- Results of bioaccessibility tests (PBET or SBET) 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
(1) Oldham MBC 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.

(2) Assumptions that the bioavailability of a contaminant at concentrations found with the natural (background) range is likely to be less than 100% will not be accepted.

(3) Oldham MBC 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) Details of assumptions made, site-specific circumstances, changes to default parameters, results of bioaccessibility tests, etc. should be included in all submissions involving CLEA assessments.

USING OTHER QUANTITATIVE RISK ASSESSMENT MODELS

The use of CLEA and SGVs 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 guidance in CLR7 to 10 which requires that certain parameters, assumptions, exposure scenarios, etc. are the same as those used in the CLEA model.

The Environment Agency has developed Fact Sheets for CLEA and 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 www.environment-agency.gov.uk.

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 QRA TO OLDHAM MBC

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) A conceptual site model
(b) Justification for the chosen QRA model
(c) Submission of ALL input data
(d) Documentation of the source of all input parameters and justification for their use
(e) Consideration of all applicable potential exposure pathways and receptors
(f) Discussion of uncertainties and unknowns within the risk assessment

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The Development of Contaminated Sites

Human Health Quantitative Risk Assessment

Oldham Council

In March 2002 the Department for Environment, Food and Rural Affairs (DEFRA) and the Environment Agency launched the contaminated land exposure assessment (CLEA) model 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.

The CLEA model and its associated soil guideline values (SGVs) help to determine whether certain contaminant soil concentrations pose a significant risk to human health. SGVs will be published for the most common chemical contaminants and have been derived for three typical land uses: residential, allotments and industrial/commercial.

For the purposes of assessing risks to human health, the CLEA model and SGVs replace the Inter-Departmental Committee on the Redevelopment of Contaminated Land (ICRCL) 'Trigger Values' (published in ICRCL Guidance Note 59/83, 2nd edition 1987) which were formally withdrawn by DEFRA in December 2002.

Purpose of this Leaflet

This leaflet primarily provides a brief introduction to the use of the SGVs and CLEA 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 Oldham MBC 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/Environment Agency 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 CLR 7, 8, 9 and 10 reports, accompanying 'TOX' and 'SGV' reports and 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?

All site investigation, remediation and validation reports submitted to Oldham MBC in support of planning applications or the discharge of planning conditions are required to take account of the CLEA model and the SGVs. Where SGVs have not been published for certain contaminants, site-specific assessment criteria can be derived using CLEA, in accordance with the principles outlined in CLR7 to 10 and the relevant TOX and SGV reports.

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 clean-up criteria and assessing the suitability of imported fill materials on redevelopment sites. This model cannot be used to assess risks to water resources or other environmental receptors.

What about other guideline values?

The use of ICRCL trigger values and the 'Kelly' guidelines will not be accepted as a means of assessing whether contaminants present an unacceptable risk to human health. Oldham MBC will only accept comparison with other generic guideline values (e.g. Dutch, WHO, US, Canadian) if considered on a site-specific basis and within the UK context, adopting the principles outlined in the CLR documentation. CLR9 outlines a hierarchy of principal source documents to be used where authoritative UK data is not available.

How should the SGVs be used?

SGVs represent generic 'intervention values' and not definitive clean-up standards. They should be used as part of the overall risk-based management of a site, enabling informed judgments about the need for further action. Exceeding an SGV does not necessarily mean that remediation should be undertaken. Moreover, it indicates that a potentially unacceptable risk to human health exists and triggers further investigation or assessment to determine whether remediation is required.

Individual soil concentrations should not be compared to SGVs. Instead, a statistical appraisal of all site data for a given contaminant should be undertaken before comparison with a SGV can be made. This appraisal should take account of the site sampling strategy and be in accordance with CLR7 and BS10175:2001. Reference should be made to the Environment Agency publication 'Development of Sampling Strategies for Land Contamination', Technical Report P5-066/TR (2001).

Will CLEA & SGVs be applicable to all sites?

The generic SGVs have been derived using the CLEA model which assumes certain 'standard' exposure scenarios, land uses and site conditions. Where site conditions are 'non-standard', certain parameters in the CLEA model can be altered accordingly to derive a 'site-specific' SGV. However, the CLEA model does not yet take account of *all* possible land uses and certain parameters within the model cannot be changed even though their use may be inappropriate for certain sites. In such cases, the use of other QRA models to assess risks and/or derive site-specific guidelines may be more appropriate. **See below for further details**.

What about elevated background concentrations?

The CLEA model does not take account of background soil concentrations in the derivation of SGVs. The following section illustrates how Oldham MBC consider this issue should be addressed by looking at arsenic as an example of a contaminant with elevated background concentrations in the Oldham area.

Where can I obtain a copy of CLEA?

Copies of the CLEA software, CLR reports, TOX and SGV data can be downloaded FREE OF CHARGE from www.defra.gov.uk/environment/landliability/pubs.htm.

ARSENIC: ELEVATED BACKGROUND CONCENTRATIONS IN Oldham

In Oldham, background arsenic concentrations in soils are often elevated above the national average of 10mg/kg, with values typically ranging up to 60mg/kg. 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 Reports SGV 1 and TOX 1. The *standard* SGVs for arsenic are as follows:

Standard land-use	SGV (mg/kg dry weight soil)
Residential with plant uptake	20
Residential without plant uptake	20
Allotments	20
Commercial/industrial	500

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 soil of pH 7 containing 5% 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) No account is taken of background concentrations/exposure
(v) Only ingestion (and not inhalation or dermal contact) has been considered
(vi) 100% of the arsenic in soil is considered to be bioavailable

Exceeding SGVs

Exceeding an arsenic SGV does not necessarily imply that there is an *actual* risk. SGVs may be lower than soil concentrations due to assumptions made in their derivation.

The CLEA model software can be used to alter default parameters so that more appropriate site-specific assessment criteria can be derived. However, the CLEA model and the SGVs cannot be adjusted/derived to take account of 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 small 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 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 Clean-up

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 should be provided as justification for leaving on site soils with concentrations in excess of SGVs. 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.

Continued over…