and mammals |
| $PNEC_{sp}$ | PNEC in soil based on secondary poisoning to birds and mammals |
| SOM | soil organic matter |
| SSD | species sensitivity distribution |
| SSV | soil screening value |
| US EPA | US Environmental Protection Agency |
| WW | wet weight |

# Glossary

| | |
|---|---|
| **Altricial birds** | Altricial bird species have newly hatched young that are relatively immobile and are unable to obtain food on their own. They must be cared for by adults. This includes species of heron, hawks, woodpeckers, owls and cuckoos. |
| **Bioaccumulation** | The biological sequestering of a substance at a higher concentration than that at which it occurs in the surrounding environment or medium. |
| **Bioavailability** | The degree to which a chemical can be taken into the tissues of an exposed organism. |
| **Bioconcentration factor (BCF)** | Bioconcentration is a measure of the tendency of a chemical to accumulate in an organism from the surrounding environment. The BCF is defined as the ratio of the concentration of a chemical in the organism to the concentration in the environment. |
| **Biomagnification** | Biomagnification is the sequence of processes in an ecosystem by which higher concentrations of a particular chemical, such as the pesticide DDT, are reached in organisms higher up the food chain, generally through a series of prey–predator relationships. |
| **Cation exchange capacity (CEC)** | CEC is the total capacity of a soil to hold exchangeable cations such as calcium, potassium and ammonium by electrostatic forces on soil particle surfaces. CEC is influenced by soil pH and the standard test uses a buffered solution at pH 7.<br><br>Effective CEC is the cation exchange capacity measured at soil pH (that is, in an unbuffered extract). This will increase with increasing soil alkalinity. |
| **Chemical Safety Report** | This type of report documents the chemical safety assessment performed as part of the REACH registration process and is the most important source of the information provided by the registrant to all users of chemicals through the exposure scenarios. |
| **Chronic** | A period representing a substantial portion of a lifespan of an organism (for example, chronic toxicity is the characteristic of a chemical to produce a toxic response when an organism is exposed over a long period of time). |
| **Concentration** | The amount of a chemical substance expressed relative to the amount of environmental medium (for example, micrograms of chemical per gram of soil). |

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| **Decomposers** | 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. |
| **Ecological risk assessment** | Evaluation of the likelihood of adverse effects on organisms, populations and communities from chemicals present in the environment. |
| **Effect concentration** | A statistically or graphically estimated concentration that is expected to cause one or more specified effects in X% (for example, 50%) of a group of organisms under specified conditions. |
| **Effect** | A change in the state of an organism or other ecological component, resulting from exposure to a chemical or other stressor. |
| **Endpoint** | The biological or ecological entity or variable being measured or assessed. |
| **Exposure assessment** | The process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways and routes, and the uncertainties in the risk assessment. |
| **Exposure** | The amount of a chemical that is available for intake by a target population at a particular site. Exposure is quantified as the concentration of the chemical in the medium (for example, air, water or food) integrated over the duration of exposure. It is expressed in terms of mass of substance per kg of soil, unit volume of air or litre of water (for example, mg $kg^{-1}$, mg $m^{-3}$ or mg $L^{-1}$). |
| **Hazard** | The intrinsic danger of a substance or process. |
| **Mesocosm** | Large multispecies test system for assessing toxicity. |
| **Microcosm** | Small multispecies test system for assessing toxicity. |
| **No Observed Effect Concentration (NOEC)** | In test organisms, the highest concentration at which no significant adverse effects, such as growth or reproduction, were observed. |
| **Potentially Toxic Elements (PTE)** | Group of 11 metals and other chemical elements identified in good practice guidance as posing a risk to soil quality through agricultural use of sewage sludge. |
| **Predicted Environmental Concentration** | Estimated or measured concentration of a chemical in soil. |
| **Predicted No Effect Concentration (PNEC)** | This is the lowest environmental concentration in soil at which the absence of any adverse effect on soil ecosystems and function is expected. |

| | |
|---|---|
| **Screening level** | A process or criterion that separates sites deemed to represent no apparent risk from those for which further analysis is desirable. Screening criteria are usually based on conservative assumptions in order to be generally protective. |
| **Speciation** | Refers to the various forms in which chemicals occur (for example, metals, ions, complexes). |
| **Toxicity** | The property of a chemical substance manifested as its ability to cause a harmful effect (for example, death, disease, reduced growth, modified behaviour) on an organism. |
| **Trace elements** | Metals and other chemical elements found in wastes and soils in minute amounts (typically less than 1,000 mg $kg^{-1}$ dry weight). |
| **Unbounded value** | Where the No Observed Effect Concentration (NOEC) is equal to the highest concentration used in an ecotoxicity study (that is, no effects were observed in any of the concentrations tested). |

# Appendix A: SSV summary sheets

The summary sheets are presented in alphabetical order for each substance for which an SSV is recommended (see Table 4.1 in the main report).

# Antimony (Sb)

The SSV for use in the risk assessment of waste recovery to land is **37 mg Sb per kg DW**, based on direct toxicity to exposures to antimony trioxide ($Sb_2O_3$) from soils. A European Union Risk Assessment Report (EU RAR), undertaken under the auspices of the Existing Substances Regulation (EEC No 793/93) (European Commission 2008a), and the Chemical Safety Report developed for REACH are the basis for the SSV recommended here (I2a, personal communication).

Antimony is a trace element for which there are relatively few terrestrial ecotoxicity data. The ecotoxicity data considered in the derivation of the PNEC are shown in the table below. A deterministic approach was adopted for the derivation of the SSV, applying an AF of 10. However, there are notable differences from the approach set out by ECHA (2008) to take into account the complexity of antimony chemistry in soils (Oorts and Smolders 2009). See the individual dossier for further information (available on request from the Environment Agency). A summary of the data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Antimony trioxide ($Sb_2O_3$) | | **CAS Number:** 1309-64-4 |
|---|---|---|
| **Summary of acceptable (chronic) data*** | | |
| **Group** | **Number of data points (and species)** | **Indicative range of chronic endpoint values (mg Sb per kg)** |
| Terrestrial – invertebrates | 6 (3) | 60 to >1,804 |
| Terrestrial – plants | 4 (2) | 43 to 2,930 |
| Terrestrial – microbial functions and enzymatic assays | 4 (2) | 73 to >1,804 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Deterministic approach, using the lowest effect concentration for aged $Sb_2O_3$ test, for which the Sb soil solution concentration was calculated giving total soil Sb concentration at equilibrium of 370 mg Sb per kg DW. An AF of 10 was used on this value. | **37 mg Sb per kg DW** | AF of 10 based on the Sb soil solution concentration from lowest chronic data point from the 3 taxa from aged tests performed with $Sb_2O_3$ |

* Summaries of the individual test data are given on the ECHA dissemination portal. I2a kindly provided wca with all the terrestrial data to review under a confidentiality agreement on behalf of the Environment Agency.

