Society of Brownfield Risk Assessment

SOCIETY OF BROWNFIELD RISK ASSESSMENT
SUMMER WORKSHOP REPORT 2011

HUMAN HEALTH RISK ASSESSMENT OF LEAD IN SOIL
THE KEY ISSUES

PUBLICATION

This report summarises the key technical issues relevant to the risk assessment of lead from contaminated soils as presented and discussed at a SoBRA (Society of Brownfield Risk Assessment) workshop in June 2011.

Whilst every effort has been made to ensure the report is an accurate account of workshop proceedings, neither SoBRA nor the authors of the report accept any liability whatsoever for any loss or damage arising in any way from its use or interpretation, or from reliance on any views contained herein.

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PREFACE

The Society of Brownfield Risk Assessment (SoBRA) was established in December 2009 with the principal aim of promoting technical excellence in land contamination risk assessment in the UK.

As part of achieving this aim, SoBRA undertook to host regular conferences and workshops on technical subjects of interest to UK risk assessors.

SoBRA's first summer workshop was held in June 2010 in York where the human health risk assessment issues surrounding polycyclic aromatic hydrocarbons in soil were considered. The event was very positively received, as was the technical report on the workshop proceedings produced by SoBRA in February 2011. The first event and associated report effectively set the benchmark for a series of SoBRA summer workshops where the aim is to engage, inform and establish consensus amongst practitioners on key technical issues.

SoBRA's second summer workshop was held on 21st June 2011 at the Mechanics Institute in Manchester with 'Lead Risk Assessment' as its topic. Following the same format as for the first event, the day was structured around four key themes as follows: 1) sources, forms and background concentrations of lead in soil; 2) health effects and toxicological approaches for lead; 3) modelling exposure to lead; and 4) bioaccessibility testing and its uses in risk estimation. During the morning session, expert speakers delivered presentations on the four topics which were followed by afternoon workshops on the same themes in which all workshop delegates participated.

Seventy eight delegates attended the second summer workshop. Over 80% of delegates who completed an event evaluation form rated the morning sessions as 'good', 'very good' or 'excellent' and over 60% of delegates scored the afternoon workshops at the same level. Overall, the event was considered to mark the excellent continuation of SoBRA's 'signature' summer workshop series.

This report fulfils an undertaking given by SoBRA to produce a formal record of the proceedings of the lead risk assessment workshop. It summarises the expert presentations given on the day, records current views on the main technical issues within each subject area and describes the challenges identified by risk assessors in dealing appropriately with lead contamination.

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Ian Martin	Environment Agency	Expert Speaker
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Mike Quint	Environmental Health Sciences	Expert Speaker, Workshop Facilitator & Report Author
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David Hall	Golder Associates	Workshop Facilitator & Report Author
Seamus Lefroy-Brooks	LBH Wembley	Workshop Facilitator
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Finally, SoBRA wishes to acknowledge the contribution to the overall success of the event made by individual workshop delegates: firstly for attending and enthusiastically participating in the day's proceedings and, secondly, for providing comments and suggestions to authors during the draft reporting stage.

Workshop delegates are listed in Appendix 1 to this report.

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1 INTRODUCTION

1.1 Background

Lead is a ubiquitous environmental contaminant and is widely distributed in soils in the UK in part due to the presence of mineral deposits but mainly through anthropogenic uses of the metal dating back to Roman times.

The chemical and physical properties of lead make it relatively easy to extract, smelt and work, and these attributes, together with it's high resistance to corrosion, have meant that lead has been widely used for a variety of purposes including: as a building material (e.g. in pipes and flashing); in ammunition, alloys and solder; and in the manufacture of glass, ceramics, prints, cables, car batteries, radiation shields and electronics. Lead has also been widely used in paint, as a petrol additive and insecticide.

The toxicity of lead is reasonably well understood and documented. However, recent research shows that lead appears to cause health effects at concentrations lower than previously thought and it may be best considered as a non-threshold toxicant.

These factors present a number of new challenges for land contamination risk assessors and policy makers, given that lead is often present at high concentrations in urban soil environments. There is still some debate about the best way of modelling exposure to lead to best reflect site specific exposure conditions, and the biological processes which operate within the body to sequestrate and/or excrete the metal.

As with many other common contaminants in UK soils, the biological availability of lead in soil is a key consideration in the accurate assessment of potential health impacts. Bioaccessibility tests for lead are available although there remains some debate about the most appropriate tests for use in land contamination applications.

1.2 The SoBRA Workshop

The SoBRA Lead Workshop aimed to define current understanding of the key issues surrounding the risk assessment of lead in soil, to identify key uncertainties in current approaches, and to establish where there is (and is not) consensus on how best to manage and resolve uncertainties.

A specific goal of the workshop organisers was to produce a formal workshop output which summarised the proceedings, consolidated ideas and made recommendations on the work required to support risk assessment efforts in the future. This report is that written output.

1.3 Structure of the Report

Following this introduction, section 2 of the report summarises key technical issues relevant to the risk assessment of lead, as described by expert speakers. Four key themes were addressed:

- the sources, forms and background concentrations of lead;
- health effects and toxicological approaches to lead;
- modelling exposure to lead, and;
- bioaccessibility testing and its use in risk estimation.

Sections 3 to 6 of the report summarise workshop discussions on each of these four themes.

Section 7 of the report draws on the outcome of the workshop discussions, identifies some common issues and highlights priorities for future consideration.

Reference documents used to support presentations and workshop discussions are shown as footnotes to the text, and are collated as a complete list in section 8 of the report.

Appendix 1 gives details of the workshop groups including names of individual participants. Appendix 2 sets out a list of the abbreviations used in the report.

2 EXPERT PRESENTATIONS

2.1 Sources, Forms and Background Concentrations of Lead

Cathy Scheib of the British Geological Survey (BGS) and Christopher Taylor of Brent Council, London, gave a joint presentation on the sources, forms and background concentrations of lead.

Cathy began with an overview of lead and its uses, and of the main natural and anthropogenic sources. She also discussed background concentrations of lead at national and regional levels, and in urban and rural contexts, before considering how background concentrations can be measured and determined. Chris provided a local authority perspective that addressed typical lead concentrations in local soils, the variability of lead concentrations in Made Ground, and the relevance of historic land use. He also presented a case study.

2.1.1 Basic Properties

Lead (Pb from plumbum) is a naturally occurring element that has been used by humanity for thousands of years, As a result of human activity it is very widely distributed about the surface of the earth.

Lead is a soft, malleable and ductile metal with low melting point (327^{o}C), high density (11 g/cm^{3}) and low reactivity. These properties have resulted in widespread use of lead, because it is relatively easy to extract, smelt and work. Lead is also useful because of its high resistance to corrosion.

Lead has low mobility in the environment: it is not volatile; has low solubility; and strongly sorbs to iron-manganese-aluminium oxyhydroxide complexation sites as well as to organic matter in soil. However, lead is biologically non-essential and it has toxic effects in humans (neurotoxicity) and in other living systems.

2.1.2 Natural Sources of Lead

Lead is the 37th most common element in the earth's upper continental crust. The main mineral source is galena, while cerussite and angelsite are also significant, as shown in Table 1.

Table 1: Natural sources of lead

Mineral	Chemical formula	Solubility (mg/L)
Galena	PbS	<1
Cerussite	$PbCO_3$	1
Anglesite	$PbSO_4$	38

Lead occurs as trace concentrations in other rock-forming minerals such as feldspars and clay minerals as it is able to substitute for calcium and potassium in their atomic structure. Lead's affinity to organic matter and clay minerals means that it occurs at higher concentrations in the clay and silt fractions of soil and sediment. Lead abundance in various rocks and other materials is shown in Table 2.

Table 2: Abundance of lead in different rock types

Rock Type	Concentration (ppm)
Upper continental crust	10-14
Granite	15-19
Basalt	6
Sandstone	6
Limestone	5
Mudstone	23
Coal	25
Oil	0.3
Phosphate fertiliser	7-92
Lime fertiliser	9
Leaded petrol	150-800
World top soils	25
European top soils	23
UK top soils	130
London soils	300
UK river sediments	85

Lead that is finely disseminated in crustal rocks has been concentrated into mineral veins by geological processes such as hydrothermal mineralisation. In the UK, lead orefields and lead mines are located in the Pennines (overall total of 500,000 tonnes), Peak District, Lake District, North Wales, Cornwall and Scotland.

2.1.3 Anthropogenic Sources of Lead

Lead has been mined in the UK since the Bronze Age, with significant production in Roman times (80,000 tonnes annually) and with peak production occurring between 1800 and 1900. Smelting and refining was originally located close to the mines but after mines were closed, and from the 1950s to the present day, the focus of activity moved to various ports (Hull, Newcastle, Bristol) for the secondary processing of imported ores.

From Roman times, lead was used as a building material for pipes, roofing, flashing, glazing, weights and also coffins. Later uses include bullets, alloys, solder, glass-making, ceramic glazes, printing, electricity cable sheathing, car batteries, radiation shields and in electronics. Other significant uses were:

- white lead ($PbCO_3$), red lead (PbO_4) and chrome yellow ($PbCrO_4$) were commonly used in paint manufacture until the 1980s;

- tetraethyl lead ($C_8H_{20}Pb$) was used as an octane booster and anti-knock additive in leaded petrol from the 1920s to 2000 with a peak in the 1970s; and
- lead arsenate ($PbHAsO_4$) was used as an insecticide in orchards from 1900 until it was replaced by DDT in the 1960s.

Industrial activity involving lead in the UK is currently confined to car battery recycling at only two sites in Derbyshire and Kent, but these are permitted sites with emission controls.

Examples of decreasing sources of lead include:

- the closure of the lead mining and smelting industries;
- the disuse of lead in pesticides since the 1960s;
- the ending of leaded paint manufacture in the 1980s;
- the halt in the use of leaded petrol in 2000;
- the (largely complete) replacement of lead water pipes;
- restrictions on the use of lead shot at nature conservation sites; and
- restrictions on the use of lead weights in angling.

2.1.4 Anthropogenic Occurrence of Lead

Lead is relatively immobile in soil and so soil acts as a significant sink for anthropogenic sources of the metal. Lead emissions into air from vehicle exhausts and industrial chimney stacks constitute the major contribution to lead in the environment. Lead has a high density and so falls to the ground relatively close to the air emission source resulting in atmospheric deposition of lead into soil.

Atmospheric deposition into soil after emissions to air has resulted from:

- leaded petrol combustion (380,000 tonnes of lead worldwide in 1973), usually within 30m of the road network;
- fossil fuel combustion (coal and oil);
- lead smelting and refining works;
- waste incinerators (less at current energy from waste plants);
- car battery manufacture (70% of worldwide lead consumption);
- car battery recycling sites; and
- alkylated lead processing and its use at oil refineries.

Other routes by which lead may be dispersed in the environment that have impacts for soil are:

- lead mining spoil tips (including downstream river sediments);
- Made Ground containing coal ash and clinker from fires and furnaces;
- exterior paint weathering to dust/flakes and falling to the ground;
- leaks and spills from leaded petrol tanks;
- insecticide applications in agriculture;
- fertiliser and lime applications in agriculture;
- sewage sludge applications to land;

- rifle ranges, MoD land, pheasant shoots and clay pigeon shooting clubs;
- landfill waste sites; and
- pulverised fuel ash (PFA) disposal sites.

2.1.5 Long-term Evidence of Lead Pollution

UK lead ores have a stable isotope ratio ^{207}Pb:^{206}Pb of 0.85. These ores ran out in 1900 and since then lead from Broken Hill in Australia has been the main source with a lead isotope ratio ^{207}Pb:^{206}Pb of 0.89. Lead in UK herbage analysis since 1820 has shown a sudden and sustained increase in the latter lead isotope ratio since 1920 (when leaded petrol was introduced) with a maximum in 1990 soon after the peak use of leaded petrol[1].

Soil pollution by lead is not only a recent phenomenon: a study at St Kilda has shown a steady increase in soil lead concentrations since 1000BC, and this has been related to the ancient land management practice of spreading manure[2].

2.1.6 Background Concentrations of Lead in the Environment

Defra's proposals for revising the Statutory Guidance on Part 2A of the Environment Protection Act 1990[3] envisage that 'normal' background contaminant concentrations should generally be excluded from the regime. For this purpose, background concentrations are taken to be those which are not significantly different to concentrations that are widespread across a Local Authority or other similar areas in England and Wales. It is clear that under Part 2A Defra expects Local Authorities to determine land with contaminant concentrations close to background on only rare occasions.

The above changes to the Part 2A regime make it important to determine the background concentrations of contaminants in the UK environment. An agreed protocol and methodology are needed to assess the spatial distribution of contaminant concentrations and to identify the following:

- natural background - normal naturally occurring concentrations in soil and water;
- natural hotspots – with locally naturally elevated concentrations compared to the surrounding area;
- ambient background – to allow for some additional elevated anthropogenic concentrations on top of the natural background, but caused by common human activity, including historical influences.

Anthropogenic contribution may be:

- generally low in rural areas;
- generally higher in urban areas;
- unusually high in industrial areas.

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1 Vane, C. H. *et al* (2011). Chemical signatures of the Anthropocene in the Clyde Estuary, UK. Phil Trans R Soc, Volume 369 (1938), pp1085 - 1111

2 Meharg, A. A. *et al* (2006). Ancient manuring practices pollute arable soils at the St Kilda World Heritage Site, Scottish North Atlantic. Chemosphere 64, 1818-1828

3 Defra (2010). Public consultation on changes to the Contaminated Land Regime under Part 2A of the Environmental Protection Act 1990

Background concentrations of lead have already been assessed at various scales of interest.

At European Level - this is controlled by bedrock and superficial geology with a median topsoil lead concentration of 23mg/kg. The data clearly show the southern limit of the Pleistocene glaciation in the form of lower concentrations in the area covered by glacial till deposits. Surveys in some European countries have identified the following lead concentrations (Table 3).

Table 3: Typical concentrations of lead in European soils

(all mg/kg)	No. Samples	Minimum	Median	Maximum
France (1)	5105	<1	24	1240
France (2)	4376	<1	27	1560
Germany	1144	2	35	280
Denmark	393	-	27	-

Notes to Table: France (1): aqua regia extraction; France (2): hydrogen fluoride extraction - see Appendix 10 of Reference 5

At National Level - BGS stream sediment surveys and top soil surveys (50mm to 200mm depth)[4] have given the results in Table 4, while the Environment Agency UK Soil and Herbage Survey (2007)[5] using samples collected from depths of <50mm has shown mean lead concentrations as shown in Table 5.

Table 4: Typical concentrations of lead in UK soils and sediments

(all mg/kg)	Minimum	Median	Mean	Maximum
UK Stream sediments	<1	34	85	23,000
UK Top soils	<1	50	130	36,000

Table 5: Typical concentrations of lead in shallow soils in the UK

(all mg/kg)	No. Samples	Minimum	Median	Mean	95%ile	Maximum
Rural	122	3	37	53	138	713
Urban	28	9	90	110	-	387
Industrial	50	-	-	145	-	-

At Regional Level – BGS soil geochemical baseline surveys have identified the distribution of some natural and anthropogenic features such as:

- natural baseline features (e.g. naturally elevated mineralised areas or naturally depleted glacial deposits);
- elevated anthropogenic urban centres; and

4 British Geological Survey, Nottingham, UK: Geochemical Baseline Survey of the Environment (GBASE), Geochemical atlas and maps at http://www.bgs.ac.uk/gbase

5 Environment Agency (2007). Environmental concentrations of heavy metals in UK soil and herbage. UK Soil and Herbage Survey Report, Number 7

- elevated drainage features relating to natural mineralisation and subsequent anthropogenic intervention (e.g. River Tent valley alluvium draining the Peak District lead mining area).

