Defra Research Project SP1010

Development of Category 4 Screening Levels
Stakeholder Workshop Reports

June 14th 2013

Poject Team

Nicola Harries – Contaminated Land: Applications in Real Environments
Mike Quint – Environmental Health Sciences Ltd
Simon Firth – Firth Consultants Ltd
Ed Stutt – wca environment
Sarah Bull – Ricardo - AEA
Camilla Pease – ENVIRON
Andy Hart, Roy Macarthur and Marc Kennedy – Fera
Steve Moreby

Stakeholder Workshops

This document presents the feedback received by the project team via the three stakeholder workshops that were held in connection with the project. Each workshop was held after the delivery of an individual Work Package (WP) to Defra, enabling the project team to present the research project as it progressed and to gain wider contaminated land community feedback on the approach being taken. The three workshops were held on the following dates:

- WP1 Workshop was held on 16th November 2012
- WP2 Workshop was held on 4th February 2013
- WP3 Workshop was held on 2nd May 2013

Attendees at the stakeholder workshops included members of the project team (see above), members of the project's Steering Group, and representatives/individuals from a variety of trade and professional organisations involved in the management of land contamination (as well as local authorities, learned societies and university departments).

The Steering Group consisted of individuals from the following organisations:

- Department for Environment, Food and Rural Affairs (Defra)
- Department for Communities and Local Government (DCLG)
- Welsh Government (WG)
- Environment Agency (EA)
- Natural Resources Wales (NRW)
- Public Health England (PHE, formerly the Health Protection Agency)
- Food Standards Agency (FSA)
- Homes and Communities Agency (HCA)

Individuals and organisations representing the wider stakeholder community who were also invited to send representatives to the workshops included the following:

Association of Geotechnical and Geoenvironmental Specialists (AGS)
British Geological Survey (BGS)
British Land Reclamation Society (BLRS)
British Property Federation
British Standards Institution (BSI) - EH/4 Soil Quality Committee
British Toxicology Society (BTS)
Chartered Institute of Environmental and Water Management (CIWEM)
Chartered Institute of Environmental Health (CIEH)
Chemical Industries Association (CIA)
City of London Law Society
Civil Engineering Contractors Association (CECA)
Committee on Toxicity (COT)
Energy Institute
Environmental Industries Commission (EIC) – Contaminated Land Working Party
Environmental Protection UK (EPUK) – Land Quality Group
Geological Society of London (GeolSoc)
Greater Manchester Contaminated Land Officers Group
Health and Safety Laboratory (HSL)
Home Builders Federation (HBF)
Institution of Civil Engineers (ICE)
Institution of Environmental Sciences (IES)

Local Authorities - East Midlands Region
Local Authorities - East of England Region
Local Authorities– London Region
Local Authorities - North East Region
Local Authorities - South Coast Region
Local Authorities - South East Region
Local Authorities - West Midlands Region
Local Authorities - West of England Region
Local Authorities– Yorkshire Region
National House Building Council (NHBC)
North-West Brownfield Remediation Forum (NWBRF)
Planning Officers Society
Professor Chris Collins, University of Reading
Professor Len Levy, Cranfield University
Professor Paul Nathanail, University of Nottingham
Professor Simon Pollard, Cranfield University
Register of Ground Engineering Professionals (RoGEP)
Royal Institution of Chartered Surveyors (RICS)
Royal Society of Chemistry (RSC) – Toxicology Group
Royal Town Planning Institute (RTPI)
Society for Environmental Geochemistry and Health (SEGH)
Society of Brownfield Risk Assessment (SoBRA)
Society of Chemical Industry (SCI)
Soil and Groundwater Technology Association (SAGTA)
Specialist in Land Condition (SiLC)
UK Contractors Group (UKCG)
UK Environmental Law Association (UKELA)
Waste and Resources Action Programme (WRAP)
Welsh Contaminated Land Working Group

It should be noted that not all of the invited stakeholder individuals / organisations attended all of the workshops. It should also be noted that the feedback has been anonymised.

STAKEHOLDER WORKSHOP 1 FEEDBACK

Introduction

As part of Defra Research Project SP1010 – Development of Category 4 Screening Levels, there was a requirement to hold three stakeholder workshops. This is a summary of the results from Stakeholder Workshop 1.

Stakeholders attending the workshop were given a series of presentations detailing proposals for the development of Category 4 screening levels (C4SLs) as part of Defra Research Project SP1010. The presentations were a summary of the draft Work Package 1 report that had recently been submitted to Defra. The purpose of the stakeholder workshop was to get feedback on the proposed methodology and options for deriving C4SLs and the reasoning behind the methodology. The presentations covered the following subjects:

- Exposure Modelling
- Toxicology
- Lifetime Averaging and Public Open Space
- Setting C4SLs

After the presentations, the stakeholders were divided into three groups and were then given the opportunity to ask questions about the presentations and provide comments and feedback. The following list summarises the questions, comments and feedback that was captured by the presenters during the feedback sessions under the different subject areas. Also provided in separate appendices are the questionnaire that stakeholders were requested to complete (Appendix 1) and a summary of the results received from the stakeholders (Appendix 2).

FEEDBACK

EXPOSURE MODELLING AND LIFE TIME AVERAGING AND PUBLIC OPEN SPACE

1. What is the overall effect of the suggested modifications on the C4SL? E.g. Is it a 10x or 100x increase compared to SGVs?
2. Changes are proposed to both exposure modelling and how toxicology is considered. People appear generally more comfortable with changes to the exposure modelling than toxicology
3. Why are we producing one C4SL number and not a distribution of exposures that could be compared with a distribution of measured soil concentrations? We discussed whether this was practical at GQRA stage. The comment was made that we are looking for screening values that are simple to use, so maybe this would be something that would be more appropriate for DQRA?
4. Johnson & Ettinger model. Out of all the uncertainties that we have presented there appears to be the greatest level of conservatism associated with the J&E model. Why are we not proposing to reduce conservatism/modify this approach for the C4SL? Mention was made of Steve Wilson's paper – are we accounting for this. We replied that this was very useful for DQRA when foundation type was known but may not be useful for derivation of generic screening values. There then followed much debate about whether a less conservative approach should be adopted but people appeared to be generally comfortable with the suggestion that J&E was not worth the bother of changing. There was a suggestion that radon concentrations in soil vapour vs indoor air concentrations could be used to assess accuracy of J&E for UK buildings or possibly to define alpha factors (this would constitute a small research project in its own right).
5. Soil ingestion. Some disagreement that soil ingestion rate was likely to be lower in winter. Justification was that wetter soils meant that more soil would be tracked into house in winter. Some discussion over differences in receptor behaviour – e.g. people with dogs or cats tend to get more tracked back soil in winter and it also depends on whether you take your shoes off in the house.
6. Relative bioavailability (RBA) – there was a general general nervousness about using an RBA < 100% - it was widely considered that there is not enough data to support this for a generic screening value. Support was expressed for incorporating generic RBA numbers IF this could be based on UK soil data
7. Allotments Exposure Frequency – recommendation to check rationale in CLR10
8. Dermal contact soil adherence factor – Is the central tendency value the geomean or arithmetic mean – use of arithmetic mean preferred but this would depend on the distribution of the data (if this can be determined)
9. Dermal absorption factor for BaP - New Zealand use a value of 7% that is worth considering
10. If we are having such heavy reliance on USEPA guidance – why are we not deriving dissolved phase and vapour phase screening values for chlorinated compounds such as TCE or VC? Should we at least signpost the possibility of risks from groundwater?
11. How are we going to assess risks from lead. Will we use IEUBK?
12. Public open space. Some stakeholders were reluctant to automatically rule out tracking back of soil. Possibility of assuming 100 mg/d soil ing rate whilst on POS and 60 mg/d soil derived dust (from tracked back soil) whilst back at home was discussed. Many people appeared uncomfortable with the assumption of no tracked back soil for POS scenario.
13. Public open space. There are so many potential scenarios, there should be C4SL for at least 3 or 4 POS scenarios.
14. Public open space – dog walker is likely to be the most persistent user of open space.
15. Public open space. What about ingestion of blackberries?

16. Use of the term “acceptable” – this was in the invitation letter to stakeholder meeting – should it be removed from the report? (Is it in the SG?)
17. The term “unacceptable risk” in NPPF has a different meaning to that used in Part 2A. In NPPFit equates not suitable for use and unsafe.
18. What modifications are deemed appropriate is dependent on whether or not the C4SL are intended to be used in planning.
19. If we want to change the ELCR used for C4SL from 1 in 100,000 to 1 in 10000 we should consider the monetary impacts of doing so – i.e. what is the cost (of operation /post-care etc) associated with cancer?
20. Why not issue a probabilistic version of CLEA for people to use to derive C4SL and SSAC?
21. Plant uptake factors – have we considered the uncertainty in these? Will we be reviewing these for derivation of the C4SL?
22. Soil ingestion – how about testing the sensitivity of using a Beta distribution for soil ingestion rate/exposure frequency indoor and outdoor?
23. It was stressed that we need to be very careful about how we explain the difference between GACs and C4SLs (i.e. how would we do this in a way that was accessible to the public).
24. Concern was expressed about using less conservative parameter values for assessment of consumption of home-grown produce as home-growing is on the increase. Is this quite recent increase (driven by lifestyle choices and austerity) likely to be captured in the most recent diet study data that we are proposing to use? [this was raised by several delegates in different groups]
25. Would it be possible to generate residential C4SLs with and without consumption of home-grown produce?
26. Will we assess ‘future-proofing’ of the assumptions underpinning our C4SLs? E.g. Relating to climate change and potential changes in social habits
27. We need to be very careful in how we define levels of risks (importance of communication again!). “Acceptable risk” is a phrase that we should be using (this is defined on a personal level)
28. Would lenders provide funds for development on land assessed by C4SLs (i.e. based on more than minimal risk). Have lenders been consulted? Issue of liability
29. Would we take a different approach if we were developing screening levels for planning rather than Part 2A??
30. We should clearly flag the aspects of exposure assessment that remain precautionary
31. Rainfall data could be used to estimate time spent outdoors (data for Wolverhampton has been compiled for recent asbestos project)
32. Pharma trials were suggested as a source for data on dermal absorption
33. Concern was expressed that C4SLs were being developed for Part 2A but that they may be used for planning/development assessments; do they represent “safe” levels?

TOXICOLOGY

34. Risk Assessment is technical, Risk Evaluation involves judgements using the technical risk assessment. To set LLTCs and C4SLs you need both risk assessment and risk evaluation. The framework includes both, therefore some judgements are going to be needed.
35. A general framework for the UK is needed so that others can derive LLTC and C4SLs for other substances
36. Can the framework be used by non-toxicologists to derive LLTCs and C4SLs for all the other chemicals for which SGV/GACs exist, or has it been derived so toxicologists need input?
37. The public are always ok with numbers that are lower and more conservative. How are we going to communicate the fact that numbers are being allowed to increase? Risk communication should be an important part of this project.
38. It is likely that when C4SLs are calculated for the six substances in this project, this will deal with the issues in contam land evaluations, SGVs/GACs for other substances are usually adequate for screening purposes – 4 or 5 people said this during the afternoon, including HPA.
39. What are you going to do about mixtures and the reality that people are exposed to many substances at the same time?
40. Person 1: UK SGVs are similar to those used in other countries, therefore why do we need to change them?
    Person 2: Actually no they are not similar, and the HCVs are very different (sometimes orders of magnitude different) in other parts of the world.
41. Can you explain the difference between using CSAFs and Margin of Exposure, as it is not clear.
42. Person 1 - How do you decide which risk assessment approach is appropriate? Person 2 - In reality when performing risk assessment it is useful to do both approaches (CSAFs and MoE) side by side and then the choice of an MoE (which is more flexible) can be informed by the CSAFs.
43. Who is going to define what 'X' should be for the BMD approach?
44. We should always aim to protect the child in risk assessment, largely due to the difficulties in communicating risk with parents. I am not comfortable about changes which might suggest we would not be doing this. Risk perception by the public in performing lifetime averaging should be considered. Also parental exposure and foetal exposure must be considered.
45. I would be comfortable with changing the exposure parameters, but not the toxicology parameters. Because it is easier to understand the exposure changes in the context of daily living etc. and common sense i.e. days children play out and how much is ingested etc are things I can understand.
46. The analogy of the cliff edge could be useful in communicating risk, can you build on this and better define it as to where SPOSH would be in relation to C4SL?
    Why are you not using probabilistic modelling of the toxicology data? What you are doing is dumbing down the science, when a better more probabilistic approach could be taken to modelling the toxicology data.
47. In changing the toxicology data you are now magically saying higher numbers are possible, which is what DEFRA want. Isn't it just a fix to meet their ends and why wasn't it done before?
48. Different curves can be fit to sparse toxicology data that can lead to large differences in outcome, how are you going to judge best fit?
49. There have been evaluations of some of the substances that have not been taken into account in EA 2009 reports, these should be reviewed and included.
50. Decision makers such as contaminated land officers and LA's were excluded in 2010-11 from the consultation on the changes to Part2A guidance and discussions on the need for C4SLs. Do we know what we are getting involved with?
51. How will we know we are in Cat 4 with these new numbers when Cat 3, 2 and 1 are not defined?

52. If we implement all changes to tox and exposure, the numbers will be too high.
53. What approaches (NOAEL or BMD) are used in other countries?
54. What approaches are used in other areas such as foods, water, air quality etc. I would like the approaches in contam land to be the same, so I compare relative risks from different sources
55. Who else uses CASFs?
56. How does using a ELCR work?
57. Should we be combining exposures from different routes or keeping them separate. We should be more transparent about the relative contributions of different routes. General feedback was from all groups that they understood the BMD approach and that it was a good approach to use. More explanation (and practical examples) on use of MoE approaches needed.
58. Where do the current bandings (<10,000 – may be of concern) come from?
59. Are we going to take this new methodology to the committees

Summary reponses for specific questions asked:

- Use BMD modelling rather than NOAELs and LOAELs to derive toxicological criteria, where possible.
- Use chemical-specific adjustment factors (CSAFs), rather than default uncertainty factors, to derive toxicological criteria, where possible.
- Use a higher ELCR than 1 in 100,000 (eg a maximal 1 in 10,000) when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).
- Use lifetime averaging when deriving C4SLs using CLEA, if judged to be appropriate on the basis of the toxicological assessment.
- Use child-specific exposure assumptions to convert media concentrations to toxicological criteria for residential land-use, as appropriate, if lifetime averaging is not employed.
- Adopt the term “low level of toxicological concern” (LLTC) to describe toxicological criteria derived for the purposes of developing C4SLs which are “more pragmatic but still strongly precautionary” compared with existing HCVs.
- Adopt the wider use of Margin of Exposure (MoE) approaches and recommend target MoEs for each substance.

SETTING C4SLs

60. Worries that some C4SLs may exceed potential acute criteria.
61. Concerns that the £140M of savings "promised" in the IA will not be delivered if there isn't read across to planning, as only approx £6M is spent on Part 2A (presumably the gov-funded bit).
62. People are warned off using the NBCs for planning (in the Concluding Remarks – "They are not a planning or risk assessment tool and must be used in the context of the SG in the manner described in the TGSs."). Could the C4SLs report say something similar?
63. NHBC warranty is triggered by Part 2A investigation/determination.
64. Discussion of precise wording of NPPF wrt contamination – "safe", "suitable for use", "not Part 2A", etc.
65. Market might decide whether SGVs or C4SLs should be used on new developments.
66. One option might be to give local authorities the discretion to allow the use of C4SLs under planning (eg, eyesore site, only economic way forward, etc etc).
67. Discussion of need for training/skills development to allow use of C4SLs
68. Suggestion that the tox modifications are not made – keep it simple...
69. Wide variability of public open space.
70. Depleting source term not considered (eg, benzene)
71. May need to address under-conservatisms (eg, chlorinated breakdown products, synergisms, reductions in ventilation rate due to energy efficiency requirements).
72. Lifetime averaging – probably OK in some cases.
73. C4SLs might not result in cost/risk savings from less remediation, but could do so due to less investigation.
74. Local decision on consideration of background exposure?
75. Importance of good SI if higher numbers adopted.
76. Can Defra decide what's acceptable under planning?
77. Enrichment factors could be important if $PM_{2.5}$ is considered versus PM_{10}.
78. Presumably benzo(a)pyrene is being considered as a "surrogate marker" of genotoxic PAHs?
79. Will these C4SL numbers become the default planning numbers ?
80. Will the project review the use of statistics – concern this is routinely poorly understood and applied by both consultants and regulators ?
81. If we can't say for certain where SPOSH is, or the other category boundaries for that matter, how can we be certain the new numbers still remain within category 4, and don't risk creeping into category 3 ?
82. Guidance very clearly needs to explain the difference between an SGV/GAC and a C4SL number. This needs to be done in a way that can be communicated with the public.
83. Suggest the guidance makes it clear the C4SL numbers are only for use in Part2A, and that they have no direct role in planning.
84. Need to take care to explain the probabilistic review aspects properly – to avoid the misunderstanding that site specific adjustments to the C4SLs would also be done probabilistically.
85. Concerned about the difficulty of communicating to the public that although contaminant levels at their home might be some way above 'minimal risk', nothing would be done because they were still below levels considered 'sufficiently precautionary'.

APPENDIX 1 – QUESTIONNAIRE

C4SL STAKEHOLDER WORKSHOP 1 – QUESTIONS ON SUGGESTED MODIFICATIONS TO CLEA

NAME: ……

COMPANY/ORGANISATION REPRESENTING:……

Please state to what extent you agree with the modifications, on a 5 point scale: strongly agree (5), agree (4), no opinion (3), disagree (2), strongly disagree (1). If you disagree please can you give your reasons.

	Suggested Modification	View
1	Reduce average soil and dust ingestion rates from 100 to 80 mg d^{-1} for residential land-use and 50 to 40 mg d^{-1} for commercial land-use to account for lower exposure in winter months.	
2	Utilise conservative generic chemical-specific RBA estimates, where feasible and supportable, rather than the current default of 100%.	

3	Halve exposure frequencies for children on allotments to better reflect likely central tendency behaviour.	
4	Reduce soil adherence factors in children for residential land-use from 1 to 0.1 mg cm^{-2} to better reflect “central tendency”.	
5	Reduce exposure frequency for dermal contact outdoors for residential land-use from 365 to 170 days per year, to better reflect “central tendency”.	
6	Update vapour inhalation rates to the mean values recommended in USEPA, 2011.	
7	Depending on the basis of the HCV_{inhal} consider reducing indoor dust loading factors to 50 and 25 ug m^{-3} for residential and commercial land-uses, respectively, to better reflect likely concentration of respirable (PM2.5) particles.	

8	Consider the use of central tendency estimates of fruit and vegetable ingestion rates rather than 90th percentiles.	
9	Consider reducing the fraction of homegrown produce for residential land-use to better reflect likely central tendency behaviour for residents with gardens.	
10	Use BMD modelling rather than NOAELs and LOAELs to derive toxicological criteria, where possible.	
11	Use chemical-specific adjustment factors (CSAFs), rather than default uncertainty factors, to derive toxicological criteria, where possible.	
12	Use a higher ELCR than 1 in 100,000 (eg a maximal 1 in 10,000) when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).	

13	Use lifetime averaging when deriving C4SLs using CLEA, if judged to be appropriate on the basis of the toxicological assessment.	
14	Use child-specific exposure assumptions to convert media concentrations to toxicological criteria for residential land-use, as appropriate, if lifetime averaging is not employed.	
15	Adopt the term “low level of toxicological concern” (LLTC) to describe toxicological criteria derived for the purposes of developing C4SLs which are “more pragmatic but still strongly precautionary” compared with existing HCVs.	
16	Adopt the wider use of Margin of Exposure (MoE) approaches and recommend target MoEs for each substance.	
17	In order to meet the requirement of 4.21(d) of the revised SG, the toxicity criteria used to derive C4SLs should be no less than a “small proportion” (say 10-25%) of chemical-specific background exposure, as estimated via published MDIs.	

18	Exclude the quantitative consideration of background exposure (via MDIs) from the derivation of C4SLs but provide relevant data for information purposes (in the form of ratios of modelled soil-related exposure to estimated total exposure).	
19	Develop C4SLs for public open space, based on exposure via ingestion of soil, dermal contact and inhalation of dusts and vapours outdoors only.	
20	Use uncertainty modelling (Monte Carlo etc) to inform decisions regarding the level of conservatism within C4SLs derived using a LLTC.	
21	Use uncertainty modelling (Monte Carlo etc) to derive C4SLs when using a MOE approach.	
22	Use qualitative approaches to capture residual unquantified uncertainty within the C4SL derivation process.	

23	Acute exposure scenarios should be considered on a site-specific basis when C4SLs are used in combination with statistical approaches.	
24	Additional Suggestion	

	Additional Suggestion	
	Additional Suggestion	

	Additional Suggestion	
25	Six substances have been provisionally selected for review in this project: arsenic, benzene, benzo(a)pyrene, cadmium, hexavalent chromium and lead. Are these substances appropriate for development of the methodology for deriving C4SL? Are there other substances you would prefer to be included in this project? If so, which substitutions would you make?	

26	Which are the first two substances you would choose for development of the C4SL methodology and why?	

ADDITIONAL COMMENTS

ADDITIONAL COMMENTS

APPENDIX 2 – SUMMARY RESULTS OF THE QUESTIONNAIRE

Suggested Modification											
1	**Reduce average soil and dust ingestion rates from 100 to 80 mg d^{-1} for residential land-use and 50 to 40 mg d^{-1} for commercial land-use to account for lower exposure in winter months.**	2 - unless there is some back up data for 80mg/d. Could get muddier - more indoor dust in winter. OK agree with central tendancy.	2 - Given it is easier to track mud into the house in winter (soil wetter) I have my doubts on this, hence ingest more indoors. It is all behaviour drive. If the theory is that you have slightly reduced exposure frequency outside look at that. I suspect changes to this vary by where you are in the country and how hardy you are. What about climate change? Need data to justify.	3/4 - most dust ingestion is indoors which may be higher in winter due to tracked back mud - agree if studies are available to show lower rates in winter months or if studies mentioned from the Netherlands which show lower soil ingestion rates when it is wet can be correlated with average rainfall / month in UK and adjusted accordingly.	5	5	5	4	4. If supported by evidence	4. even these it can be argued may be over-conservative given expecially on commercial land where it is liable to be 80%+ hard cover	5
2	**Utilise conservative generic chemical-specific RBA estimates, where feasible and supportable, rather than the current default of 100%.**	5 - But could be misapplied - so need to be clear under what species/circumstanc there should be used. If we consider background (MSC's) here to account for bioavailability.	2 - We need to be careful that the toxicity studies RBA is taken into account. For lead I have had sites with RA of 95% to 15% even where there is no clear so was. For PAHs I remain unconvinced that the studies are there but will stand corrected. If supportable we should be doing it but suspect the supportable and reasible is not there.	4 - but only in cases where there is sufficient evidence in the literature to support it. This remains something that can (should) be measured on site and used for DQRA	5	3	5	4	4. If supported by evidence	4. I have yet to be presented with any chemical or scenario where 100% was actually likely to be the exposure	5
3	**Halve exposure frequencies for children on allotments to better reflect likely central tendency behaviour.**	5 - Yes	2 - This should be the central tendany for children of families who regularly go to allotments.	4 - with clear justification for modification and explanation of why central tendencies used together with implications on the conservatism / level of protection offered by the resultant screening values (i.e. what percentage of the population is expected to be protected by the screening level with this and other changes to the exposure modelling).	2. There needs to be more study before any generalisation can be drawn	5	5	3	1. this seems unlikely to be supported by reality	4. Agreed, most kids on allotments do not just sit there and eat the soil....	3
4	**Reduce soil adherence factors in children for residential land-use from 1 to 0.1 mg cm^{-2} to better reflect "central tendency".**	? Presume outdoors only? Why so low, why not 0.2mg/cm which is geometric mean?	2- This is skewed distribution. The critical tendancy will be relatively low. Children's hands have a high adherence (ref USEPA 2004) Do not ignore this. Children in mud can have very little adherence. C4SL will be a do nothing and don't even warn lived so we should be cautious	4 - with clear justification for modification and explanation of why central tendencies used together with implications on the conservatism / level of protection offered by the resultant screening values (i.e. what percentage of the population is expected to be protected by the screening level with this and other changes to the exposure modelling).	4	5	5	3	3. Is there evidence for this? Seems like a large reduction	4. most parents feeding children vegetables are likely to wash them fairly well	4
5	**Reduce exposure frequency for dermal contact outdoors for residential land-use from 365 to 170 days per year, to better reflect "central tendency".**	5 - Yes 180 days as 1/2 year.	2 - What age group are we talking about. This change with age significantly.	5 - with clear justification for modification and explanation of why central tendencies used together with implications on the conservatism / level of protection offered by the resultant screening values (i.e. what percentage of the population is expected to be protected by the screening level with this and other changes to the exposure modelling).	4	5	5	3	4. A good idea to reduce from 365 but justification for the 170 is needed, does sound a bit low	4. Very few people spend more than their weekends in gardens actually in scenarios where they could come into contact with it, so even this is probably over-conservative	5
6	**Update vapour inhalation rates to the mean values recommended in USEPA, 2011.**	5 - yes	4 - Yes	5 - if updated data is available that is in accordance with the data used in SR2 there is no reason why the new data should not be used as this represents the most current best available data. However, along the same lines if updated data is readily available for other parameters it should also be used, even if it has the affect of making the screening levels lower.	4	3	5	5	5. Provided this is agreed with by the experts in this area	4. this should hopefully mitigate the inhalation super-pathway issues with the CLEA model	5
7	**Depending on the basis of the HCV_{resi}, consider reducing indoor dust loading factors to 50 and 25 ug m^{-3} for residential and commercial land-uses, respectively, to better reflect likely concentration of respirable (PM2.5) particles.**	5 agreed	2/3 - If tox data OK. We need to be aware of enrichment in our assessments and reflect to this in the guidance. Do the dust inhalation tox studies look at only PM 2.5? Is there data to support the <PM 2.5 fraction having no effect? You do inhale some PM10 which are <PM 2.5. No. Unless on a chekcal specific basis this is justified. It could be coarses particulates are more toxic/carcinogenic even if in lower concentrations. If this is a systemic effect.....definately not as it should be	4 - if supported by the toxicological studies and evidence is available to support the lower dust loading factor for the alternative particle fraction.	4	5	5	4	3. Is there evidence for this? Why a reduction by half?	4. recent studies (University of Wales?) indicate the actual amount of metals (for example) in indoor dust is much then even 25 and may be better off at 10 for certain parameters.	5
8	**Consider the use of central tendency estimates of fruit and vegetable ingestion rates rather than 90th percentiles.**	5 - if it is 90th. Think we might have to be cautious on this.	2 - Where people grow and eat vegetable they do so a lot. It's a bit of an all or nothing so central tendency is not very applicable.	4 - with clear justification for modification and explanation of why central tendencies used together with implications on the conservatism / level of protection offered by the resultant screening values (i.e. what percentage of the population is expected to be protected by the screening level with this and other changes to the exposure modelling).	4	2	5	4	4. If supported by evidence	4. People are so variable in uptake from vegetables and fruit that a central tendancy makes much more sense	5
9	**Consider reducing the fraction of homegrown produce for residential land-use to better reflect likely central tendency behaviour for residents with gardens.**	2 - Because this seems to be increasing in last 10 years	2 - Where people grow and eat vegetable they do so a lot. It's a bit of an all or nothing so central tendency is not very applicable.	4 - with clear justification for modification and explanation of why central tendencies used together with implications on the conservatism / level of protection offered by the resultant screening values (i.e. what percentage of the population is expected to be protected by the screening level with this and other changes to the exposure modelling).	4	2	5	4	2. There is probably a lot of variability around the central tendancy, evidence needed for such a reduction.	4. most gardens and open spaces in industrial scenarios probably vastly over-estimate this contribution. Ideally soemone should update the information this was originally based on as in my experience only about 20% of gardens I visit have vegetables and fruit people actually harvest.	5
10	**Use BMD modelling rather than NOAELs and LOAELs to derive toxicological criteria, where possible.**	4 - Does the UK risk assessment community have enough access to results/software? However agree in principle.	1 - If the data is available by all means revise this but make sure we use appropriate uncertainty. Be consistent with CDT, COM and COC. DO NOT USE STRAIGHT BMD but BMDL.	5 - with a clear explanation of why this has been done and the justification for it from the scientific studies, depending on the design of the studies, use of NOAELs / LOAELs can be very conservative.	4	3	5	3	3. Evidence needed to support this	4. this is a much more realistic way of doing this, Noals and Loaels are in some ways more scientific but do suffer from over conservatism	4
11	**Use chemical-specific adjustment factors (CSAFs), rather than default uncertainty factors, to derive toxicological criteria, where possible.**	Agree but think there will be huge variation between risk assessors - DEFRA derived?	1- we need to be consistent with UK policy here including CDT, COM and COC. There are few cases where the uncertainty factors are not chemical and study specific.	5 - again with a clear explanation of how this has been done and the justification for it from scientific studies. As with updating of the inhalation rates (6), this seems like something that can be done to the model to still allow calculation of minimal/negligible risk criteria.	4	3	5	3	Don't know, but evidence required	5. This has been a major bugbear as for some substances we do have a very good idea that the species default may be over (or in the case of rats and metals) or under-compensating	4
12	**Use a higher ELCR than 1 in 100,000 (eg a maximal 1 in 10,000) when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).**	5 - Yes (1 in 10,000) We are too cautious	1 - NO. This is category 4SLs Low or No risk not verging on a real issue. That is Cat 2/3. Need to be strongly precautionary.	3 - I think this modification will be harder to justify and will likely mean lower levels of acceptance of the C4SLs if it is adapted.	4	5	5	3	3. A decision for government	4. much better choice and should be more reflective of actual exposure data	4
13	**Use lifetime averaging when deriving C4SLs using CLEA, if judged to be appropriate on the basis of the toxicological assessment.**	4 - Agree	1 (Not Cat 4) - It seems fine in principle. However the issue is latency period. How long before the dose was applied for it to take effect. Was it just the first month/year of the rat study? We need to be cautious, is childhood cancer is then cancer at the end of life .....perhaps?	4 - With caution, as again I think this will be harder to justify to the wider community. However, if there is evidence from the toxicological studies that children are not a more sensitive receptor to the contaminant, it should be justifiable to use lifetime averaging.	4	5	5	3	3. Don't know, but evidence required	3. given how relatively unlikely it is in modern society that people will live in the same place all of their lives, it is perhaps a conservative assumption I am not sure this is of benefit. Ideally there is still a good case to consider the most vulnerable receptor in most cases.	4
14	**Use child-specific exposure assumptions to convert media concentrations to toxicological criteria for residential land-use, as appropriate, if lifetime averaging is not employed.**	3	Do not understand so no comment	4 - where tox values are calculated from published guidelines for concentrations of the substance in various media (e.g. UKDWS) and children are the critical receptor in the CSM, child specific factors should be used for the conversion.	3	5	5	4	3. Don't know, but evidence required	4. this is ideally what we should do anyway and the default in CLEAUK, but I debate the definition of the "average child" especially in relation to PICA for example	3
15	**Adopt the term "low level of toxicological concern" (LLTC) to describe toxicological criteria derived for the purposes of developing C4SLs which are "more pragmatic but still strongly precautionary" compared with existing HCVs.**	2 - But can't think of anything better !	1- The definition of C4SL is low or no risk. The HCVs are generally appropriate. If they are not = over cautious we should change the UCVs. This should be agreed with CDT, COM and COC.	5 - the term seems to describe what the tox criteria are intended to be used for in calculating C4SLs. What will become important then is what does a low level of toxicological concern mean? Is it precautionary enough? How protected are receptors by these values? An estimation of the level of protection still represented by these LLTC compared to minimal / negligible risk HCV would be useful to help stakeholders understand what these values represent and how precautionary they still are.	3	5	3	3	1. There would have to be compelling evidence to support this	2. we should be thinking in terms of existing risk criteria rather than making up new buzwords that could only confuse people. That said, this does open the debate about what any given term in risk assessment actually means in real terms anyway...	2
16	**Adopt the wider use of Margin of Exposure (MoE) approaches and recommend target MoEs for each substance.**	4- Agree where poss	1 - This ties in to the BMD (or in fact BMDL). It would help transparency if it can be done.	3	4	3	4	4	4. If supported by evidence	3. not convinced it would help	4
17	**In order to meet the requirement of 4.21(d) of the revised SG, the toxicity criteria used to derive C4SLs should be no less than a "small proportion" (say 10-25%) of chemical-specific background exposure, as estimated via published MDIs.**	3 - Maybe ignore background	2 - Unless background is acceptably high already. The comparison is useful but do not change c5SLs to do this. Just show differences so LAs can decide. This is a separate test to the C4SL.	3 - unsure how this would effect the toxicological values used in the assessment. As background exposure can change significantly over time as new environmental standards are brought in for example this could then make any C4SL based on these factors to become obsolete. This may be a modification best left for DQRA with the report describing a method for how background can be used to determine appropriate tox criteria.	5	3	3	3	2. Evidence on both elements would be needed to support this.	3. not sure this would actually work	3
18	**Exclude the quantitative consideration of background exposure (via MDIs) from the derivation of C4SLs but provide relevant data for information purposes (in the form of ratios of modelled soil-related exposure to estimated total exposure).**	4 - Agree- assessing site not whole world.	3- The reason to include is for the threshold substance. If we believe there is a threshold above which effects happen we should include it.	3 - any change to the way in which background exposure is used in the derivation of the screening values will need to be clearly explained and justified. See also reasons in (17) above. Some feedback I've had from other EIC members indicates that they think this could lead to confusion.	1. This is a key part of the challenge in setting C4SLs and cannot be ignored	3	3	4	4. But background data needs to be robust	2. background has to be considered because the risk must be assessed in relation to what is already present generally and what the difference between that and what you have on your site actually is or it has no meaning at all. It is the increase in risk that needs to be determined to drive what you do about it.	3
19	**Develop C4SLs for public open space, based on exposure via ingestion of soil, dermal contact and inhalation of dusts and vapours outdoors only.**	2 - But for "low intensity use" such as dog walkers.	1 - Yes but this is tricky and may not be practical. What age group? How close to houses will this be the park behind my house where all the kids near me play? (ie a garden)	3 - it is understood that the derivation of C4SL is required by the project specification. However, this land use needs to be carefully considered and the CSM derived for it needs to be clear it what it includes as well as what is not included in terms of exposure. In my experience, a significant portion of tracked back soil to the house can be from POS (kids playing sport in mud, parents standing in mud watching etc.) Additionally, cars used to travel between POS and home can become filled with dried mud from the POS - should there be an exposure pathway for time spent in	1. There are half a dozen totally different exposure scenarios within the term POS	5	5	3	4. But study data needed to back this up	5. and can we have a realistic exposure time as well? Most kids in open spaces rarely spend more than 6 hours a week in the same one.	5
20	**Use uncertainty modelling (Monte Carlo etc) to inform decisions regarding the level of conservatism within C4SLs derived using a LLTC.**	2- I think it's a good idea but, given companies are making redundancies and not encouraging training or software purchase, and given it probably needs a higher level of skill, this is unlikely to fly	1 - understanding the use HCVs the uncertainty would be good however because there is a lack of clarity in the actual uncertainty of dermal and ingestion rates this is very hard and can give/take sense of uncertainty.	4 - The communication of uncertainty in the C4SLs will be very important and help for them to be adopted by the contaminated land community.	4	5	1- probabilistic modeling produces its own uncertainty - can be very difficult to assess the result	3	4. If supported by evidence	3. not convinced here that it helps unless it actually allows a viable uncertainty to actually be determined	5