# Benzo[a]pyrene (BaP)

The SSV for use in the risk assessment of waste recovery to land is **0.15 mg BaP per kg DW, normalised to 3.4% SOM**, based on direct toxicity to benzo[a]pyrene exposures from soil. New terrestrial toxicity data were found since the previous search undertaken in 2006 (Environment Agency 2008b).

Polycyclic aromatic hydrocarbons (PAHs) are a large group of organic compounds which contain only carbon and hydrogen atoms and whose molecular structure includes 2 or more connected aromatic rings (Environment Agency 2007). Although there are potentially thousands of different PAH compounds in the environment, only a few hundred have been isolated and identified (IPCS 1998). BaP is one of the PAHs routinely tested and investigated because it is relatively persistent in the environment and a known human carcinogen.

PAHs are formed naturally by plants and the incomplete combustion or pyrolysis of organic materials, and always occur as mixtures (IPCS 1998, Environment Agency 2007). The exact composition of any mixture depends on the source and combustion conditions (IPCS 1998). In 2008, the Canadian Council of Ministers of the Environment proposed categorising PAH compounds based on whether they are kinetically or thermodynamically favoured, or whether they are partly synthesised through biologically mediated processes (CCME 2008). Kinetically favoured PAHs including BaP are formed preferentially by combustion processes, while those that are thermodynamically favoured such as chrysene are likely to be found in oil and coal because of their long-term stability (CCME 2008).

The new data are available for invertebrates, plants and microbial function. However, there are insufficient data to derive a SSV by SSD. The endpoint used to derive the original SSV (Environment Agency 2008b) remains the lowest chronic endpoint at this time. Therefore, the recommended SSV remains the same. The SSV was derived by the deterministic method according to ECHA guidance (ECHA 2008), based on earthworm data and an AF of 10. There is a moderate level of relative regulatory uncertainty associated with the recommended SSV for benzo[a]pyrene due to the limited dataset. A summary of the data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Benzo[*a*]pyrene | | **CAS Number:** 50-32-8 |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **Group** | **Number of data points (and species)** | **Range of chronic endpoint values (mg BaP per kg DW)** |
| Terrestrial – invertebrates | 11 (6) | >1.5 to >23,800 |
| Terrestrial – plants | 11 (5) | <10 to >48,000 |
| Terrestrial – microbial function | 21 | 2.18 to 1,229 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Cited from Environment Agency (2008b) | **0.15 mg BaP per kg DW (normalised to 3.4% SOM)** | Derived from earthworm data with an AF of 10 |

# Bis(2-ethylhexyl) phthalate (DEHP)

The SSV for use in the risk assessment of waste recovery to land is **13 mg DEHP per kg DW** based on the direct toxicity to DEHP exposures from soil. The SSV was derived by the deterministic method, following ECHA guidance (ECHA 2008) and using an AF of 10. A PNEC for secondary poisoning of 18 mg DEHP per kg DW was also derived.

DEHP is the most common member of the class of phthalates used as plasticisers in polymers such as PVC (European Commission 2008b). This colourless viscous liquid is soluble in oil but not in water. It can be found in many plastic items, including carrier bags and bottles. Although the DEHP content varies, it is often around 20% by weight. In 2014, the Member State Committee under REACH agreed to identify DEHP as a substance of very high concern (SVHC) because of its endocrine disrupting properties in the environment (ECHA 2014b).

Reliable and relevant chronic terrestrial ecotoxicity data for DEHP are limited. Data were obtained from the summary of the Chemical Safety Report on the ECHA dissemination portal[29] and from a previous derivation (Environment Agency 2009c). The data considered in the derivation of the SSV and the PNEC for secondary poisoning are shown in the table below. All the ecotoxicity data used in this derivation were unbounded (that is, no effect concentrations were identified in the tests). DEHP is a reproductive toxin (European Commission 2008b), affecting both male and female fertility and lactation in mammals. Moderate levels of relative regulatory uncertainty were associated with the PNEC derivation for direct toxicity and secondary poisoning.

**Overview of the data used in the assessment**

| **Substance:** Bis(2-ethylhexyl) phthalate | | **CAS Number:** 117-81-7 |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **Group** | **Data (species)** | **Range of chronic endpoint values (mg DEHP per kg DW)** |
| Terrestrial – invertebrates | 1 (1) | >1,000 to >5,000 |
| Terrestrial – plants | 2 (2) | >130 |
| Terrestrial – microbial function | 1 (1) | >300 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Deterministic method using an AF on the NOEC for seedling emergence of wheat *Triticum aestivum* of 130 mg DEHP per kg | **13 mg DEHP per kg (direct toxicity)** | Four data points: 3 tropic levels are available. However, all data used in this derivation are unbounded. |
| **PNEC derivation method** | **PNEC** | **Comments** |
| Secondary poisoning method (ECHA 2008, 2012). NOAEL = 4.8 mg DEHP per kg body weight per day for irreversible testicular damage in male rats; a conversion factor (CF) of 10 and an AF of 30 were applied, resulting in a $PNEC_{oral}$ = 1.63 mg DEHP per kg food. A BCF of 1 L per kg earthworms was adopted (European Commission 2008b). | **18 mg DEHP per kg DW (secondary poisoning)** | AF of 30, being a three-multigenerational study |

[29] http://echa.europa.eu/ja/registration-dossier/-/registered-dossier/15358/1

# Cadmium (Cd)

The SSV for use in the risk assessment of waste recovery to land is **0.62 mg Cd per kg DW**, based on direct toxicity to cadmium exposures from soils. A probabilistic approach was used with an AF of 2 based on ECHA guidance (ECHA 2008). A PNEC for cadmium exposure via secondary poisoning of 0.9 mg Cd per kg DW was also derived.

Cadmium is a non-essential element that naturally occurs in the environment in its inorganic form as a result of geogenic weathering. Anthropogenic sources have increased the background levels of cadmium in soil, water and living organisms (EFSA 2009). Cadmium bioaccumulation may occur through terrestrial food chains (Rafiq et al. 2014) and, for such substances, the relevant guidance can be used to derive a PNEC for secondary poisoning (see Section 3.5.3 in the main report).

A European Union Risk Assessment Report (EU RAR), undertaken under the auspices of the Existing Substances Regulation (EEC No 793/93), was the basis of the previous SSV for cadmium (European Commission 2007a; Environment Agency 2008b). Additional direct toxicity data to those used in the EU RAR for invertebrates and plants were found from a literature search covering 2006 to 2015. All the data used in derivation of the PNEC values are summarised in the table below.

