

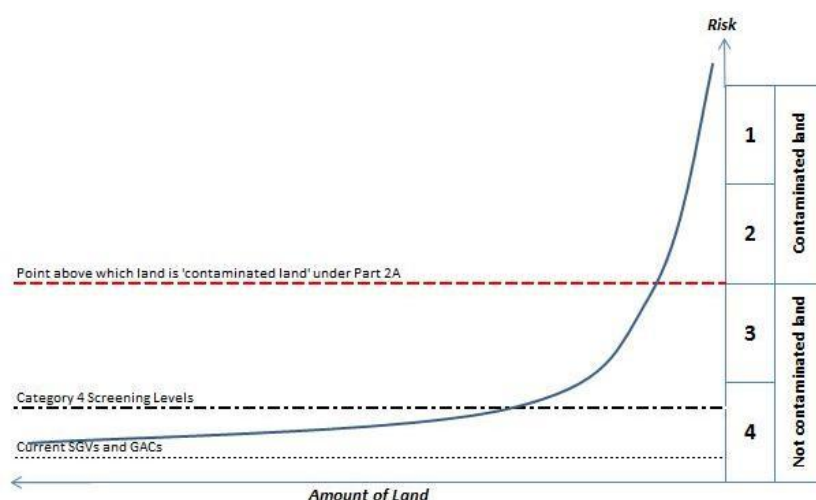
METHODOLOGY FOR THE DERIVATION OF GENERIC QUANTITATIVE ASSESSMENT CRITERIA TO EVALUATE RISKS TO HUMAN HEALTH FROM SOIL & GROUNDWATER CONTAMINATION

UK APPROACH

In the UK, the potential risks to human health from contamination in the ground are usually evaluated through a generic quantitative risk assessment (GQRA) approach. This allows generic and conservative exposure assumptions to be readily applied to risk assessments, and can be a useful tool for rapidly screening data and to identify those contaminants or scenarios that could benefit from further investigation and/or site-specific detailed quantitative risk assessment (DQRA). Current industry good practice is to use the approach presented in the Environment Agency (EA) publications SR2¹ and SR3². This approach allows the derivation of Generic Assessment Criteria (GACs), primarily for chronic exposure.

In April 2012, the Department of Environment, Food and Rural Affairs (Defra) published updated statutory guidance³ which introduced a four category approach to determining whether land in England and Wales is contaminated or not on the grounds of significant possibility of significant harm (SPOSH). **Figure 1** presents a graphical representation of the categories.

Figure 1: Four Categories for Determining if Land Represent a SPOSH



Cases classified as Category 1 are considered to be SPOSH based on actual evidence or an unacceptably high probability of harm existing. Category 4 cases are those where there is no risk, or a low risk of SPOSH.

¹ Environment Agency 'Human Health Toxicological Assessment of Contaminants in Soil', Report SC050021/SR2. January 2009.

² Environment Agency 'Updated Technical Background to the CLEA Model,' Report SC050021/SR3. January 2009.

³ Defra 'Environmental Protection Act 1990: Part 2A Contaminated Land Statutory Guidance'. April 2012.

GACs represent a minimal risk level, well within Category 4. A 2014 publication by Contaminated Land: Applications in Real Environments (CL:AIRE), SP1010⁴ and endorsed by Defra⁵ provided an approach to determine Category 4 Screening Levels (C4SLs) which are higher than the GACs whilst being “more pragmatic but still strongly precautionary”. It also provided C4SLs for six contaminants of concern. Although the C4SLs were designed to support Part 2A assessments to determine ‘contaminated land’ they are specifically mentioned, along with reference to the Part 2A statutory guidance, by the Department for Communities and Local Government (DCLG) for use in a planning context⁶.

An updated version the Contaminated Land Exposure Assessment (CLEA) Workbook (v1.071) was released by the EA in September 2015 to take into account the publication of SP1010. The updates comprised: additional toxicity data for the six chemicals for which C4SLs were derived; two new public open space land use scenarios; updated exposure parameters; options to run the model using C4SL exposure assumptions; and increased functionality. There were no changes to algorithms, so it is still possible to replicate the withdrawn SGVs using the input parameters held within v1.071.

It should be noted that the four category approach has not been adopted in Scotland under Part 2A or the planning regime. The Part 2A statutory guidance applicable in Scotland (Paper SE/2006/44 dated May 2006) does not reflect the changes introduced by Defra in April 2012 which allow for the use of C4SLs within Part 2A risk assessments. Additionally, it is considered that the principal of ‘minimal risk’ should still apply under planning in Scotland, based on current guidance.

