SoBRA
The Society of Brownfield Risk Assessment

SOCIETY OF BROWNFIELD RISK ASSESSMENT
SUMMER WORKSHOP REPORT 2015

UNCERTAINTY IN HUMAN HEALTH RISK ASSESSMENT

PUBLICATION

This report summarises the key technical issues relevant to uncertainty in human health risk assessment as presented and discussed at a SoBRA (Society of Brownfield Risk Assessment) workshop in July 2015.

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 United Kingdom (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 of polycyclic aromatic hydrocarbons in soil was considered.

SoBRA's second Summer Workshop was held in June 2011 at the Mechanics Institute in Manchester. It addressed the assessment of the risks associated with lead contamination in soil.

SoBRA's third Summer Workshop was held in June 2012 at Armada House in Bristol. It addressed the assessment of risks associated with petroleum hydrocarbons in groundwater.

SoBRA's fourth Summer Workshop was held in June 2013 at the Priory Rooms in Birmingham. Rather than the usual thematic format established by previous events, the specific aim of the event was to support the Joint Industry Working Group (JIWG) risk assessment chapter. Therefore, the event focussed on the risk assessment aspects of asbestos throughout the CLR11 process.

SoBRA's fifth Summer Workshop was held in June 2014 at the Cathedral Centre in Sheffield. It addressed the assessment of risks associated with chlorinated solvents.

SoBRA's sixth Summer Workshop was held in July 2015 at the Miners Institute in Newcastle. It addressed uncertainty in human health risk assessment and is the subject of this report.

SoBRA provides risk assessors with a peer group, as well as keeping them up to date with and allowing them to participate in the development of best practice. Whilst waiting for formal proceedings to start, the room was full of lively conversation, demonstrating the vibrancy of the SoBRA community. Chris Taylor, the SoBRA Chair introduced the formal proceedings, and extended a welcome to all delegates, remarking that the location of the conference in Newcastle was in fulfilment of SoBRA's ongoing commitment to accessibility to SoBRA members across the UK. Delegates heard five presentations from expert speakers on uncertainty in a general context, uncertainty arising from site investigation and the conceptual site model, uncertainty in exposure assessment, uncertainty in bioaccessibility measurements and uncertainty within toxicological evaluation. During the afternoon, expert speakers and delegates were divided into groups and participated in four workshops on the themes of: site investigation; the conceptual site model; bioaccessibility; and exposure.

Seventy eight delegates, including expert speakers and SoBRA Executive Committee members, attended the 2015 Summer workshop. Feedback provided by delegates after the event was extremely positive with more than 80% of responding delegates rating the event as "excellent" or "good". Overall therefore the 2015 Summer Workshop consolidated SoBRA's commitment to hosting high quality and stimulating meeting on technical topics of relevance to its members.

This report fulfils an undertaking given by SoBRA to produce a formal record of the proceedings of the 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 uncertainty. It is recommended that readers consider this report in conjunction with the presenter slides as there may be information on the slides that is not repeated in this report.

ACKNOWLEDGEMENTS

SoBRA wishes to thank the following individuals for their considerable assistance in the successful delivery of the SOBRA 2015 Summer Workshop and associated report.

Chris Taylor	National Grid Property Holdings Ltd (NGP)	Workshop Chair
Andy Hart	Food and Environment Research Agency	Speaker
Jonathan Welch	AECOM	Speaker (and Workshop 2 rapporteur)
Simon Firth	Firth Consultants	Speaker (and Workshop 4 facilitator)
Mark Cave	British Geological Survey	Speaker
Camilla Pease	Ramboll Environ	Speaker
Seamus Lefroy Brook	LBH Wembley	Workshop 1 facilitator
Geraint Williams	Alcontrol Laboratories	Editor and Workshop 1 rapporteur
Lucy Thomas	RSK	Workshop 2 facilitator
Stephen Lowe	University of Reading/British Geological Survey	Workshop 3 facilitator
Joanna Wilding	RSK	Workshop 3 rapporteur
Naomi Earl	Freelance Consultant	Editor and Workshop 4 rapporteur

Special thanks are due to Hannah White (Atkins and SoBRA's treasurer) who looked after financial matters, Jason Bale (Shared Regulatory Services (Wales) and SoBRA's secretary) who organised bookings, and again, finally to our Chair for the event, Chris Taylor (NGP and SoBRA's Executive Committee Chair) for providing a thought provoking introduction to the event.

Finally, SoBRA wishes to acknowledge the contribution to the overall success of the event made by individual workshop delegates for attending and enthusiastically participating in the day's proceedings.

Workshop delegates are listed in Appendix 1 to this report.

Contents

1. Introduction

1.1 *Background*

Uncertainty is intrinsic in all of the decisions that we make as risk assessors. If we firstly consider the concentrations of soil and sub-surface water that we use within our human health risk assessments, even on a site without past historical uses, concentrations of geogenic substances will vary. On a brownfield site where there has been a rich history of different industrial uses, we may not even know exactly what processes occurred, where and at what depths they occurred or what contaminants they resulted in. We introduce further uncertainty to compound the wide variation in contaminant concentrations by our choice of sampling locations/ contaminant suites. Then we sample only a miniscule proportion of the sub-surface, subsampled further by the laboratory, who will introduce further sources of uncertainty by the choice of analytical technique and the level of precision of the instrument. Our efforts to make sense of the analytical results by assigning them to different areas of the site, classifying them by depth and deriving "representative concentrations" using statistical processing create more uncertainty, as very different answers can be produced depending on the choices we make.

Once we have processed the site data, we then move onto the generic assessment criterion (GAC) or site-specific assessment criterion (SSAC) to which the "representative" soil or groundwater concentration is compared. Within these there is uncertainty within how we model the transport of contaminants within soil or sub-surface water into other environmental media, such as site-grown produce or into soil vapour, let alone into indoor air. This reflects both a variation in natural media, such as how different cultivars of the same plant species or even members of the same cultivar, take up a particular contaminant, as well as our use of simplistic models calibrated with limited empirical data, to represent, for example, complex soil structures, chemical and biological processes, and building characteristics.

Modelling human exposure means making decisions about an individual's height, weight and inhalation rate; within all of these there is natural variation but they can, at least, be measured with some accuracy. However, it also means making decisions about human behaviour, ranging from how clean a person keeps his or her house, to how many hours are spent outdoors, how much site-grown produce is grown and consumed, how dirty a child will get before washing, and how much soil they ingest over the course of a day. Not only do such parameters vary from person to person, but in some cases limited research means that there is also

considerable difficulty in establishing what the range of reasonable values is with any degree of accuracy. In some cases, we may even not fully understand how a site is being used or will be used in the future, so that we do not account for an important pathway such as the consumption of eggs from chickens kept on-site, or use of a private water supply.

Deriving a GAC or SSAC means comparing our best estimate of such exposure to a toxicological criterion, that is our best estimate of a level which will not cause harm. The toxicological studies used in the derivation of such values are often based on animal data, with relatively arbitrary "uncertainty factors" or "safety factors" applied to account for the difference between humans and animals (inter-species variation) and for the fact that some humans react differently to the same dose than others (intra-species variation). Additional factors may be applied because an adverse effect was noted at even the lowest dose, for a limited database, to account for extrapolation from a short-term or medium-term study to a long term effect, and/ or to account for particularly serious effects, such as cancer. Even where human epidemiological data is available, there is often uncertainty about the dose that individuals were exposed to, as well as confounding factors such as simultaneous exposure to other contaminants, or exposure to the same contaminant in a workplace as well as in diet and/ or drinking water. In both cases, different expert bodies frequently arrive at different conclusions from the same data, emphasising the inherent uncertainty. Toxicological studies will rarely have been conducted using soil as the medium within which the contaminant of concern is applied; far more frequently data is based on food or drinking water, meaning that the bioavailability intrinsic to the toxicological criterion may be very different for soil.

Yet despite this concatenation of uncertainties, we frequently find others, or even ourselves reducing the outcome of the risk assessment to whether or not one single number used to represent the concentration of a contaminant in soil, is higher or lower than a second single number, the GAC or SSAC used to represent a "safe" level in soil with little or no discussion of the uncertainty associated with either. Usually at best there is a brief "Risk Evaluation" outlining key uncertainties associated with a detailed quantitative risk assessment (DQRA), and how these may affect the outcome of the assessment. This lack of emphasis on uncertainty will often be for reasons of scope, budget and/or time. However, it often also reflects a lack of connection through the risk assessment when taken as a whole. For instance the person performing the DQRA and (hopefully) writing the associated report, may not be aware of uncertainties within the preliminary risk

assessment, which in turn will impact significantly on the sampling strategy leading to serious omissions during the site investigation. The risk assessor may also not have been present on site or even able to liaise closely with those that have, to discuss how fully uncertainties about, for instance, the extent of the contamination, were or were not chased out. He or she may not have access to the foundation designs, the architectural plans showing the intended height of the building, or even information about whether soft landscaping is present.

It is vitally important that risk assessments do result in clear decisions being made, but this needs to be done in the light of the uncertainties present. This may require an honest conversation with a clear presentation of the uncertainties, between the risk assessor and their client and sometimes also other stakeholders who may be involved. To do this, we as risk assessors, need to improve our understanding of the uncertainties within our work and what they mean for ourselves and others. SoBRA members demonstrated their interest in doing so by voting to have uncertainty as the theme of the 2015 Summer Workshop. SoBRA is committed to listening to the views of its members expressed during the day as to how we can drive improvements in risk assessment practice.

1.2 *The SoBRA Workshop*

The objectives of SoBRA's summer 2015 workshop were to define the current state of our understanding of the key issues surrounding uncertainty in human health risk assessment and to establish where there is (and is not) consensus on mitigation measures.

The specific aims of the workshop were to:

- provide high quality speakers who could outline the challenges faced for their topic area that affect the risk assessment process, including site investigation, laboratory analysis, the legal framework, toxicology, exposure modelling and remediation; and
- break out into workshop groups to discuss issues pertaining to a topic area in more detail and identify how such issues might be resolved. The four topic areas were:
    - Site Investigation;
    - the Conceptual Site Model;
    - Bioaccessibility; and
    - Exposure.

1.3 *Structure of the Report*

A specific goal of the workshop organisers was to produce a formal workshop output that 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.

Following this introduction, section 2 of the report sets the scene for the workshop proceedings as a whole by providing an account of the background relevant to uncertainty in human health risk assessment. This section sets out the key technical issues relevant to each workshop topic as described by expert speakers.

Four themes were addressed:

- Site Investigation;
- Conceptual Site Model;
- Bioaccessibility; and
- Exposure.

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

Section 7 of the report draws on the outcome of the workshop discussions, identifies some common issues and highlights key recommendations.

Reference documents used to support presentations and workshop discussions are shown as footnotes to the text, the first time they appear within a section 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 *Uncertainty in a general context*

Andy Hart of the Food and Environment Protection Agency (FERA) presented a summary of uncertainty in a general context. Andy began by reviewing the reasons why we need to address uncertainty in risk assessment, why we need to quantify it where we can, and the importance and consequences of uncertainties we cannot quantify. As an illustration, Andy talked about the 1997 flooding of Grand Forks in North Dakota by the Red River, which rose 54 feet. This exceeded the 51 foot levee - constructed following the National River Service prediction of 49 feet given three months before the rise. As well as between $3 billion and $4billion of damage, the flood resulted in a loss of credibility and trust. Later analysis of the uncertainty within the prediction found that there was an error margin of +/-9 feet, and that if the authorities and public were made aware of this, different decisions might have been made. The key information that was missing was an estimate of how much higher than the estimate might the river plausibly rise, and how likely was this. Andy explained that for all types of risk assessment, the likelihood of exceeding the risk estimate is important information.

He then outlined the main principles and methods for addressing uncertainty in risk assessment, emphasising the need for a flexible approach that starts with simple methods and refines the analysis only as far as is needed for decision-making.

Important concepts for assessing uncertainty included:

- The need to be systematic about sources of uncertainty in order to minimise the risk of missing subtle sources which are hard to spot because of the way our thinking is framed;
- The need to express the impact of uncertainty on the outcome; and
- The need to express this impact by providing the range and likelihood of alternative outcomes.

Andy explained that there were qualititative methods such as using narrative text or ordinals such as high/ medium/ low, and quantitative methods such as uncertainty/ safety factors, performing interval analysis and "What if" calculations, using probability distributions which look at both range of outcomes and likelihood, or imprecise, bounded probability assessment.

He drew attention to the need to quantify overall uncertainty as far as scientifically achievable. The purpose of this is to clearly express the range of and

likelihood of alternative outcomes, avoiding the ambiguity of qualitative expressions such as "likely" and the value judgement inherent in words such as "negligible", as, in his opinion it is not the job of the risk assessor to provide judgements of this nature. This is an interesting perspective as much of the guidance within brownfield risk assessment requires such terms.

The use of quantification also lends itself to expressing the likelihood of the combination of two or more different events. Qualitative assessment is descriptive and the differences between two similar terms may not be clear. Moreover, the terminology of terms like "negligible" may be interpreted as the risk assessor's opinion about whether anything should be done when this is the task of the decision-maker. Where quantification is not possible, ordinal scales such as low/medium/high and +/ - scales should be used. However, Andy emphasised that, where at all possible, quantification is better, in conjunction with a range at the lower end of desirability followed by probability assessment, as this lets the assessor explicitly consider less likely but serious adverse outcomes. Bounded probability correlates narrative terms to the numerical likelihood, an example being the Intergovernmental Panel on Climate Change (IPCC) scale.

Where it is not possible to quantify all uncertainties individually, it is necessary to quantify the overall uncertainty.