Suggested Modification											
21	**Use uncertainty modelling (Monte Carlo etc) to derive C4SLs when using a MOE approach.**	2. I think it's a good idea but, given companies are making redundancies and not encouraging training or software purchase, and given it probably needs a higher level of skill, this is unlikely to fly	1- Possibly but use BMDL. Really for cat 2/3 boudary.	3	4	2	1. probabilistic modelling produces its own uncertainty - can be very difficult to assess the result	3	4. If supported by evidence	3. not sure this would actually work	5
22	**Use qualitative approaches to capture residual unquantified uncertainty within the C4SL derivation process.**	4 - Agreed	4 - yes	**4** - The communication of uncertainty in the C4SLs will be very important and help for them to be adopted by the contaminated land community.	5	3	3	3	5 means a fudge factor	4. yes, make it more reflective of the actual situation rather than just making potentially conservative assumptions	3
23	**Acute exposure scenarios should be considered on a site-specific basis when C4SLs are used in combination with statistical approaches.**	4- Yes we need to consider acute	4 - Yes	**4** - However, it would be useful to highlight in the report where it is likely that acute exposure to the contaminant may be a significant factor. This will aid those reviewing assessments in which C4SLs have been used to determine if they should also require an assessment of acute risks.	3	5	3	3	3. Not clear how cat 4 relates to acute exposure.	4. yes, make it more reflective of the actual situation rather than just making potentially conservative assumptions	
24	**Additional Suggestion**	If we're tweaking soil and dust ing, soil adherence factors etc then we might as well tweak tracked back dust.	Change testing regime to look at surface soil + examine correct soil fractions for ingestion and dust. Split each end point eg should we add exposure via inhalation to exposure via ingestion or change data for eg ingestion when adding to be inappropriate to lung effects.	As I attended the workshop to represent the membership of EIC I have tried to combine feedback that I received from an EIC sub-group, who have shown an interest in assisting with matters surrounding the new Part 2a Statutory Guidance, and those of my own. Additional comments from our members for consideration are included in the boxes below.				These six are well selected given either their particular toxicology or the 'difficulties' in the current CLEA & UK regime that they highlight.	Naphthalene	Remove Benzene, add Cyanide	Yes I generally agree with these as being the initial priorities
			Asbestos. It is everywhere and lacks guidance. Lead. The threshold has been withdrawn + a new threshold should be derived using appropriate models.	For this research project to have a significant impact on the contaminated land community and meet the promises of the Part 2a impact assessment of reducing the amount of unnecessary remediation currently being undertaken in the UK it will have to be applicable to sites being remediated under planning. It is unlikely that the C4SLs will be applicable to routine planning assessments. However, if the report is prepared with clarity and transparency the principles used to derive the C4SLs can then be used for DQRA as justified by the specific circumstances of each site							
				The scientific logic behind the derivation of the C4SLs can be absolutely fine, but if the resultant soil criteria are not robustly tested outside the scientific bubble (in terms of the practicalities of what contamination could be left in-situ if using these numbers at sites with multiple contaminants present), there is a potential that they are not fit for purpose. The issue of additivity, though mentioned in the CLEA guidance is largely ignored. With less precaution in these C4SLs will it be necessary to reopen the discussion on additivity and caveat the use of the numbers on sites with multiple							
				The so what - the proposals when viewed individually may seem reasonable, but the acid test is what they do as a whole to the criteria. We need to see the so what before we can properly judge whether the proposals are fit for purpose.							
				With the move to central tendency throughout and a less precautionary approach to tox, it is important that the resultant criteria are evaluated carefully in terms of the significance of slightly higher exposures (i.e. by using central tendency there is potentially a large proportion of the population that might experience higher exposures). The significance of these higher, plausible, exposures will be dependent on the dose-response of the contaminant in question. It needs to be demonstrated that the revised criteria do not represent wholly unsafe concentrations for a							
25	**Six substances have been provisionally selected for review in this project: arsenic, benzene, benzo(a)pyrene, cadmium, hexavalent chromium and lead. Are these substances appropriate for development of the methodology for deriving C4SL? Are there other substances you would prefer to be included in this project? If so, which substitutions would you make?**	Nickel - we could then consider acute - ie sensitisation etc		The important substances from the list will be BaP and lead followed by arsenic and benzene as these are commonly found on many sites in excess of the SGV/GAC. Cadmium and hexavalent chromium are generally not found to be critical in risk assessment terms, though it is acknowledged that they will apply to some sites.			benzo(a)pyrene and lead: benzo(a)pyrene occurs widely, the high toxicity and resulting low human health screening criteria result in possibly unecessary costs in remediation/treatment of land; moreover, this substance can be used to determine screening	Benzo[a]pyrene: lack of certainty about how BaP will be assessed in the future combined with the current, very conservative HCV, that seems to be driving unnecessary remediation, makes this a key substance. Lead: the current anomalous assessment basis for		BaP and hexavalent chromium as they are the two biggest pains when undertaking current risk assessment	Benzo(a)pyrene - as it's the most common contaminant that is engrained above the GACs and Lead as there is currently little guidance on the UK approach to its exposure modelling from soil
26	**Which are the first two substances you would choose for development of the C4SL methodology and why?**	Benzene - relatively well known and researched. Less uncertainty. Possibly Arsenic.		BaP and lead given the low value of the BaP GAC when compared to typical values found on sites and lead as there is currently a lack of available guidance. These low substances will allow the proposed modifications to be tested adequately and each will present its own unique challenges in terms of deriving toxicity data.							

Suggested Modification							
1	**Reduce average soil and dust ingestion rates from 100 to 80 mg d^{-1} for residential land-use and 50 to 40 mg d^{-1} for commercial land-use to account for lower exposure in winter months.**	(2) It is believed that that the 100mg/d ingestion rate is based on accepted scientific studies which tend to all conclude that this level best represents the average ingestion rate so it is not clear how a reduction can be scientifically justified. However it is accepted that it would seem a reasonable assumption that direct ingestion should be lower in Winter months as children are unlikely to spend much time outside particularly when raining or very cold. Conversely dust ingestion rates could plausibly increase given that soil is more likely to be tracked back into a dwelling whilst heating and thus dust distribution increased in winter. Perhaps the two exposure pathways should be separated to take account of lower exposure frequencies & a sensitivity analysis undertaken to see if this would make any significance to the overall ADE. If not, why change & spend great effort trying to justify this change in absence of scientifically validated data	4 I understand from the workshop that the justification for this was related to halving the exposure frequency for outdoor exposure for 6 months in winter. I trust that the methodology report will make this clear. I also understand from the workshop that the indoor dust component will not be adjusted from that currently assumed - this needs to be clear otherwise will be mis-used. On the basis that this does reflect central tendancy for the winter months for the key receptors this sounds reasonable. Does this take into account the whole population - there is a risk that we are considering how we would use our own gardens and do we take into account the average person?		4	4 - providing the science supports this??	Seems sensible but should be checked using surveys. 4
2	**Utilise conservative generic chemical-specific RBA estimates, where feasible and supportable, rather than the current default of 100%.**	(2) It is felt that chemical specific RBA really should remain site (or geology) specific & perhaps is always best approached via site testing (or use of Conservative estimates already known for that geology/area). This data is easy to obtain from LA. For example Arsenic within the Northampton Ironstone deposits do not generally exceed 14% RBA & using 28% (double) assumption is unlikely to be rejected. For Devon/Cornwall the Devonian Slates offer typically offer Arsenic RBA not exceeding 40% & again the LA is best placed to advise. However Made Ground (excluding reworked naturals) in our experience can vary significantly & are chemically less stable (can still be undergoing chemical species changes). Offering a best guessimate of RBA in this circumstance would be hard to accept & in our opinion very risky.	2 We didn't have enough time to discuss this in great detail at the workshop - but I was wondering what the proposed approach will be for those contaminants where there is limited evidence to support use of bioaccessibility (i.e. where no in vivo data). Have you consulted with BGS/BARGE and if so, what are their thoughts? It would be preferable to ensure that the C4SL was applicable to the majority of sites and therefore thought would need to be given to the source and what a typical site is		3	2 - must be defendable not sure you can do this on all chemicals	Yes 4
3	**Halve exposure frequencies for children on allotments to better reflect likely central tendency behaviour.**	(4) In our opinion this proposal seems reasonable as it is our experience that many allotment owners do restrict child presence at allotments for other reasons (adverse weather, risks from activities etc) & therefore the exposure frequency currently assumed seems too conservative. However it is unclear what central tendency data actually means (ie what is the source of the central tendency data and how contemporary it is in current thinking).	4 On the basis that this does actually reflect likely central tendency - is there evidence to support this? Does this take into account the whole population - does it take into account the actual average person?		3	2 - not keen on central tendancy this as we must be seen to be protective of the wider population but there may be room to use on allotments	OK 4
4	**Reduce soil adherence factors in children for residential land-use from 1 to 0.1 mg cm^{-2} to better reflect "central tendency".**	(2) Similar to answer given for question 1, it seems difficult to robustly justify a change unless new scientific evidence suggests otherwise. Furthermore it is felt that soils in the UK are more wet & loamy than countries where the studies were implemented & therefore the current assumption seems reasonable. Perhaps this parameter should be increased to reflect these conditions or a factor applied to reflect sites where exhibited soils are more granular & perhaps presenting a lower risk. Rather than trying to justify this change perhaps the exposure frequency could be looked at to more reasonably reflect the lowered likelihood of playing outside & wearing more clothes during winter months.	On the basis that the 1 is based on e.g. 95th percentile data, it would be more appropriate to use a central tendency value. Also provided 0.1 is protective of the potential of exposure to wet soil.		3	1 - central tendency is not appropriate in my view and US may not be appropriate for the UK	OK 4
5	**Reduce exposure frequency for dermal contact outdoors for residential land-use from 365 to 170 days per year, to better reflect "central tendency".**	(4) See Comment to Question 3 & 4. However the reduction might be able to be backed up by robustly scrutinising weather data (Average rainfall) for UK rather than just plucking for 170 days	4 I understand from the workshop that the justification for this was related to halving the exposure frequency for outdoor exposure for 6 months in winter. I trust that the methodology report will make this clear. On the basis that this does reflect central tendency for the winter months for the key receptors this sounds reasonable. Does this take into account the whole population - there is a risk that we are considering how we		3	2 - central tendancy are not appropriate in my view but would consider some reduction	Is this too great a reduction? Survey data reaaded.
6	**Update vapour inhalation rates to the mean values recommended in USEPA, 2011.**	(3) Based on the presentations given on the day, it appears that improved data is available from an USEPA 2011 study. This proposal seems reasonable for change if backed up scientifically. However EPUK would need to review the study & ensure that other UK authoritive bodies are comfortable/confident that the study is not flawed and/or applicable within the UK context			4	4 - Yes if scientifically defendable	Yes
7	**Depending on the basis of the HCV_{soil}, consider reducing indoor dust loading factors to 50 and 25 ug m^{-3} for residential and commercial land-uses, respectively, to better reflect likely concentration of respirable (PM2.5) particles.**	(2) Whilst in principle this seems reasonable for contaminants whose main intake relates to inhalation into the respiratory bronchiole's; presumably PM10 particles can adhere to nasal passages & can still enter the larger respiratory system. For Asbestos fibres it is believed that small fibres (below a certain aspect ratio) can enter the respiratory system but then are more likely to be expelled, which is a reason why only fibres of a certain aspect ratio are considered. Could this be the same for finer dust particles? There is too much uncertainty on this aspect & EPUK believe this may be unjustified unless scientific evidence is presented stating otherwise. I believe that the IOM assume the UK typical dust generation for UK scenarios is 0.1mg/m3 which appears to be in line with the current CLEA assumption	4 Following the discussions from the workshop it seems reasonable for the indoor dust loading factors to be reduced to reflect the PM2.5 particles - are these values representative of the PM2.5, or is this an assumption? Can empirical data / other studies showing that 2.5 is the fraction to be assessed be presented in the methodology to ensure that it isn't seen as a fudge?		4	4 - providing that the evidence is defendable	OK
8	**Consider the use of central tendency estimates of fruit and vegetable ingestion rates rather than 90th percentiles.**	(3) Really don't know either way. It is assumed that the current value is scientific & unless new data suggests otherwise this would be difficult to justify.	1-2 There is insufficient data presented to date to demonstrate that this is representative of those who do grow fruit & vegetables. For those who regularly/consistently grow produce it is reasonable to assume that they would eat alot of their own produce. This needs more supporting evidence to be changed.		3	2 - Not for housing	Must only use one "worst case" in any analysis so central estimate probably scientifically better, but public perception may prevent this
9	**Consider reducing the fraction of homsgrown produce for residential land-use to better reflect likely central tendency behaviour for residents with gardens.**	(2) It is assumed that the current value is scientic & unless new data suggests otherwise this would be difficult to justify. However the current assumption assumes a certain size garden so perhaps this is best tackled via DQRA (i.e. simple to adjust in the current CLEA model by reducing the existing Home grown fractions for average user accordingly based on garden size (i.e. half the existing fractions for each garden item under Advanced Settings within the home grown produce data sheet, if the garden is 50m2 as opposed to 100m2). Furthermore it is felt that more people are embracing homegrown produce, so possibly this change would present increased risks to a large proportion of the future population	1-2 There is an increasing trend in those who grow their own produce from available data and clear justification needs to be presented to demonstrate that this is a reasonable approach to take, especially given the slope of the graph.		3	3 - No. I understand it does not take much land to supply a family with Veg for a year and the numbers of people growing their own veg is on the increase?	OK
10	**Use BMD modelling rather than NOAELs and LOAELs to derive toxicological criteria, where possible.**	(4) This is very chemical specific but it already seems that toxicologists are in general agreement that this is the most accurate approach, where such data is available. The key questions appear to be which level of effect should be selected (i.e. 10% increase in tumors or 5% etc) & which confidence interval should be selected where BMDL are adopted (90%ile, 95%ile?) & this seems very chemical &/or political decision specific. It is felt that only the toxicological experts can make this decision & should be backed up scientifically. However EPUK welcome news that the HPA/EA etc are intending to provide a toxicological review for each selected chemical & present findings in a transparent & in a simplified (easy to use) spreadsheet	4 Where there is sufficient appropriate justifiable data. The approach for doing this needs to be clearly laid out in a step by step basis so that it can be followed and repeated for other contaminants outside the 6 .		3	5 - providing the data is robust	Very important - improves accuracy of departure value used markedly
11	**Use chemical-specific adjustment factors (CSAFs), rather than default uncertainty factors, to derive toxicological criteria, where possible.**	(4) Similar to answer given for Question 10; It is felt that only the toxicological experts can make this decision & should be backed up scientifically. However EPUK welcome news that the HPA/EA etc are intending to provide a toxicological review for each selected chemical & present findings in a transparent & in a simplified (easy to use) spreadsheet	2 This may be more of a specialist DQRA approach. Consideration needs to be given to how the CSAFs will be done for other contaminants outside the 6 - there needs to be a hierarchy (and how would you come up with a hierarchy), and how the CSAF will be regulated (expert judgement only?). It will be difficult for the Local Authority to understand the differences between consultancies for example, and there is already alot of pressure given to 'expert opinion' for toxicology.		4	3 - no view	Very important when data available but judgement needed.
12	**Use a higher ELCR than 1 in 100,000 (eg a maximal 1 in 10,000) when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).**	(1) It is believed that this was first discussed in the Way Forward publication & rejected. It can only really ever be a political decision. What level of risk is really acceptable to the public & are the general public really appreciative of what this really means. (i.e. They are relying on experts to protect them as best as we can)	2 Is this representative of low risk? Is this "safe"? Is this contaminent specific - how will it be judged? More evidence/justification required. What were the key objectors to this in the 2006 Way Forward exercise?		4	1 - I would not be keen on this. It was reject by the SGV taskforce and believe this needs to be a political decision we should use what the impacts of the other. proposed changes are first. I don't think we can sell this to the home buyer	10 to power 5 OK but 10 to the power 4 not OK
13	**Use lifetime averaging when deriving C4SLs using CLEA, if judged to be appropriate on the basis of the toxicological assessment.**	(3) It is felt that only the toxicological experts can make this decision (i.e. selected for Cadmium) but any decision should be backed up scientifically.	2 Does lifetime exposure take into account consideration of the lifetime the receptor spends at the site in question (i.e. Does a child spend 70 years at a site?)? Should it be related to the tox and critical receptor - i.e. Should we consider a critical receptor of 30 years, 70 years to tie in with the tox? Is this going to take into account cumulative effects (e.g. cadmium)? Would it be better to apply this on a contaminent specific basis at DQRA?		3	1 - child-specific scenario should be used for housing	If you must.
14	**Use child-specific exposure assumptions to convert media concentrations to toxicological criteria for residential land-use, as appropriate, if lifetime averaging is not employed.**	(3) In terms of the presentations given on the day is would seem reasonable that HCV's derived from specific mediums (drinking water, Air) that are based on life time exposure, when are then converted for child receptor are providing overly conservation HCV's & is one area that could be more carefully looked into. This seems a scientifically valid proposal	4 This seems reasonable with HPA agreement to counteract the double counting (assume the report will make the double counting basis clear)		3	4 - completely sensible	Yes for public perception reasons.
15	**Adopt the term "low level of toxicological concern" (LLTC) to describe toxicological criteria derived for the purposes of developing C4SLs which are "more pragmatic but still strongly precautionary" compared with existing HCVs.**	(4) Whilst it is accepted that the term LLTC would explain more explicitly what C4SL are so their person's using them or relying upon them are clear that these values do present a risk (albeit a low risk), as opposed to the minimal risk as presented by current SGV's. It is considered that soil values should be appropriately protective of human Health within the realms of our current knowledge (why should the population accept a low level of risk unless this is appropriately communicated & can be demonstrated as acceptable). It should be made clear that minimal risk levels (e.g. SGVs) are a good starting position for planning. However it is perceived that by having a minimal risk (using current CLEA Model to determine site suitable for use) & a low risk level (as published as a C4SL) that this may present confusion or blight & difficulties by LA, Developers & advisers, in communicating the differences to the general public, particularly if C4SL are abused for planning purposes and/or to justify why remedial	2 - 4 The 4 relates to the LLTC term (no objection to it) The 2 relates to are LLTC Category 4 screening levels - if so, they must be suitable for use under planning (i.e. Not SPOSH and safe). Are you actually deriving C4 levels or C3 levels? Strongly precautionary suggests that they are - is a 1 in 1000 ECLR strongly precautionary? If TOX is still strongly precautionary (i.e. safe) then this would be appropriate		4	1 - strongly precautionary still relates to minimal risk in my view and can see no reason to introduce new terms. We will find it very difficult to sell this to home owner and developers they will accept minimal risk but 'Low Risk' No. All we should be doing is to update the Tox and exposures to be more pragmatic. Let sea what happens to the numbers after this. I would also note that builders will be developing sites and will be keen to ensure that clean up targets are within the C4 band. on this basis in my view they will be	Beware TTC (threshold of toxicological concern) make sure there is clear differentiation.
16	**Adopt the wider use of Margin of Exposure (MoE) approaches and recommend target MoEs for each substance.**	(3) It is felt that only the toxicological experts can make this decision (i.e. this has been adopted for Cadmium) but any decision should be backed up scientifically.	2 How will a Local Authority regulate the MoE outside the 6 chemicals? Is this another expert opinion? Is MoE only appropriate in a hazard quotient assessment and thus DQRA?		4	3 - have no view on this	Yes. MOE is a more honest approach does not mix risk assessment and risk evaluation
17	**In order to meet the requirement of 4.21(d) of the revised SG, the toxicity criteria used to derive C4SLs should be no less than a "small proportion" (say 10-25%) of chemical-specific background exposure, as estimated via published MDIs.**	(4) This seems reasonable but needs to be transparant & effectively communicated. It is also felt that other regulations are in existance to reduce other none soil source exposures (i.e. Air Quality Objectives, Drinking water standards) & it is assumed that these, in the long term, are aimed to reduce existing environmental exposure levels	What will be the approach for where there is low/insufficient data for background concentrations? Can one assume it is negligible?		4	3 - have no view on this	?
18	**Exclude the quantitative consideration of background exposure (via MDIs) from the derivation of C4SLs but provide relevant data for information purposes (in the form of ratios of modelled soil-related exposure to estimated total exposure).**	(4) See Answer to Question 17	4 Personally, I am in agreement with this. However - would this represent LLTC? How does this fit with total exposure and strongly precautionary and safe, especially where the MDI > ADE?		3	3 - not sure I fully understand this but some account of background exposure needs to be considered.	Have to look at background values when deriving.
19	**Develop C4SLs for public open space, based on exposure via ingestion of soil, dermal contact and inhalation of dusts and vapours outdoors only.**	(5) This seems reasonable. However it depends on the defined definition of POS	1 All depends on what the C4SLs are for. If for Local Authorities and SPOSH, we need to provide criteria for the commonly assessed site. In many cases, the open space sites which are causing uncertainty in category 2-3 are those adjacent to houses. Therefore, tracked back pathways need to be considered. If on the other hand, data from LA show that the open space land to be too far from houses for TB pathways to be relevant, the proposed approach is		3	4 -would be keen to see something for POS particularly for housing developments.	Very difficult because of different ?
20	**Use uncertainty modelling (Monte Carlo etc) to inform decisions regarding the level of conservatism within C4SLs derived using a LLTC.**	(5) This is considered critical & welcomed	4 and 2 More information on how the results will be used to inform decisions is required before this can be fully agreed - however, in principle, this seems like a sensible option to evalute the impact of the changes. Will this be presented in the next workshop together with an opportunity to make decisions?		4	4 - agree but not the use of LLTC	YES !!!!!!

Suggested Modification						
21	**Use uncertainty modelling (Monte Carlo etc) to derive C4SLs when using a MOE approach.**	(3) Unsure; would need to understand what this proposal exactly means. More information/clarification would be needed	2 Insufficient information on how the results will be used to inform decisions so have given a disagree - but this answer could be changed. Will this presented in the next workshop?	4	4	Yes, limit
22	**Use qualitative approaches to capture residual unquantified uncertainty within the C4SL derivation process.**	(3) Unsure; would need to understand what this proposal exactly means. More information/clarification would be needed	2 This is a DQRA step as qualitative information will depend on the site specific factors. Is this not one of the ways a Local Authority will ascertain Cat 2-3?	4	3	Doubtful if this will lead to anything useful.
23	**Acute exposure scenarios should be considered on a site-specific basis when C4SLs are used in combination with statistical approaches.**	(4) This is critical & welcomed	2 and 4 Is this saying that acute exposure will be excluded from C4SLs? C4SLs need to be protective of acute exposure otherwise there is the danger that acute exposure won't be assessed and C4SL not protective? However, if the C4SLs are not relevant under Planning, DQRA could be used to catch the acute exposure scenario?	4	2	relate is acute toxicity + episodic exposure
24	**Additional Suggestion**	The accepted use of the C4SL needs to be carefully explained within the published guidance. The publication should make it explicitly clear that these are values to aid decision making under P2A and not planning	More thought needs to be given to what the C4SLs are and what they are to be used for - this may be a question for the Steering Group rather than the consortium. We discussed this during the workshops. At the moment, they are defined as category 4 screening levels i.e. Represent land that is not contaminated land. If they are low risk, then they could be considered to be safe. Under Planning, they therefore meet the NPPF definitions and therefore are suitable for use / not unacceptable.			
		Extra advice and/or consideration of synergisic effects for certain chemical groups etc	Significant decisions relate to the toxicology and are required on a contaminant specific basis, and most likely are going to be given the "required expert judgement" label? Given that the C4SLs are going to be developed for 6 contaminants, there is a gap (as with the SGVs) of a number of compounds for which someone (individual consultancies as LA's won't have time? EIC?) will most likely need to fill. If the C4SLs are only to be used as a step towards SPOSH (i.e. not under planning), then arguably site specific DQRA will need to take place and the	I don't disagree with any of the suggestions put forward. The differences in my scoring simply reflects my level of understanding. I think it is important that we still err on the side of caution but our modelling is more realistic. The concern would still be how this is communicated and used. I know the scope of this project is C4SL, but I would still be concerned how the regulator will view a particular site if the values are exceeded. Also it is difficult to communicate what could be seen as a relaxation of standards. It is somewhat easier to	
			There were discussions over this being an opportunity to result in DQRA guidance which is clearly beyond the scope of the C4SL works (although I guess there is nothing to prevent the other options being written up externally as perhaps a SoBRA/CL:AIRE publication/newsletter/technical bulletin (I'm more than happy to assist with this? Would the old EA draft not published document be of any use here? If some of these reduced conservatism ideas were placed as DQRA guidance then it may mean that			
			How are you going to establish the CEM for the open space scenario? How will you establish the EF? Will you use data collected from actual sites, base it on your understanding of how sites are used (if so, are your assumptions accurate for the 'central tendency' population!)? Will you use information collated by others? LAs?			
25	**Six substances have been provisionally selected for review in this project: arsenic, benzene, benzo(a)pyrene, cadmium, hexavalent chromium and lead. Are these substances appropriate for development of the methodology for deriving C4SL? Are there other substances you would prefer to be included in this project? If so, which substitutions would you make?**	The selected chemicals are considered sensible	At the present time, I rarely assess cadmium, hex chromium for SPOSH and therefore would not object if these compounds are removed. (With site specific bioaccessibility, these compounds can easily be assessed at DQRA and aren't required at SPOSH level). Substitutions would be cyanide (easily liberatable, complex, hydrogen cyanide), a chlorinated solvent, another compound from a 'group'? If these are C4SLs which are not used under Planning, consideration should be given to those	This is obviously industry specific.	No - the main substance of concern have been selected	No
26	**Which are the first two substances you would choose for development of the C4SL methodology and why?**	Lead & BaP	lead and benzo(a)pyrene. BaP - key contaminant, occurs on a great number of sites, inconsistency in understanding what the TOX means and thus SPOSH, GAC derived are perceived to be too conservative, yet there is huge reluctance to accept a higher GAC (even though the NPPF is being met) - resulting in too much remediation being undertaken? Lead - very interested to know what the impact of the TOX will be to a LLTC. Standards appear to be falling. Huge uncertainty on what to use as a GAC - the withdrawn SGC is commonly used but this has been withdrawn as not sufficiently protective. Therefore there is a huge information gap which needs to be filled. Lead is commonly encountered on a number of sites. How do you intend to model lead with the uptake vs intake and given the conclusions in the SoBRA report?		BaP and Lead followed by Arsenic	Banzene (human epi. Data). Arsenic

