

Using Other Quantitative Risk Assessment Models

The use of CLEA, SGVs and GACs may not be appropriate for all sites and in these cases, alternative QRA models may be required to assess human health risks. The use of such models must take account of UK policy and best practice which requires that certain parameters, assumptions, exposure scenarios, etc. are the same as those used in the CLEA model.

The EA has developed Fact Sheets for five alternative QRA models commonly used in the UK for assessing risks to human health from land contamination, namely SNIFFER framework, RBCA Tool Kit for Chemical Releases, RISC-HUMAN 3.1, RISC; and Risk* Assistant (1.1). Fact Sheets can be obtained from the EA website.

The purpose of these Fact Sheets is to provide assessors with:

- A brief description of the selected model (receptors, land use and exposure scenarios, etc.)
- An overview of each model's principal features (including what the model is supposed to do; model usability; toxicological information; contaminants and contact media; receptor characterisation; land use; pathway characterisation)
- Description of model outputs and interpretation
- Impacts of sensitive model parameters
- Common problems with the model, and common mistakes made when using the model
- Model limitations – what the model does not do

CHECKLIST FOR SUBMITTING A RISK ASSESSMENT TO LCC

Prior to undertaking a quantitative human health risk assessment, it is advised that agreement on the model and parameters to be used is sought with the Contaminated Land Team. In all cases, reports which detail the use of QRA models to assess data and aid decision-making must include the following:

- A conceptual site model.
- Justification for the chosen QRA model.
- Documentation of the source of all input parameters and justification for their use.
- Consideration of all applicable potential exposure pathways and receptors.
- Details of assumptions made, site-specific circumstances, changes to default parameters, results of bioaccessibility test, and submission of all input and output data.
- Discussion of uncertainties and unknowns within the risk assessment.

Please note:

1. Details of assumptions made, site-specific circumstances, changes to default parameters, results of bioaccessibility tests, etc., need to be included in all submissions involving CLEA and other QRA models.
2. Assumptions that the bioavailability of a contaminant is likely to be less than 100% will not be accepted.
3. LCC will only consider the suitability of bioaccessibility tests and the use of any corresponding correction factors on a site-specific basis and in light of current best practice.
4. LCC will not accept results from leachability tests as evidence of reduced bioavailability. A reduction in apparent solubility within a particular solution is not necessarily reliable evidence of a reduction in bioavailability to the human body.

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The Development of Contaminated Sites

Human Health Quantitative Risk Assessment

Since January 2009, the Department for Environment, Food and Rural Affairs (DEFRA) and the Environment Agency (EA) have launched the new Contaminated Land Exposure Assessment Model (CLEA) and a series of reports that provide a scientifically based framework for the assessment of long-term chronic risks to human health from land contamination in the UK. This framework enables decisions regarding land contamination and brownfield sites to be based on sound science, thus removing doubt and potential blight from many sites. It also provides for easier identification of sites that could present a possibility of significant harm to human health.

Reference to the CLEA model assumes the use of the current version of the model at the time the risk assessment is undertaken. The EA website should be consulted to confirm the current version. The CLEA model and its associated soil guideline values (SGVs) help to determine whether certain contaminant soil concentrations may pose a significant risk to human health. SGVs are being published for the most common chemical contaminants and are being derived for three typical land uses: residential, allotments and commercial.

Please note that since January 2009 the former CLEA model, SGV and TOX reports and CLR 7, 8, 9 and 10 have been revoked and replaced with new guidance documents. CLR 11 is still used to guide the risk assessment process. The EA website should be consulted for the current publications available.

Purpose of this Leaflet

This leaflet primarily provides a brief introduction to the use of the CLEA model and the SGVs related to the model, but also details the use of other human health quantitative risk assessment (QRA) models. It specifically outlines how their use will be considered by Leeds City Council (LCC) when assessing information submitted in support of planning applications. This leaflet does not serve in any way to replace the detailed technical content of DEFRA/EA and other authoritative publications. In particular, applicants, developers and their environmental consultants are strongly advised to familiarise themselves with the contents and requirements of the available EA Science Reports (SR), the accompanying 'TOX', 'SGV' and supplementary information reports and the CLEA software.

The use of the CLEA model, SGVs and other QRA packages requires specialist technical expertise and a good understanding of human health risk assessment associated with land contamination. **Applicants/developers are therefore advised to ensure that consultants employed in the assessment of land contamination data are appropriately qualified and experienced in these fields.**

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USING THE CLEA MODEL & SOIL GUIDELINE VALUES

➤ **When do you need to use CLEA and the SGVs?**

Where quantitative human health risk assessment is required to support site investigation, remediation and validation works, the current CLEA model may be used. However it is not obligatory to use this model and indeed this model may not be applicable to all circumstances and if so other QRA models may be more applicable.

➤ **What will CLEA and the SGVs be used for?**

The CLEA model and the SGVs should be used for assessing long-term chronic human health risks associated with soil contamination, deriving site-specific remediation criteria and assessing the suitability of imported material. This model cannot be used to assess risks to water resources, other environmental receptors or short term/acute human health risks.