Andy outlined some good practice for expert judgment. He explained that human judgement is subject to cognitive biases and heuristics including:

- Anchoring (a tendency to stay close to the first number thought of without sufficient adjustment);
- Availability (a tendency to adhere to easily recollected values);
- "Group-think" (where all agree with the most senior and/ or most outspoken person present, especially when there is a time-scale or people want to leave);
- Over-confidence (leading to a failure to test ourselves and consider alternative outcomes).

Instead he recommended the use of techniques from expert elicitation, such as estimating the range first, **not** the central tendency and considering what "surprising" outcomes might be. The reasoning behind the eventual choice of values should be documented for peer review, and that formal elicitation should be considered for important uncertainties.

He stated that the reliability of risk assessments could be improved by combining uncertainties using calculation where possible, reducing the proportion of overall

uncertainties assessed collectively and increasing how many are assessed quantitatively. Sensitivity analysis can be used on parameters which are identified as being the most important.

Quantification techniques to estimate uncertainty should be fit for purpose to enable decision-making, and not as an end in themselves, starting simple and targeting refined approaches on the most important uncertainties.

Andy then talked about how different experts make different judgements, which will be personal and subjective. Although the decision-maker should be informed by experts, it is his or her judgement that ultimately matters. The example was given of the Bin Laden compound attack where some experts though there was a 30%-40% chance he was there and others 80%-90%. Obama reached the view that the probability was essentially 50/50 and stated, "*I thought it was worth taking a shot*". This illustrates that it is fine for experts to hold different views as long as the decision-maker takes their views into account, and then reaches a final decision. Andy was clear that he considers this to be the responsibility of risk managers, not risk assessors.

There was an overview of how these principles were applied in the work to propose Category 4 Screening Levels (C4SLs) to Defra (described within CL:AIRE 2014a[1]), and their implications for case-specific assessments. Andy referred to an interesting discussion that he had had with the expert toxicologists during this project where uncertainties within toxicology were referred to as "unquantifiable", making the uncertainty within the whole risk assessment process unquantifiable. He stated that at this point, honesty is important and that assessors should be clear that such large uncertainties mean that the eventual outcome is unknown. This should have the effect of making decision-makers more precautionary.

Risk assessment methods can be broadly divided into two categories, probabilistic methods and deterministic methods. Probabilistic methods of risk assessment take account of the variability and uncertainty that exists in the real world. Deterministic methods take only limited account of variability and uncertainty. Deterministic methods for assessing risks use fixed values for toxicity and exposure and produce a single measure of risk (*e.g.* toxicity-exposure ratio). In the real world, toxicity and exposure are not fixed, but variable. Many aspects of risk assessment involve uncertainty. Consequently, the effects are both variable and uncertain.

[1] CL:AIRE (2014a). SP1010 Development of Category 4 Screening Levels. Rev 2.

Probabilistic methods can incorporate variability and uncertainty in toxicity and exposure, because they use probability distributions instead of fixed values. Distributions for toxicity and exposure are combined, to estimate a distribution for measure of risk. This provides a much more complete description of the range of risks, which can be helpful for decision-making. For example, instead of producing a single value for the toxicity-exposure ratio, probabilistic methods can estimate how often the ratio will exceed a regulator trigger.

Andy explained how the methodology to derive C4SLs had been developed. Steps 1-3 comprise proposals for modified toxicological assessment and exposure modelling. The modified exposure model is then used in Step 4 to calculate the soil concentration that would result in an exposure equal to the toxicological benchmark used specifically for the derivation of C4SLs, the Low level of Toxicological Concern (LLTC): this soil concentration is the provisional C4SL (pC4SL). In step 5, a probabilistic version of the Contaminated Land Exposure Assessment (CLEA) software is used to estimate the probability of the exposure of an individual hypothetical critical receptor exceeding the LLTC, assuming a substance is present in soil at the pC4SL. This is one of the factors considered when deciding in step 7, whether the level of precaution implied by the pC4SL is appropriate, the others being:

- Uncertainties associated with setting the LLTC (step 6A);
- Additional sources of variability and uncertainty in exposure that are not quantified by the probabilistic version of CLEA, which may have caused under- or over-estimation of the probability of exceeding the LLTC in step 5 (step 6b);
- Other relevant scientific considerations (*e.g.* background concentrations in soil, exposure via routes other than soil and epidemiological evidence for or against health effects from the chemical under assessment) (step 6c); and
- Social and economic scientific considerations such as the costs of further assessment or remediation or societal perceptions of risk (step 6d).

If, taking account of all relevant considerations, the pC4SLs are considered appropriately precautionary, then they may be judged suitable for use. If however, the relevant authority considers that the level of precaution associated with the proposed pC4SLs is too high or too low, the level of precaution could be reassessed until final C4SLs with appropriate degrees of precaution are derived,

as shown in Figure 5.1 of the C4SL report (CL:AIRE 2014a) which is reproduced below as Figure 2.1 of this report.

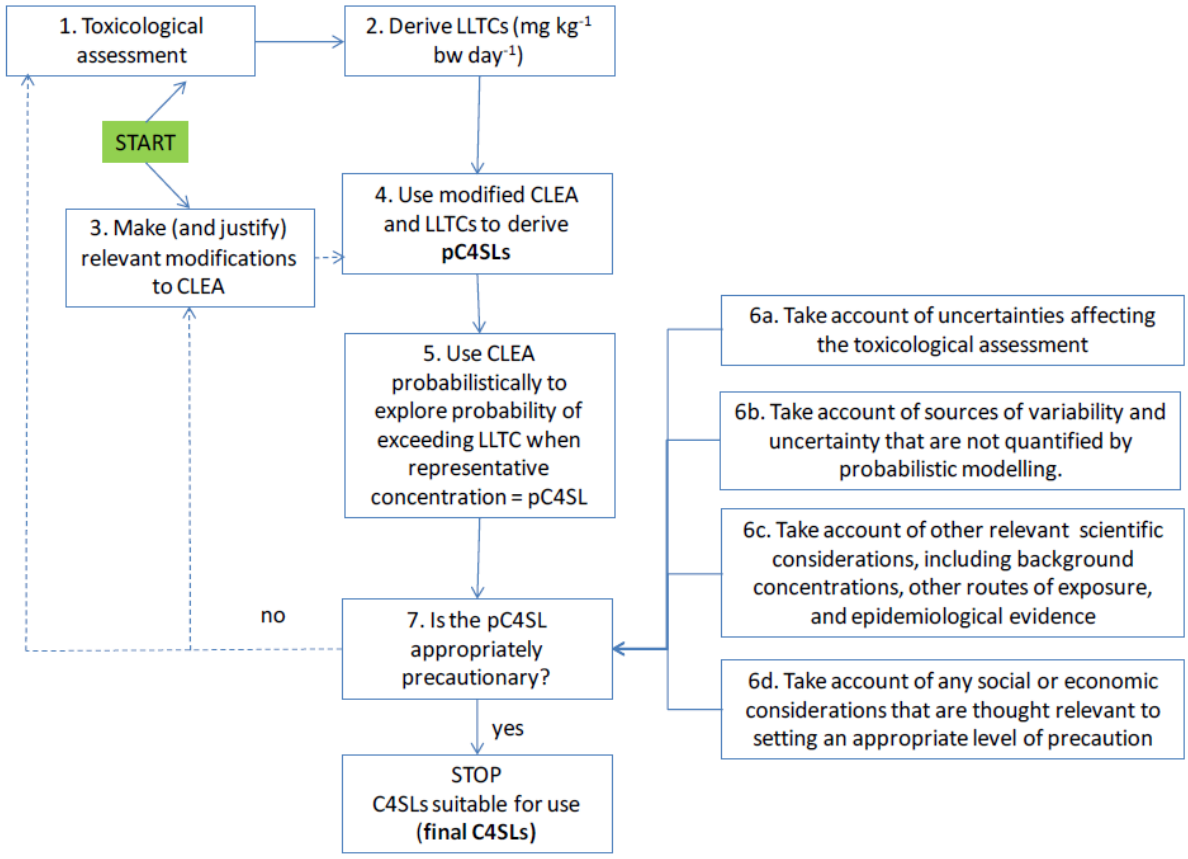


Figure 2.1 Suggested overall methodology for developing C4SLs, after Figure 5.1 of CL:AIRE 2014a

2.2 Uncertainty in site investigation and the Conceptual Site Model

Jonathan Welch (AECOM), gave a presentation on sources of uncertainty within site investigation and the conceptual site model (CSM). Development of a robust CSM is fundamental to the design of an appropriate sampling strategy. As with any kind of sampling survey, a site investigation must consider the study population, the variability, and the level of confidence required. Statistical based sampling is useful where knowledge is more limited, or estimates of average concentrations and size of affected areas or volumes are required. Prior knowledge of the contaminative history of a site can be used to justify a targeted approach to make best use of the available resources. Often an investigation considers future development rather than just existing conditions, and therefore separate sampling plans may be needed for the soils present in different areas of the site, to characterise them for re-use or disposal.

The importance of the mean contaminant concentration was discussed and with it the concept of an averaging area. Fundamental variability in soil properties may lead to uncertainty associated with the estimate of a mean value. This may be counteracted by increasing the sample size, the number of samples, by using stratified sampling techniques or by composite sampling. Spatial variability at the scale of the averaging areas or greater may also lead to uncertainty especially for the application of classical statistical approaches. The CSM provides a framework for the interpretation of variation between samples and avoidance of sampling bias.

It is important to note that confidence in whether the screening threshold is exceeded is more important than the absolute variability of the concentration. Two types of statistical error were identified. For UK (Part 2A) Contaminated Land; a Type I error occurs when the site is mistakenly found to be contaminated, whereas a Type II error occurs with failure to identify that land is in fact truly contaminated. Since Type II errors result from a lack of evidence, the importance of an adequate CSM is paramount.

Advanced techniques using geostatistical methods are available in the public domain for the analysis of spatial variability. These can be used to interpolate confidence intervals for concentrations and hence estimate the likelihood that a threshold is exceeded, as well as optimise the design of further investigation.

Assessment of sample concentrations using data exploration methods can be highly informative for confirming or refining the CSM. In addition to looking at the concentrations of individual contaminants, techniques such as cluster analysis and principal component analysis can be helpful to determine the source and distribution of the contamination.

2.3 Uncertainty in estimating exposure to humans

Simon Firth, Firth Consultants, gave a presentation on uncertainty in estimating exposure to humans. Simon emphasised that estimating exposure is an integral part of quantitative human health risk assessment. For sub-surface sources of contamination (*e.g.* contaminants in soil, groundwater or soil vapour) equations or models are typically used to estimate exposure to a "critical" receptor or to back calculate the soil, vapour or groundwater concentration (assessment criterion) that would result in exposure equal to some pre-defined health based guidance value (derived from toxicological assessment). Risks are then characterised by comparing the estimated exposure with toxicological information (such as a health based guidance value (HBGV) or, where assessment criteria

have been derived, by comparing measured concentrations in the subsurface with the applicable assessment criteria. Finally, the risks are evaluated (in order to determine whether they are acceptable or not) by considering the results of the risk characterisation and associated uncertainties.

The consideration of uncertainty is a key part of the risk evaluation. For example, if it can be shown that predicted exposure is likely to have been significantly over-estimated but nevertheless is still significantly below protective health based guidance values, then it would be reasonable to conclude that the risks are not unacceptable. Whereas, if central tendency (most likely) estimates of exposure are significantly above levels that are known to cause significant harm, then it would be reasonable to conclude that the risks are unacceptable. In the area between these two scenarios, where decision making is less clear cut, the proper consideration of uncertainty becomes all the more important.

There are three main areas of uncertainty in estimates of exposure, each of which is addressed in turn below:

- Conceptual Site Model;
- Model Uncertainty; and
- Parameter Uncertainty.

2.3.1 Conceptual site model

Have the migration and exposure pathways been properly defined? Are there pathways that are unlikely to be active that have been modelled (thus over-estimating exposure) or are there plausible pathways that have been excluded from exposure estimates (*e.g.* diffusion of hydrocarbons through plastic drinking water pipes or exposure to Polychlorinated Biphenyls (PCBs) from ingestion of eggs from hens kept at the site). Have we properly conceptualised migration pathways? For example, have we assumed that vapours migrate into buildings via cracks around a foundation slab when they are actually entering via migration along sewers? Have we chosen to model an appropriate type of receptor? Is it reasonable to assume a young child as the critical receptor in a risk assessment for a shooting range?

2.3.2 Model uncertainty

Are the models/equations that we are using able to accurately predict exposure for the pathways we are assessing? Are they empirical (such as measured soil vapour or indoor vapour concentrations) or do they simulate actual processes (such as estimated soil to indoor air attenuation factors)? Are the assumptions

used for the modelling valid for our site? For example, vapour models normally assume equilibrium partitioning between soil sorbed, vapour and dissolved phase concentrations as if there was a closed system. What happens if air flushing through the soil prevents equilibrium partitioning occurring – what are the implications of the estimates of exposure?

2.3.3 Parameter uncertainty

Exposure models such as CLEA (Environment Agency, 2015[2]) are deterministic, meaning that they give one estimate of exposure based on one set of input parameter values. There is uncertainty in these values due to:

- Natural variability, *e.g.* variability in body weight, the amount of soil that children eat, the amount we breathe, fraction of organic carbon in soil etc. We can measure variability and account for this in the risk assessment, but there will still be residual uncertainty in the estimates of exposure, especially considering future scenarios where we do not know exactly who the receptor will be.
- Unknowns. Unknowns arise through lack of data. For example, we may suspect that the bioavailability of a contaminant in soil is less than that in the toxicological study used to derive the health based guidance value, but we have no data to show by how much. Equally, the soil ingestion rates that we typically use in the UK are largely based on studies involving US children. We assume that UK children are no different in terms of the amount of soil they eat but we do not know this with certainty.

Exposure models can be relatively complex, particularly where we are modelling multiple pathways. It could take a long time to consider all the uncertainties associated with these complex models but this is not strictly necessary. We only really need to consider the critical areas of uncertainty in the exposure assessment; that is, those that affect the overall uncertainty in the exposure estimates.

