Environment Agency

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Using Soil Guideline Values

Better Regulation Science Programme
Science report: SC050021/SGV introduction

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This report is the result of work undertaken by the Environment Agency's Science Programme.

Published by:
Environment Agency, Rio House, Waterside Drive,
Aztec West, Almondsbury, Bristol, BS32 4UD
Tel: 01454 624400 Fax: 01454 624409
www.environment-agency.gov.uk

ISBN: 978-1-84911-037-2

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Dissemination Status:
Publicly available / released to all regions

Keywords:
Contaminated land, exposure assessment, guideline values, human health, land contamination, risk assessment, soil pollution

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Science Project Number:
SC050021

Product Code:
SCHO0309BPQM-E-P

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Legal Status and Disclaimer
The CLEA Guidance incorporates the following

1) *Science Report SC050021/SR2: Human health toxicological assessment of contaminants in soil.*

2) *Science Report SC050021/SR3: Updated technical background to the CLEA model.*

3) *Science Report SC050021/SR4: CLEA Software (Version) Handbook.*

4) *CLEA Software version 1.04 (2009)*

5) *Toxicological reports and SGV technical notes*

The CLEA Guidance can help suitably qualified assessors to estimate the risk that a child or adult may be exposed to a soil concentration on a given site over a long period of exposure that may be a cause for concern to human health. The CLEA Guidance does not cover other types of risk to humans, such as fire, suffocation or explosion, or short-term and acute exposures. Nor does it cover risks to the environment or the pollution of water.

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The CLEA guidance describes the soil concentrations above which, in the opinion of the Environment Agency, there may be concern that warrants further investigation and risk evaluation for both threshold and non-threshold substances. These levels are a guide to help assessors estimate risk. It does not provide a definitive test for telling when risks are significant.

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- **Delivering information, advice, tools and techniques**, by making appropriate products available to our policy and operations staff.

Steve Killeen

Head of Science

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1 Background

1.1 Introduction

This introductory note is part of a series published by the Environment Agency that describe Soil Guideline Values (SGVs) for individual, or groups of similar, chemicals for use in assessing the chronic risk to human health from long-term exposure to chemicals in soil.

The series is divided into three parts:

- An introduction to the series that explains what SGVs are, their purpose and advice on their use (this note).
- Technical notes that present SGVs for a range of chemicals that together make up a comprehensive compendium.
- Supplementary information notes that contain more detailed technical discussion and reviews that support individual SGV technical notes.

These documents should be used only in conjunction with:

- the framework documents *Updated technical background to the CLEA model* (Environment Agency, 2009a) and *Human health toxicological assessment of contaminants in soil* (Environment Agency, 2009b);
- the relevant chemical TOX reports that recommend Health Criteria Values (HCVs) for use in assessing risks to human health from long-term human exposure to chemicals in soil.

The SGV technical notes and supplementary information for each contaminant or groups of similar chemicals can be downloaded from our website (http://www.environment-agency.gov.uk/clea). Further documents for additional chemicals will be published on our website as they become available.

1.2 Update to R&D SGV publications

In November 2006, the Department for Environment, Food and Rural Affairs (Defra) issued a discussion paper entitled *Soil Guideline Values: The Way Forward* (Defra, 2006a). The paper sought views from key organisations and groups on various ideas for how non-statutory technical guidance might be amended to make it more useful to assessors carrying out risk assessments, and to make clearer when land qualifies as contaminated land under Part 2A of the Environmental Protection Act 1990 in England and Wales. This exercise culminated in the publication by Defra of:

- *Improvements to contaminated land guidance. Outcome of the "Way Forward" exercise on Soil Guideline Values* (Defra, 2008a);
- *Guidance on the legal definition of contaminated land* (Defra, 2008b).

We have produced framework documents that provide a methodology to help risk assessors develop generic assessment criteria to evaluate whether a child or adult might be exposed to harmful or potentially harmful levels of a chemical on a given site over a long period of exposure.

1.2.1 Framework documents

- **Updated technical background to the CLEA model (SR3)** (Environment Agency, 2009a) incorporates many of the updates to exposure assessment introduced in *Soil Guideline Values: The Way Forward* (Defra, 2006a) together with other changes. The report describes the technical principles of the Contaminated Land Exposure Assessment (CLEA) model.

  The CLEA model uses generic assumptions about the fate and transport of chemicals in the environment, and a generic conceptual model (referred to in this report as generic land use scenarios) for site conditions and human behaviour, to estimate child and adult exposures to soil contaminants for those living, working and/or playing on contaminated sites over long time periods. We use the CLEA model to derive SGVs.

- **Human health toxicological assessment of contaminants in soil (SR2)** (Environment Agency, 2009b) incorporates the updates to how the toxicity of chemicals in soil are assessed that were introduced in *Guidance on the legal definition of contaminated land* (Defra, 2008b) together with further guidance on chemical risk assessments for soil.

  The report describes a framework developed by the Environment Agency (in collaboration with the Health Protection Agency and the Food Standards Agency) for the collation and review of toxicological data in order to derive Health Criteria Values (HCVs).

  HCVs describe a benchmark level of exposure to a chemical at which, unless stated otherwise, long-term human exposure to chemicals in soil is tolerable or poses a minimal risk. HCVs are derived from available toxicity data. We use HCVs to derive SGVs.

- **CLEA software (version 1.04) and handbook** (Environment Agency, 2009c, 2009d). The CLEA software is based on the modelling approach described in the framework report (Environment Agency, 2009a).

  The software enables assessors to derive assessment criteria (AC) to assist in the evaluation of the risks posed to human health from chronic exposure to chemicals in soil in relation to land use.

  Assumptions in the CLEA software apply to the derivation of generic assessment criteria (GAC), but also offer a useful starting point for the development of site-specific assessment criteria (SSAC).

  The accompanying handbook contains further information on using the CLEA software (outside the scope of the CLEA report SR3) for deriving SSAC. We use a version the CLEA software to derive SGVs.

1.2.2 SGV technical notes

In addition to the framework reports we are publishing SGV reports for a selection of common contaminants relevant to the assessment of land contamination. We have selected these chemicals, in consultation with industry and the former Soil Guideline Value Task Force, because they are likely to be found on a large number of contaminated sites in the UK and have the potential to affect human health.

The SGV technical notes explain how the framework documents and individual chemical toxicology (TOX) reports have been used to derive SGVs.