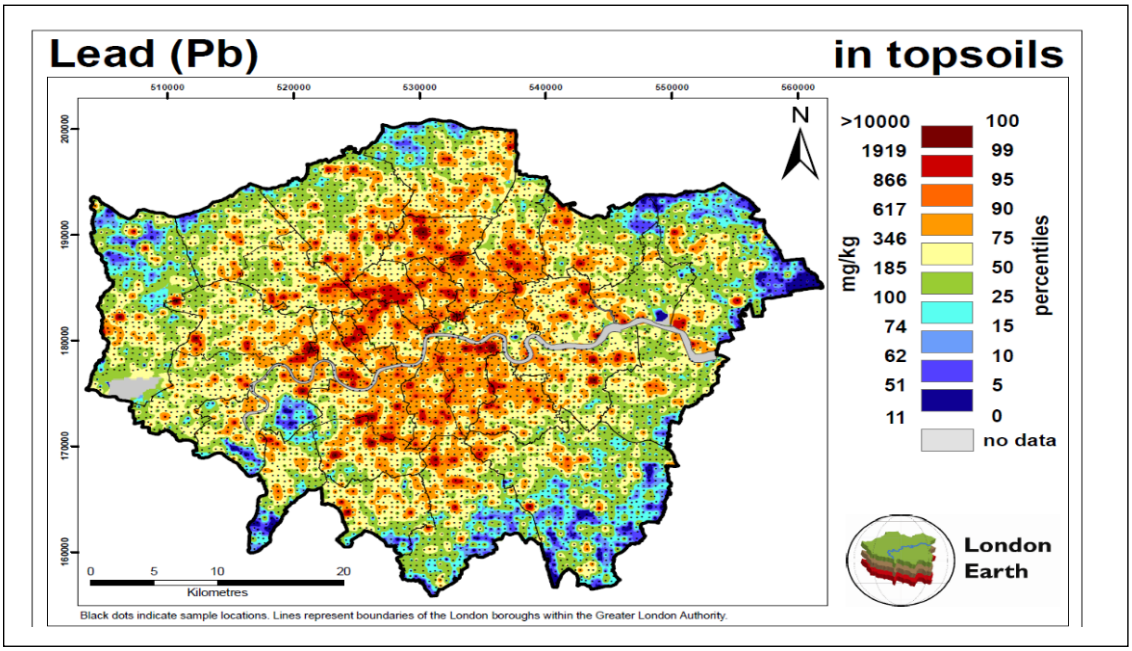
At Local Level - London Earth BGS soil surveys (2011)[6] show the lateral distribution of lead concentrations in London soils as shown in Table 6.

Table 6: Typical concentrations of lead in London soils

(all mg/kg)	No. Samples	Minimum	Median	Mean	Maximum
London	6288	11	185	301	>10,000

The map below indicates a clear pattern of increasing concentrations towards the centre of Greater London with large parks (e.g. Richmond Park and Wimbledon Common) showing lower concentrations. This distribution is likely to reflect soil deposition of airborne lead from vehicle emissions.

Box 1: Map of lead concentrations in top soils in the London area



BGS soil surveys show that lead concentrations are higher in urban areas than in the surrounding rural soils. Data from the East Midlands show that urban soils have consistently higher lead concentrations than the typical rural soil concentration of 30mg/kg, as shown in Table 7.

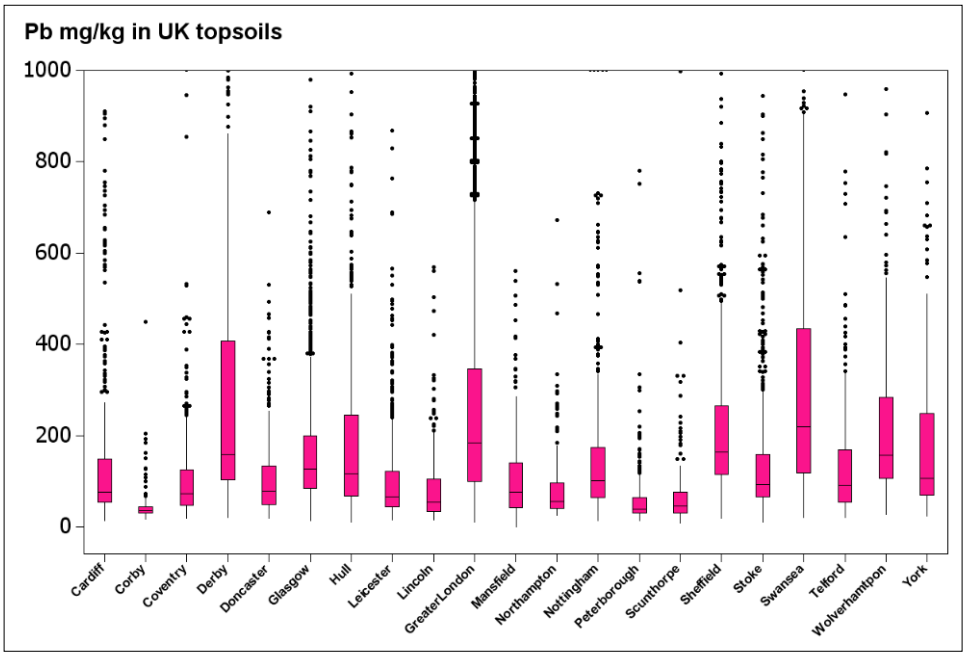
6 British Geological Survey (2011). London Earth: Lead in surface soils. G-BASE geochemical map, Keyworth, Nottingham, UK

Table 7: Lead concentrations in soils in the East Midlands

Urban area	No. Samples	Median Lead Concentration (mg/kg)	
		Top soil (50-200mm)	Sub soil (350-500mm)
East Midlands	7293	-	30
Corby	133	36	32
Coventry	396	73	71
Derby	276	159	157
Leicester	680	65	59
Northampton	275	56	53
Nottingham	637	101	-
Peterborough	276	39	36

A wider comparison of lead concentrations within top soil in 21 UK urban areas is shown in the chart below[7]. Most of the results are in the range from 50mg/kg to 200mg/kg, with higher concentrations identified in Derby, London and Swansea, where the 75th percentile concentration is close to 400mg/kg.

Box 2: Lead concentrations in top soil in 21 UK urban areas



2.1.7 Determination of Lead Background Concentrations for Regulatory Comparison

Proposed changes to the Part 2A Statutory Guidance state that land with 'normal' background concentrations of contaminants is not expected to be captured by the

7 British Geological Survey, Keyworth, Nottingham, UK: Geochemical surveys of urban environments (GSUE)

regime. However, background concentrations are very variable with significant heterogeneity at all scales of interest, particularly on small scales. An agreed and standardised protocol is needed to establish a methodology for determining and identifying background concentrations of contaminants. Lead concentrations determined in soil are strongly dependent on, but not exclusively limited to, the following:

- underlying solid geology and superficial geology;
- location within urban or rural areas;
- nature of the ground, e.g. Made Ground or natural ground;
- soil type;
- sampling methodology;
- depth of sample;
- sample preparation;
- soil particle size fraction analysed;
- analytical technique used;
- laboratory QA/QC procedures;
- number of samples per averaging area;
- statistical interpretation of the data obtained.

2.1.8 Environmental Quality Standards for Lead

The SGV-10 Soil Guideline Values for Lead Contamination (2002)[8] were withdrawn in 2008. The values were derived using a bespoke model based on the relationship between exposure and blood lead concentration (note that the more recent CLEA software (2009)[9] needs an approach based on intake) but the European Food Safety Authority has recently reviewed the toxicology of lead and has concluded that the neurotoxicity health effects in children occur at lower exposure levels than was previously thought.

Although former soil quality guidelines for lead in soil were relatively consistent at around 450 mg/kg, the current view is that minimal risk levels should be lower. This is reflected in the current Dutch Target level of 85 mg/kg and the USEPA (Region 9) Screening Level of 15 mg/kg.

2.1.9 Local Authority Perspective on Lead in Soil

Chris Taylor continued the presentation with a Local Authority perspective from Brent Council in North West London. Brent was included in the BGS London Earth soil survey and lead concentrations in local soils were in the range from <73-2800mg/kg.

Chris presented soil descriptions of typical Made Ground from two site investigations in Brent, where both samples had lead concentrations >1000mg/kg. Typical lead concentrations in the soils of the North West London boroughs are as shown in Table 8.

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8 Defra and Environment Agency (2002). Soil Guideline Values for lead contamination. R&D Publication SGV 10

9 Environment Agency (2009). Contaminated Land Exposure Assessment (CLEA) Model. Software version 1.06. Science Report SC050021/SR4

Table 8: Typical lead concentrations for soils in NW London

Borough	Land use	Minimum (mg/kg)	Maximum (mg/kg)
Brent	Allotments	24	1100
Brent	Residential gardens	14	2100
Brent	Industrial sites	56	2300
Camden	Residential gardens	110	4177
Kensington/Chelsea	Public open space	72	1200
Hounslow	-	-	900
Islington	-	500	1000

Chris showed that elevated lead concentrations in North West London soils are not necessarily associated with previous industrial use. This is illustrated in Table 9 which shows lead concentrations at two recent development sites, where the industrial buildings have shielded underlying soils from historic atmospheric deposition of lead[10].

Table 9: Lead concentrations in soils protected from atmospheric deposition

(all mg/kg)	Former use	Dates	Minimum (mg/kg)	Mean (mg/kg)	Maximum (mg/kg)
Site 1	Industrial buildings	1935-2010	18	96	360
Site 2[11]	Allotments	1935-1966	54	481	1738
	Care Home	1966-2006			

2.1.10 Regulation under the Planning Regime

Environmental consultants engaged by developers typically use simple Generic Assessment Criteria (GAC) of 400-450mg/kg for lead, rather than derive Site-Specific Assessment Criteria (SSAC) using Detailed Quantitative Risk Assessment (DQRA) that are likely to be less conservative. When these GACs are exceeded, the remedial solution adopted is to dig and dump then replace with cleaner imported soils.

The regulator then has to decide whether or not to agree with proposed remedial strategies, and needs to consider the following:

- is the GAC of 400-450mg/kg for lead too conservative?
- is it sustainable if: GAC < mean lead concentration < urban background?

10 Soiltechnics (2007). Proposed residential development off Edgeware Road, Colindale, London. Ground Investigation Report. Ref. R-STD1075R-G01

11 Eldred Geotechnics (2006). A geoenvironmental and geotechnical assessment of ground conditions of the site of the former Roberts Court Centre, Stag Lane, Kingsbury, London. Ref. GO0601-RP-01-E1

2.1.11 Regulation under Part 2A of EPA 1990

Chris presented a case study of a site comprising 16 residential gardens that was investigated under Brent Council's contaminated land inspection strategy[12]. The housing estate was built upon the site of a former liquid oxygen works that operated from 1943 until 1973. The site investigation involved soil analysis for a wide suite of potential contaminants but only lead concentrations exceeded the GAC of 450mg/kg. The soil analysis results for lead were as shown in Table 10.

Table 10: Lead concentrations in gardens built on former industrial land

Location	No. of samples	Minimum (mg/kg)	Mean (mg/kg)	Maximum (mg/kg)
Brent gardens	15	77 - 1200	115-1675	190-2300

In this case, bioaccessibility testing was conducted, site-specific plant concentration factors were developed, and a DQRA was carried out to derive an SSAC of 873mg/kg for lead in soil. This was still considered to be a conservative minimal risk concentration.

Site-specific Health Criteria Values (HCV) were then used to derive a lead concentration that would be representative of the Significant Possibility of Significant Harm (SPOSH). This resulted in a SPOSH concentration for lead designed to be protective of human health of >2000mg/kg. This was considered to be appropriate when compared to the urban background concentrations.

This case study illustrates the difficulty faced by Local Authorities having to make decisions that strike the right balance between protection of human health and over-conservative and (environmentally, financially and socially) unsustainable assessment criteria.

2.1.12 Overall Conclusions

Overall conclusions on the sources, forms and background concentrations of lead were summarised as follows:

- Lead has been used in the UK for a multitude of purposes over millennia.
- Significant quantities of lead have entered the UK environment via vehicle emissions, industrial chimney emissions, mining and waste disposal.
- Emissions in the UK have decreased significantly in recent years.
- However, lead will remain in UK soils for a long time to come because of its very low mobility in soil.
- Lead concentrations in industrial and urban areas are higher than in rural locations.
- Natural background concentrations of lead in soil vary from < 3mg/kg to > 700mg/kg.
- Made Ground concentrations of lead vary from < 50mg/kg to > 2000mg/kg.
- Lead assessment values for protection of human health are sometimes below the relevant background concentrations.

12 URS (2010). London Borough of Brent. Phase IV Environmental Report - Strathcona Road, London. Project No. 49318631, 13th January, 2010

- Local Authorities must make difficult decisions with regard to lead, and other contaminants, in both the planning and Part 2A scenarios.
- Standardised guidance for determining background concentrations of lead for the purposes of Part 2A is likely to be crucial.

2.2 Health Effects and Toxicological Approaches to Lead

The potential health effects of lead exposure and the toxicological approaches used to assess it were described by Dr Sarah Bull of the Health Protection Agency (HPA). A summary of the key points of Dr Bull's talk is provided below.

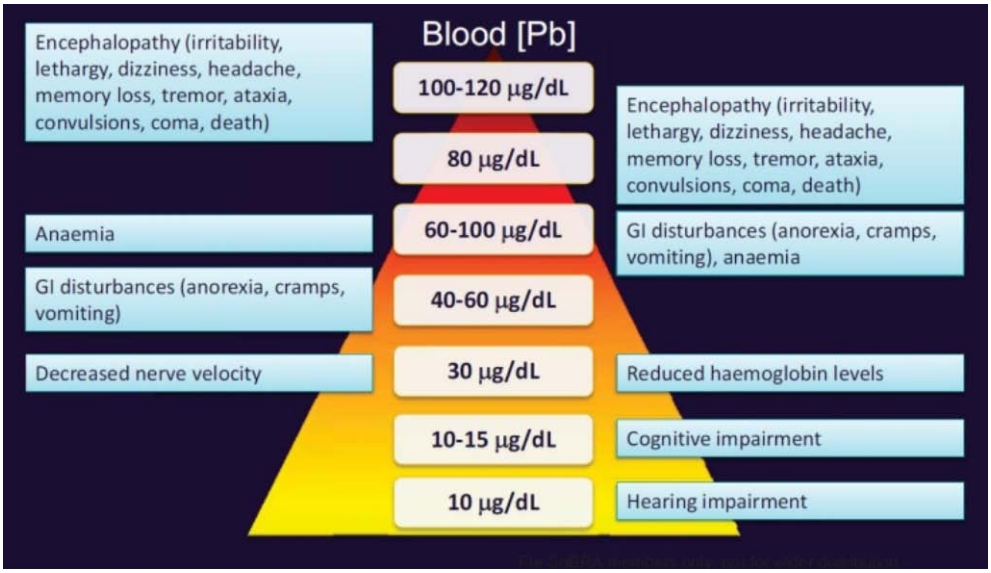
Dr Bull described how exposure to lead can occur from many sources, including food, water (mainly due to lead pipes), soil, homemade/imported ceramics and imported toys. Potential exposures were also highlighted via "traditional" remedies or cosmetics, paint chips, leaded petrol and snooker chalk.

