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Development of Category 4 Screening Levels for Assessment of Land Affected by Contamination

Policy Companion Document

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Contents

Abbreviations

BMD - Benchmark Dose

BMDL - Lower Confidence Limit of BMD

BMR - Benchmark Response

C4SL Category 4 Screening Level

CLEA - Contaminated Land Exposure Assessment

COC - Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment

COT - Committee on Toxicity

CSM - Chemical Specific Margin

Defra - Department for Environment, Food and Rural Affairs

DQRA - Detailed Quantitative Risk Assessment

EA - Environment Agency

EFSA - European Food Safety Authority

ELCR - Excess Lifetime Cancer Risk

FSA - Food Standards Agency

GAC - Generic Assessment Criteria / Criterion

GQRA - Generic Quantitative Risk Assessment

HCV - Health Criteria Value

IA - Impact Assessment

LLTC - Low Level of Toxicological Concern

LOAEL - Lowest Observed Adverse Effect Level

LOEL - Lowest Observed Effect Level

MDI - Mean Daily Intake

MOE - Margin of Exposure

NOAEL - No Observed Adverse Effect Level

NOEL - No Observed Effect Level

NRW - Natural Resources Wales

pC4SL - Provisional Category 4 Screening Level

POD - Point of Departure

SGV - Soil Guideline Value

SPOSH - Significant Possibility of Significant Harm

POLICY COMPANION DOCUMENT FOR WALES: DEVELOPMENT OF CATEGORY 4 SCREENING LEVELS FOR ASSESSMENT OF LAND AFFECTED BY CONTAMINATION

Background

1. Wales has a considerable legacy of historical land contamination from a wide range of substances. Nearly all soils have some small presence of substances that could be called 'contaminants' (for example, as a result of underlying geology or diffuse pollution). However, the sites most likely to pose an unacceptable risk almost always result from site-specific industrial pollution and waste disposal activities (for example, from the oil, gas, steel, mining and chemicals manufacturing industries, landfills and illegal chemical dumps).

Part 2A regime

2. The main legislative driver for dealing with land affected historically by contamination is Part 2A of the Environmental Protection Act 1990. Under Part 2A, land is determined as contaminated if it is deemed to be causing significant harm, or where there is a Significant Possibility of Significant Harm (SPOSH) to human health. Land can also be contaminated land where it causes, or there is a significant possibility that it will cause, significant harm to other receptors, or where it causes significant pollution of controlled waters; however human health is the focus of this document.

3. Revised Statutory Guidance to support Part 2A of the Environmental Protection Act 1990 was published in April 2012. This Guidance introduced a new four-category system for classifying land under Part 2A for cases of SPOSH to human health,[1] where Category 1 includes land where the level of risk is clearly unacceptable and Category 4 includes land where the level of risk posed is acceptably low. In relation to the four category system, land is determined as 'contaminated land' under Part 2A if it falls within Categories 1 or 2, such that the Category 2/3 border defines the point at which land is determined under the legislation. Category 3 would include sites that regulators conclude should not be

[1]See the Contaminated Land Statutory Guidance (sections 4.5 & 4.6)

http://wales.gov.uk/topics/environmentcountryside/epq/contaminatedland/guidance2012/;jsessionid=105207F9AC23B337DFCE47E6FA2B1C69?lang=en

designated as contaminated under Part 2A taking into account the broad aims of the regime as set out in Section 1 of the Statutory Guidance. These categories are illustrated by the diagram in Figure 1.