WSP APPROACH

Following the withdrawal of the SGVs, and in the absence of an industry-wide, accepted set of GACs it is down to individual practitioners to derive their own soil assessment criteria. WSP has used the approach provided within SR2, SR3, SP1010, CLEA Workbook v1.071 and SR4⁷ to produce a set of minimal risk GACs. The chemical-specific data within two key publications were considered during their production: CL:AIRE 2010⁸ and LQM 2015⁹. Both documents provide comprehensive sets of GACs for different contaminants of concern.

The LQM Suitable For Use Levels (S4ULs) have selected exposure parameters consistent with the C4SL exposure scenarios. This approach was rejected by WSP as not representing minimal risk. However, the LQM S4UL document was critically reviewed and the approach and chemical input parameters were utilised where considered to be appropriate.

An industry-led C4SL Working Group is in the process of deriving a larger set of C4SLs in the near future, for approximately 20 contaminants. This will include a critical review of the chemical input data for all selected substances, and may therefore lead to further amendments to the chemical input data used in the WSP in-house screening values. It is considered likely that the contaminant list will

⁴ CL:AIRE ‘Development of Category 4 Screening Levels for Assessment of Land Affected by Contamination’ SP1010, Final Project Report (Revision 2). September 2014.

⁵ Defra ‘SP1010: Development of Category 4 Screening Levels for Assessment of Land Affected by Contamination – Policy Companion Document’. December 2014.

⁶ DCLG Planning Practice Guidance ‘Land Affected by Contamination’, particularly Paragraphs 001 and 007. Ref IDs: 33-001-20140306 & 33-007-20140612.

⁷ Environment Agency ‘CLEA Software (Version 1.05) Handbook (and Software)’, Report SC050021/SR4. September 2009.

⁸ CL:AIRE ‘The EIC/AGS/CL:AIRE Soil Generic Assessment Criteria for Human Health Risk Assessment’. ISBN 978-1-05046-20-1. January 2010.

⁹ Nathanail et al ‘The LQM/CIEH S4ULs for Human Health Risk Assessment’, Land Quality Press, ISBN 978-0-9931084-0-2. 2015.

crossover with the 2009 EIC/AGS/CL:AIRE GACs. As such, this document was not critically reviewed by WSP.

WSP's current approach to the assessment of risks to human health is to continue to evaluate minimal risk through the use of in-house derived GACs, and to use the published C4SLs as a secondary tier of assessment until such time as additional C4SLs are published and/or in-house values are derived.

EXPOSURE MODELS

LAND USES

WSP has largely adopted the exposure assumptions of the generic land use scenarios included within SR3, with two additional public open space scenarios included from within SP1010 and two bespoke exposure scenarios (highways):

- à Residential with homegrown produce consumption;
- à Residential without homegrown produce consumption;
- à Allotments;
- à Commercial;
- à Public open space near residential housing (POS_{resi});
- à Public park (POS_{park});
- à Highways (surface soils); and
- à Highways (subsurface soils).

Exceptions are described in the following Sections.

SOIL PROPERTIES

SR3 assumes a sandy loam soil with a pH of 7 and a Soil Organic Matter (SOM) content of 6% for its generic land uses, based on the geographical spread of topsoils in the UK. WSP has adopted these default values. In addition, GACs based on an SOM of 1% and 2.5% have been derived, based on common experience of the nature of Made Ground and lack of topsoil on many brownfield sites.

RECEPTOR CHARACTERISTICS AND BEHAVIOURS

SP1010 provides some updated exposure parameters for long-term inhalation rates¹⁰ and the consumption rates for homegrown produce¹¹ compared to those provided in SR3. This data was used to derived WSP's GACs.

The changes in inhalation rates do not apply to the allotment generic land use scenario, as these are based on the breathing rates for short-term exposure of light to moderate intensity activity which were derived from a study that was not updated in USEPA 2011, so the SR3 rates were retained.

¹⁰ USEPA, National Centre for Environmental Assessment 'Exposure Factors Handbook: 2011 Edition' EPA/600/R-09/052F. September 2011.

¹¹ National Diet and Nutrition Survey 2008/2009 to 2010/2011.

HIGHWAYS EXPOSURE SCENARIOS

Human health GAC for a Highways exposure scenario have been derived. The site area is defined by publicly accessible land adjacent to highways, comprising both hard and soft landscaped areas. Exposure is considered to be largely transitory.