It was then explained that the toxic effects of lead are the same whether exposure occurs via ingestion or inhalation, and that children tend to more readily absorb lead than do adults: children absorb up to 40% into the bloodstream from ingested or inhaled lead, versus 5-15% in adults. Following absorption, lead is transported in red blood cells bound to plasma proteins and distributed to the soft tissues (liver and kidney) and bone. Adults tend to have a larger fraction of their lead body burden in bone (98.5%) compared to children (73%). Lead is mobilised from the bone to the blood during pregnancy and is readily transferred to the placenta, with the concentration of lead in cord blood being up to 85-90% of maternal blood. In adults, up to 85% of ingested lead is eliminated unabsorbed, while in children this figure is up to 60%.

In terms of toxicity, Dr Bull explained how lead is essentially a chronic toxin, with few health effects being seen following an acute exposure at low concentrations. Acute effects are possible, however, with high concentrations potentially causing: non-specific gastro-intestinal (GI) and central nervous system (CNS) effects (tiredness, lethargy, headaches); abdominal cramps (diffuse or colicky); anorexia; vomiting: and constipation.

Other end-points include: effects on the kidney (reversible morphological changes); cardiovascular system (hypertension); and liver (inhibition of metabolic enzymes). Dr Bull informed the audience that most patients with a blood lead of ≥50 µg/dL will show some symptoms of adverse effects. Box 3 shows the potential effects of acute exposure to lead at different blood lead levels.

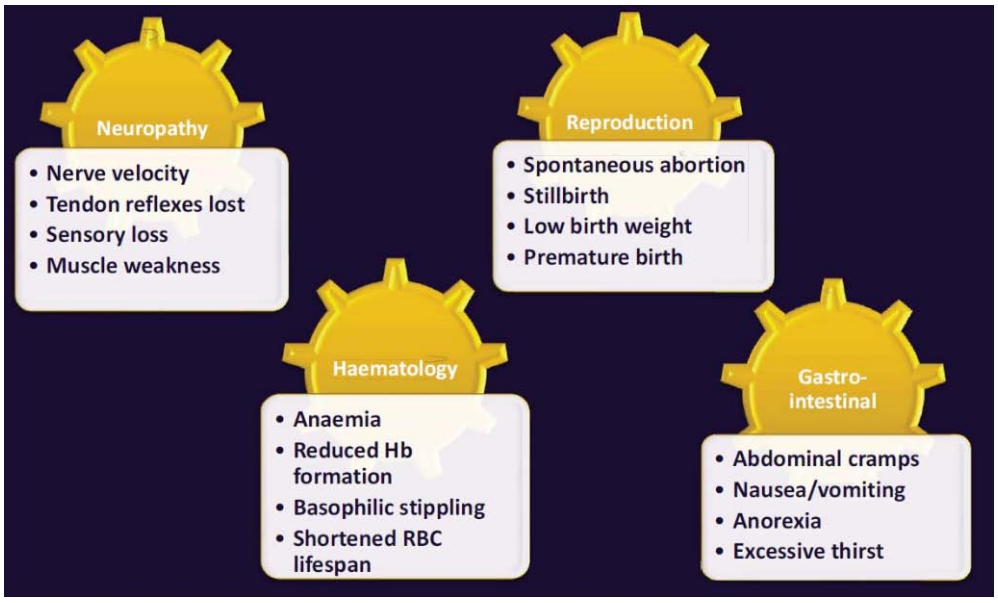
Box 3: The acute toxicity of lead as a function of blood lead level



Moving on to discuss chronic toxicity, Dr Bull described how lead can cause neurotoxic effects, in the form of fatigue, headache, irritability, slurred speech, convulsions, muscle weakness, tremors and anxiety. Exposure to lead can also cause decreases in reaction time, hand dexterity and Intelligence Quotient (IQ) with a blood lead level of 5.6 µg/dL being reported to cause IQ deficits. There is a consensus view that there is probably no threshold for lead's neurotoxicity.

Cardiovascular effects are also possible, with epidemiological data showing a correlation between lead and blood pressure / hypertension (systolic). Renal (kidney) toxicity has also been demonstrated, in the form of renal tubular dysfunction and progressive renal impairment. Other non-carcinogenic effects of chronic lead exposure are shown in Box 4.

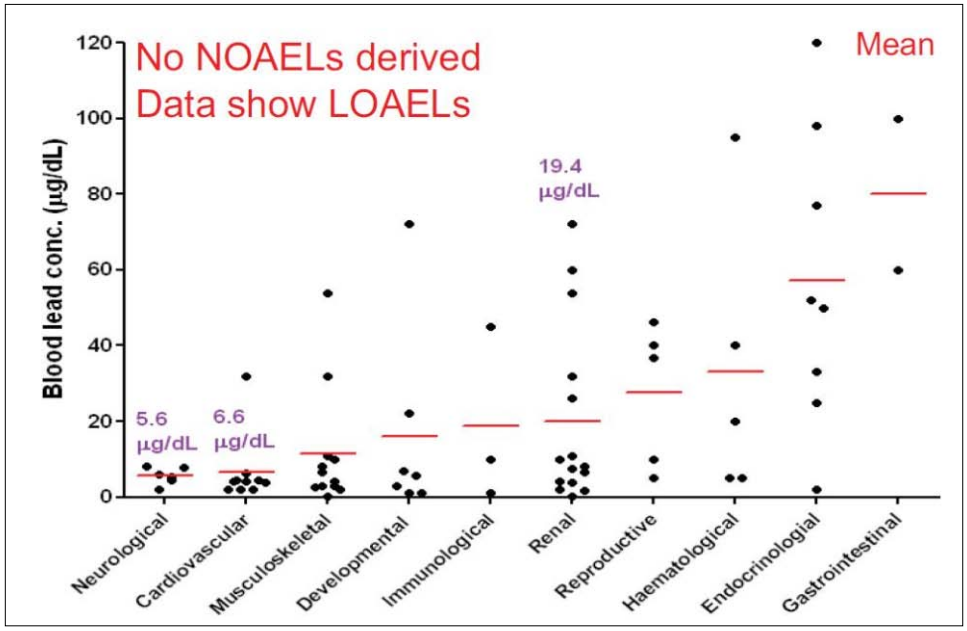
Box 4: Other non-carcinogenic effects of chronic lead exposure



In terms of potential carcinogenicity, lead is classified by IARC as belonging to Group 2B (possibly carcinogenic in humans), with inorganic lead compounds being classified as belonging to Group 2A (probably carcinogenic in humans, on the basis of little evidence of carcinogenicity in humans but sufficient evidence in animals). There is little evidence that lead interacts with DNA - it is thought to act by production of reactive oxygen species and the inhibition of DNA repair.

Based on information presented in ATSDR's toxicological profile for lead[13], and for illustrative purposes, Dr Bull presented a graph showing the spread of the lowest observed adverse effect levels (LOAELs) for numerous toxicological end points reported from various studies of the effects of chronic lead exposure. The graph is reproduced as Box 5, and shows the mean of the reported LOAELs for each particular adverse effect or target organ (in red).

Box 5: Illustration of the spread of reported LOAELs for various toxicological end-points



The two most common toxicological approaches to assessing lead from soil in UK risk assessments were then examined, as follows: 1) the old UK approach (see TOX 6[14]), which used a blood lead concentration of 10 µg/dL to derive the SGV (while acknowledging that lead does not have a threshold so exposures should be kept as low as reasonably practicable); and 2) the old WHO joint FAO/WHO Expert Committee on Food Additives (JECFA) Provisional Tolerable Weekly Intake (PTWI) of 25 µg/kg bw (3.6 µg/kg bw/day)[15].

By referring to the information in Box 5, Dr Bull showed how both of the above approaches are likely to be under-conservative in relation to the "minimal risk"

13 http://www.atsdr.cdc.gov/ToxProfiles/tp13.pdf

14 Defra and Environment Agency (2002). Contaminants in Soil: Collation of Toxicological Data and Intake Values for Humans. Lead. R&D Publication Tox 6

15 FAO/WHO (1987). Evaluation of certain food additives and contaminants. Thirtieth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, No 751

requirements of health criteria values (HCVs). This under-conservatism caused JECFA to state, at their 73rd meeting in 2010[16] that:

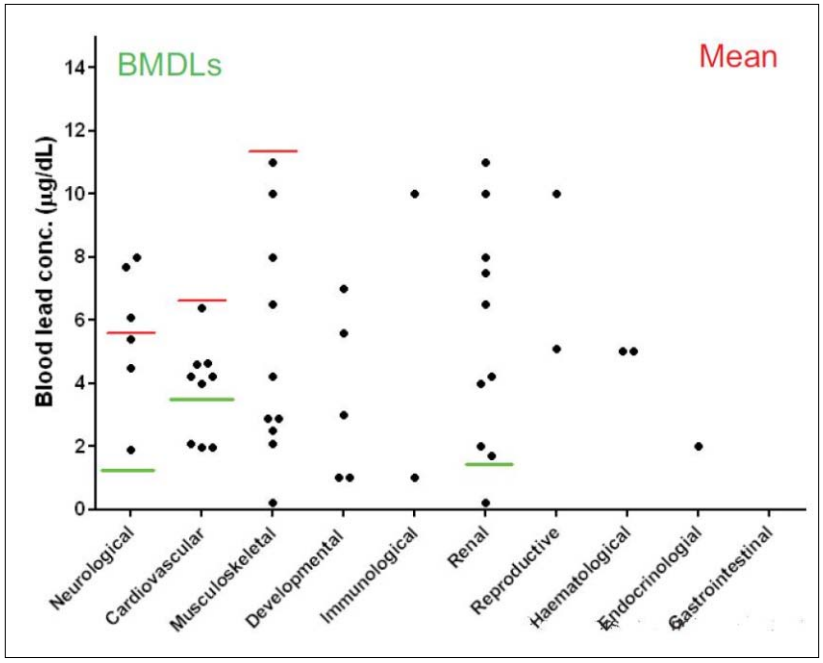
- the PTWI of 25 µg/kg bw (3.6 µg/kg bw/day) is associated with at least a 3 IQ points decrease and an increase of systolic blood pressure of 3 mmHg;
- the above effects may be insignificant at in individual level but important at the population level;
- lead does not show a threshold for the key adverse effects.

On the above basis, the PTWI could no longer be considered health protective and was withdrawn, and JECFA concluded that it was not possible to establish a new PTWI that would be health-protective. At around the same time as the JECFA re-evaluation, the European Food Standards Agency (EFSA) undertook a review of lead's toxicity[17] and provided bench-mark doses (in the form of lower confidence limits, or BMDLs), as follows:

- developmental neurotoxicity in children (full scale IQ): $BMDL_{01}$ = 12 µg/L (1.2 µg/dL);
- cardiovascular effects in adults (systolic blood pressure): $BMDL_{01}$ = 36 µg/L (3.6 µg/dL);
- chronic kidney disease in adults (glomerular filtration rate of <60 ml/min): $BMDL_{10}$ = 15 µg/L (1.5 µg/dL).

As indicated in Box 6, the above benchmark doses fall below the range of LOAELs for the relevant end-points.

Box 6: EFSA BMDLs for various toxicological end-points



16 FAO/WHO (2011). Evaluation of certain food additives and contaminants. Seventy-third Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, No 960

17 FAO/WHO (2010). Scientific Opinion on Lead in Food. EFSA Panel on Contaminants in the Food Chain (CONTAM). European Food Safety Authority, Parma, Italy. Standards Agency. EFSA Journal; 8(4):1570

In terms of the use of the above BMDLs, Dr Bull described how "margin of exposure" (MOE) approaches could be used, where the MOE is the ratio of the BMDL to exposure. It was suggested that a MOE of >10 should not give rise to an appreciable risk of clinically significant effects while at a MOE >1 the risk is likely to be low but could not be dismissed as being of no potential concern. Importantly, current background lead exposure in Europe, when compared with the above BMDLs, indicate the following:

- the risk of clinically significant effects on the cardiovascular system or kidneys in adults is low to negligible;
- for infants, children and pregnant women, there is potential concern at current levels of exposure for neurodevelopment; and
- the protection of children and women of child bearing age against the risk of neuro-developmental effects would protect against all adverse effects of lead in the population.

Summing up, Dr Bull concluded that historic approaches to the risk assessment of lead based on intake (e.g. the JECFA PTWI) were considered to be no longer sufficiently health-protective, whereas those based on modelled blood lead and the EFSA BMDL of 1.2 µg/dL are likely to be sufficiently protective, but would give rise to very low assessment criteria.

2.3 Modelling Exposure to Lead

Ian Martin, Principal Scientist with the UK Environment Agency, presented the current regulatory understanding of how exposure to lead can be predicted. He started with a discussion of common sources of lead in soil and the key exposure pathways to humans in a residential setting. He then went onto discuss alternative methods for predicting exposure from lead in soil.

2.3.1 Sources of Lead Exposure

Key sources of lead in soil include:

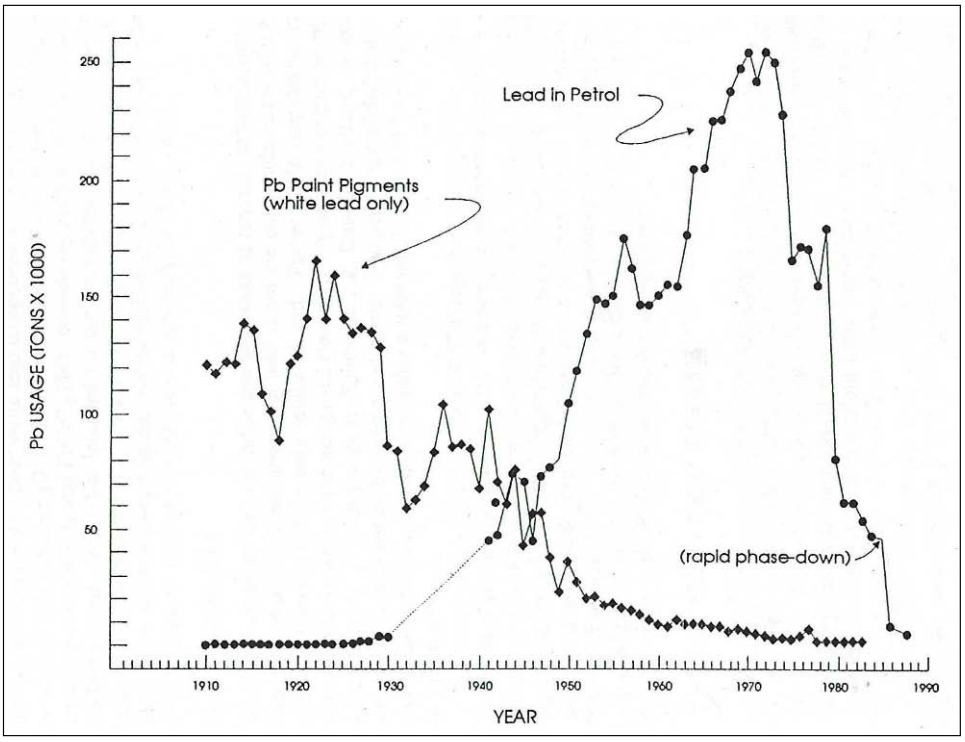
- naturally occurring lead in soils - concentrations can be highly elevated in mineralised areas;
- local and regional hot spots from mining and smelting; and
- urban diffuse pollution from use of lead in petrol and paints.