When using models that consider multiple pathways, such as CLEA, it can be helpful to focus on the principal exposure pathways, *i.e.* those predicted to give the greatest contribution to total exposure. However, there are provisos:

- Firstly, it should be recognised that different routes of exposure can have different toxicological effects with very different toxicological potencies. Health based guidance values for benzo(a)pyrene, for example, tend to be

[2] Environment Agency, (2015). Contaminated Land Exposure Assessment (CLEA) Software Version 1.071.

orders of magnitude lower for the inhalation route than for the oral route of exposure. Thus, even though the inhalation pathways typically present a relatively small contribution to total exposure to benzo(a)pyrene, these pathways can still be significant in terms of overall risk.

- Secondly, given that the models can only estimate exposure, just because a model predicts a particular pathway to give the highest exposure does not necessarily mean that this is the case.

Simon further discussed uncertainties associated with three common key exposure pathways further. These were:

- Incidental ingestion of soil and dust;
- Consumption of homegrown produce; and
- Vapour intrusion into buildings.

2.3.4 Incidental ingestion of soil and dust

This can be a key exposure pathway, particularly for non-volatile contaminants in surface soils. Sensitivity analysis can be used to identify key uncertain parameters and is achieved by varying one parameter at a time between a minimum and maximum reasonable value and assessing what effect this has on the exposure estimates. By combining worst case parameter values, an absolute worst case exposure estimate can be derived. However, such worst case estimates may be of limited use because the likelihood of such an exposure occurring may be very low. Probabilistic modelling (such as Monte Carlo analysis) can help to better understand the significance of combined uncertainties on the exposure estimates. An example of site-specific sensitivity analysis was presented for exposure to a two to three year old female child from lead in surface soil; Monte Carlo analysis indicated that there is only a 0.6% probability of the worst case exposure (derived from the sensitivity analysis) occurring.

2.3.5 Consumption of homegrown produce.

This can be a key exposure pathway for contaminants readily taken up by plants and where fruit and/or vegetables are grown for consumption. Both sensitivity and Monte Carlo analysis indicate that there can be considerable uncertainty in the exposure estimates for this pathway. This is largely due to uncertainty in the extent to which plants take up contaminants (the soil to plant concentration factor), but there is also considerable variability in the amount of homegrown produce consumed. For most residential properties with gardens in the UK, the cultivation of fruit or vegetables for home consumption either does not occur or is negligible. Where it does occur, this can vary from limited quantities to self-

sufficiency, although the size of garden tends to limit the extent to which this could plausibly occur.

Although probabilistic modelling can help to better understand the effects of uncertainty on exposure estimates it does not address all the uncertainties. For example, it is hard to quantify the impact of sources of uncertainty within the overall CSM (for instance within our understanding of the contaminant source term in both the soil and the various types of homegrown produce) or the mathematical representation of the uptake from one into the other using probabilistic modelling. It should also be recognised that there is uncertainty in the probability distribution functions (PDFs) used as input parameters for the probabilistic modelling. An example was presented to explore the effects of using different input parameter PDFs on the Monte Carlo results for the consumption of homegrown produce pathway. This showed how the use of different plausible input PDFs can have a large influence on the predicted probability of exposure exceeding a particular dose (such as a HBGV).

2.3.6 Vapour intrusion into buildings

This is often a key exposure pathway for volatile contaminants that are present in soil or groundwater beneath a building. Although models are available to predict indoor air concentrations from sub-surface contamination, uncertainty in the exposure estimates derived using these equations can be very high. Much of this uncertainty relates to the ability of the models to accurately represent the migration pathway. The Johnson and Ettinger model (Johnson and Ettinger 1991 [3]) algorithms are used within the CLEA model to estimate indoor air concentrations arising from organic soil contamination beneath the building. This model is based on the assumption of a building with a ground bearing concrete floor slab or basement. Vapour intrusion occurs via upwards diffusion and advection through an assumed crack around the perimeter of the floor slab. Deviation from the assumptions does not necessarily preclude the use of the model but, like any model, the uncertainty caused by such deviation should be considered. For example, Wilson (2008) has shown that the Johnson and Ettinger

[3] JOHNSON AND ETTINGER, (1991). *Users Guide for the Johnson and Ettinger (1991) Model for Subsurface Intrusion into Buildings*, accompanied by original version of the model available from available from https://rais.ornl.gov/johnson_ettinger.html. Accessed 18th January 2018.

Updated version *Johnson and Ettinger Model Spreadsheet Tool, Version 6.0*, available from https://www.epa.gov/vaporintrusion/epa-spreadsheet-modeling-subsurface-vapor-intrusion. Accessed 18th January 2018

model is likely to be highly conservative for buildings with passive subfloor ventilation[4].

Another key source of uncertainty for the modelling of the vapour intrusion pathway is the prediction of soil vapour concentrations from measured soil or groundwater concentrations. Equations for this are typically based on the assumption of equilibrium partitioning. These equations tend to significantly over-estimate the concentrations in soil vapour for petroleum hydrocarbons, possibly as a result of equilibrium conditions rarely being achieved in the unsaturated zone. For example, comparison of measured and predicted concentrations of hydrocarbons in soil vapour show that measured concentrations are typically more than two orders of magnitude below those predicted (CIRIA, 2009)[5].

Attenuation of vapours along the vapour intrusion pathway, by processes such as biodegradation, introduces another source of uncertainty. Biodegradation of hydrocarbons in the unsaturated zone can be significant, especially for deeper sources (of a few metres or more). As a result, models that neglect biodegradation (such as Johnson and Ettinger) can significantly over-estimate exposure.

There are various ways in which uncertainty in the estimates of exposure can be managed. A simple technique is to use a precautionary set of assumptions/parameter values with a deterministic model to derive an estimate of "reasonable maximum exposure" (RME). A better understanding of uncertainty may be obtained by deriving two estimates of exposure: one based on central tendency (*i.e.* most likely) values for input parameters and one based on RME. Probabilistic modelling can help to further understand uncertainty in the exposure estimates but the results can be harder to explain to the lay-person, especially where there is considerable uncertainty in the probabilistic model inputs. Lastly, one method for managing uncertainty that should not be forgotten is further work to reduce the uncertainty. For example, consideration could be given to obtaining site-specific estimates of bioavailability or soil to plant concentration factors, or to the direct measurement (rather than estimation) of soil vapour concentrations.

2.4 Uncertainty in soil bioaccessibility measurements

Mark Cave provided a presentation on uncertainty in soil bioaccessibility. The accurate determination of bioaccessibility has the potential to make a significant

[4] WILSON S., (2008). Modular approach to analysing vapour migration into buildings in the UK. and Contamination and Reclamation, 16 (3), 223-236.

[5] CIRIA (2009) The VOC Handbook. Investigation, assessing and managing risk from inhalation of VOCs at land affected by contamination C682, CIRIA. London.

impact on current risk assessment practice. He introduced the topic by explaining that studies into soil bioavailability and bioaccessibility are part of the bigger question of whether contaminants in soil actually do cause problems to human health. Ideally such studies would take place on humans, but for obvious reasons cannot. Therefore, estimates are based on *in vitro* bioaccessibility tests and *in vivo* bioavailability animal tests.

The concepts of bioaccessibility and oral bioavailability are fundamentally important for quantifying the risks that are associated with oral exposure to environmental contaminants. Bioaccessibility refers to the fraction of a contaminant that is released from soil into solution by digestive juices. It represents the maximum amount of contaminant that is available for intestinal absorption. In general, only a fraction of these bioaccessible contaminants can be absorbed by the intestinal epithelium. Inorganic contaminants are subsequently transported to the liver via the portal vein for biotransformation. The fraction of parent compound that reaches the systemic circulation is referred to as the bioavailable fraction. Given the fact that bioaccessibility is one of the principal factors limiting the bioavailable fraction, it is an important parameter to measure for risk assessment purposes.

Mark began by summarising some of the ways in which bioaccessibility based estimates are typically misused[6]. These include:

- Insufficient samples (the recommendation being 10 per averaging area);
- Use of values taken from literature, rather than site specific data;
- Application of bioaccessibility methods designed for the direct ingestion pathway only to other pathways;
- Application of bioaccessibility estimates for one substance to a completely different substance (all methods are substance-specific);
- Lack of evidence, where bioaccessibility results are not tied into and/ or are incompatible with the geology and geochemistry of the site;
- Mixing samples from different soil/ ground types together, as bioaccessibility varies with the matrix;
- Poorly documented test procedures (interpretation will vary with the specific methodology used);
- Selection of samples for bioaccessibility analysis which are not representative of the concentrations of concern (although bioaccessibility

[6] Based on work by Nathanail (2009), *Professional Practice Note: Reviewing human health risk assessment reports invoking contaminant oral bioavailability measurements or estimates*. Chartered Institute for Environment and Health.

varies with total concentration, the relationship is not necessarily either linear or positive);

- Inappropriate use of statistics, resulting in a mismatch between the bioaccessibility estimate and the total concentration to which it is applied;
- Application of either average or single values to a dataset (due to the non-linear relationship between total and bioaccessible concentrations);
- Use of the wrong methodology for the substance in question; and
- Lack of adequate reporting (meaning that a reviewer cannot evaluate).

He then went on to state that the biggest misuse of all was not to undertake bioaccessibility testing and use it within risk assessment. He also advised that while bioaccessibility data may be used to refine the level of estimated risk, misuse could potentially be used to demonstrate negligence.

Mark cautioned that future land uses and their associated practices should be considered when conducting a bioaccessibility assessment. This is because land use practices such as liming low pH soils, adding phosphate fertiliser and applying soil enrichment that increases the soil organic matter content can all affect the biochemical conditions within the soil, and hence the bioaccessibility.

Mark provided a set of benchmark criteria for the evaluation of laboratory-based bioaccessibility methodologies as follows:

- Tests should be physiologically based, mimicking the human gastro-intestinal (GI) physico-chemical environment in both the stomach and the small intestine. This is both for the purposes of obtaining good agreement with *in vivo* data, but also to enhance communication with the public of the nature and applicability of the test;
- It should represent a conservative case;
- There should be a single, standard set of conditions for all contaminants under consideration;
- There must be a demonstration that the test is a good analogue for *in vivo* conditions; and

- The test must be repeatable and reproducible within and between different testing laboratories.

- Mark presented a summary of the sources of uncertainty from the initial soil sampling to the final bioavailability estimate, and other considerations when evaluating them, using an Ishikawa or "fish diagram" (Figure 1)[7].

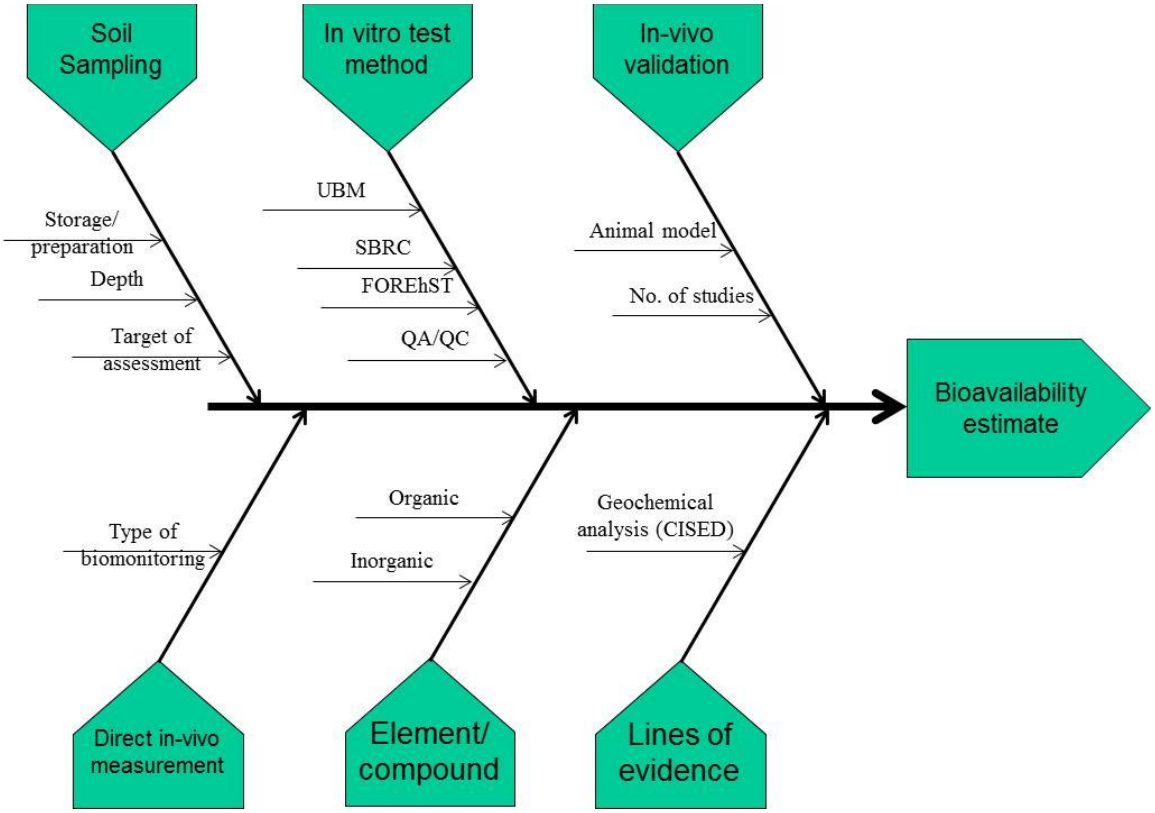


Figure 2.2 Uncertainty Fish Diagram

The key sources discussed were:

- Soil sampling (with factors including depth, particle size, storage/ preparation, and target of assessment);
- Whether accompanying direct *in vivo* measurements are available (and if so what the biomonitoring technique involved is, and how applicable it is to the contaminant in question, and any confounding factors);
- Factors specific to the element or compound in question, including whether they are inorganic or organic, which will then influence the choice of *in vitro* test methodology;
- Whether *in vivo* validation is available for the *in vitro* test, and, if so, what animal model or models have been used, how many supporting studies are available, and how applicable they are to the site in question (swine

[7] Acronyms within Figure 2.2 Chemometric Identification of Substrates and Element Distributions (CISED), Fed Organic Estimation human Simulation Test (FOREhST), Unified Barge Method (UBM), Solubility/ Bioavailability Research Consortium assay (SBRC)

models having been shown to be a more robust representation than mouse models); and

- Whether there are accompanying lines of evidence, such as geochemical analysis.