**Overview of the data used in the assessment**

| **Substance:** Cadmium | | **CAS Number: 7440-43-9** |
|---|---|---|
| **Summary of acceptable (chronic) data*** | | |
| **Group** | **Number of data points (and species)** | **Indicative range of chronic endpoint values (mg Cd per kg)*** |
| Terrestrial – invertebrates | 9 (5) | 1.8 to 29 |
| Terrestrial – plants | 7 (5) | 0.3 to 320 |
| Terrestrial – microbial functions and enzymatic assays | 14 (2 microbial processes) | 3.6 to 3,000 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Probabilistic approach, SSD, log-normal distribution, giving an $HC_5$ of 1.24 mg $kg^{-1}$ (confidence limits 0.44–2.65) | **0.62 mg Cd per kg DW (direct toxicity)** | AF of 2: dataset based on 12 species and microbial functional endpoints |
| Probabilistic approach plotting an SSD of critical kidney cadmium concentrations in mammals, giving an $HC_5$ of 400 mg per kg DW, corresponding to a critical soil concentration of 0.9 mg Cd per kg | **0.9 mg Cd per kg DW (secondary poisoning)** | No differences in feeding physiology and efficiency uptake of cadmium were accounted for. No new mammalian toxicity data were considered in the present analysis. |

* Chronic endpoint values were not normalised to any specific soil properties. Studies were carried out with several Cd salts (cadmium chloride, cadmium nitrate and cadmium sulphate). Additional data to those used in European Commission (2007a) are detailed.

# Cobalt (Co)

The SSV for use in the risk assessment of waste recovery to land is **4.2 mg Co per kg DW**, which applies to the direct toxicity to cobalt exposures from soil**.** This generic value does not take into account leaching and ageing effects, or the modifying influence of soil properties on cobalt ecotoxicology. However, the SSV can be modified using the relationships and processes described by Smolders et al. (2009). See the individual dossier for further information (available on request from the Environment Agency). For example, the SSV would be 20.7 mg Co per kg DW based on a soil pH of 6.5, SOM of 3.4% and a clay content of 10%. A spreadsheet is available to perform these calculations to derive a soil-specific SSV (Environment Agency 2017).

Cobalt is a trace element for which there are many terrestrial ecotoxicity data. A summary of the data used in the assessment is shown in the table below. The most sensitive taxa in the SSDs across all soil characteristics tend to be higher plants.

The SSV is based on the large dataset collated and summarised in the Chemical Safety Report on the ECHA dissemination portal. A probabilistic approach has been taken for the derivation of the PNEC following ECHA guidance (ECHA 2008). The ecotoxicity data were plotted as individual values in an SSD. An AF of 2 was applied to the $HC_5$ from the SSD to give the PNEC.

**Overview of the data used in the assessment***

| **Substance:** Cobalt and its compounds | | **CAS Number:** 10141-05-6 |
|---|---|---|
| **Summary of acceptable (chronic) data*** | | |
| **Group** | **Number of data points (and species)** | **Indicative range of chronic endpoint values (mg Co per kg)#** |
| Terrestrial – invertebrates | 30 (4) | 16 to 1,121 |
| Terrestrial – plants | 83 (7) | 3.5 to 647 |
| Terrestrial – microbial functions and enzymatic assays | 28 (3) | 23 to >4,000 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Probabilistic approach, SSD, log-normal distribution – this gives an $HC_5$ of 8.4 mg Co per kg | **4.2 mg Co per kg DW** | AF of 2 applied, based on 141 $EC_{10}$/NOEC values from long-term toxicity tests for at least 14 species and microbial processes and enzymatic activity assays |

* Summaries of the individual test data are given on the ECHA dissemination portal. Cobalt Development Institute/Cobalt REACH Consortium kindly provided wca with all the terrestrial data to review under a confidentiality agreement on behalf of the Environment Agency.
**#** These values are not corrected for leaching–ageing and are not normalised, so differences due to the soil properties in the individual tests remain.

# Copper (Cu)

The SSV for use in the risk assessment of waste recovery to land is **35.1 mg Cu per kg DW**, based on direct toxicity to copper exposures from soil. This generic value does not account for leaching and ageing effects on the soil ecotoxicity of copper or soil-specific properties. To modify the SSV for the effects of leaching and ageing, and for specific soil properties, it is necessary to apply all the relationships and processes described by Smolders et al. (2009). See the individual dossier for further information (available on request from the Environment Agency). For example, the SSV would be 71.5 mg Cu per kg DW based on a soil pH of 6.5, SOM content of 3.4% and a clay content of 10%. A spreadsheet is available to perform these calculations to derive a soil-specific SSV (Environment Agency 2017).

The proposed SSV value is based on the large dataset of ecotoxicity values collated in the Voluntary European Union Risk Assessment Report (EU VRAR) (European Commission 2008c) and also used in the Chemical Safety Report for copper compounds available on the ECHA dissemination portal; 108 individual chronic data points were collected for invertebrates (resulting in 10 species mean NOEC values), 67 individual chronic data points for higher plants (resulting in 9 species mean NOEC values) and 77 individual chronic data points for microbial processes (resulting in 9 process mean NOEC values). From a literature search, additional terrestrial toxicity data for plants and invertebrates were found from 2008 onwards. However, excluding these data in the analysis did not influence the PNEC derivation.

A probabilistic approach was taken for the derivation of the copper PNEC following ECHA guidance (ECHA 2008), accounting for bioavailability. The ecotoxicity data were neither corrected for leaching and ageing (Smolders et al. 2009) nor normalised for soil properties. To avoid averaging data for high and low bioavailability soils, the individual ecotoxicity data were plotted in an SSD. An AF of 1 was applied to the $HC_5$ from the SSD to give the PNEC. A summary of the data used in the assessment is given in the table below. The most sensitive taxa in the SSD vary depending upon the soil-specific physicochemical conditions.

**Overview of the data used in the assessment**

| **Substance:** Copper and its compounds | | **CAS Number: 7440-50-8** |
|---|---|---|
| **Summary of acceptable (chronic) data*** | | |
| **Group** | **Number of data points (and species)** | **Indicative range of chronic endpoint values (mg Cu per kg)#** |
| Terrestrial – invertebrates | 108 (10) | 8.4 to 1,460 |
| Terrestrial – plants | 67 (9) | 18 to 698 |
| Terrestrial – microbial functions and enzymatic assays | 77 (9) | 30 to >2,400 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Probabilistic approach, SSD, log-normal distribution – this gives an $HC_5$ of 35.1 mg Cu per kg | **35.1 mg Cu per kg DW** | AF of 1, based on over 250 $EC_{10}$/NOEC values representing 28 different species |

* An in-depth analysis is available in the EU VRAR (European Commission 2008c).
# These values are not corrected for leaching–ageing and are not normalised, so differences due to the soil properties in the individual tests remain.

# Hexachlorobenzene (HCB)

The SSV for use in the risk assessment of waste recovery to land is **0.002 mg HCB per kg DW, normalised to 3.4% SOM**, based on secondary poisoning of birds and mammals.

HCB is one of a group of hydrocarbons characterised by a benzene ring in which the hydrogen atoms are substituted by one or more chlorine atoms. Due to its persistence and bioaccumulation in the environment, it was classified as a Persistent Organic Pollutant and banned for use under the Stockholm Convention in 2004 (Stockholm Convention 2015). It is a fungicide, extensively used in the past as a seed coating and to control wheat bunt. Previous applications also included the production of rubber, ammunition and fireworks. HCB can also be released unintentionally through combustion and other processes, and occurs as an impurity in other chemicals.