The principal anthropogenic inputs of lead to the environment have changed over time. In the UK, the principal inputs were likely to be associated with mining and smelting up until the early 1900s, whereas more recent inputs have likely been from the use of lead in paint and petrol. As can be seen from Box 7 the use of lead in paint has decreased since 1920, whereas the use of lead in petrol has increased from 1930, reaching a peak in 1970, and has now been almost entirely phased out.

The form of lead in soil has a large influence on its mobility and bioavailability and is dependent on the nature of the source. Releases of lead associated with mining are generally in the form of lead sulphide (galena), and may also include lead sulphates and carbonates. Lead from smelting is generally in the form of lead oxides and sulphates and may also be present in metallic form. Lead associated with combustion is typically in the form of lead oxides and halides. Lead in paints includes lead oxides, carbonates and sulphates, calcium plumbate, basic lead silicate, lead chromate and lead molybdate. Finally, lead in lead shot (e.g. associated with firing ranges) is in metallic form.

Once in soil, the fate of lead will vary according to its form. For example, lead halides from combustion are generally far more soluble than lead oxides and sulphates. Metallic lead will corrode over time to generally more soluble compounds, which later weather to largely insoluble salts. Weathered lead is generally strongly adsorbed onto clays and organic matter and as a result is sparingly soluble and has low bioavailability. Soil pH is expected to have a strong influence on the mobility of lead, with a decrease in pH leading to an increase in lead solubility.

Box 7: Usage of lead in paint and petrol in the US (from SEGH[18])



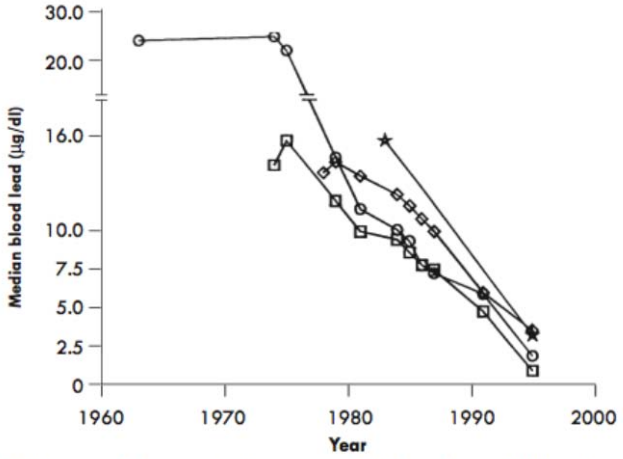
Lead has an estimated half-life in soils of around 700 to 6000 years and therefore tends to be highly persistent in soils.

An IEH report[19] on blood lead surveys in the UK shows that blood lead concentration in children has shown a steady decline since the 1970s, corresponding with the decline in use of lead in petrol since that time. Median blood lead concentration has decreased from approximately 25 $\mu g.dL^{-1}$ in the 1970s to 3 $\mu g.dL^{-1}$ or less in 1995 (see Box 8). This also corresponds roughly to a drop in the concentrations of lead in air. In 1980, the average concentrations of lead in air from five UK cities ranged from 0.26 to 0.77 $\mu g.m^{-3}$, whereas in 2006, the average concentrations had decreased to 0.006 to 0.017 $\mu g.m^{-3}$ in the same five cities.

Box 8: Median blood lead levels in the UK (1964 – 1995) (from IEH, 1998)

18 SEGH (1993). Lead in Soil: Recommended Guidelines, Wixson B. G. and Davies B. E. eds, Society for Environmental Geochemistry and Health, Science Reviews

19 IEH (1998). Recent UK blood lead surveys, Report R9

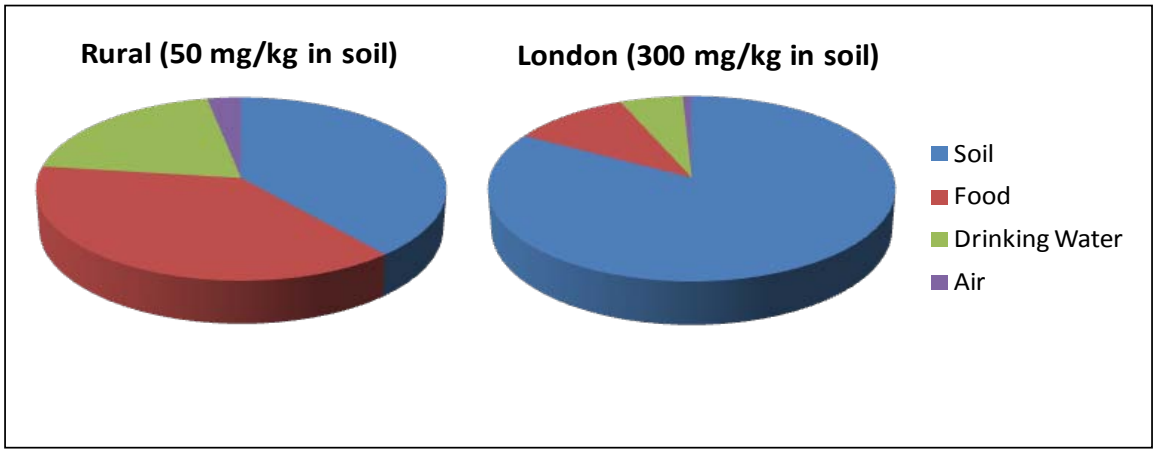


Children, ○ <16years; ★ <3 years; □ Adult females; ◇ Adult males

All analyses conducted by Great Ormond Street Hospital (1964–78) and Southampton General Hospital (1979–95). From Moncrieff *et al.* (1964); Elwood *et al.* (1977); Pocock *et al.* (1983); DoE (1981, 1983); Harvey *et al.* (1984); DoE (1990); Delves *et al.* (1996); and from the ALSPAC study (*Blood Lead Levels at Two and a Half Years,* Report to the DoE) and a study at a contaminated land site at Portsmouth, 1991

The decline in air emissions of lead now means that lead in soil can be a key source of exposure. For example, use of the CLEA model with central tendency estimates of exposure parameters suggests that soil may contribute approximately 40% of total exposure in rural areas (assuming a soil concentration of 50 $mg.kg^{-1}$) and 80% in urban areas (assuming a soil concentration of 300 $mg.kg^{-1}$) (see Box 9).

Box 9: Exposure contributions of lead in a rural vs an urban area



2.3.2 Predicting Lead Exposure

SEGH Model

The now withdrawn Soil Guideline Value (SGV) for lead for a residential land-use used the Society for Environmental Geochemistry and Health (SEGH) model as the basis for deriving the SGV.

The SEGH model relates blood lead concentration in children to soil concentration via an empirically derived delta (δ) factor:

$$S = \left(\frac{\frac{T}{G^n} - B}{\delta} \right) x1000$$

Where:

- S is the soil or dust guideline ($mg.kg^{-1}$)
- T is the blood lead target concentration (10 $\mu g.dL^{-1}$) and is the Health Criteria Value nominated by the old approach SGV (DEFRA and Environment Agency, 2002[8]).
- G is the generic standard deviation (GSD) of blood lead distribution (default value is 1.4). This typically lies in the range 1.3 to 1.5, but may be higher for groups exposed to multiple and heterogeneous sources (DEFRA and Environment Agency, 2002).
- B is background or baseline blood lead level (3.44 $\mu g.dL^{-1}$). It is the geometric mean of blood lead concentrations in young children observed as part of the UK ALSPAC study (DEFRA and EA, 2002).
- n is the number of standard deviations corresponding to the degree of protection required for the population at risk. The default value is 1.645. It is chosen on the basis of the degree of protection needed for a population at risk at the target concentration (T) - default value is 95%.
- δ is the slope or response of blood lead versus soil and dust lead relationship (5 $\mu g.dL^{-1}$ blood increase per 1000 $\mu g.g^{-1}$ of soil or dust lead).

The key parameter in the SEGH model is the delta factor (δ). It is the critical variable derived from an observed empirical relationship between blood lead concentrations in children and exposure to soil and non-soil sources (DEFRA and Environment Agency, 2002). Empirical estimates from approximately 19 studies, dating from the 1970s and 1980s, range from 0.6 to 9.0 $\mu g.dL^{-1}$ blood lead increase per 1000 $\mu g.g^{-1}$ of soil or dust lead (see Table 11).

Table 11: Empirically derived delta factors relating soil to blood lead concentration (from SEGH, 1993[18])

Study	Area	Soil/dust (µg/g)	Blood Pb (µg/dl)	Estimated δ
Bornschein *et al* (1989)	Mining	172	6	2.2
Moffat (1989)	Mining	213 - 69,025	10 - 18	1.2
Phillips *et al* (1989)	Mining	70 - 2,258	7 - 22	2.2
Rabinowitz and Bellinger (1988)	Urban	702	6	0.9
Laxen *et al* (1987)	Urban	500 (d)	11	1.9
Milar and Mushak (1982)	Battery plant	250 - 3,000 (d)	18 - 44	9.0
Reeves *et al* (1982)	Urban	24 - 842	12 - 19	5.0
Stark *et al* (1982)	Urban	230 - 1,330	27	0.6, 2.0, 2.2
Roels *et al* (1980)	Smelter	112 - 2,560 (d)	9 - 25	2.1, 3.5
Angle and McIntire (1979, 1982)	Urban	81 - 339	23 - 30	4.0, 6.8
Neri *et al* (1978)	Smelter, Urban	225 - 1,800	19 - 29	7.6, 8.5
Schmitt *et al* (1979)				4.6, 7.2
Watson *et al* (1978)	Battery plant	718 - 2,239 (d)	21 - 32	6.8
Baker *et al* (1977)	Smelter	500 - 5,500 (d)	22 - 68	8.6
Yankel *et al* (1977)	Smelter	400 - 7,500	21 - 66	1.1
Barltrop *et al* (1975)	Mining	420 - 13,970	21 - 29	2.3
Galke *et al* (1975)	Urban	173 - 1,400	32 - 43	2.5
Shellstear *et al* (1975)	Urban	150 - 1,950	18 - 25	3.9
Roberts *et al* (1974)	Smelter, Urban	99 - 1,715	17 - 27	6.0

Notes to Table: (d) refers to 'dust' as opposed to 'soil'. The reader is referred to SEGH (1993) for full details

The SEGH considered that 2 to 5 would be a reasonable range for the delta factor and that the value could be adjusted depending on site specific factors. For example, lower values of δ relate to conditions involving:

- older children and well maintained vegetative cover;
- mine tailings (or chemical forms of lead with low bioavailability);
- cleaner houses and more frequent hand washing; and,
- heavier textured soils.

Higher values of δ relate to conditions involving:

- young children (1½ - 2 years old);
- dusty conditions and bare soil;
- poor levels of hygiene;

- soluble forms of lead such as paint (or chemical forms of lead with high bioavailability); and,
- light textured soils or those with low organic matter content.

A reasonable worst case delta factor of 5 $\mu g.dL^{-1}$ blood increase per 1000 $\mu g.g^{-1}$ of soil or dust lead was chosen for deriving the SGV for residential land-use.

It is generally accepted that blood lead concentration is an appropriate assessment end-point for assessing the risks to human health. The SEGH model has the advantage that it directly relates soil concentration to this assessment end point. However, a disadvantage of the SEGH model is that there is little opportunity for the user to make objective adjustments to exposure or the bioavailability of lead in soil.

CLEA Model

The CLEA model offers an alternative method for predicting exposure from lead in soil. The CLEA model has the following advantages:

- it is consistent with the approach used in the UK for modelling exposure to other chemicals in soil; and
- it allows adjustments in many exposure parameters to be made (e.g. gender/age, soil type, building type) and can model the relative exposure contributions from different exposure pathways.

The CLEA model is able to predict intake of lead (in units of ug.kg $(bw)^{-1}.d^{-1}$) but has the disadvantage (to the SEGH model) that it does not allow direct comparison with the commonly accepted assessment end-point of a blood lead concentration.

Exposure modelling for the standard residential scenario described in the Environment Agency SR3 report[20] shows that the principal exposure pathways for the 0 to 6 year old female resident are predicted to be the incidental ingestion of soil and soil derived dust (72%) and the ingestion of home-grown produce (28%). This is based on the soil to plant concentration factors for lead presented in Table 12, which are based on an unpublished Environment Agency report from 2009.

Table 12: Geomean soil to plant concentration factors derived from empirical data

Produce	Concentration Factor (mg.kg-1 FW per mg.kg-1 DW)
Green vegetables	4.2×10^{-3} (371)
Root vegetables	4.0×10^{-3} (222)
Tuber vegetables	7.3×10^{-3} (41)
Herbaceous fruit	7.5×10^{-4} (99)
Shrub fruit	2.0×10^{-4} (12)
Tree fruit	2.3×10^{-4} (19)

Note to Table: Number in ( ) in second column is number of data points

As with all modelling there are uncertainties associated with the predicted exposure using the CLEA model. One uncertainty is the contribution of exposure

[20] Environment Agency (2009). Updated technical background to the CLEA model. Science Report: SC050021/SR3

from ingestion of lead in soil to that of lead in house dust. The CLEA model assumes that a child ingests a daily average of 100 mg of soil and soil derived dust per day but makes no distinction between these two sources. Oomen and Litzen (2004)[21] reviewed data from various studies in Europe and North America and found that the concentration of lead in indoor dust was frequently greater than in soil. Furthermore, Layton and Beamer (2009)[22] showed that tracked back soil indoors could be an important pathway for exposure to lead. There is considerable variation in how much lead in indoor dust comes from soil and to what extent indoor dust contributes to combined ingestion. Therefore it is difficult to make generic assumptions about the contribution of lead in dust to total exposure.

The IEUBK Model

The USEPA's Integrated Exposure Uptake Biokinetic (IEUBK) Model (USEPA, 2007[23]) was designed to predict the probability of elevated blood lead levels in 0 to 7 year old children within the residential land use scenario. It is the most widely validated model for blood lead in young children, and can consider multiple lead sources via oral and inhalation routes. It is a probabilistic model that takes account of population blood lead distributions.

The IEUBK model uses four separate modules to estimate blood lead concentrations as illustrated by Box 10 and described below:

- **Exposure (Intake) Module.** This module is deterministic and uses lead concentrations in the environment and the rate at which a child breathes or ingests contaminated media to determine lead intake. Intakes are calculated for exposure to lead in the following media: soil (indoor and outdoor), dust (indoor), air (indoor and outdoor), drinking water and diet. Other sources such as paint can be included on a site-specific basis.
- **Uptake Module.** This module is deterministic and predicts uptake of lead into the bloodstream from the predicted intake calculated above. Uptake is defined as the fraction of the total lead intake that crosses from the lungs or GI tract into the bloodstream - also termed bioavailability. The model assumes that 50% of intake from drinking water and food and 30% of intake from soil and dust is absorbed. Absorption factors can be altered for site specific values but requires thorough understanding and assessment.
- **Biokinetic Module.** This module is deterministic and models (a) the transfer of absorbed lead between blood and other body tissues; (b) the elimination of lead from the body via urine, faeces, skin, hair, and nails; and (c) the storage and/or disposition of lead in the extra-cellular fluid, red blood cells, liver, kidney, spongy bone, compact bone (femur), and other soft tissue. A variety of complex equations are used to calculate compartmental lead transfer times. Based on site-specific environmental exposures input by the user, a geometric mean lead concentration is predicted. There are no user-specified input values for this module. The parameters used in this module have been hard-wired into the program code and cannot be changed.