There are no publicly available GAC for this exposure scenario. Consequently, WSP have derived GAC for the following exposure scenarios:

- à Highways (surface soils); and
- à Highways (sub-surface soils).

Surface soils GAC are for soil at ground level and within 300mm of the surface. Conversely, subsurface GAC are for soils at a depth exceeding 0.3m bgl. These GAC are not to be used as import criteria.

The critical receptor is a young female child, CLEA age classes 4-9. This is consistent with the critical receptor for the POS(resi) exposure scenario, and considered to be appropriate for a child potentially playing outside without direct adult supervision.

For all GAC, a sandy loam soil and a soil organic matter content of 1% is assumed. There is no building on site.

Exposure scenarios for surface and subsurface soils are detailed below. These are considered to be conservative estimates, due to the mostly transitory use of publically accessible lands adjacent to highways.

HIGHWAYS GAC (SURFACE SOILS)

The relevant exposure pathways include direct soil and dust ingestion, dermal contact (outdoors) and the inhalation of outdoor dust and vapour.

The exposure frequency is 170 days per annum, and the occupancy period outdoors is 1 hour per day (as per the POS (resi) exposure scenario). The soil and dust ingestion rate has been set at 50 mg/day, consistent with a POS(park) exposure scenario.

HIGHWAYS GAC (SUBSURFACE SOILS)

The single relevant exposure pathway is the inhalation of outdoor vapour. Direct exposure pathways are not viable due to the depth of the soils below ground level.

The exposure frequency is 170 days per annum, and the occupancy period outdoors is 1 hour per day (as per the POS (resi) exposure scenario). The soil and dust ingestion rate has been set to zero, as direct exposure pathways to soils at this depth are not viable.

CHEMICAL DATA

PHYSICO-CHEMICAL PARAMETERS

Physico-chemical properties for the contaminants for which GACs have been derived have been obtained following critical review of the following hierarchy of data sources:

1. Environment Agency/Defra SGV reports where available;
2. Environment Agency '*Compilation of Data for Priority Organic Pollutants for Derivation of Soil Guideline Values*', Report SC050021/SR7, November 2008; and
3. Published fate and transport reviews within Nathanail et. al 2015 and CL:AIRE 2010.

Where appropriate, and where sufficient data is available, values were adjusted to reflect a UK soil temperature of 10°C (e.g. K_{aw}).

TOXICOLOGICAL DATA

Toxicological data for the derivation of minimal risk Health Criteria Values (HCV) for each contaminant was selected with due regard to the approach presented in SR2. Where appropriate, the following hierarchy of data sources was used:

1. UK toxicity reviews published by authoritative bodies including:
 - < EA;
 - < Public Health England (PHE);
 - < Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT); and
 - < Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC).
2. Authoritative European sources such as European Food Standards Agency (EFSA)
3. International organisations including:
 - < World Health Organisation (WHO); and
 - < Joint FAO/WHO Expert Committee on Food Additives (JECFA).
4. Authoritative country-specific sources including:
 - < United States Environmental Protection Agency (USEPA);
 - < US Agency for Toxic Substances and Disease Registry (ATSDR);
 - < US Integrated Risk Information System (IRIS); and
 - < Netherlands National Institute for Public Health and the Environment (RIVM).

Factors such as the applicability of the data to human health (e.g. epidemiological vs. animal studies), the quality of the data, the level of uncertainty in the results and the age of the data were also taken into account in the final selection. Details for specific substances are available on request.

MEAN DAILY INTAKES

Estimations of background exposure for each threshold substance have been updated. In line with the SR2 approach, the exposure from non-threshold substances in the soil does not take into account exposure from other sources, and as such GACs were derived without consideration of the Mean Daily Intake (MDI) for those substances.

The data published by the EA in its series of TOX reports between 2002 and 2009 was evaluated to determine whether the values were considered to remain valid today. Values from these current UK published sources were not amended unless they were considered to be significantly different so that the GACs remained as comparable as possible with the revoked SGVs.

ORAL MEAN DAILY INTAKES

Oral MDI were generally estimated as the sum of exposure via the ingestion of food and drinking water using the default adult physiological parameters presented in Table 3.3 of SR2.