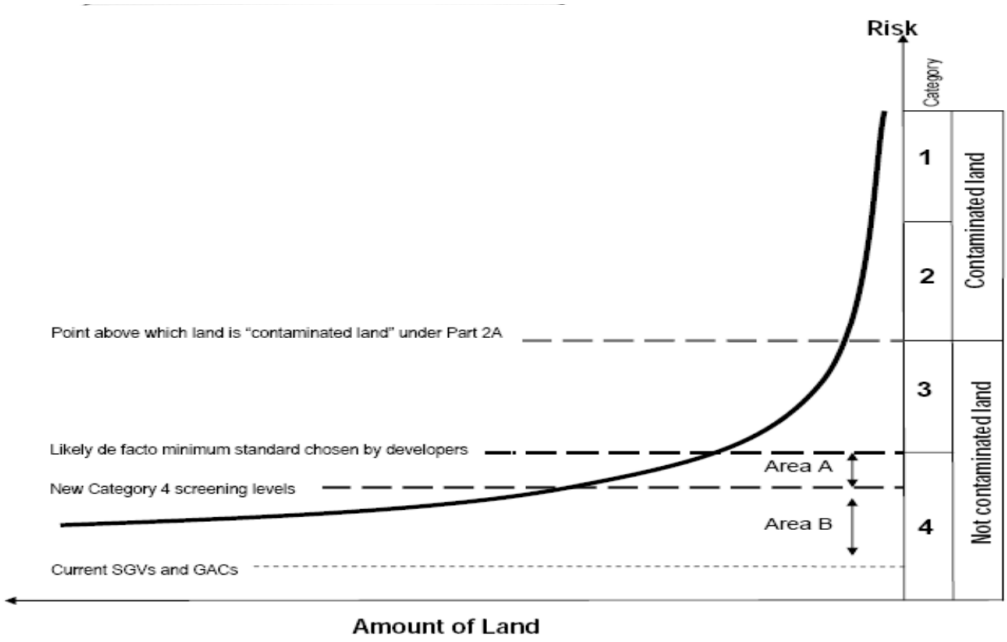

Figure 1: Summary of Category 1 – 4 system (Defra & Welsh Government Impact Assessment)

4. There is some uncertainty over the scale of health risks posed by land contamination. To date, there is little direct evidence of serious health effects from the types and levels of land contamination found in Wales. Soil can contain pollutants that are harmful to health, although it is inherently difficult to prove causality. There are good science-based reasons to be concerned that some sites could pose significant risks to health from long-term exposure.[2]

5. In light of these potential risks there is good reason to take a precautionary approach to dealing with land affected by contamination and the Welsh Government is committed to taking such an approach. This is particularly the case in relation to risks to human health where (with little evidence of actual health effects) the contaminated land regime is inherently precautionary. However, such precaution should be avoided or reduced where possible because regulatory intervention can itself have a range of negative impacts. For example:

[2] A Defra-funded research report, published in March 2010, on "Potential health effects of contaminants in soil" can be found at http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=16185

intervention can cause property blight, anxiety over possible health risks and the effects on house prices as well as high levels of inconvenience and disruption for those affected (for many months or years) whilst sites are investigated;

there is growing evidence that stress-related health impacts of regulatory intervention could outweigh any health benefits of investigating and remediating land where there is only a low/hypothetical risk (see footnote 2);

remediation can create risks if contaminants are mobilised during remediation works, there are various environmental impacts from heavy engineering works, and remediation often destroys soil or sees it dumped in landfills; and

remediation of land is also expensive and costs to individuals, businesses and the taxpayer need to be justified.

Screening values

6. Current practice during the Generic Quantitative Risk Assessment (GQRA) stage of assessing land affected by contamination is to use generic screening values. These usually take the form of risk-based Soil Guideline Values (SGVs) or other Generic Assessment Criteria (GACs) that are most typically derived using the Environment Agency's Contaminated Land Exposure Assessment (CLEA) model[3] and based on Health Criteria Values (HCVs). SGVs and supporting technical guidance were developed to assist professionals in the assessment of long-term risk to health from human exposure to chemical contamination in soil.

7. The Impact Assessment (IA) that accompanied the revised Part 2A Statutory Guidance identified a potential role for new 'Category 4 Screening Levels' (C4SLs) in providing a simple test for deciding when land is suitable for use and definitely not contaminated land. It was envisaged that these new screening levels would allow 'low-risk' land to be dismissed from the need for further risk assessment more quickly and easily, allowing regulators to focus efforts on the highest-risk land. The C4SLs were proposed to be more pragmatic (whilst still strongly precautionary) compared to existing generic screening levels. It is anticipated that, where they exist, C4SLs will be used as generic screening criteria that can be used within a GQRA, albeit describing a higher level of risk than the currently or previously available SGVs.

