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The LQM/CIEH Generic Assessment Criteria for Human Health Risk Assessment 2nd edition



Frequently Asked Questions

Last updated: 1 May 2012 (answers are added at the top of the file)

Copies of the LQM/CIEH GAC publication may be ordered from www.lqm.co.uk

<p>14 The GAC for Copper (residential including home grown produce consumption) has gone up from 111mg kg⁻¹ in the LQM/CIEH GAC 1st Edition publication to 2330mg kg⁻¹ in the 2nd Edition. Is this correct?</p>	<p>The GAC for Copper (residential with home grown produce consumption) stated within Table 6-6 correctly reflects the outcome predicted by the CLEA v1.04 (now v1.06) model for the stated input parameter values presented in Table 6-5. (Note no difference is predicted between the v1.04 and v1.06 model, see FAQ answers 5 and 6 below).</p> <p>When comparing the two sets of GAC's it is important to remember some of the fundamental differences between the two modelling methodologies used. The 1st Edition GAC's were derived using upon the pseudo probabilistic methodology and algorithms presented within CLR10 (now withdrawn) and the 2006 CLEA UK model (beta version). The 2nd GAC's were derived using the methodology and algorithms presented within SR3 and the 2009 CLEA v1.04.</p> <p>Therefore, the 1st Edition GAC's were derived using a methodology whereby for substances exhibiting threshold behaviour (such as Copper) with an assumed high background intake (MDI_{oral}) the Tolerable Daily Soil Intake (TDSI) would be set at 20% of the Tolerable Daily Intake (TDI), based on the technical guidance presented within CLR7. This is a more conservative assumption compared to the current technical guidance presented within SR2, which attributes a maximum of 50% contribution to the soil being assessed.</p> <p>Another potentially more important factor to consider when comparing the differences between the two GAC values are the soil-to-plant concentration factors used in the two Editions. The current approach uses the most conservative out of the default PRISM model or literature review undertaken by LQM, and is an approach more consistent with that currently used by the Environment Agency in deriving their SGV's.</p> <p>Other contributing factors will relate to other differences in the modelling methodology and assumed default input parameters.</p>
<p>13 Typo in the inhalation TDI for Vanadium stated in Table 7-1</p>	<p>The inhalation TDI for Vanadium stated within Table 7-1 is a factor of 10 too low, the correct inhalation TDI of 0.286µg kg bw⁻¹ day⁻¹ (based on the WHO (2000) air quality</p>

	<p>guideline of $1\mu\text{g m}^{-3}$) is presented within paragraph 55 of Chapter 7 and is the same inhalation HCV that was used within the LQM/CIEH GAC 1st Edition publication. Please note that this typo does not change the GAC derived and presented within Table 7-4.</p>
<p>12 Erratum to Chromium III inhalation health criteria value and its effect on the GAC for each land use exposure scenario</p>	<p>In deriving the LQM/CIEH GAC for chromium[III], an inhalation TDI of $0.0001\text{ mg kg}^{-1}\text{ bw day}^{-1}$ was used. This TDI is incorrect and arises from an oversight in Paragraph 66 of Chapter 5 which states that "an inhalation TDI of $0.0001\text{ mg chromium[III] m}^{-3}$ was selected to derive the LQM/CIEH GAC for chromium[III]". The oversight is that the value of $0.0001\text{ mg chromium[III] m}^{-3}$ is indeed an inhalation MRL for soluble chromium[III] particulate compounds reported by the ATSDR and requires further conversion based on an assumed inhalation rate and body weight to become a TDI with units of $\text{mg kg}^{-1}\text{ bw day}^{-1}$. Assuming an inhalation rate of $20\text{ m}^3\text{ day}^{-1}$ and a body weight of 70 kg, the inhalation TDI for chromium[III] would be $0.00003\text{ mg kg}^{-1}\text{ bw day}^{-1}$ or $0.03\text{ ug kg}^{-1}\text{ bw day}^{-1}$ (see revised Table 5-1 below).</p> <p>Employing this revised inhalation TDI into the CLEA model leads to a reduction in the chromium[III] GAC values for each generic land use exposure scenario (see revised Table 5-7 below). For the residential land use, the revised GAC becomes 627 mg kg^{-1}. For the allotment and commercial land uses, the revised GAC becomes 15300 mg kg^{-1} and 8840 mg kg^{-1}, respectively. The revised contributions to total exposure for the relevant pathways as calculated for chromium[III] by the CLEA software for the generic land uses are given in Table 5-8 below.</p>