Suggested Modification							
1	**Reduce average soil and dust ingestion rates from 100 to 80 mg d^{-1} for residential land-use and 50 to 40 mg d^{-1} for commercial land-use to account for lower exposure in winter months.**	3 - without the detailed rationale for reducing the soil ingestion rate to this value it is difficult to provide useful comment. As I understand it the 100mg/d is already the mean value rather than a realistic worst case albeit uncertainty exists regarding the proportion of the 100mg/d that is from soil and soil derived dust rather than other dust. Within SR3 various studies are reported to try and distinguish soil and dust with Smith and Jones recommending differnet soil ingestion rates varying from 100 to 50 mg/day for average children aged 1 and 5 and a dust ingestion rate of 100mg/day. Paustenbach reported between 50 and 90% of the combined soil and dust ingestion rate is dust depending upon the source and receptor behaviour. For adults within SR3 a study by Paustenbach reports between 5 and 25mg/day for the soil ingestion rate reported to be closer to the median than mean. Dust is considered an important component but uncertainty exists as to the percentage it contributes to the combined soil and dust ingestion rate and this should be used in the justification for reducing the soil and dust ingestion rates.	5. Sounds logical if it is a better approximation of reality.	Yes. I agree with this proposal. 5	4 - Agree	(2) as I prefer an alternative means to be adopted. I don't really see/perceive that there are many occasions where this is justified. However if one considers the explanation of commercial property and the likely green space I agree lower values are likely. What I would say though this is typical for commercial offices as opposed to business parks with units. I don't see why we need to reduce the ingestion of soil and dust at home, Otte et al consider it reasonable for children & indicate that 150 to 200mg/d being worst case. I come back to a lot of families having pets which introduce soil/dust and hygiene previously used with lead in the SEGH. Where houses are kept clean this is fine, but generically I would anticipate ~50% are clean and the remainder perhaps with more young families and single men with an increased reduction in cleanliness. In winter months the variation is likely to be very different if you come from Kent or the South Downs as opposed to higher and more northern climates. I think this should be justified in each risk assessment. Besides 100mg/day is used internationally.	4 No objection as the modifications appear to be based upon sound science.
2	**Utilise conservative generic chemical-specific RBA estimates, where feasible and supportable, rather than the current default of 100%.**	3. Agree this would be very useful since this is an area where published data exists and many consultants already have analysis results to show RBA estimates for different soil types and contaminants. Guidance should be clear on its applicability for use in the oral / inhalation pathways though since this often seems to be an area of uncertainty / mis-use.	4. Only if defensible and sure it is set at an appropriate credible 'maximum' of the data set. However, there must be care with respect to natural versus anthropogenic sources and perhaps RBA should apply only where the assessor is sure the chemical species present are those for which the RBA has been measured.	In my experience RBA varies too much to make a generic estimate. If RBA varies considerably in Newcastle it's certain to vary even more so across E and Ws. 2	4 - Agree	4 This option is available within HHRA, however if through study and wide base of UK results (via BGS) we are able to say the range of w As lies between 10 & 80%, then by all means adopt 80% as opposed to 100%, but justify using studies and the same lab. BGS are perfectly placed to help with this. If not available my view would be leave as is.	4 In an ideal world! A lot of data would however be required to ensure that these values are defensible, therefore although this would be a welcome modification, in practice it may be difficult to achieve.
3	**Halve exposure frequencies for children on allotments to better reflect likely central tendency behaviour.**	3. The frequencies were based on a study in 1993 (albeit the child frequencies were assumed) and a rote made in SR3 these were subject to review. Providing halving these is based on this review then this seems reasonable.	5. Sounds logical if it is a better approximation of reality.	Don't agree, allotment usage is increasing rapidly and many families use their allotments as play areas for their children - play equipment etc is now present on many sites. 2	4 - Agree	2 as I prefer an alternative means to be adopted & this really needs justification in new supporting guidance. Allotment holders have changed with an emergence of young families/organic growers etc. Admittedly when visiting allotments I didn't see lots of kids, but I did see them especially during holidays or as young kids in prams. If these are to be changed, we should do some research through allotment user groups at varying locations in the country and establish use, that way it would be justified. Admittedly exposed skin to soil is likely to be much less, kids are unlikely to help out digging in shorts and short sleeves, those in prams are not really going to get exposed & frequency for > five yrs old probably less. Most digging would be done in cooler part of the year on an allotments when	4 Would have no objection to this, as the children's exposure parameter is already assumed in CLEA (form likelihood of accompanying parents/grandparents. Though it does say in footnote 15 that the EA is undertaking a review of these assumptions with the NSALG - could the group acquire this information?
4	**Reduce soil adherence factors in children for residential land-use from 1 to 0.1 mg cm^{-2} to better reflect "central tendency".**	3. Without the rationale ofr the reduction it is difficult to comment on this value. The value of 1mg/cm2 is based on a 95th percentile reflective of wet and dry soil with a geometric mean of 0.2mg/cm2 reported by the USEPA in 2004. If the value of 0.1mg/m3 reflects more recent research then I'd agree with the reduction.	3. If viable, I am all for making it more realistic, but would this mean under-predicting for 50% of the population if central tendency is chosen? If there is a risk of this, perhaps a different cut-off should apply, such as 75%ile?	Yes, I agree with this proposal. 4	4 - Agree	(4) This would be fine for gravelly, sandy soil, however for finer fractions, I would err on the side of caution with slightly higher values. Soil adherence factors outdoors in USEPA Rags indicates that rugby players have a mean of 0.1 mgcm2 & 0.8 ass 95% and teenage soccer players with values of 0.04 and 0.3 respectively. These indicate it is reasonable to reduce adhesion factors. Nb I will explain in other comments the problem with central tendency & CLEA guidance. Pharmaceutical studies for newer drug applications that are being applied to the skin as opposed to taking tablets, would probably help support this. It is becoming far more common and reliable for drug uptake. If there is a problem with PAHs or more specific for BaP, then this demands research between creosotes, coal tars and	3 Would have no objection to looking at this parameter, but it is noted that from the 2004 USEPA study the 95th percentile for dry soil is 0.4 mg cm-2 and the 95th percentile for wet soil is 3.3 mg cm-2. As UK summers (when children are more likely to be out in the garden) tend to be wetter than drier (especially in recent times), should this alter much?
5	**Reduce exposure frequency for dermal contact outdoors for residential land-use from 365 to 170 days per year, to better reflect "central tendency".**	3. I'm uncertain about reducing exposure for one pathway only although if its to cover a child playing in shorts in summer months only I can see the logic.	3. If viable, I am all for making it more realistic, but would this mean under-predicting for 50% of the population if central tendency is chosen? If there is a risk of this, perhaps a different cut-off should apply, such as 75%ile?	Yes. I agree with this proposal. 5	5 - Strongly Agree	(2) as I prefer an alternative means to be adopted & this really needs justification in new supporting guidance. I would be in favour of reducing (4) to something that reflected a reduced exposure from winter snow or high rainfall events & holidays, but not to 170 days. The central tendency is contra what the model and guidance was set up for. I agree many children will probably be away for 3 weeks per year and knock off four weeks for winter rain/snow, but again you are entering into site specifics that should be negotiated as part of HHRA. The South Downs will be vastly different to higher and more northerly climates. The young girl only being outside for half the year may be representative for cautious inner city or urban areas, but surely not that little elsewhere. But if changing we should	4 Can definitely see benefit in altering this, as it is accepted that children will not be out in the garden every day of the year. However, CLEA provides reasoning for the adopting of 365 days per year in section 3.2.5 of SR3 due to the nature of the studies used. Providing this can be accounted for, the proposed frequency of 170 days per year seems to be reasonable.
6	**Update vapour inhalation rates to the mean values recommended in USEPA, 2011.**	3. Agree this would be beneficial since it represents the most up to date information consistent with the data source used in CLEA. It also makes a reasonable difference to the model output for contaminants driven by inhalation pathways since the revised breathing rates are lower	5. Yes.	Yes. I agree with this proposal. 5	4 - Agree	(5) OK	5 Updated data - therefore should be used.
7	**Depending on the basis of the HCV_{soil}, consider reducing indoor dust loading factors to 50 and 25 ug m^{-3} for residential and commercial land-uses, respectively, to better reflect likely concentration of respirable (PM2.5) particles.**	3. Without the rationale for the reduction it is difficult to comment on this value. As I understand it particles up to PM10 are respirable and can reside in the lungs, finer particles are associated with haze / smoke, and those >PM2.5 associated with windblown dust, i.e. those >PM2.5 are likely to be the ones we're interested in for soil sources. Therefore the proposed rationale of reducing the dust loading factor does not seem appropriate.	5. Sounds logical if it is a better approximation of reality.	Yes. I agree with this. 4	3 - No Opinion	(4) Quite happy with the PM2.5 approach as it appears supported by current air quality work moving to PM2.5 as opposed to PM10.	4 No objection to this as the basis for this change appears to be reasonable.
8	**Consider the use of central tendency estimates of fruit and vegetable ingestion rates rather than 90th percentiles.**	3. Agree it is beneficial to use central tendency estimates (S a day campaign to be reduced?!)	3. If viable, I am all for making it more realistic, but would this mean under-predicting for 50% of the population if central tendency is chosen? If there is a risk of this, perhaps a different cut-off should apply, such as 75%ile?	Don't agree, we should protect people who eat above average fruit and vegetables.2	4 - Agree	(2) I'm not sure this is really suitable for consumption of home grown food. The guidance has steered away from central tendency as a fundamental principal considers that all homes with gardens will grow produce thus accommodating the family that will or may grow a staple variety that are represented in the model. If we looked at central tendency, I think (and from my experience in South Wales & Yorkshire) you will find that there are less than 5% of householders (with gardens) that grow meaningful amounts of produce. In fact I would suggest that <1-2% grow meaningful amounts of fruit & vegetables. So if truly adopting the central tendency approach you may aswell remove vegetable uptake from the model in residential scenarios, just leave it for allotments. Again I would prefer a change to	2 Would be reluctant to adjust this parameter, the CLEA data is based on NDNS data from the 1990s/2000 but given the current trend for growing more at home due to economic conditions, it is possible that at this time this may have even increased. A potentially better way of addressing this issue, as it is accepted that some people do not grow anything,
9	**Consider reducing the fraction of homsgrown produce for residential land-use to better reflect likely central tendency behaviour for residents with gardens.**	3. Agree it is beneficial to use central tendency estimates if these are available. However, we ned to link this back into the legislation and guidance such that we are certain the C4SL are designed to be protective of a typical individual	3. If viable, I am all for making it more realistic, but would this mean under-predicting for 50% of the population if central tendency is chosen? If there is a risk of this, perhaps a different cut-off should apply, such as 75%ile?	Don't agree with this. We should protect people who consume much more home grown fruit and vegetables than 'central tendancy'. The consumption of home grown produce is very likely to increase with allotment usage increasing rapidly, 'gorilla' gardening and people utilising thier own gardens more. 2	4 - Agree	(2) I'm not sure this is really suitable for consumption of home grown food. The guidance has steered away from central tendency as a fundamental principal considers that all homes with gardens will grow produce thus accommodating the family that will or may grow a staple variety that are represented in the model. If we looked at central tendency, I think (and from my experience in South Wales & Yorkshire) you will find that there are less than 5% of householders (with gardens) that grow meaningful amounts of produce. In fact I would suggest that <1-2% grow meaningful amounts of fruit & vegetables. So if truly adopting the central tendency approach you may aswell remove vegetable uptake from the model in residential scenarios, just leave it for allotments. Again I would prefer a change to	2 Although the data used in CLEA is more recent (2004/5) than the data used in the above question, comments are similar to those above.
10	**Use BMD modelling rather than NOAELs and LOAELs to derive toxicological criteria, where possible.**	3. Agree	5. Yes, if this is now accepted best practice. Ie any new approach has to be based on good science and not just adopting a different methodology just because it gives a higher value.	Good justification for this approach where data available. 5	3 - No Opinion	(5) yes please.	5 Where possible, this would be welcomed as it encompasses the whole dataset rather than one specific point. However, this is likely to be difficult as a good dataset would be required for each contaminant of concern.
11	**Use chemical-specific adjustment factors (CSAFs), rather than default uncertainty factors, to derive toxicological criteria, where possible.**	4. Agree	5. Yes, if this is now accepted best practice. Ie any new approach has to be based on good science and not just adopting a different methodology just because it gives a higher value. My reservation is how reliable are they (I have no personal experience)? If there is uncertainty in setting the CSAF then logically at some point you have to revert to the default x10 UF.	Yes - where this is available. 4	3 - No Opinion	(4) I'm reasonably happy with this, though this does become somewhat subjective. I favour BMD & MoE route approaches & this would be secondary, preferably to be agreed with the regulator in HHRA.	4 It would definitely be worth looking at this, but the deriving of uncertainty factors can differ between toxicologists, so there would have to be a robust justification for the derivation of each CSAF.
12	**Use a higher ELCR than 1 in 100,000 (eg a maximal 1 in 10,000) when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).**	3. For the purposes of these category 4 values I can see the logic in increasing the ELCR although I have some reservations in that the CDC and HPA do not support this approach and I believe we are better using BMDs to take account of the curve shape	2. Pushing the envelope to 1:10,000 may be OK from a scientific point of view, but there could be adverse reaction to this because cancer is an emotive subject and risk perception is also important here (CF the Daily Mail Test). There is also the problem of additivity. If each substance is 1:100,000 it is less important to consider additivity since it might be argued that a series of substances brings the site as a whole to 1:10,000. Once you lose this buffer you could exceed the 1:10,000 in total. This also has a	Don't agree, I don't think this level of protection is adequate. 2	2 - Disagree. Not convinced that a ELCR of 1 in 10000 is either 'low risk' or sufficiently protective of human health.	(3) If using BMD one would not need to amend this. I would be tempted to allow CoC, HPA or Toxicologist provide advice in this area. Iunderstand the issue, but a formal health response is required here in my view.	4 The current ELCR represents minimal risk, so it would be reasonable to look at an alternative ELCR for low risk.
13	**Use lifetime averaging when deriving C4SLs using CLEA, if judged to be appropriate on the basis of the toxicological assessment.**	3. Uncertain of when it would be appropriate and thus cannot comment at this stage	???2. Very difficult to say, but if used it would need to be appropriate and would have to be defined quite clearly in the report (not just lost in some equation) to be transparent. I tend not to agree, because by doing so you will be 'diluting' the most sensitive receptor (ie the child) by averaging over more that 6 years. By the same logic, you would not average out the skin area or body weight because you end up with an adult receptor. On balance, probably no, unless there is some tox reason I am not aware of that can	I think we should continue using the 1 - 6 year old child. 2	4 - Agree	(3) This may prove positive in some instances, but not others. Would be interesting if applied for benzene, naphthalene & methyl mercury vapours, assuming a non depleting source beneath a property.	3 There is the potential to move away from the child being the most sensitive receptor, but any changes from this should be appropriate and based on a robust assessment. It should also be assessed on a contaminant by contaminant basis, given the differences that substances have with respect to toxicological pathways and effects etc.
14	**Use child-specific exposure assumptions to convert media concentrations to toxicological criteria for residential land-use, as appropriate, if lifetime averaging is not employed.**	3. Uncertain of when it would be appropriate and thus cannot comment at this stage	5. More logical than question 13. Base everything on a child and not mix child and adult data.	No sure about this. 3	3 - No Opinion	(3) I'm not sure I understand the question, however I think sufficient in my response allows a large degree of latitude, without further consideration here.	5 There is no reason why the conversion of data should not be rationalised.
15	**Adopt the term "low level of toxicological concern" (LLTC) to describe toxicological criteria derived for the purposes of developing C4SLs which are "more pragmatic but still strongly precautionary" compared with existing HCVs.**	4. Agree the wording sounds reasonable. If we're saying these are pragmatic but still strongly precautionary will the supporting text be clear about where the inputs are 'strongly precautionary'?	4. Agree in principle and logic says yes because this is the purpose of the C4SL. However, caution re the use of C4SL in planning (and we must assume it will be considered in planning no matter what caveat is given in the report). If 'low risk' is not accepted by CLOs and they want to remain with 'minimum risk' they could not be used. If LLTCs are used it would be a very good idea to try and bring along the planning community by way of some explanation in the text as to why 'low risk' is appropriate, perhaps comparing the	Yes, I agree with this. Its important that the term LLTC is clearly defined and the differences between SGVs/GACs is clearly stated. 5	4 - Agree	(3) The acronym used is not that important except for how members of the public interpret it. Lower Risk/Tox Level Threshold?	5 It is sensible to adopt a new term, if tox data are to be adjusted for the purposes of the C4SL project (low risk rather than minimal risk).
16	**Adopt the wider use of Margin of Exposure (MoE) approaches and recommend target MoEs for each substance.**	3. Agree providing the backup for the recommended target MoE is provided and thus can be updated easily as new data becomes available	3. Not sure of the implications as I don't understand it sufficiently, but probably OK if this is now an accepted approach.	Not sure about this.	3 - No Opinion	(5) OK	5 Agree with potentially using this approach, though guidance in SR2 should be followed.
17	**In order to meet the requirement of 4.21(d) of the revised SG, the toxicity criteria used to derive C4SLs should be no less than a "small proportion" (say 10-25%) of chemical-specific background exposure, as estimated via published MDIs.**	2. Wouldn't it be more straightforward to provide detailed estimates of MDI and then set a value whereby if say exposure from soil contributes 10-25% of the MDI the land would be placed into category 4	3. I am not sure this clause links with screening levels as these are mentioned in 4.21 (c) and not sure how this can be used in setting C4SLs. If you are saying a C4SL should represent no more than 10-25% on intake, then this would automatically restrict C4SLs to a proportion of MDI irrespective of anything else in the model.	Yes, I agree with this. 4	3 - No Opinion	(3) There's quite a big variation there. I am quite comfortable for a child to have this, however if looking at an adult I think it is more difficult to reason as workplace exposure becomes relevant and workers in heavy industry need to be accommodated.	4 It would be sensible to look at this, especially in light of the revised SG.
18	**Exclude the quantitative consideration of background exposure (via MDIs) from the derivation of C4SLs but provide relevant data for information purposes (in the form of ratios of modelled soil-related exposure to estimated total exposure).**	3. I think this is a more transparent and straightforward approach.	3. Does the government at al have a duty of care to land users to prevent the inputs from soil tipping them over the balance of total intake, or is it enough to simply say the soil alone will not harm them? This would really have to be a policy decision and ignoring other intakes could be seen as putting people at involuntary risk. However, the current SGVs purport to do the former, but when it comes to the crunch the 50% rule is used when the GAC should in fact be negative. This is not an open approach to the general public, but I	Yes, agree with this. 4	3 - No Opinion	(2)-(3) see above I think this could be problematic and we do need to allow flexibility for working adults	3 This may be more relevant for some contaminants of concern than others - it would be worth looking into this aspect though
19	**Develop C4SLs for public open space, based on exposure via ingestion of soil, dermal contact and inhalation of dusts and vapours outdoors only.**	3. Agree this would be beneficial	5. Multi-user park where children play and kick balls about would be more appropriate than dog walking or formal sports pitches.	Yes, this would be useful. It will however be necessary to clearly explain the type of POS use the value has been calculated for - formal gaes field, informal games, ornamental park, woodland, etc etc. 5	4 - Agree. The main types of POS are school playing fields, sports pitches and parks which should all be modeled separately. Could some element of inhalation of dust [indoors] be incorporated into the modeling i.e. a reduced factor from the residential model to keep this precautionary and to account for instances where soil is tracked	(2) I think this would be fine especially for typical school playing field sports pitches would be good. Though I feel the dog walking scenario would nt provide a benefi as results will be massive.	5 Although it is felt that a C4SL for POS will have to be highly caveated with respect to the land-use scenario employed, the proposed pathways seem reasonable. The most useful POS scenario in my opinion would be the standard area of open grass/playing field type POS, as this is the type of POS I've most often encountered in Part 2A work. This is due to the fact
20	**Use uncertainty modelling (Monte Carlo etc) to inform decisions regarding the level of conservatism within C4SLs derived using a LLTC.**	3. No comment either way.	3. Yes if LLTC are used. Even if not much different from the deterministic calculation, at least you looked at it. If experience shows it is not necessary then it can be cut out. May be pragmatic to do a sensitivity analysis for the 6 substances, make a decision as to its usefulness and report the result using the recommended method. If you keep it in, there may be issues with the software that will need to be issued for general release so that others can run the model. The problem with CLEA was that it would have	Yes 4	3 - No Opinion	(2) I don't see a need for this if some of the above is undertaken. Again in HHRA if levels are causing an issue for the regulator then the risk assessor can provide this type of info to help the regulator appreciate the margins (ie upper and lower tolerances for the specific case.	4 If current uncertainty factors are to be revisited, uncertainty modelling would be useful to detail the level of conservatism.

Suggested Modification							
21	**Use uncertainty modelling (Monte Carlo etc) to derive C4SLs when using a MOE approach.**	3. No comment either way.	3. As Q20, but I am not really qualified to comment.	Yes 4	3 - No Opinion	(2) as above	4
22	**Use qualitative approaches to capture residual unquantified uncertainty within the C4SL derivation process.**	2. Would prefer some quantitative uncertainty modelling	4. Yes, but will people read it?	Yes, this would be useful as long as you clearly explain the process. 4	4 - Agree	(3) Varied approaches can still be used to help regulators through HHRA process & build confidence. Further understanding or clarification around this may help, however if a number of options are chosen from this workshop, then this option remains available for negotiation. How essential will it be for LLTC?	3
23	**Acute exposure scenarios should be considered on a site-specific basis when C4SLs are used in combination with statistical approaches.**	2. Surely acute exposure would need to be considered on a site-specific basis anyhow since the toxicity data the C4SLs would be based on are themselves based on chronic studies.	1. Acute exposure is a whole new ball game. Best to leave it out. Is it feasible given tox. data are all related to low level effects?	Not sure about this.	3 - No Opinion	(3) Not really sure what is meant here. Acute exposure isoften considered for CN and also with H&S & WELs.	4 It is my experience that statistical assessments are often used in the wrong situations and would be especially relevant with acute exposure scenarios.
24	**Additional Suggestion**	We need to be clear on whether the legislation and guidance requires protection of the most sensitive individual or the mean of the population (see Section 4.3 of statutory guidance)	There must be a link to planning because it is fundamental to the SGiRIA documents. So even if it is formally caveated out (as appears to be the case from your presentation) there are two options. Firstly, you put it back in. Secondly, if this is politically or contractually not possible, you proceed as if it were the case, but don't discuss it. Paul Nathanail said you should go about this task with the view that it WILL be adopted by planning and I agree. If you adopt this approach you can focus of Part 2A, but at each stage you		General Comments: Whilst the proposed C4SLs will be of some benefit to regulators to screen out some sites [or specific properties within a site] they will not help in addressing the real issue of defining the boundary between category 2 and category 3. I can only presume from this that the real intent of the C4SL's is to use		
		Should we use "central tendency values" or 90th percentile values for a range of parameters. I don't feel qualified to say which specific ones should be central or at the margins of a range, but anticipate that some will have little effect on the outcome of a calculation, and others will have a lot of effect. We need to have work done to look at the sensitivity of changes and balance decisions on which ones should be changed.	I think you need a better explanation of why the J&E model is OK despite the fact that it over-predicts soil vapour concentrations by 3 orders of magnitude otherwise people will ask why you have left it in.		The selection of the six substances is considered reasonable although naphthalene and asbestos C4SL's would also be very useful.	I have included discussion on central tendency and how it fits with vegetable uptake from a scenario like residential property and gardens. They do not marry together well & I would be inclined to stick with the profile we have.	
		Some questions are about default values. I dislike default values (call it 100%), so I would support values for parameters being based on whatever science exists for the parameter in question.	These are comments sent to me by other SILCs prior to the workshop and are of a general nature. Again, they are the individuals' personal opinions not any SILC policy. A) Health protection is paramount. Any suggestion that the generic basis of the HCVs should be relaxed for soil contamination should be resisted as it would place land contamination on a very different toxicological basis than other environmental exposure routes (eg air quality).		Lead and benzo(a)pyrene as these are the two main contaminants that exceed GAC's on a regular basis when investigating sites under Part 2a.		
		I'd support derivation of C4SLs for public open space.					
		I have a concern regarding the potential cumulative impact of the possible changes being proposed/ discussed. If all of the amendments to the model were adopted, the cumulative effect on these "low risk" screening values would be massive [one of my friends from another Company has estimated that the impact of adopting all the suggested measures would put the C4SL for arsenic up to 3,600mg/kg]. Now I am sure that this would not happen, but it does illustrate that we do need to be careful not to ignore the cumulative effects.	Seems a good list of the usual suspects.				
		SILC members are dissapointed by the very short time allowed for responses to this important issue after the workshop. This does not allow adequate time for our representative to obtain opinions from the other SILCs.					
25	**Six substances have been provisionally selected for review in this project: arsenic, benzene, benzo(a)pyrene, cadmium, hexavalent chromium and lead. Are these substances appropriate for development of the methodology for deriving C4SL? Are there other substances you would prefer to be included in this project? If so, which substitutions would you make?**		BaP and Pb as they are the most common P2A risk drivers. BaP has v low GAC but background is often higher so we need something to give guidance here. Pb has no methodology but needs to be tackled quickly, even if there is still not a full data set. We need something rather than nothing. If you can't come up with something now, no one can, so I think you should give it your best shot.	These are the most important substances to develop the methodology for. I would like to have seen mercury also included in the list.		These are fine, lets focus on resolving these and adding others as & when necessary. Naphthalene would be another good one particularly for vapours.	I think that these substances capture a wide range of contaminants of concern and toxicological modes of action etc. They are also substances which are most likely to come up in Part 2A investigations (with the exception of asbestos, but we are aware that is being dealt with by another body).
26	**Which are the first two substances you would choose for development of the C4SL methodology and why?**			BaP and Lead		**Benzo(a)pyrene:** This happens to be quite ubiquitous in urban environments or areas associated with coal combustion. Second would be lead or arsenic; I would be tempted for **lead** as the old SEGH model is no longer used and we generate low values using CLEA v1.06. Arsenic is fairly readily understood in HHRA & enrichment/depletion in fines & RBA can be applied quite easily.	It would be most useful to choose benzo(a)pyrene as it has always historically had very low assessment criteria, and is a contaminant of concern on a lot of Part 2A sites. It is also a non-threshold contaminant of concern with limited human toxicological data, which would test the methodology well. The other CoC I would choose would be Cr(VI), just because it is very different to benzo(a)pyrene (a metal with a level of acute toxicity to human health) and would make an interesting contrast in developing the methodology. It would also be useful to look at lead, but as the background data surrounding this CoC is different to the other five, it may have to take a different route for the derivation of a C4SL.