Because of the high bioconcentration potential of HCB, exposure of predatory birds and mammals through secondary poisoning is the most critical protection goal to be assessed (RIVM 2011). In a terrestrial food web study (Hebert et al. 1994), concentrations of NCB were also found to increase from the lower to the higher trophic level species (ATSDR 2015). HCB has a relatively low direct terrestrial toxicity (Sochová et al. 2007). Many test data are unbounded values. No reliable and relevant chronic terrestrial data were found in the search of the open literature from 2006 to 2015. A summary of the data used in the assessment is given in the table.

**Overview of the data used in the assessment**

| **Substance:** Hexachlorobenzene | | **CAS Number:** 118-74-1 |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **PNEC derivation method** | **SSV** | **Comments** |
| Secondary poisoning method (ECHA, 2008, 2012)<br>NOEC = 0.5 mg HCB per kg food for reproduction and mortality in minks; an AF of 30 was applied, resulting in a $PNEC_{oral}$ = 0.0167 mg HCB per kg food. BCF of 6,000 L $kg^{-1}$ WW earthworm was used. | **0.002 mg HCB per kg DW normalised to 3.4% SOM (secondary poisoning)** | AF of 30, being a one-generation chronic study |

# Molybdenum (Mo)

The SSV for use in the risk assessment of waste recovery to land is **5.1 mg Mo per kg DW**, which applies to the direct toxicity from exposure to molybdenum from soil. This generic SSV can be corrected to account for leaching–ageing and normalised to site-specific soil characteristics. For example, the SSV would be 19.0 mg Mo per kg DW based on a soil pH of 6.5, SOM content of 3.4% and a clay content of 10%. Given its solubility characteristics, the most sensitive soils to molybdenum exposures are those with a neutral to alkaline pH and low clay content. A spreadsheet is available to perform these calculations to derive a soil-specific SSV (Environment Agency 2017).

Terrestrial ecotoxicity data for molybdenum are summarised on the ECHA dissemination portal[30] with more detailed information in the Chemical Safety Report provided by the International Molybdenum Association (IMOA, personal communication, 2016). A probabilistic approach was adopted for the derivation of the PNEC following ECHA guidance (ECHA 2008). The SSV is calculated as the $HC_5$ derived from the distribution of all individual $EC_{10}$/NOEC values rather than species/process mean values. This ensures a suitably conservative generic screening value because it avoids removal of the lowest $EC_{10}$/NOEC values from the distribution. An AF of 1 was applied to the $HC_5$ from the SSD to give the PNEC. The effects of excessive molybdenum intake on the physiological availability of copper (known as molybdenosis) in ruminants such as cattle and sheep were considered in the present report. A PNEC for secondary poisoning is not appropriate, but a threshold dietary ratio (copper to molybdenum) of 1.3 mg $mg^{-1}$ could be used in the assessment and management of risk. A summary of the data used in the assessment is given in the table below. The most sensitive taxa in the SSD vary according to soil-specific physicochemical conditions.

**Overview of the data used in the assessment***

| **Substance:** Molybdenum | | **CAS Number:** 7439-98-7 |
|---|---|---|
| **Summary of acceptable (chronic) data*** | | |
| **Group** | **Number of data points (and species)** | **Indicative range of chronic endpoint values (mg Mo per kg DW)#** |
| Terrestrial – invertebrates | 23 (3) | 8.9 to 1,865 |
| Terrestrial – plants | 45 (5) | 5 to 3,479 |
| Terrestrial – microbial functions | 18 (3) | 10 to 3,841 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Probabilistic approach, SSD, log-normal distribution, this gives an $HC_5$ of 5.1 mg Mo per kg **without** the use a leaching–ageing$ factor | **5.1 mg Mo per kg DW (direct toxicity)** | AF of 1, based on 86 $EC_{10}$/NOEC values from long-term toxicity tests for 11 species and microbial processes |

* Summaries of the individual test data are given on the ECHA dissemination portal. The International Molybdenum Association kindly provided wca with all the terrestrial data to review under a confidentiality agreement on behalf of the Environment Agency.
# These values are not corrected for leaching–ageing and not normalised, so differences due to the soil properties in the individual tests remain.
$ Experimentally derived (see, for example, Oorts et al. 2016).

[30] http://echa.europa.eu/registration-dossier/-/registered-dossier/15524/6/1

# Nickel (Ni)

The SSV for use in the risk assessment of waste recovery to land is **28.2 mg Ni per kg DW**, based on direct toxicity to nickel exposures from soil. This generic value does not account for leaching and ageing effects on the soil ecotoxicity of nickel or soil-specific properties. To modify the SSV for leaching, ageing and specific soil properties, it is necessary to apply all the relationships and processes described by Smolders et al. (2009). See the individual dossiers for further information (available on request from the Environment Agency). For example, the SSV would be 52.3 mg Ni per kg DW based on a soil pH of 6.5, SOM content of 3.4% and a clay content of 10%. A spreadsheet is available to perform these calculations to derive a soil-specific SSV (Environment Agency 2017).

Nickel is a trace element for which there are many terrestrial ecotoxicity data (see table below). A European Union Risk Assessment Report (EU RAR), undertaken under the auspices of the Existing Substances Regulation (EEC No 793/93) (European Commission 2008d), was the basis of the previous SSV for nickel (Environment Agency 2008b, European Commission 2008d). Since then, some new high-tier data have become available that lead to a revision of the PNEC.

A probabilistic approach was adopted for the derivation of the nickel PNEC following ECHA guidance (ECHA 2008). The ecotoxicity data have not been normalised for leaching and ageing (Smolders et al. 2009; Section 3.6 in the main report), but plotted as individual values in an SSD. An AF of 1 was to the $HC_5$ from the SSD to give the PNEC. A summary of the data used in the assessment is given in the table below. The most sensitive taxa in the SSD vary depending on the soil-specific physicochemical conditions.

**Overview of the data used in the assessment**

| **Substance:** Nickel and nickel compounds | | **CAS Number:** 7440-02-0 |
|---|---|---|
| **Summary of acceptable (chronic) data*** | | |
| **Group** | **Number of data points (and species)** | **Indicative range of chronic endpoint values (mg Ni per kg)#** |
| Terrestrial – invertebrates | 37 (6) | 37 to 1,136 |
| Terrestrial – plants | 68 (11) | 11 to 1,127 |
| Terrestrial – microbial functions and enzymatic assays | 68 (26) | 28 to >7,000 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Probabilistic approach, SSD, log-normal distribution – this gives an $HC_5$ of 28.2 mg Ni per kg | **28.2 mg Ni per kg DW** | AF of 1, based on 150 $EC_{10}$/NOEC values from long-term toxicity tests for at least 42 species and microbial processes and enzymatic activity assays |

* Summaries of the individual test data are given on the ECHA dissemination portal.
# These values are not corrected for leaching–ageing and are not normalised, so differences due to the soil properties in the individual tests remain.