Table 5-1 Toxicological values for chromium(III)

Threshold effects		Non-threshold effects
Oral TDI ($\mu\text{g kg}^{-1} \text{ BW day}^{-1}$)	Oral MDI ($\mu\text{g day}^{-1}$)	Oral ID ($\mu\text{g kg}^{-1} \text{ BW day}^{-1}$)
150	60.2	Not applicable
Inhalation TDI ($\mu\text{g kg}^{-1} \text{ BW day}^{-1}$)	Inhalation MDI ($\mu\text{g day}^{-1}$)	Inhalation ID ($\mu\text{g kg}^{-1} \text{ BW day}^{-1}$)
0.03	0.27	Not applicable

Table 5-7 LQM/CIEH Generic Assessment Criteria for Chromium(III) according to land use

Land Use	GAC ($\text{mg kg}^{-1} \text{ DW}$) ^{a,b,c}
	Chromium(III)
Residential	627
Allotment	15300
Commercial	8840

^a Based on a sandy loam soil as defined in SR3 and 6% soil organic matter (SOM).

^b Figures are rounded to two significant figures

^c In applying the rules for non-soil background to the GAC, the background ADE is limited to being no larger than the contribution from the relevant soil ADE

Table 5-8 Contribution to total exposure for the relevant pathways as calculated for Chromium(III) by the CLEA software for the generic land-uses

Land use	ADE to HCV ratios		
	Residential	Allotment	Commercial
Oral ADE to HCV ratio at GAC	0.03	0.29	0.03
Inhalation ADE to HCV ratio at GAC	0.97	0.71	0.97
	Contribution to total exposure from soil and background sources according to land-use (%)		
Ingestion of soil and indoor dust ²	57.1	65.8	81.7
Consumption of homegrown produce and attached soil	0.94	26.8	NA
Dermal contact (indoor)	0.0	NA	0.0
Dermal contact (outdoor)	0.0	0.0	0.0
Inhalation of dust (indoor)	0.18	NA	0.5
Inhalation of dust (outdoor)	0.0	0.03	0.0
Inhalation of vapour (indoor)	0.0	NA	0.0
Inhalation of vapour (outdoor)	0.0	0.0	0.0
Oral background	41.6	7.3	17.7
Inhalation background	0.18	0.03	0.08

¹ Rounded to one decimal place

² Treated as one pathway (Environment Agency, 2009)

ADE = Average Daily Exposure

HCV = Health Criteria Value

NA = Not applicable (This exposure pathway is not included in the generic land use)