Mark went on to present some of the recent research conducted by the British Geological Survey (BGS) and others to validate *in vitro* bioaccessibility tests. Firstly he discussed the work of Denys *et al.* 2012[8] in which *in vivo* validation of the Unified Barge Method (UBM) was conducted for arsenic, antimony, cadmium and lead for 16 different soils using juvenile swine, in order to derive a statistical relationship between % Bioaccessibility and % Bioavailability, using the R^2, intercept and slope parameters. The relative bioavailability using four different biological endpoints (kidney, bone, liver and urine) was evaluated against the relative bioaccessibility results from both the stomach and the stomach and intestine compartments of the UBM method, and regression line descriptive statistics were produced, allowing correction of UBM results. Overall, the study showed that the UBM met benchmark criteria of repeatability and regression statistics for arsenic, cadmium and lead, but was not suitable for antimony. The data indicated a small bias in the UBM relative bioaccessibility (5% or less) for arsenic and lead.

He went on to discuss an RIVM report (Kesteren *et al.* 2014[9]) which evaluated the bioavailability of lead in samples of six different Dutch Made Ground soils using juvenile swine and then a comparison with three different in vitro bioaccessibility tests (UBM, Tiny-TIM and IVD). The report concluded that while both the UBM and Tiny-TIM method showed the same overall pattern as the animal experiments, the Tiny-TIM method consistently underestimated the true bioavailability. In contrast, results of the IVD model only showed a correlation after correction for the calcium content of the soil.

Mark also briefly discussed an *in vivo* mouse study conducted on 12 different Chinese soils contaminated with lead (Li *et al.*, 2015[10]). This found a good correlation between the UBM gastric phase and the relative bioavailability of the

[8] Denys, S. *et al.* (2012). In Vivo Validation of the Unified BARGE Method to Assess the Bioaccessibility of Arsenic, Antimony, Cadmium, and Lead in Soils. Environmental Science & Technology, 46 (11), pp 6252-6260.

[9] Van Kesteren *et al.*, P. (2014) Bioavailability of lead from Dutch made grounds: A validation study, RIVM Report, 607711015, Bilthoven: National Institute of Public Health and the Environment.

[10] Li, J*. et al.* (2015) Lead bioaccessibility in 12 contaminated soils from China: Correlation to lead relative bioavailability and lead in different fractions, Journal of Hazardous Materials, 295 pp55-62.

soils. It also concluded that the greatest contribution to lead bioavailability was from the exchangeable and carbonate lead containing fractions of the soil.

Mark continued by describing recent BGS work to extend the applicability of the UBM to other substances besides arsenic, cadmium and lead, using the BGS reference soil and considering 57 different elements. This concluded that further work in this area is worth pursuing for both environmental assessment and food security objectives.

Mark gave an overview of the Fed Organic Estimation human Simulation Test FOREhST) method for polycyclic aromatic hydrocarbons (PAHs) which simulates the nutritional status and intestinal phase of a 2-3 year old child (Cave *et al*. 2010[11]). The method simulates fed status since in the presence of food (in particular fats) the PAHs are likely to be more soluble, result in a higher uptake and be more conservative. The protocol for measuring PAHs in the simulated gastro-intestinal fluids used methanolic KOH saponification followed by a combination of polymeric sorbent solid phase extraction and silica sorbent cartridges for sample clean-up and preconcentration. The analysis was carried out using high pressure liquid chromatography with fluorescence detection. The repeatability of the method, assessed by the measurement of the bioaccessibility of 6 PAHs (benz(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, dibenz(ah)anthracene, and indeno(1,2,3-c,d)pyrene) in eleven gasworks soils, was ~10% relative standard deviations (RSD). The method compared well with the results from an independent dynamic human simulation reactor comprising of the stomach, duodenal and colon compartments tested on the same soils. The method described has potential for site specific DQRA either to modify the risk estimation or to contribute to the risk evaluation.

Mark concluded by summarising best practice for using UBM data within a risk assessment, illustrating his guidance using a step by step example:

- Calculate mg/kg bioaccessible element and convert to % bioaccessibility;
- Use recovery of the soluble salt in the UBM to convert to relative bioaccessibility (from Denys et al. 2012);
- Convert to relative bioavailability by correcting for the slope and intercept on the graph provided in the Denys et al. 2012 study; and
- Take into account the effect of increasing uncertainty in the bioaccessibility and bioavailability calibration data on the predicted bioavailability.

[11] 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.

2.5 Toxicology evaluation and uncertainty

Camilla Pease (Ramboll Environ) discussed uncertainty in the toxicology evaluation using trichloroethene (TCE; trichloroethylene; CAS No. 79-01-6) as a case study. TCE is a soil contaminant found commonly at a range of sites. Generic assessment criteria are based upon a human health value as derived from the most up to date toxicology information on a substance. The most recent toxicology review for TCE, as performed by the United States Environmental Protection Agency (USEPA) (USEPA 2011a[12], USEPA 2011b[13]), has been met with some controversy in the approaches taken and choices made in the evaluation. In particular, the derivation of a Reference Dose (RfD) for oral exposure and Reference Concentration (RfC) for inhalation exposure have relied heavily on physiologically-based pharmacokinetic (PBPK) modelling for route-to-route and species-to-species extrapolation. Thus specific choices of toxicological benchmark with associated uncertainty factors may or may not be acceptable by all international regulatory bodies.

Historically, the key human health effect of concern for TCE has been kidney cancer. In the USEPA 2011 review, the most sensitive effects are three-fold, identified as foetal heart malformations, developmental immunotoxicity and effects on the thyroid in adults. Kidney cancer remains a sensitive effect, but not the most sensitive of those considered in the new evaluation. All of these effects are considered together, as they occur at similar intake doses, making the evaluation relatively complex in comparison to other contaminants. This has led to a significant reduction in the RfD and RfC values compared to those derived before 2011 and it is important to understand the basis of these changes before using the US EPA values in UK contaminated land risk assessment. The reference values are lower than previously; the new RfD (0.5 µg/kg/day) and RfC (2 µg/m^3, equivalent to an intake of 0.57 µg/kg/day) as derived by the USEPA, would be considered to be 15-fold higher than a 'minimal risk' position in the UK context.

[12] USEPA. (2011a), *Toxicological Review of Trichloroethylene (CAS No. 79-01-6) In Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-09/011F.* U.S. Environmental Protection Agency.

[13] USEPA. (2011b), *Toxicological Review of Trichloroethylene Appendices (CAS No. 79-01-6) In Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-09/011F.* U.S. Environmental Protection Agency.

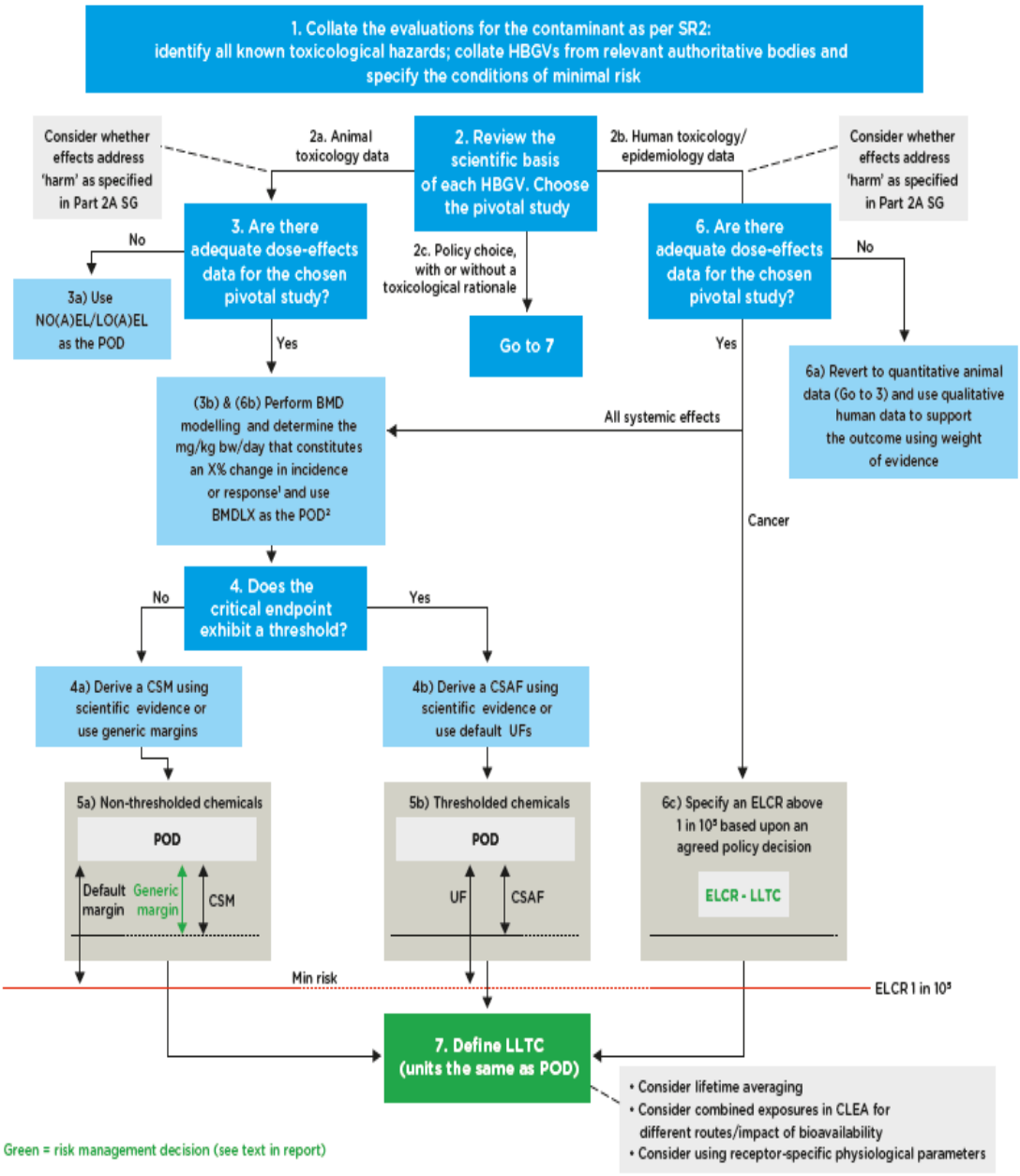
Camilla began by discussing the approach published by Defra for the derivation of C4SLs (Defra 2014)[14]. C4SLs are designed to represent 'low risk' and to provide a simple test for deciding when land is suitable for use and definitely not contaminated land. The change in UK contaminated land policy has increased the onus for detailed review of toxicology information by a suitably competent person and in a new framework introduced the new term, LLTC, that represents defined risk levels using specified measures of uncertainty. The principles of a Health Criteria Value (HCV), which represents minimal risk, as defined within Environment Agency SR2[15] and SR3[16] guidance from 2009, remain consistent with the new framework illustrated in Box 1. The framework approach starts with an overview of the authoritative toxicology data reviews for TCE.

[14] DEPARTMENT OF THE ENVIRONMENT, FOOD AND RURAL AFFAIRS (2014) *SP1010: Development of Category 4 Screening Levels for Assessment of Land Affected by Contamination – Policy Companion Document.* Defra, London.

[15] ENVIRONMENT AGENCY, (2009a.) *Human health toxicological assessment of contaminants in soil. Science Report – SC050021/SR2.* Environment Agency. Bristol, 2009.

[16] ENVIRONMENT AGENCY (2009b) *Updated technical background to the CLEA model*, *Science Report SC050021/SR3*. Bristol: Environment Agency.

Box 1: A toxicological framework to derive a LLTC for land contaminants as used in the context of implementing the revised Statutory Part 2A guidance of the Environmental Protection Act 1990 (England and Wales) for developing C4SLs (Taken from Defra Project SP1010 2014 report)



2.5.1 Overview of Recent Authoritative Toxicology Reviews for TCE

The Environment Agency last produced an HCV for TCE in 2004[17]; the value of 5.2 µg/kg/day for both oral and inhalation intakes was based on minimal risk. Since this time, new toxicology reviews have been published (which suggest a

[17] Environment Agency, (2004) Contaminants in Soil: *Collation of Toxicological Data and Intake Values for Humans. Trichloroethene. Science Report Tox 24*. Environment Agency. Bristol.

significant reduction in health based guidance values for TCE) that would change the conclusions of the (now withdrawn) toxicological report.

In 2011, the USEPA performed a lengthy and comprehensive review of the TCE toxicology, and proposed candidate RfDs based around three pivotal studies: Table 2.1 below details pivotal studies together with the health effects, doses and types of point of departure (POD), uncertainty factors applied and final RfDs derived (for the oral pathway).