2 Purpose of Soil Guideline Values

Soil Guideline Values and the framework documents provide relevant, appropriate, authoritative and scientifically based information and advice on the assessment of risks to human health from land contamination. They provide non-statutory technical guidance to regulators and their advisors in support of the statutory regimes addressing land contamination, particularly Part 2A of the Environmental Protection Act 1990 and the consideration of land affected by contamination under the Town and Country Planning Acts (Defra 2008a, 2008b). When we refer in this report to terms that are subject to legal definitions under Part 2A, we will use italics (for example, *contaminated land*).

2.1 Part 2A of the Environmental Protection Act

Part 2A of the Environmental Protection Act 1990 created a regime for the identification and remediation of contaminated land. It defines *contaminated land* according to whether it poses a significant risk to human health and/or the environment. It establishes that local authorities are solely responsible for deciding when land is *contaminated land*.

In relation to health effects not attributable to radioactivity, it considers land to be *contaminated land* where it:

> "... appears to the local authority in whose area the land is situated to be in such a condition by reason of substances in, on or under the land that (a) significant harm [to human health] is being caused or there is a significant possibility of such harm being caused…"

The definition is the subject of statutory guidance issued by the Secretary of State (Defra, 2006b), which defines *significant harm* and *a significant possibility of such harm*, with respect to the definition of contaminated land. Defra has issued further, non-statutory guidance on the legal definition of contaminated land (Defra, 2008b).

The statutory guidance (Defra, 2006b) sets the definition of contaminated land within the context of Government policy including the "suitable for use" approach. Action is necessary only where there are unacceptable risks to health or the environment, taking into account the current use of the land and its environmental setting.

Part 2A includes the concept of a *pollutant linkage*. In the context of land contamination, there are three essential elements to any risk (Defra and Environment Agency, 2004):

- A **contaminant** – a substance that is in, on or under the land and has the potential to cause harm;
- A **receptor** – in general terms, something that could be adversely affected by a contaminant, such as people;
- A **pathway** – a route or means by which a receptor can be exposed to, or affected by, a contaminant.

Each of these elements can exist independently. They create a risk only where they are linked together, so that a particular contaminant affects a particular receptor via

one or more pathways. This kind of linked combination of contaminant–pathway–receptor is described as a pollutant linkage (Defra and Environment Agency, 2004).

2.2 The planning regime

Land contamination is also a material consideration under the planning regime.

A local planning authority has a duty to consider the potential implications of contamination:

- when it is developing a Local Development Framework;
- when it is considering applications for planning permission.

Planning Policy Statement 23: Planning and Pollution Control (PPS 23) explains the relationship between the planning regime and Part 2A (ODPM, 2004a, 2004b).

In the granting of planning permission for new development (including permission to carry out remediation), PPS 23 states that remediation must remove unacceptable risk to human health and make the site suitable for its intended use. As a minimum, after carrying out a development and commencement of its use, the land should not be capable of being determined as *contaminated land* under Part 2A (Defra, 2008b).

2.3 What are Soil Guideline Values and how are they derived?

2.3.1 What are Soil Guideline Values?

SGVs are scientifically based generic assessment criteria that can be used to simplify the assessment of human health risks arising from long-term and on-site exposure to chemical contamination in soil. They do not, however, consider risks to construction workers or risks from occupational exposure arising from activities in the work place.

SGVs are a screening tool for the generic quantitative risk assessment of land contamination (Defra and Environment Agency, 2004). They are not (unless clearly stated otherwise) relevant for assessing risks to human health from short-term exposure to chemicals in soil including injury arising from direct bodily contact and do not take account of other types of risks to humans such as explosion or suffocation risks (associated with the build-up of gases such as methane and carbon dioxide) or aesthetic issues such as odour or colour.

SGVs do not take account of other non soil based sources of contamination such as contamination in groundwater, surface waters or drinking waters. They cannot be used to evaluate risks to non-human receptors such as controlled waters, ecosystems, buildings and services, domestic pets or garden plants. Where, for example, phytotoxic effects are an important consideration in the current or future intended land use further investigation should be undertaken.

SGVs are guidelines on the level of long-term human exposure to individual chemicals in soil that, unless stated otherwise, are tolerable or pose a minimal risk to human health. They represent “trigger values” – indicators to a risk assessor that soil concentrations above this level **may** pose a possibility of *significant harm* to human health (Defra, 2008b). *Significance* is linked to:

- the margin of exceedance;
- the duration and frequency of exposure;
- other site-specific factors that the enforcing authority may wish to take into account.

SGVs do not of themselves represent the threshold at which there is a *significant possibility of significant harm* (SPOSH). Nor do they automatically represent an unacceptable intake in the context of Part 2A of the Environmental Protection Act 1990. However, they can be a useful starting point for such an assessment.

Science alone cannot answer the question of whether or not a given possibility of significant harm is significant, since what is either "significant" or "unacceptable" is a matter of socio-political judgement. The law entrusts decisions on this to the enforcing authorities (Defra, 2008b).

SGVs are not derived explicitly to be used as remediation standards. The process for setting remedial objectives and standards for remediation is outlined in CLR 11 (Defra and Environment Agency, 2004). Further guidance is also available on required remediation standards under Part 2A (Defra 2006b) and planning (ODPM 2004b).

- SGVs can be used as a starting point for evaluating long-term risks to human health from chemicals in soil.
- SGVs can be used as an indication of chemical contamination in soil below which the long-term human health risks are considered to be tolerable or minimal.
- SGVs do not represent the "trigger" for an unacceptable intake.
- Unless specifically stated, SGVs do not cover other types of risk to humans such as fire, suffocation or explosion, or short term and acute exposures.
- SGVs cannot be used to evaluate risks to construction workers or non-human receptors.
- SGVs are not explicitly derived to define remediation standards

2.3.2 How are SGVs derived?

SGVs are derived using the framework guidance (Environment Agency, 2009a and Environment Agency, 2009b). The CLEA software estimates exposure to chemicals from soil sources by adults and children living or working on land affected by contamination over long periods of time, and compares this estimate to established health criteria values (HCVs). HCVs are benchmark levels of exposure to a chemical that describe the levels at which long-term human exposure to chemicals in soil is tolerable or poses a minimal risk. HCVs differ according to whether they relate to adverse effects that are expected to demonstrate a threshold (Tolerable Daily Intake, TDI) or effects for which no threshold is assumed (Index Dose, ID) (Environment Agency, 2009b).