Suggested Modification						
1	**Reduce average soil and dust ingestion rates from 100 to 80 mg d^{-1} for residential land-use and 50 to 40 mg d^{-1} for commercial land-use to account for lower exposure in winter months.**	4 As with many of the suggested changes the evidence to support this change should be provided in order to ensure that such changes are robust.	4 - sounds like a logical thing to do. But the figures need to be supported by transparent calculations and justifications.	2 unless studies looking at soil ingestion rates during all four seasons are conducted the assumption to reduced the rate of ingestion is unbacked also if this change is made along with reduction in dermal absorption and period of exposure the model will become very unproductive of some parts of socity. also if the period children are being exposed to soil is being reduced to only cover the 170 days of good weather then the reduction in rate to account for winter months is not nessesary as the reduced period of exposure has already accounted for this	5 If 5 key studies all give approximately the same values even accounting for variability then there must have surely been variability in the weather conditions already factored in. Agreed that if all studies undertaken in the summer in similar weather conditions then might not be representative of a full year in this country.	2 disagree - There is no clear evidence or basis for such a suggestion.
2	**Utilise conservative generic chemical-specific RBA estimates, where feasible and supportable, rather than the current default of 100%.**	2- unless robust generic RBA are available then the default value should remain at 100%. The use of RBA should really only be considered where DQRA is required and site specific data is used.	1- given the variability of RBA, dependent on the site specific contaminants and which bioaccessibility procedure you use, I don't see this as a viable option	1 though the use of RBA is a useful DQRA tool RBA generally varies widly even within a single site. As a LA that uses RBA with arsenic regularly I have seen it vary from 7% to 70% along 1 street as such I feel that this is a better tool used for DQRA assessments that generic criteria	3 If RBA information is available it should be used, dependent on availability	1- Strongly disagree - There are no such reliable estimates available & such a proprosal is not supported by the Environment Agency or the CIEH Professional Practice note on Bioaccessibility.
3	**Halve exposure frequencies for children on allotments to better reflect likely central tendency behaviour.**	3 - evidenced obtained through a user survey at one of our allotment sites identified that children were frequent users. In addition there is the potential for a continued increase in use of allotments by children as the popularity of allotments increases.	2 - I am uncomfortable with the use of central tendency representing "low risk". I would prefer a point that still sits on the conservative side of the fence (as a minimum, the midpoint betweeen the central tendancy and the 95th%ile).	2 what percentage of child population would not be protected by this change	3 Agreed 365 days a year is not representative of children's exposure on allotments	2 disagree - Some children spend significant time on family allotments. There is a growing demand in many communities for acess to allotments as a family venture.
4	**Reduce soil adherence factors in children for residential land-use from 1 to 0.1 mg cm^{-2} to better reflect "central tendency".**		2 - I am uncomfortable with the use of central tendency representing "low risk". I would prefer a point that still sits on the conservative side of the fence (as a minimum, the midpoint betweeen the central tendancy and the 95th%ile).	2 what percentage of child population would not be protected by this change	3 Area of adherence uses % of clothes in this country the central tendency might be more representative	2 disagree - Recent trends in climate change towards increasing rainfall suggests that it is not sensible to reduce adherence factors.
5	**Reduce exposure frequency for dermal contact outdoors for residential land-use from 365 to 170 days per year, to better reflect "central tendency".**	4 - Agree current studies based on US/ European data, which is based on summer months. UK summers can be very wet and thus further reduce. However changes should be based on data perhaps use of days without rainfall etc. in order for change to be robust and supported by wider audience.	2 - Again, I am uncomfortable with the use of central tendancy representing "low risk". I would prefer a point that still sits on the conservative side of the fence (as a minimum, the midpoint betweeen the central tendancy and the 95th%ile). This figure is one that is potentially in constant flux given social trends, and rather than having to constantly revist the model to adjust it, I would prefer a more conservative (and still pragmatic) figure.	2 what percentage of child population would not be protected by this change	3 Probably more representative of exposure, where's the evidence	2. disagree - this would be at at odds with the exposure scenario for soil ingestion which is for 365 days per year.
6	**Update vapour inhalation rates to the mean values recommended in USEPA, 2011.**		4 - I am in favour of using the most up to date data, as long as it is relevant.	3 this appears an appropriate scientifically backed change	4 If the USEPA have updated there values based on presumably good scientific knowledge then there is no reason not to fall in line	No comment.
7	**Depending on the basis of the HCV_{soil}, consider reducing indoor dust loading factors to 50 and 25 ug m^{-3} for residential and commercial land-uses, respectively, to better reflect likely concentration of respirable (PM2.5) particles.**		1 - The PM2.5 fraction of the dust is source dependant. Yes it is currently trendy to consider that the PM2.5 fraction is potentially that fraction that poses the higher risk, but this is chemical specific. I am not comfortable with ignoring the impact of the rest of the respirable fraction. Dust loading of the entire PM10 fraction should be considered, as is the case for our air quality assessments.	5 YesAppears an appropriate scientifically backed change	4 As PM 2.5 are the respirable fraction then the move to PM2.5 from PM10 is more representative and in line with the USEPA.	2 disagree - There seems to be some confusion over this suggestion which does not represent any change.
8	**Consider the use of central tendency estimates of fruit and vegetable ingestion rates rather than 90th percentiles.**	3. not sure this is appropriate given the potential increase of people 'growing their own'.	2 - This is tricky one. Yes one can argue that we don't grow as much fruit and veg as we did during the war, but within the local authority I am approached more and more by community groups wanting to use open spas for produce growing, guerilla gardeners, and given the economic recession more people are moving towards growing their own produce in their gardens. So a change may reflect a "current snapshot" that may not be relevant in the near future.	3 what percentage of population is nolonger protected by this change	4 With the encouragement to eat more fruit and vegetables and grow your own the 90th percentile used is precautionary and in line with fsa guidance	2. disagree - This seems to be at odds with growing trends for more people being interstsed in growing their own produce.
9	**Consider reducing the fraction of homsgrown produce for residential land-use to better reflect likely central tendency behaviour for residents with gardens.**	3. again whilst I can understand the reasoning behind this, need to be careful as more and more people are growing their own. However of the Part2A assessment of residential properties I have been involved with the number of properties where significant F&V was grown was minimal.	2 - same answer as 8.	3 what percentage of population is nolonger protected by this change	3 In light of the recession it may not be wise to adjust this as data used for the basis of the is now old and they not reflect the recession driven changes to grow your own.	2 - disagree see comment for question above.
10	**Use BMD modelling rather than NOAELs and LOAELs to derive toxicological criteria, where possible.**	4, as long as this is supported by wider authoritive bodies BMDL used are robust.	4 - I would agree, but with caution. NOAELs and LOAELs are perhaps more indicative of minimal risk than low risk. However where do we draw the line for what constitutes a BMD indicative of low risk? If a BMDL10 represents minimal risk for benzo(a)pyrene, what constitues low risk? BMDL12, 15, 20? At what point do we start entering the realms of SPOSH? Perhaps ultimately it's a societal or policy decision that needs to dictate this?	2 The use of BMD is a worrying change as what % BMD is appropriate to represent low risk unless a %BMD equivalent to the cat 2/3 boundary is published how do you establish a %BMD that actually represents "low" risk. The use of BMD10% nearly because the 10% response change is outside of the error margin of the Tox data does not mean that it is "LOW" risk and protective of human health	3 It should be made clear what BMD is to be used and why e.g. BMD10 or BMD1S.	2 disagree - This would need to involve a radical change of policy relating to the practice which would require reference to be made to other Government authoritative advisers .
11	**Use chemical-specific adjustment factors (CSAFs), rather than default uncertainty factors, to derive toxicological criteria, where posible.**	4. as per the response to Q10 and the data used to derive CSAF is robust and appropriately reviewed.	4 - I see the logic. Why use a default interspecies UF of 10, if the data supports a factor of 3? But, you need to ensure that the data is robust and appropriate before it can be used. What eligibility criteria will be used for the studies before a CSAF can be considered?	4 where there is sufficent data for this it seems appropriate	4 Agreed provided it is clear the background and source of the data used	1. strongly disagree - This would represent a deviation from current accepted good practice.
12	**Use a higher ELCR than 1 in 100,000 (eg a maximal 1 in 10,000) when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).**	2- think this is a wider policy issue which will need further input and agreement from wider bodies before it could be considered by this project.	1 - I am uncomfortable with a less conservative ELCR for non-threshold carcinogens and feel this should not be hampered with. In theory, exposure from a single molecule can have an effect. Would a 1 in 10,000 ELCR not be more representative of SPOSH than low risk?	2 who defines an acceptable "low" cancer risk	2 Would need to see evidence and proof to use this rather than the ID currently used for non threshold carcinogens.	1. Strongly disagree - This is strictly a policy consideration which must be made by the appropriate authority on behalf of society.
13	**Use lifetime averaging when deriving C4SLs using CLEA, if judged to be appropriate on the basis of the toxicological assessment.**	4. Would tie into other risk assessment approaches, however these needs to be backed by further data, i.e., what is the average time that people live at one property.	3	3 may be appropriate	3 As there are many variables in this it would here to be appropriate and specific to each chemical based on scientific evidence that is clear and proven.	2. disagree - again this would be a significant propsed deviation from current policy and outside the scope of this project.
14	**Use child-specific exposure assumptions to convert media concentrations to toxicological criteria for residential land-use, as appropriate, if lifetime averaging is not employed.**		3 - I don't understand this question.	3 may be appropriate	3 The current method is extra conservative by using adults and converting to child so child specific may be appropriate	
15	**Adopt the term "low level of toxicological concern" (LLTC) to describe toxicological criteria derived for the purposes of developing C4SLs which are "more pragmatic but still strongly precautionary" compared with existing HCVs.**	in principle would agree, however who determines where 'low level' is defined? Therefore again it would appear that a wider policy decision needs to be made elsewhere in order to determine such values.	4 - If the purpose is to derive a low risk figure, then the use of a minimal risk HCV is not appropriate and could lead to confusion, so it's good to make a distinction between the two. However, as stated above, who gets to decide what "low" is? Will you provide a definition for our consideration?	2 I think that a more c4sl specific description would be more appropriate something along the lines of "level of toxicological concern highly unlikely to respresent sposh"	2 There will be some confusion over why there is a LLTC when we have a HCV. Do we need another acronym, if the data used is proven and appropriate why are we just not using more appropriate TOX data and update the SGV's accordingly	2.disagree - This is again a policy decision. The introduction of a second "low level" in addition to the established SGV/GAC values which are recognised as "minimal risk" levels. There is a suggested presumption that the proposed new C4SL values are intended for application to Part 2A action with no implications for planning.
16	**Adopt the wider use of Margin of Exposure (MoE) approaches and recommend target MoEs for each substance.**	4, whilst agreed in using MOE approach consideration of their use should be considered from a wider authoritive bodies.	2 and 4 - The MoE has been used by many agencies such as the EFSA, and in instances where a HCV is not available. But if we have a HCV what then? What criteria will be used to determine when to use the MoE approach? The danger exists of cherry-picking the approach that gives the results that meets the spec of the project, rather than the most appropriate approach. But I have used the MoE approach before, as a line of evidence in establishing a SPOSH level for BaP, so if fully justified, with appropriate margins, it could be acceptable.		3 Dependent on complete characterisation of the substance of concern.	2. disagree - as above this should be subject to a consered policy dcision involving the various government authoritative bodies.
17	**In order to meet the requirement of 4.21(d) of the revised SG, the toxicity criteria used to derive C4SLs should be no less than a "small proportion" (say 10-25%) of chemical-specific background exposure, as estimated via published MDIs.**		3 2 - I am uncomfortable with this still representing "low" risk.		3 TOX is only one criteria used unsure about this.	2. disagree - This approach would tend to produce screening levels which are above what is conceived to be represented by the concept of Category 4 and would lead to significant regional variations.
18	**Exclude the quantitative consideration of background exposure (via MDIs) from the derivation of C4SLs but provide relevant data for information purposes (in the form of ratios of modelled soil-related exposure to estimated total exposure).**		2 - background should not be excluded, as the background exposure contributes towards the overall risk and should not be ignored.	2 due to the liklley use of these values in planning this seems inappropriate	2 MDI is only taken into account for threshold contaminents where background effects are important for non threshold background concentrations they are not used and non soil sources are excluded, this is in line with other protective guidelines. For soils exposure it is best to keep the current use of background concentrations .	2. disagree - as above - it is considered inappropriate to ignore exposure form other media.
19	**Develop C4SLs for public open space, based on exposure via ingestion of soil, dermal contact and inhalation of dusts and vapours outdoors only.**	Whilst in principle such values would be useful, the variety of such spaces and their different uses could make it difficult to define a singular 'PoS'. In addition other pathways such as tracked back soil and dust could be considered depending on proximity of open spaces to properties etc.	2 - I don't think it is appropriate to ignore exposure from soil tracked back into the home. Many people use open space more than their gardens (like dog walkers), and given the variation in human behaviour in taking off shoes (or not), I feel that this pathway should not be left out.	2 the exclusion of tracked back dust injuries more consideration as the majority of public open space in regular use is likely close to residential properties. Public open space which is further away is likely to have been driven to which will also increase the likely hood of soil being brought back to the home	3	2. disagree - There is a need for the developement of a series of" Open Spaces" scenarios but these will need to include consideration of track back soils which will very according to the distance from the residential base.
20	**Use uncertainty modelling (Monte Carlo etc) to inform decisions regarding the level of conservatism within C4SLs derived using a LLTC.**	4, but the software package used to run the modelling needs to be considered. The old CLEA model was notoriously slow due to this function and therefore uncertainty modelling may not be appropriate for and update CLEA in excel.	3	2 this data would only be useful if there is a baseline level of conservatism to compare it to (i.e. a monte carlo assessment of the GAC)	3	With Questions 20 , 21 & 23 there is a need for further information abot the process before any meaning ful comment and opinion can be provided.

Suggested Modification						
21	**Use uncertainty modelling (Monte Carlo etc) to derive C4SLs when using a MOE approach.**			3 2 this data would only be useful if there is a baseline level of conservatism to compare it to (i.e. a monte carlo assessment of the GAC)	3	3 see above.
22	**Use qualitative approaches to capture residual unquantified uncertainty within the C4SL derivation process.**		3 - I'm not sure what this means.	2 this data would only be useful if there is a baseline level of uncertainty to compare it to	3	3 see above
23	**Acute exposure scenarios should be considered on a site-specific basis when C4SLs are used in combination with statistical approaches.**	1 Don't think these values/ model is the appropriate avenue to assess acute exposures and this should be considered as a separate issue.	2 - I was under the impression that CLEA was not appropriate for acute exposure scenarios.	3	2 Acute exposures should be considered	1 strongly disagreee. - any C4SL values need to be calculated using CLEA which is based upon the assessment of chronic exposure. Consideration of temporal acute exposure conditions may lead to underestimation of the risk to the human receptor.
24	**Additional Suggestion**	Have concerns over the use of the C4SL through the development control process and understanding that there were to inform sites that are not likely to be determined under Part 2a.	Comments - What happens if the cumulative impact of all the changes prodices values that are very high, that you know will not widely be accepted? Will you then adjust parameters to bring the levels down? If so, the process becomes less scientific and credible. Even though it is not stated in black and white, the C4SLs will end up being used for Planning Purposes. The consortium should bare this and all the implications in mind. I feal that overall, I was left with an overwhelming uneasiness about the lack of a definition for what constitutes low risk. I feal that this needs to be clearly defined from the start to ensure that all changes work towards a common definition			
		With regards to using central tendency values, whilst it is appreciated that such a move is designed to remove a lot of the conservatism it does run the risk of place vulnerable/ sensitive groups at a higher risk. One consideration could be for the central tendency values to be included as an option to select to enable LA to re calculate specific values depending on site specific conditions.				
		I think more information on the selection of the values to be used needs to be provided perhaps in a draft report of some sort in order that such values can be appropriately considered and judged.				
25	**Six substances have been provisionally selected for review in this project: arsenic, benzene, benzo(a)pyrene, cadmium, hexavalent chromium and lead. Are these substances appropriate for development of the methodology for deriving C4SL? Are there other substances you would prefer to be included in this project? If so, which substitutions would you make?**		Yes, these choices are fine.		Asbestos	
26	**Which are the first two substances you would choose for development of the C4SL methodology and why?**		benzo(a)pyrene and cadmium (1 non-threshold and 1 threshold, so see how the approach will work for the 2 different types).	Benzo(a)pyrene and lead	benzo(a)pyrene and lead - current lack of guidance on lead and widespread occurrence across the country of both.	

Suggested Modification					
1	**Reduce average soil and dust ingestion rates from 100 to 80 mg d^{-1} for residential land-use and 50 to 40 mg d^{-1} for commercial land-use to account for lower exposure in winter months.**	2 disagree. Positive evidence is required to support this type of change. The basis for the selection of the revised values needs to be available to enable robust technical comment on their appropriateness or otherwise. As with some of the other suggestions it is difficult to explore the implications of the changes without the benefit of a sensitivity analysis.	2 disagree. We know of little or no data to support this suggestion. The basis for the selection of any revised values needs to be provided to enable scientific comment on their appropriateness or otherwise. As with many of the other suggestions it is difficult to explore the implications of the changes without an impact assessment.	5 - This is a sensitive approach and do agree with it.	1 This is the wrong adjustment to make to correct for exposure duration. If there is good evidence the exposure duration is 365 * 0.6 then say so. The change to 100 from 150 mg/kg should also be acknowledged and its basis made clear to ensure no double counting is going on. temporal variation in soil ingestion should be accounted for by the exposure frequency
2	**Utilise conservative generic chemical-specific RBA estimates, where feasible and supportable, rather than the current default of 100%.**	1 strongly disagree. Robust generic RBA estimates are not available in published literature. RBA must be measured on a site specific basis to reflect the conditions at that site as the results will be influenced by a range of variables including material type. This approach could significantly under estimate exposure on some sites. In addition the proposed approach is at odds with the Environment Agency view on the use of bioaccessibility estimates in human health risk assessment and the CIEH Professional Practice Note on the review of reports involving the use of bioaccessibility data.	1 strongly disagree. In the first place, RBA requires a site-specific estimation. Whereas this suggestion could have a large impact, in the second place, there is again little literature to support it (and most is not of UK origin) . As the attitude of the Env Agc reflects, there remains much work to be done in the field of BA but until it is done we should remain extremely cautious.	5	1 The data do not exist for most media and substances; temporal variation in soil ingestion should be accounted for by the exposure frequency
3	**Halve exposure frequencies for children on allotments to better reflect likely central tendency behaviour.**	2 disagree. This has the potential to underestimate exposure for children who may spend a significant proportion of their time on allotment sites. The growing trend in allotment use means that children will be spending more time on such sites and indeed some allotment associations have recognised this and provide play areas for children which is likely to further increase exposure frequency.	2 disagree. I note the uncertainty in 'likely' but, clearly, this proposal would leave some children's exposure unrepresented.It is unsatisfactory to have no estimate of how many and to what extent. Moreover, the growing trend in allotment use suggests that children may spend more time on such sitesin the future which is likely to increase exposure.	4	1 the proposal is unclear as to which frequencies should be halved. SR3 Table 3.7 is based on averaging homegrown consumption over a year; 2.5 stats/ week seems reasonable (once during the week and twice over the weekend until the child goes to school); movement to central tendancy behaviour on too parameters will make a reasonable worst case outcome more likely in practice - the combined impact on final C4SL's will require good justification and a transparent display of impact (generic answer to this and related questions). **In any event, if a move to**
4	**Reduce soil adherence factors in children for residential land-use from 1 to 0.1 mg cm^{-2} to better reflect "central tendency".**	2 disagree. In SRthree the soil adherence factor of 1mg cm-2 is considered to be 'reasonably protective of soil conditions throughout the year' and includes a consideration of the difference in adherence factors for dry and wet soils. The proposed value is not considered protective particularly when considering wet soils which are more likely to predominate in the UK.	2 disagree. The soil adherence factor of 1mg cm-2 in SRthree is already considered to be 'reasonably protective of soil conditions throughout the year' and includes consideration of the difference in adherence factors for dry and wet soils. To reduce that factor to 1/10th of its current value is unjustifiable, particularly consideringthat wet soils are, notwithstanding climate change, likely to continue to predominate in the UK.	If based on sound & technical evidence yes - it will further suggest that you decide to use child specific exposure 4	1 which measures of central tendency is being used? SR3 recommends a higher geometric mean at the workshop reference was made to conservative estimates of central tendency but no details were given about what these might be.
5	**Reduce exposure frequency for dermal contact outdoors for residential land-use from 365 to 170 days per year, to better reflect "central tendency".**	2 disagree. Positive evidence is required to support this type of change. Conceptually this proposal seems odd when the exposure frequency for soil ingestion will remains at 365 days/year.	2 disagree.Again, we know of no good evidence to support this proposal which would, in any event, appear inconsistent with preserving the exposure frequency for soil ingestion at 365 days/year.	4 - Yes good idea, but you may investigate seasonal variation effects (winter vs summer) bimodal distribution	1 Bother justification is needed; there is a lot of concern at how little time many children spend outdoors - central tendency of what? If ALL Children, then the mode and median may well be close to no time outdoors; for those children who DO play outdoors (and there is pressure to raise the number of children and the amount of time they spend playing outside) then the 'average' may well be higher than that proposed. The following **Guardian** http://www.guardian.co.uk/lifeandstyle/2010/aug/16/c hildre-nature-outside-play-health and **Daily Mail** lasts
6	**Update vapour inhalation rates to the mean values recommended in USEPA, 2011.**	Unsure of the implications of this proposed and I have not had a chance to go back and look at the USEPA 2011 data. Interested to understand why a mean value is judged appropriate as opposed to higher percentile level - will this be suitably protective for a Claegory 4 screening level given the significance of this exposure pathway for many organic contaminants. Assume that the inhalation rates will be adjusted to reflect UK body weight data.			5 Since it is not clear which US EPA 2011 report is being referred to. Probably should do so providing it is consistent with UK bodyweight/receptors.
7	**Depending on the basis of the HCV_{soil}, consider reducing indoor dust loading factors to 50 and 25 ug m^{-3} for residential and commercial land-uses, respectively, to better reflect likely concentration of respirable (PM2.5) particles.**	2 disagree. The proposed values appear to be incorrect in the question as the representative indoor dust loading factor (SR3 page 102) is 50ug m-3 for residential properties. It is not considered appropriate to discount the potential exposure from PM10. In other fields such as air quality PM10 particulate matter is taken account of in deriving assessment criteria.	2 disagree. It is difficult to understand this proposal when the representative indoor dust loading factor in SR3 is already 50ug m-3 for residential properties. In any event, we do not think it is justifiable to discount the potential exposure from larger particles, at least up to PM10, which are taken into account in other fields such as local air quality management.	5 - Yes would be more appropriate that PM10	1 SR3 is silent on the basis on which the value was chosen; need to unpack the literature cited in SR3 and show why halving the DL is appropriate. BTW Check if the stated values are the wrong way round.
8	**Consider the use of central tendency estimates of fruit and vegetable ingestion rates rather than 90th percentiles.**	2 disagree. There is a growing social trend towards more people growing produce in their gardens and this proposal is at odds with this. It has the potential to under estimate exposure for an increasing number of people. In a Part 2A context this exposure pathway can be addressed more robustly in the DORA.	2 disagree. There is a growing encouragement for people to grow more produce in their gardensand allotments and this proposal runs counter to that with the potential to under estimate exposure for an increasing number of people. If necessary, this hazard can be addressed more realistically in the course of DORA.		1 (2) movement to central tendancy behaviour on too parameters will make a reasonable worst case outcome more likely in practice - the combined impact on final C4SL's will require good justification and a transparent display of impact (generic answer to this and related questions)
9	**Consider reducing the fraction of homsgrown produce for residential land-use to better reflect likely central tendency behaviour for residents with gardens.**	As above	2 disagree. Again, this is against the direction of sustainability policy.		1 Is there any significance that exposure is likely to be LARGER but on fewer occasions? How will this be factored into the exposure estimate and will it be considered when choosing a HCV?
10	**Use BMD modelling rather than NOAELs and LOAELs to derive toxicological criteria, where possible.**	2 disagree. Notwithstanding the reference to BMD in SR2 this is a deviation from the current approach which would need to be considered in a much wider remit . As with any potential changes to the interpretation of toxicological data it is considered necessary to obtain detailed opinions from UK authoritative bodies e.g. committees of the Department of Health and the HPA. It is also of paramount importance that the approach used in assessing risks to human health from land are in line with the approaches used for other media. This proposed approach is linked directly to the definition of 'low risk' which needs a much wider consideration than this research project can offer.	2 disagree. Though SR2 mentions BMD, such a change from the current approach needs to be considered in a much wider context . Along with proposals for any other changes to the interpretation of tox data, we would wantr to see explicitand unconditional support for this approach (which is linked directly to the definition of 'low risk') from UK authoritative bodies e.g. Department of Health and the HPA.	3 - Yes BMD will be more appropriate and if not available back to NOAEL LOAEL	(4) But who is going to do the modelling or will the UK be reliant on the program of USEPA IRIS updates ...
11	**Use chemical-specific adjustment factors (CSAFs), rather than default uncertainty factors, to derive toxicological criteria, where posaible.**	1 strongly disagree. In principle the use of chemical specific adjustment factors may be considered appropriate however it is a significant deviation from the current good practice guidance in SR2 and would require a much more comprehensive review of the potential implications. This proposed approach is linked directly to the definition of 'low risk' which needs a much wider consideration than this research project can offer.	1 strongly disagree.This would represent a significant deviation from the current good practice guidance in SR2 and it needs a much more comprehensive review of the potential implications. This proposed approach too is linked to the definition of 'low risk' which needs a much wider consideration than this research project can offer.		5 Not sure why this is included; it is already an option in SR2 – cf Box 2.4 and other references; SR2 cites COT 2007 and IPCS 2005.
12	**Use a higher ELCR than 1 in 100,000 (eg a maximal 1 in 10,000) when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).**	1 strongly disagree. This proposed approach is also linked to the definition of 'low risk' which should be a judgement made by society not by a research project of this nature. This proposed approach has the potential to move the resulting screening levels out of Category 4. If this approach is considered to still constitute a C4SL it begs the question as to what sort of levels would constitute a significant possibility of significant harm.	1 strongly disagree. This is another proposal with a direct bearing on the definition of 'low risk' which it is not appropriate to be made by a research project of this nature. We do not understand how it would maintain the 'strongly precautionary' nature maintained for C4SLs and it begs the question as to what order of risk its proponents would condone before deciding a significant possibility of significant harm existed.	4 - It will be chemical specific and land use	1 Need to be confident that the estimated ELCR is a cautious one and that other adverse effects do not kick in at the 'higher' doses being proposed. This would reduce the HCV for As by a factor of 4 giving a 'BGV' of 8. In any event a change in ELCR should be a consensual decision across many departments representative of health protection, such a change driven by a group appointed to implement Defra projected cost savings could be viewed with scepticism amongst the general public
13	**Use lifetime averaging when deriving C4SLs using CLEA, if judged to be appropriate on the basis of the toxicological assessment.**	2 disagree. A significant deviation from current UK policy such as this needs much greater consideration by society. As above the approach to assessing risks from land need to be consistent with that for other media. Not sure if this approach is proposed for threshold and non threshold effects?	2 disagree. Such a significant deviation from current UK needs much greater consideration by society. As with other proposals above, this approach to assessing risks from land would also be inconsistent with that for other media.	? Possibly	1 This is a policy decision and was much debated around the time of CLEA2002; a review of that decision would require addressing the concerns raised at the time and showing why they are not valid the ratio of exposure duration to lifetime average is 1 in NL and ca 0.5 in USA; this proposal would change the ratio from 1 to ca 0.1 putting us out of kilter with international practice.
14	**Use child-specific exposure assumptions to convert media concentrations to toxicological criteria for residential land-use, as appropriate, if lifetime averaging is not employed.**	This proposal may be appropriate but I guess appropriateness would be influenced by the assumptions underpinning the derivation of the media concentration		4 - It's a regulators led decision so it has to be based on child specific exp. Assumptions.	unclear question
15	**Adopt the term "low level of toxicological concern" (LLTC) to describe toxicological criteria derived for the purposes of developing C4SLs which are "more pragmatic but still strongly precautionary" compared with existing HCVs.**	2 disagree. Who defines 'low level' - this is considered to be a policy decision rather than the output from a research project. In addition this 2 tier approach will potentially cause widespread confusion among the contaminated land community as it must be recognised that although there is no 'explicit link to planning' many will seek to use these C4SLs in the planning context.	2 disagree. What may be considered a 'low level' is a policy decision which is not appropriate for this research project to make.	4	1 This would compromise the relevance of the C4SL to the NPPF - the test remains safe and suitable for use and departure from the negligible and minimal levels of risk represented by the HCVs would make it difficult for developers to demonstrate the land has met the test. It could also have the effect of making mortgage lenders less willing to land on land which is LOW risk and not necessarily suitable for use. Furthermore introducing an additional term within the DL community which could be mis-interpreted is probably not helpful. The tox data and any
16	**Adopt the wider use of Margin of Exposure (MoE) approaches and recommend target MoEs for each substance.**	2 disagree. As above the recommended target MoEs should be a policy decision. It would be necessary to obtain a view from authoritative bodies e.g. DoH on the use of the MoE approach from assessing risks from land contamination.	2 disagree. As above, the setting of any "recommended target MoEs' is a policy decision which would need the support of the relevant authoritative bodies.	4	2 The MOE is easy to understand but hard to interpret; a clear statement from CLG or COT/CDC would be needed to confirm what MOE meets the test of safe and suitable for use. The words of Table 1 of COC 2012 (http://www.iacoc.org.uk/papers/documents/CC2012 11GWSeconddraft.pdf) need to be unambiguously couched in NPPF terms. Would MOE be developed for a substance or by exposure route? How would mixtures be handled?
17	**In order to meet the requirement of 4.21(d) of the revised SG, the toxicity criteria used to derive C4SLs should be no less than a "small proportion" (say 10-25%) of chemical-specific background exposure, as estimated via published MDIs.**	2 disagree. This proposed approach will push the calculated screening levels out of Category 4. It must be recognised that background exposure to some substances can vary significantly across the country.	2 disagree. This proposal would push the resulting screening levels out of Category 4. It must be recognised that background exposure to some substances can vary significantly across the country.	5 - Yes this is a sound approach	1 This would limit the TDSI to no less than say 0.1 to 0.25 of the TDI; it used to be no less than 0.2 and was changed to no less than 0.5 - this proposal would undo an agreed policy decision taken only a few years ago and REINTRIDUCE conservatism where the RIA expects conservatism to be reduced.
18	**Exclude the quantitative consideration of background exposure (via MDIs) from the derivation of C4SLs but provide relevant data for information purposes (in the form of ratios of modelled soil-related exposure to estimated total exposure).**	2 disagree. As above - this proposed approach will potentially push the calculated screening levels out of Category 4. When assessing exposure it is considered inappropriate to ignore exposure from other media.	2 disagree. As above - this proposed approach would still seem to have the potential to push the calculated screening levels out of Category 4. It is not appropriate to ignore exposure from other media when assessing exposure from land.	4- Yes	1 This would compromise the relevance of the C4SL to the NPPF - the test remains safe and suitable for use and departure from the negligible and minimal levels of risk represented by the HCVs would make it difficult for developers to demonstrate the land passes that test
19	**Develop C4SLs for public open space, based on exposure via ingestion of soil, dermal contact and inhalation of dusts and vapours outdoors only.**	2 disagree. From site specific experience of dealing with public open spaces it is considered that the potential for exposure from track back soils cannot be ignored in the modelling - muddy boots/dogs/pushchairs etc and the proximity of the open space to residential properties are all valid considerations. Any consideration of open spaces needs to be future proofed to reflect changes in their use including increased use of such spaces for community gardening.	2 disagree. We agree that screening values for public open space would be useful, nevertheless, experience suggests that the potential for exposure from 'track back' - from muddy boots/dogs/pushchairs etc - should be included. The proximity of the open space to residential properties needs to be considered too. Such values need 'future proofing' too to reflect changes in their use including increased use of such spaces for community gardening		5 This is a task under the project specfication - not sure what is being asked for here
20	**Use uncertainty modelling (Monte Carlo etc) to inform decisions regarding the level of conservatism within C4SLs derived using a LLTC.**	Notwithstanding previous comments on the consideration of the use of LLTC probabilistic modelling may have a role to play to inform the decision making process however further information would be required before robust technical comment can be provided.	3 neutral. Though this suggestion would seem to run counter to the various suggestions to reduce considerations of distribution in favour of 'central tendencies'.	5 - especially to demonstrate which parameters influenced CSSL values and will help to inform decisions	1 This is too vague a statement to comment on; the presentations at the workshop were too cursory to allow detailed consideration of this; the continued refusal by CLAIRE to countenance a stochastic model (cf the outcome of the CLAIRE facilitated Way Forward workshops) is suprising given the continued use of probabilistic models such as CONSIM, GASSIM and LANDSIM and the demonstration by LQM of a stochastic version of CLEA - termed P-CLEA - in the work for deriving coking works assessment criteria.

Suggested Modification					
21	**Use uncertainty modelling (Monte Carlo etc) to derive C4SLs when using a MOE approach.**	Notwithstanding previous comments on the consideration of the MoE approach probabilistic modelling may have a role to play to inform the decision making process however further information would be required before robust technical comment can be provided.	3 As above.	4	4 This is too vague a statement to comment on: the presentations at the workshop were too cursory to allow detailed consideration of this; the continued refusal by CLAIRE to countenance a stochastic model (cf the outcome of the CLAIRE facilitated Way Forward workshops) is suprising given the continued use of probabilistic models such as CONSIM, GASSIM and LANDSIM and the demonstration by LQM of a stochastic version of CLEA - termed P-CLEA - in the work for deriving coking works assessment criteria.
22	**Use qualitative approaches to capture residual unquantified uncertainty within the C4SL derivation process.**	2 disagree. I am a little unclear as to what is actually being proposed. Will there be a robust basis for these qualitative approaches? Will the approaches vary for each contaminant? Professional judgement will always be required in risk assessment to deal with issues such as residual uncertainty however it is influenced by the assessor's knowledge of the site and many lines of evidence will help inform robust udgement and I am unsure as to how this can be done on a more generic basis by the use of qualitative approaches.		4 - Well, what will be the other options?	1 the text is too vague to comment on - what unquantified uncertainty is being considered and what sort of qualitative approaches are being suggested? How will the use of such approaches NOT be misused as a means of hiding epistemic or even aleatory uncertainty and thereby generate higher C4SLs that would not be scientifically valid - a key test in the stat guidance.
23	**Acute exposure scenarios should be considered on a site-specific basis when C4SLs are used in combination with statistical approaches.**	1 strongly disagree. The C4SLs will be calculated using CLEA which is based on the assessment of chronic exposure and the use of these in assessing acute exposure has the potential to significantly underestimate the risk to the receptor.	1 strongly disagree. The C4SLs will be calculated using CLEA which is based on the assessment of chronic exposure and the use of these in assessing acute exposure has the potential to significantly underestimate the risk to the receptor.	Not sure that you need the acute exp. Scenario there as you want to define criteria level for category 4	1 It is not clear what statistical approaches are being considered, acute exposure scenarios are already considered and quantitative tools were demonstrated by SNIFFER (2005) for cyanide; the approach is valid for other substances too
24	**Additional Suggestion**	General Comments: It is considered that the proposed C4SLs are not required by the regulatory community and will not help in addressing the real issue of defining the boundary between category 2 and category 3.	As we have made clear to Defra,we see no need for the proposed C4SLs by the regulatory community and they offer no help in addressing the real issue of defining the boundary between category 2 and category 3. It is ironic that so much attention is apparently being given to toxicology in the suggestions above when so little is now given to it in the more crucial context of determinations and it remains disingenuous to deny that the principal use of the values will be as remediation targets. As for the process so far, though we know that the contract has tight time limits, we cannot accept that setting such a short time to respond to these proposals is helpful or is likely to lead to the most considered comments. Applies across to the	It seems there are some confusions on the need of C4SL - as in the contect of Part 2A, they won't be relevant. Need possibly to look at category 3.	
		This project must recognise the potential for the use of these screening levels in planning and development. Although it was stated during the workshop that there is no explicit link to planning the projected cost savings cannot be made through Part 2A which is recognised in the Impact Assessment. The potential for misuse in the planning regime and the implications of this must be recognised during the development of the C4SLs.			
		It is difficult to consider the proposals and the associated implications without the benefit of a comprehensive sensitivity analysis.			
		A move towards the selection of central tendancy values has the potential to ignore exposure of some individuals which is not considered to in line with the precautionary approach'. The Statutory Guidance allows local authorities to use their discretion and this type of consideration should not be prescribed by a research project.			
		A number of the proposals have the potential to raise the screening levels out of Category 4 and would raise serious questions around the levels which would constitute SPOSH.			
25	**Six substances have been provisionally selected for review in this project: arsenic, benzene, benzo(a)pyrene, cadmium, hexavalent chromium and lead. Are these substances appropriate for development of the methodology for deriving C4SL? Are there other substances you would prefer to be included in this project? If so, which substitutions would you make?**	The selection of the six substances is considered reasonable.		Yes a good start would be good to provide some guidance on how the approach can be used for mixture in the future.	guidance on mixtures (eg petroleum hydrocarbons) is needed
26	**Which are the first two substances you would choose for development of the C4SL methodology and why?**	Lead and Benzo(a)pyrene	BaP and Pb	BaP Risk driver & Pb	BaP and lead

Defra Research Project SP1010

Development of Category 4 Screening Levels
Stakeholder Workshop 2

STAKEHOLDER WORKSHOP 2 FEEDBACK

Introduction

As part of Defra Research Project SP1010 – Development of Category 4 Screening Levels (C4SLs), there was a requirement to hold three stakeholder workshops. This is a summary of the results from Stakeholder Workshop 2.

