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# The LQM/CIEH Generic Assessment Criteria for Human Health Risk Assessment 2<sup>nd</sup> edition



## Frequently Asked Questions

Last updated: 4 November 2009 (answers are added at the top of the file)

Copies of the LQM/CIEH GAC publication may be ordered from [www.lqm.co.uk](http://www.lqm.co.uk)

<p><b>9</b> 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 &gt;1,000,000 mg/kg (i.e. &gt;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 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 &gt;1,000,000 mg/kg (i.e. &gt;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><b>8</b> 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</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</p>

<p><b>relevant SOM%. Should I use the GAC value or saturation limiting value for my risk assessment?</b></p>	<p>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><b>7 Within Table 9-15, there is a suffix '6' for the 6% SOM values for Aromatic fractions EC &gt;16-21, &gt;21-35, &gt;35-44 and &gt;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 something?</b></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>
<p><b>6 Does the release of CLEA V1.06 mean the LQM/CIEH GACs are now out of date?</b></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>
<p><b>5 The Environment Agency have now released CLEA V1.05. Does this also mean that the LQM/CIEH GACs are now out of date?</b></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>
<p><b>4 The solubility values for the metal</b></p>	<p>The solubility values for metal compounds vary widely in the literature and have been</p>

<p><b>compounds reported in the physical-chemical property tables are often very high. Are the units quoted (i.e. mg/L) correct?</b></p>	<p>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>
<p><b>3 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?</b></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><b>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?</b></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 <b>MUST</b> enter the soil to plant availability correction (<math>\delta</math>) and root to edible plant part correction factors for each produce group (<math>f_{int}</math>) into the CLEA model and ask CLEA to "model" the soil to plant concentration factors. The values for <math>\delta</math> and <math>f_{int}</math> 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) <math>K_d</math> 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</p>

	<p>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 <b>should not</b> 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><b>1 Why have the input parameters not been provided electronically for inclusion within the CLEA v1.04 model ?</b></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><b>0 To how many significant figures are the GAC reported ?</b></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 risk evaluations on a site-specific basis, should the need arise.</p>