# Pentachlorophenol (PCP)

The SSV for use in the risk assessment of waste recovery to land is **0.6 mg PCP per kg DW, normalised to 3.4% SOM,** based on the direct toxicity to PCP exposures from soil.

First produced in the 1930s, PCP is an organochlorine compound used as a pesticide and a disinfectant (Stockholm Convention 2014). It can be produced as the pure chemical or as esters and simple salts (for example, sodium pentachlorophenate). It has been used for a wide range of applications including wood preservation, but these have declined due to concerns over persistence and toxicity. In 2015, the Stockholm Convention concluded that PCP and its compounds were persistent organic pollutants due to their long-range environmental transport and many uses were further restricted (Stockholm Convention 2015). Notable exceptions included the treatment of utility poles and cross-arms.

No new terrestrial toxicity data were found since the previous search undertaken by the Environment Agency in 2006 (Environment Agency 2008b). As the terrestrial toxicity dataset and ECHA guidance (ECHA 2008) have not changed significantly since the previous assessment, the revised SSV remains the same as the earlier value (Environment Agency 2008b). The SSV was derived by the probabilistic method using an AF of 1. A summary of the data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Pentachlorophenol | | **CAS Number:** 87-86-5 |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **Group** | **Number of data (and species)** | **Range of chronic endpoint values (mg PCP per kg DW), normalised to 3.4% SOM** |
| Terrestrial – plants | 6 (2) | 4.2-47.1 |
| Terrestrial – invertebrates | 6 (4) | 1.5-139.1 |
| Terrestrial – microbial function | 9 | 1.5-80 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Probabilistic approach, SSD, $HC_5$ with 50% confidence interval; (95% confidence intervals = 0.1 and 1.6 mg PCP per kg DW) | **0.6 mg PCP per kg DW** in soil with 3.4% SOM | AF of 1, based on 65 $EC_{10}$/NOEC values from long-term toxicity tests |

# Perfluorooctanoic acid (PFOA)

The SSV for use in the risk assessment of waste recovery to land is **0.019 mg PFOA per kg DW,** based on the secondary poisoning of birds and mammals.

Perfluorooctanoic acid is one of a number of perfluorinated compounds, which are characterised by a fully fluorinated carbon chain. These compounds have had a variety of uses and many are still used as surfactants, surface protectants, anti-reflective coatings, gaskets, seals, membranes, tubing, pipe liners, cable insulation, ion exchange, lubricants, and as water/oil repellents. PFOA has also been used as an emulsifier in the production of fluoropolymers and fluoroelastomers (COT 2006). In 2015, PFOA was proposed by ECHA for restriction under REACH and was also put forward for listing as a persistent organic pollutant under the Stockholm Convention.

Terrestrial toxicity data for invertebrates, plants and a soil enzymatic function test were found from a search of the open literature from 2006 to 2015. The SSV was derived from the critical concentration in earthworms according to ECHA guidance on bioaccumulation in the terrestrial compartment using a geometric mean bioaccumulation factor ($BAF_{worm}$) of 0.37 kg DW/kg WW from relevant studies (see Section 3.5.3). There is a moderate level of relative regulatory uncertainty associated with the recommended SSV due to limitations in the assessment methodology. A summary of data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Perfluorooctanoic acid and its salts | | **CAS Number:** 335-67-1 |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **Group** | **Number of data (and species)** | **Range of chronic endpoint values (mg PFOA per kg DW)** |
| Terrestrial – plants | 6 (1) | 10-200 |
| Terrestrial – invertebrates | 5 (2) | 10-792.5 |
| Terrestrial – microbial function | 1 | 2.5 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Deterministic approach for direct toxicity. Lowest $EC_{10}$ of 3.22 mg PFOA/kg DW, normalised to SOM, assessment factor (AF) of 10 | **0.32 mg PFOA per kg DW, normalised to 3.4% SOM** | AF of 10<br>11 chronic values from at least 3 trophic levels available |
| Secondary poisoning method. NOAEL of 0.06 mg PFOA/kg BW/day for liver toxicity in rats; a CF of 10 and an AF of 90 applied, resulting in $PNEC_{oral}$ of 0.007 mg PFOA/kg food. A geometric mean BAF of 0.37 kg DW soil/kg WW earthworm was used. | **0.019 mg PFOA per kg DW** | AF of 90 applied to NOAEL because it is a 90-day study |

# Perfluorooctane sulfonate (PFOS)

The SSV for use in the risk assessment of waste recovery to land is **0.013 mg PFOS per kg DW** based on the secondary poisoning of birds and mammals.

Perfluorooctane sulfonate is one of a number of perfluorinated compounds, which are characterised by a fully fluorinated carbon chain. It was widely used in industrial processes and consumer goods to provide grease, oil and water resistance to materials (Environment Agency 2004). Examples included coatings on textiles, upholstery, paper and leather. It was also used in firefighting foams. PFOS was confirmed as a persistent organic pollutant under the Stockholm Convention in 2009 and is restricted for use under REACH.

Environment Agency (2009c) reviewed the available evidence on the terrestrial toxicity of PFOS including publications up to 2006. As part of this study, additional data on plants, soil invertebrates and microbial processes was found by a search of the open literature from 2006 to 2015. The SSV was derived from the critical concentration in earthworms according to ECHA guidance on bioaccumulation in the terrestrial compartment using a geometric mean bioaccumulation factor ($BAF_{worm}$) of 1.58 kg DW/kg WW from relevant studies (see Section 3.5.3). There is a moderate level of relative regulatory uncertainty associated with the recommended SSV due to limitations in the assessment methodology. A summary of data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Perfluorooctane sulfonate and its salts | | **CAS Number:** 2795-39-3 (for potassium salts) |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **Group** | **Number of data (and species)** | **Range of chronic endpoint values (mg PFOS per kg DW)** |
| Terrestrial – plants | 12 (5) | 15.6-150 |
| Terrestrial – invertebrates | 5 (2) | 10-373 |
| Terrestrial – microbial function | 0 | not applicable |
| **PNEC derivation method** | **SSV** | **Comments** |
| Deterministic approach for direct toxicity. Lowest NOEC of 17.6 mg PFOS/kg DW, normalised to 3.4% SOM, assessment factor (AF) of 50 | **0.352 mg PFOS per kg DW, normalised to 3.4% SOM** | AF of 50<br>data for only 2 trophic levels available |
| Secondary poisoning method. NOAEL of 0.03 mg PFOS/kg BW/day for liver toxicity in monkey; a CF of 20 and an AF of 30 applied, resulting in $PNEC_{oral}$ of 0.02 mg PFOS/kg food. A geometric mean BAF of 1.58 kg DW soil/kg WW earthworm used. | **0.013 mg PFOS per kg DW** | AF of 30 applied to NOAEL because it is a chronic study |

# Polychlorinated-*n*-alkanes ($C_{14}$ – $C_{17}$, MCCP)

The SSV for use in the risk assessment of waste recovery to land is **2.2 mg MCCP per kg DW**, **normalised to 3.4% SOM**. It is based on calculations for the secondary poisoning of birds and mammals. A PNEC of 11.9 mg MCCP per kg DW was also derived for the direct toxicity of exposure to MCCP mixtures from soil.