The basic principle used to establish SGVs is that they are set at the soil concentration where the Average Daily Exposure (ADE) from soil sources by a particular exposure route equals the HCV for that route (Environment Agency, 2009a). However, for many substances, exposure by all routes may contribute to the same systemic toxic effect.

Thus, there may be a risk to health even when exposure via each separate route is less than its corresponding HCV. In order to take this into account, the SGV is set at a soil concentration where the total risk from soil exposure via all routes of entry into the body is mathematically no greater than the risk due to exposure by any single route of entry compared to relevant pathway-specific HCVs (see Equation 2.4 in Environment Agency, 2009a).

For threshold contaminants the average background exposure (Mean Daily Intake, MDI) from non-soil sources (predominantly, ambient air, drinking water and food products) is taken into account in the derivation of SGVs to determine the proportion of the TDI that may be allocated to exposure from soil. The underlying principle is that the MDI is subtracted by the CLEA software from the TDI to give the Tolerable Daily Soil Intake (TDSI) and it is the TDSI that is compared with estimated exposures from soil to derive the SGV. However, where background exposure from non-soil sources is more than half of the TDI, the TDSI should be no greater than 50 per cent of the TDI, in order to avoid disproportionately targeting exposures from soil (Defra, 2008b).

In order to implement this approach in the CLEA software, background exposure via oral and inhalation pathways is not allowed to be greater than the corresponding soil exposure. When calculating individual oral or inhalation assessment criteria, which are estimated by comparing soil exposure by the relevant route with an oral or inhalation TDSI, this means that soil exposure will always contribute a minimum of 50 per cent of the TDI and a minimum of 50 per cent of total exposure at a soil concentration equal to the relevant assessment criterion.

However, this will not be the case when deriving a combined assessment criterion to take into account systemic toxicity, where there are multiple routes of exposure and both an oral and inhalation HCV. This is because there is no combined TDI and therefore it is not possible to calculate a combined TDSI, or to ensure that soil contributes a minimum of 50 per cent compared with it. By capping background exposure via oral and inhalation pathways to be no greater than the corresponding soil exposure, the software continues to ensure that the calculations do not disproportionately target exposure from soils. In the combined assessment criterion, background exposure will always be less than 50 per cent of the individual oral and inhalation TDSI but may be capped at a lower level than would be the case when calculating individual oral and inhalation assessment criteria.

The CLEA software estimates the ADE from soil sources via three main routes of entry:

- ingestion through the mouth (oral);
- absorption through the skin (dermal);
- inhalation through the mouth and nose.

The following exposure pathways are included:

- ingestion of contaminated soil, indoor dust and homegrown/ allotment grown produce;
- absorption of the contaminant through the skin from soil and indoor dust;
- inhalation of contaminated dust and vapour from indoor and outdoor air.

The inclusion of an exposure pathway in the derivation of the SGV depends on:

- the generic land use scenario used;
- the chemical properties;
- health effects.

In general, there is a lack of good dermal toxicity data upon which dermal HCVs can be proposed. SGVs are derived using the default assumption that dermal exposure is compared with the HCV for the oral exposure pathway (and to add this directly to the oral exposure in the calculation of ADE from soil sources) (Environment Agency, 2009a).

SGVs are derived for three different generic land use scenarios as described in detail in Environment Agency (2009a):

- residential;
- allotment;
- commercial.

2.4 Why use Soil Guideline Values?

SGVs are provided as a technical tool to assist in the assessment of human health risks from land contamination. However, there is no statutory requirement to use them. Alternative technical guidance or assessment criteria produced by other organisations can be used provided they meet the requirements of the legislation. For instance, under Part 2A of the Environmental Protection Act 1990, the requirements of the statutory guidance should be met.

In the context of Part 2A, and if applied appropriately, SGVs can be used to identify sites where there is unlikely to be a possibility of *significant harm* (Defra, 2008b).

Where representative soil concentrations of contaminants on a site are **at or below** the SGV (and the generic land use scenario used to derive the SGV is sufficiently representative of, or conservative for, the site under evaluation), it can be assumed that it is very unlikely that a *significant possibility of significant harm* exists (Defra, 2008b).

This is on the basis that:

- SGVs are based on generic exposure scenarios whose aggregated exposure from all pathways is likely to be well above average; and
- SGVs and HCVs describe only where there **may** start to be a significant human health risk.

If representative soil concentrations of chemicals on a site **exceed** the SGV, there are three possibilities in terms of determining significant possibility of significant harm under Part 2A (Defra, 2008b):

(1) There may be **no** possibility of *significant harm*.

(2) There may be a **non-significant** possibility of *significant harm*.

(3) There may be a ***significant*** *possibility of significant harm*.

Where representative soil concentrations of chemicals on a site exceed an SGV, further evaluation and assessment of the human health risks will normally be required to determine if a *significant possibility of significant harm* exists.

- Representative site soil concentrations **at or below an SGV** indicate that it is unlikely that a *significant possibility of significant harm* exists.
- Representative site soil concentrations **above an SGV** might represent a *significant possibility of significant harm*. Further investigation and/or more detailed evaluation of human health risks will usually need to be conducted.

3 Advice on using SGVs

Generic assessment criteria such as SGVs are a tool that can be used as part of a Generic Quantitative Risk Assessment (GQRA) for considering the risks to health from long-term exposure to chemicals in soil. Their use should form one part of the GQRA process as outlined in *Model procedures for the management of land contamination* (CLR11), which applies to the range of potential receptors affected by land contamination (Defra and Environment Agency, 2004).

The model procedures provide a technical framework for structured decision making about land contamination. The risk assessment process that forms part of this framework is presented as 3 tiers:

Stage 1 - Preliminary risk assessment – a qualitative assessment, the dominant part of which is the development of the conceptual site model. This stage must be completed before a GQRA is undertaken.

Stage 2 - Generic Quantitative Risk Assessment

Stage 3 - Detailed Quantitative Risk Assessment

Once the need for risk assessment has been identified, it will always be necessary to carry out a preliminary risk assessment. However, depending on the circumstances and the outcome, it may not be necessary to carry out further risk assessment, or, it may be appropriate to use only one of the two approaches to quantitative risk assessment rather than both (i.e. in some situations, it might be appropriate to conduct a DQRA without having conducted a GQRA).