<p>11 There appears to be some discrepancies in the inhalation HCVs cited in the GAC publication and the source materials from which they are derived for the hydrocarbon fractions aliphatic EC5-6 and EC6-8, and for aromatic EC8-10, EC10-12 and EC12-16. Have these values been rounded to 2 significant figures?</p>	<p>In all cases where RfCs (mg/m³) have been converted to TDIs (mg/kg BW/day) there are issues concerning the number of significant figures to cite in the resulting estimate. While we tried to be consistent, we may not have achieved this in all cases, particularly where other factors such as conflicting estimates and large uncertainty, were also taken into account. Unfortunately, toxicology is not an exact science and involves considerable room for discussion and disagreement.</p> <p>There is considerable discussion of a relevant oral and inhalation HCV for the Aliphatic EC5-6 & EC6-8 fractions in TPHCWG (Vol4). Close reading of this section, suggests that the RfD was actually estimated from the RfC via route-to-route extrapolation. It therefore seems somewhat inappropriate for TPHCWG to have subsequently recommended different values for the two routes of entry (i.e. 5.0 mg/kg/day via oral and 5.3 mg/kg/day via inhalation). While it could be argued that both values should be 5.3 mg/kg/day, we were more cautious and selected 5.0 mg/kg/day. All the sources cited in the appropriate section of the GAC publication acknowledge that there is considerable uncertainty about the toxicity of these fractions (for example, values based on the toxicity of n-hexane would be considerably lower). Given the uncertainty and assumptions made, we considered 5.0 mg/kg/day for both TD_Ioral and TD_Iinhal to be reasonable and consistent values for this fraction. In hindsight, Section 9.3.1 could have benefited from additional discussion and explanation of this apparently disconcerting matter.</p> <p>Regarding the Aromatic EC8-10, EC10-12 & EC12-16 fractions, the discussion in TPHCWG again shows that there is much uncertainty and debate regarding an appropriate TD_Iinhal for these fractions. In this case, the TD_Iinhal used to derive the GAC was rounded to 2 sig fig (i.e. 60 rather than 57.1 µg/kg/day) to be consistent with the "guesstimate" for the RfD presented by the TPHCWG of 0.04 mg/kg/day or 40 µg/kg/day.</p>
<p>10 Why are the aqueous solubility and Koc values used to derive the GAC for the petroleum hydrocarbon fractions not exactly the same as those cited in Table 7 by the TPHCWG (1997)?</p>	<p>In deriving the physical-chemical inputs for the petroleum hydrocarbon fractions, we explored many ways to generate justifiable estimates of all the parameters needed by CLEA from the data available, including that in the TPHCWG documents. We also conducted several discussions with Ed Stutt, who was doing similar work on behalf of Mole Valley Council and others (as acknowledged at the end of the chapter). This led both LQM/CIEH and Ed Stutt to adopt methods similar to those used by TPHCWG to derive correlations for</p>

	<p>the various parameters based on the experimental data available for individual substances.</p> <p>In producing the input parameters for the LQM/CIEH GAC, we attempted to be as uniform as possible, including checking that the values presented by the TPHCWG could be replicated. In attempting to be consistent some of these recalculated values were used in deriving the GAC. However, in these cases the values were all in good agreement with those originally cited by TPHCWG.</p> <p>In the case of solubility, the values presented in the GAC publication are described as "mainly based on the values presented by TPHCWG" but we neither stated nor meant to imply that they were taken directly from Table 7 - although they are in very close agreement with the values presented in Table 7. The values used to derive the GAC were re-calculated to 3 significant figures using the correlations described in Equations 22 and 23 (page 57) in Vol3 of the TPHCWG reports. The values cited in Table 7 were only expressed to 2 sig fig.</p> <p>Similarly the log Koc values were recalculated to 3 sig fig using Equations 29 and 30 (page 61) in Vol3 of the TPHCWG reports.</p>
<p>9 Why are saturation limiting values not presented for all substances (e.g. PAHs) when reporting the LQM/CIEH GACs, have they been forgotten about? In addition, some of the GAC presented for TPH fractions and phenol are >1,000,000 mg/kg (i.e. >100%) which is a physical impossibility.</p>	<p>No they have not been forgotten about. The introductory chapter of the LQM/CIEH GAC publication addresses the procedure that was followed in the reporting of saturation limits (paragraphs 62 and 63 on page 1-7). Specifically, where the GAC calculated by the CLEA model exceeds the lower saturation limit (i.e. the lower of either the aqueous or vapour based saturation limit) and is highlighted in red within the CLEA model output (i.e. where the vapour pathway is calculated by the CLEA model as being an important contributor to exposure) the lower saturation limit is also reported in brackets. It should be noted that the saturation limits are estimated within the CLEA model based upon site- and contaminant-specific user inputs, as described within Section 5.3 of SR3. The appearance of a saturation limit in any of the GAC tables within the LQM/CIEH publication is dependent on the outcome of the 'traffic light' approach taken within the CLEA model and also the contaminant, site specific inputs and landuse scenario selected. Further explanation of the approach taken within the CLEA model and 'traffic light system' is provided within Section 4.12 of SR4, which also provides some points for consideration by the risk assessor when interpreting outputs from the CLEA model. The answer to Q8 may also be useful for further background on this issue.</p> <p>The GAC presented within the publication are taken directly from the CLEA model output</p>