➤ **How should the SGVs be used?**

SGVs and Generic Assessment Criteria (GAC) derived using the “basic” mode in the CLEA software represent generic ‘intervention values’ and not definitive remediation standards. GAC can be derived in the “basic” mode in the CLEA software by varying a small number of parameters including soil type, pH, and percentage of soil organic matter (%SOM). The “basic” mode can also be used to derive GAC for a standard residential without plant uptake scenario. SGVs and GAC should be used as part of the overall risk-based management of a site, enabling informed judgments to be made about the need for further action. Exceeding an SGV or GAC does not necessarily mean that remediation should be undertaken. Exceedance indicates that a potentially unacceptable risk to human health exists and prompts further investigation and/or assessment to determine whether remediation is required.

➤ **Will SGVs and GAC be applicable to all sites?**

No, the generic SGVs have been derived using the “basic” mode in the CLEA model which assumes certain ‘standard’ exposure scenarios, land uses and site conditions. Where site conditions do not reflect standard conditions, certain parameters in the “advanced” mode in the CLEA software can be altered accordingly to derive a ‘site-specific’ assessment criteria (SSAC). For example the model can be changed to reflect school playing fields or sports pitches. However, the CLEA model does not yet take account of *all* possible land uses and possible pollutant linkages. Therefore in certain cases the use of other QRA models to assess risks and/or derive site-specific guidelines may be more appropriate. **See overleaf for further details.**

➤ **What about other guideline values?**

LCC will accept the use of GAC publications by other reliable sources as long as the parameters used are appropriate to the subject site and in line with UK policy. The use of these other values must be suitably justified in the report.

➤ **How should I assess the data?**

An appropriate statistical appraisal of all site data for a given contaminant may be undertaken before comparison with an SGV, GAC or SSAC is made. This appraisal should take account of the site sampling strategy. Reference should be made to the EA publication ‘Development of Sampling Strategies for Land Contamination’, Technical Report P5-066/TR (2001) and the Chartered Institute of Environmental Health Guidance on Comparing Soil Contamination Data with a Critical Concentration (May 2008).

➤ **Where can I obtain a copy of CLEA?**

Copies of the CLEA software, SR reports, TOX and SGV and other data can be downloaded free of charge from the EA website.

ARSENIC: ELEVATED BACKGROUND CONCENTRATIONS IN LEEDS

An example of where the use of site specific assessment criteria may be appropriate is for sites with soil concentrations of arsenic that exceeds the SGV. In Leeds the background levels of arsenic in the soil are often elevated above the national average (typically up to 60mg/kg) and may naturally be above the SGV for arsenic. Although this is considered to be mainly attributable to the natural underlying geology (Lower Coal Measures), there are also likely to be manmade contributions to these elevated background concentrations.

Soil Guideline Values (SGVs)

The derivation of SGVs for arsenic is detailed in the SGV, TOX and supplementary information reports. The SGVs for arsenic are as follows:

Standard land-use	SGV (mg/kg dry weight soil)
Residential	32
Allotments	43
Commercial	640

NB: There are a number of key assumptions made in the derivation and application of these arsenic SGVs; these values will therefore not automatically be appropriate to use on all sites:

- (i) The standard values are for a sandy loam soil of pH 7 containing 6% organic matter
- (ii) The key receptor is considered to be a female child in the 0-6 age group
- (iii) Only total inorganic arsenic (i.e. the more toxic form) is considered
- (iv) 100% of the arsenic in the soil is considered to be bioavailable

Exceeding SGVs

Exceeding an arsenic SGV does not necessarily imply that there is an *actual* risk. The SGVs for arsenic will not have taken into account the following:

- Traditional chemical testing provides information about the *total* arsenic concentration in a soil sample. However, the arsenic SGVs have been derived for *inorganic* arsenic compounds which may comprise only a proportion of the total arsenic present.
- Where arsenic is strongly bound to soil particles or present in an insoluble form its bioavailability to the human body may be less than the 100% assumed in the SGV derivation.

Consequently, a direct comparison of **total** arsenic concentrations with the SGVs may be representative of a worst case scenario and may therefore lead to an over-estimation of risk and an undertaking of unnecessary remediation.

Avoiding Unnecessary Remediation

In order to avoid the potentially unnecessary remediation of arsenic-contaminated soils, applicants/environmental consultants should take into account site-specific circumstances when assessing contaminant data. Scientific-based arguments and altered parameters can be used to derive SSAC which may indicate that certain levels of arsenic elevated above the SGV are acceptable to leave on site. Such arguments might be based on:

- A re-appraisal of local receptor behaviour and characteristics or soil conditions, which may vary from the possible defaults within the CLEA model.
- Results of bioaccessibility tests which could be used to indicate whether or not the contaminant is present in a bioavailable form and thus likely to present an unacceptable risk to human health. Please note that any bioaccessibility testing will need to be undertaken on samples from the site in question. The SR2 report refers further to the use of bioaccessibility testing.