[3]As described in the Environment Agency's SR2, SR3 and SR7 reports (EA, 2009b & c; EA, 2008)

SP1010: The Category 4 Screening Level project

8. The project was awarded to a consortium led by *Contaminated Land: Applications in Real Environments* (CL:AIRE) and overseen by a Steering Group, which included representatives from a wide range of Government departments and agencies (Defra, DCLG, Environment Agency, the Homes & Communities Agency, Food Standards Agency, Public Health England, Welsh Government and Natural Resources Wales). The Steering Group, along with the wider contaminated land community, provided feedback to the Contractor over the course of the project. The final report, and this Policy Companion Document, do not necessarily represent the collective view of the Group. The aims of the project were three-fold:

    To produce a draft methodology for developing C4SLs

    To finalise the methodology by determining C4SLs for two test substances (cadmium and benzo(a)pyrene)

    To develop final C4SLs for four further substances (benzene, arsenic, lead and chromium VI).

    The six substances were chosen because of their ubiquity in contaminated land risk assessment and because they covered a range of exposure pathways and toxicological effects. The project specification also required C4SLs to be derived for different land uses: Residential (with and without home-grown produce), Allotments, Commercial and two alternative types of Public Open Space.

9. In commissioning this research, it was specified that the contractor was required to undertake a significant amount of stakeholder engagement throughout. Stakeholder workshops were incorporated into each of the three work packages and stakeholder feedback was taken into account in the development of the final report.

<u>Peer review</u>

10. Due to the nature of this project a significant amount of peer review was undertaken. The draft methodology was submitted to the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). On the advice of the COT, specific issues were referred to the Committee on Carcinogenicity (COC). The minutes of these meetings are available on the respective websites. The final reports in their entirety have also been reviewed by experts specialising in toxicology and risk/exposure assessment; these

comments have been published on Defra's SP1010 project pages. The consortium was given the opportunity to update the final reports in light of the peer reviewers' feedback.

Risk management decisions

11. In deriving the new C4SLs, 'risk management' (policy-based) decisions have to be taken that reflect the intended use of these new screening levels. In the final reports, the consortium has presented a range of 'provisional C4SLs (pC4SLs), demonstrating alternative values depending on the risk management decisions taken. This Policy Companion Document has been produced to provide clarity on those risk management decisions, such that a final C4SL can be presented for each contaminant and for each land use scenario. It also sets out the Welsh Government's assessment of the wider policy implications of the results of the project and should be read alongside the report itself and the Part 2A Statutory Guidance.

Consortium's approach

12. The C4SLs consist of estimates of contaminant concentrations in soil that are considered to present an 'acceptable' level of risk, within the context of Part 2A. The methodology for deriving both the previous SGVs and the new C4SLs is based on the CLEA methodology. The project suggests that the development of C4SLs Levels may be achieved in one of three ways, namely:

    by modifying the **toxicological** parameters used within CLEA (while maintaining current exposure parameters)

    by modifying the **exposure** parameters embedded within CLEA (while maintaining current toxicological 'minimal risk' interpretations), or

    By modifying **both toxicological and exposure** parameters.

13. Using the methodology described in the main report, its workability is demonstrated through six substance-specific reports providing a range of pC4SLs for each land use. The report presents details of sensitivity and probabilistic analyses that have been undertaken as part of the research in order to help illustrate some of the uncertainty present in the exposure modelling. There is also a suggested check on 'other considerations', for example, background levels, epidemiological data and sources of uncertainty.

Toxicological Assessment

14. The toxicological assessment of contaminants is a key part of land contamination risk assessment. The report recognises that such assessments are typically complex evaluations involving a significant amount of data, with different toxicity endpoints and study designs needing to be considered. **As a consequence, toxicological assessments and reviews should only be performed by a suitably qualified individual who sufficiently understands the nature of the toxicological data.**

15. The CLEA methodology relies on the availability or calculation of a HCV, which is the estimated concentration of a contaminant that would pose a tolerable or **minimal** risk to human health. In order to derive C4SLs, which are designed to reflect a more pragmatic approach to contaminated land risk assessment (albeit still strongly precautionary), the consortium has defined a new term, 'Low Level of Toxicological Concern' (LLTC), to be used in place of the HCV, which represents the estimated concentration of a contaminant that would pose a **low** risk to human health. A LLTC represents an exposure equivalent to an intake of low concern but that definitely does not approach an intake level that could be defined as causing a SPOSH to human health.

Exposure Modelling

16. Exposure modelling is an integral part of the assessment of risks to human health from soil contamination. There are two general approaches to exposure modelling:

    a. A 'forward' modelling approach can be used to predict the actual exposure at a site from measured or estimated soil concentrations. The exposure can then be combined or compared with toxicological dose-response data to characterise risk.

    b. Alternatively, a 'reverse' modelling approach can be used to estimate the theoretical soil concentration at which the estimated exposure equals some predefined toxicological benchmark.