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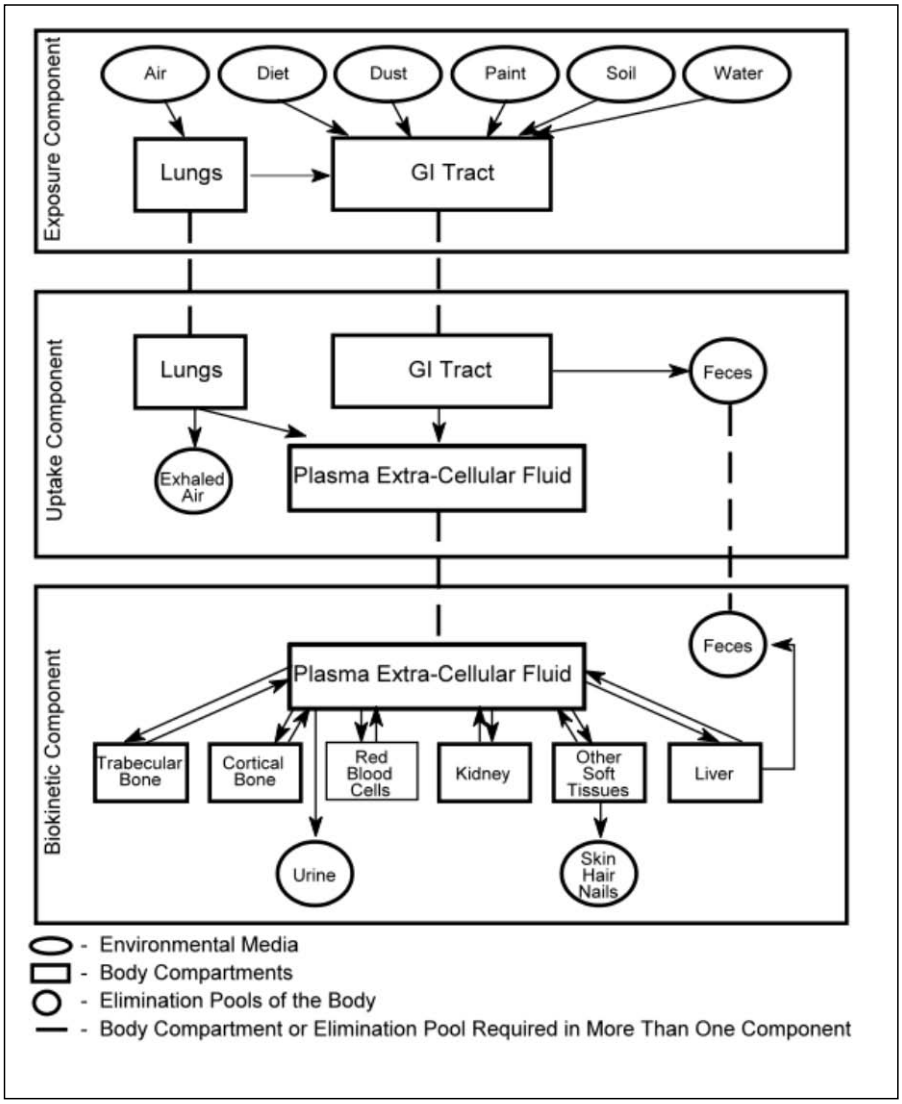
21 Oomen, A.G. and Lijzen, J.P.A. (2004). Relevancy of human exposure via house dust to the contaminants lead and asbestos. RIVM Report 711701037/2004, National Institute of Public Health and the Environment, Bilthoven

22 Layton, D.W. and Beamer, P.I. (2009). Migration of contaminated soil and airborne particulates to indoor dust. Environ. Sci. Technol. 2009, 43, 8199–8205

23 USEPA (2007). User's Guide for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK)

- **Probability Distribution Module**. This module uses the geometric mean blood lead concentration (calculated by the Biokinetic Module) with a geometric standard deviation (GSD) to estimate a plausible log normal distribution of blood lead concentrations in 0 to 7 year old children. This module takes account of the fact that a cohort of children exposed to the same intake dose of lead will have differing blood-lead concentrations. Using this distribution, the model calculates the probability or risk that a child's blood lead concentration will exceed a user selected blood lead level of concern. The user-specified parameters in this component of the model are the blood lead level of concern (LOC) and the GSD. The USEPA recommended default value for the GSD is 1.6. This value was derived from empirical studies with young children where both blood and environmental lead concentrations were measured. GSD should not be changed without detailed site-specific analysis.

Box 10: Schematic diagram of IEUBK model (from USEPA, 2007)



Over 100 parameters are used in the IEUBK model, 46 of which may be changed by the user. Users are encouraged to enter site-specific lead media

concentrations, but are discouraged from changing other factors including mass fraction of soil to dust (MSD), bioavailability, geometric standard deviation (GSD), blood lead level of concern (LOC), soil ingestion rates, and dietary data, unless they have thorough understanding of the underlying methodologies.

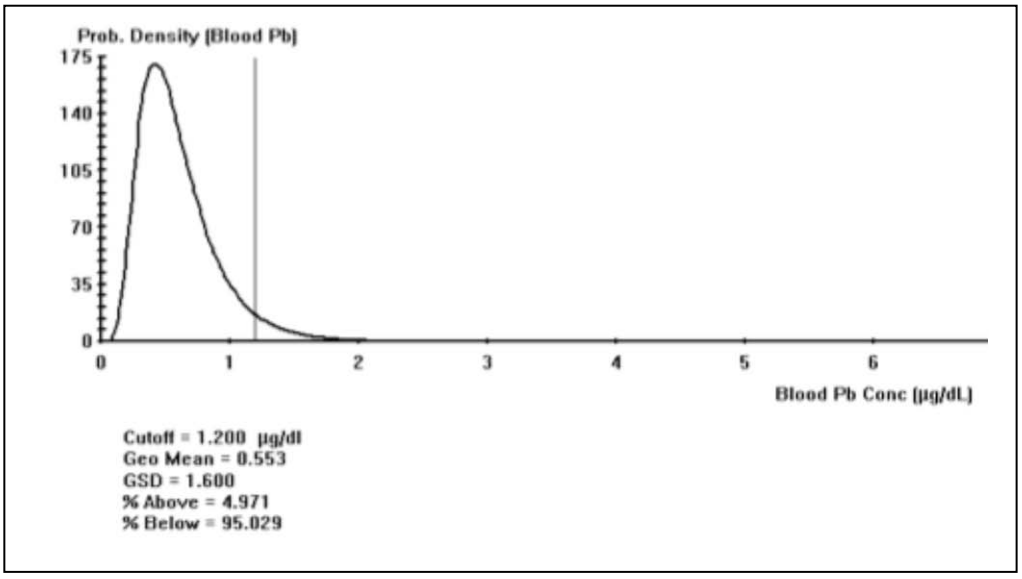
Table 13 shows a comparison between key exposure parameters used in CLEA to those used in the IEUBK model.

Table 13: Comparison of default values used in IEUBK and CLEA for some parameters

Parameter	IEUBK	CLEA
Body weight (kg)	14.6 (average)	13.3 (average)
Fraction of soil in indoor dust (-)	0.7	0.5
Soil and dust ingestion rate (mg.day-1)	113 (85 – 135)	100
Percent home-grown foods (%)	Site-specific	2 - 9
Lead levels in home-grown fruit and vegetables	Site-specific	Modelled or site-specific
Absolute bioavailability from diet / soil	50 / 30	-

Results from the IEUBK model are presented as a log normal probability distribution of blood lead concentration. The output presents the predicted geometric mean blood lead concentration and the probability that the LOC is exceeded in a child. An example output is shown in Box 11 and shows that 95% of children are predicted to have a blood lead concentration of less than the user defined LOC of 1.2 $\mu g.dL^{-1}$ and that the geomean blood lead concentration is predicted to be 0.553 $\mu g.dL^{-1}$.

Box 11: Example output from IEUBK model



The IEUBK model offers the following advantages relative to the SEGH and CLEA models:

- it allows flexibility in modelling exposure from different sources;
- it models the predicted concentration of blood lead, which is the commonly accepted appropriate assessment end-point for lead; and
- it can account for the observed distribution of blood lead concentrations in the population.

A summary comparison between the SEGH, CLEA and IEUBK models is shown in Table 14.

Table 14: Comparison of different lead exposure models

Factor	SEGH	CLEA	IEUBK
Easy to use	Y	N	N
Uptake / intake	Uptake	Intake	Uptake
Exposure adjustments	N	Y	Y (limited)
Bioavailability adjustments	N	Y (limited)	Y
Uncertainty analysis	Y	N	Y

2.3.3 Conclusions

There are a number of challenges when predicting exposure from lead in soils:

- Selecting an appropriate health criterion value (HCV). Firstly, should it be uptake or intake based? Secondly, should it include or ignore background exposure from non-soil sources? Thirdly should there be a minimal risk level for IQ decrements?
- Differentiating soil and indoor exposure components. This may be an important consideration when trying to accurately predict exposure, especially given the importance of household dust as an exposure pathway for lead.
- Communicating outcomes. The estimation of exposure and characterisation of risk from lead in soil is not straightforward and presents a particular challenge for risk communication.

2.4 Bioaccessibility Testing and its Use in Risk Estimation

There were two presentations on the bioaccessibility of lead in soil. The first was by Dr Claire Stone of i2 Analytical Ltd on the practicalities of lead bioaccessibility testing. The second was prepared by Mike Quint and Ed Stutt. It addressed the application of bioaccessibility data in human health risk assessments and was presented by Mike Quint of Environmental Health Sciences.

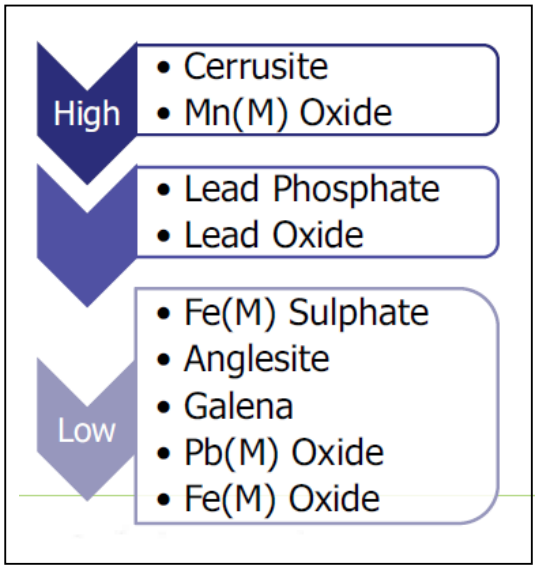
2.4.1 Lead Bioaccessibility Testing

Dr Claire Stone's presentation started by setting out the definitions of the key terms associated with bioaccessibility testing. Laboratory testing is *in vitro* testing of the bioaccessibility of lead and is designed to simulate the human digestive system in the laboratory. Laboratory results of bioaccessibility are often incorrectly referred to 'bioavailability'. Bioavailability can only be ascertained through *in vivo* testing.

The process of validating bioaccessibility *in vitro* tests against *in vivo* tests was described. One of the key points highlighted was that validation of *in vitro* tests is required for a variety of soil types and metal concentrations, either naturally occurring or anthropogenic.

The general principles of testing for bioaccessibility in a laboratory were discussed, focusing on the process of acid extraction and what particular components are likely to be extracted at each stage of the test. The mineralogy of lead is important with regards to its bioaccessibility. Work undertaken by the USEPA[24] indicated that depending on the associated mineral form of the lead compound, bioaccessibility test results can vary considerably as illustrated below.

Box 12: Bioaccessibility of different forms of lead



A number of laboratory bioaccessibility test methods are available including:

- PBET (Ruby, 1996)[25] - The Physiologically Based Extraction Test which has been modified for ease of performing the test and is primarily used for metals such as arsenic.
- SBET (Drexler, 1998)[26] - The Simplified Bioaccessibility Extraction Test upon which the USEPA based their validated methodology for lead.
- UBM (BGS, 2009)[27] - The unified BARGE method (UBM) which has been developed in collaboration with other European countries. It has been designed for use with inorganic and organic contaminants (assuming the

[24] USEPA (2009). Validation Assessment of In Vitro Lead Bioaccessibility Assay for Predicting Relative Bioavailability of Lead in Soils and Soil-like Materials at Superfund Sites. OSWER 9200.3-51

[25] Ruby, M.V. *et al* (1996). Estimation of lead and arsenic bioavailability using a physiologically based extraction test. Environ. Sci. Technol. 30(2):442-430

[26] DREXLER, J.W. (1998). An in vitro method that works! a simple, rapid and accurate method for determination of lead bioavailability. In: EPA bioavailability workshop, August 1998 Durham, NC

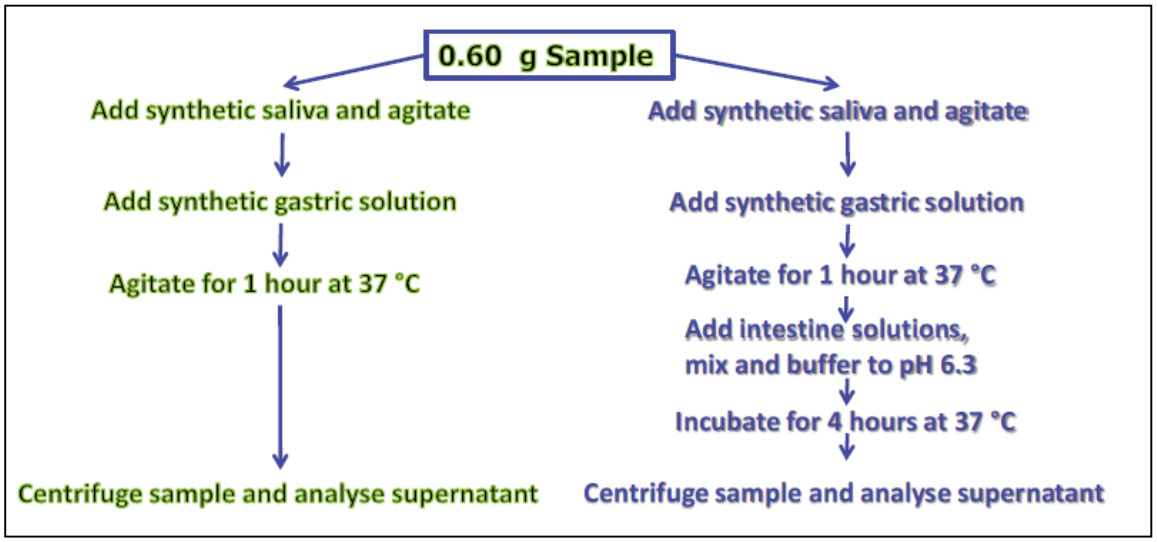
[27] Wragg, J. *et al* (2009). Inter-laboratory trial Inter-laboratory trial of a unified bioaccessibility testing procedure. Available at: http://nora.nerc.ac.uk/7491/

receptor is in a 'fed' or 'fasted' state), and has been validated with bioavailability data, inter-laboratory and inter-method comparisons.