Data on the exposure of substances from food ingestion was generally obtained from UK Total Diet Studies (TDS) published by the Food Standards Agency (FSA) and its predecessor the Ministry of Agriculture, Fisheries and Food (MAFF) and from studies commissioned by COT. Where no UK-specific data was available, MDI were derived from the European Food Safety Authority (EFSA), Health Canada and US sources. This was a rare occurrence, and in these instances, the data was evaluated to determine its applicability to the UK.

Data on the concentrations of substances in tap water was obtained from a variety of sources. UK data was used where available, with preference given to Drinking Water Inspectorate (DWI) 2014 data from water company tap water testing (LOD, 1st and 99th percentile data is available). Where the substance was not included in tap water testing, other UK sources of information were considered including:

- à DWI data from water company tap water testing from previous years;
- à COT; and
- à FSA.

Where UK data was not available, a number of other data sources were considered, largely WHO International Programme on Chemical Safety (IPCS) Concise International Chemical Assessment Documents (CICADs) and background documents for the development of Guidelines for Drinking Water Quality, using professional judgement on the relevance of the data to the UK. The final decision on the MDI from drinking water was made using professional judgement on the balance of relevance and probability, taking into account the detection limit where not detected, Koc and solubility, reduction in use of the substance, banned substances, tight controls (e.g. on explosives) and with due consideration to the SR2 instruction that “if no data or information in background exposure are available, background exposure should be assumed to be negligible and the MDI set to zero....”.

Data from other countries was generally not used because it was considered that the hydrogeology of these countries along with industrial practices were unlikely to be reflective of the UK.

INHALATION MEAN DAILY INTAKES

Inhalation MDIs were based on estimates of average daily exposure by the inhalation pathway and calculated using the default adult physiological parameters presented in Table 3.3 of SR2.

The inhalation MDIs were generally estimated using background exposure data from the UK, derived from Defra's UK-AIR: Air Information Resource¹², which provides ambient air quality data from a number of sites forming a UK-wide monitoring network. The MDIs for heavy metals were based on rolling annual average metal mass concentration data from Defra's UK Heavy Metals Monitoring Network from the period October 2009 to September 2010¹³.

Information for some substances was obtained from UK sources including Environment Agency TOX reports and data from the UK Expert Panel on Air Quality Standards (EPAQS). Where recent UK data was not available, data was sourced from the International Programme on Chemical Safety (IPCS), the World Health Organisation (WHO), the Agency for Toxic Substances and Diseases Registry (ATSDR), Health Canada, and various other peer-reviewed sources summarised by LQM/CIEH¹⁴.

For other substances, where no data or information on background exposure was available, background exposure was assumed to be negligible and the MDI set at 0.5*TDI in accordance with guidance in SR2.

PLANT UPTAKE

Soil to plant concentration factors are available in CLEA v1.071 for arsenic, cadmium, hexavalent chromium, lead, mercury, nickel and selenium. For all remaining inorganic chemicals, concentration factors were obtained using the PRISM model. Substance-specific correction factors have been selected in accordance with the guidance established within SR3. This is consistent to the approach utilised in the derivation of the LQM S4UL and the EIC/AGS/CL:AIRE GAC.

Where there is a lack of appropriate data to enable the derivation of specific soil to plant concentrations factors for organic chemicals, plant uptake was modelled within CLEA v1.071 using the generic equations recommended within SR3, as follows:

- à Green Vegetables – Ryan et al. (1988);
- à Root Vegetables – Trapp (2002);
- à Tuber Vegetables – Trapp et al. (2007); and
- à Tree Fruit – Trapp et al. (2003).

There are no suitable models available for modelling uptake for herbaceous fruit or shrub fruit. Exposure is considered negligible.

¹² Crown 2016 copyright Defra via uk-air.defra.gov.uk, licenced under the Open Government Licence (OGL).

¹³ Defra, 2013 Spreadsheet of historic data for multiple years for the Metals network. Available online at: <http://uk-air.defra.gov.uk/data/metals-data>. [Accessed 13/03/2016].

¹⁴ LQM/CIEH, 2015. The LQM/CIEH S4ULs for Human Health Risk Assessment.

SOIL SATURATION LIMITS

GACs are not limited to their theoretical soil saturation within CLEA, although where either the aqueous or the vapour-based saturation is exceeded, this is highlighted within the Workbook (compared with the lower of the two values). This affects pathways which depend on partitioning calculations so in reality this only affects the vapour pathways and is relevant to organic substances and other substances, such as elemental mercury, that have a significant volatile component. However, the Workbook highlights saturation for direct contact pathways to indicate to the user where further qualitative consideration of free phase contamination at the surface may be required.