Stakeholders attending the workshop were given a series of presentations summarising the draft Work Package 2 report that had recently been submitted to Defra on the development of interim C4SLs and the proposed methodology for Cadmium and Benzo (a) Pyrene as a surrogate marker for geotoxic PAHs.

The presentations at the workshop covered the following subjects:

- Introduction and Background to the Project
- Outline of the Proposed Methodology
- Key Issues for Stakeholder Input
- Application of the Proposed Methodology to Cadmium
- Application of the Proposed Methodology to BaP
- Public Open Space (POS)
- Statistical Considerations in the Use of C4SLs

After the presentations, the stakeholders were divided into three groups and given the opportunity to ask questions and provide comments / feedback. The following section provides a transcript of the flip-chart notes that were made by the presenters during the feedback sessions, although it is inevitably subject to error. Separate appendices provide a copy of the questionnaire that stakeholders were also requested to complete (Appendix 1) and a summary of their responses to the questions (Appendix 2).

VERBAL FEEDBACK CAPTURED

TOXICOLOGY

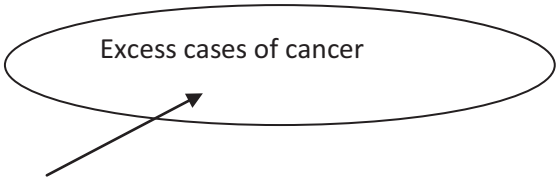
GROUP 1

BaP BMD/BMDL? Which?

Only use 1 worse case!

Is it uncertainty or conservatism.

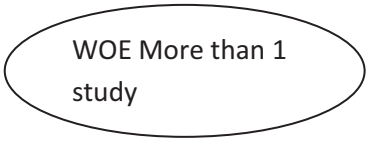
Linear dose-response assumptions.



Extra

Mustn't cause x number of cases etc……

10^{-6} – nuclear risks cases per year. (deaths PUBLIC)



Inter 5

Intra 10

Mouse data

Adequacy of Study – 2

Severity – 50

Why for cancer? Is this 50 just for this?

Cadmium

B2M Biomarker of effect

300 µg/g creatinine reversible

1000 µg/g creatinine irreversible

Conservative modelling

GROUP 2

NO AGGREEMENT ON WHAT CONSTITUTES LOW

CoC Approval would give credibility

GROUP 3

Flow diagram might not necessarily by followed – simple summary needed.

Maybe keep same response (BMR) the same as for “minimal risk” but change to BMD (depends on database/quality etc)

Process needs to be widely applicable and not require lots of chemical specific deliberations etc

Basis for 1 in 10,000 ELCR for BaP in air.

Simplified C4SL approach needed.

Can Defra publish periodic literature reviews?

Canadian CCME approach re. coal tar (ref.Ed)

Surrogate marker approach?

CSAF – just pick a number?

MOE calculation for background (NBC)

EXPOSURE MODELLING INCLUDING POS

1. PAH – physical parameter variability – New Zealand studies (Barry Mitchison to forward paper)

2. Q > soil parameter assumptions? Particle Size Distribution etc
   - Fractions/fines – paper from Paul Nathaniel sent to Alex early 2013

3. Should we seek to define the % population that exceed LLTC? – Question for Defra? Can we treat LLTC as PDF?

4. Metals & pH?

5. J&E vapour model

   - Is this the best choice? > source degradation should probably be incorporated.

6. Q> will we publish the Monte Carlo modelling spreadsheets?

7. Q> Are all referenced data available? (e.g. EA unpublished)

8. CLEA produce concs should be compared to FSA Maximum Permissible Levels (MPLs) – e.g. “Could Tesco sell this potato” grown in soil at the C4SL

9. Multiple Source Exposure (Parks + Home)

10. Q> Can we usefully characterise POS? Too much variability in the land uses that this covers?

11. Respiration rate for POS1 (Active/Passive)

12. Sensitivity Analysis – Include **ALL** Exposure Adjustments??? (Final Report???)

13. Discuss probably precautionary nature of final outputs from this project

14. Importance of POS

15. Further study is required on use of POS (MSc or PhD)

16. RBA for Pb & As UK Soils (M Cave)

17. ?? Tracking Back – Does all POS have trackback?

18. ~ 2 hours reasonable

19. Importance of consistency & training

20. Concern about objectivity & reproducibility of LLTC derivation.
    (should be centralised initiative on TOX)

21. Need for policy decision on whether C4SLs ‘suitable for use’ (i.e. for planning) ?

22. Should we keep SGVs?

SETTING C4SLs (Yellow Group)

- What is appropriately precautionary?
  - Policy decision – who will take?
  - Not gov? passed responsibility to LAs.

- Suitable for planning?

  Yes-5

  No – 1 (unethical)

- Concern re. stats proposals
  - Need for opportunity to review

Question 10

- Are we saying P>LLTC=30% is acceptable?
  - Remember need to consider conservatism of LLTC and use of upper 95% ile for soil conc.
  - In the report – YES
  - In individual cases – only where substantial reason to do
  - Decisions need to consider at risk groups e.g. allotment holders

Question 11

- Is it an issue for further steps? (rather than setting C4SL)
- Useful context/transparency
- Better to drop residents + vegetables and use allotment C4SL instead?

Question 12

Policy Number – but basis needs to be reviewed

- Water standards
- Background (?) (true/natural?) – useful context but should not change C4SL
- Biomonitoring
- Cost of remediation

SETTING C4SLs (Red Group)

- Any formal mechanism for incorporating background concs? Needs to be included in process.
- Any recommendations on considering bioavailability?
- How do you cope with the high vegetable eaters when plant uptake is important?
- Not OK for allotment but OK for home + garden?

Question 10

- P exceedence LLTC.
- Extent to which LLTC is exceeded.
- Why bother with P modelling?

Question 11

- Qual. Uncertain
  - How do you combine
  - How can you assess LLTC when level of risk is not set?
  - How will it be used to set C4SL?
  - How will it be done by others?
  - Won't work under planning.

Question 12

- Other considerations
  - Useful information – no more
  - Socio/economic?
  - How much data is needed to exit C4 – poss who doing a DQRA

Question 15

Useful

Add in background.

Relationship between concentration and particle size.

APPENDIX 1 – QUESTIONNAIRE

C4SL STAKEHOLDER WORKSHOP 2 – QUESTIONS ON DERIVATION OF C4SL FOR BAP AND CADMIUM

NAME: ……

COMPANY/ORGANISATION REPRESENTING:……

Please state to what extent you agree with the following, on a 5 point scale: strongly agree (5), agree (4), no opinion (3), disagree (2), strongly disagree (1). If you disagree please can you give your reasons.

	QUESTION		Score (1 – 5)	Reasoning
1	The point of departure from which to derive the $LLTC_{oral}$ for BaP being a BMD or BMDL and the benchmark response of 10, 15 or 20% being used.	Use of BMD; or use of BMDL		
		Use of BMR 10%; or Use of BMR 15%; or Use of BMR 20%		
2	A chemical specific margin of 5000 being used to derive the $LLTC_{oral}$ for BaP?			
3	The $LLTC_{inhal}$ of 0.3 ng kg^{-1} bw day^{-1} for BaP being based on a policy basis on the UK Air Quality Standards Regulation (ELCR = 1 in 10000) ?			
4	Based upon the description of the toxicology, the choice of $LLTC_{oral}$ (0.54 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?			
5	Based upon the description of the toxicology, the choice of $LLTC_{inhal}$ (0.00286 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?			
6	The proposed modifications to deterministic exposure parameters for deriving C4SL?			
7	The choice of exposure scenarios for public open space (i.e. public open space next to residential properties [POS1] and parks [POS2] ?			
8	The choice of exposure parameters for POS scenario 1?			
9	The choice of exposure parameters for POS scenario 2?			
10	The use of probabilistic modelling as a line of evidence in setting of the C4SL?			
11	The use of the qualitative evaluation of uncertainty as a line of evidence in setting of the C4SL?			
12	The inclusion of 'other considerations' as lines of evidence in setting of the C4SL?			
13	The proposed C4SL meet the policy objectives?			
14	The proposed C4SL are they sufficiently precautionary?			
15	The proposed C4SL will be useful for assessing risks from land contamination under the Part 2A regime or otherwise ?			

ADDITIONAL COMMENTS

APPENDIX 2 – SUMMARY RESULTS OF THE QUESTIONNAIRE

1	The point of departure from which to derive the LLTC$_{ind}$ for BaP being a BMD or BMDL and the benchmark response of 10, 15 or 20% being used.	Use of BMD	3	Whichever value is chosen it should be clearly stated. As we are dealing with a genotoxic carcinogen and higher or lower CSAFs, this becomes another factor in the judgement.	3	Depends largely on the difference between the BMD and the BMDL and the intra + inter species adjustment used	3		1	BMD is the dose of increased incidence & therefore offers insufficient precaution for use to derive C4SLs	1	
		Use of BMDL or use of BMDL	5	One application of conservatism for the PoD is sensible provided that the exposure scenarios are best estimate rather than adding to unreality by applying multiple worst cases.	3	see above	4	The level of uncertainty in the data should be accounted for RF	4	Use of confidence limits offers greater degree of confidence that the benchmark response is not exceeded within a stated confidence level & therefore better reflects the stated purpose of C4SLs	5	
		Use of BMR 10%; or	5		4		4		4	It is considered appropriate to use the most precautionary option being proposed & takes on board the toxicological assurances of its validity for use given by the presentors on the day. (ii) Acceptance for Cadmium is understood to be based on the revisible adverse effects level so considered appropriate for stated purpose of C4SLs. (i.e. it offers a better degree of precaution)	4	
		Use of BMR 15%; or	2		2		4	If it can be shown that BMR of 15% gives a value that can be considered a 'minimal risk' RF	2	Not precautionary enough	2	
		Use of BMR 20%	1		2		1		1	Not precautionary enough (i.e. allows 20% increased incidence of a response occuring). This is not considered a LLTC rather a HLTC)	2	
2	A chemical specific margin of 5000 being used to derive the LLTC$_{ind}$ for BaP?		4	The justification for the choice must be given.	4	figures presented seem reasonable	4	The inter specieas difference needs looking at more closely, just halving the value has little basis as far as I understand. RF	4	Although it is felt that the selected MOE is quite subjective, it was felt that the value being proposed was adequately justified by the presenters. However it is felt that the Committee of Carcinogenicity should be consulted to ensure that the value selected is 'endorsed' or 'justifiable' within the wider 'expert' community, particularly given the importance of this parameter is deriving the proposed HCV.	1	1
3	The LLTC$_{ind}$ of 0.3 ng kg^{-1} bw day^{-1} for BaP being based on a policy basis on the UK Air Quality Standards Regulation (ELCR = 1 in 10000) ?		4	Note the definition used to develop the air quality standard - is it a pure health based limit or is it an interim limit as the purely health based limit is technically unfeasable. A certain amount of pragmatism is inevitable as the two standards should not be grossly out of line with one another.	4	in keeping with agss for arsenic and benzene	4	This is a practical solution but it needs to be investigated if the UK air quality standards represent a 'low risk' as is required by C4 numbers. Its possible this value will change with policy over time so care is required RF in adopting this approach. RF	4	This proposal aligns with the UK AQS. As such it makes sense politically & would be justifiable in the eyes of the general public (i.e. easy to communicate)	4	
4	Based upon the description of the toxicology, the choice of LLTC$_{ind}$ (0.54 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		4	Once we talk pragmatism there is room for judgement - an inevitability when dealing with toxicological risk assessments	2		4	This seems likely RF	4	Assume this question relates to Cadmium? Acceptance primarily based on the assurances of the presenting toxicologists & the justifications provided to its appropriateness in terms of use to derive C4SLs	5	
5	Based upon the description of the toxicology, the choice of LLTC$_{ind}$ (0.00286 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		4				4	This seems likely RF	4	Assume this question relates to Cadmium? Acceptance primarily based on the assurances of the presenting toxicologists & the justifications provided to its appropriateness in terms of use to derive C4SLs	5	
6	The proposed modifications to deterministic exposure parameters for deriving C4SL?		4	OK			3		2	Cadmium - It is felt that the use of central tendency estimates for fruit & vegetable uptakes rather than 95%ile values is unlikely to be adequately protective. The research presenters admit that there is a large variability/uncertainty in population tendency with respect to the amount of consumption of home grown produce (i.e. a proportion of the population are more radical & eat a lot of home grown produce; conversely a large proportion of population hardly eat any home grown produce). The resultant affect being that there could be a high probability that certain sectors of the general population (around 30 %?) could plausibly receive exposure from cadmium over the suggested LLTC. This is not considered appropriate for a C4SL. Additionally, it is considered that this issue becomes particularly relevant in the current 'difficult' economic climate. When food prices rise & wages remain static; a greater proportion of the population are more likely to attempt (or increase) tendency towards home grown produce in an attempt to reduce/control expenditure.	5	
7	For POS 1, please could you indicate your preference for developing this scenario from the 3 options presented:	1) Adoption of "Residential without consumption of homegrown consumption" CLEA scenario (i.e. using Age Classes 1-6 for critical receptor)?	4	Most people do not grow food plants in their garden - those that do tend to grow only part of their food supply.	2	Overly protective exposure model assumptions not likely to be reasonable for land use though would be protective	3	This seasm a sensible way forward for the small areas of POS near houses,. Based on the available data for usage it appears sensible. More research on how areas of POS are used would be useful to refine this scenario RF	4	Seems reasonable	1	1
		2) Use of 'Residential without consumption of homegrown consumption' scenario (AC 1-6) with adjusted soil ingestion rate?			3	as above	2	Based on the available information option 3 appears a better fit. RF	2	Less reasonable?	4	
		3) Use of Option 2 with consideration of older children (AC 4-9)?			3	as above	4	From the available info it does appear that older childrenn should be the focus as the proposed scenario seems ok. RF	3	Option 1 seems more reasonable particularly in deprived areas where children may be more likely to be unsupervised. Currently uncomfortable on how the "supervision" element is relevant, with grassed areas close to housing. Younger children just as likely to use grassed areas near housing as older children, to be within view of home.	4	
8	The choice of exposure parameters for POS scenario 1?				4	assumptions seem reasonable	4	The parameters seem to be appropriate and likely suitably protective RF	4			
9	The choice of exposure parameters for POS scenario 2?				4	on the whole assumptions seem reasonable though for substances where dust inhalation is a key driver the exclusion of track back dust may mean it is not sufficiently protective	3	I am not convinced that tracked back dust should be totally excluded, some of these areas could be close to homes. RF	2	Not sure about fully excluding tracking back of dust		
10	The use of probabilistic modelling as a line of evidence in setting of the C4SL?		4	I think this is important	4	seems a reasonable method for calculating appropriate exposure parameters for future deterministic modelling	4	This seems like a sensible and pragmatic approach to adopt for numbers that are 'a low risk' level RF	5	This is considered extremely useful & welcomed.	5	
11	The use of the qualitative evaluation of uncertainty as a line of evidence in setting of the C4SL?		3	It is probably as far as it is worthwhile doing.	4	detailed assessment of uncertainty within the exposure model is useful for assessing where less consevative assumptions can be made	3		5	This is considered extremely useful & welcomed.	3	
12	The inclusion of 'other considerations' as lines of evidence in setting of the C4SL?		4	The general catch-all phrase is inevitable - but when used the reasons should be carefully stated		as a generic screening assessment the potential costs of remediation / further investigation should not be considered	5	This is an important addition but would only be suitable for experienced risk assessors. To take account of social economic factors could be difficult. In order to be able to make judgements for these 'other considerations' the assessor would need to understand what is ment by the term 'low risk' in the context of the C4SL numbers, currently this is not defined. RF	2	Whilst other considerations such as background level data etc are considered useful when considering risks on a site specific basis it is considered inappropriate for the purpose of this research project for justifying C4SL (C4SLs are supposed to be generic in nature)		
13	The proposed C4SL meet the policy objectives?		5	It is as good as can be expected - given that judgements are required and therefore	3		3	The policy objective is unclear, what is 'low risk'? RF	4	The range of values suggested for BaP seem reasonable. There is however more concern regarding values suggested for Cadmium	4	
14	The proposed C4SL are they sufficiently precautionary?		4	Precaution implies consistent with the precautionary principle, which is chiefly aimed at unknown unknowns (toxicities we do not know about). I prefer the word conservative as we are only capable of assessming for knowns and the judgements are concerning known effects where there is less than fully understood translation from the information available to the human situation.	3		3	Low risk' has to be defined (probably at a policy level) to then define if the values being produce meet that criteria and are therefore sufficently precautionary RF	3	Discussed in other sections	4	
15	The proposed C4SL will be useful for assessing risks from land contamination under the Part 2A regime or otherwise ?		4	Yes, but there may be a need for toxicological expertise to be available to both local authorities (as regulator) and the submitter of the plans.	4		2	The C4SL will provide benefit in assessing Part 2A land but will only allow land to be defined as 'not Part IIA' rather than allowing land to be defined as Part 2A. If C4SL numbers are to be used for planning purposes then a clear understanding of what 'low risk' is and an agreement that such a level of risk is accepable over 'minimal risk' as per the current SGVs is required. RF	3	It is felt that regulatory authorities would never designate P2A at a C4SL, although they will now allow sites to be eliminated from further enquiry at more pragmatic levels & therefore useful. However it seems likely that these values will be more frequently used by developers/consultants to satisfy requirements under the planning regime (or for use as remedial targets) in that C4SL are defined as levels of contamination at which risks are likely to be negligible or minimal. Whilst it is understood that C4SL represent low levels of toxicological concern they also represent risk levels which should not enable the site to be defined 'Contaminated Land', which is the minimal requirement under NPPF. The project team therefore needs to be mindful of this potential application when deriving C4SLs.	4	
16	When using C4SLs in a risk assessment, should a statistical approach be applied which involves the comparison of the 95% upper confidence limit of the arithmetic mean of the measured soil concentrations with the C4SL?		3	Beware multiple applications of conservatism. If the toxicology is assessed conservatively and the exposure assessed conservatively (i.e. both using 95% confidence limits) this should be sufficient conservativeness. (0.05 x 0.05 gives 0.0025 - i.e a one in 250 probability of a problem). In reality the CSAFs will make this even more conservative.	3	this depends largely on the size of the assessment area, the number of samples and the appropriateness of the averaging area. This is a decision to be made by the risk assessor and would be inappropriate for this study to make the assertion	4	This statistical approach appeared to be suitably robust. RF	4	Yes - unless data is targeted	3	
ADDITIONAL COMMENTS						DCLG needs to state whether the low risk level of C4SLs is inline with the Suitable for use criteria of paragraph 120 of the NPPF				i) It is felt that the Research Document findings need to be relayed to the wider contaminated land community via consultative workshops. Training is crucial to relay the report findings & to ensure that practitioners understand how & when to use & apply the document. EPUK would welcome the opportunity to host/assist in such workshops for our members. Feel free to contact David Rudland (DRudland@swindon.gov.uk) if this is of inteest.		
										ii) Whilst not strictly forming part of this project remit; it is considered important that the project team (& more importantly that the report dialogue) includes clear reminders of the purpose of the C4SLs. In particular that the C4SLs solely consider risks to Human Health & that users of the report findings may need to consider wider issues; such as aesthetics; waste management & risks to controlled waters etc when determining the appropriateness of using the C4SLs.		

1	The point of departure from which to derive the $LLTC_{soil}$ for BaP being a BMD or BMDL and the benchmark response of 10, 15 or 20% being used.	Use of BMD	Using BMDL for the C4SL leaves us with the ability to look at BMD in a DQRA. However, I don't mind which we use so long as it is scientifically robust, we're transparent in what is used and the alternatives available. Also see answer 2	4	Favour BMD as more central tendency			2	In my opinion, the setting of the POD for a low risk should be a policy decision made by DEFRA. But personally, I would tend towards the more conservative end of the scale.	1	Would not consider to be protective enough for C4S
		Use of BMDL or use of BMDL	To give us 95% confidence the BMD is not exceeded which I think is important when considering a population and a carcinogenic substance	3	10 or 15%		Can't comment. Don't have enough expertise in toxicology	4		4	Would consider this to be more appropriate than BMD
		Use of BMR 10%; or	This is typically used and thus most likely to result in acceptance by other regulatory bodies	3				4		4	Would consider this to be appropriate
		Use of BMR 15%; or	I'm concerned that selecting 15 or 20% may not be considered scientific	3				4		4	Would not consider to be protective enough for C4S
		Use of BMR 20%	I'm concerned that selecting 15 or 20% may not be considered scientific	2				2		1	As above
2	A chemical specific margin of 5000 being used to derive the $LLTC_{soil}$ for BaP?		Specifically, I diagree with the 'nature and severity of effect' value. I think if we stick with recognised BMDL10 approach but reduce the uncertainty factors owing to the quality in the dataset and that the data suggests humans are not 10 times more sensitive than mice this would be appropriate rather than arbitrarily selecting 50 for nature and severity of effect. Alternatively, as reducing the 10,000 to 100 doesn't sit comfortably with me either then we use the BMD with 10% response and keep the chemical specific margin of 5000.	4	Provided logic is sound and supported by evidence. Simply taking a lumped value of 500 would be a policy decision and how would this be justified?		Can't comment. Don't have enough expertise in toxicology	4	I am in agreement with the derivation but different toxicologists will have different thoughts on this, especially as we are considering a low risk rather than a minimal risk.	4	Would consider appropriate but would be suggest that the Committee of Carcinogenicity is consulted for their comments
3	The $LLTC_{soil}$ of 0.3 ng kg^{-1} bw day^{-1} for BaP being based on a policy basis on the UK Air Quality Standards Regulation (ELCR = 1 in 10000) ?		Agree there is little to be gained from setting an HCV below a UK air quality standard	3	I am not qualified to give an answer, but cannot see anything wrong in this.	2	This is a complete change in approach and whilst the reasoning has been presented it is not really a justification. This approach would be like the Environment Agency allowing contaminated discharges into contaminated watercourses. They take the approach that one should assume things will get better and therefore the fact that the watercourse is contaminated should not be reason for allowing a more lax standard for discharges.	4		4	Would consider this to be appropriate and defendable as it does have a policy basis
4	Based upon the description of the toxicology, the choice of $LLTC_{soil}$ (0.54 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		On the basis there is little point in setting a HCV below that to which people are exposed to through food and is within the range of HCV internationally	3	I am not qualified to give an answer, but cannot see anything wrong in this.		Can't comment. I don't have a clear understanding of LLTC as there seemed to be some variation during the presentations	4	Is this for Cd now? If so, I am agreement with the methodology proposed.	4	Providing the toxicologist are happy (cadmium?)
5	Based upon the description of the toxicology, the choice of $LLTC_{soil}$ (0.00286 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		On the basis there is little point in setting a HCV below that to which people are exposed to through air and represents ELCR of 1 60,000	3	I am not qualified to give an answer, but cannot see anything wrong in this.		Can't comment. I don't have a clear understanding of LLTC as there seemed to be some variation during the presentations	4		4	As above (cadmium?)
6	The proposed modifications to deterministic exposure parameters for deriving C4SL?		These are logical and also reflect more recent US guidance where appropriate	4		4		5	Obviously these changes were made on the basis of comments from the last workshop.	2	Some concern that there is a probability that a percentage of the population (30 %?) are at risk from exposure from cadmium over the suggested LLTC. Would not consider this appropriate as a generic C4S.
7	For POS 1, please could you indicate your preference for developing this scenario from the 3 options presented:	1) Adoption of "Residential without consumption of homegrown consumption" CLEA scenario (i.e. using Age Classes 1-6 for critical receptor)?	I consider it unlikely that a conceptual model for public open space area would be consistent with a private garden (albeit without the homegrown produce pathway). However, exposure parameters are likely to be very site specific to consider proximity of residential propertiesand whether attractions such as a playground are present.	3						4	NHBC would consider this to be appropriate
		2) Use of 'Residential without consumption of homegrown consumption' scenario (AC 1-6) with adjusted soil ingestion rate?	I consider amending the soil ingestion rate is appropriate since children will not only be exposed to soil at this site and are unlikely to spend their whole time outdoors on one area of public open space.	3		3		X	This option appears to be sensible. Although you would doubt that parents would let very young children play on a POS like this, you never know!	2	Not comfortable with this
		3) Use of Option 2 with consideration of older children (AC 4-9)?	I think this very much comes down to site specific use and actually think it would be helpful to demonstrate the sensitivity of the modelling by including this in addition to option 2.	5	Tends to be older children who play out.	5				4	Would consider this to be more appropriate
8	The choice of exposure parameters for POS scenario 1?		With both this and scenario 2 I think we need to be very careful that the exposure parameters are reflective of people using open space across the UK since this varies widely. Do the studies reviewed include the range of responses and could that be made transparent in the accompanying report?	4		3		5	See above comments	4	Agree
9	The choice of exposure parameters for POS scenario 2?		See answer to 8	4		3		4	All of the exposure parameters appear to be well justified	4	Agree
10	The use of probabilistic modelling as a line of evidence in setting of the C4SL?		I think this is a very useful tool in understanding the model sensitivity and the effect on populations. This has particular value when looking at the potential magnitude of exceedance of average daily exposure, i.e. 20% of the population may be exposed but they will only be exposed to a small versus 10x exceedance.	5	Good checks & balances approach without having to use probabilistic methodology in all future calculations, such as DQRA	5		4		4	Agree
11	The use of the qualitative evaluation of uncertainty as a line of evidence in setting of the C4SL?		I think this is also a helpful aid	5	Good checks & balances approach without having to use probabilistic methodology in all future calculations, such as DQRA	5		4	It is a good line of evidence but again, a bit of this will depend on the toxicologist undertaking the work and their justifications.	4	Agree
12	The inclusion of 'other considerations' as lines of evidence in setting of the C4SL?			5	Adds to transparency, which is vital as there is clearly no unambiguous methodology and there will always be a judgement call.	5		5	Useful as a comparison but the results of these considerations may not prompt any revisiting of previous stages.	2	NHBC Would not consider it appropriate if refreance is made to natural background levels
13	The proposed C4SL meet the policy objectives?		Agree they should help screen sites out of Part 2A. I think the accompanying report should be very clear in what the numbers are seeking to achieve so that an exceedance of these isn't taken as Part 2A (hopefully this wouldn't occur now the statutory guidance clear but I still think it would be worth re-iterating this and making the assumptions and decision making clear	4	Will do if you provide greater than minimum risk values and are more realistic whilst still protective. The devil is in the detail eg the checks mentioned in Qs 10-12 above.	3	Yes if they are for Part 2A only	4	Depends which you end up using! There should be a consensus what low risk is (DEFRA?), and there should be room for further DQRA.	4	The BaP C4S numbers seem reasonable. Some possible concern over Cadmium. Wa do not number
14	The proposed C4SL are they sufficiently precautionary?		I believe they remain conservative and thus can be applicable to individual sites. The potential exception to this is open space as I feel this is very specific to the land in question	4	Probably yes, but who decides what percentage can be allowed to exceed, especially v10 LLTC? There is a balance. If too precautionary you get left with GAC so there must be some higher risk by definition.	3	Yes if they are for Part 2A only	5	As said above, this really needs to be a policy decision made by DEFRA	4	Yes for Part 2A and would accept for Human health under planning providing the wider aspects are consider such as visual and odour impacts
15	The proposed C4SL will be useful for assessing risks from land contamination under the Part 2A regime or otherwise ?		Agree they will result in more balanced assessment of land contamination and promote understanding of the inputs to the C4SL which can only lead to more informed decision making	4	If sufficiently greater than GAC whilst still remaining protective, it will screen out some sites where otherwise there is uncertainty as GACs are so low re Part 2A. It will only be any good if the methodology can be followed by others to derive C4SLs for other substances. Look what happened to SGVs and GACs. DEFRA should be encouraged to fund more C4SLs or, at least, fund the derivation of LLTCs for other substances.	5	They will be a useful less conservative set of values than SGVs/current GACs	4	They would be useful under P2A but there needs to be a decision made on whether they will be allowed under the planning regime too. There is a difference of opinion on this matter in the con land community and it would be useful for the project team to provide a definite comment on this in the final document.	3	Useful for screening out sites under Part 2A but DQRA must still be completed before determination
16	When using C4SLs in a risk assessment, should a statistical approach be applied which involves the comparison of the 95% upper confidence limit of the arithmetic mean of the measured soil concentrations with the C4SL?		Ideally, yes to account for population variation and particularly where only a few samples have been obtained per data set and thus greater uncertainty exists	3	This appears to be OK for planning sites, but what about the guidance given by CIEH concerning LC95 in the case of Part 2A sites? Does this comment mean CIEH is wrong? If not, how can you suggest the opposite. The fact that this question has been asked says to me that the stats. guidance must be reviewed and an approved method published.	2	50%ile and 75%iles should also be used. There could be an option for using different percentiles in different circumstances eg Part 2A versus Planning	4	This is in line with the previously released CIEH/CLAIRE guidance.	3	Yes - most definatlly on untargeted data but not for targeted data
ADDITIONAL COMMENTS			Throughout the workshop in the afternoon it seemed we were pushing numbers up but then stopping when we got to a value we consider sensible. Whilst this is logical, I'm not sure of the scientific validity of this process. Also in the report can we be transparent over the decisions made, alternatives available and include ELCR estimates for clarity. It is difficult to understand what certain exceedances of the HCV mean which could make communicating the results of the C4SLs difficult		The link with planning is vital. DCLG should be urged to come off the fence and positively endorse C4SLs by saying clearly and precisely that C4SL equates to fit for purpose in the planning regime. The phrase quoted at the workshop that DCLG is "happy C4SLs are compatible with the NPPF" is rather nebulous and only says to me the DCLG does not disagree with them in some way. Too much like politician / civil service speak in that it could be twisted to mean something later, if required / convenient.		The new approach to use of tox data is a big change. This is welcomed but we should be cautious. I suggest that there should be a rigorous scientific peer review of the new proposals. The stakeholders group is too diverse to be able to provide the equivalent of peer review.				It is felt that the Research Document findings need to be relayed to the wider contaminated land community through consultative workshops. Training is crucial to relay the report findings and to ensure that practitioners understand how and when to use and apply the document
					It is vital that the methodology for defining LLTCs is clearly stated and that the definition of low risk is defined. This is important to show how far above minimum risk we are (given that Government has not made any policy decisions on this).						
					I noted the comments on statistical analyses re the CIEH document and would welcome a clear statement on the methods that are considered appropriate.						