- DIN 19738 (2004)[28] - a German method for organic and inorganic contaminants assuming the receptor is in a fasted state.
- FOREhST (2010)[29] - The Fed Organic Estimation human Simulation Test which is a newly developed test for organics.

The BARGE test (UBM) is the method recommended by i2 Analytical Ltd. It is physiologically based and is validated against the juvenile swine model for various metals, including lead. The testing procedure is summarised below with the stomach phase shown on the left and the intestinal phase on the right.

Box 13: Testing procedure for the BARGE (UBM) test



Methods for ensuring quality control within the laboratory include processing duplicates of test samples, conducting recovery tests on fraction matrices, and using system and extract solution blanks, routine AQC and certified or in-house reference materials.

The presentation was concluded by summarising that:

- bioaccessibility not bioavailability is measured by *in vitro* laboratory tests;
- UBM and EPA 9200[30] methodologies are the most suitable validated methods for bioaccessibility testing for lead; and,
- there needs to be further correlation between methods with real contaminated land samples.

28 DIN (2004). Soil quality - Absorption availability of organic and inorganic pollutants from contaminated soil material. Available at: http://www.en-standard.eu/din-19738-soil-quality-bioaccessibility-of-organic-and-inorganic-pollutants-from-contaminated-soil-material/

29 Cave, M. R. *et al* (2010). Comparison of batch mode and dynamic physiologically based bioaccessibility tests for PAHs in soil samples. Environ. Sci. Technol. 44 (7), pp 2654–2660

30 USEPA (2008). Standard operating procedure for an in vitro bioaccessibility assay for lead in soil. EPA 9200. 1-86

2.4.2 Use of Bioaccessibility Data in Lead Risk Assessment

Mike Quint started his presentation by outlining that the default assumption within the CLEA software model is that relative bioavailability is one. Further explanation was given that for the relative bioavailability to be one, the absolute bioavailability of the chemical in the soil sample must be the same as the absolute bioavailability of the chemical in the media used in the relevant toxicological studies on which the Health Criteria Value is based.

Several international approaches to using bioaccessibility in risk assessment were presented including those used in the US and Netherlands. The approach adopted in the US is based on the relationship between results for *in vitro* bioaccessibility and measurements of the relative bioavailability (RBA) determined by the juvenile swine test[24]. From this, the USEPA has derived the following relationship between *in vitro* bioaccessibility (IVBA) and RBA:

RBA = 0.878 x IVBA- 0.028 (r^2 = 0.924)

The Dutch approach has been based on a considerable amount of work done on the difference in bioavailability of lead under fasted and fed conditions[31]. Within the Dutch Soil Intervention Value (DIV) for lead there is a "generic intervention correction factor" of 0.74 (based on the 80th percentile of measured/assumed RBA factors).

Practical experience was presented with the results from two sites described. At the first site, 15 shallow samples were analysed for lead bioaccessibility using UBM. The results at the site ranged from 41-95%, with the highest measurements of lead bioaccessibility (90+%) being found within the ash-fill and not in 'typical soil'.

The second site described in the presentation had more 'typical soil' than the first site. It utilised both the UBM and IVBA approaches. The results for the two methods were:

- bioaccessibility measured by UBM: 27-52%
- bioaccessibility measured by IVBA: 27-75%

The results indicated some consistency between the two methodologies, with IVBA giving higher bioaccessibility than UBM.

The presentation was concluded with the following points:

- site-specific bioaccessibility measurements of lead can be used (with care!) in risk assessment;
- as with all laboratory testing, the methodology used can influence the results;
- validation of *in vitro* methods with *in vivo* data is important;
- the US and Netherlands have both developed testing protocols and guidance on the use of *in vitro* bioaccessibility measurements in risk assessment;
- the basis of the dose-response criteria (e.g. HCV) used in risk assessment is important.

31 RIVM (2009). Relative oral bioavailability of lead from Dutch made grounds. RIVM Report 711701086/2009

3 SOURCES, FORMS AND BACKGROUND CONCENTRATIONS OF LEAD

3.1 Introduction

The initial presentation on sources and forms of lead from Cathy Scheib (BGS) and Chris Taylor (Brent Council) shows that lead is ubiquitous in the environment. It results from both local geological sources (natural or geomorphic lead) and from human industrial activity (anthropogenic). The widespread nature of this contaminant makes it a difficult and challenging issue to consider.

According to the expert presentation, the UK Soil and Herbage Survey (2007) showed that mean lead concentrations in top soils in rural locations ranged from 3-713 mg/kg with a mean of 53mg/kg, while the London Earth – BGS soil surveys (2011) indicates a mean of 301mg/kg with elevated values significantly greater than 1000mg/kg being a common occurrence in most Inner London Boroughs. This poses a series of difficult questions regarding the setting of intervention levels for lead in terms of balancing human health protection and the cost of remediating potentially large areas of land containing elevated concentrations of lead.

A key policy objective regarding brownfield development is the need to ensure that land which has been remediated / developed through the land use planning system cannot be determined as "contaminated land" under Part 2A once development is complete[32]. There is a potential for conflict between policy and legislative requirements regarding the development of brownfield land, and wider public health protection matters, and the issue is further complicated by proposals to revise the Statutory Guidance to Part 2A regarding the approach to 'background' concentrations of contaminants[3].

This workshop addressed some of the key policy and technical issues around the sources, forms and background concentrations of lead. It was facilitated by Rob Ivens and John Barber.

3.2 Key Issues

At the start of the workshop discussion a number of key issues were posed as set out below.

Table 15: Key issues for the 'sources, forms and background' workshop

Conceptual and Societal Issues	Technical Issues
• What is a background measurement? • How can a better understanding of 'background' help regulators and others to make better decisions? • Are background lead contributions significant in a given area? • How should health protection considerations be balanced against cost/commercial needs?	• Accounting for and measuring different sources of lead • Assessing the source and biological availability of lead • Quantifying background concentrations • What is an appropriate averaging area? • Obtaining representative data • Laboratory analysis and bioaccessibility testing

32 Defra (2006). Circular 01/2006, Environmental Protection Act 1990: Part 2A Contaminated Land

3.2.1 Conceptual and Societal Issues

The main discussion related to what constituted a background measurement and the determination of whether it was significant or not. It was felt that this issue was of sufficient technical difficulty that it required supplementary guidance to be provided. In this context it was noted that Defra has commissioned BGS to prepare guidance on background concentrations of contaminants in UK soils to support regulators and others in assessing background contamination under the proposed changes to the statutory guidance to Part 2A. It is expected that the guidance will be published shortly.

It was thought that any guidance which is produced would need to present a considered approach that could be consistently followed across a given region, while allowing some flexibility for different view points to be applied. There was a widely held belief that, because of the wide range of issues to be considered, any approach should actively promote cross-regional working across administrative districts. This cross-regional working was felt to be important in allowing for the moderation of any decisions made, and for making such decisions consistent and transparent.

In particular, it was recognised that any regulatory decision framework needs to consider the relative burdens of cleaning up contamination versus the health risks of leaving it in place. To that extent, any decisions would need to take into account:

- the historical causes of lead contamination;
- the extent and magnitude of the source;
- its distribution within the soil profile.

These local factors need to directly influence the technical methods used in attempting to estimate an actual background level and the assessor should also take into account any specific local objectives that might affect the outcome.

Having obtained a meaningful measure of the lead concentrations it was felt that regulators need to take account of social, economic and health protection objectives and consider whether regulatory intervention is required to either:

- relax the intervention level for lead - on the basis that the concentrations identified were still unlikely to be considered ‘significant’ under Part 2A; or
- tighten regulatory control through the planning process to generally reduce the impact of lead, despite increased societal costs.

These choices could then provide a policy basis on which it could be decided to either reduce the cost of development by accepting increased risk levels or, conversely, to progressively clean up very elevated lead levels in a particular district.

3.2.2 Technical Issues

The group considered that most of the societal and technical issues would be best addressed by clusters of similar Local Authorities working together to follow and, where necessary, adapt a core guidance document. A number of key issues were identified. Broadly, these were considered to break down into three areas:

i) characterisation of [an] area and the identification of the primary (lead) sources;

ii) sampling and analysis;

iii) deciding the scale of interest/prioritisation taking into account the significance of local factors.

3.2.3 Characterisation of Background Levels

The Local Authority should consider if its district, or the wider region where it is located, is affected by particularly elevated concentrations of lead in soil. A range of views were put forward from macro considerations such as *"London has very elevated lead levels so we will adopt that"* to the micro view of *"we need to consider the elevated lead within 30m of every main road"*. No consensus could be found on the approach but all members of the group agreed that both the scale of interest and the significance of the impact were important. The following two questions were thought to be important:

- are there known patterns of lead sources or lead distribution in the district?
- do any of the sources identified show significantly elevated levels of lead that are of regulatory concern?

If the answers to the above questions are 'yes', then it was thought that background concentrations of lead should be considered further. In this case the following terms were identified as being potentially useful:

- natural background – 'typical', naturally occurring concentrations of lead in soil and water;
- natural hotspots– local, naturally elevated concentrations of lead compared to the surrounding area;
- ambient/urban background – this allows for some additional elevated anthropogenic concentrations of lead on top of the natural background, but caused by common human activity, including historical influences;
- top soil - widely considered to be the top 200mm or 300mm of the soil profile.

The broad classifications of background concentrations are very likely to be variable with significant heterogeneity at all scales of interest. Any assessment of the background level needs to be carefully considered to ensure the following are appropriate:

- averaging area;
- number of samples;
- vertical stratification.

It was agreed that a standardised protocol is needed to establish a methodology for determining and identifying background concentrations of contaminants. Lead distributions in soil are strongly dependent on, but not exclusively limited to, the following:

- underlying solid geology and superficial geology;
- location within urban or rural areas;
- nature of the ground, e.g. Made Ground or natural ground;
- influences of localised aerial deposition;
- for residential gardens, the age of the housing stock because of specific factors such as ash deposition from coal fires used for soil improvement and old lead-based household paints.

The workshop group agreed that a likely outcome of such an approach would be that a number of discrete background concentrations in a given geographical region would be identified.

The protocol used to determine lead background concentrations should include the following:

- number of samples per averaging area;
- sampling methodology;
- depth of sample;
- sample preparation and associated laboratory quality assurance procedures;
- soil particle size fraction analysed;
- analytical technique used;
- statistical interpretation of data obtained.

The group also recognised the need to consider the form of the lead but it was felt that at a practical level this would be taken account of by an appropriate use of bioaccessibility testing.

The most contentious issue identified was laboratory sample preparation. Concern was expressed that soil samples may be ground-up as received, without this being made explicit in the laboratory schedules, and there was a strong view that this could substantially alter the results. The group recommended consideration of sieved or 'as received' testing with substantial duplicate sampling to enable uncertainty assessment of the results[33] especially if the data are to be used within a regulatory context.

3.3 Conclusions

Background measurement of lead is not a straightforward issue, as there are significant and substantial conceptual challenges for regulators to understand the lead distributions in their district. There are also social and economic consequences to the decisions made. It is important that flexible guidance be produced allowing local decisions to be made that are transparent, robust and justified. A careful consideration of background levels is a genuine opportunity to avoid excessive regulation and substantial costs.

3.4 Recommendations

1. Supplementary guidance should be produced to assist Local Authorities and others to assess the presence of potentially elevated lead levels in a given area. Any guidance which is produced should follow a prescribed hierarchy and avoid unnecessary consideration of factors that will not significantly affect outcomes. The guidance should encourage assessors to consider whether:
    - there are identified lead distribution patterns in the district?
    - any of the sources identified show significantly elevated levels of lead that are of regulatory concern?
2. The guidance should then require a review of Local Authority background values in light of decisions made in similar areas in the surrounding region.

[33] Eurachem, EUROLAB, CITAC, Nordtest and the RSC Analytical Methods Committee (2007). Measurement uncertainty arising from sampling: A guide to methods and approaches. A joint publication edited by M. H. Ramsey and S. L. R. Ellison

If it is considered that there are anomalous background levels of lead, specific steps should be prescribed and taken to establish the broad nature of the anomalous concentrations and to identify the key areas to be characterised in more detail, having due regard to:

- geological characteristics;
- general anthropomorphic influences such as the age and distribution of housing stock, parks and open spaces;
- specific anthropomorphic considerations such as aerial disposition or localised point sources;
- size of the respective sources, the averaging area, and the number of samples to be taken;
- specific exclusion rules for those sites to be exempted from sampling;
- consideration of lithology, such as inclusion or exclusion of Made Ground.

4 HEALTH EFFECTS AND TOXICOLOGICAL APPROACHES TO LEAD

4.1 Introduction

The toxicology workshop was designed to encourage the discussion of the health effects associated with lead and the various toxicological approaches underpinning the risk assessment of lead contaminated soil. The workshop was facilitated by Mike Quint and Ed Stutt.

Prior to the day, the following reference materials were circulated for consideration by the participating delegates, as follows:

- 2010 EFSA Report[34]
- CLEA FAQs[35]
- HPA profile[36]
- US EPA Draft Integrated Science Assessment[37]
- Carlisle *et al* 2009[38]
- Cal-EPA Revised HHSL[39]
- COT 2008 Statement[40]
- FSA 2009[41]
- Bristol University study[42, 43]
- Lanphear *et al*, 2005[44]

Delegates were also asked to notify the group of any other relevant papers and/or bring them along on the day. One such paper was highlighted in this regard[45].

The content of each of these documents was summarised by the facilitators at the beginning of the workshop, with various points being highlighted, including:

- The extremely low benchmark doses, lower confidence limit (BMDLs) presented in the EFSA report (see above).
- The CLEA FAQs, which state the following:

"What is the approach to lead (Pb)?

Previously, the now withdrawn Report SGV10 (published in 2002) used a bespoke model for deriving an SGV for Pb based on a relationship between exposure and blood Pb concentration. We have considered using an approach based on intake that would allow use of the CLEA software.

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34 http://www.efsa.europa.eu/en/efsajournal/pub/1570.htm
35 http://www.environment-agency.gov.uk/static/documents/Research/110418_FAQ.pdf
36 http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947319565
37 http://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=226323
38 http://www.esequips.org/sitebuildercontent/sitebuilderfiles/carlisledowlingetaljesh2009.pdf
39 http://oehha.ca.gov/risk/pdf/LeadCHHSL091709.pdf
40 http://cot.food.gov.uk/pdfs/cotstatementtds200808.pdf
41 Food Standards Agency (2009). Measurement of the concentrations of metals and other elements from the 2006 Total Diet Study. http://www.food.gov.uk/multimedia/pdfs/fsis0109metals.pdf
42 http://www.bristol.ac.uk/alspac/documents/lead-education.pdf
43 http://adc.bmj.com/content/early/2009/09/21/adc.2008.149955.abstract
44 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1257652/pdf/ehp0113-000894.pdf
45 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60745-3/fulltext

Recently, the European Food Safety Authority published an opinion on the toxicology of Pb, which significantly reduced the level of exposure at which experts considered a measurable reduction in development neurotoxicity in children might occur. We are currently considering this further."