Polychlorinated-*n*-alkanes or chlorinated paraffins are a family of complex mixtures representing more than 200 commercial formulations. They are classified according to their carbon chain length into short chain (SCCP, $C_{10}$ – $C_{13}$),[31] medium chain (MCCP, $C_{14}$ – $C_{17}$) and long-chain (LCCP, C > 17). The degree of chlorination varies between 30% and 70% by weight. They have a wide range of uses, which include extreme pressure additives in lubricants, secondary plasticisers in paints and plastics, and as flame retardants in various plastics and textiles (CPIA undated, Chapter 1). MCCP have been proposed as an alternative replacement for SCCP (European Commission 2005b).

Terrestrial toxicity data for invertebrates, plants and a soil enzymatic function test were obtained from a search of the open literature from 2006 to 2015. A summary of the data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Medium chain polychlorinated alkanes (MCCP) | | **CAS Number:** 85535-85-9 |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **Group** | **Number of data points** | **Range of chronic endpoint values (mg MCCP per kg DW)** |
| Terrestrial – plants | 6 (3) | 5,000 |
| Terrestrial – invertebrates | 14 (5) | 280 to 10,000 |
| Terrestrial – microbial function | 1 (1) | ≥400 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Deterministic approach, lowest NOEC = 119.2 mg MCCP per kg DW, normalised to 3.4% SOM, AF 10 | **11.9 mg MCCP per kg DW normalised to 3.4% SOM (direct toxicity)** | AF of 10<br>Three chronic values from at least 3 trophic levels available. |
| Secondary poisoning method (ECHA 2008). NOAEL = 30 mg MCCP per kg body weight per day for liver toxicity in dogs, a CF of 40 and an AF of 90 were applied, resulting in a $PNEC_{oral}$ = 13.33 mg MCCP per kg food. BCF of 58194 L $kg^{-1}$ WW earthworm was used (European Commission 2005a and 2007b). | **2.2 mg MCCP per kg DW normalised to 3.4% SOM (secondary poisoning)** | AF of 90, because the study lasted 90 days |

[31] Assessed separately.

# Silver (Ag)

The SSV for use in the risk assessment of waste recovery to land is **0.3 mg Ag per kg DW**, which applies to the direct toxicity from silver exposures from soil. Recent research by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) in Australia (see, for example, Langdon et al. 2014, 2015) means that the influence of soil properties on silver bioavailability can now be taken into account. This generic SSV can be corrected for ageing and normalised to site-specific soil characteristics. For example, the SSV would be 1.2 mg Ag per kg DW for a soil with a pH of 6.2, 2.7% SOM and a clay content of 17.1%. A spreadsheet is available to perform these calculations to derive a soil-specific SSV (Environment Agency 2017).

Silver is a trace element for which the terrestrial ecotoxicity data are extensive. These data are detailed in the summary of the Chemical Safety Report on the ECHA dissemination portal and fulfil the requirements to adopt a probabilistic approach to the derivation of the PNEC following ECHA guidance (Sections R.10.3.1.3 and R.10 in ECHA 2008). An AF of 3 was applied to the $HC_5$ from the non-normalised and unaged SSD to give the SSV. A summary of the data used in the assessment is given in the table below. The most sensitive taxa in the SSDs across all soil characteristics tend to be higher plants.

**Overview of the data used in the assessment**

| **Substance:** Silver and its compounds | | **CAS Number:** 7440-22-4 |
|---|---|---|
| **Summary of acceptable (chronic) data*** | | |
| **Group** | **Number of data points (and species)** | **Indicative range of chronic endpoint values (mg Ag per kg)#** |
| Terrestrial – invertebrates | 192 (4) | 0.22 to 253 |
| Terrestrial – plants | 456 (7) | 0.13 to 301 |
| Terrestrial – microbial functions | 101 (4) | 0.3 to 488 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Probabilistic approach, SSD, log-normal distribution, this gives an $HC_5$ of 0.9 mg Ag per kg **without** the use of an ageing$ factor. | **0.3 mg Ag per kg DW** | AF of 3, based on an overall dataset of 749 $EC_{10}$/NOEC values for at least 12 species and microbial processes. No field studies were available. |

* Summaries of the individual test data are given on the ECHA dissemination portal, The European Precious Metals Federation kindly provided wca with all the terrestrial data to review under a confidentiality agreement on behalf of the Environment Agency.

# These values are not normalised, so differences due to soil properties in the individual tests remain.

$ The ageing factor refers to the effect of ageing due to long-term reactions in the soil on trace element bioavailability and toxicity in soil, and is experimentally derived (for example, Smolders et al. 2009). For silver, there is no correction for leaching but an ageing factor is determined according to soil properties (Langdon et al. 2015):

$$log_{10}\, AF = 0.78 + (0.46 * log_{10} CEC) + (-0.50 * log_{10} OC) + (-0.92 * log_{10} pH) \quad (6.1)$$

where AF = ageing factor, CEC is effective cation exchange capacity and OC is organic carbon content.

# Triclosan

The SSV for use in the risk assessment of waste recovery to land is **0.13 mg triclosan per kg DW, normalised to 3.4% SOM**, based on the direct toxicity to triclosan exposures from soil. The SSV was derived by the deterministic method, following ECHA guidance (ECHA 2008), using an AF of 10. A PNEC for secondary poisoning of 3.6 mg triclosan per kg DW was also derived.

Triclosan is an antibacterial and antifungal agent found in consumer products. Developed for medical uses such as surgical scrubs, it is now prevalent in soaps, shampoos, deodorants, toothpastes, mouthwashes, cleaning supplies, kitchen utensils, toys, bedding and clothing (Clarke and Smith 2011). Recently, the Biocidal Products Committee (ECHA 2015) concluded that triclosan is both toxic and very bioaccumulative, posing a general risk to the food chain.