Where the lower of the two saturation limits is exceeded and the vapour pathway is the only exposure route being considered, the chronic risks to human health are likely to be negligible. Further evaluation could be undertaken using an alternative model suitable for evaluating non-aqueous phase liquids (NAPLs), such as the Johnson & Ettinger (J&E) approach described in USEPA 2003. However, WSP considers that if NAPLs are suspected, given the known limitations and over-simplifications of J&E, soil vapour monitoring is a more accurate way of assessing potential risks.

Where the lower saturation limit is exceeded for the vapour pathway and a number of exposure routes are being considered, then the contribution from the NAPL via vapour inhalation to the overall exposure can be evaluated using the procedure provided in SR4. WSP would evaluate this as part of a DQRA process or through soil vapour monitoring on-site to determine site-specific soil vapour concentrations.

CHEMICAL SPECIFIC ASSUMPTIONS

CYANIDES

Cyanide has high acute toxicity, and short term exposure is an important consideration when assessing the risks from soils contaminated with cyanide. The primary risk to human receptors from free cyanide in soils is an acute risk.

There is no current UK guidance available for calculating acute risks from free cyanide. Consequently, GAC for acute exposure were derived using the algorithms presented in MADEP 1992¹⁵ and assuming a one-off ingestion of 10g of soil (this conservative value has been taken as an upper bound estimate for a one-off soil ingestion rate amongst children). Receptor body weights have been selected according to the critical receptor for each exposure scenario. The lowest of the chronic and acute GAC for each land use scenario were adopted by WSP.

LEAD

The SGV for lead was withdrawn by the EA in 2009, and in 2011 the EA withdrew their published TOX report in light of new scientific evidence. The C4SL for lead was derived using the latest scientific evidence from a large human dataset. As such, no chemical-specific margin was applied in the derivation of the C4SL for lead. It may be possible for WSP to derive a GAC for lead using the same dataset and applying a chemical-specific margin, but the value is likely to be lower than UK natural background concentrations. Therefore, WSP has adopted the toxicological data used to derive the C4SLs in deriving the GAC for lead until such time as alternative GACs are published by an authoritative body. The relative bioavailability was set at 100% in line with the approach taken for other GACs, whereas the C4SL assumes 60% for soil and 64% for airborne dust. Thus, the WSP GAC are lower than the C4SLs.

¹⁵ MADEP 'Background Documentation for the Development of an "Available Cyanide" Benchmark Concentration' 1992. http://www.mass.gov/dep/toxics/cn_soil.htm

POLYCYCLIC AROMATIC HYDROCARBONS

WSP's approach to the assessment of polycyclic aromatic hydrocarbons (PAHs) uses the surrogate marker approach. BaP was used as a surrogate marker for all genotoxic PAHs in line with the Health Protection Agency 2010¹⁶ recommendations and SP1010. This assumes that the PAH profile of the data is similar to that of the coal tars used in the Culp *et al* oral carcinogenicity study from which the toxicity data for BaP was produced. In reality, this profile has been shown by HPA to be applicable on the majority of contaminated sites based on assessment of sites across the country.

The alternative is the Toxic Equivalency Factor (TEF) approach which uses a reference compound and assigns TEFs for other compounds based on estimates of potency. Key uncertainties with this approach include the assumption that all compounds have the same toxic mechanism of action within the body and that no compounds with a greater potency than the reference compound are present. It is considered by the HPA that the TEF approach is likely to under predict the true carcinogenicity of PAHs and therefore favours the surrogate marker approach.

For these reasons, WSP considers that the adoption of BaP as a surrogate marker for genotoxic PAHs, as opposed to the TEF approach, is reasonable. In rare cases where the PAH profile may differ from the wide definitions of the Culp *et al* study the user should discuss their project with an experienced risk assessor. In addition, WSP has derived a GAC for naphthalene, which is commonly a risk driver due to its high volatility, relative to other PAH compounds.

TRIMETHYLBENZENES

The GAC for trimethylbenzenes can be used for the assessment of any individual isomer (1,2,3-trimethylbenzene, 1,2,4-trimethylbenzene or 1,3,5-trimethylbenzene), or a mixture of the three isomers.