Table 2.1 Review of TCE Toxicological Studies

Health Effect	POD value mg/kg/day	POD type	Uncertainty Factor (UF)	Ref Dose mg/kg/day	Pivotal study
Thymus – decreased weight	0.048	Human Equivalent Dose (99th percentile) based on a **LOAEL[18] (0.35 mg/kg/day)** expressed as an internal dose (0.139 mg/kg/day)	100 (10 for use of a LOAEL; 3.16 as a PBPK model used for interspecies extrapolation; 3.16 as PBPK model for interindividual variability)	0.00048 mg/kg/day	Keil *et al.* (2009)[19] 30 week drinking water study in B6C3F1 mice
Immunotoxicity – delayed type hypersensitivity in pups	0.37	LOAEL	1000 (10 for use of a LOAEL; 10 for interspecies and 10 for intrahuman variability)	0.00037 mg/kg/day	Peden-Adams *et al.* (2006) [20]from placental, lactational and drinking water exposure
Foetal heart malformations	0.0051	Human Equivalent Dose (99th percentile) based on a Benchmark Dose (**BMD**)[21] **1% (0.065 mg/kg/day**; converted to 0.0142 mg TCE oxidised/kg/day as expressed as an internal dose)	10 (3.16 as a PBPK model was used for interspecies extrapolation; 3.16 as PBPK model was used for interindividual variability)	0.00051 (mg/kg/day)	Johnson *et al.* (2003)[22] Rat developmental study – drinking water

In 2013, the US Agency for Toxicity and Disease Substance Registry (ATSDR) published an addendum to its toxicity profile for TCE published in 1997[23]. This

[18] Lowest observed adverse effect level

[19] Keil, D., et al. (2009). Assessment of trichloroethylene (TCE) exposure in murine strains genetically-prone and non-prone to develop autoimmune disease. *J Environ Sci Health A Tox Hazard Subst Environ Eng 44:* pp443-453.

[20] Peden-Adams, M., et al. (2006). Developmental immunotoxicity of trichloroethylene (TCE): Studies in B6C3F1 mice. *J Environ Sci Health A Tox Hazard Subst Environ Eng 41*: pp249-271.

[21] Benchmark Dose

[22]Johnson, P.,D, *et al.* 2003. Threshold of trichloroethylene contamination in maternal drinking waters affecting fetal heart development in the rat. *Environ Health Perspect 111*(3):289-292.

[23] ATSDR. (1997). *Toxicological Profile for Trichloroethylene.* Atlanta, GA: Agency for Toxic Substances and Disease Registry.

was largely a reiteration of the USEPA preferred RfD value of 0.51 µg/kg/day as a Minimal Risk Level (MRL).

In 2014, both the US National Toxicity Program (NTP) and International Agency for Research on Cancer (IARC)[24] reviewed new evidence on carcinogenicity and NTP concluded that the current listing in the Report on Carcinogens for TCE as '*reasonably anticipated to be a human carcinogen*' should be changed to '*known to be a human carcinogen*' based on sufficient evidence of carcinogenicity from studies in humans regarding kidney, liver and non-Hodgkin lymphoma. TCE is also genotoxic *in vitro* and *in vivo*, which means it should be considered as a non-threshold carcinogen, even though its metabolites are likely to be causative of carcinogencity.

All of the most sensitive and serious non-cancer (development) endpoints are based on animal studies; cancer endpoints are kidney and non-Hodgkin lymphoma, for which there are human data. The preferred oral RfD in the US EPA evaluation, is that derived in relation to foetal heart malformations as the most sensitive endpoints in rates (Johnson *et al.* (2003). PBPK modelling has been used to predict internal human relevant doses from the rat drinking water study.

Cancer risk was also reviewed in the USEPA evaluation using the human inhalation data in Charbotel *et al.* (2006)[25] on incidence of kidney cancer with TCE exposure; for inhalation the risk is 4×10^{-6} per ug/m^3 and the oral slope factor, resulting from PBPK modelling of route-to-route extrapolation from the same inhalation study, is 5×10^{-2} per mg/kg/day. The total unit risk of 2×10^{-6} from all cancers (kidney, Non-Hodgkin Lymphoma and liver, with consideration of early life susceptibility) from drinking water containing 1 µg TCE/L water is calculated in US EPA 2011 page 5-162; similarly, it is 4.8×10^{-6} per µg/m^3 in USEPA 2011 page 5-159.

2.5.2 Possible LLTCs for TCE

The following tables present options on how an oral and inhalation LLTC can be derived for TCE for use in human health risk assessment. The key end points chosen are the most sensitive (and potentially severe/fatal) non-cancer endpoints

ATSDR. (2013). *Addendum to the Toxicological Profile for Trichloroethylene.* Atlanta, GA: Agency for Toxic Substances and Disease Registry.

[24] IARC (2014). Trichloroethylene, Tetrachloroethylene and Some Other Chlorinated Agents, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. vol. 106, Lyon, France: International Agency for Research on Cancer.

[25] Charbotel, B., et al. (2006). Case-control study on renal cell cancer and occupational exposure to trichloroethylene. Part II: Epidemiological aspects*. Ann Occup Hyg 50*: pp777-787.

of foetal heart malformations (FHM) (Johnson *et al.*, 2003) and human total cancer unit risk values of 2 x 10^{-6} per µg/m^3 air, both human total cancer unit risk values of 2 x 10^{-6} per µg/L drinking water and 5 x 10^{-6} µg/m^3 air, both accounting for early life susceptibilities and lifetime exposure (USEPA 2011 evaluation).

Table 2.2. Results of using the Toxicological Framework to interpret the data and provide evidence such that an appropriate Oral LLTC can be defined for TCE C4SL,

Potential Basis for LLTC	Value	Unit	Comments
2004 Minimal Risk Health Criteria Value (EA) now withdrawn as no longer defensible	5.2	µg/kg BW/day	Index dose – mouse inhalation study – dose-independent cancer endpoints. ELCR [26] 1 in 100,000. No longer valid.
Using Johnson *et al*. 2003 – based on BMD01 (also similar to provisional World Health Organisation (WHO) EU 2011 4th Ed drinking water guideline 20 µg/L) with margin of 100	0.65	µg/kg BW/day	Applied dose – **with no PBPK modelling** Based upon a BMD01 for Foetal heart malformations in rat Incidence FHM = 1 in 10,000. Human cancer risk = 1 in 22,000
US EPA RfD Using BMD01 Johnson *et al.* (2003) as most sensitive endpoint – foetal heart malformations – with internal human equivalent dose using PBPK modelling with a margin of 10.	0.5	µg/kg BW/day	**BMD01 but translated to HED_{99} [27] using PBPK modelling.** Human cancer risk = 1 in 28,600
Current European drinking water standard http://dwi.defra.gov.uk/consumers/adviceleaflets/standards.pdf	10	µg/L	Based in unit risk of 2 x 10^{-6} per µgTCE/L (USEPA 2011 – total risk of all cancer, including early life susceptibility and lifetime exposure) Oral Cancer Risk at 10 µg/L is 1 in 50,000
	0.3	µg/kg BW/day	(10 µg x 2L per day)/70 kg
Oral LLTC – Based upon a Cancer Risk of 1 in 50,000 (also equates to the current drinking water standard which avoids disproportionately targeting soil) and is suitably protective of non-cancer endpoints	**0.3**	µg/kg BW/day	• Protective of a sensitive developmental immunotox endpoint (RfD 0.37 µg/kg/day) • Protective of foetal heart malformations: the LLTC is 216-fold lower than the BMD01 of 0.065 mg/kg/day. Approximate notional incidence rate of 1 in 22,000.

[26] Excess lifetime cancer risk

[27] The lower 99th percentile for the continuous human equivalent ingestion dose

Potential Basis for LLTC	Value	Unit	Comments
Oral LLTC – driven by FHM, based on BMD10 and a margin of 5000 (*i.e.* as per policy companion for non-threshold carcinogens, use similar for this severe developmental endpoint)	0.14	µg/kg BW/day	*i.e.* BMD10 =0.7mg/kg/day divided by a margin of 5000 Incidence FHM = 1 in 50,000 Cancer risk – 1 in 102,000 (minimal risk)
Considerations of minimal risk for FHM			
Using Johnson *et al.* 2003 based on BMD (UF 10,000)	0.07	µg/kg BW/day	Applied dose BMD10 = 0.7 mg/kg/day divided by a margin of 10,000 – with no PBPK modelling
Using Johnson *et al.* 2003 – based on BMDL01 (95^{th} %ile) and margin of 1000	0.02	µg/kg BW/day	Applied dose – BMDL01 = 0.02 mg/kg/day divided by a margin of 1000 – with no PBPK modelling
Minimal Risk HCV using Johnson *et al.* 2003 for the most sensitive endpoint. BMDL 10 (UF 10,000) as per EA SR2 guidance	0.02	µg/kg BW/day	Applied dose – BMDL10 = 0.23 mg/kg/day divided by a UF of 10,000

From the evidence in the Table 2.2 above it is suggested it would be appropriate to set an **Oral LLTC at 0.3 µg/kg BW/day** for use in developing a C4SL for TCE. The value is:

- Equivalent to an excess lifetime cancer risk via oral route of 1 in 50,000, as based upon an evaluation of human study data (which is in accordance with Defra's policy companion for the C4SLs relating to low risk excess lifetime cancer risk (ELCR) (Defra 2014).
- Is lower than the RfD (0.37 µg/kg BW/day) for developmental immunotoxicology endpoints.
- Represents low risk of foetal heart malformations, a developmental endpoint, with this intake being 216-fold lower than a highly sensitive POD, the BMD01.
- Equates to the intake of the current drinking water standard.

Table 2.3 Results for using the Toxicological Framework to interpret the data and provide evidence such that an appropriate Inhalation LLTC can be defined for TCE C4SL.

Potential Basis for LLTC	Value	Unit	Comments
2004 Minimal Risk Health Criteria Value (EA) – now withdrawn as no longer defensible	5.2	µg/kg BW/day	Index dose – mouse inhalation study – dose-independent cancer endpoints. ELCR 1 in 100,000. No longer valid.
Based on Cancer Risk of 1 in 50,000	1.1	µg/kg BW/day	Assuming a 70kg person inhales 20m^3 air per day containing 4 µg TCE/m^3.
	4	µg/m^3	Cancer risk – 1 in 50,000 based on a unit risk of 5 x 10^{-6} (human study Charbotel *et al.* 2006).
US EPA RfC The basis is cited as the non-cancer effects; fetal heart malformations, adult and developmental immunotoxicity. PBPK modelling has been used to perform route to route extrapolation for these three most sensitive endpoints originally from drinking water study data in rodents	0.57	µg/kg BW/day	Assuming a 70kg person inhales 20m^3 air per day containing 2 µg TCE/m^3.
	2	µg/m^3	The dose in µg/kg BW/day is based upon route to route PBPK extrapolation from oral non-cancer effects (drinking water studies) Cancer effects: kidney tumours: Non-Hodgkin Lymphoma, and liver cancers are based on human inhalation exposure data. Cancer risk = 1 in 100,000 based on a unit risk of 5 x 10^{-6} (human study Charbotel *et al.* 2006) **Minimal Cancer Risk at RfC = 1 in 100,000.**
Recommended Inhalation LLTC equates to the oral LLTC, as driven by the most sensitive non-cancer endpoints. Remains suitably precautionary as per Defra's guidance	0.3	µg/kg BW/Day	Non-cancer toxicity drives the risk: assumes the toxicological consequences of absorption through the gut and lungs is the same, as per previous Environment Agency 2004 guidance. Factors in no PBPK extrapolation or differential route-specific metabolism – at the moment these assumptions carry high uncertainty and methods have not been fully considered and reviewed at a national level in the UK
	1	µg/m^3	Air concentration equates to 0.3 µg/kg BW/day for a 70 kg person inhaling 20m^3 air Unit cancer risk = 5 x 10^{-6} *i.e.* ELCR 1 in 200,000
Minimal risk considerations as above could also apply here with the above assumption that the toxicology is route dependent.			

From the above evidence, it is suggested to set an **Inhalation LLTC at 0.3 µg/kg BW/day** for using in developing a C4SL for TCE. This value is:

- Equivalent to the oral LLTC applying the current assumption that the inhalation route kinetics are the same as the oral route kinetics leading to the same non-cancer effects. This is a suitably precautionary position for current regulatory use in the UK, as PBPK modelling is used in multiple ways in the US EPA assessment to perform route-to-route extrapolations, internal human dose estimates and incorporating oxidative metabolism assumptions.
- Protective of all cancer effects by the inhalation route; ELCR is calculated at 1 in 200,000 at this intake dose.

2.5.3 Conclusions

The Oral and Inhalation LLTC vaue for TCE should be set at a suitably precautionary 0.3 µg/kg BW/day. These LLTC values would be lower than the RfD (0.5 µg/kg BW/day) and RfC (2µg/m^3 equivalent to 0.57 µg/kg BW/day) proposed by the US EPA in 2011 following their review of the next toxicological data, but protective of all non-cancer and cancer end points.

It should also be noted that the most sensitive effects (FHM and immunotoxicity) are developmental in nature and therefore sensitive time windows for exposure (*i.e.* during gestation) require careful consideration when undertaking exposure modelling, where the C4SL should be derived for pregnant women and the developing foetus, as the most sensitive human receptors potentially exposed to TCE.

PBPK modelling techniques are metabolism studies useful in refining risk assessment across species and performing route-to-route extrapolations. PBPK modelling and assumptions around oxidative metabolism have been used heavily in the US EPA assessment. Measured data to parameterise the models is not comprehensive, and it is possible that there is a high degree of uncertainty in the modelling underpinning the US EPA values. It is important, before using the EPA values directly in risk assessment, that there is a review and discussion about this parameterisation of the PK models used, a critique of the underlying assumptions made and data on metabolism reviewed in order that there is full transparency about the uncertainties in the US EPA evaluation.

Given these specified details for TCE modelling, and indeed the general use of PBPK modelling and metabolism data, are yet to be debated and reviewed at national level in the UK for risk assessment purposes, it remains suitably

precautionary to set the LLTCs for values slightly lower than the US EPA reference doses until such a review is performed.