New terrestrial toxicity data were found since the previous search undertaken in 2009 (Environment Agency 2009c). The new data are available for invertebrates and plants. The lowest NOEC of 1.33 mg triclosan per kg DW is for survival and reproduction of the predatory mite *Hypoaspis aculeifer*, normalised to 3.4% SOM (proprietary study 2010b, cited in summary of Chemical Safety Report on ECHA dissemination portal). A summary of the data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Triclosan | | **CAS Number:** 3380-34-5 |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **Group** | **Number of data points (and species)** | **Range of chronic endpoint values (mg triclosan per kg DW)** |
| Terrestrial – invertebrates | 15 (10) | 1.96 to >1,026 |
| Terrestrial – plants | 22 (13) | 0.065 to 802 |
| Terrestrial – bacteria | 5 (3) | 1 to 28.9 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Deterministic method<br>NOEC = 1.33 mg triclosan per kg DW for survival/reproduction of *Hypoaspis aculeifer*, normalised to 3.4% SOM; an AF of 10 was applied, resulting in a PNEC = 0.133 mg triclosan per kg DW | **0.13 mg triclosan per kg DW normalised to 3.4% SOM (direct toxicity)** | AF of 10 assigned based on NOEC values from long-term toxicity tests for at least 3 species from 3 trophic levels |
| Secondary poisoning method (ECHA 2008). NOAEL = 30 mg triclosan per kg body weight per day for brain toxicity in baboons; a CF of 20 and an AF of 30 were applied, resulting in a $PNEC_{oral}$ = 20 mg triclosan per kg food. A BAF of 5.6 kg DW per kg WW earthworm was adopted. | **3.6 mg triclosan per kg DW (secondary poisoning)** | AF of 30 applied to NOAEL, being a one-year repeated dose toxicity study |

# Tris(2-chloroethyl) phosphate (TCEP)

The SSV for use in the risk assessment of waste recovery to land is **1.1 mg TCEP per kg DW**, **normalised to 3.4% SOM**. It is based on direct toxicity to TCEP exposures from soil and was derived by the deterministic approach (ECHA 2008) using an AF of 10.

TCEP is a chlorinated alkyl phosphate ester, which is primarily used as a flame retardant for unsaturated polyester resins for applications in the textile and construction industries (RIVM 2005). It has a low bioaccumulation potential (European Commission 2009) and therefore an assessment for secondary poisoning was not carried out.

Terrestrial toxicity data for invertebrates, plants and a soil enzymatic function test were found from a search of the open literature from 2006 to 2015. A summary of the data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Tris(2-chloroethyl) phosphate | | **CAS Number:** 115-96-8 |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **Group** | **Number of data points (and species)** | **Range of chronic endpoint values (mg TCEP per kg DW)[#]** |
| Terrestrial – plants | 2 (1) | 10 to 64 |
| Terrestrial – invertebrates | 8 (5) | 5 to 1,000 |
| Terrestrial – microbial function | 3 (1) | 5 to 50 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Deterministic approach; the lowest chronic value was the dehydrogenase activity $EC_{15}$ 11.11 mg TCEP per kg DW, normalised to SOM, AF = 10 | **1.1 mg TCEP per kg DW normalised to 3.4% SOM (direct toxicity)** | AF of 10<br>Three chronic values from at least 3 trophic levels available |

[#] Including acute toxicity data (that is, $LC_{50}$ values).

# Tris(2-chloro-1-methylethyl) phosphate (TCPP)

The SSV for use in the risk assessment of waste recovery to land is **1.8 mg TCPP per kg DW**, **normalised to 3.4% SOM**. It is based on direct toxicity to TCPP exposures from soil and was derived by the deterministic approach (ECHA 2008) using an AF of 10. A PNEC for secondary poisoning of 17.5 mg TCPP per kg DW was also derived.

TCPP is a chlorinated alkyl phosphate ester, which was identified as a possible substitute for pentabromodiphenyl ether (PBDE) as part of the risk reduction strategy for that substance (European Commission 2008e). It is a flame retardant used mainly in polyurethane foam. The European Union Risk Assessment Report (EU RAR), undertaken under the auspices of the Existing Substances Regulation (EEC No 793/93) (European Commission 2008e) classified it as an environmentally persistent compound, but with a lack of any significant bioaccumulation potential.

Terrestrial toxicity data for invertebrates, plants and a soil enzymatic function test were found from a search of the open literature from 2006 to 2015. A summary of the data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Tris(2-chloro-1-methylethyl) phosphate | | **CAS Number:** 13674-84-5 |
|---|---|---|
| **Summary of acceptable (chronic) data** | | |
| **Group** | **Number of data points (and species)** | **Range of chronic endpoint values (mg TCPP per kg DW)** |
| Terrestrial – plants | 6 (3) | 11to 98 |
| Terrestrial – invertebrates | 4 (1) | 32 to 196 |
| Terrestrial – microbial function | 1 (1) | 145 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Deterministic approach, the lowest chronic value was reproduction NOEC 18.02 mg TCPP per kg DW for *Eisenia fetida*, normalised to SOM, AF 10 | **1.8 mg TCPP per kg DW normalised to 3.4% SOM (direct toxicity)** | AF of 10.<br>Three chronic values from at least 3 trophic levels available. |
| Secondary poisoning method (ECHA 2008). NOAEL = 85 mg TCPP per kg body weight per day for paternal toxicity in rats; a CF 10 and an AF of 30 were applied, resulting in a $PNEC_{oral}$ = 28.33 mg TCPP per kg food. Estimated $BCF_{worm}$ 6.58 L $kg^{-1}$ WW was used (European Commission 2008e). | **17.5 mg TCPP per kg DW normalised to 3.4% SOM (secondary poisoning)** | AF of 30, being a two-generational study. |

# Vanadium (V)

The SSV for use in the risk assessment of waste recovery to land is **2.0 mg V per kg DW**, which applies to the direct toxicity to vanadium exposures from soil. This generic SSV takes into account only leaching and ageing effects on the soil ecotoxicity of vanadium. It is based on 'added risk', which means that the ambient background soil concentration must be included in the site-specific SSV (see Section 4.3.1 in the main report).[32] For example, the SSV would be 19.0 mg V per kg DW based on an ambient background soil concentration of 17.0 mg V per kg DW. It is not possible to further modify the SSV for specific soil properties.

Vanadium is a trace element for which there is a relatively large terrestrial ecotoxicity data. A summary of the data in the Chemical Safety Report can be found on the ECHA dissemination portal.[33] The Chemical Safety Report indicates that vanadium is not expected to bioaccumulate and so an assessment of secondary poisoning is not required (Vanadium REACH Consortium, personal communication, 2015).

A probabilistic approach was adopted for the derivation of the vanadium PNEC following ECHA Guidance (ECHA 2008), accounting for ambient background concentration. The ecotoxicity data were corrected for background concentrations, and leaching and ageing (Smolders et al. 2009), before the plotting of an SSD. An AF of 3 was applied to the $HC_{5–50}$ from the SSD to give the recommended SSV. A summary of the data used in the assessment is given in the table below.

**Overview of the data used in the assessment**

| **Substance:** Vanadium and its compounds | | **CAS Number:** 7440-62-2 |
|---|---|---|
| **Summary of acceptable (chronic) data*** | | |
| **Group** | **Number of data points (and species)** | **Indicative 'added' range of chronic endpoint values (mg V per kg)#** |
| Terrestrial – invertebrates | 9 (3) | 2.0 to 96 |
| Terrestrial – plants | 16 (8) | 11 to 250 |
| Terrestrial – microbial functions | 10 (2) | 3.2 to 670 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Probabilistic approach, SSD, log-normal distribution; this gives an $HC_{5–50}$ of 6.1 mg V per kg with the use a leaching–ageing$ factor of 1.5. | **2.0 mg V per kg DW** | AF of 3, based on 35 $EC_{10}$/NOEC values from long-term toxicity tests for 13 species and microbial processes |

* Summaries of the individual test data are given on the ECHA dissemination portal and have been provided to wca to review on behalf of the Environment Agency by the Vanadium REACH Consortium.
# These values are non-normalised, so differences due to the soil properties in the individual tests remain. Most of the testing was made using sodium metavanadate (i.e. penta valent vanadium).
$ The leaching–ageing factor refers to the combined effect of leaching (due to changing ionic strength) and ageing (due to long-term reactions in the soil) on trace element bioavailability and toxicity in soil, and is experimentally derived (see, for example, Smolders et al. 2009). For vanadium the value of this factor is 1.5.