- The HPA profile for lead which, at the time of the Workshop, still referred to the withdrawn PTWI, SGV and HCV values (although it has since been updated to exclude these references).
- The Carlisle *et al* and Cal-EPA work, which provide modelled soil assessment criteria based on the assumption that a site-related decrease in IQ of 1 point, due to potential lead exposure, is *"de minimis"*.
- The COT 2008 statement, which is the most recent document from a UK authoritative body (the Committee on Toxicity) that includes a review of lead's toxicity and risk.
- The FSA 2009 review of metals in the UK diet, which refers to the now-withdrawn JECFA PTWI (NB. FSA indicated since then that they would provisionally use the EFSA BMDL in food risk assessment, e.g. Alan Dowding's presentation at the December 2010 meeting).
- The Bristol University-led study (Emond *et al*, 2009) which recommended a threshold for clinical concern of 5 µg/dL.
- The meta-analysis study by Lanphear *et al* (2005) which was the primary basis for the conclusions of EFSA. These indicate a non-linear dose-response between blood lead level and loss of IQ points; the dose-response curve is steeper at lower blood lead levels, i.e. more IQ points are lost where blood lead ranges from 0-10 µg/dL than where it ranges from 10-20 µg/dL.

4.2 Key Issues

Following discussion of the documents listed above, a number of issues were identified as being relevant to the selection of appropriate toxicological criteria for the risk assessment of lead in soil (based on an outline provided by the workshop facilitators, as well as points raised by the workshop delegates). These were as follows:

- what is the "critical effect" in terms of lead toxicity?
- how should the dose-response information for lead be interpreted in setting a Health Criteria Value (HCV) for use in contaminated land risk assessment?
- should lead be viewed as a threshold or non-threshold contaminant and should an Index Dose (ID) or Tolerable Daily Intake (TDI) be assigned?
- should an intake dose (applied dose) or an absorbed dose (e.g. blood lead level) be used as the basis for the HCV?
- if a TDI is assigned, what should this be? How should it be derived? Should it include a consideration of background intake, existing blood levels and potential effects at these concentrations?
- if an ID dose is assigned, what should this be and how should it be derived?
- should an "unacceptable intake" or other benchmark for assessing SPOSH due to lead be assigned? If so, how?

4.3 Conclusions

The above issues were discussed by the group, with the following points being noted.

There was consensus that lead exhibits non-threshold toxicological behaviour and that an Index Dose (ID) approach should be followed in recommending a HCV (i.e. with no consideration of exposure from sources other than the land/site being considered).

There was general agreement that an absorbed dose is more relevant than an intake dose and a blood lead level should be used as the HCV metric.

Following on from acceptance of an ID approach and use of a blood lead level, it was highlighted that the most practical approach would probably be to define an allowable **site contribution** to the blood lead level as the basis for the HCV.

Based on the large amount of scientific evidence there was consensus from the group that the critical health end-points are:

- impairment to the cognitive development of children (as measured by loss in IQ points);
- renal effects in adults

On an individual basis, the loss of a few IQ points may not be significant or discernible but such a view may be difficult for the public to accept and there is evidence from socio-economists that there would be a noticeable effect on economic output if extrapolated to a population level.

A large amount of the discussion centred on the very low BMDLs recommended by EFSA. Some members of the group considered this to be the only scientifically justifiable HCV (despite the fact that its implementation in contaminated land risk assessment would give impractically low GAC) but others pointed out that it had not yet been fully considered and endorsed within the UK.

The allowable level of harm from this non-threshold toxicant is not a purely scientific issue and should be a political and societal judgment.

It was acknowledged that understanding of the impact of lead exposure and regulatory interpretation of this were still evolving[46]. Due to the complexity of the toxicological and epidemiological evidence, and some variation in the recommendations from various studies and regulatory authorities, the workshop concluded that it would be extremely difficult to agree on a definition of 'minimal risk' from lead that could used as the basis for a HCV to inform derivation of a GAC. It was also accepted that the definition of unacceptable harm to inform SPOSH is likely to be even harder.

4.4 Recommendations

1. Following the discussion, it became apparent that there are numerous issues that require further consideration with regard to the toxicological aspects of assessing lead contaminated soil. Importantly, there is an apparent need for a multi-disciplinary approach to understand the scientific evidence and to use this to establish a practical HCV for use in contaminated land risk assessment.

[46] For example, the European Commission is currently discussing the policy context of the EFSA recommendations.

2. In addition to a conventional review of the evidence on lead by an expert committee (e.g. CoT) a broad range of expertise needs be brought together comprising toxicologists, experts in exposure assessment, social scientists and epidemiologists.
3. It is considered to be important to consider “multiple lines of evidence in an area of scientific noise” (i.e. there should be equal consideration of a range of studies and reports).
4. As has been done for the level of risk from lead in drinking water, it may be advisable to undertake a cost-benefit analysis on the various options for setting HCVs to inform an SGV.
5. It was considered essential to have some consideration of existing ‘background’ levels of soil lead in order to ensure derivation of a workable GAC.
6. It was agreed that further work by the relevant government agencies (e.g., HPA and Environment Agency) and/or by SoBRA could assist with the above.

5 MODELLING EXPOSURE TO LEAD

5.1 Introduction

This workshop was intended to look at the key issues associated with the exposure modelling of lead in soils. The workshop was facilitated by Simon Firth and Seamus Lefroy-Brooks.

5.2 Key Issues

The key issues identified by the group are presented and discussed below.

5.2.1 Model Approach

The group considered the various models presented by Ian Martin of the Environment Agency. There was a general agreement that the SEGH model did not allow sufficient flexibility in modelling different exposure scenarios. The user cannot account for differences in exposure frequency, body weight, soil ingestion rate, ingestion of home-grown produce and so on. Minor adjustments can be made to the delta factor but such adjustments are hard to justify other than in a qualitative and relatively arbitrary manner.

The group agreed that CLEA was a good model for predicting intake but has the disadvantage over the SEGH and IEUBK models that it does not predict blood lead concentrations, which is now generally accepted as the suitable assessment end-point for lead.

The group agreed that IEUBK model was likely to be the most appropriate exposure tool for assessing risk from lead in soil to children for the residential scenario. Like CLEA, the IEUBK model allows intake to be predicted via various routes of exposure. Both models can account for bioavailability but IEUBK offers greater flexibility than CLEA in this respect. IEUBK allows separate values of absolute bioavailability (i.e. the ratio of uptake to intake) to be added for soil, dust, water and diet. CLEA allows separate values of relative bioavailability (i.e. the ratio of the absolute bioavailability of contaminant in soil to the absolute bioavailability of contaminant in the toxicological study that the health criterion value is based on) for soil and dust, but not background exposure (such as water and diet).

The principal advantage that the IEUBK model offers over CLEA is the biokinetic modelling component. IEUBK models the transfer of absorbed lead between blood and other body tissues, its storage/deposition within various body elements and its elimination via urine, faeces, hair, skin and nails. This enables IEUBK to estimate the (geometric) mean blood lead concentration in children with the same exposure scenario, which can be compared directly with the blood lead level of concern (LOC). The probability distribution model then uses a simple equation to predict the probability of the LOC being exceeded in a child. This module accounts for the variation in the pharmokinetics of lead between children, i.e. it accounts for the fact that children exposed to the same intake of lead will have different blood lead concentrations.

The IEUBK model has been validated using a limited number of empirical studies from the US. These show a reasonable agreement between the predicted geomean concentrations of blood lead and the measured concentrations in children in residential exposure scenarios. A summary of these comparisons is presented in Table 16 below.

Table 16: Comparison of observed and predicted geometric mean blood lead and risk of exceeding 10 µg.dL^{-1} for three community blood lead studies (from USEPA, 2006[47])

Dataset	N	Observed Blood Lead (µg/dL)		Model Predictions (µg/dL)	
		GM (95% CI)	Percent >10 (95% CI)	GM (95% CI)	GM (95% CI)
Galena, KA Jasper Co, Mi (a)	111	5.2 (4.5-5.9)	20 (13-27)	4.6 (4.0-5.3)	18 (11-25)
Madison Co, IL (a)	333	5.9 (5.5-6.4)	19 (15-23)	5.9 (5.4-6.3)	23 (19-28)
Palmerton, PA (b)	34	6.8 (5.6-8.2)	29 (14-44)	7.5 (6.6-8.6)	31 (16-47)

Notes to Table:

CI = confidence interval; GM = geometric mean; N = number of children; (a) = Children away from home ≤10 hours/week; (b) = Children away from home ≤20 hours/week

There are many similarities between the IEUBK exposure modelling module and CLEA when used for the residential land-use but there are some key differences. Firstly, some exposure parameters that are hard wired into IEUBK cannot be changed, such as body weight and exposure frequency. The IEUBK body weights are similar to those used in CLEA and exposure frequency is assumed to be 365 d.yr^{-1} as with CLEA, but this does offer a disadvantage if non standard land-uses are being considered. Secondly, IEUBK does not model plant uptake of lead. The user can either specify total dietary intake of lead or input the concentration and home-grown fractions of lead in home-grown fruit and vegetables, and other food categories if appropriate. However, the total consumption rates of fruit and vegetables are hard-wired into the model and cannot be altered.

The group discussed the possibility of using the IEUBK model to back calculate a Health Criteria Value (in units of mg.kg(bw)$^{-1}$.d^{-1}) for use in the CLEA model. EFSA, in its Scientific Opinion on Lead in Food[17], used the IEUBK model to estimate that a dietary intake of 0.5 ug.kg(bw)$^{-1}$.d^{-1} (assuming negligible exposure from air and soil) would correspond to a most likely blood lead concentration of 12 ug.L^{-1}. Caution should be adopted if using this information to calculate a suitable Health Criteria Value for use in CLEA. Firstly, the relationship between dietary intake and blood lead concentration calculated by EFSA is based on the assumption of an absolute bioavailability for dietary intake of 50%. Furthermore, because of the complexity of the biokinetic module, the relationship between intake and blood lead level is not necessarily linear and thus it cannot simply be assumed that a dietary intake of 5 ug.kg(bw)$^{-1}$.d^{-1} will lead to a blood lead concentration of 120 ug.L^{-1}.

The group had a brief discussion on suitable models for predicting lead exposure to adults. The withdrawn SGV is based on the USEPA adult lead model (USEPA, 1996) which relates exposure via soil and dust ingestion to blood lead concentration via a biokinetic slope factor (BKSF). The adult lead model allows for adjustments to exposure frequency, soil and dust ingestion rate, absolute bioavailability and background blood lead concentration, amongst others. The

47 USEPA (2006). Air Quality Criteria for Lead. October 2006. EPA/600/R-5/144aF

Carlisle and Wade model[48] was also mentioned as a possible alternative to the USEPA adult lead model. These models, along with others are discussed in a USEPA review of models used for predicting lead exposure to adults[49].

The question was raised as to whether variability in intake should be accounted for as well as variability in pharmokinetics when predicting exposure to lead, i.e. should the exposure modelling elements be probabilistic? The group felt that this would over-complicate an already complex problem.

5.2.2 Dominant Risk-driving Pathways

As discussed above, the CLEA model is a useful predictor of intake and can be used to identify the key exposure pathways for lead. For residential land-use, the key exposure pathways are predicted to be soil and dust ingestion and ingestion of home-grown produce. For allotments, ingestion of home-grown produce may be the most important route of exposure to lead.

For most soils contaminated with lead, the lead is present in relatively insoluble forms and therefore dermal exposure is expected to be negligible. There may be exceptional circumstances where this is not the case, such as the presence of lead nitrate (historically used as a dye and paint pigment), which in soluble form, can have a dermal absorption factor of 25 to 30%[50].

Dust inhalation is also not expected to be a significant exposure pathway for lead.

5.2.3 Soil/Dust Ingestion

The soil and indoor dust ingestion pathway is a key exposure pathway for lead. In the IEUBK model, ingestion of soil outdoors and dust indoors are considered as two separate pathways and allowance is made for differing lead concentrations between these exposure media. In the IEUBK model, children in the 0 to 7 year age bracket are assumed to ingest between 85 to 135 mg of soil and dust per day, averaging to 113 $mg.d^{-1}$, slightly greater than that assumed in CLEA for residential land-use (100 $mg.d^{-1}$). In IEUBK, 55% of this is assumed to come from ingestion of indoor dust and 45% from ingestion of soils outdoors. In CLEA, it is assumed that the concentration of contaminant in indoor dust ingested is the same as that in outdoor soil, but there is some evidence that the concentration of lead in indoor dust may be higher than outdoor soil. For example, Oomen and Lijzen (2004)[21] found that the concentration of lead in indoor dust was an average of 2.9 times greater than the concentration in outdoor soil considering 19 sites across Europe and the US. This may be due to non-soil sources of lead (such as paint, or petrol exhaust particulates) but may also be due to enrichment of dusts that are blown in or tracked in from outside soils. Separation of the ingestion of outdoor soil from indoor dusts enables this uncertainty to be more easily assessed in the exposure assessment.

The group agreed that sampling household dust would improve confidence in the exposure modelling results for Part 2A assessment involving lead.

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48 Carlisle, J.C. and M.J. Wade (1992). Predicting blood lead concentrations from environmental concentrations. Regul. Toxicol. Pharmacol. 16: 280-289

49 USEPA (2001). Review of adult lead models evaluation of models for assessing human health risks associated with lead exposures at non-residential areas of superfund and other hazardous waste sites. EPA OSWER #9285.7-46

50 Stauber J.L., Florence, T.M., Gulson, B.L. and Dale, L.S. (1994). Percutaneous absorption of inorganic lead compounds. Science of the Total Environment, 145 (1-2), 55 – 70

5.2.4 Ingestion of Home-grown Produce

The uptake of lead from soil by plants and subsequent consumption of home-grown produce is a plausible exposure pathway for lead. The exposure from this pathway is dependent on the amount of home-grown produce ingested and the concentration of lead in the produce consumed. In CLEA, the latter is calculated from the soil to plant concentration factor, which can either be estimated (for example using the PRISM model within CLEA) or derived from empirical data (i.e. the ratio of measured concentration in the plant to measured concentration in soil). The Environment Agency has conducted a literature review of soil to plant concentration factors for lead. This work has not been published but the results have been summarised in Table 12. Use of these generic values suggests that plant uptake can be a key exposure pathway, especially for allotment sites where allotment holders and their households are assumed to eat a relatively high proportion of home-grown produce compared to the UK average.

The group discussed the value of site specific soil to plant concentration factors derived by comparison of site measured concentrations in soil with associated concentrations in produce. It was agreed that a database collating UK derived relevant soil to plant concentration factors for lead would be useful and several group members stated that they had data that could be added to such a database. The group recognised that pH can have a large influence on plant uptake of lead, with increased mobility and uptake for soils with low pH.

As discussed above, the IEUBK model does not model plant uptake. A possible workaround was suggested which was to calculate the dietary intake outside of IEUBK and then input this into the model.

5.2.5 Other Land-uses

As discussed above, there was general agreement that the IEUBK model was a suitable tool for assessing exposure to children in the residential scenario. The group recognised that the IEUBK model may not be suitable for modelling other land-use scenarios. There was not a consensus in opinion in how land-use scenarios such as public open space or schools should be modelled. Whereas the age range considered in the IEUBK model (0 to 7 years) is suitable for residential scenarios, it may not be suitable for these other land-use scenarios.