	<p>to facilitate the comparison with criteria generated by the assessor themselves. However, the CLEA model does not cap media concentrations based on saturation limits or maximum values, rather the outputs are based on worst-case health criteria based assumptions. Hence, in a limited number of situations the GAC presented are >1,000,000 mg/kg (i.e. >100%), particularly where the inhalation pathway is not considered to be a significant contributor to exposure. As with all assessment criteria, the risk assessor needs to exercise their judgement as to the appropriateness of the LQM/CIEH GAC taking into consideration site-specific circumstances.</p>
<p>8 Some of my site samples submitted for fractionated TPH analysis are reported to be above the LQM/CIEH GAC and stated saturation limiting value at the relevant SOM%. Should I use the GAC value or saturation limiting value for my risk assessment?</p>	<p>The partitioning processes modelled within CLEA <i>'depend upon a number of limiting assumptions and are primarily based on linear behaviour observed at low chemical concentrations in soil'</i> (SR3, Environment Agency, 2009). The solubility and vapour saturation concentration limits calculated within CLEA (Section 5.3 of SR3) suggest boundary conditions and are provided as a check to aid the risk assessor in interpreting the model output. Specifically, where the calculated GAC exceed the saturated aqueous and/or vapour concentrations it is up to the risk assessor to decide whether uncertainty in the partitioning approach used by CLEA would affect the outcome of the assessment. SR3 also states that the partitioning approach <i>'is not designed to consider situations where residual phase contamination may be present'</i> and the saturated soil concentrations calculated (Section 5.3 of SR3) are <i>'useful indicators for this behaviour'</i>. Where residual phase contamination is suspected, alternative methods for risk assessment are recommended (SR3 provides some suggested sources of information).</p> <p>It is not the intention of the LQM/CIEH GAC publication to provide site-specific advice and therefore, it is up to the individual risk assessor, who is more conversant with the site-specific conditions and circumstances to make a decision on the selection of the appropriateness or otherwise of GAC or site-specific assessment criteria generated by the CLEA model.</p>
<p>7 Within Table 9-15, there is a suffix '6' for the 6% SOM values for Aromatic fractions EC >16-21, >21-35, >35-44 and >44-70 (combined – has a '6' and a '7'). I can't see a footnote for suffix '6' or '7'. Is it a misprint, or have I missed</p>	<p>The numerical suffix's within Table 9-15 are both typographical errors: the suffix '6' should be ignored/deleted; suffix '7' should be replaced with a suffix 'f'.</p>