In deriving the C4SLs using these LLTCs for the various exposure scenarios and considering the risks of developmental effects, the most sensitive human receptors should be the pregnant woman and developing foetus during the sensitive window of gestational exposure. For other effects the receptor is the standard residential child and the commercial adult worker.

3. SITE INVESTIGATION (WORKSHOP GROUP 1)

3.1 Introduction

The group were tasked with discussing aspects of uncertainty in site investigation. The group included representatives from regulators, consultancies, laboratories and academia.

3.2 Objective

The overall objective was to identify and address areas of uncertainty in site investigation. The following questions were provided to assist in achieving the broader objective:

- Identify the sources of uncertainty in site investigation and provide suggestions on how they can be mitigated?
- Is the uncertainty associated with different techniques understood?
- Can statistics be used to help understand uncertainty?
- How do we communicate and report uncertainty associated with site investigation?

It was acknowledged that currently the identification of uncertainty is inadequately covered in site investigation or reporting. It is important to provide detailed information to identify and describe the uncertainties in any site investigation. There was a discussion about priorities, and, given the limited timeframe, most focus was given to first three questions.

3.3 Key sources of uncertainty

Overall uncertainty in site investigation arises from a combination of the heterogeneity of the contaminant in the soil, uncertainty associated with sampling as well as contributions from laboratory preparation and analysis. Made ground, by its nature, tends to be highly variable. This spatial variation will be a significant contributing factor to the total uncertainty associated with any investigation.

The preliminary investigation and development of a robust and reliable CSM are a prerequisite for designing the investigation. The initial development of a CSM is fundamental to the design of an appropriate sampling strategy. The purpose of the site investigation is to reduce the uncertainty in the CSM to an acceptable level for decision-making. The CSM integrates what is already known about a site and identifies both what still needs to be discovered and how that information should be used. Underpinning the site investigation, therefore, must be a clear set of objectives.

Recognition of uncertainty is required and evaluation of its significance should be assessed. The site investigation process typically involves phases of investigation which begin with the initial setting of objectives for the investigation. This is an iterative process where the findings of each phase are used to refine and update the CSM. This is then reviewed to determine remaining uncertainties and decide if the objectives have been reached with sufficient confidence. Refining the CSM may include modifying, removing or retaining pollutant/ contaminant linkages, or in some cases, the addition of new ones which have become apparent as a result of the investigation.

There is always uncertainty regarding the degree of confidence in the data *i.e.* how certain are we that a result is a 'true' value ? This is because samples are never perfectly representative and chemical analyses are always wrong to some extent. Although we never know the true values of contaminant concentrations, we know the range in which they lie, and we can make reliable decisions. The assessment of linkages may include direct comparison of individual concentrations to the GAC, or comparison using an estimate of the true mean obtained from statistical analysis appropriate to the context and end-use.

The investigation and assessment of land contamination is essentially a cost-led activity. In reality there are never sufficient resources to fully investigate all aspects of the CSM, and therefore the key role of a practitioner is to make a qualified and reasonable assessment of the site based upon the available information. This information will always have a degree of uncertainty associated with it.

3.4 Uncertainty in the sampling strategy

P5-066/TR (Environment Agency 2000)[28], CLR4 (Department of the Environment, 1994[29]), BS10175 (2011 & 2017)[30] and ISO 18400[31]provide extensive guidance on the development of soil sampling strategies. The aim here is not to reproduce

[28] Environment Agency (2000). *Secondary Model Procedure for the Development of Appropriate Soil Sampling Strategies for Land Contamination. R&D Technical Report P5-066/TR.* Environment Agency, Bristol.

[29] DEPARTMENT OF THE ENVIRONMENT (1994). *Sampling strategies for contaminated land. Report Prepared by The Centre for Research into the Build Environment. Contaminated Land Research Report CLR Report No. 4 (CLR 4)*. Prepared by The Nottingham Trent University. London.

[30]BS 10175:2011+A2:2017 *Investigation of potentially contaminated sites. Code of practice,* British Standards Institution.

[31] ISO 18400-101:2017 *Soil quality -- Sampling -- Part 101: Framework for the preparation and application of a sampling plan*, International Organization for Standardization (ISO).

this guidance but to consider the uncertainties associated with different strategies:

3.4.1 Targeted (judgemental) sampling

Targeted sampling is based on prior information collected during the preliminary investigation and may be used to confirm if an area is or is not affected by land contamination. It aims to confirm the presence or absence of a particular pollutant/ contaminant linkage established in the initial development of the CSM. This approach allows specific horizons to be sampled such as discoloured layers or odorous material as well as pockets of distinct materials such as ash and clinker. It is therefore important that the sample is recorded as being targeted. This is so the results from such hotspots, which are clearly not representative of the surrounding material, are not subsequently used incorrectly in statistical analysis.

3.4.2 Non-targeted (systematic) sampling

Non-targeted sampling uses a statistical approach to cover the site. This is normally undertaken on a grid or consistent shape of variable dimension and spacing, dependent on the level of confidence or reduction of uncertainty that is required. The herringbone pattern, which uses a form of offset regular grid, is statistically more likely to identify linear contamination in two dimensions than a square grid pattern, as explained within CLR4 (Department of the Environment, 1994). The reliability of interpolation between sampling locations declines significantly as distance increases. BS10175 identifies typical recommended densities of sampling grids, depending on the nature of the site investigation (BS10175, 2011 & 2013)). In practice the number of sampling points is often a trade-off between the costs of mitigating a potential risk posed by a given volume of unknown contamination between sampling points that is either acceptable within the project budget and/or less than the cost of additional investigation at a later stage.

3.4.3 Random sampling

Random sampling can actually be reasonably statistically relevant in terms of the way it can be applied in the field. In addition, the degree of confidence can also be determined reasonably accurately. This method, however, requires more samples than other approaches in order to reach the levels of confidence generally considered to be acceptable.

3.5 Ways to Mitigate Uncertainty

Consideration was given to a number of pragmatic ways in which uncertainty could be reduced. These were:

- Sample descriptions & photography;
- Rapid Measurement Techniques;
- Geophysics;
- Sample preparation;
- Combined investigation;
- Experience and supervision; and
- Planning Conditions.

Each is discussed in turn below.

3.5.1 Sample descriptions & photography

Sample descriptions have an important role in identifying layers and strata which can be correlated to analytical results in order to understand the source of contamination, assist in statistical analysis and in the understanding of uncertainty between sampling locations. Soil descriptions in accordance with BS 5930:2015[32] and BS EN ISO 14688-1:2002+A1:2013[33] provide standardisation but have a strong geotechnical focus. Comments on contamination and made ground conditions should always be used in combination with the standard descriptions.

Although not all contaminants are visible, the use of photography was considered to be a very useful additional line of evidence. Photography is often a contractual requirement. Even where it is not, the inclusion of photographic records were recommended. The photographs should include a project reference, trial pit/borehole reference, depth, date, scale and colour chart.

In addition, laboratories could provide a photograph of all samples received. This would supplement descriptions made in the field and act as an additional quality control check.

3.5.2 Rapid Measurement Techniques

The contribution from sampling uncertainty is far greater than the uncertainty associated with laboratory measurements. It may therefore be more effective to

[32] BS 5930:2015 Code of practice for ground investigations, British Standards institution.

[33] BS EN ISO 14688-1:2002+A1:2013 Geotechnical investigation and testing. Identification and classification of soil. Identification and description

spend a greater proportion of the investigation budget on field testing. On-site analytical techniques generally have a lower cost per sample associated with them than traditional off-site methods for the same analytes, which means it is possible to analyse a larger number of samples. This can therefore result in a higher sampling density from which decisions can be made about the extent of areas affected by land contamination, and how they should be zoned.

The appropriate use of field testing can reduce the overall uncertainty and has been shown to be fit-for-purpose in achieving the required level of data quality and reliability (Ramsey *et al.* 2012)[34]. Field testing such as X-Ray Fluorescence (XRF), Membrane Interface Probes (MIP) and Laser-Induced Fluorescence (LIF) can provide another line of evidence in the site investigation process, leading to expedited decision-making and cost savings. Such dynamic approaches to site investigation can only be achieved using real-time data.

The application of field techniques requires suitable training and use, in accordance with clear standard operating procedures. Some of the techniques require full field laboratory capabilities and are impractical to operate without these facilities. The detection limits of field testing techniques are typically higher than those associated with off-site laboratories and may therefore not be low enough to meet the requirements of GAC (to be considered as part of the data quality objectives).

Field testing techniques have benefits and limitations. These are dependent upon the technique, how it is used, and the contaminants of concern. There has to be a demonstration of method applicability. Such techniques should be used to complement traditional laboratory analysis in order to improve overall data quality.

3.5.3 Geophysics

Alongside other approaches, non-intrusive geophysical techniques such as ground penetrating radar, electromagnetic, resistivity and magnetic gradiometry can be used in the investigation of sites. Geophysical techniques measure variations in physical properties of the ground or pore water fraction within the sub-surface (*e.g.* in conductivity, acoustic velocity, magnetic permeability, density and resistivity). These methods can be useful within an exploratory investigation, if carried out, or as part of a main investigation where the presence of features

[34] Boon, K., A. and Ramsey, M. (2012) Judging the fitness of on-site measurements by their uncertainty, including the contribution from sampling. *Science of the Total Environment, 419*. pp. 196-207.

associated with contamination is suspected, but the specific locations are not known.

The value is these measurements can be used to further knowledge of geological and hydrogeological conditions, leading to more targeted intrusive investigation. An improved understanding of the distribution and transport of contaminants can be gained when these measured properties are integrated into the CSM.

3.5.4 Sample Preparation

Statistical errors and variability occur within laboratory procedures and this contributes to the measurement uncertainty. Workshop participants highlighted sample preparation as an area of significant inconsistency between laboratories, and discussion followed on the impact that this will have on the test results. For human health risk assessment, consideration needs to be given to the likely exposure pathways. Analysis of the fine particles following sieving and the exclusion of the stone content from the analysis would appear to be most appropriate.

When the chemical analyses indicate that the soil in residential settings contain contaminant concentrations where there is marginal exceedance, it would be worth considering the effect of the sample preparation method and whether re-testing a sieved sample may produce a more appropriate concentration to compare with the generic assessment criteria, considering the assumed critical pathway.

3.5.5 Combined Investigations

Where a single investigation is being carried out to address multiple potential receptors and objectives, a broader sampling strategy may be required. However, it is important to ensure that when environmental investigations are combined with geotechnical and/ or archaeological investigations that may have other objectives, the proposed integrated investigation achieves all of the required objectives for the individual disciplines.

3.5.6 Experience and supervision

Workshop participants emphasised the importance of adequate supervision of the intrusive investigation for ensuring continuity in the site investigation process and ultimately for reducing uncertainty. The consultant has to be present on site during the intrusive works as he/she will be involved in the writing of the interpretative report/risk assessment. The fieldwork takes forward the desk study and ideally the person who wrote the preliminary investigation should have a

supervisory role. There is a requirement to have knowledge of the site's background and history, which would prevent unsupervised investigations taking place. Instead of reducing the uncertainty in the CSM, unsupervised or poorly managed investigations can have the opposite effect.

Even for supervised investigations, the engineer has to be appropriately knowledgeable, qualified, trained and experienced. Whilst financial constraints have meant that only limited mentoring is being carried out, a minimal level of competency and training are still required to ensure representative samples are collected at suitable depths and frequencies. Experienced engineers would notice visual or olfactory indicators of contamination, rather than simply collecting samples at predefined depths or following a rigid procedure. The investigation needs to be adaptive and incorporate an element of flexibility.

3.5.7 Planning conditions

There is a requirement to ensure consistency and good practice in implementing site investigation. Sampling strategies rarely accompany a desk study; the group thought submission of a sampling strategy along with the desk study would be a useful standalone planning condition. The regulators within the group thought that good practice would involve a written sampling strategy being submitted to, and agreed by, the local authority before the commencement of any site investigation works.

It was recommended that the consultant's sampling strategy should include the following:

- The purpose of the intended investigation – including rationale and justification of sample locations, depths, patterns and numbers and the frequency and duration of sampling or monitoring to be undertaken;
- Sampling and/or monitoring methods used;
- The contaminants and parameters that will be assessed, together with full justification for the analytical strategy;
- The likely number of samples (soil, water, leachate and/or ground gas) that will be taken for subsequent laboratory analysis; and
- The laboratory methods that will be used.

There was also a recommendation that evidence should be submitted demonstrating compliance with acceptable data quality objectives (method statements, field and laboratory quality assurance/ quality control (QA/QC))

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3.6 Is the uncertainty associated with different techniques understood?

The selection of most appropriate site investigation techniques should be made on a rational basis with the aim of reducing uncertainty in the CSM. There is no "one best" solution and selection of the intrusive technique(s) are required on a site-specific basis.

Trial pits and trial trenches allow for much better visual inspection of ground conditions. The ability to visually inspect a larger area reduces the uncertainty in the site investigation process. Examining the excavation and spoil of a trial pit with typical dimensions of 3000 x 500 x 2500 mm provides considerably more information to a competent and trained person than, for example, a narrower window sampling hole at the same depth.

Although the pros and cons of different intrusive investigation techniques are stated clearly in BS 10175 (BS 10175:2011+A2:2017), there was an acknowledgement that it is not always possible for excavators to access locations, there may be depth constraints, service constraints, trial pitting/ trenching is not suitable for sampling below the water table, and that this method creates more disturbance of the site than other approaches. The consensus was that the method of investigation should be based on health and safety requirements, ground type, depth required, contaminants of concern, access and disruption constraints, whether there is a requirement for permanent installations and also project budgets.

3.7 Can statistics be used to help understand uncertainty?

Statistical analysis is encouraged to identify uncertainties in site investigation but there was also recognition that statistics can often be misused.