The group agreed that the IEUBK model should only be used for modelling exposure to children and that other models (such as the USEPA adult lead model, as used for the former commercial-use SGV, or the Carlisle and Wade model) should be considered for scenarios where adults are the critical receptor.

5.2.6 Soil Sampling for Exposure Assessment

The group had a brief discussion on soil sampling for exposure assessment. In particular, the depth of sampling and sample sieving were discussed. USEPA guidance[51] on estimating the soil lead concentration for input to the IEUBK model recommends that the top 1" (2.5 cm) of soil are sampled and analysed for lead for exposure assessment for current use scenarios. This reflects the fact that routine exposure to soil and generation of soil derived dust is associated with surface soils only and therefore concentrations from deeper soils are not relevant unless these can be assumed representative of surface soils. Exposure to deeper soils may occur as a result of digging or re-profiling of soils and the USEPA point out that deeper sampling may be required for future use scenarios. Deeper

[51] USEPA (2007). Short sheet: Estimating the Soil Lead Concentration Term for the Integrated Exposure Uptake Biokinetic (IEUBK) Model. OSWER 9200.1-78

sampling may also need to be considered where the consumption of home-grown produce occurs.

The USEPA also recommend that lead concentrations are measured in the <250 µm soil fraction as this is most relevant to ingestion of soils and dusts[52]. The reader is referred to the SOBRA PAH (polycyclic aromatic hydrocarbons) workshop report[53] for further discussion on this issue.

5.3 Conclusions

The main conclusions from the discussion group are presented below:

- The group agreed the USEPA IEUBK model is the most suitable method for predicting blood lead concentrations in children for residential scenarios. Although CLEA is a suitable predictor of intake for lead, it is not able to predict blood lead concentration, which is the commonly cited assessment end-point.
- The IEUBK model accounts for dietary intake of lead, including from home-grown produce but, unlike CLEA, the model does not calculate plant uptake of lead from soil. Dietary intake of lead from home-grown produce must be calculated outside the IEUBK model.
- The IEUBK model is suitable for estimating blood lead concentrations in children of 0 to 7 years. It is not suitable for assessing exposure scenarios for adults. Other models such as the USEPA adult lead model (as used for the withdrawn commercial land-use SGV) or the Carlisle and Wade model should be considered for assessing risk to adults.
- The suitability of the IEUBK model for assessing risk to older children for non standard land-uses, such as public open space or schools, is questionable. There was no consensus on what was the best methodology for assessing such land-use scenarios.
- The ingestion of soil and soil derived dust are key exposure pathways for lead in soil. The consumption of home-grown produce may also be important especially where home-grown produce is a large contributor to a receptor's total consumption, such as might be expected for allotment holders and their households. There is a considerable degree of uncertainty associated with exposure from these pathways, especially in relation to the relative contribution of exposure from ingestion of indoor dust versus outdoor soil and with soil-to-plant concentration factors.
- The group agreed that sampling depth and the soil fraction analysed were key considerations when assessing risk from lead in soil. Concentrations from surface soil are most relevant for the soil and dust ingestion pathways. It was also noted that the USEPA recommend that lead is measured in the <250 µm soil fraction.

[52] USEPA (2000). Short sheet: TRW recommendations for sampling and analysis of soil at lead (Pb) sites. EPA #540-F-00-010. OSWER #9285.7-38

[53] SoBRA (2011). Society of Brownfield Risk Assessment Summer Workshop Report 2010. Human Health Risk Assessment and Polycyclic Aromatic Hydrocarbons, ISBN 978-0-9568241-1-0

5.4 Recommendations

The group made the following recommendations:

1. The IEUBK model should be considered for assessing risk from lead in soil for the residential scenario.
2. A working group is initiated to discuss suitable modelling approaches for other land-uses.
3. Consideration should be given to sampling indoor dusts to more accurately characterise risks for Part 2a assessments of lead in soil.
4. Consideration should be given to measuring lead concentration in the < 250 µm soil fraction.
5. A database should be initiated and maintained for collating site derived values of soil-to-plant concentration factors for lead.

6 BIOACCESSIBILITY TESTING AND ITS USE IN RISK ESTIMATION

6.1 Introduction

This workshop was intended to look at the key issues associated with bioaccessibility testing for lead and the use of bioaccessibility test data in risk estimation. The workshop was facilitated by Yolande Macklin and David Hall.

All members of the workshop introduced themselves and described their level of expertise and experience on the topic of bioaccessibility. Experience ranged from those with zero experience to one delegate with over 10 years of detailed research and practical experience.

6.2 Key Issues

There are a number of different methods for carrying out bioaccessibility testing; some are batch tests and some are flow through tests. Some tests have multiple names – so there is potential for confusion amongst those who are unfamiliar with the individual test methods. Some test methods have been validated against juvenile swine (a good surrogate for children), but much of the validation has been undertaken on grossly contaminated sites where lead concentrations are in the 10s of thousands of mg/kg, i.e. cases which are not representative of contaminated sites where concentrations are borderline and where bioaccessibility testing is likely to be most relevant.

Two of the most common tests are:

- RIVM – a physiological based test – applicable to a number of heavy metals; and
- UBM – Unified Barge Method.

Bioaccessibility is invariably a site specific measure so bioaccessibility factors derived from other sites have little or no relevance. The main factors that affect the results are lead mineralisation (speciation) and soil properties.

Note that exposure models, such as CLEA, require measures of 'bioavailability' and not 'bioaccessibility', so some relationship needs to be applied to convert bioaccessibility to bioavailability. The USEPA has developed a relationship that spans many orders of magnitude based on comparison of *in vitro* and *in vivo* testing. The "stomach" phase (pH 1.2) should be followed by an intestinal phase (higher pH) where some lead will re-precipitate and thus be passed out of the body – hence bioavailability is always lower than bioaccessibility. It is good practice to use the higher of the two data sets to be protective of human health and to remain conservative.

Good practice dictates that laboratories should report total metal (mg/kg), total bioaccessibility from the stomach phase (mg/kg and %), and total bioaccessibility from the intestinal phase (mg/kg and %).

It is recognised that there is a general lack of Good Practice Guidance and Laboratory Accreditation for these test methods and that, if there is guidance, it is not well publicised.

Guidance from the Chartered Institute of Environmental Health[54] suggests a minimum of 10 tests per averaging area (but only after lead is shown to be a Contaminant of Concern). Testing should avoid examining hot spots alone - high concentrations of lead do not necessarily correlate with high lead bioaccessibility.

Sample preparation should not involve crushing the sample; rather the < 250 µm fractions should be segregated from the larger particles and subjected to the testing. It is important to make sure that this is also the same fraction that is used to determine total lead content and that the laboratory reports exactly what they have done and how they have derived the concentrations (i.e. whether the mass of stones >250 µm have been included or not). Most of the *in vivo* testing is undertaken using only the < 250 µm fractions.

The mineralogy of lead (speciation) will control bioaccessibility with sulphides having low availability (often the most common species in old lead mining areas) and carbonates and halides having higher availability. XRD analysis is not usually sensitive enough at sub ore grade concentrations, so BGS recommend sequential extraction methods to empirically determine the likely mineral phases (using a sequence or ever more aggressive extraction reagents). However, these tests can be expensive (circa £1000 per test) so it may be possible only to undertake a small number of tests.

The workshop group agreed that data from such tests is important to develop the lines of evidence to support bioaccessibility testing results.

Bioaccessibility testing is only relevant to the ingestion pathway – not to inhalation - albeit that lead, irrespective of the route of exposure has the same health effects, and that blood lead level is the overall key toxicological measure.

6.3 Conclusions

The workshop group agreed that bioaccessibilty testing has an important role to play in assessing the risks that lead may pose to human health. However, there are a number of possible test methods (and potentially some confusion about the name, capabilities and limitations of each) and some uncertainty regarding issues such as: appropriate sample preparation; number and selection of samples for bioaccessibility testing; and how the results of testing should be used in risk estimation.

6.4 Recommendations

The group made the following recommendations:

1. Good Practice Guides on the types, uses, capabilities and limitations of the various bioaccessibility test methods are needed.
2. Proficiency and accreditation in testing would assist in giving bioaccessibility testing more credibility.
3. There is a need to understand the mineralogy of lead in order to develop lines of evidence to back up bioaccessibility testing results.

[54] CIEH (2009). Professional Practice Note: Reviewing human health risk assessment reports invoking contaminant oral bioavailability measurements or estimates - available from: http://www.cieh.org/library/Policy/Environmental_protection/Contaminated_land/Standing_Conference_on_Contaminated_Land/CIEH_PPN_Bioavailability_Final_June09.pdf

7 CONCLUDING REMARKS

7.1 Key Issues and Recommendations

Compared to some of the contaminants routinely encountered in UK soils, there is a generally good level of knowledge and understanding regarding the sources, forms and concentrations of lead, the pathways by which humans may be exposed to it, the adverse effects it may have on human health, and the factors which control its availability to biological systems.

However the particular attributes of lead, the way it has been used historically, new developments in understanding of the toxicology of lead, and recent UK policy changes on the regulation of 'background' contamination, mean that lead poses particular challenges to risk assessors working in the land contamination field.

Because lead and its compounds are highly versatile materials, they have been used in a wide range of products and applications over a very long period of time. These factors, together with the fact that soil acts as an effective sink for lead, mean that lead is widely distributed in the soil environment and is often present at high concentrations in urban soils.

Elevated concentrations of lead from an assortment of historic and, at least partially, diffuse sources, means that implementing new UK policy on handling 'background' concentrations of contaminants under Part 2A may be problematic. Recent research which shows that lead is toxic at doses lower than was previously thought creates fresh uncertainties about the level of exposure to lead which may be regarded as being "acceptable", let alone "unacceptable".

These issues are reflected in the recommendations put forward by each of the workshop groups as detailed in the relevant sections of this report.

Key issues and recommendations were as follows.

Sources, Forms and Background Concentrations

This workshop group considered that Local Authorities and others need guidance on how best to approach assessments of 'background' concentrations of lead. They recommended that whilst such guidance should ensure consistency in decision-making, it should also be sufficiently flexible to allow for 'local' judgements about the 'significance' of background concentrations of lead in particular areas.

In this context, it is noted that Defra has commissioned BGS to prepare guidance on background concentrations of contaminants in UK soils. It is intended that this should support regulators and others in assessing background contamination under proposed changes to the statutory guidance to Part 2A. It is expected that the guidance will be published shortly.

Health Effects and Toxicological Approaches to Lead

This group concluded that there is a generally good level of scientific/technical understanding of the health impacts of lead and it agreed that the 'blood lead' level is the most appropriate metric for assessing the health impacts of exposure to lead in soil.

However, the group felt that there is a need to further develop current understanding of the toxicology of lead to create a practical basis for conducting lead risk assessments, and for deciding, for example, what are appropriate criteria for assessing whether there is a "significant possibility of significant

harm". The group felt that such an approach is likely to involve more than just an understanding of the relevant toxicological principles and data, and may require input from a broad range of expertise, including experts in exposure assessment, social sciences and epidemiology.

Modelling Exposure to Lead

This group concluded that the USEPA IEUBK model is the most suitable of the available models for predicting blood lead concentrations in children in residential scenarios. However, the group felt that there is a need to consider further what modelling approaches may be suitable for assessing exposure to lead in non-standard land uses.

Other issues considered to require further consideration and resolution were: the contribution to blood lead levels made by exposure to indoor dust (as opposed to soil) and whether this should be characterised separately in Part 2A assessments; whether the measurement of lead in [soil] samples should be confined to the <250mm fraction; and the role that site derived, empirical data may play in further refining the soil-to-plant concentrations factors used in lead risk assessments.

Bioaccessibility Testing and its Use in Risk Estimation

This group concluded that bioaccessibility testing can play a key role in lead risk assessment but there is a need for clear and simple guidance on the uses and limitations of bioaccessibility testing for lead, and how an understanding of the mineralogy of lead can help in developing lines of evidence to support bioaccessibility test data.

This group also called for proficiency and accreditation in bioaccessibility testing to give greater credibility to the use of this technique in land contamination applications.

7.2 Delivering the Recommendations

Although not a formal part of the workshop proceedings, the question again arises as to how some of the recommendations set out above might be taken forward.

SoBRA has successfully established a number of working groups which are actively addressing particular technical topics of interest to SoBRA members. Such working groups offer at least one route for progressing recommendations arising from the SoBRA summer workshops. All members are urged to contact the SoBRA Executive Committee if they wish to play an active role in achieving such outcomes.

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APPENDIX 1 - WORKSHOP GROUPS

WORKSHOP 1: SOURCES, FORMS AND BACKGROUND CONCENTRATIONS

Workshop Facilitators

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WORKSHOP 3: MODELLING EXPOSURE TO LEAD

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WORKSHOP 4: BIOACCESSIBILITY TESTING AND ITS USE IN RISK ESTIMATION

Workshop Facilitators

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APPENDIX 2 - ABBREVIATIONS

ATSDR	Agency for Toxic Substances and Disease Registry
BARGE	Bioaccessibility Action Research Group of Europe
BGS	British Geological Society
BMD	Benchmark Dose
$BMDL_{01}$	The lower 95th percent confidence limit on the benchmark dose producing a 1% response
$BMDL_{10}$	The lower 95th percent confidence limit on the benchmark dose producing a 10% response
CIEH	Chartered Institute of Environmental Health
CLEA model	Contaminated Land Exposure Assessment model
CNS	Central Nervous System
COT	Committee on Toxicity
DIV	Dutch Intervention Value
DNA	Deoxyribonucleic Acid
DQRA	Detailed Quantitative Risk Assessment
EA	Environment Agency
EFSA	European Food Standards Agency
EPAQ	Expert Panel on Air Quality Standards
FAO	Food and Agriculture Organization
FOREhST	The Fed Organic Estimation human Simulation Test
FSA	Food Standards Agency
GAC	Generic Assessment Criterion
GI	Gastro-intestinal
GSD	Geometric Standard Deviation
HCV	Health Criteria Value
HHSL	Human Health Screening Level
HPA	Health Protection Agency
IARC	International Agency for Research on Cancer
IEH	Institute of Environmental Health

ID	Index Dose
IEUBK model	Integrated Exposure Uptake Biokinetic model
In vitro	[Latin] meaning *"in the glass"*
In vivo	[Latin] meaning *"in the living"*
IQ	Intelligence Quotient
IVBA	In Vitro Bioaccessibility
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
MOE	Margin of Exposure
MSD	Mass fraction of Soil to Dust
NOAEL	No Observed Adverse Effect Level
PAH	Polycyclic Aromatic Hydrocarbon
Part 2a	Part 2A of the Environmental Protection Act 1990
Pb	Lead
PBET	Physiologically Based Extraction Test
PTWI	Provisional Tolerable Weekly Intake
QA/QC	Quality Assurance/Quality Control
RIVM	Dutch National Institute for Public Health and the Environment
RBA	Relative Bioavailability
SEGH	Society for Environmental Geochemistry and Health
SGV	Soil Guideline Value
SPOSH	Significant Possibility of Significant Harm
SSAC	Site Specific Assessment Criterion
TDI	Tolerable Daily Intake
UBM	Unified BARGE Method
USEPA	United States Environmental Protection Agency
WHO	World Health Organization