    Both approaches can be used with the CLEA model, but it is the latter approach that is used to derive soil assessment criteria.

Risk management decisions

17. A framework for evaluating chemical-specific toxicology data for the purposes of deriving C4SLs is presented in the final report, which should be read in conjunction with the recommendations in this Policy Companion Document. The framework is provided in the form of a flowchart and is structured to guide the reader through by referring to, and providing further information on, its numbered elements. The report recommends that a suitably qualified individual (who sufficiently understands the nature of toxicological data) collates the evidence, produces a document for each substance being considered and works through the steps of the framework for each route of exposure. The framework highlights a number of risk management decisions that need to be taken when defining a LLTC and these are discussed below. For ease those elements of the flow-chart not requiring a risk management decision have not been detailed here.

Benchmark Response (BMR)

18. The first step in the derivation of any Health-Based Guidance Value is the selection of the pivotal study and identification of the 'critical endpoint' from an array of toxicity studies. This is done by reviewing all available toxicology data and identifying suitable Points of Departure (PODs) in the form of No Observed Adverse Effect Levels (NOAELs) or Lowest Observed Adverse Effect Levels (LOAELs). However, the NOAEL or LOAEL can be a highly uncertain value in some studies and as an alternative approach, a Benchmark Dose (BMD) may be derived. This is the dose that produces a predetermined change in response, the Benchmark Response (BMR), for a given toxicological effect. For risk assessment purposes, the 95% lower confidence limit of the BMD, the BMDL, is often used as the Point of Departure.

19. Elements 3(b) and 6(b) of the flowchart relate to the use of animal and human toxicology data (respectively) to derive a LLTC. These elements require a suitably qualified individual (who sufficiently understands the nature of toxicological data) to consider whether there are adequate data from the chosen pivotal study to perform BMD modelling. If there is adequate dose-effects data for the chosen pivotal study, then BMD modelling should be performed in order to provide a more quantitative interpretation of the data. A chemical-specific decision is necessary regarding the choice of % increased incidence of effect, the BMR.

20. A BMR of 10% is currently accepted as good practice in 'minimal risk' evaluations of animal carcinogenicity data given the sensitivity often seen in such datasets.

Use of a higher BMR on a generic basis was deemed too high to represent 'low concern'.

21. **Conclusion:** Based on the consortium's approach, the Welsh Government recommends the following:

> A maximum Benchmark Response of 10% should be used in relation to all types of data, unless toxicology supports the use of a higher Benchmark Response; such as when it is associated with effects that would not be considered adverse.
>
> For data from animal carcinogenicity studies, a Benchmark Response of 10% should be used.
>
> For data from human epidemiology studies with large populations, Benchmark Dose modelling should be used in preference to an Excess Lifetime Cancer Risk (ELCR), where data allow. Lower Benchmark Responses should be used as the sensitivity of the data allows.

22. This approach was also recommended for the derivation of HCVs used to produce SGVs in the Environment Agency 2009 Science Report '*Human health toxicological assessment of contaminants in soil*'[4].

Generic Margin (non-thresholded chemicals)

23. The 'margin of exposure' approach is used to indicate the level of concern in situations where exposure is unavoidable. There is no precedent set for what safety margin may constitute 'low' concern. For non-thresholded chemicals, flowchart element 5 requires the derivation of the LLTC by dividing the Point Of Departure by either a generic margin or a Chemical Specific Margin (CSM). A CSM should be defined based on a scientifically defensible rationale around the uncertainties in the toxicological data and with the use of expert judgement.

24. If robust data are not available on which to make an informed decision on how to derive a CSM, then a default generic margin should be used. This yields a fixed value based upon the uncertainties in the toxicology data for the pivotal study on which the Point Of Departure is based.

[4] http://www.environment-agency.gov.uk/static/documents/Research/TOX_guidance_report_-_final.pdf

25. The Committee on Carcinogenicity (COC, 2012) proposed that a suitable margin might be 10,000 as applied to a $BMDL_{10}$ derived from an animal carcinogenicity study, for minimal risk or is 'unlikely to be of concern' (COC 2012). The European Food Standards Agency (EFSA) Scientific Committee (2005) also considered this generic figure of 10,000 for a Margin of Exposure (MOE) with a $BMDL_{10}$ from an animal study (which parallels the COC-proposed margin approach) (EFSA 2005). Similarly, SR2 (Science Report 2) mentioned the application of a factor of 10,000 to a $BMDL_{10}$ as representing minimal risk (EA, 2009b).