Statistical methods can allow for variability of contamination caused by large scale heterogeneity, sampling precision and laboratory uncertainty. These techniques can be used to judge fitness-for-purpose criteria. The simplest method to estimate measurement uncertainty from the field sampling and the laboratory analysis is the duplicate method (Boone and Ramsey 2012). The cluster sampling approach is shown, statistically, to reduce sampling uncertainty ((BS 10175:2011+A2:2017))

There is frequently large variability within contaminant concentrations across a site. Variography is an empirical means of estimating the uncertainty of measurement from the combined sources of samples and analysis. It is particularly useful in situations where there is large-scale spatial and/or temporal variation in contaminant concentration that can be quantified and modelled.

It may be useful to consider whether perceived outliers consist of the same material as the other samples. This may provide an indication as to whether they belong to the same population or are visibly different. Similarly, where sufficient samples permit, it would be useful to consider whether a specific zone belongs to the same population as the rest of the site.

Site investigation lends itself well to a Bayesian modelling approach. The Bayesian method allows us to deal with uncertainty and treats model parameters as random variables. This will lead to a reduction of uncertainty so that decisions can be made with improved levels of confidence. The number of sampling locations required to achieve a given level of confidence of finding a hot spot can be reduced by using variable rather than uniform sampling densities (involving the application of Bayesian statistics *i.e*. making *a priori* assumptions about the probability of finding a contaminated area in sub areas of the site) and by undertaking sampling in two or more stages (staged investigation) as discussed within CLR 4 (Department of Environment 1994).

3.8 Conclusions

The measurements of contaminant concentrations are only estimates of the true concentration. Estimates of uncertainty can be used to assess the reliability of their interpretation and improve the quality and robustness of the risk assessment. Simple and practical steps can be taken that greatly increase confidence in site investigation outcomes.

Approaches to site investigation have now become broader with an increasing amount of complementary techniques. These techniques can assist in reducing the uncertainty; their selection depends on the data needs, budget and ground conditions. Making best use of the latest methods or applying traditional ones in a novel way requires an understanding of their capabilities and limitations, both technical and practical.

An outlier assessment should be considered to evaluate whether perceived outliers consist of the same material as the other samples. This may provide an indication as to whether they belong to the same population or are visibly different.

Statistics can be used to help quantify uncertainties and provide confidence in making decisions.

3.9 Recommendations

No recommendations for future guidance/workshops were specifically discussed during the workshop because of time constraints. However, arising from the discussion the following practitioner recommendations can be made:

- There should be a clear set of objectives for a site investigation, building on a CSM derived from a robust and reliable preliminary risk assessment;
- A written comprehensive sampling and analytical strategy, which fulfils the objectives and provides a full justification and rationale (including acceptable data quality objectives) should be produced prior to the site investigation taking place. Where a geoenvironmental investigation is combined with one or more other investigations, care should be taken to ensure that the objectives of each are specifically met. Ideally the sampling and analytical strategy should be submitted to the regulator, alongside the preliminary risk assessment/desk study. Regulators should consider making this an explicit planning condition;
- In some situations, especially on large sites or where there is considerable uncertainty (*e.g.* where particular contaminative practices took place following the desk study, or the extent of a hotspot revealed during a preliminary investigation), consultants should consider using field techniques and geophysical techniques to complement traditional laboratory based analysis, refine the CSM and maximise the benefit from a fixed budget;
- Site investigations should be supervised by adequately trained/ competent personnel, who are familiar with the preliminary risk assessment, the objectives of the site investigation and the sampling and analytical strategy and allow for adaptive assessment on site. These personnel should then have direct involvement in writing the site investigation and interpretative reports;
- There may be a need for additional training and mentoring for staff and budgets should be put aside for this;
- Where measured contaminant concentrations are close to the assessment criteria, consultants should consider the effect of sample preparation on the results, and whether the sampling preparation methodology could impact the critical exposure pathways. This could involve additional liaison with the laboratory and for laboratories to be more transparent;

- Consultants should produce full soil descriptions and photographs to accompany the soil samples which they have taken;
- Laboratories may wish to consider producing photographs of sampled soils either/both 'as received' and 'after preparation';
- In some cases, a valid decision may be made that insufficient information has been collected to produce a reliable conceptual model, so that further work is genuinely needed to reduce the uncertainties. The risk assessor should stop and evaluate whether additional information would make any real difference to the conclusions reached.
- Consultants should consider appropriate use of statistical techniques to understand and/ or reduce the uncertainty at all stages of the risk assessment process from designing a sampling strategy through to interpretation of results; and
- Sufficient information should be provided at each step by relevant parties to enable the writer of the final report to document the uncertainty from start to end.

4. Uncertainty and the Conceptual Site Model (WORKSHOP GROUP 2)

4.1 Introduction

The workshop was given seven key points to discuss / questions to answer. They were:

1. Introduce the session by identifying key areas of uncertainty in the CSM
2. Do people know where data can be found?
3. What are the data sources for uncertainty and are they publicly available?
4. What are the sources of uncertainty in the CSM?
5. How can we consider when the number of data points is sufficient and the cost versus benefit of taking more?
6. Is there enough analysis at the right depth?
7. How will C4SL influence site investigation design?

These points are discussed in turn below.

4.2 Key Sources of Uncertainty

Introductions revealed a broad range of interests from the focus group, which comprised representatives from regulators, consultancies and academia. An initial poll was held to identify key sources of uncertainty for development of a CSM. These can be grouped as;

- Temporal changes to the source/ contaminant-pathway-receptor linkages (*e.g.* during development)
- Identification of plausible pathways
- Confirmation of the CSM through site investigation and forensics
- Information gaps due to wide spatial and temporal separation of data
- Historical failure to investigate pollutant/ contaminant linkages (*e.g.* emerging chemicals of concern such as asbestos fibres in soil)

It was recognised that development of the CSM and site investigation (SI) were strongly interrelated and that the CSM should be used throughout the sampling and analysis process in addition to being reviewed and refined according to the SI findings. Since design of the SI is dependent on the CSM, there is a risk that insufficient development of the CSM will lead to insufficient site investigation and risk assessment. Ultimately this could lead to either insufficient remediation, resulting in residual liabilities, or unnecessary and/ or unsustainable remediation.

4.3 Site Data – do people know where data can be found?

It was generally agreed that commercial pressure and the availability of "ready-made" site information from computerised databases had led to a reduction in the

amount of independent research undertaken to inform the CSM. The convenience and value of the computerised searches was not disputed, and various rival offerings appeared to be widely known. However, a concern was expressed that other data sources were no longer being considered especially by new graduates (who had not been exposed to the "old way" of doing things). Just by considering the potential sources of data, many of them freely available, it is obvious that relying on computer databases is restrictive and leads to greater uncertainty in the initial CSM. The following list itemises some of the data sources that should be considered.

Local Information

- Site walkover
- Local library
- Interviews with neighbours
- Interviews with Site personnel
- Planning Authority
- Building Control
- Company archives
- Petroleum Officer
- Kelly Trade Directories
- Town maps

Publications

- Geological Memoirs (BGS)
- Department of Environment Industry Profiles

Interactive mapping

- British Geological Survey (1:50,000 mapping)
- Environment Agency interactive mapping
- Coal Authority (at BGS)
- Magic Map
- Topography / Ordnance Survey / Bing

National resources

- WW2 Aerial Photography
- Historic England / Heritage Gateway
- Google Earth / Streetmap / timeline
- Unexploded ordnance (UXO) mapping
- Topography / Ordnance Survey

- Mining Museum
- BGS Background Chemistry
- Radon Atlas

Even a simple internet search may reveal useful information, for example, local history sites or biographies of factory owners.

4.4 Sources of Data Uncertainty – what are they, are they publicly available, how can they be identified?

Old drawings and maps are often found to be inaccurate, although this might be due to subsequent poor geo-referencing. Sometimes it will be difficult to differentiate between plans and as-built drawings, or the features shown may have been obliterated by subsequent development.

Maps are only a snapshot in time. Some features, such as earthworks and landfills in particular but also short-lived industrial processes, may not have been present during the mapping process, or the extent of the feature such as a backfilled quarry may not be fully realised. This is a particular problem for sites with military uses since these may have been deliberately missed off the official Ordnance Survey mapping. Aerial photography in particular, but also other archival material such as (dated) plans and drawings, may be useful in completing the site history between map issues. Highlighting possibilities in an uncertainty section also helps clarify the uncertainty and may help with subsequent investigation design. For example, if two former brick pits are either side of the site you are commissioned to work on, rather than only saying brick pits are located adjacent to the site, add an uncertainty section commenting on the location of the brick pits and saying whilst mapping does not indicate these extend onto your site they may well do so. All historical data should be viewed in relation to the standards at the time of recording. Colliery plans for example may reflect the official mine extent however there are cases where unofficial mining has also taken place - not to mention shallow unrecorded mining prior to mandatory record keeping. The description given to waste as "inert" is also problematic since this may not meet the current definition of what constitutes Inert Waste (Environment Agency, 2010)[35]. Often ground investigation will be required to confirm the expected situation as well as target known data gaps.

[35] Environment Agency (2010) *Waste acceptance at landfills: Guidance on waste acceptance procedures and criteria*. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/296422/geho1110btew-e-e.pdf Accessed 23rd January 2018

It is also important to recognise that the data depicted may be intrinsically uncertain, for example, the interpretation of buried geological features such as faults or sub-crops. The scale of the original mapping should also be taken into account especially where geological features are originally mapped onto a much larger scale map. This may give a false sense of the precision of the original mapping and lead to an erroneous conclusion as to whether a feature lies on or off the site.

General database searches as well as previous site reports provide a ready source of information. However, it is important to understand how and for what purpose the data have been collected, and to read carefully any disclaimers or footnotes which explain the uncertainty inherent in the data.

4.5 Sources of Uncertainty for the Conceptual Site Model

The CSM not only incorporates the relevant data about the site, it must also identify the areas of uncertainty in order that these may, if necessary, be investigated further. Arguably this requires more skill and experience than simply collecting the data since it requires a judgement call on the quality of the data, sometimes in comparison with problems found on other similar sites.

For a pollutant/ contaminant linkage to be active there needs to be a source/ contaminant, pathway and receptor. Theoretically it may be sufficient to prove the absence of just one element. In practice, they will generally be interlinked because the sensitivity of the receptor will be dependent on the characteristics of both the source and the pathway.

The sources of uncertainty relevant to each aspect of the pollutant/ contaminant linkage are presented below.

4.5.1 Source/ Contaminant

Characterisation of the source term requires that the correct media (*e.g.* soil, water, gas and vapour) have been tested for the correct contaminants. A separate focus group (Chapter 3) has considered the uncertainties within site investigation, and therefore the proper procedures for collection, storage, transportation and analysis of samples was not considered by this workshop. Whilst it is important that the site investigation data are reliable, it is also important that the reliability or otherwise of the data be considered in refining the CSM.

The initial CSM will be important for the design of a suitable site investigation to predict the extent of the source laterally and vertically, the nature of the

contaminant matrix and possible interference with mixtures, the types of strata and the possible physical and chemical characteristics of the contaminants *e.g.* speciation, and whether more detailed analysis such as leachability, bioaccessibilty or respirable fibres should be included within the scope of work, and the variability of the concentrations expected between sampling points. Computer models of contaminant fate and transport and geochemistry may be useful to predict the likely extent of impact and plan the scope of investigations.

Since concentrations of contaminants may be highly variable, the CSM should take account of the cause and nature of this variability in order to establish the uncertainty of interpolation between sampling points. This might take account, for example, of the correlation of contaminant concentrations with soil descriptions and/or historical map overlays in order to make the most of the available data.

4.5.2 Pathway

The identification and evaluation of contaminant pathways was considered to be the source of greatest uncertainty for the CSM. This was due to several factors including the difficulty of assessing geological properties, the uncertain distribution of buried structures or preferential pathways, and changes to the pathways during development. The CSM should not be seen as a static document as it will require updating in response to new data, changes in the site conditions and design of mitigation measures. The accuracy of pathway characterisation was believed to be particularly sensitive to the specialised skill and experience of the risk assessor.

Groundwater monitoring might be more representative than point sampling of soil because water quality could reflect average conditions over a wider area, and mobile contamination that would otherwise be hard to find might be easier to detect, albeit it at diluted concentrations. Contaminants may be mobilised in groundwater and free-phase leading to migration from the original source and introduction of new pathways. The same is true for ground gas and vapours. Broken drains, pipe bedding, basements and foundations in particular may form preferential horizontal and vertical pathways for liquid and gaseous contaminants.

The interaction between buried structures, contaminant concentrations in all media and preferential flow pathways may be extremely complex. There is a limit to what can be known at the initial CSM stage especially where there are buried structures or thin confining strata; and sometimes even after investigation there may be significant uncertainty. The CSM should consider whether the uncertainty

is significant or reducible through further investigation and/or monitoring. In the event that a significant hazard has been found or may plausibly exist, it may be more efficient, and hence preferable, to provide precautionary remedial action, rather than conducting further site investigation to reduce the uncertainty further, especially when it may not, in any case, remove the requirement for remediation.

4.5.3 Receptor

The risk for a particular contaminant-source-pathway linkage in part depends on the sensitivity of the receptor. The risk associated with contamination is therefore affected by the land use (for example, a residential land use with the consumption of homegrown produce is more sensitive than a commercial land use) or aquifer sensitivity. The CSM should take account of the sensitivity of the proposed land use (or other resource) and also the other plausible uses to which the land may be put without the need for further planning permission.

Changes in site development; for example, transport of topsoil from a less sensitive to a more sensitive area of the site, installation of air bricks, removal of an under-slab void or impervious hardstanding, may have an impact on the receptor. While it would be difficult to construct a CSM that covers all eventualities, establishing the suitability of various site soils for placement within certain source/ contaminant-pathway-receptors scenarios may be instrumental in managing the development risk. This requires a more holistic approach to development of the CSM than that required to investigate only the existing conditions.