1	The point of departure from which to derive the $LLTC_{ind}$ for BaP being a BMD or BMDL and the benchmark response of 10, 15 or 20% being used.	Use of BMD	2	is the best estimate of the BMD. whereas the BMDL is a more conservative approach	3		3			Before selecting a BMD criteria, it is first necessary to define 'low level of toxicological concern'? This term, which we think is potentially very helpful in the context of this project, needs to be elaborated before the subsequent decision drop out. BMDL10 is the minimum risk which equates to 1 in 10000. SR2 states that we can have chemical specific adjustment for threshold contaminants , and the project is looking to break this down into the individual species (animal). The question was raised as to how in line this was with other toxicological opinions, in the tox industry? Query as to whether this would be possible for all chemicals, reply was affirmative, that the approach would be agreed once all 6 chemicals had been derived. Noted that RIVM is category2/3? boundary but UK policy not agree with this, and there was comment that RIVM is not a relevant criteria for the UK anyway. Further comment that it is only reasonable to use 1 worse case scenario so if you use it here you shouldn't use it else where in the model. discussion about the difference between uncertainty and conservatism. conservatism shouldn't replace uncertainty.
		Use of BMDL or use of BMDL	3	would not result in less conservatism, therefore not consistent with aims of C4SL	3	A BMDL10 based on total tumor incidence (and not just forestomach tumors) pooling the available data (from rats and mice, not just mice) would be a pragmatic approach.	3			
		Use of BMR 10%; or	3	is currently accepted good practice for carcinogenicity data, and provides a precedent for the MOE of 10,000	3		3			
		Use of BMR 15%; or	1	No precendent for MOE, cannot assume linear dose response	3		3			
		Use of BMR 20%	1	No precendent for MOE, cannot assume linear dose response	3		3			
2	A chemical specific margin of 5000 being used to derive the $LLTC_{ind}$ for BaP?		4	Provided it was clear that it is a policy decision and not scientifically based	4	Seems sensible	3		2	This looks to adjust the severity factor in deriving factors for species transposition. Currently we use 10000 as a multiplier, suggestion is to use 5000 instead, but they also asked the question about using 1000. the reason is that they believe that the metabolism rates for mice are not dissimilar for humans. It was recognised that this was also dependant upon the severity effect as an outcome of kidney disease is very different to death, so part of this is based on perception. NHBC advised that they set a BaP warranty limit of 5mg/kg - CHECK 0.5. The question was raised as to whether or not this was a policy decision in line with SR2 and will this number be set for all chemicals for the UK or will it be species and chemical dependant? This input adds 4 orders of magnitude safety factor to the calculations. Particular feedback -perfectly content with 1000 as a FoS.
3	The $LLTC_{ind}$ of 0.3 ng kg^{-1} bw day^{-1} for BaP being based on a policy basis on the UK Air Quality Standards Regulation (ELCR = 1 in 10000) ?		3	Have not looked into the basis for this	4	At least there is consistency then across the two regimes, as long as the scientific justification behind the figure is sound.	3	The use of varying Excess Lifetime Cancer Risks for non-threshold substances is an approach we [East Cambs DC] have used in the past for Part IIa, receiving both support amongst our peers as well as criticism. Whether the use of this approach is supported or not, it does require detailed site specific investigation to address some of the uncertainties which the approach involves. That would be the case in any Part 2a site, but for screening levels it would not. Especially as the absence of any detailed investigation is highlighted as one of the primary fiscal benefits in the NPPF Impact Assessment. There are also social issues to consider when deeming a certain level of (elevated) cancer risk 'acceptable' to the LPA. This level would no doubt be higher than what has been minimal risk from the previous regime in 2002-13, so this could be a pitfall unless a benchmark threshold can be adopted which has had the necessary socio-political involvement in its derivation. We can't have a situation where risks in properties from CL are considerably higher from say those developed in 2013-2017 than from 2002-13. Also with ELCRs you have to consider whether the combined risk from all sources is still acceptable, not just		All clear that we felt we could not change the UK air quality standard.
4	Based upon the description of the toxicology, the choice of $LLTC_{ind}$ (0.54 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		4	Based on 90% of the population rather than 95% therefore less conservative, but not excessively	4	I assume this is for cadmium?	3			Response for cadmium - Seemed to be little knowledge as to whether the urine marker was an effect of harm having taken place or whether this was exposure but with no effect and at this concentration is it reversible. Discussion as to whether there was a half life of 11 years and then a kinetic fall over of gradual chronic illness from constant exposure over years and then fatal. Noted at 300 it was reversible at 1000 it was fatal. Policy states that at 300 it is not significant harm but this would be a political decision for the local authority as to it's increase then causing harm. -
5	Based upon the description of the toxicology, the choice of $LLTC_{ind}$ (0.00286 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		3	Have not looked into the basis for this	3		3			For cadmium
6	The proposed modifications to deterministic exposure parameters for deriving C4SL?		3	Am not entirely clear what all of these are. It is important to use data for consumers, rather than total population (in which the consumption figures are diluted by non-consumers). Use of central tendency rather than 90th centile allows for the possibility that garden/allotment produtcion might be supplemented by commercial produce due to e.g. seasonality. Lifetime averaging is OK for Cd due to long accumulation times	4		3			
7	For POS 1, please could you indicate your preference for developing this scenario from the 3 options presented:	1) Adoption of "Residential without consumption of homegrown consumption" CLEA scenario (i.e. using Age Classes 1-6 for critical receptor)?	4	Young children could be playing outside regularly with a carer	1		2	Remains too conservative and age classes are too unrealistic for unsupervised playing outdoors not in the confines of a private garden.	1	
		2) Use of 'Residential without consumption of homegrown consumption" scenario (AC 1-6) with adjusted soil ingestion rate?	3	Proposal is unclear	1		2	Remains too conservative and age classes are too unrealistic for unsupervised playing outdoors not in the confines of a private garden. Though welcome the use of more realistic/seasonal/behavioural use.	1	yes - children habits have changed
		3) Use of Option 2 with consideration of older children (AC 4-9)?	3	As noted above, young children could also be outside, and hand to mouth transfer is more likely in the younger age group	2	From my experiences, this is the most likley scenario for this land use.	1	Consider this to be the most acceptable option	1	Yes as these are often out playing unsupervised. Prospect of very young children (<7) playing unsupervised in public open space for long periods is remote.
8	The choice of exposure parameters for POS scenario 1?		3	Unclear what is proposed	4	They are reasonable and logical	4			POS scenario 1 is children playing in a area of grass - and in particular the tracking back of mud into the home and secondary exposure within the home. There was discussion about the need for sensitivity analysis on the frequency a child plays and the time has reduced to 170 days per year for 2 hours per day. I to 6 child most sensitive receptor. Not agree as less likely to be out rolling in mud unsupervised compared to 4 to 9 year old.
9	The choice of exposure parameters for POS scenario 2?		4		4	Again, reasonable parameters	4			POS scenario 1 is children playing in a park - and in particular the included no tracking back of mud into the home and secondary exposure within the home. Consensus was that this was wrong and that it should include tracking back.
10	The use of probabilistic modelling as a line of evidence in setting of the C4SL?		3	Not clear how would be used - could lead to big differences between LAs	4	Yes, it's another tool at our disposal that can provide insight, so why not use it?	4			General consensus that this was a yes. Idea was that for 1st 6 will do deterministic and probabilistic and only probabilistic thereafter. There was discussion about incorporating normal background into the model but agreed that this would be used as a line of evidence approach so would not be part of the derivation of the number. Bioavailability is outside scope of the project and should not be used unless have very good in/vivo data. Questions as to how accommodate the large uncertainty of, for example, lead in the population data and the high uncertainty factors for plant uptake in the model. Also questioned the amount of data required to be able to quantify the uncertainty in the probabilistic model.
11	The use of the qualitative evaluation of uncertainty as a line of evidence in setting of the C4SL?		3	Not clear how would be used - could lead to big differences between LAs	5	I liked this. It's a good idea.	4	Though may not promote replicability for further contaminants. Approach should be part of a framework for others to use though, so should be a usefull addition.		No - the numbers are the numbers, the other lines of evidence are the level of risk assessment that lies above the C4SLs. Lines of evidence will be site specific and the numbers are meant to be generic.
12	The inclusion of 'other considerations' as lines of evidence in setting of the C4SL?		3	What other considerations?	5	Yes, if there ever are "other considerations" that have a bearing on the C4SL, they cannot be ignored.	5	Good as a reality check and to take a pragmatic approach		No - the numbers are the numbers, the other lines of evidence are the level of risk assessment that lies above the C4SLs. Lines of evidence will be site specific and the numbers are meant to be generic.
13	The proposed C4SL meet the policy objectives?		5		5	I think that the work undertaken by the C4SL team goes a long way towards meeting the policy objectives. Whether or not you have "cracked it" is a matter for debate, but I am feeling more comfortable with the approaches as they develop.	5	I think the concept of the C4SLs, what they are, what they will replace and what they are not, needs to be re-iterated and made clear. Without this clear objective it will become very confusing and possibly unachievable because some of what CL:AIRE are attempting to do has been tried many times before in relation to SPOSH, as there seems to be a lot of overlap in their proposed approach. I would consider that C4SLs must replace GACs/SGVs and represent suitable for use criteria. They cannot be in addition to these figures as then we could have, with SPOSH figures, 3 tiers of assessment criteria which would not be workable.		There are potentially multiple policy objectives; however the two main areas are planning and PartIIA. Upon completion of the C4SL project SAGTA would anticipate a statement is needed from: - CLG that C4SLs, as defined by Part IIA Statutory guidance, are intended for use in planning - CLG that C4SLs are legally suitable for use in planning - DEFRA the C4SL project has met its objective and the outputs are suitable for use in PartIIA assessments SAGTA acknowledge that these are not the direct concerns of the CL:AIRE C4SL team who are focussed on the science, but they are critical pre-cursors for the use of the project outputs.
14	The proposed C4SL are they sufficiently precautionary?		2	They are not precautionary - the use of this term is policy based and not scientific, and how does one judge "sufficiently"?	4	Yes, I think so. As demonstrated by the sensitivity analysis and reality checks that form part of the derivation process, you have placed the proposed C4SL in context, and they are still precautionary.	4			This is a policy question rather than a technical question - so please refer to this answer above for SAGTAs view on policy. From a contaminated land practitioners view point the BaP and cadmium numbers emerging do seem to be more workable than SGVs, for example in relation to BaP background levels. However it is hard to comment on the basis of two compounds. It is noted that the acceptable risks in the contaminated land area tend to be more stringent than they are for other sectors e.g. radioactivity.
15	The proposed C4SL will be useful for assessing risks from land contamination under the Part 2A regime or otherwise ?		3		4		3	Where C4SL have been derived by others and agreed to be used by industry this will be useful. However uncertain how easy this makes it for others to follow and derive C4SL for additional contaminants. If the C4SLs are provided for only 6 substances, that leaves the question mark over what criteria will be used for all the other substances we commonly analyse for. Even if this project is constrained to just these products, it would be useful for the approach to be applicable to other contaminants, even if the actual assessment criteria are not provided.		Yes - the approach is likely to provide a more realistic screen to clearly indicate when risks are not unacceptable.
16	When using C4SLs in a risk assessment, should a statistical approach be applied which involves the comparison of the 95% upper confidence limit of the arithmetic mean of the measured soil concentrations with the C4SL?		3	Policy issue - under some legislation it would be the lower confidence limit in order to be reasonably certain of non-compliance. But will also be dependent on the way that sampling is performed and how many samples are analysed	4		5			This depends upon the risk of liability a land owner is prepared to take and the confidence the consultant has in the outliers detected and averaging areas identified. I think 95% is fine provided the uncertainties are realistically assessed and quantified where possible. This test differs from the test for contamination, which is a positive test 'on the balance of probability'. This potentially leaves a situation where a parcel of land has not been demonstrated to be contaminated, but cannot be proved as fit for development. This situation is highly undesirable and policy should seek to avoid this.
ADDITIONAL COMMENTS										A number of associated reactions are as follows:
									1	The problem that the team are trying to overcome is primarily a economic / social one. Given the task the team have been asked to do, they have appeared to have taken a thorough and diligent approach
									2	That said, the approach is felt to be a bit subjective. As such there may be questions as to how reproducible it will be, which returns to the point in 1 above that the team is really trying to solve a social-economic problem by squeezing numbers to get the answer they may perhaps have been told to find....
									3	Back-filling technical solutions to this problem is not elegant. The proposition is that it would be much more appropriate to take the SGVs (or similar) and apply a policy judgement that increases those number on social / economic grounds
									4	The values the team is proposing seems reasonable, and there is basic comfort that they lie in the bounds of 'acceptable risk'
									5	The effort is all about deriving soil concentrations, but there may be other ways to screen out sites. In particular the group are advised to consider:
									5	Exclusion distance criteria for petroleum hydrocarbons at depth (recent work by EPA and others suggests the presence of 5m cogenerated unsaturated zone eliminates vapour intrusion risk for petroleum (not chlorinated) VOCs)

1	The point of departure from which to derive the $LLTC_{ind}$ for BaP being a BMD or BMDL and the benchmark response of 10, 15 or 20% being used.	Use of BMD		5	I understand that this gives the most conservative result and therefore I would support its use.	5	I believe you should pick the most appropriate based on the dose response . Ideally I would like to see for carcinogens BMD10, BMD 15 and BMD20L I would then like yo to chose the most appropriate based on each chemical specific appraisal	4	This feels right.	2	I am not sure that this would be accepted by the land contamination community as being representative of a low level of toxicological concern as it is a significant departure from accepted protocol in determination of minimal risk.
		Use of BMDL or use of BMDL		1		3		2	It would not object to this.	5	Accepted method currently used
		Use of BMR 10%; or		2		1		4		5	Accepted method currently used
		Use of BMR 15%; or		1		5		3		3.5	In order to differentiate between minimal risk and LLTC I agree that a higher departure point may be justifiable. A decision will have to be made as to what response is acceptable to still be precautionary that can be justified. The higher the departure point that is selected the more difficult it will be to justify and get buy in from the community. Consideration should also be given to the shape of the dose response curve in the region of the % responses being considered on a contaminant specific basis.
		Use of BMR 20%		1		5		2		2.5	see above
2	A chemical specific margin of 5000 being used to derive the $LLTC_{ind}$ for BaP?			4	There seems to be a good rational for doing this so I would generally support it.	5	I thought the logic was strong and I liked the break down of the way you tried to account for it	4	In general accept this as being reasonable. However, the justification of using 5 rather than any other number is non-existent for interspecies variation.	4.5	As long as there is clear justification for the derivation of the CSAF it should be applied. I understand from the discussions in my group at the workshop that there is not clear precedent for the breakdown of the categories used to derive the CSAF - the justification / reasoning behind these categories should therefore also be clearly explained in the final report. To a non-toxicologist, the CSAF of 5,000 with the reasoning provided at the workshop appear reasonable.
3	The $LLTC_{ind}$ of 0.3 ng kg^{-1} bw day^{-1} for BaP being based on a policy basis on the UK Air Quality Standards Regulation (ELCR = 1 in 10000) ?			4	Yes I would generally suppor this	5	I am happy to see 1in 10000 as a target	5	Agree - makes sense.	5	Precedent set for other substances in production of SGVs. If the method is consistent with setting SGVs representing minimal risk it is appropriate and suitable protective to use in setting C4SL representing a low level of risk.
4	Based upon the description of the toxicology, the choice of $LLTC_{ind}$ (0.54 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?			4	There was a good case for this made during the presentation and I would support it for C4SVs	3		4	Believe this is correct as just above the 300 reversible effect marker and believe conservatism is built into the model which would cover accumulation of Cd within the body.	3.5	Not clear that the lower CSAF is justifiable and / or in line with the derivation of the CSAF for inhalation. Otherwise method seems reasonable and justifiable to set LLTC.
5	Based upon the description of the toxicology, the choice of $LLTC_{ind}$ (0.00286 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?			4	There was a good case for this made during the presentation and I would support it for C4SVs	3		3		4	Needs to be consistent with approach to setting oral LLTC
6	The proposed modifications to deterministic exposure parameters for deriving C4SL?			4	Would support these for category 4 sites. However, I don't think that these are suitable for development control sites.	4		4	I think this is sensible.	5	Justification needs to be provided for transparency in final report.
7	For POS 1, please could you indicate your preference for developing this scenario from the 3 options presented:	1) Adoption of 'Residential without consumption of homegrown consumption' CLEA scenario (i.e. using Age Classes 1-6 for critical receptor)?		1		1		4	This would be conservative for some sites but would cover most.	3	These modifications to the residential standard CSM are reasonable as long as they are clearly set out in the report. It will then be up to the user to establish that the CSM used to set the POS C4SL is appropriate for their site. The two POS types described seem a reasonable attempt to describe types of open space that are commonly found / used where exposure to land contamination needs to be considered.
		2) Use of 'Residential without consumption of homegrown consumption' scenario (AC 1-6) with adjusted soil ingestion rate?		1		1		2		3	see above
		3) Use of Option 2 with consideration of older children (AC 4-9)?		4	I think this is the most realistic scenario	5		2		3	see above
8	The choice of exposure parameters for POS scenario 1?			4	More realistic choices than using residential without plant uptake. The choices made will still be conservative, given that it is unlikey that POS will realistically be used at this frequency.			4		3	see above
9	The choice of exposure parameters for POS scenario 2?			4	As above			3	Exposure frequency needs further thought. Dog walking is a daily activity and some dogs can track back considerable amounts of soil, additionally in this scenario tracking back into cars is significant.	4	see above - it may be prudent to allow for some tracked back soil in the model as use of these sites for picnics and sporting activities will inevitable bring soil (mud) back to the home.
10	The use of probabilistic modelling as a line of evidence in setting of the C4SL?			4	Given sufficient data the use of Probabilistic modelling should provide a more reliable result	4	but not as a widespread tool	4	Shows variation of population and helps to make a judgement. Enables understanding of how precautionary the deterministic method is.	4	The feedback mechanism described is considered useful in checking the appropriateness of the C4SL and the probabilistic modelling is useful to see the potential effect of the cumulative changes to the modelling inputs. When finalised this information should be presented to justify the selection of parameters used to derive C4SL. It would also be useful to see a comparative probabilistic model run using the default CLEA parameter values and HCV so that the level of exceedence can be compared against that for derivation of minimal risk levels.
11	The use of the qualitative evaluation of uncertainty as a line of evidence in setting of the C4SL?					4		3		5	Again the feedback mechanism will help to justify that the C4SL have been set at an appropriate level that is still precautionary if applied correctly.
12	The inclusion of 'other considerations' as lines of evidence in setting of the C4SL?		The use of pH for Cd, the use of PSD and establishing if enrichment or depletion exists.			5		4	There could be ambiguity on what constitutes enough data. The cost of remediation should not be a consideration.	5	see above
13	The proposed C4SL meet the policy objectives?			4	Yes they will if they are used for Cat 4 sites. If they are used more widely, particularly development control type scenarios there's a risk they wont. They're not designed for that function although I find it difficult to understand how Defra consider the savings to remedial costs that will be made if they are adopted - given the low number of Part IIA sites determined.	5		4		3	It is difficult to comment on this as a range of C4SL were proposed for both Cd and BaP. How well they meet the policy objective will depend on how the parameters are set and if it can be justified that the choice of LLTC is still highly precautionary.
14	The proposed C4SL are they sufficiently precautionary?			4	Yes I feel they are. I'm not sure that they would be for development control sites though. I would need to see the values for the range of contaminnes you propose to produce them for. Many of the difficulty with excessively low GACs/SGVs experienced, particularly with BaP can be overcome by accepting the principle that we should not remediate below a normal background concentration.	5		4		3	see above
15	The proposed C4SL will be useful for assessing risks from land contamination under the Part 2A regime or otherwise ?			4	Yes they are a good starting point for such assessment. However, very few LAs will be looking at such sites as we prioritise our high risk sites - Cat 1 and 2 first. It will be a long time, if ever, that the systematic assessemnt of Cat 4 sites will be made.	4		3		4	It will be necessary for the final report to be fully transparent and provide justification for each individual change together with the cumulative changes to the modelling for the C4SL to be useful and accepted by the community.
16	When using C4SLs in a risk assessment, should a statistical approach be applied which involves the comparison of the 95% upper confidence limit of the arithmetic mean of the measured soil concentrations with the C4SL?		Thank you for the opportunity to respond, however due to a range of work commitments I have been unable to provide time at work to interpret the 122 powerpoint slides and provide meaningful feedback as requested. Whilst there appears merit to utilise some of the aspects advocated, I am mindful that there were wide ranging questions raised by many of the human health risk assessment practitioners who were present at the stakeholder meeting. The questions raised had in my view some merit and feel that the process of requiring timely feedback from a wide range of stakeholders is intended to help deliver a decision that has already to a great extent already been made. This is not a criticism of the project, however when other work commitments are inevitably present another option of liaising with stakeholders would possibly have derived greater benefit. The liaison process could have been longer or as two steps, though naturally this may also have been liable to criticism. A two step approach would have been favourable, the first step using toxicologists and human health risk specialists in order to derive some form of consensus and then to project these findings to regulators as step 2 with reasoned justification.	4		5		4		3.5	the choice of statistics will depend on the quality of the data available for the site and under which regime the C4SL are being applied.
ADDITIONAL COMMENTS			The lack of having information prior to the event meant that those with neither specialisms in toxicology or considerable experience in human health risk assessment were at a significant disadvantage and the ability to contribute was severely compromised. This workshop led members through the options of BMD, BMDL, BMR10-15-20, however the choices available appeared somewhat disingenuous when questioned on the Fitzgerald report and the use in Australia with a BMDLS. Once again it allows me (possibly incorrectly) to consider that an outcome has already been percieved and this "consultation" is a means to an end. The importance of enrichment and/or depletion is an important element that currently does not appear to be mentioned. There was also a reliance on BGS data especially for the Cd work, however it would have been interesting to understand where the elevated cadmium was identified. Is this with a particular formation such as veined mineralisation in host strata like Carboniferous limestone or identified in dark heavy mudstones. The alternate may be that the elevated results are randomly spread across urban UK. I ask this as early BGS studies in Cardiff had random 1Km grid sampling and actually sampled from a		Provide a short cut so that people who have identified a relavent study can them model a new BMD in proprietory tox softwares...				
			I understand that the new study has filtered these out, however I would be cautious with the use as normally Cd is not normally ubiquitous in soils and in my experience rarely a problem. Again perhaps just another query of why Cd was chosen as opposed to another metal. I would dearly have liked to have worked through the slides in order to provide feedback on C4SL development and make a positive contribution, however the timescale has been against me and I'm therefore unable to provide positive or constructive comment. My apologies to the team.			To do this defra would have to regularlyl review paper eg every 3 years.				