26. One suggestion proposed in the report is that a generic margin of 5,000 could constitute 'low concern' when chosen to apply to a BMD_{10} or $BMDL_{10}$ from animal data. This would lead to a notional risk level of 1 in 50,000, as compared to the risk level of 1 in 100,000 used currently to represent minimal risk in contaminated land risk assessment and the derivation of SGVs. COT agrees that the use of a chemical-specific margin (CSM) approach, which parallels the MOE approach, was appropriate to derive a LLTC for non-thresholded chemicals. Most stakeholder feedback was in agreement with the report that a margin of 5,000 could be used for non-threshold chemicals.

27. **Conclusion:** Based on stakeholder engagement and the discussion within the final report, the Welsh Government recommends that **a generic margin of 5,000** be used for the purposes of deriving LLTC for non-threshold chemicals when a BMD_{10} from animal data is used as the Point of Departure.

Excess Lifetime Cancer Risk (ELCR)

28. If there are adequate dose-effects data for the chosen pivotal study (human data) then BMD modelling can be performed on the human data or an ELCR can be defined[5]. As the report indicates, quantitative dose-response modelling of cancer data involves the concept of ELCR defined as:

> *'Potential carcinogenic effects that are characterized by estimating the probability of cancer incidence in a population of individuals for a specific lifetime from projected intakes (and exposures) and chemical-specific dose-response data (i.e., slope factors). By multiplying the intake by the slope factor, the ELCR result is a probability.'*

[5]If both are performed, the BMD modelling route should carry more weight over an ELCR calculation, the latter of which is only a rough estimation of risk. However, worldwide authoritative bodies do use the concept of ELCR and it is useful as a comparator alongside the BMD approach.

29. From such quantitative risk estimations, relevant guidance has stated that an ELCR of 1 in 100,000 (10^5) should constitute minimal risk (EA, 2009a; DEFRA, 2008). However, it is also considered in previous guidance that ELCR calculations are approximations of risk (i.e. what could be considered a rough estimate rather than an accurate prediction of risk). For the purposes of deriving C4SLs, a risk estimate of 1 in 50,000 could be specified as 'low risk' and this would be a generic level used for all human gentoxic carcinogens.

30. Following approaches to COT and COC it is the interpretation of the consortium that defining an ELCR risk estimate above minimal risk cannot be undertaken scientifically.

31. **Conclusion**: The Welsh Government recognises that ELCR calculations are approximations of risk and are not necessarily scientifically justifiable. BMD modelling should also carry more weight over an ELCR calculation. The majority of stakeholder workshop feedback was to set a higher ELCR than 1 in 100,000 when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data). The Welsh Government recommends that for the purposes of derivingC4SLs, a risk estimate of 1 in 50,000 could be specified as 'low risk' and this would be a **generic level used for all human genotoxic carcinogens.**

32. To avoid disproportionately targeting soils compared with other media such as water or air, the LLTC may be associated with a higher ELCR. In such cases, a toxicologically-based LLTC could be derived, which would then be over-ridden by a policy-based LLTC recommended elsewhere[6,7,8].

[6] Arsenic: A health-based IDoral based on a minimal ELRC derived in accordance with the principles described in the toxicological framework report (Environment Agency, 2009a), would be about 0.0006–0.003µg kg-1 bw day-1. However, the UK drinking-water standard of 10µg L-1 is equivalent to a higher intake of approximately 0.3µg kg-1 bw day-1. Therefore, in order to avoid disproportionately targeting exposures from soil, a choice has been made to align the LLTC with the intake that equates to that from the UK drinking water guideline.

[7] Benzene - The proposed LLTCinhal is based on the Air Quality Objective of 5µg m-3, which represents an approximate ELCR of 1 in 34,000.

[8] BaP - The proposed LLTCinhal is based on the Air Quality Standard of 1ng m-3, which, based on WHO (2006a&b), represents an approximate ELCR of 1 in 10,000.

Determination of a LLTC for lead (Pb) and subsequent Category 4 Screening Levels

33. The consortium presented three options for determining the LLTC for lead, taking into account the range of toxicological effects on neuro-behaviour, the cardiovascular system and the renal system. Three options for the LLTC for blood lead concentrations were presented in the final report: 1.6µg/dL, 3.5µg/dL and 5µg/dL.