something?	
6	<p>Does the release of CLEA V1.06 mean the LQM/CIEH GACs are now out of date?</p> <p>CLEA V1.06 is identical to CLEA V1.05 with only changes made to the password protection to ensure integrity of CLEA output reports. See also the response to Q5 and CLEA Bulletin for October 2009.</p>
5	<p>The Environment Agency have now released CLEA V1.05. Does this also mean that the LQM/CIEH GACs are now out of date?</p> <p>Most of the changes incorporated into the new CLEA V1.05 are cosmetic improvements and usability tweaks, such as the inclusion of a contaminant data base and additional exposure data and scenarios. These do not affect the LQM/CIEH GACs. The only change that could have affected the GAC values relates to a minor underestimation of exposure duration in some land use scenarios but this is described by the Environment Agency as having only a <i>"minor effect on assessment criteria calculated using the CLEA software v1.04"</i>. To date, having tested a variety of inorganic and organic contaminants in the new CLEA V1.05, no detectable difference has been identified in the resulting GAC. Finally, we note that the existing "new" SGVs have all been generated using CLEA V1.04 and these have not been withdrawn; the basis for the LQM/CIEH GACs is the same as that for the "new" SGVs.</p>
4	<p>The solubility values for the metal compounds reported in the physical-chemical property tables are often very high. Are the units quoted (i.e. mg/L) correct?</p> <p>The solubility values for metal compounds vary widely in the literature and have been reported to range up to several thousand grams per litre for some compounds. In an attempt to employ caution in the derivation of the GAC values, the highest solubility values for metal compounds have been invariably selected. As one gram per litre is equivalent to one thousand milligrams per litre, the solubility values reported for the metal compounds in the physical-chemical property tables appear to be very high (often in the order to 1E+06 mg/L).</p>
3	<p>Why has the GAC for some substances been set as the lower of the two individual assessment criteria for oral and dermal exposure or inhalation exposure rather than the combined assessment criteria?</p> <p>The reason for this is related to differences in the site (body tissue) of the toxicological effect(s) following exposure to a substance through ingestion and dermal contact or inhalation. For some substances, the site of the toxicological effect(s) following exposure through a specific route of entry is 'localised' as opposed to 'systemic'. Local toxicity occurs when the identified effects may be confined to the site (body tissue) of contact / administration, such as lung cancer. Localised toxic effects have been identified for several substances addressed in the GAC Publication including beryllium and chromium(VI). Furthermore, in some cases the health criteria value for intake of the substance via the exposure route that leads to the localised effect is much lower than for the exposure route that can lead to a systemic effect. In such cases (i.e. where a substance exhibits a localised toxic effect), the GAC has been set as the lower of the two assessment criteria to ensure that the GAC is protective of the localised effect.</p>

<p>2 I am unable to reproduce the LQM/CIEH GAC for chromium(III) in the allotment land use using the input values provided in Table 5-1 and Table 5-5 of Chapter 5. What am I doing wrong?</p>	<p>The reason for this is related to the way in which the soil to plant concentration factors have been derived. In order to reproduce the LQM/CIEH GAC for chromium(III) you MUST enter the soil to plant availability correction (δ) and root to edible plant part correction factors for each produce group (f_{int}) into the CLEA model and ask CLEA to “model” the soil to plant concentration factors. The values for δ and f_{int} for chromium(III) are discussed in Section 5.7.5 of the chapter. CLEA will then use these input values, in conjunction with the water-filled soil porosity (for the selected soil type), the dry soil bulk density (for the selected soil type), and the chromium(III) K_d to model the soil to plant concentration factors.</p> <p>The soil to plant concentration factors reported in Table 5-5 of Chapter 5 have been calculated for the generic sandy loam soil type using the exact same equations as those used in the CLEA model. However, they have been rounded up to allow their presentation within the Table 5-5. Due to the importance of the consumption of home-grown produce as an exposure pathway in the allotment land use, the rounding up of the soil to plant concentration factors has a noticeable effect on the allotment GAC if they are entered directly into the CLEA model as numeric fresh weight (FW) values. Therefore, these values should not be entered directly into the model as numeric FW values in order to reproduce the LQM/CIEH GAC. Instead, these values are presented for information only to compare to literature values.</p>
<p>1 Why have the input parameters not been provided electronically for inclusion within the CLEA v1.04 model ?</p>	<p>It is considered important that the underlying source, justifications and/or discussion relating to any selected input parameter should be clearly provided to allow as transparent an audit trail for the derivation of the GAC as possible. Therefore, provision of an electronic table of input parameters purely for use for ‘copy and paste’ purposes without suitable justification would not be in keeping with the stated remit of the GAC publication. In addition, provision of a suitable data file containing all of the relevant justification and sources would take up significant additional resources to ensure accurate transcription, which is not considered justifiable at this time.</p>
<p>0 To how many significant figures are the GAC reported ?</p>	<p>In order to ensure a degree of consistency the substance and landuse specific GAC’s have been rounded to two significant figures throughout the report, with a footnote to that effect in most instances. Due to last minute editorial changes some GACs may have mistakenly not always have been reported to two significant figures within the tables. It would be expected that individual risk assessors would provide justification and/or discussion for the level of significant figures reported in the GAC they are using within their</p>

risk evaluations on a site-specific basis, should the need arise.