1	The point of departure from which to derive the $LLTC_{oral}$ for BaP being a BMD or BMDL and the benchmark response of 10, 15 or 20% being used.	Use of BMD	1		3	I'm not sure that we have the whole story to make a sufficiently robust decision here. I think I need a clear evaluation over why the approach you have recommended is considered to be appropriate and how it correlates to significant harm and Category 2/3 versus Category 4 on TOK alone (i.e. without consideration of exposure, which presumably, as TOX was done independently from exposure, this is). In the past, there has been huge resistance in compiling a Part 2A assessment deviating from a Minimal Risk Level (e.g. using an oral HCV of 0.2µg/kg bw/day) and I do not feel that I have enough information to answer these questions (without perhaps reading your written documentation). I'm not sure whether this is a contaminant specific decision and how you have made the decisions to use 15 or 20 (other than to go above MRL you have to use more than 10) and whether making decisions here will mean others will try and apply that approach to other contaminants. I don't fully follow how you can disregard the BMDL from the information I have.	1	Without a definition for the LLTC it is not considered possible to select an appropriate scientifically robust POD. It is considered unreasonable to expect the stakeholder workshop delegates, many of whom have no detailed toxicological knowledge to provide an informed opinion on this. During the workshop the project team indicated that for other contaminants (i.e. those not covered by this research project) that toxicological skills would be required to derive C4SLs however in this question the stakeholders are being asked to select the POD. In addition it is considered that the selection of appropriate toxicological benchmarks needs a wider consultation with informed bodies such as the Committee on Carcinogenicity and the Committee on Toxicology. The presentation indicates that recent recommendations of the COC regarding carcinogens have been taken into account which I understand to be a reference to the Risk Characterisation Methods. COC/G06. October 2012 paper which is a second draft stating 'It is a draft for discussion. It should not be quoted, cited or reproduced'. The presentation of the options presupposes that this approach is considered appropriate by the project team. CIEH does not consider this to be the case.	1		1
		Use of BMDL or use of BMDL	3	Established precedent	3		3		3		3		3	3
		Use of BMR 10%; or	3	Established precedent	3		3		3		3		3	3
		Use of BMR 15%; or	2	Higher departure points not justified	2		2		2		2		2	2
		Use of BMR 20%	1	Higher departure points not justified	2		2		1		2		2	2
2	A chemical specific margin of 5000 being used to derive the $LLTC_{oral}$ for BaP?		4	Appears reasonable	4	Provided that the choice for this is based on study specific data or that there are guidelines over how to define the approach you have taken (e.g. what constitutes robust data/sample size) and that calculating the margin is clearly documented, what assumptions were made in the pivotal study or other jurisdictions using tahl pivotal study, and clear how each compent factor is applicable, this is logical.	4	Does this margin represent low risk? The COC paper indicates that an MoE of >10000 based on a $BMDL_{10}$ from an animal study may be a concern. It is considered that a decision as to what constitutes low risk is a plicy decision and this is of great significance given how any published C4SLs are likely to be used. The COC paper also reiterates that ALARP should always apply for compounds with no identifiable threshold of effect.	2	We need a generic approach	4
3	The $LLTC_{oral}$ of 0.3 ng kg^{-1} bw day^{-1} for BaP being based on a policy basis on the UK Air Quality Standards Regulation (ELCR = 1 in 10000) ?		4	Consistent with existing decisions on use of AQS for other substances such as benzene	4	The precedence of using Air Quality Standards was set by SR2 and this approach is probably already widely used. However, some comments/consideration should be given to the likely impact/potential of the AQS reducing and over what timeframe.	3	The Air Quality Standard is based on achievability not the protection of human health. Does this mean that an ELCR of 1 in 10000 is considered to represent 'low' risk?	4		4
4	Based upon the description of the toxicology, the choice of $LLTC_{oral}$ (0.54 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		2	15% increase risk not justified as being acceptable and not consistent with additional risk associated with LLTCinhal. Choice of CSAF using 95th percentile data not presented as being consistent with approach for CSAF for LLTCinhal either. Inconsistency in approach not clear and should be justified/clarified	3	It seems pragmatic on the basis that the assessment criteria derived are in the region of what is currently considered to be what lies within Category 4 and is justifiable if you clearly present the approach of what you have done and what the data means with respect to Categories 2, 3 & 4 (i.e. does this represent significant harm, or a safe level (and thus ok for use in planning) for both tox and exposure individually (not just as a combined evaluation). Whether toxicologists are sufficiently confident that this is protective and represents land that is safe - I don't feel I have enough information to conclude that. (Unless I've missed something somewhere).	2	Without a definition for the LLTC it is not considered possible to determine whether the selected value is suitably protective. Although the calculated C4SLs and the probability of exceeding a LLTC would indicate that it is not.	2	We cannot judge what is "suitably protective" until the intended use of the C4SLs has been clarified by DEFRA and DCLG.	2
5	Based upon the description of the toxicology, the choice of $LLTC_{oral}$ (0.00286 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		4	Seems reasonable	4	Suitably protective - depends whether you consider a ELCR of 1x10-4 being safe and suitable protective. Again, am interested to understand how this relates to significant harm with Category 2, 3, 4. Pragmatic - based on current guidance, yes.	3	The selected LLTC represents an ELCR of 1 in 60000 - does this mean that this defines low risk? What will be the impact of its decision on the selection of LLTC for other contaminants not covered by this research project.	3	We cannot judge what is "suitably protective" until the intended use of the C4SLs has been clarified by DEFRA and DCLG.	3
6	The proposed modifications to deterministic exposure parameters for deriving C4SL?		5	Agreed	4		3	As stated in the response to the workshop 1 questions positive evidence needs to be provided to justify any modifications (although this may be provided in the Work Package 1 report). The move towards central tendancy can only result in a reduced level of protection and it must be recognised that more cautious estimates were often selected in SR3 due to the limitations of the available datasets. CIEH would not be in favour of limiting the scope of protection to 'central tendency'. For cadmium the consumption of homegrown produce is a significant exposure pathway and it is evident from the cumulative probability chart for cadmium that a significant proportion of individuals would not be afforded an adequate level of protection by the proposed C4SL in the residential and allotment scenarios. In addition a sensitivity analysis illustrating the effect of the proposed changes has not been made available. It is considered that the proposed modifications do not take adequate account of lifestyles changes where an increasing number of people are growing and consuming homegrown produce. The retention of the utilisation of RBA estimates is also of great concern as robust data to support a generic change from the default 100% is	4		4
7	For POS 1, please could you indicate your preference for developing this scenario from the 3 options presented:	1) Adoption of "Residential without consumption of homegrown consumption" CLEA scenario (i.e. using Age Classes 1-6 for critical receptor)?	3	Overly precautionary if lines of evidence are considered to be sufficiently robust	4	I would be interested to know the impact of looking at e.g. 4-9, 4-11 who probably have considerably higher exposure than those in AC 1-6 as suggested in the third option. If the 0-6 year old isn't protective then this needs re-visiting.	4	As POS 1 may represent areas close to residential properties that do not have gardens it is necessary to consider Age Classes 1-6 as the critical receptor	3		3
		2) Use of 'Residential without consumption of homegrown consumption' scenario (AC 1-6) with adjusted soil ingestion rate?	3	Seems reasonable			4		3					
		3) Use of Option 2 with consideration of older children (AC 4-9)?	2	Not adequately demonstrated that this would be the critical receptor			2		3					
8	The choice of exposure parameters for POS scenario 1?		3	Seems reasonable	3	Not entirely sure what you mean by this question - we haven't been given a full list of the assumptions that you have made. I don't know the full reasoning behind why you chose to reject adopting the soil ingestion rate for residential assumptions and I would suggest that the same rationale is applied here and soil ingestion rate isn't adjusted One question - isn't is likely that the areas of public open space adjacent to the properties is on the same soil source as le residential properties, so would the hazard quotient be >1 for these 2 scenarios, and would that still equate to Category 4?	4	The choice of exposure parameters seems reasonable. The exposure scenario must be presented with sufficient detail (similar to that in SR3 for the standard land uses) to enable the user to make an informed decision as to whether it fits the conceptual model for the site under consideration.	3		3
9	The choice of exposure parameters for POS scenario 2?		4	Seems reasonable	4	Do you sufficiently consider the potential for warmer times. We could be in a small 'wet blip' and maybe we'll go back to hotter summers?! I know you said you could go less conservative, are you sufficiently conservative? Should it be county specific (i.e. rainy places versus sunny places)? I would suggest calculating a specific inhalation rate rather than using allotment (taking into account light activity etc asdocumented in SR3 - Londo data?)	4	The choice of exposure parameters seems reasonable. The exposure scenario must be presented with sufficient detail (similar to that in SR3 for the standard land uses) to enable the user to make an informed decision as to whether it fits the conceptual model for the site under consideration.	3		3
10	The use of probabilistic modelling as a line of evidence in setting of the C4SL?		2	As presented the choice of PDFs is inconsistent between cadmium and BaP, with additional considerations bolted on to BaP evaluation. Use of probabilistic modelling is supported but it needs to be used consistently and not seen to be manipulated for a desired outcome.	2	Needs to be reproducible and clear how it has been done - everyone must be able to replicate it (acknowledge results slightly different every time). Should anyone else try to derive a C4SL then they will be pulled up for not following the same decision making process. The cumulative probability graphs seem to tell a good story but are only useful if they are simple enough to replicate, follow and understand.	4	Probability modelling is a reasonable means of considering uncertainty in the generation of the C4SLs however the basis of the selection of the probability density functions must be transparent. In addition it could be queried whether an adequate number of Monte Carlo iterations have been undertaken given the number of probabilistic parameters. The cumulative probability charts need to include background exposure. Some of the variables are interlinked which needs to be taken into account.	4		4
11	The use of the qualitative evaluation of uncertainty as a line of evidence in setting of the C4SL?		2		4	Qualitative analysis is very subjective and can work both ways to work with you or against you. In general, I am in agreement as it strengthens your argument but I haven't given sufficient thought to the against argument to see what the uncertainties then become.	3	The qualitative evaluation is based on expert judgement and notwithstanding the need for expert judgment this type of approach is open to potential misuse. It is difficult to comment without seeing a comprehensive example and in particular how the total is generated - is it a judgement call?	4		4
12	The inclusion of 'other considerations' as lines of evidence in setting of the C4SL?		5	5	4	Not sure on the NBC for urban areas. How much of the country is in an urban area and is the urban NBC sufficiently robust? If these are C4SLs (and if they are found to be appropriate for use under planning), will be interesting to see what value the NBC then holds.	2	Not entirley clear what is meant by 'other considerations' however if it is referring to wider socio economic considerations these will potentially vary from area to area and will ned to be considered on a lie specific basis. If there are more technical considerations then these should be taken into account via the toxicological and/or exposure assessments. For example there are issues around particle size distribution and enrichment that will require consideration for some contaminants - how will this be taken on board?	4		4
13	The proposed C4SL meet the policy objectives?		5		5	Unclear on ability for use under planning based on information proposed so far - need to read your supporting information to answer.	1	The proposed C4SLs do not meet the policy objectives set out in the Impact Assessment which quite clearly states that the C4SLs will replace the SGV/GACs and will provide a higher simple test that land is suitable for use and definitely not contaminated land. The C4SLs will not be appropriate for determining that land is suitable for use. A full discussion around the policy basis and subsequent use of the C4SLs has not taken place at either workshop although valid questions have been raised on both occasions. The reluctance of the project team and Defra to enter into these discussions is particularly concerning given the issues that have been raised by the stakeholders. It is recognised that this is a research project however the potential impact is wide reaching outside of the Part 2A context.	2	The policy goal posts appear to be on the move...	4
14	The proposed C4SL are they sufficiently precautionary?		3	25-30% risk that LLTC will be exceeded for cadmium is hardly precautionary. Choice of highest LLTC for use in probabilistic modeling not justified and graph indicates 30% of ADEs above that LLTC at the resi C4SL. Second graph showing soil ingestion/2 and additional inclusion of RBA estimate not clarified or justified, and again inconsistent with presentation for cadmium. There has to be consistency in the quantitative lines of evidence used, not a seemingly random choice to derive desired endpoint.	3	Insufficient understanding on TOX and detail as no written information. Would rather evaluate more fully before agreeing.	1	A situation where there is what is described as a "relatively high" (in some cases 25% or 30%) probability that an individual will have an exposure that exceeds the LLTC is not sufficiently percautionary as is the case with cadmium and BaP (>C4SL of 5, 1mg/kg. Neither is a situation whereby 5% of the population may exceed 10 LLTC as is the case for cadium in the allotments scenario. What will be judged to be an acceptable level of exceedance of the LLTC - is this not a policy decision?	2	We cannot judge what is "sufficiently precautionary" until the intended use of the C4SLs has been clarified by DEFRA and DCLG.	4
15	The proposed C4SL will be useful for assessing risks from land contamination under the Part 2A regime or otherwise ?		3	Subject to comments above.	4	Unclear on ability for use under planning based on information proposed so far - need to read your supporting information to answer.		Not sure if 'otherwise' in the question relates to the Part 2A regime or other regimes. The C4SLs may be useful under the Part 2A regime in assisting local authorities in concluding that land falls within Category 4 and is not contaminated land. However the Statutory Guidance clarifies that Part 2A is a positive test and local authorities should seek to give priority to land that it considers most likely to pose the greatest risk to human health or the environment hence the need for C4SLs is questionable. The lack of recognition as to how these C4SLs will be used in other regimes is naïve at best and will have a significant impact on local authority staff trying to undertake their duties under the planning regime. This issue has been raised by a number of delegates and not addressed at either stakeholder workshop. It is considered alarming that this issue has not been given due consideration and will lead to a situation whereby 'numbers' are used inconsistently and incorrectly across the country.	4		4
16	When using C4SLs in a risk assessment, should a statistical approach be applied which involves the comparison of the 95% upper confidence limit of the arithmetic mean of the measured soil concentrations with the C4SL?		3	Statistical approach should be commensurate with the available dataset and the assigned objectives of the investigation. It should be recognised that there is not a single one size fits all statistical solution. Ferd's evaluation (as presented) appears to miss a fundamental aspect of all statistical testing, and that is the power of the statistical test being used. Hypothesis tests are fine as long as the power of the test is calculated, the significance of it understood and taken into consideration in the evaluation of the result	2	Unclear on whether you are suggesting to go against the CLAIRE / CIEH guidance and full reasoning behind this. I presume you mean under Part 2A not Planning, so you are suggesting to go against this guidance?? How does it apply to the two null hypotheses? Need more information.	3	Very little information presented on the statistical approach. Don't disagree with the use of 95%UCL but would query the selection of the arithmetic mean particularly where there may be a wide range of values as is likely to be the case.	4		4
ADDITIONAL COMMENTS				It is not clear whether the recommendations of the US EPA (2009) w.r.t the use of air concentrations as opposed to inhal doses for inhal risk has been implemented (i.e. avoidance of adjusting an air concentration to a dose using adult parameters and then comparing that to a dose calculated using a PEC in air and different (i.e. child) parameters		It is a shame that timeframes did not allow for your written work packages to be completed or for drafts to be issued with the information. I feel like we are have half the story and expected to sign it off. Bit like a Regulator who is told what a consultant wants to tell them and they want sign off there and then but the Regulator reserves the right to read the fully documented data to make a suitabley informed decision.		Explicit link to planning: there needs to be a recognition as to how these numbers will be used once published. The proposed C4SLs are not considered appropriate for use under the planning regime as a low risk (as used in Category 4) does not map to the NPPF.			
				Related to this it is not clear whether modifications 14 and 15 have been applied consistently in the Cd and BaP examples presented.		I'm unclear on how these won't be used under Planning as if they meet the NPPF and are in Category 4 and are effectively what the Impact Assessment says will be used for Planning. I would appreciate a really clear statement which means that there is no ambiguity.		Reproducibility: the methodology has been used for 2 substances with another 4 planned before the end of the project however I would query the reproducibility of the proposed approach for other substances.			
						Every decicion made needs to be documented and transparent so that others can follow the rationale. Clear discussions need to be presented on how approach is not applicable to other contaminants if that is the case with a focus as to how that decision is specifically applicable to that one contaminant alone.		It is the CIEH view that the policy context for all of this is misconceived and the justification for C4SLs has been misrepresented. In particular they are clearly intended to have a regulatory role - something underlined by the composition of the steering group - and in indicating what amounts to a LLTC if not otherwise, this 'research' is clearly and inappropriately straying into health policy-setting and the preserve of regulatory authorities.			
						What happened to the adjusment for CLEA where you were changing the double counting of childhood factor with inhalation rates and bodyweights?		The timescale for responding to the workshop outputs is considered unreasonable. It is understood the project is working to a very tight timeline however many of the issues raised require careful consideration and consultation with others from the organisation/body represented by the participant and this timescale does not allow this.			
						How do you define appropriately conservative / precautionary?		There are a couple of references to unpublished data - unpublished data is not robust and defensible.			

1	The point of departure from which to derive the $LLTC_{oral}$ for BaP being a BMD or BMDL and the benchmark response of 10, 15 or 20% being used.	Use of BMD		1	There is a difficulty in making any judgement here as there is no quantative definitionof the LLTC as it is a concept of a level higher than the minimal outvalues of the SGV/GACs but which can be considered as beingacceptably safe. The suggested basis here for a recommended POD is not scientifically robust. It will also be difficult for stakeholder delegates who are not toxicologists to make reasonably informed judgement. This will also apply when dealing with the remaining 4 contaminants in stage 3. These decisions really relate to to national policy and should involve other government advisory committees dealing with toxicological issues and nationally agreed acceptable leveles of risk.	2	C4SLs are low or no risk. Why are we removing reasonaly uncertainty in the levels. This has nnot been justified.	1		1	The LLTC needs to be defined before a basis for assigning a numerical value to it can be agreed upon.
		Use of BMDL or use of BMDL	Feel this would give greater confidence in the final value.	1		5	This accounts for uncertainty and is based on a commonly stduied PoD	5	Incorporates uncertainty	1	The LLTC needs to be defined before a basis for assigning a numerical value to it can be agreed upon.
		Use of BMR 10%; or		1		3	yes this si policy	2		1	The LLTC needs to be defined before a basis for assigning a numerical value to it can be agreed upon.
		Use of BMR 15%; or		1			No attempt has been made to justify this approach. It is not commonly applied. It does not reflect low or no risk. If you wish to fiddle with something look at the the uncertainty factors. (Please note the margin of safey is linked to this).	4		1	The LLTC needs to be defined before a basis for assigning a numerical value to it can be agreed upon.
		Use of BMR 20%		1			No attempt has been made to justify this approach. It is not commonly applied. It does not reflect low or no risk. If you wish to fiddle with something look at the the uncertainty factors. (Please note the margin of safey is linked to this).	4		1	The LLTC needs to be defined before a basis for assigning a numerical value to it can be agreed upon.
2	A chemical specific margin of 5000 being used to derive the $LLTC_{oral}$ for BaP?		What constitutes a low risk is unclear, this is ultimately a Policy call.	1	This is also surely relates to a policy decision with a margin of 10,000 or higher is morelikely to be compatible with a national level of acceptable risk.	2	This has not been properly justified. The number is arbitrary and does not seem to a sound basis. It does not help that his LLTC has not been defined. For the approach (and that is what you are setting out) to be consistent. There must be a consistent justification for the changes which can be applied to other substance. The factor of 5000 used in the Australian paper was based on a BMDL5 not a BMDL10.	3		1	There is neither national nor international discussion let alone consensus on this; the recent CoC documents (the pertinent ones are not for citation anyway) do not provide a basis for what would be a major policy step
3	The $LLTC_{oral}$ of 0.3 ng kg^{-1} bw day^{-1} for BaP being based on a policy basis on the UK Air Quality Standards Regulation (ELCR = 1 in 10000) ?		Gives policy consistency and pragmatic. Avoids being disproportionately onorous.	2	This value quoted is based upon what is achievable in the context of air quality testing and regulation and therefore not directly relevant to this situation.	5	yes. Based on UK policy	5		1	This is the basis for the Index Dose - why is the LLTC being set at the same level as that for which an up to date Index Dose would be set?
4	Based upon the description of the toxicology, the choice of $LLTC_{oral}$ (0.54 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		Acceptable compromise	2	Difficult to answer without a definition of LLTC - but seems not to be suitably protective.	1	As noted above, it has not been justified for a C4SL. Please note this is not about deciding whether or not something is contaminated land it is whether it is low or no risk.	4		1	The phrase suitably protective cannot be upheld in the absence of a definition of LLTC
5	Based upon the description of the toxicology, the choice of $LLTC_{oral}$ (0.00286 µg/kg/day) seems pragmatic and remains suitably protective for setting the C4SL?		Acceptable compromise	2	I understand that this LLTC is equivalent to an ECLR of 1 in 60,000 - is this suitable protective from a policy point of view?	5	Yes based on Uk policy	4		1	not clear which substance this refers to!!
6	The proposed modifications to deterministic exposure parameters for deriving C4SL?		Logical. Best of knowledge at this point. Deterministic exposure also retains consistency with the way that the GACs are currently being assessed and removes the conservatism of the origially used probabalistic determination.	1	The move towards consideration of the central tendency willresult in a significantreduction in the level of protection. This will effectively discriminateagainst various important minority groups.	?		4		1	each needs specific feedback; why are you trying to catch them ALL into one question?
7	For POS 1, please could you indicate your preference for developing this scenario from the 3 options presented:	1) Adoption of "Residential without consumption of homegrown consumption" CLEA scenario (i.e. using Age Classes 1-6 for critical receptor)?	Reality is complex but this appears to be the best comprimise. Fits with the "a-loss generation" whose obsession with gaining is attributed with the reduction in antisocial behaviour as well as increased obesity (increase average body weight??) Reduced indoor dust; 50:50 split indoor/outdoor dust inhalation;and respiratory rate? Is there too much range to accurately characterise the POS ? Could it be addressed as a regional location?	4	This section of the project is welcome because of the lack of any other alternative generally accepted consideration of guideline values for Open Space scenarios. This presumably includes areas close to residentila prop=erties;without gardens where children (aged 1-6) would be the most sensitive receptor.	4	Not convince ont he point of these as they are too variable. Would suggest if this is a creening tool be conservative.	3		1	unnecessarily over cautious
		2) Use of Residential without consumption of homegrown consumption" scenario (AC 1-6) with adjusted soil ingestion rate?		2		4		1		1	unnecessarily over cautious
		3) Use of Option 2 with consideration of older children (AC 4-9)?		2		2	Not sure there is that much justification for increasing the aregroup.	5	allows relevance	4	
8	The choice of exposure parameters for POS scenario 1?			4	Exposure Scenarios seem reasonable but there will be a need for sufficinet details to enable comparison with site specific considerlation of conceptula model.	3		5			
9	The choice of exposure parameters for POS scenario 2?			4	as above	3		5			
10	The use of probabilistic modelling as a line of evidence in setting of the C4SL?		Use must be justifiable i.e. there is an aspect of the CSM that warrants it. Define 'appropriate' . Caveat use	4	Accepted as a reasonable approach, but is more complex to apply than the deterministic model, and therefore less likely to be adopted commonly for development or checking of new values.	4	Useful as a line of evidence. Technical problems need to eb resolved (e.g. Properly inclduing backgound as the cadmium results presented were misleading)	5	yes - good even though "difficult". Update of knowledge incorporate	1	The probabilistic modelling needs to be reported more fully; the afternoon discussions did not give confidence that the modelling was robust. If such modelling was shown to be robust they ought to replace the deterministic steps altogether.
11	The use of the qualitative evaluation of uncertainty as a line of evidence in setting of the C4SL?		Uncertainty remains a key issue and this would help but you would need to test the assumptions on a case by case basis and indicate how much you can rely on the curves.	2	This requires the application of expert judgement and may be rarely available in practice. Difficult to comment further.	4	Can't do any harm	4		1	The uncertainty should be quantitatively incorporated into the basis for the C4SL doing so qualitatively is subjective.
12	The inclusion of 'other considerations' as lines of evidence in setting of the C4SL?		Aspects such as the role of soil type and organic content together with background concentrations etc need to be taken into account. However, care must be taken when using air quality standards etc owing to the policy drivers.	2	It is unclear what is reference to here, but may include consideration of toxicological, technical or remediation process factors which are all dependent upon site specific conditions.	1	Not sure that the non-technical queires are part of this projecct.	5	update with knowledge	1	Too subjective and difficult to map across to other substances.
13	The proposed C4SL meet the policy objectives?		Whilst more pragmatic it is still very precautionary, so arguably it does meet the policy objective. However, as you are aware, within the industry a number of SGRA's have been compiated for BaP which in general have produced higher acceptable concentatins in soil. This begs the question of whether further work is required to better understand the key variables so that we can be sure that they are adequately accounted for in the screening values and that the balance between conservatism and pragmatism is achieved without compromising protection.	1	The C4SVs will not meet policy objectives as presented in the related Impact Assessment. They will not be of value in identifying sites for consideration fo Part 2A determination as contaminated, but only as an indicator of sites which should not be considered further in that context.	2	At this moment I remain unconvinced that the C4Sls (in particularly LLTC) will represent low or no risk. That is not to say they will not by the end.	4		1	The C4SL as presented fail to address the issue of planning - the departure from negligible and minimal risk levels as the basis for the toxicological benchmarks (however these are derived - cf SR2) means they do not clearly map on to the words of the NPPF. The RIA for Part 2A promises savings mainly within the development sector and the C4SL proposals would be open to challenge at public inquiries.
14	The proposed C4SL are they sufficiently precautionary?		Due to the amount of continuing uncertainty and gaps in our scientific understanding they are most likely too conservative. Hence, it is probably safe to assume they are overly precautionary	1	The use of some considered approaches are such that there is a probability that 20% or more of a community will experience exposures exceed ing LLTC. this is not acceptable and not sufficiently precautionary. This would effectively discriminate against significant minorities fo the population.	1	At this moment I remain unconvinced that the C4Sls (in particularly LLTC) will represent low or no risk. That is not to say they will not by the end.	4		1	Not for planning; they would act as screening values for Part 2A.
15	The proposed C4SL will be useful for assessing risks from land contamination under the Part 2A regime or otherwise ?		The CSLs will be useful in assessing the risks under Part 2A and possibly Planning, but what is needed is a focus on reducting uncertainty so that we can move away from unnecessarily 'conservative' values.	3	The C4SVs will only be useful in identifying land that is untilkey to be capable of contamination under Part 2A. The SG states that Local authorities should give priority to sites with greatest risk to human health and the environment. Thus in this contex their value is questionable. There is however much confusionabout how else teh C4SVs may be used in other regimes, and there will be great reluctance by the CLG community to be a party to changes which will effectively reduce the lewel of protection fo human health in the contxet of the Planning process where they have the responsibility for all regulatory decisions. Furthermore any developers will be reluctant to use higher guidance values in their remediation proposals which will effcatively increase the level of residual liability they retain for sensitive developemnts such as housing after completion.	3	It would be more useful to have data on the Cat 2/3 boundary if that was the aim. We already have bocos for assessing if we are well below that.	5		1	The question is invalid as it begs the question of what does 'otherwise' mean - is this an implicit reference to usefulness under planning?
16	WHen using C4SLs in a risk assessment, should a statistical approach be applied which involves the comparison of the 95% upper confidence limit of the arithmetic mean of the measured soil concentrations with the C4SL?		Yes this makes absolute sance within the context of a screening level.	2	The effective statistical treatment of results of sampling and analysis of soil from sites affected by contamination in most cases is prejudiced by inadquate sampling frequency and poor differentiation of the wide range of samples typed encountered during an investigation. This is a constant problem but the use of a 95%UCL is supported whenever appropriate.	1	I think the porpblem here is the difference between assumptions in Part 2A and planning and the assumption that the land is contaminated or not. In practice I think that under Part 2A the mean will effectively be used to screen sites as it is on the balance of probabilities is the land contaminated with some reference to the uncertainty. As we already have guidance on this from CLAIRE Bone of the sponsors of this project) I do not understand why a whole new can of worms is being opened nor what will happen to the CLAIRE guidance if there is a change to this and it is outside the scope of the C4SL project. Sadly the reasoning behing the possible change was not explained at the meeting.	5		1	The research contractors own reviewer pointed out the shortfall of distilling a dataset down to a measure of central tendency; statistics (whether spatial or non spatial) has a very limited role.
ADDITIONAL COMMENTS			My enduring concern is that we are still using conservatism to compensate for the gaps in our scientific understanding rather than focussing on reducing the uncertainty at every stage.		The Defra revised Part 2A Statuory Guidance was initially rejected by the Government's Regulatory Committee as any changes to rgeulatory practice would only be approved if it could be demonstrated that its introduction would result in an acievable financia benefit. The coospt of the C4SVs was introduced as a level higher than the SGV/GAC minimal risk levels whose application was assumed to result in considerable "unnecessary" remediation. The savings which it was estimated would be made by their introduction and application to the Part 2A procss was understood to be £140 per annum. In the current general circumstances with severe reductions to local authrotiy funding and resouces available for application to regulatory action in this area it is inconcievable that this is capable of being achieved. The process of development of the C4SVs is difficult because there is no other quantative definition what they are intended to achieve and what national policy on acceptable risk will allow. There is confusion about whether it is intended that these values should be applied to the Planning process. This will be strongly resisted by the regulatory		The LLTC approach has not been properly set out. It needs to be applicable to any substances and as such needs to be properly defined to enable consistency. It currently appears to be arbitrary.				The research contractor reluctance to recognise their work must be applicable under the NPPF is worrying.
							There appears to be no opportunity to comment on Cadmium				Relying on COC documents that are marked as do not cite and as not necessarily representing the views of the COC is worrying.
							The statistics appears to be outside the scope of works.				The robustness of the numerical processing (especially the use of an in house analogue of Monte Carlo sampling) is unproven.
							The comparison with background in soil and elsewhere is really a separate test under Part 2A.				The desire to get stakeholder basis for toxicological policy is worrying; the researchers are asking for us to give them a green light to deviate from long held UK policy without having the consensus of the relevant expert bodies.
							The comparison with background in soil should look at mean as well as 95% tile as we note that the statistics proposed by BGS are very different to elsewhere.. (any single sample exceeding means assume not vackground.				
							Consider comparing the vegetable concentrations with FSA levels.				
							The attached the Bap absorption.				
							(It is hard to comment on a lot of the work when nothing is written down.)				

Defra Research Project SP1010

Development of Category 4 Screening Levels
Stakeholder Workshop 3

STAKEHOLDER WORKSHOP 3 FEEDBACK

Introduction

As part of Defra Research Project SP1010 – Development of Category 4 Screening Levels, there was a requirement to hold three stakeholder workshops. This is a summary of the results from Stakeholder Workshop 3.

The workshop consisted of technical presentations on the finalised methodology as well as the draft proposed C4SLs for arsenic, lead, chromium (VI) and benzene. After each substance-specific presentation there was opportunity to ask questions about it and at the end of the afternoon there was further discussion of the overall project. Detailed below is a summary of the discussions had at the workshop (Appendix 1) and further individual feedback that was received after the event (Appendix 2).

APPENDIX 1 – NOTES FROM WORKSHOP

Notes from the C4SL Stakeholder Workshop 3 – May 2nd 2013 for the Development of Category 4 Screening Levels for Assessment of Land Affected by Contamination

Welcome and House Keeping

Nicola Harries (CL:AIRE) provided the welcome to the stakeholders and housekeeping.

Chair's Introduction

Steve Moreby (SM) provided an introduction to the event, encouraging attendees that this was their opportunity to have their say and to have an open and frank discussion with the presenters about the research project. He explained that this was an opportunity for the stakeholders to ask for clarification on parts that were not clear and reminded people that there is nothing to be gained from holding back.

SM explained the format for the day and that there was going to be plenty of opportunity for discussion.

Defra's Comments

Morwenna Carrington (MC) provided an update on the C4SL project from Defra's perspective and described the process once the research project has been delivered in final draft format from the research contractors.

Overview of Research Findings and Methodology

Mike Quint (MQ) provided an overview of the research project, the different stages of the project and the original scope of what the research contractors were asked to deliver on. He explained the level of stakeholder feedback and engagement the project has had at every stage and the wide spectrum of groups and organisations that had been invited to engage.

The remainder of the day was given to presentations of the remaining four substances, Arsenic, Benzene, Chromium VI and Lead with question and answer sessions after each substance.

Arsenic

Camilla Pease presented a full review of the toxicological evaluation covering 3 health effects (skin, lung and bladder cancer) for arsenic and Simon Firth presented the exposure modelling and proposed draft C4SL values.

Discussion

There appeared to be consensus for the LLTC oral value **0.3 µg kg^{-1} bw day^{-1}** seemed a sensible choice, on the basis that it represents:

- BMDL0.5 (lowest estimations) with a CSM of 10

- BMD1 (average estimations of intake) with a CSM of 30

- equivalent to the intake based on the UK drinking water standard (10 µg dL^{-1}), therefore does not disproportionately target the soil

- equivalent to the HCV (EA 2009)
- equivalent to an ELCR of 5 in 10000

There was a discussion as to whether the DWS is overly conservative. Based upon weighing up all of these factors (scientific and policy), going higher than this value (which is also the HCV) in this instance would not be recommended. This indicates that the HCV is already at a level of low concern and not minimal risk.

The 2009 HCV was principally based upon a policy choice (ie a level that is equivalent to the UK drinking water standard), however, using the scientific data from the recent WHO 2011 evaluation, the science supports this value as being 'low concern'.

There was a request whether the Steering Group comments made on the reports will also be published. Defra to consider this request.

Discussion was had regarding the ease of reproducibility of deriving LLTCs if companies did not have in-house toxicologists. It is known that there are not many toxicologists working in this field. It was asked whether there were some simple lessons that have been learnt that are generic principles. The consortium do aim to include suggestions for generic criteria (eg choices of BMDs margins etc) within the final report, but responded that these were not only scientific choices but policy choices based on societal acceptability, so it should be the role of government to endorse any generic 'criteria' that could be applied to the generic structure of the toxicological framework.

It was also explained that there is the option to just allow an increase of exposure to represent a low risk C4SL, but to do this without a description of the toxicological context could be dangerous, as the dose response curves for different chemicals can be hugely different, and a small increase of exposure for a chemical can lead to a significant increase in toxicological concern and thus concomitant increase in risk. Therefore, it is important to know where you sit on the toxicology dose response, at different levels of exposure in a substance specific way.

Benzene

Sarah Bull presented the full toxicological evaluation for benzene and Ed Stutt presented the exposure modelling and proposed draft C4SL values.

Discussion on Benzene

Public Health England reminded the stakeholders that the work being presented is first and foremost a research project and the consortium is presenting the results of the trial to see how the methodology and approach works against 6 different substances. The toxicological framework is being presented to the Committee of Toxicology shortly and then further internal conversations within government departments and government agencies will be had on the findings of the research. It is important for the stakeholders to let this process occur.

With respect to the exposure modelling presentation, the retention of the Johnson and Ettinger model was questioned when it is known to over-estimate vapour intrusion as it is based on US style buildings. This was acknowledged but the consortium are developing screening values and therefore alternative modelling approaches should be reserved for detailed quantitative risk assessments. The screening value that the consortium needs to consider should be protective for the vast majority of the UK housing stock and therefore it was felt a more precautionary approach should be taken; this approach was endorsed by a number of stakeholders present.

From the presentations on probability of exceeding the LLTC, it shows that for benzene that there are large uncertainties in determining the probability of exceedence and therefore this is difficult to quantify. The consortium was interested in how this should be communicated in the final report.

General Discussion

There was a request as to whether the Monte Carlo analysis spreadsheets are going to be made available for others to use? The consortium will discuss with Defra if an example spreadsheet could be released, however it was not part of the research outputs to make all the spreadsheets available.

Was synergism considered when developing C4SLs? It will be noted within the final report that the potential for synergistic interactions between contaminants should be considered by risk assessors and we will refer to the discussion of the issue in SR2. It was important to remember that the project is about developing generic screening levels (cf, SGVs) and specific issues such as synergism should be covered when carrying out detailed risk assessment.

Will a revised CLEA model be issued? It was confirmed that the consortium had used CLEA 1.06 and manually changed exposure parameters, therefore an example paper spreadsheet may be provided but this will be discussed with Defra and the Environment Agency.

Are the proposed C4SL values going to be used in planning? Will local authorities be comfortable with the principles that the proposed C4SLs are above minimal risk?

It will be up to local authorities to decide, however one local authority confirmed that they would be content if it can be demonstrated that the right study has been chosen to determine LLTC and could demonstrate that the screening value was appropriate.

There were questions on whether the framework being presented was generic enough for non-toxicologists to follow especially as most consultants don't have in-house toxicologists. It was pointed out that DQRA should not be undertaken by non specialists anyway and that toxicology is an inherent part of the risk-based approach to decision-making required by the Statutory Guidance. Some members of the audience specifically mentioned the necessity of having qualified toxicologists involved in the process of deriving HCVs/C4SLs.

What will happen with the development of further C4SLs? Who will undertake this work? Is there an assumption that industry would undertake this work collectively as before, is there the appetite? This would be discussed with DEFRA.

The presentations so far have provided ranges of LLTC and proposed C4SLs (pC4SLs), is this how they are going to be presented in the final report? Will actual numbers be presented? The consortium confirmed that the steering group has encouraged the consortium to present ranges and make suggestions for LLTC and pC4SLs if possible, however as it is a research project and for some substances policy decisions need to be made this may not be possible for all substances.

Chromium VI

Sarah Bull presented the toxicological evaluation for Chromium VI and Ed Stutt presented the exposure modelling and proposed draft C4SL values.

Discussion on Chromium VI

With the presentation of a range of LLTC values, would the consortium always be advocating using the lower number? This will be discussed with Defra.

Has the modelling added exposure pathways together? Not in this case, because the toxicological effects are localised. Points about combining routes of exposure based upon the nature of the health effects will be included in the reports.

Lead

Camilla Pease presented the full toxicological evaluation for Lead covering 3 overlapping health effects (neurobehavioural effects, systolic blood pressure lowering effects and kidney effects) and Simon Firth presented the exposure modelling and proposed draft C4SL values.

Discussion on Lead

In the biokinetic modelling why did the consortium consider dietary effects? The consortium explained that the LLTC is based on the estimated dietary intake (in the studies from Lanphear *et al.* 2005) that would lead to the various blood lead target levels. An oral RBA of 60% has been used in CLEA to account for the relative bioavailability between soil and dust ingestion vs oral dietary exposure.