34. It is the Welsh Government's view that a LLTC Concern of 3.5µg/dL should be chosen to derive C4SLs for lead. The Level of 1.6µg/dL is considered to be too close to minimal risk to support its use in the derivation of the more pragmatic C4SLs. The Level of 5µg/dL, identified as the Centres for Disease Control and Prevention's target blood lead concentration in children for all exposure to lead, is not considered suitably precautionary given the role of C4SLs.

35. The proposed LLTC of 3.5µg/dL is considered to be more pragmatic, whilst still representing a low level for risk in relation to the toxicological effects of lead on neuro-behaviour and the cardiovascular system. The Welsh Government acknowledges that some stakeholders expressed concern about whether the use of a LLTC of 3.5 µg/dL would be sufficiently precautionary in relation to its toxicological effects on the renal system but notes that the data on which this effect was studied were based on glomerular filtration rate, which is a secondary measure of actual effect.

36. The Welsh Government supports the consortium's approach to derive C4SLs Levels for Residential, Allotments and Public Open Space based on the use of the IEUBK model to convert a blood Pb level into a dietary intake level for use in the CLEA model, where a child is considered to be the critical receptor. The consortium presents two options for deriving C4SLs for lead for Commercial land use, both based on the use of an adult as the critical receptor. The Welsh Government recommends the use of the USEPA adult lead methodology to convert a blood Pb level into a dietary intake level for use in the CLEA model in order to derive a C4SL for Commercial land use as this is considered to be suitably precautionary.

Derivation of Category 4 Screening Levels following changes to both exposure and toxicology

37. The consortium presented a range of pC4SLs for each contaminant and for each land use scenario based on changes to the toxicology only, changes to the exposure assessment only, and changes to both the toxicology and the exposure. Given the role of C4SLs in the more pragmatic, risk-based approach to

contaminated land risk assessment, we recommend that final C4SLs should be derived following changes to both the toxicology and the exposure assessment.

Final Category 4 Screening Levels based on the risk management decisions outlined above[9]

Substance	Residential (with home-grown produce)	Residential (without home-grown produce)	Allotments	Commercial	Public Open Space 1	Public Open Space 2
Arsenic	37 mg/kg	40 mg/kg	49 mg/kg	640 mg/kg	79 mg/kg	170 mg/kg
Benzene	0.87 mg/kg	3.3 mg/kg	0.18 mg/kg	98 mg/kg	140 mg/kg	230 mg/kg
Benzo(a)pyrene	5.0 mg/kg	5.3 mg/kg	5.7 mg/kg	77 mg/kg	10 mg/kg	21 mg/kg
Cadmium	22 mg/kg	150 mg/kg	34.9 mg/kg	410 mg/kg	220 mg/kg	880 mg/kg
Chromium VI	21 mg/kg	21 mg/kg	170 mg/kg	49 mg/kg	21 mg/kg	250 mg/kg
Lead	200 mg/kg	310 mg/kg	80 mg/kg	2300 mg/kg	630 mg/kg	1300 mg/kg

This table should be read in conjunction with the Final C4SL R&D report.

[9] The C4SLs in this table apply to the standard land-uses as set out in the main C4SL research report and the CLEA framework reports for a sandy loam soil with 6% soil organic matter. Un-adjusted C4SLs should not be used where site conditions or land use vary significantly from these assumed characteristics. The C4SLs should only be used in conjunction with the information contained in the relevant substance-specific appendix of the C4SL research report, and with an understanding of the exposure and toxicological assumptions contained in the main C4SL report, this Companion Document, and the CLEA framework reports. The user should also understand the use and role of GAC in assessing the risks from land contamination and may find the introductory guide on Using SGVs useful.

Wider implications

Use of Category 4 Screening Levels in planning under Planning Policy Wales

38. The Part 2A regime and the planning regime are inter-linked such that Planning Policy Wales states that planning policies and decisions should be consistent with Part 2A. The Part 2A Statutory Guidance and accompanying IA were developed on the basis that C4SLs could be used under the planning regime, as they would be in Part 2A investigations directly. The estimated benefits that were expected to accrue from the changes to the Part 2A Statutory Guidance and specifically from the use of the new C4SLs were based on this assumption. The planning position is that the C4SL may provide a useful means of assisting local planning authorities in deciding whether land is suitable for its proposed use.