The overall process of risk assessment is often iterative, and there can be iterations within each tier, especially when information is evaluated and gaps in knowledge (uncertainties) are identified. Equally, in some circumstances it may be appropriate to exit the process part way through, if enough is known about the potential risk. This could be because no possibility of unacceptable risks have been identified, or because the risk is such that it is appropriate to move straight to the next part of the framework – remedial options appraisal. The effort expended in risk assessment should be proportionate to the circumstances.

This section provides good practice advice on using SGVs as part of a risk assessment for land contamination and uses the GQRA process from the model procedures (Defra and Environment Agency, 2004) as a guiding framework throughout. The primary purpose of GQRA is to establish whether generic assessment criteria and assumptions are appropriate for assessing the risks at a site, and if so, to apply them to establish whether there are actual or potential unacceptable risks. This can also determine whether further detailed assessment is required.

Figure 3.1 sets out the recommended approach to GQRA for human health and the use of SGVs as part of that process. It is a modification of Figure 2B in CLR 11 and the sections below should be read in conjunction with CLR11 Part 1 Section 2.3. Cross-references are made to further information provided in CLR 11 Part 2 Supporting Information in the form of signposts to Inputs, Criteria, Tools and Outputs. The sections below do not provide advice on all the steps shown in the flow chart in Figure 3.1. Advice is not provided for Step 4 ‘Calculate GAC’, because this is the subject of the CLEA framework documents (Environment Agency 2009a, 2009b, 2009c, 2009d); see also section 1.2.1 of this report.

The conceptual site models used in the derivation of SGVs are referred to in this report as generic land use scenarios in order to distinguish between the use of a conceptual site model developed for a particular site.

In some instances, SGVs may be used as a screening tool for other land-uses for which generic land-use scenarios have not been developed. This may be appropriate if it can be justified that the generic land-use assumptions will be sufficiently protective of health for the other land-use scenario in question.

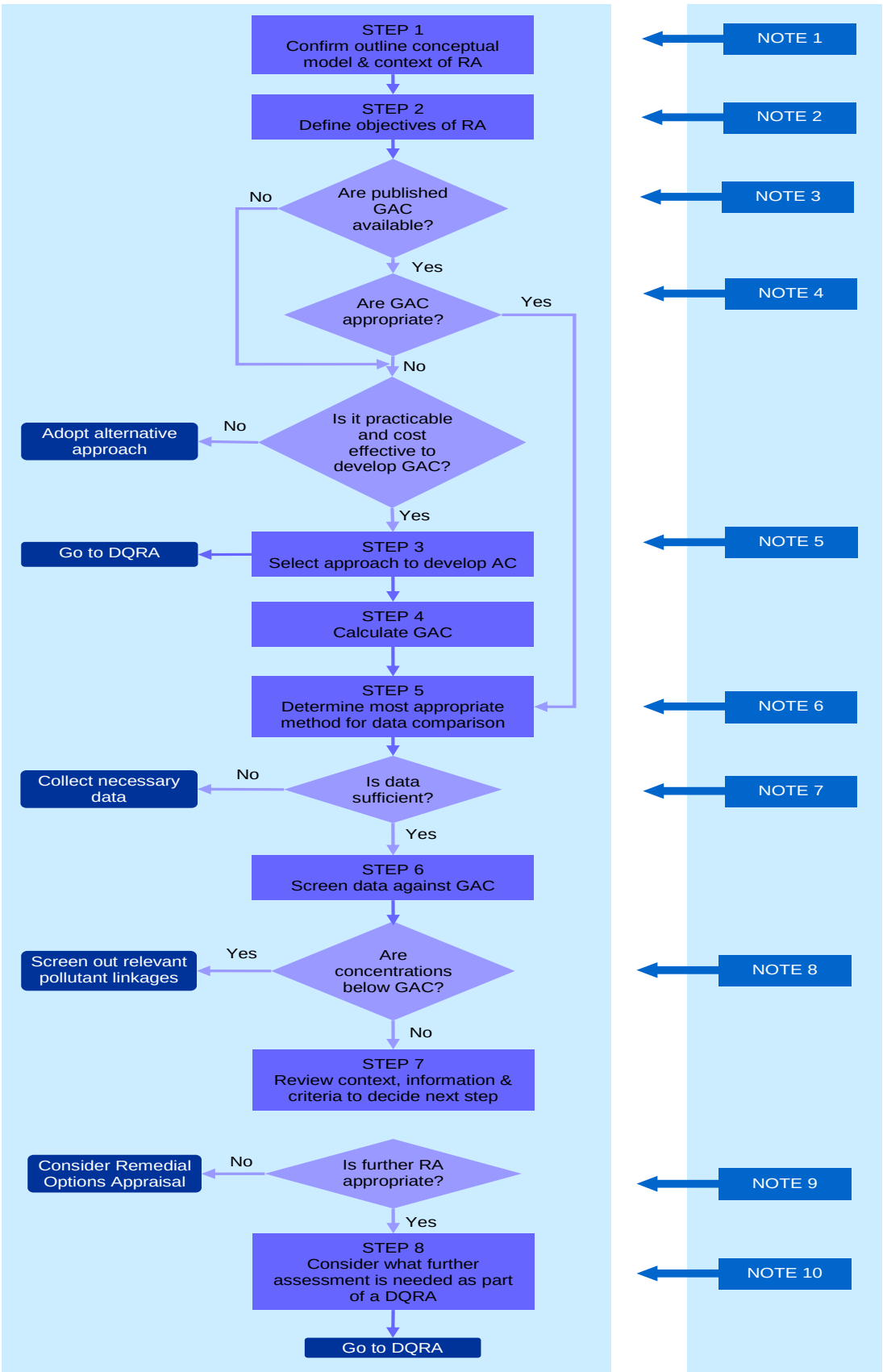
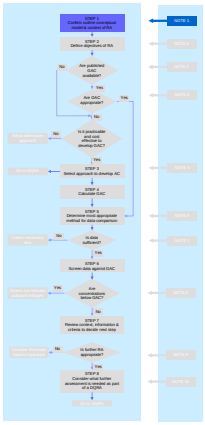


Figure 3.1 GQRA flowchart for human health risk assessment (after Defra and Environment Agency, 2004)

3.1 Step 1 Confirm outline conceptual model and context of risk assessment



NOTE 1

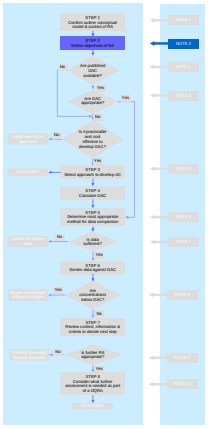
The GQRA should be:

- relevant to the site-specific circumstances of the land in question, both in terms of its condition and its use;
- appropriate to the context in which the assessment is being undertaken.