What will happen to the WHO Drinking Water Standard at 10 µg/l if there is no safe threshold value for Lead ? This is obviously providing a much higher dose than indicated, should be allowed? This is the same for Arsenic as well. WHO have to develop worldwide values that are achievable. The consortium replied, that this is a matter for the relevant government departments to address.

What is the impact on the population with higher values of Lead in their diet? There are now studies in the US suggesting high Lead levels > 1 µg dL^{-1} leads to a significant drop in IQ. Therefore the level of Lead in the environment will be determined to what is socially acceptable as the science is suggesting that very low levels ie < 5 µg dL^{-1} has more broad spectrum health effects.

What will happen to sites that have already been cleaned up to between 5-700 ppm? It should be noted that there is still lots of uncertainty and further avenues for refinement in the lead risk assessment, but furthermore detailed and resource intensive work needs to be performed to implement refinements or derive new data that can better inform a risk assessment that could be closer to reality.

It is important to understand what a 1 point drop in IQ levels across society really means. This needs to be taken in a broader context and taking into consideration other factors such as poverty etc. This needs to be considered on a political context. Authoritative statements at the moment (eg from EFSA, WHO etc) indicate that a 1 point drop in IQ at a population level is socio and economically significant.

Ultimately it will be a policy decision across a number of government agencies and departments that will decide what Lead levels will be acceptable.

WRAP UP

Do not underestimate the need for specialist input with regard to toxicological aspects for deriving C4SL values or undertaking land contamination risk assessment on a site-specific basis.

What happens now?

The toxicological framework will be peer reviewed by the Committee of Toxicologists (CoT) and the notes from this meeting will be published in due course. A number of questions have been proposed to the CoT including views on the toxicological framework and the term Low Level of Toxicological Concern (LLTC).

Workshop delegates will be kept informed of the projects progress.

All stakeholders were encouraged to provide comments and thoughts on the presentations that were given by the consortium and the discussions that had occurred at the stakeholder workshop. The stakeholders were asked to provide comments by 17th May 2013.

APPENDIX 2 – SUMMARY RESULTS OF THE QUESTIONNAIRE

Individual Stakeholder Feedback

Respondent 1

Following the third Stakeholder Workshop we have had a meeting of the EIC Part 2A sub-group, which was attended by eight members, to discuss the progress of the C4SL project to date and the latest proposals as presented at the Workshop on 2 May 2013 in particular. I have also solicited written comments from additional EIC members who could not attend the sub-group meeting. Owing to the diverse membership of the EIC there are opposing views regarding some issues surrounding the project. The following bullet points attempt to summarise the general feelings of the group and are provided as the requested feedback to the final Stakeholder Workshop.

General Comments on Project

· All but one member at the sub-group meeting thought that the C4SLs were needed for Part 2A.

· Support for the issues raised within the SiLC Letter to Defra was expressed by some members.

· A member questioned the graph which is widely used by Defra and the Project Team (reproduced on slide 9 of the presentation) and requested that justification for the amount of land included at each risk level be provided to support its continued use.

· A majority of members felt that the C4SLs would be applicable to planning as long as their use was justified on a site specific basis.

· There was a concern that some of the pC4SL derived for the POS scenarios (especially POS_{park}) could be straying into the region where acute risk could become an important consideration. Clarification was requested to confirm if acute exposure had been included in the other considerations used in the C4SL Evaluation Process (steps 6a-d). Details of how acute exposure has been used in this process should be included in the final reporting. Concern was also expressed that some POS pC4SL (based on a child receptor) are greater than those proposed for commercial land uses (based on an adult receptor).

· It is requested that as much clarity as possible is provided by Defra and/or the Project Team about how the C4SL should/can be used and how they link with policy, planning guidance etc.

· It is requested that the final report is fully transparent and includes justification for each of the choices that have been made by the Project Team.

· It is requested that Defra and the Project Team continue to engage the stakeholder community and release a timetable for peer review and final publication of the report.

· It is requested that any ‘generic’ methods that can be used for the derivation of LLTC are included in the report. Derivation of LLTC is seen as a significant hurdle in the application of the method and production of further C4SL for additional substances. General rules about the derivation of LLTC would be welcomed.

· There is concern that there is inconsistency between the outdoor Soil Ingestion Frequency & Dermal Contact Frequency. Amending the Outdoor Dermal exposure frequency from 365 to 170 has been accepted; but amending the Outdoor Ingestion exposure frequency from 365 to 170 has been rejected. Since the CLEA software models indoor and outdoor ingestion as a single pathway this amendment was to be implemented by producing a time weighted soil and dust ingestion rate of 80mg/kg. It is stated that the amendment was rejected due to ’some felt tracking back of soil could be higher in winter months’ but this ‘feeling’ appears to be contrary to the findings of the mass balance studies from which ingestion rates are estimated from such as Van Wijnen et al. Justification is requested regarding the ingestion of soils (with reference to the Outdoor Ingestion Frequency used)that are not touched (with reference to the Outdoor Dermal Frequency).

· The use of central tendencies in the modelling of exposure was discussed. While it is claimed that central tendencies are not protective of a proportion of the population, it is worth noting that we are dealing with chronic exposure modelling and so the exposure parameters are meant to estimate 'average daily intake' over the exposure period. Is it really likely that an individual will exhibit 90%ile intakes each and every of the 365 days for 6 years of exposure? Or that some days it will be lower and some days it will be higher, normalising out over longer time periods (2190 exposure days for residential landuse) towards a central tendency for pretty much all individuals.

Contaminant Specific Comments
Benzo(a)pyrene

· Clarification is requested regarding the commercial pC4SL for BaP with only exposure changes. The pC4SL increases from 14mg/kg to 36mg/kg, however the only changes to the commercial land use are those relating to updating the vapour inhalation rates which should result in a decrease in the pC4SL with only exposure changes.

· The majority of sub-group meeting attendees felt comfortable with the proposed level of residential pC4SL for BaP. This is backed up by experience of DQRA on sites and previous discussions with regulators. None of the sub-group meeting participants were overly concerned with the levels of the pC4Sl for BaP.

Arsenic

· The group was in agreement with the level of the LLTC oral for arsenic as it is in line with the Drinking Water Standard associated with direct ingestion. However, it was considered that there could be a danger in setting a precedent as it is understood that this LLTC relates to an ELCR of 1 in 2,000. Further justification will be needed for this LLTC so that an ELCR of 1 in 2,000 does not become an acceptable level to set LLTC for other substances.

Lead

· Concern was expressed over the level of the pC4SL for lead and the potential implications. It was considered necessary to comment in the report about the form of lead and the assumed bioavailability used in the modelling. The example of the Environment Agency production of SGVs for various forms of mercury was used as an example of how this may potentially be applied to lead.

· It is not clear why background exposure has been included in the derivation of pC4SL for lead as non-threshold toxicity endpoints have been used in the derivation of the LLTC. Further clarification is requested in the final report if pC4SL using background exposure are used.

· An assessment of the biokinetic modelling used to convert blood lead levels to dose is requested to ensure that the models are based on appropriate and up to date data.

· There is a need to understand the potential implications of publishing a residential C4Sl of 40mg/kg for lead and what the consequences will be. It is requested that Defra / the Project Team sign post routes to DQRA for lead to assist with screening in this instance.

· It is felt that additional research into the toxicity associated with the various forms of lead in soil would be beneficial, though it is understood that this is not within the scope of this project.

Respondent 2

Following on from the last workshop, I would like to provide feedback to the steering group. The workshop was helpful with the overview of findings and detailed evaluation of individual substances. As anticipated when tackling a range of substances a range of different issues arose, which hinder developing a consistent approach for all substances. It appeared evident that there was an underlying concern with the approach, however this may largely reflect the approach involving external stakeholders. The technical toxicological detail did start to loose me and I would need time to develop a greater understanding to comment on which point of departure, BMR or BMDL10, BMDL5 or BMDL20 was the best approach. Whilst I have a healthy understanding of substance concentrations in the industrial and urban environment, plus remediation work with earthworks contractors, I still wonder on the appropriateness of including POS for residential and/or parks.

The presentations on substances were helpful, however the subtle differences not only between organic and inorganic substances, but differences between them outline that there cannot be a consistent approach with a one size fits all. I also reflect on two points:-

1] an early Workshop 3 slide that identifies C4SLs as a level of risk that whilst above "minimal" is still low. The associated graphic identified it within the category 4 level and not a differentiator between cat 3 and cat 4; and

2] the use of derived values may, as DEFRA pointed out, be available for use within the Planning regime.

Whilst I do not disagree with above points, I am concerned that the development of especially POS values either as residential open space or parks typeset open space can have values that are particularly elevated and as indicated at the conference for VOCs, SVOCs or even TPHs this will allow some pretty smelly or oily soil to be used that can be detrimental to amenity or even pollution of controlled waters. I fear if these are just allowed into the Planning Arena the impact on controlled waters could be detrimental and am mindful that many sites would not have undertaken individual P20 assessments to qualify appropriate remediation levels. I appreciate the same can be said with some of the commercial values, however with wide variations in concentrations for PoS in As, Cr VI (parks), Pb (parks) and As, I ask the steering group whether PoS is a category that should be developed and used. I agree that PoS residential may have a place with certain substances not populated, however am of the view that it would be simpler to not include PoS at all.

Again I am also uncertain how the guidance can be issued as consistent advice unless the information is provided as substance specific, which means varied parameters will be used across the substances.

On a positive note, I do see how the review and provision of data will enable the community to use this information (with input from toxicological advice) more consistently when developing C3GAC or SSAC.

Apologies my comments are generic, however on this occasion I have not been provided with a work sheet seekingspecific comments. I attach a spreadsheet that I quickly prepared, as I sought to try and succinctly potray the information that I could assimilate a little more easily. The Steering Group may choose to consider a similar approach with summary documents when undertaking wider consultation.

I missed the opportunity last time of commenting on Cd & BaP, however in respect of As, I do not think it will make a great deal of difference whichever inhalation LLTC is adopted. With regard to lead the use of 1.6ug/dL will lead to incredibly low values, I favour 3.5 or 5.0ug/dL, probably 5.0ug/dL with exposure parameters with an option to use with or without background quality. With other substances I am of the view that the steering group should consider which is the more consistent approach. In consideration that the resultant values will remain within Cat 4, pity may be more appropriate to be conservative if the methodology and purpose for developing C3 GAC/SSAC can be more readily realised.

Respondent 3

Thank you very much for the excellent work you are doing.

Following on from the workshop my personal feedback is as follows bearing in mind my experience in London Borough of Camden as a representative London borough:

I apologise for not having made contact with the London grouping but I have only been in the office 2 days since the work shop so if I can submit some draft comments first then Hopefully I won't miss the boat.

1. Policy Q1 : I realise the project is walking a tight line between acceptable risk for planning (ie the LQM conservative approach) and the C4SL can you ensure that documentation will be clear that a site where the level of contamination exceeds the c4sl level may still be regarded by the regulator as being with category 4

2. Policy Q2: Given the pressure from the engineers to have a formula they can role out (god help us) then I would try and turn this into a separate part of the overarching framework that revisits the options for the various BMD's and the use of the L and none L measure. This might be a really good place to dust off the work done as part of WS2 where u considered the potential range of Endpoints. You could have a Matrix of decision and grid them off in according to recklessness of the combination

	BMDL	BMD
BMD10	Y	Y/?
BMD15	?	?
BMD20	?/X	X/?

X/?= (part2a)

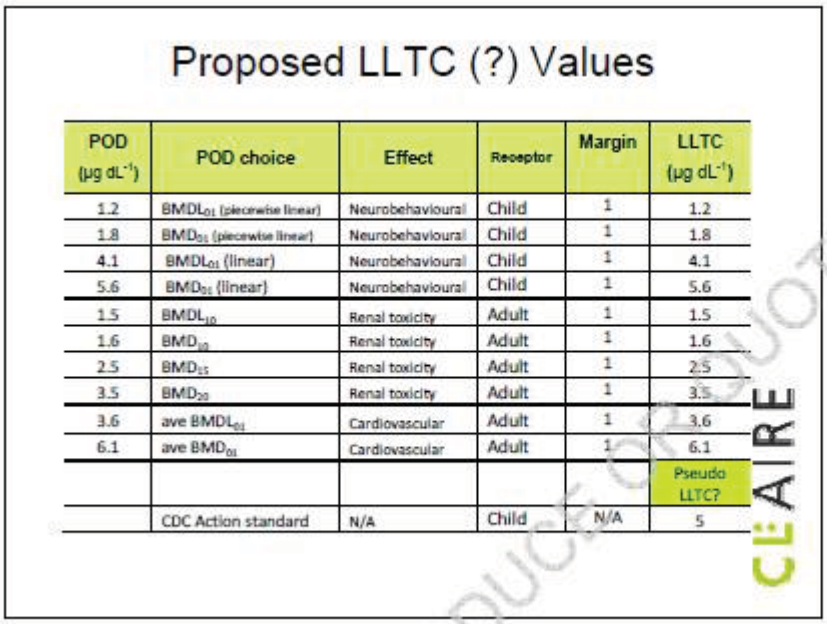
You could then make a firm recommendation of a reasonable set of tox parameters that can be used as a generic relaxation by the man on the Clapham omnibus. Eg reducing the 10,000 to 50,000 etc.. However, I would reiterate the various checks that need to be carried out before this is done

- Animal data not human..
- Review of the health endpoints shows no significant overlapping effects
- Review of the site chemistry and make up of the chemical contam's- does not show common target organs in the body affected by multiple contaminants using the same pathway- in the same physical parts of the site. (eg Benzene and toluene both impacting lungs)

I think the advantage of the ground setting before the stating of the rules would be that this might show people the potential way forward on the types of decision that can be made within Part 2A- it would also discourage none expert people using the data cloud idea to just make a judgement on numbers alone without considering the toxicological context of what they are doing.

3. Lead: Much as I would normally ask that you think really hard about the LLTC- I can see that within the framework of a conventional literature review of a tox report that for nephritic damage you have pushed the endpoint of 3.5ug/dl as far as you can go <u>without fundamentally answering</u> the question of "so what does this elevated creatinin mean- and how much is actually harmfull"- It strikes me that there is a real issue here for the metropolitan districts where we have commonly got elevated lead levels of 500ppm+ and that some much better resourced consideration of lead needs to be done… or that there should be a single one off exercise like Who have done for noise and one set of lead numbers could be offered as a policy decision. Eg if lead > 300- for planning = remove the risks lead <1500ppm = acceptable risk for society- >1250 not sposh but like EA and water there should be plans in

place to improve the local environment and LA may carry out more detailed assessments to identify a sposh level.. (I am rambling now)



Proposed LLTC (?) Values

POD ($\mu g\ dL^{-1}$)	POD choice	Effect	Receptor	Margin	LLTC ($\mu g\ dL^{-1}$)
1.2	$BMDL_{01}$ (piecewise linear)	Neurobehavioural	Child	1	1.2
1.8	BMD_{01} (piecewise linear)	Neurobehavioural	Child	1	1.8
4.1	$BMDL_{01}$ (linear)	Neurobehavioural	Child	1	4.1
5.6	BMD_{01} (linear)	Neurobehavioural	Child	1	5.6
1.5	$BMDL_{10}$	Renal toxicity	Adult	1	1.5
1.6	BMD_{10}	Renal toxicity	Adult	1	1.6
2.5	BMD_{15}	Renal toxicity	Adult	1	2.5
3.5	BMD_{20}	Renal toxicity	Adult	1	3.5
3.6	ave $BMDL_{01}$	Cardiovascular	Adult	1	3.6
6.1	ave BMD_{01}	Cardiovascular	Adult	1	6.1
					Pseudo LLTC?
	CDC Action standard	N/A	Child	N/A	5

Respondent 4

For the timescales allowed, the amount of good work that has gone into this project is impressive. I have the following comments to make:

1.Exposure scenarios

The exposure scenarios seem to be well thought out and have in the main stayed reasonably conservative.

The changes appear to be relatively minor overall.

Changing inhalation rates is eminently sensible.

·Dermal contact is probably has changed significantly but the sensitivity study should also take that into account the importance of this pathway. As there is more conservatism in the dermal absorbed dose (measured over a 24hr period) these are probably OK.

I am comfortable with using the J-E model as there would be too much work to devise (and presumably validate) any other models. J_E is suitably conservative for screening.

I am concerned that the POS scenarios will be routinely misused, but other than clearly spell out he scenarios and where they should be applied I'm not sure what else we can do.

In terms of splitting inhalation and ingestion for some contaminants I assume that this is justified in the toxicology section with the exposure being based on local effects.

2.Toxicology

I think a lot of work has gone into the toxicology assessment, and based on the presentations it appears to be scientifically based.

I have concerns about the changes from minimal risk to LLTC and the degree of professional judgement involved, but this is really related to setting policy rather than the actual approach.

I am pleased and would like the group/DEFRA to ensure the approach is taken to the toxicology committee to confirm the approach is considered valid and to advice on adopting the policy and any specific concerns they have on this. I hope their feedback is included with the final document. **I believe this is IMPORTANT and would make me more comfortable with the LLTC's use.**

3.Stats and usage

In terms of use of the numbers I wondered if it was worth making a comment on the contaminants being assumed to be in fines for ingestion and dermal contact. (we have had cases of about double the concentration of arsenic and BaP in fines in soil before as well as the reverse.

would say that the stats applied to these values is probably outside the scope of original remit and is probably best left for the moment. There are a whole load of issues about zoning/ dividing data and what has been measured, before we get involved in the statistical test chosen which are more significant in terms of impact that the actual test.

4. Specific substances

a. Arsenic

For benzo(a)pyrene there was a mechanistic reason for lifetime cancer doses not to be considered. It would be worth comment the same for arsenic if this is true. I am comfortable with using the Drinking water standard as per the SGV as it is consistent with the SR2 guidance and the SGV decision and the Part 2A guidance on category 4.

b.Chromium VI

My only real comment here is that I know dermal contact can pose a specific local effects and wondered if it was worth referring to that and making sure that you are nowhere near?

In relation to uncertainty in the ingestion tox data, it's probably worth emphasising that the final value appears to relate to inhalation only

c.Lead

I have the following comments which I hope may add to the document.

Policy and drinking water

Once I have my units right, the lead threshold in drinking water is lower than that derived in the LLTCs, so there is not an effect of overburdening soil.

Use of IQ

In relation to toxicology the previous comments were all in relation to a BMDL10 for carcinogenicity. IQ is clearly a very different effect, thus there may be room to review a BMDL1% based on a change in IQ in terms of significance.

I note that JECFA in 2010 (http://www.who.int/foodsafety/publications/chem/summary73.pdf) indicate that:

Based on the dose–response analyses, the Committee estimated that the previously established PTWI of 25 µg/kg body weight is associated with a decrease of at least 3 intelligence quotient (IQ) points in children and an increase in systolic blood pressure of approximately 3 mmHg (0.4 kPa) in adults. ***While such effects may be insignificant at the individual level***, **these changes are important when viewed as a shift in the distribution of IQ or blood pressure within a population**

It may be worth considering in relation to category 4 Screening levels, where a tox value that is "insignificant at an individual level" sits in relation to a threshold that poses significant possibility of significant harm and whether that gap is low enough to be cat 4. It may help support the use of the higher tox thresholds.

Lead in diet

A comment made in relation to diet was that diet is small compared to the thresholds used. This seems a fussy point but the implications of the dietary intake will impact on the reasonableness of LLTCs selected as we don't want to disproportionately clean up soil compared to food.

When I went to check this I noted there appears to be a significant difference between the Food Standards Agency total diet study which indicates that in adults the exposure is in the range 0.09 and 0.1ug/kgbw/day for mean and 0.17-0.18ug/kgbw/day for high end and EFSA which indicates in the UK adults have a mean intake in the range 0.43 to 0.57ug/kgbw/day and .44 to .92 for women of child bearing age. (there is no data in children in the UK in the EFSA paper). (The range for children's diet

in the EFSA report is aged 1 to 3 years mean lead dietary exposure estimates range from 1.10 to 3.10 µg/kg b.w. per day based on lower bound and upper bound assumptions, respectively; for high consumers, lead exposure estimates range from 1.71 to 5.51 µg/kg b.w. per day, respectively. (Tables and references are below)

The differences probably relate to different sources for the lead content in each dietary product as EFSA pooled data from across Europe on the basis of transborder trade. This seems not unreasonable and I am not aware that the UK applies a high level of lead in food to elsewhere in the Europe or of restrictions on food transfer due to lead. **There would be value in the group using the steering panel's expertise to understand where this difference arises as the EFSA data appears to indicate that there is a significant effect of lead in food on people already and placing a greater onus on soil than on food may be disproportionate or if the EFSA is at a more extreme end of the UK diet spectrum to at least to reflect the uncertainty in the dietary intake.**

Table 4b. Estimated total dietary exposure to cadmium, chromium, copper, germanium, indium and lead from the 2006 Total Diet Study

Population Group	Estimated dietary exposure (µg/kilogram bodyweight/day) [1-3]											
	Cd		Cr		Cu		Ge		In		Pb	
	Mean	High-level	Mean	High-level	Mean	High-level	Mean	High-level	Mean	High-level	Mean	High-level
Adults	0.14 - 0.17	0.25 - 0.29	0.28 - 0.37	0.50 - 0.62	17.23	34.47	0.001 - 0.018	0.002 - 0.033	0.06 - 0.24	0.22 - 0.47	0.09 - 0.10	0.17 - 0.18
Toddlers (1.5-4.5 years)	0.37 - 0.45	0.65 - 0.75	0.81 - 1.03	1.38 - 1.67	44.71	77.82	0.002 - 0.053	0.006 - 0.085	0.24 - 0.75	0.93 - 1.48	0.21 - 0.25	0.38 - 0.42
Young people (4-18 years)	0.27 - 0.31	0.50 - 0.57	0.51 - 0.65	1.03 - 1.22	29.41	54.92	0.001 - 0.032	0.004 - 0.058	0.13 - 0.44	0.51 - 0.97	0.13 - 0.15	0.26 - 0.30
Elderly (free...	0.13	0.26	0.25	0.48			0.001	0.002	0.05	0.25	0.08	0.16

January 2009

MEASUREMENT OF THE CONCENTRATIONS OF METALS AND OTHER ELEMENTS FROM THE 2006 UK TOTAL DIET STUDY

Reference: TDS 2006

Table 27: Lower (LB), middle (MB) and upper (UB) bound mean and 95th percentile (P95) lead dietary exposure in adults in µg/kg b.w. per day.

Country	Survey	N	Mean			P95		
			LB	MB	UB	LB	MB	UB
Belgium	Diet National 2004	1,304	0.44	0.51	0.58	0.79	0.92	1.04
Czech Republic	SISP04	1,666	0.51	0.58	0.65	0.84	0.96	1.09
Denmark	Danish Dietary Survey	2,822	0.50	0.58	0.65	0.79	0.90	1.02
Finland	FINDIET 2007	1,575	0.47	0.54	0.60	0.81	0.92	1.01
France	INCA2	2,276	0.39	0.46	0.53	0.70	0.79	0.89
Germany	National Nutrition Survey II	10,419	0.42	0.49	0.56	0.74	0.85	0.97
Hungary	National Repr Surv	1,074	0.34	0.40	0.46	0.56	0.65	0.74
Ireland	NSIFCS	958	0.43	0.52	0.61	0.71	0.90	1.05
Italy	INRAN SCAI 2005/06	2,313	0.38	0.45	0.53	0.71	0.81	0.91
Latvia	EFSA TEST	1,306	0.35	0.41	0.46	0.63	0.71	0.82
Netherlands	DNFCS 2003	750	0.49	0.57	0.65	0.83	0.99	1.16
Spain	AESAN	410	0.51	0.59	0.67	0.61	0.76	0.89
Spain	AESAN FIAB	981	0.35	0.44	0.53	0.57	0.70	0.84
Sweden	Riksmaten 1997/98	1,210	0.42	0.49	0.55	0.65	0.75	0.85
United Kingdom	NDNS	1,724	0.43	0.50	0.57	0.72	0.83	0.96
Minimum			**0.34**	**0.40**	**0.46**	**0.56**	**0.65**	**0.74**
Median			**0.43**	**0.50**	**0.57**	**0.71**	**0.83**	**0.96**
Maximum			**0.51**	**0.59**	**0.67**	**0.84**	**0.99**	**1.16**

Reference: EFSA

Table 28: Total dietary exposure to lead (µg/kg b.w. per day) for average (Mean) and 95th percentile (P95) females aged between 20 and 40 years across a number of subjects in European countries using the lower (and upper bound lead concentrations.

Country	N	Mean LB	Mean UB	P95 LB	P95 UB
AT	725	0.58	1.05	1.03	1.77
BE	220	0.44	0.92	0.69	1.54
BG	190	0.42	0.76	0.77	1.48
CZ	313	0.50	0.90	0.82	1.51
DE	965	0.80	1.28	2.03	2.60
DK	742	0.56	1.07	0.86	1.65
EE	622	0.38	0.64	0.68	1.13
FI	411	0.60	0.93	1.11	1.53
FR	328	0.52	1.00	0.75	1.47
GB	459	0.44	0.92	0.72	1.49
HU	212	0.51	0.92	0.76	1.31
IE	368	0.59	1.07	1.06	1.87
IS	269	0.56	1.07	1.13	1.79
IT	420	0.54	0.95	0.84	1.39
NL	1,080	0.51	0.95	0.81	1.49
NO	593	0.48	1.07	0.78	1.90
PL	591	0.59	1.01	0.99	1.72
SE	259	0.46	0.82	0.86	1.43
SK	626	0.38	0.76	0.70	1.51
Minimum		0.38	0.64	0.68	1.13
Median		0.51	0.95	0.82	1.51
Maximum		0.80	1.28	2.03	2.60

AT: Austria; BE: Belgium; BG: Bulgaria; CZ: Czechoslovakia; DE: Germany; DK: Denmark; EE: Estonia; FI: Finland; FR: France; GB: Great Britain; HU: Hungary; IE: Ireland; IS: Iceland; IT: Italy; NL: The Netherland; NO: Norway; PL: Poland; SE: Sweden; SK: Slovakia; N: number of subjects; LB: lower bound: UB: upper bound; P95: 95th percentile.

SCIENTIFIC OPINION

Scientific Opinion on Lead in Food[1]

EFSA Panel on Contaminants in the Food Chain (CONTAM)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

This Scientific Opinion, published on 22 March 2013, replaces the earlier version published on 20 April 2010[4].

Reference: EFSA

Respondent 5

Feedback – the questions might have been answered during the stakeholder meeting, so I'm only going by the slides and subsequent gossip.

General – I have no problem with transparency – I think the process has been, although at times the tox gets hard to keep up with!

Whilst the ranges have been stated, I think single values will have to be released as "the single C4SL" to make them usable for the LA's – remember that LA's have to explain in a non technical manner to the public/other stakeholders why their site is Determined or not. Ranges will make this v difficult.

The consortium will need to agree with DEFRA whether they write in WP4 that these values are for Part 2A only, or can also be used for planning. This is a policy decision, so I guess unless DEFRA make a statement then the consortium should state that these are for Part 2A.

Arsenic
Oral LLTC the lung cancer value was used – was this lung cancer from an oral study or due to some inhal? If some inhal wouldn't we be better with the bladder cancer value. The LLTC uses a ELCR of 1 in 2,000. Not happy that this is less than 1 in 10,000, but this is a policy statement. Other countries can make them – probably about time we made one as this has always caused grumblings with the HCVs.
Second policy note – what do we do if C4SL is lower than background? This implies that in mineralised areas there is some element of risk to the population. There will have to be some statement in WP4 even if its that "the relationship with NBCs is not considered and it's a policy decision!"

Benzene
ELCR as above. Wasn't there any dermal benzene work done on the old USEPA Dermal Exposure Assessment: principles and applications (it was 1992, but not sure ref number). CLEA 2002 considered skin application for volatile substances, but it was hugely sensitive and made any VOC a massive problem. If I've read the graphs right (text is a bit grainy on pdf) are we saying that the main sensitive pathway is veg on the probability of exceeding the LLTC? That's poss more a problem with veg uptake models than the C4SL LLTCs/exposure assumptions.

CR(VI) seems reasonable to call it threshold. Agree with plant uptake approach, although should we also model CrIII and amalgamate this pathway?

Lead
Agree that is not a threshold compound. Agree 5ug/dL is too high, and think that 1.6ug/dL is defensible, and the RBA of the IEUBK is quite high and probably more protective that actual bioavailability in many areas. Think that Lead will be controversial.
DEFRA could talk to the Dept of Education on IQ points. Every primary school (well everyone in Cheshire and I suspect nationwide) test their intake. There is probably a known "rule of thumb" for poverty or lack of mobility in the population. As an ex- school governor when my daughter was a primary school in a lack of mobility area (we were in-comers!) there is a definite drop shown in IQ – only a few points but clearly there. Maybe this data could be used to support the 1 (or more) IQ points. However this is again a policy decision like ELCR values.

We need an agreement from DEFRA for TOX reports (possibly after the final C4SL report)

We need policy decisions on ELCR, IQ points (so the final report can be issued)
We need a policy statement if the C4SL is less than NBC (possibly after the final C4SL).

Frankly if lead writes off big chunks of every major city we can either make a policy decision and stick lead at 820mg/kg (after all we've done this on air quality, DWS, and other countries have gone this route – ie Netherlands and PAHs), or we can stick with the science and face the consequences. After all we are specifying protection for radon after ignoring it for years. We might have to recommend not eating too many homegrown vegetables. This has precedent in smoking - Dept of Heath have campaigned for sometime to encourage adults not to smoke in front of children. Recommend that veg growing is in raised beds with clean soil, say no to guerrilla gardening, but we might need to clean up allotments. Don't think this is popular, but politically can't hurt too much as lead in petrol is now banned and this is a result of past processes.

Respondent 6

The project seems to have drifted away from responding to policy towards an unnecessary attempt to open up a policy debate. To be clear this was never intended to be simply a research project to inform future policy on toxicology but one to help implement existing policy.

Given the direction the project is now taking, I think some high level comments are most appropriate at this stage:

1. The project team should consider dropping the concept of Low Level of Toxicological Concern and base the C4SL on minimal and negligible levels of risk

2. If the project retains the LLTC concept then it needs to consider the possibility of synergy among contaminants at levels above the HCV (cf statement in SR3)

3. The principles of SR2 – including the use of benchmark dose levels and chemical specific adjustment factors – should be used to inform the derivation of relevant HCV

4. The way the IEUBK model is used to derive the proposed, potentially unworkably low, C4SL for lead should be revisited; while the toxicology may be robust the exposure assumptions seem out of kilter with broader lines of evidence in the UK. The uncertainty in the IQ and in the link of blood lead to IQ should be factored in to the decision about what toxicological value would represent a minimal risk level.

5. Full transparency of working methods, including all spreadsheets, is paramount

6. A clear statement of the applicability or otherwise of the C4SL under planning and other legal frameworks is needed

7. The project team should recognise that the policy crisis has been created entirely by its decision to abandon minimal and negligible levels of Health Criteria Values. The policy crisis is unnecessary and was not envisaged by the project brief. It will considerably delay the onset of using the C4SL and therefore slow down the anticipated cost savings.

I look forward to hearing more about the project in due course.