Derivation of additional Category 4 Screening Levels

39. This project was designed with the intention that one of the outputs would be an agreed and tested methodology that would then be available for the sector to develop further C4SLs for additional contaminants as necessary. It is the Welsh Government's view that sufficient guidance is provided in the final reports from the project together with this Policy Companion Document for additional C4SLs to be developed with confidence by those in the sector, bearing in mind the need for specialist toxicological input into the derivation of the LLTC. However, the Welsh Government recognises the potential value in there being some central oversight of additionally developed C4SLs and will consider this further but, in any case, endorses significant stakeholder input into the derivation of additional C4SLs.

Relationship between normal background concentrations and Category 4 Screening Levels

40. The outputs of Defra/ Welsh Government-funded research to determine 'normal' background concentrations of various contaminants in England and Wales and the outputs of this research project to develop new screening levels for contaminants in soil, are both designed as tools to be used by contaminated land risk assessors to inform decisions about whether or not it is necessary to proceed to a Detailed Quantitative Risk Assessment (DQRA) on a particular site taking into account the broad aims of the regime as set out in Section 1 of the Statutory Guidance. Questions have been raised about how these tools relate and interact.

41. Ultimately, it is up to individual risk assessors to make the most appropriate decisions on a site-by-site basis and to use the most appropriate tools in each case. However, with reference to the Part 2A Statutory Guidance, which states that ‘normal’ background concentrations should not be considered to cause a site to be determined as contaminated under Part 2A unless there is a reason to consider otherwise, it is envisaged that, where available, C4SLs should be the initial value against which site concentrations can be compared. Where a value on a particular site exceeds the C4SL for that substance, reference can then be made to the normal background concentration for that contaminant in that area. If concentrations are higher than the relevant C4SL but within ‘normal’ background concentrations for that area, it is not envisaged that a site would be determined as contaminated under Part 2A (unless there was a reason to consider otherwise).

42. The British Geological Survey has derived ‘normal’ background concentrations for lead for England and Wales. In Wales the ‘normal’ background concentrations of lead are 230 mg/kg for the ‘principal’ domain, 280 mg/kg for the ‘mineralisation’ domain and 890 - 1300 mg/kg for the ‘urban’ domain (Welsh Government, 2013). Current advances in our understanding of the toxicology of lead have resulted in C4SLs for Residential, Allotments and Public Open Space 1 that are lower than the ‘normal’ background concentration of lead in **urban** areas. This was also the case for the (now withdrawn) SGV for lead of 450 mg/kg.

43. The report identifies other relevant considerations that may have a bearing on the final choice of C4SLs and the background level in soil is one of these. A pragmatic approach for lead would be to recommend the use of the ‘normal’ background concentration when the land use and domain permit (for example, providing other site and contaminant specific characteristics such as chemical form, bioavailability, soil depth, site use, etc. are comparable between the background and the site under investigation) so as not to disproportionately target land where there is widespread diffuse pollution of lead.

Normal background concentrations of contaminants in Wales[10]

Substance	Principal domain	Urban domain	Urban domain 1	Urban domain 2	Mineralisation	Mineralisation domain 1	Mineralisation domain 2
Arsenic	36 mg/kg		250 mg/kg		67 mg/kg		
Benzo-a-pyrene	0.5 mg/kg	3.6 mg/kg	3.6 mg/kg				
Cadmium	1.4 mg/kg		6.2 mg/kg			Nd	2.2 mg/kg
Lead	230 mg/kg		1,300 mg/kg	890 mg/kg		nd	280 mg/kg

Relationship between Soil Guideline Values and Category 4 Screening Levels

44. Where a valid SGV exists for a contaminant where a C4SL has also been derived, it is anticipated that risk assessors will use the C4SL in line with the Part 2A Statutory Guidance. In the absence of a suitable C4SL, risk assessors should identify and select appropriate GAC in accordance with established good practice. It is for the Environment Agency to decide whether or not any of the SGVs will be updated in the light of more recent toxicological data or whether any particular SGV should be withdrawn (as has already been the case with the SGV for lead).

45. Regardless of the withdrawal or otherwise of any SGVs, related Environment Agency guidance, including the CLEA software, SR2 and SR3, should be retained.

