

YAHPAC Guidance on Human Health Quantitative Risk Assessment

Following the withdrawal of the Inter-Departmental Committee on the Redevelopment of Contaminated Land (ICRCL) Guidance Note 59/83 2nd edition 1987 by DEFRA in December 2002, it is no longer acceptable to use this publication for human health contamination risk assessments. This guidance leaflet outlines YAHPAC's position in relation to human health quantitative risk assessment in light of current UK best practice.

Purpose of this Guidance

- To provide developers and their consultants/contractors with advice about using acceptable risk assessment methodologies for the purpose of:
 - providing scientific and authoritative data on contamination risks to human health identified at proposed development sites
 - making robust, valid decisions
- To assist the assessor in deciding whether contaminants pose a significant long-term chronic risk to human health at a site

UK Human health risk assessment – CLEA and CLR reports

In March 2002, the UK launched the contaminated land exposure assessment (CLEA) model and a series of reports (CLR7-10; TOX and SGV reports) providing a scientific framework for the assessment of chronic risks to human health from land contamination.

Soil Guideline Values (SGVs) are derived from the CLEA model. SGVs represent intervention values which indicate to an assessor that soil concentrations above this level **could** pose an unacceptable long-term risk to human health and that further investigation and/or remediation is required.

When do you need to consider using the CLEA model and the SGVs?

Immediately. All site investigation, remediation and validation reports associated with land contamination issues are required to take account of the CLEA model and SGVs, where applicable.

Where SGVs have not been published, site-specific assessment criteria (SSAC) can be derived using CLEA but must be in accordance with the principles outlined in CLR7 to CLR10 and relevant TOX and SGV reports, where applicable:

- CLR7 sets out the legal framework, the development and use of SGVs, and references to related research

- CLR8 sets out which key contaminants are likely to be associated with particular industrial land uses
- CLR9 sets out the UK approach that must be adopted to derive tolerable daily soil intakes and index doses for contaminants
- CLR10 sets out the technical basis for modelling exposure and provides a comprehensive reference to all default parameters and algorithms used

Details on where to obtain the above CLR documents are given in the Key Publications section at the end of this leaflet.

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. For other guideline values (eg Dutch, WHO, US, Canadian), the LA will only accept comparison with such generic values if these values have been considered on a site-specific basis and in the UK context, adopting the principles outlined in the CLR documentation. It is important to note that CLR9 outlines a hierarchy of principal source documents to be used where authoritative UK data is not available. In descending priority order, these sources are as follows:

- European Commission's committees or international authoritative organisations (eg EU, WHO guidance)
- other national organisations (eg Dutch, US, Canadian guidance)
- reports produced by authoritative organisations, but for different purposes

How should the SGVs be used?

SGVs are generic assessment criteria that have been derived using exposure assumptions for a number of land uses and therefore do not take into account site-specific conditions. SGVs are **not** binding standards for clean up. They should be used as part of an overall risk assessment to make informed judgements about the need for action to ensure that a new use of land does not pose any unacceptable human health risks. Exceedence of a SGV:

- indicates that a potentially significant risk to human health could exist;
- is a trigger for undertaking further investigation or assessment to determine whether remediation/risk management is required; and,
- does not necessarily mean that remediation/risk management is required.

Individual soil concentrations should not be compared to the 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, BS10175:2001 and reference should be made to the Environment Agency publication 'Development of Sampling Strategies for Land Contamination', Technical Report P5-066/TR (2001).



Other risk assessment models

There may be circumstances where the use of other risk assessment models may be more appropriate. Any use of other models must take account of guidance contained in CLR7 to 10.

As well as for CLEA, the Environment Agency has developed Fact Sheets for five other risk assessment 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).

The purpose of these fact sheets is to provide assessors with:

- A brief description of the selected model (including receptor types, land use and exposure scenarios)
- An overview of the 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

Details on where to obtain the fact sheets are given in the Key Publications section at the end of this leaflet.

CHECKLIST FOR HUMAN HEALTH RISK ASSESSMENTS

- Has a conceptual model been provided?
- Has justification been provided for the chosen human health risk assessment model?
- Has all input data to a model been submitted with the risk assessment? Has the source of the input parameters been documented and justified?
- Have all applicable exposure pathways and receptors been considered?
- Have the uncertainties and unknowns within the risk assessment been highlighted?

NB Prior to undertaking a quantitative human health risk assessment, it is advised that agreement on the model to be used is sought with the relevant LA officer dealing with land contamination issues.

Key Publications

CLEA

- CLR7 Assessment of Risks to Human Health from Land Contamination: An Overview of the Development of Soil Guideline Values and Related Research
- CLR8 Potential Contaminants for the Assessment of Land
- CLR9 Contaminants in Soils: Collation of Toxicological Data and Intake Values for Humans
- CLR10 The Contaminated Land Exposure Assessment Model (CLEA): Technical basis and algorithms
- Series of toxicological reports currently available are: TOX1 Arsenic; TOX2 Benzo(a)pyrene; TOX3 Cadmium; TOX4 Chromium; TOX5 Inorganic Cyanide; TOX6 Lead; TOX7 Mercury; TOX8 Nickel; TOX 10 Selenium; TOX11 Benzene; TOX12 Dioxins, Furans and Dioxin-like PCBs ⁽¹⁾
- Series of Soil Guideline Value Reports currently available are: SGV1 Arsenic; SGV3 Cadmium; SGV4 Chromium; SGV5 Inorganic Mercury; SGV7 Nickel; SGV9 Selenium; SGV10 Lead ⁽¹⁾

The CLEA software and associated reports can be downloaded FREE OF CHARGE from www.defra.gov.uk/environment/landliability/pubs.htm.

⁽¹⁾ Please refer to DEFRA's website for updated information on the availability of TOX and SGV reports

Fact sheets for CLEA and other human health risk assessment models

Fact sheets about the following human health risk assessment models are available from the Environment Agency's website at www.environment-agency.gov:

- Fact Sheet No. FS-01 – SNIFFER framework
- Fact Sheet No. FS-02 – RBCA Tool Kit for Chemical Releases
- Fact Sheet No. FS-03 – RISC-HUMAN 3.1
- Fact Sheet No. FS-04 – RISC
- Fact Sheet No. FS-05 – Risk* Assistant (1.1)
- Fact Sheet No. FS-06 – Contaminated Land Exposure Assessment (CLEA) 2002 model

Please note that this guidance has been drafted to assist developers and consultants to assess human health risks at redevelopment sites. Not considering the guidance in this leaflet could result in a delay to the planning process.