SGVs are intended to be used as a screening tool under Part 2A, but may also be applicable to the planning regime. The generic land use scenarios used in the derivation of SGVs are described in *Updated technical background to the CLEA model* (SR3) (Environment Agency, 2009a).

CLR 11 Figure 2B signpost ← OUTPUT 1

3.2 Step 2 Define objectives of risk assessment



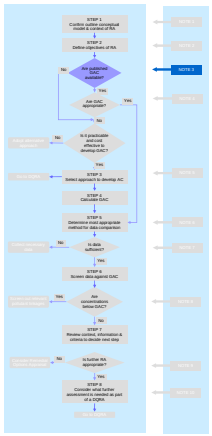
NOTE 2

The objective of the GQRA should be stated explicitly.

The objective should be the use of GAC to screen out pollutant linkages established as part of the Preliminary Risk Assessment.

CLR 11 Figure 2B signpost ← INPUT 1

3.2.1 Are published SGVs available?



NOTE 3

SGVs are authoritative, scientific GAC relevant to decisions about the risks to health from land contamination.

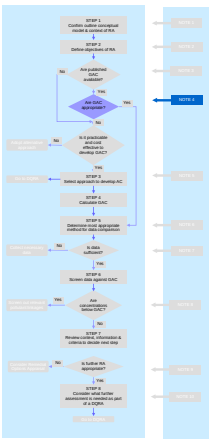
If an SGV (or equivalent) is not available for a substance identified in soil at a site, the simplest option might be to derive a generic assessment criterion using (where appropriate) the generic models used to define SGVs, and based on appropriately sourced physical-chemical and toxicity data. This might not always be

appropriate, for example, for asbestos[1], or where it might be more efficient to move directly to a detailed quantitative risk assessment (DQRA).

Physical-chemical data for some organic chemicals are available in *Compilation of data for priority organic pollutants for derivation of Soil Guideline Values* (SR7) along with guidelines for data collation and review, and estimation methodologies (Environment Agency, 2008).

HCVs should be selected in accordance with the guidance given in *Human health toxicological assessment of contaminants in soil* (SR2) for the collation and review of toxicity data (Environment Agency, 2009b).

3.2.2 Are SGVs appropriate?



NOTE 4

It is only appropriate to use SGVs if the generic land use scenario is sufficiently representative of (or suitably conservative for) the conceptual site model. The conceptual site model sets out a discrete set of circumstances where exposure may occur including:

- the source;
- pathways;
- exposed population;
- site circumstances such as the soil type and soil organic matter (SOM).

Guidance on whether a departure from a generic land use scenario is likely to be significant is given in SR3 (Environment Agency, 2009a).

SGVs are generic, calculated on the basis of a number of parameter choices. They do not represent absolute minimum numbers independent of site condition. SGVs will therefore **not** be equally protective of human health at every site. They may under- or over-estimate risk if the conceptual site model and specific site conditions do not match the choices made in their derivation.

If the available generic land use scenarios are not suitable for the land use in question, SGVs should not be used. Instead either generic assessment criteria broadly applicable to the site in question should be derived (e.g. a generic conceptual site model for a school or a park) or a DQRA undertaken to derive site-specific assessment criteria (SSAC) (Defra and Environment Agency, 2004).

[1] Asbestos is different from most chemicals in that it is fibrous and only causes notable toxicity if fibres become airborne and are inhaled. Potential risks from asbestos in soil depend critically on its form and human activities, such as digging or vehicle movements, which might lead to release of fibres to air.

Example considerations for acceptance criteria derivation and use

We want to assess the human health risks posed by land contamination at a “city secondary school”.

We could:

(1) Satisfy ourselves that an existing generic land-use scenario is suitably precautionary for this non-standard land-use. In this example we might use residential SGVs as screening criteria. This may be an option when considering an existing site but overly conservative when considering a future/proposed land-use.

(2) Derive a GAC based on a generic conceptual site model suitable for all types of school. This might be a suitable approach if a number of assessments of school sites were to be made, and might assume for example:

- receptor age classes that are relevant to a primary school child as a reasonable worst-case (young children are generally more likely to have higher exposures to soil contaminants);
- exposure frequency for time spent on site might reflect that of a secondary school where children may be likely to spend more time at the school taking part in after school activities.

(3) Alternatively we could derive a SSAC. This would be much more tailored to the site circumstances, for example:

- receptor age classes would reflect the actual age range of children likely to be at the school;
- exposure frequency for time spent on site would reflect the actual time spent on site, including after school activities.

Additional guidance on factors likely to vary significantly between sites includes:

- CLEA software and handbook (Environment Agency, 2009c, 2009d);
- *Sensitivity analysis of the CLEA model: critical input parameters and areas of uncertainty* (Environment Agency, in preparation);
- *The VOCs handbook: investigating, assessing and managing risks from inhalation of VOCs at land affected by contamination* (CIRIA, in press).

In determining whether the generic land use scenarios used in the derivation of the SGVs are sufficiently representative of the site under evaluation, the risk assessor should seek to answer the following questions:

- Are additional sources present that are not considered in the derivation of the SGVs?

- Are the soil conditions assumed in the derivation of the SGVs sufficiently similar to, or conservative for, soil conditions on site?
- Are additional exposure pathways present that are not considered in the derivation of the SGVs?
- Are there receptors present on site that are determined to be more sensitive than the default receptor type used in the derivation of the SGVs?
- To what extent do exposure durations reflect those used in the derivation of the SGVs?
- Are there additional activities that take place on the site that are not included in the derivation of the SGVs and which may increase human exposure to soil contamination?

It is extremely unlikely that every detail of the generic land use scenarios presented in SR3 (Environment Agency, 2009a) will reflect the conditions found at any one specific site. A judgement on whether such differences are important must be made. Such a decision should take into account the following:

- Whether the differences between conceptual site model and assumptions within the generic land use scenario mean that the estimated exposure or outcome decision would be vastly different. If in doubt, the generic land use scenario must be more conservative than, and therefore adequately account for the pollutant linkages in, the conceptual site model.