[10] http://www.bgs.ac.uk/gbase/NBCDefraProject.html

Defra response to recommendations from the Committee on Toxicity and Committee on Carcinogenicity

Recommendation 1: Sociological research into the terminology developed for the project

The Committee felt that the "low level" in the new term, "Low Level of Toxicological Concern" that was proposed as part of the revised toxicological framework might be overlooked by the public, who would focus more on the "toxicological concern". Members recommended that sociological research on how the public would perceive the term would be useful.

Defra Response: Although Defra hasn't commissioned any specific research, the Social Science Research Unit at the Food Standards Agency was contacted on this issue but is not aware of any specific work that has been undertaken in this area.

There was a majority agreement at the first Stakeholder Workshop that this term was acceptable. More specifically there was agreement to:

Adopt the term "low level of toxicological concern" (LLTC) to describe toxicological criteria derived for the purposes of developing Category 4 Screening Levels that are "more pragmatic but still strongly precautionary" compared with existing Health Criteria Values.

Recommendation 2: Current risk Health Criteria Values/ Soil Guideline Values should be revised to take account of new data

Defra Response: This would be for the Environment Agency to consider but there is currently no intention or funding to take this forward.

Recommendation 3: Further advice from the Committee on Carcinogenicity (COC) should be sought on Excess Lifetime Cancer Risk (ELCR). Specifically, in the context of cancer, would the use of an ELCR higher than 1 in 100,000 (e.g. 1 in 10,000 to 1 in 50,000) be appropriate to define an intake dose that would represent 'low risk' when defining a Category 4 Screening Level?

Defra Response: As recommended, COC was approached in September 2013 and did not disagree with the approach of using an ELCR higher than 1 in 100,000 to define a LLTC but concluded there was no scientific basis for using a default margin smaller than those recommended by COC to derive a LLTC. In general COC works towards a minimal risk approach whereas the approach being taken for Category 4 Screening Levels (C4SLs) is 'low risk'.

The majority of stakeholder workshop feedback was to set a higher ELCR than 1 in 100,000 when setting toxicological criteria for non-threshold carcinogenic effects using quantitative dose-response modelling (based on human data).

Therefore Defra recommends that for the purposes of deriving C4SLs, a risk estimate of 1 in 50,000 could be specified as 'low risk' and this would be a generic level used for all human genotoxic carcinogens.

To avoid disproportionately targeting soils compared with other media such as water or air, the LLTC may be associated with a higher ELCR. In such cases, a toxicologically-based LLTC could be derived, which would then be over-ridden by a policy-based LLTC recommended elsewhere[11][12][13].

Recommendation 4: To ensure transparency expert panels should be used for the peer review

Defra Response: There has been a significant amount of peer review undertaken. The reports in their entirety have been reviewed by experts specialising in toxicology and risk/exposure assessment; a summary of their comments is being published separately. Additionally, the two independent scientific committees approached to review certain toxicological aspects of the report COT and COC are public meetings with minutes available on their respective websites.

Recommendation 5: Category 4 Screening Levels should be produced centrally

Defra Response: This project was designed with the intention that one of the outputs would be an agreed and tested methodology that would then be available for the sector to develop further C4SLs for additional contaminants as necessary. It is Defra's view that sufficient guidance is provided in the final reports from the project together with this Policy Companion Document for additional C4SLs to be developed

[11] Arsenic: A health-based IDoral based on a minimal ELRC, derived in accordance with the principles described in the toxicological framework report (Environment Agency, 2009a), would be about 0.0006–0.003µg kg-1 bw day-1. However, the UK drinking-water standard of 10µg L-1 is equivalent to a higher intake of approximately 0.3µg kg-1 bw day-1. Therefore, in order to avoid disproportionately targeting exposures from soil, a choice has been made to align the LLTC with the intake that equates to that from the UK drinking water guideline.

[12] Benzene - The proposed LLTCinhal is based on the Air Quality Objective of 5µg m-3, which represents an approximate ELCR of 1 in 34,000.

[13] BaP - The proposed LLTCinhal is based on the Air Quality Standard of 1ng m-3, which, based on WHO (2006a&b), represents an approximate ELCR of 1 in 10,000.

with confidence by those in the sector, bearing in mind the need for specialist toxicological input into the derivation of the LLTC. However, Defra recognises the potential value in there being some central oversight of additionally developed C4SLs and will consider this further but, in any case, endorses significant stakeholder input into the derivation of additional C4SLs.