[32] The 10th percentile concentration from the GEMAS survey of UK arable and grassland soils is 17.0 mg V per kg DW (Reimann et al. 2014).
[33] http://echa.europa.eu/registration-dossier/-/registered-dossier/15421/6/1

# Zinc (Zn)

The SSV for use in the risk assessment of waste recovery to land is **35.6 mg Zn per kg DW**, which applies to the direct toxicity to zinc exposures from soil. It is based on 'added risk', which means that the ambient background soil concentration must be included in the site-specific SSV (see Section 4.3.1 in the main report).[34] This generic SSV does not account for leaching and ageing effects (see Section 3.6 in the main report) or the influence of soil properties on the ecotoxicity of zinc. It is necessary to apply all of the relationships and processes described by Smolders et al. (2009). For example, the SSV would be 122.3 mg Zn per kg DW based on a soil pH pf 6.5, SOM content of 3.4%, a clay content of 10% and an ambient background soil concentration of 24.1 mg Zn per kg DW. A spreadsheet is available to perform these calculations to derive a soil-specific SSV (Environment Agency 2017).

Zinc is a trace element for which there are many terrestrial ecotoxicity data (see table below). A European Union Risk Assessment Report (EU RAR), undertaken under the auspices of the Existing Substances Regulation (EEC No 793/93), was the basis of the previous SSV for zinc (Environment Agency 2008b; European Commission 2010[35]). Since then, some new data and a scientifically improved approach have been followed in the derivation of a revised PNEC for REACH that is the basis for this SSV.

A probabilistic approach was adopted for the derivation of the zinc PNEC following ECHA guidance (ECHA 2008), accounting for bioavailability and also ambient background concentration. The ecotoxicity data were corrected for background concentrations before the plotting of an SSD. An AF of 1 was applied to the $HC_5$ from the SSD to give the PNEC. A summary of the data used is given in the table below. The most sensitive taxa in the SSD vary with soil physicochemical conditions.

**Overview of the data used in the assessment**

| **Substance:** Zinc and its compounds | | **CAS Number:** 7440-66-6 |
|---|---|---|
| **Summary of acceptable (chronic) data*** | | |
| **Group** | **Number of data points (and species)** | **Indicative 'added' range of chronic endpoint values (mg Zn per kg)#** |
| Terrestrial – invertebrates | 61 (8) | 15 to 1,630 |
| Terrestrial – plants | 45 (18) | 32 to 5,855 |
| Terrestrial – microbial functions | 108 (17) | 17 to >2,000 |
| **PNEC derivation method** | **SSV** | **Comments** |
| Probabilistic approach, SSD, log-normal distribution of all individual values **without** correction for ageing or normalisation; this gives an HC5 of 35.6 mg Zn per kg. | **35.6 mg Zn per kg DW** | AF of 1, based on 214 $EC_{10}$/NOEC values from long-term toxicity tests for at least 25 species and microbial processes |

* Summaries of the individual test data are given on the ECHA dissemination portal.
# These values are not corrected for leaching–ageing and not normalised, so differences due to the soil properties in the individual tests remain.

[34] The 10th percentile concentration from the GEMAS survey of UK arable and grassland soils is 24.1 mg V per kg DW (Reimann et al. 2014).
[35] Although the EU RAR was published in 2010, the last literature search for this assessment was completed in 2004.

# Appendix B: Search strategy

The collection of terrestrial data for a substance identified by the Environment Agency followed a four-step procedure. The search range extended from the date of the last assessment by the Environment Agency to present, or from 2006 to present for substances which have not yet been assessed.

1. The ECHA dissemination portal was used to search for the substance REACH dossier based on the substance name and/or CAS number. Any terrestrial toxicity studies dated from 2006 or from the year of the last assessment were summarised in the individual dossiers (see Section 4.2 in the main report). Many of these studies were proprietary reports that are not publically available for assessment and therefore the Klimisch scores for these studies are cited from the REACH dossier.

2. A literature search was conducted in TOXLINE and Thomson with the following search string:

   (substance name OR CAS number) AND (soil OR terrestrial) AND (toxico* OR toxicity OR mortality OR reproduction OR acute OR chronic OR subchronic OR sublethal OR NOEC OR NOEL OR PNEC OR poison*)

   TOXLINE is the US National Library of Medicine's bibliographic database for toxicology. TOXLINE records provide bibliographic information covering the biochemical, pharmacological, physiological and toxicological effects of drugs and other chemicals. It contains over 4 million bibliographic citations, most with abstracts and/or indexing terms and CAS Registry Numbers. TOXLINE covers much of the standard journal literature in toxicology, complemented with references from an assortment of specialised journals and other sources.

   The Thomson database covers scientific literature from the other Thomson Reuters products – Web of Science, Current Contents Connect, Conference Proceedings and Inspec. Web of Science provides access to current and retrospective multidisciplinary information from more than 10,400 of the most prestigious, high impact research journals in the world in the sciences, social sciences and arts and humanities – with coverage back to 1900 (sciences), 1956 (social sciences) and 1975 (arts and humanities).

   Search results from TOXLINE and Thomson were combined into one Excel spreadsheet and duplicates were removed. All results were then screened for long-term terrestrial toxicity data. Data were summarised from the abstract when possible and studies were obtained for reliability and relevance assessment if they potentially contained the lowest effect value suitable for SSV derivation.

3. The US EPA ECOTOXicology (ECOTOX) database was searched for terrestrial toxicity data based on substance name and/or CAS Registry Number. ECOTOX is a source for locating single chemical toxicity data for aquatic life, terrestrial plants and wildlife. The search outputs were organised in an Excel file summarising experimental details and results in tabular format. Relevant NOEC and L(E)$C_{10}$ values were summarised in the individual substance dossiers. Studies were obtained for reliability and relevance assessment if they potentially contained the lowest effect value suitable for SSV derivation.

4. A Google search was performed with the following search string:

   (substance name and/or CAS number) terrestrial PNEC

The first 4 pages of results were scanned in search of high-level risk assessments published by regulatory agencies and institutions. PNEC values derived in this project were compared with terrestrial PNEC values determined within the corresponding date range. If a terrestrial PNEC lower than the updated SSV was found, the primary source of data was located and assessed for reliability and relevance to determine its suitability for inclusion in this report.

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