  For example, the relative importance of exposure pathways that are not included should be determined (e.g. consumption of meat or dairy products, use of on-site water for drinking/bathing/showering through direct use of an on-site source or permeation of drinking-water pipes, or vapour intrusion from shallow groundwater contamination).

  If this is the case, a different modelling approach to CLEA is necessary to address these additional pathways.
- Whether site circumstances are based on robust observations and take into account reasonable foresight (given physical and other constraints on land use).
- Minor differences between the generic land use scenarios and the conceptual site model (e.g. adjustments of a few days to exposure frequency) are unlikely to result in major differences to the resulting exposure estimate.
- It is important that other choices in the derivation of the SGVs reflect site circumstances such as the ground conditions. Most notable is the choice of soil type and soil organic matter (SOM) content.

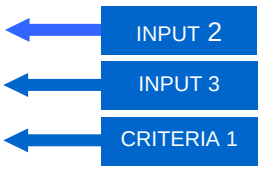
The SGVs are based on a sandy loam soil with 6 % SOM (Environment Agency, 2009a). If the soil at the site in question departs from the generic assumptions inherent in the SGV, three options are presented to the risk assessor:

- If the soil type is likely to be less protective of receptors, the risk assessor should derive a new GAC by adjusting the SGV for soil type and SOM. For example, a sandier, SOM-deficient soil is likely to provide less protection against exposure to volatile sources than that used in the derivation of the SGV.
- If the soil type is likely to be more protective (for example a soil with a higher clay content and greater SOM for the same volatile source), or is sufficiently similar to the SGV assumption, the SGV can be used.
- If the soil type is likely to be more protective, a new GAC could be derived (particularly where the representative soil concentration of a chemical on a site exceed an SGV) by adjusting the SGV, thereby providing a less overly conservative screening tool.

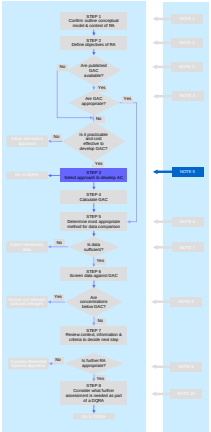
SR3 (Environment Agency, 2009a) provides some advice specifically on made ground. Risk assessors should consider very carefully whether SGVs based on natural soil conditions can be used reliably where contamination exists within made ground. The significance of the presence of the coarser materials in the made ground compared with the finer soil matrix in which these materials might be present will depend on the relative proportions of each. If the coarser materials dominate, it may not be appropriate to use SGVs and alternative GAC should be developed by, for example, making adjustments to the SGVs (as discussed above). This is equally applicable if the organic matter content of the made ground is significantly less than that assumed in the derivation of the SGVs.

Further guidance on site-specific adjustment of an SGV is provided in Section 3.3.

CLR 11 Figure 2B signposts



3.3 Step 3 Select approach to develop Assessment Criteria



NOTE 5

There are two options for developing Assessment Criteria by adjusting SGVs so that they have greater relevance to the site in question:

- **Simple adjustment of the generic SGV model**. Such adjustment is restricted to the choice of exposure routes selected for the generic land use, building type, soil type and soil organic matter content within the CLEA software (Environment Agency, 2009c and 2009d).
- **Detailed adjustment.** It may be relevant to make greater modifications to the model due to the specific use of the land in

question. This can include modification to any parameter value, including exposure assumptions, building parameters, and the choice and application of fate and transport models. This is equally relevant to site-specific modifications of existing generic land uses, the development of new land uses, and the inclusion of additional exposure pathways. Much of this can be undertaken using the CLEA software. Depending on the complexity of the detailed adjustments required, it may be necessary to use other tools either alone or in conjunction with the CLEA software.

Both options should follow established protocols for DQRA and require sufficient justification and supporting information for the adjustments made. Detailed adjustments are likely to require substantially greater technical justification and supporting documentation, especially if modifications are based on information not contained within the SGV framework documents.

The two choices present the risk assessor with three options/decisions:

(1) Use a published SGV if it can be demonstrated that the assumptions inherent in the value are appropriate to the site in question. If they are not, proceed to either option 2 or 3 below.

(2) Make simple site-specific adjustments to the generic exposure model used to derive the SGV. Three examples of when this could be appropriate are:

   a. High density residential development with no exposed contaminated soil at surface. It is appropriate in this case to consider the relevance of direct contact pathways and consumption of homegrown produce.

   b. Soil type is significantly different (specifically when soil type is likely to be less protective e.g. made ground) to that assumed in the SGV.

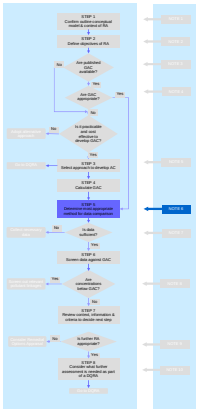
   c. Soil organic matter content is significantly different to that assumed in the derivation of the SGV.

(3) If simple adjustments are not sufficient to reflect site conditions, undertake a DQRA. This may be undertaken using the CLEA software or by using an alternative risk assessment methodology that is relevant, appropriate, authoritative and scientifically based (Defra, 2006b)

In the context of this guidance, simple adjustments of a generic land use scenario for soil type or SOM content for example are not considered sufficient to be classed as a DQRA. The resultant AC from such simple adjustment remain generic in terms of the balance of the assumptions being made in total.

CLR 11 Figure 2B signpost 

3.4 Step 5 Determine most appropriate method for data comparison



NOTE 6

The type, quantity and quality of the available soil data influence the method chosen to obtain a site representative soil concentration that is compared with a SGV in the screening process.

The soil data should be representative of the exposure scenario being considered. This can include factors such as:

- averaging area over which exposure occurs;
- sample depth;
- heterogeneity of soil.

Site investigations take discrete samples from a given area (and to a certain depth). It has to be assumed that these samples are to some degree representative of the contaminant concentration throughout that volume of soil. The critical soil volume (taking into account area and depth) which might be usefully compared with a SGV is a site-specific decision, but a starting point is the generic land use scenarios used in the derivation of the SGV.