CHEMICAL GROUPS

For a number of chemical groups, the available toxicity data is for combinations of chemicals. Given that the physico-chemical parameters may differ between the chemicals, the GACs for the chemicals within the groups have been calculated and then the lowest GAC selected to represent the entire group. This was the approach taken by the EA for m-, o- and p-xylenes, and has also been adopted by WSP for:

- à 2-chlorophenol, 2,4-dichlorophenol, 2,4,6-trichlorophenol and 2,3,4,6-tetrachlorophenol;
- à 2-, 3- and 4-methylphenol (total cresols);
- à aldrin and dieldrin; and
- à α - and β -endosulphan.

¹⁶ HPA Contaminated Land Information Sheet 'Risk Assessment Approaches for Polycyclic Aromatic Hydrocarbons (PAHs) 2010

EXPOSURE TO VAPOURS

INHALATION OF MEASURED VAPOURS

WSP has derived a set of soil vapour GACs (GAC_{sv}) that allow for the assessment of measured site soil vapour concentrations, using J&E, in order to establish potential risks via indoor inhalation of vapours. This methodology enables a more robust assessment of exposure via the inhalation of soil vapours indoors than using CLEA-derived soil GAC, as it is based upon measured soil vapour concentrations beneath the site. It also allows for the assessment of vapours from all source terms (i.e. groundwater, soil or NAPL). Outdoor inhalation was not included. WSP considers that the indoor inhalation pathway is the significantly dominant risk-driver.

The generic land use scenarios within CLEA (residential and commercial) that were used to derive the soil GAC were used to define the receptor and building characteristics for the soil vapour GAC. Only residential and commercial generic land use scenarios include the indoor inhalation of vapours pathway.

The GAC_{sv} were derived for three different soil types; sand, sandy loam and clay, reflecting the importance of this parameter within the J&E model. A depth to contamination of 0.85 m below the base of the building foundation was assumed (i.e. 1 m below ground level). This differs from the depth assumed for the soil GAC (0.5 m bgl), but was selected by WSP as a reasonable worst case scenario.

It is acknowledged that the J&E commonly over-predicts indoor vapour concentrations. In particular, it will significantly over-predict vapour concentrations for suspended floor slabs, which many new builds are constructed with, it does not take into account lateral migration and assumes an infinite source of contamination at steady state conditions. In addition, it is common for soil gas/vapour wells to be installed with at least 1 m of plain riser at the surface and this equates to a total depth of 0.85 m below the building foundation plus a 0.15 m thick foundation, and so is more representative of the depth that samples will be taken from.

The TDSIs and IDs for each substance were converted from $\mu g kg^{-1} bw day^{-1}$ to $\mu g m^{-3}$ using the standard conversions quoted in Table 3.3 of SR2, thereby replacing the need to model C_{air} in the equation:

$$C_{air} = \alpha \cdot C_{vap} \cdot 1,000,000 cm^3 m^{-3}$$

Where:

C_{air} is the concentration of vapours within the building, $mg m^{-3}$

α is the steady state attenuation coefficient between soil and indoor air, dimensionless

C_{vap} is the soil vapour concentration, $mg cm^{-3}$

The target concentrations within indoor air for each substance (C_{air}) are a function of receptor inhalation rates and occupancy periods, as defined by the site conceptual exposure model (assuming standard CLEA occupancy periods and receptors).

The attenuation factor was calculated using J&E (Equation 10.4 in SR3) and the resulting C_{vap} is equivalent to the GAC_{sv} for the modelled exposure scenario.

Where reported soil vapour concentrations exceed the relevant saturated vapour concentration, free product may occur, and the user should discuss their project with an experienced risk assessor.

INHALATION OF GROUNDWATER-DERIVED VAPOURS

WSP has derived a set of groundwater GACs (GAC_{gw}) to evaluate the potential risks through the indoor inhalation of groundwater-derived vapours by first applying the approach described above for the derivation of the WSP GAC_{sv} to determine the acceptable concentration in soil vapour directly above the water table.

The depth to groundwater was assumed to be 1 m bgl (i.e. 0.85 m below the base of the building foundation). This depth was considered to be more representative of commonly encountered groundwater conditions than the 0.5 m below the base of the building foundation (i.e. 0.65 m bgl) that is used by CLEA for an unsaturated source present in the overlying soil.

The GAC_{gw} was then back-calculated from the GAC_{sv} using the air-water partition coefficient (K_{aw}) for each substance.

The WSP Groundwater Vapour GAC are protective against a dissolved phase contaminant source only. If the presence of NAPL is suspected, the risks from this source will need to be assessed. Where reported groundwater concentrations exceed the relevant solubility limit, free product may occur, and the user should discuss their project with an experienced risk assessor.