The critical soil volume depends on two factors:

- Contaminant distribution and vertical profile (bands of highly contaminated material or lateral hot spots should not necessarily be averaged out with more extensive cleaner areas of soil without justification)
- Contribution to average exposure underpinning the SGV. Direct contact exposure pathways depend on the adult or child coming into contact with near-surface soils and the area over which that exposure occurs is usually important (i.e. the averaging area). Vapour pathways are less dependent on surface area, for example vapour intrusion may result from a highly concentrated hot spot beneath a building leading to elevated average indoor air concentrations.

For the three standard land uses for which SGVs are derived, relevant considerations are:

- For the standard **residential or allotment land use**, the critical soil volume is the area of an individual garden, communal play area or working plot from the surface to a depth of between 0.5m and 1.0m. This is the ground over which children are most likely to come into contact with soil or from which vegetable and fruit produce will be harvested. In the case of volatile contaminants, it may also be appropriate to consider the volume of soil underneath the footprint of the building although vapour intrusion may be driven by a soil volume much smaller than this if the contaminant source is highly concentrated.

- For the standard **commercial land use**, the critical soil volume has to be decided on a case-by-case basis due to the wide range of possible site layouts. However, for non-volatile contaminants, landscaped and recreational areas around the perimeter of office buildings are likely to be most important. For volatile contaminants, the footprint occupied by the building itself should also be considered.
- For **most exposure pathways**, the contamination is assumed to be at or within one metre of the surface.

The use of averaging areas must be justified on the basis of relevance to the exposure scenario. SGVs are relevant only when the exposure assumptions inherent in them are appropriate for the identified exposure averaging area.

Further guidance on critical soil volumes and the consideration of averaging exposure areas can be found in:

- *Secondary model procedure for the development of appropriate soil sampling strategies for land contamination* (Environment Agency, 2000a);
- *Guidance on comparing soil contamination data with a critical concentration* (CIEH/CL:AIRE, 2008).

There are two principal options available to obtain site representative soil concentrations from a site investigation dataset – statistical and non-statistical methods. Data objectives, quality and quantity are likely to determine which approach is most appropriate. If statistical methods such as those presented in CIEH/CL:AIRE (2008) are to be used, sufficient data need to be available or obtained.

No one single statistical approach is applicable to all sites and circumstances. The wider range of robust statistical techniques developed by organisations including the US Environmental Protection Agency (USEPA) are also important tools. Risk assessors should choose an appropriate statistical approach on the basis of the specific site and the decision that is being made.

For further guidance on the appropriate use of statistical approaches, refer to USEPA 2006 or good environmental monitoring statistics textbooks.

When statistical approaches are inappropriate (this will depend on the objectives of the site investigation), individual or composite samples should be compared directly to the SGV. Guidance on use of alternative data handling approaches such as the use of composite sampling can be found in documents such as:

- *Verification of remediation of land contamination* (Environment Agency, in press);
- *Sampling and testing of wastes to meet landfill Waste Acceptance Criteria* (Environment Agency, 2005);
- *Guidance on choosing a sampling design for environmental data collection* (USEPA, 2002);

- *Soil Quality – Sampling, ISO 10381 series* (ISO, 2002–2007).

The statistical tests should not be used as arbiters for decisions under Part 2A. They are an additional, useful line of evidence to assist in decision-making.

The implications of the basis for the derivation of the site representative soil concentration must be taken into account in any decision-making process and clearly documented.

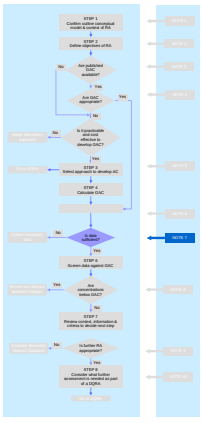
Good data quality is defined in CLR11 (Defra and Environment Agency, 2004) as relevant, sufficient, reliable and transparent.

Data quality should be judged on factors such as:

- **Choice of sampling points**. Is it judgemental or random? How certain is it that contamination has been identified?
- **Sampling method**. Does it follow good practice guidance? Does it maximise the integrity of the sample?
- **Sample handling and storage**. Does it minimise contaminant losses or transformation?
- **Sample preparation**. Is it in accordance with good practice and appropriate for the contaminant of interest?
- **Analytical detection limit relative to the SGV**. The analytical limit of detection (LOD) should be sufficiently below the SGV to satisfactorily address quantification uncertainty at the LOD.
- **Analytical method quality assurance**. MCERTS accredited analytical methods must be used when available.

CLR11 Figure 2B signpost ← CRITERIA 3

3.4.1 Is data sufficient?



NOTE 7

The review of the available data and the consideration of all the factors mentioned in Note 6 may necessitate the collection of additional data. If data uncertainty is considered to be unacceptably high (based on either statistical analysis and/or qualitative judgement on data quality), further site investigation to support the GQRA might be necessary.

Further guidance on site investigation design and data uncertainty can be found in publications such as:

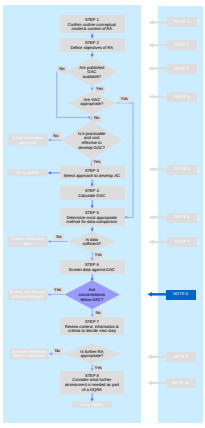
- *Secondary model procedure for the development of appropriate soil sampling strategies for land contamination* (Environment Agency, 2000a);
- *Technical aspects of site investigation* (Environment Agency, 2000b);
- *Cost-effective investigation of contaminated land* (RP4) (CL:AIRE, 2007);

- *Guidance on choosing a sampling design for environmental data collection* (USEPA, 2002).

CLR 11 Figure 2B signpost ← CRITERIA 2

3.5 Step 6 Screen data against GAC

3.5.1 Are concentrations below GAC or SGV?



NOTE 8

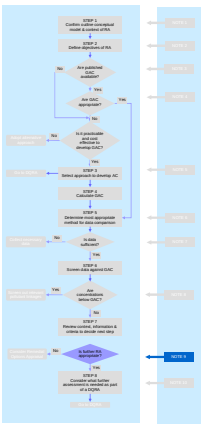
SGVs are presented in terms of a mass of contaminant per mass of dry weight (DW) soil (mg kg^{-1} DW soil). Therefore, if analytical data are not reported by the laboratory on a dry weight basis, results should be adjusted for soil moisture content before being compared to an SGV.

Human health pollutant linkages are unlikely to be causing a significant possibility of significant harm if the representative site soil concentration falls below the SGV or equivalent. However, it is important to consider:

- possible toxic additivity if chemical mixtures are present – refer to Environment Agency (2009b) for further information;
- potential for acute risks to human health being present if "hotspots" of highly elevated individual concentrations (above the SGV) are present, and the significance of chronic risk is low based on exposure averaging;
- potential for acute risks to human health if there is a significant increase in the value of a GAC as a result of simple site-specific adjustment.

3.6 Step 7 Review context, information and criteria to decide next step

3.6.1 Is further risk assessment appropriate?



NOTE 9

If a SGV is exceeded, it is recommended that:

- the pollutant linkage(s) associated with the relevant contaminant are re-affirmed;
- the significance of the linkage(s) is considered further.

In evaluating the significance of any site soil representative concentration being above a SGV, consider the context in which the evaluation is being taken (e.g. whether the site is being

examined under planning or Part 2A, whether the context is redevelopment or asset transfer).

Guidance relevant to Part 2A is available from *Improvements to contaminated land guidance* (Defra, 2008a).

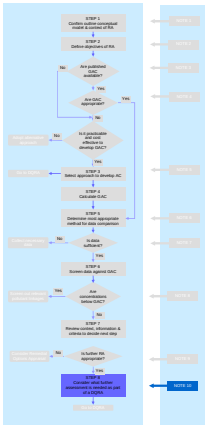
Guidance relevant to the planning regime can be found in *Planning Policy Statement 23: Planning and Pollution Control* (ODPM, 2004b) and from individual local authority guidance.

If representative soil concentrations are above the SGV, it is generally recommended that DQRA is undertaken as a next step. A decision on the need for either further risk assessment or the consideration of remedial options should take into account the magnitude by which the soil concentration exceeds the SGV. The acceptability of the margin by which the concentration exceeds the SGV will be site-specific and a function of:

- sampling uncertainty;
- analytical uncertainty;
- generic data, such as exposure frequencies, used to derive the GAC relative to actual site use;
- the nature (including the dose-response relationship and seriousness) of the potential toxic effects and the uncertainties in the chemical's toxicology (guidance on this aspect of risk characterisation is given in Environment Agency 2009b);
- the matrix on which the toxicological benchmark was based;
- other factors that the regulator may wish to take into account.

SGVs and their equivalent are not explicitly derived to be remediation standards. Remedial objectives should be set consistent with the guidance given in CLR 11 (Defra and Environment Agency, 2004).

3.7 Step 8 Consider what further assessment is needed as part of a DQRA



NOTE 10

There are two principal issues that should be addressed by DQRA:

- establishing the plausibility that generic exposure pathways exist in practice by measurement and observation;
- better model parameterisation using site data.

The collation of data for site-specific assessment should focus on those exposure pathways identified as the most significant. The aim of obtaining the additional data should be the clarification/better definition of likely exposure at the site. Relevant considerations could include:

- **For all exposure pathways:**

- Refine the conceptual exposure model for the specific land use (e.g. age groups, exposure frequencies and duration).
- Obtain further soil data.

- **For the soil ingestion route:**
  - Bioaccessibility – obtain bioaccessibility estimates for contaminants where scientific evidence supports the use of such techniques (refer to the Environment Agency website for further guidance).
  - Degree of tracked backed soil incorporated into indoor dust.

- **For the homegrown fruit and vegetable consumption route:**
  - Plant uptake – obtain chemical analysis of edible crops grown at the site and/or re-evaluate the sensitivity of the predictive models used. However for organic chemicals, the sampling and chemical analysis of edible parts of fruits and vegetables is unlikely to be an easy task, given the difficulties in analysing organic substances in an organic matrix. Refer to Environment Agency (2006), Food Standards Agency advice and other international regulatory guidance and scientific studies for further information.
  - Physical space available to grow crops.

- **For the vapour intrusion route:**
  - Obtain soil vapour attenuation *in situ* and/or specific details on building design in order to better estimate site-specific vapour intrusion.
  - Conduct a sensitivity analysis of the predictive models used. Refer to authoritative guidance such as CIRIA (in press) for further information.

- **For dust exposure routes:**
  - Measure the amount of indoor dust found on living surfaces and the concentrations of contaminants in the dust.
  - Measure airborne dust levels.

It is important when evaluating indoor concentrations of chemicals in air and dust that appropriate account is taken of non-soil sources of pollution.

3.8 Summary guide

Figure 3.2 provides a summary guide to using SGVs.

Figure 3.2 Summary guide to using SGVs

SGVs are:	***SGVs are not:***
• Scientific risk-based generic assessment criteria. • A numerical definition of exposure related to a chemical in soil which is without appreciable health risk. • Based on generic reasonable worst-case exposure scenarios for long-term aggregated exposure that are health protective for the vast majority of the UK population. • Concentrations in soil which can be used to screen out human health pollutant linkages when the generic land use scenarios used to derive the SGV is sufficiently representative of the site under evaluation.	• Remediation standards. • Applicable to every site. • Absolute minimum values • A definition of SPOSH under Part 2A. • Screening values applicable to construction workers and occupational exposures. • Screening values applicable to other receptor groups such as ecology and property. • Protective of potential acute risks to human health from soil contamination.
GQRA data screening using a SGV is:	***GQRA data screening using a SGV is not:***
• A means of identifying an area of land and/or a specific contaminant that does not warrant further, more detailed, evaluation. • A mechanism for focusing subsequent effort on likely risk-driving areas/chemicals/exposure pathways. • Designed to simplify the risk assessment process.	• Valid unless the assumptions inherent in the SGV are broadly applicable to the site in question. • Mandatory. • A substitute for a thorough qualitative understanding of a site's condition and the risks it might pose to human health.

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List of abbreviations

AC	assessment criteria
ADE	Average Daily Exposure
CLEA	Contaminated Land Exposure Assessment
CLR	Contaminated Land Report
Defra	Department for Environment, Food and Rural Affairs
DQRA	Detailed Quantitative Risk Assessment
DW	dry weight
GAC	generic assessment criteria
GQRA	Generic Quantitative Risk Assessment
HCV	Health Critical Value
LOD	limit of detection
MCERTS	Monitoring Certification Scheme
PPS	Planning and Policy Statement
RA	risk assessment
SGV	Soil Guideline Value
SOM	soil organic matter
SPOSH	Significant possibility of significant harm
SSAC	site-specific assessment criteria
TOX	toxicology [report]
USEPA	US Environmental Protection Agency

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