4.5.4 Overall considerations of reducing uncertainty in the CSM

The need to reduce uncertainty should be proportionate to the risk. Thus more data may be required to characterise the likelihood of an occurrence where the impact would be more severe; for example, more site investigation may be required to demonstrate that pollution of a principal aquifer or public water supply well is/ are unlikely than when a secondary aquifer is involved; or that near-surface ground quality is better understood in the rear gardens of residential properties than for public grassland, since the margin of safety will be less (due to greater exposure frequency and exposure duration in rear gardens). There will always be uncertainty; it is the job of the risk assessor to make a judgement as to whether sufficient data is available to make an informed decision with respect to the report objective and aims.

4.6 How can we consider when the number of data points is sufficient and the Cost versus benefit of taking more?

Exposure calculations for chronic risk are based on arithmetic mean concentrations of the contaminant over an averaging area. This requires an understanding of the average and variation of concentrations for the chemicals of concern generally from testing samples taken from the site (more rarely field measurements). By convention the estimate of the mean concentration is taken as the upper 95th percent confidence interval (UCL95) under the planning regime or verification testing. Having more (relevant) data will tend to reduce the UCL95 value but the need for this will depend on how close concentrations are to the decision point. From the designer's point of view the question is whether there are sufficient data to be comfortable making a decision in relation to the applicable screening level for the proposed land use.

The designer will need to take account of potential costs and delays with other potential liabilities and stakeholder views in deciding what level of risk is appropriate at the particular stage of development. If there are issues of fundamental design or viability it would be better to find out sooner rather than later; if the cost of investigation outweighs the cost of selective treatment then an observational approach at a later stage may be preferred.

Where the design indicates that remediation would be expensive, more site investigation may be warranted in order to avoid unnecessary remediation while still providing a robust solution. These types of scenarios where alternative types or extents of remediation are required are prime candidates for modelling cost vs. value for additional site investigation.

The investigation strategy may also be adapted to optimise the value obtained from site investigation. Testing for total metals is cheap; therefore it often makes sense to test many samples to build up an accurate picture of the variability and mean concentrations (although total metals may not be a good indication of leachable metals which is important in groundwater risk assessment). In the case of organic contaminants these tend to be more difficult to obtain as representative samples and also more expensive to test. Therefore it may be more appropriate to test a few samples for a broad suite of contaminants initially, and identify a much reduced testing suite for chemicals of concern early in the investigation. Samples could be selected based on the results of relatively routine field testing where appropriate, such as photo ionisation detectors (PID), to provide maximum benefit for the least cost and therefore a sustainable analysis process. If possible

"over sample" to obtain and store reserved samples, as long as these can be tested as needed within the QA/QC allowance for holding times.

In addition to the sampling on a predetermined basis, it is important to be prepared to take additional samples based on observations in the field. Field testing such as XRF, MIP and LIF may be used to "chase out" the extent of contamination, although confirmatory conventional laboratory testing will usually be required. Consultants should consider collection of additional samples above and below the targeted source area, or inside and outside of the plume in order to confirm the observed extent of contamination. It is important to ensure that observations positively noting the absence of visible or olfactory contamination indicators are logged and gridded to avoid an exaggeration of the extent of contamination.

4.7 Is there enough analysis for the right depth?

The group's belief that the attention given to the CSM when designing and undertaking a site investigation is often inadequate was amply demonstrated by the issue of whether sufficient data analysis is undertaken out for the appropriate depth. The group agreed the sampling depth should be based upon the CSM and consideration be given to the following:

- Often the main risk from direct exposure to contaminants would be within the top 1 m of soil for residential developments and for asbestos it would be the top 0.1/0.2 m in particular. The durability of the existing or proposed soil concentration profile and possibility of future exposure or mixing also needs to be taken into account.
- Variations in the top 1m should be considered since this is the soil people are more likely to come into contact with and therefore the source of greatest uncertainty in the CSM.
- Soil may be redistributed during development. It is therefore necessary to understand the vertical and lateral extent of any potentially unsuitable material such as ashy layers whilst it remains in context. It should also be borne in mind that site levels may change and cut and fill operations could redistribute materials around the site and also affect the depth of re-use; and hence the exposure risk to future site users.
- Redevelopment plans may alter between phases of site investigation altering the CSM and relevance of samples taken previously.

It was considered that there was a commercial aspect to under-sampling of surface soil levels. To counteract this trend consideration should be given to more

efficient characterisation methodologies such as composite sampling (where this is statistically justifiable and agreed with the regulator).

4.8 How will C4SLs influence site investigation design?

In general it was considered that C4SLs would not make any difference to site investigation design. Amongst the consultants there was a belief that few Local Authorities were insisting on high standards of statistical analysis, whereas the regulators were concerned that there was no agreed minimum number of samples whereby the sufficiency of an investigation could be judged. Since each site is different and the required number of samples would depend on the CSM there was little probability of the group agreeing an appropriate number of tests for statistical analysis.

As far as C4SLs are concerned, it was noted that an Appendix had been provided on statistical assessment which if adhered to would in many cases (under planning) substantially increase the number of samples required.

4.9 Summary

The group agreed that whilst computer-based literature reviews were a quick and efficient method of gaining information, their availability often meant that other useful, and often critical, data in reducing uncertainty in the initial CSM were not being considered.

Data uncertainty for the initial CSM includes: historical map details with respect to spatial boundaries, labelling of 'works', geo-referencing and features being intentionally missed; geological mapping boundaries; and mine entries. These lead to uncertainty with respect to source and pathway characterisation, with additional uncertainty identified for pathway characterisation including hydrogeological and geological variations in the sub-surface.

In the experience of those in the room, the goal of reducing uncertainty in the CSM was often forgotten, or at least put to the back of the mind, during sampling and scheduling analysis. Hence, samples at pre-determined depths are often taken and analysed for a wide range of contaminants as specified in a tender document but not always relevant to the CSM. Subsequently this makes interpretation during the Generic Quantitative Risk Assessment (GQRA) more difficult owing to inadequate data with respect to depth, matrix or contaminant and also results in unnecessary expense being incurred.

The group agreed there was a balance to be struck with respect to how much data were collected to reduce uncertainty versus the cost of doing so. It was agreed

that data should only be collected where relevant to reducing uncertainty in the CSM and this principle needed communicating across the contaminated land community including clients.

Finally, the group noted that substantially more samples would need to be obtained than at present if the statistical analysis presented in the C4SL appendices were to be undertaken routinely.

4.10 Recommendations

No recommendations for future guidance/workshops were specifically discussed during the workshop because of time constraints. However, arising from the discussion the following practitioner best practice recommendations can be made:

- Practitioners should develop a robust CSM prior to site investigation so that the strategy with respect to sample numbers, locations, depths and contaminant suite is founded upon it. Site engineers should be thoroughly apprised of it so that they can actively contribute to its refinement based on site observations;
- Practitioners should consult additional sources for desk studies, rather than relying solely on commercial offerings;
- Practitioners should explicitly refer to uncertainties inherent in mapping when developing the CSM, especially when considering the extent or nature of significant features such as potentially infilled voids, and geological features such as outcrops and faults;
- Practitioners should consider the reliability or otherwise of analytical data when refining the CSM accounting for source/age/quality;
- Practitioners should carefully consider the implications of the initial site investigation for the CSM when planning more detailed investigations. In particular, they should consider whether the results merit incorporating more specialist laboratory testing into the scope, and, where possible relate variations in contaminant concentrations to historical information and soil descriptions within the logs and continually refine the CSM as new information becomes available;
- Practitioners should actively consider that preferential pathways may exist on site and that these may change following site investigation and mitigation measures;
- Practitioners should make a clear decision on whether uncertainty relating to a significant hazard can be reduced sufficiently through further investigation and/or monitoring, or whether to progress directly to remedial action;

- Practitioners should consider the impacts to changes to the CSM that may result from foreseeable changes to existing conditions including during development or changes in land use; and
- Risk assessors should actively consider whether there is sufficient information to make an informed decision about the site at each stage and avoid recommending further investigation that will not change the understanding of risks (*i.e.* proportionate).

5. BIOACCESSIBILITY WORKSHOP (WORKSHOP GROUP 3)

5.1 Introduction

This workshop was designed to encourage a discussion of the current issues associated with the use of bioaccessibility testing in human health risk assessment.

5.2 Objective and Selection of Key Issues

Through an open discussion delegates presented many opinions, experience and ideas on what they considered were the key issues. There was much overlap within the discussions for each question, but the following key issues were identified, and are addressed in turn in the sub-sections below.

- At what point in an investigation would we consider the need for bioaccessibility testing and for which substances?
- What are the differences between the test methods available? To what extent have they been validated?
- How many samples are needed and how can we understand the cost versus benefit of taking more?
- How should the results be used in modelling?
- What is the applicability of these tests to organic compounds such as benzo(a)pyrene?

5.3 Applicability of bioaccessibility testing

It was generally considered by the group that the need for, or the need to consider, bioaccessibility testing arose following the exceedance of a GAC used in a GQRA undertaken as part of a ground investigation at a site.

However, for areas where naturally occurring (geogenic) contaminants are known to be present, such as those associated with the Northamptonshire Ironstones, in Cornwall, the Mendip Hills and South Pennine Orefield, the need for bioaccessibility testing was often considered at the design stage of a ground investigation. As such, a sufficient number samples or sample volumes could be collected to negate the need for re-visiting a site to collect further samples should bioaccessibility testing be undertaken.

The group agreed that typically bioaccessibility testing was undertaken for arsenic and lead, both of which are naturally occurring as well as having anthropogenic sources. The group had experience of undertaking bioaccessibility testing for cadmium, PCBs and other organic substances.

Delegates considered it practical to refine the exposure assumptions associated with a GAC, as part of a DQRA, prior to considering bioaccessibility testing. Should bioaccessibility testing still be considered necessary, then the results of laboratory testing should be incorporated into the refined exposure assumptions for the site. Ultimately bioaccessibility testing is one of many lines of evidence when undertaking a DQRA for a site, therefore a failure to refine or consider the uncertainty associated with default exposure assumptions used to derive GAC was considered to be a significant omission.

Should there only be a marginal exceedance of a GAC, refining the exposure assumptions associated with the GAC to take account of site specific factors, or to remove conservatism associated with exposure pathways used to derive the GAC, was considered to be the most appropriate initial response as part of a DQRA. This approach to deriving a more site-specific, or less conservative, assessment criterion may remove the need for bioaccessibility testing to further refine the risk assessment. Additionally, it was agreed that revised exposure modelling was unlikely to require additional site visits or investigation (although this does not preclude undertaking surveys of behaviour and/or land use on a site-specific basis) and therefore may be a more cost effective initial approach to the exceedance of a GAC.

The group agreed that the key risk driver(s) for a site should be considered, as these may ultimately influence remediation at a site, and may not be influenced by the results of bioaccessibility testing on certain substances. Laboratory (*in-vitro*) bioaccessibility testing has only been validated for certain metals (see Question 2). Therefore if there are key risk drivers for a site other than these metals, undertaking bioaccessibility testing may have no overall bearing on the remediation requirements for a site.

The group considered it useful to undertake test model runs (*e.g.* in CLEA) incorporating hypothetical results of bioaccessibility testing (*i.e.* various Relative Bioavailability ($RBA_{soil,tox}$) percentages). Undertaking this prior to taking forward bioaccessibility testing would give the risk assessor an appreciation of the likely $RBA_{soil,tox}$ required to derive SSAC that would be protective of chronic exposure. The outcome of such sensitivity testing, combined with knowledge of previous reported bioaccessibility test results, may lead to a decision not to proceed with bioaccessibility testing.

Additionally an awareness of the relative contributions of each pathway (*e.g.* direct soil and dust ingestion) will aid with an understanding of how SSAC for a substance will vary when the $RBA_{soil,tox}$ is altered within a model such as CLEA.

For example, if direct soil and dust ingestion is a minor exposure pathway, varying the $RBA_{soil,tox}$ will have a considerably smaller effect on the resulting SSAC than for a substance where the direct soil and dust ingestion pathway makes a large contribution to exposure.

Delegates raised the lack of guidance from regulatory agencies (*e.g.* Environment Agency, Natural Resource Wales, Scottish Environmental Protection Agency) and Public Health England on the use of bioaccessibility testing, and on the lack of consistency between Local Authorities in their acceptance of bioaccessibility testing within human health risk assessments. The group noted that guidance issued by the Environment Agency (Environment Agency 2005[36], Environment Agency 2007[37]) is now a number of years out of date and does not reflect improved test methodology since their publication. The default (conservative) assumption of 100% RBA used in the CLEA model preceded the Unified Barge Method (see Question 2) and its associated *in-vivo* validation for certain metals.

The outcome of this discussion was that practitioners writing reports should include a clear audit trail behind the use of bioaccessibility testing and its associated uncertainty. The report should justify the reasoning behind the use of bioaccessibility testing, background to the type of testing used (including relevant references), details of the tested soil sample(s) description and classification, and quality assurance (QA) and quality control (QC) associated with the testing laboratory. It was considered laboratories should be able to provide evidence of QA/QC for the test method used, including details of the test methodology and any internal QC tests that they routinely run (*e.g.* testing blank samples; testing of samples of the BGS "UK reference sample" for bioaccessibility and total element determinations).

5.4 Test Methods

There are a wide variety of test methods available, and delegates had experience of the majority. All methods relate to soil ingestion, and not inhalation of soil or dust. The choice of test was often influenced by cost, with simpler methods being more cost effective if a large number of samples were being tested. Initial discussions were around the difference in results between methods. It was noted by some delegates that percentage bioaccessibility was different when soils were tested using the Physiologically Based Extraction Test rather than the Unified

[36] Environment Agency (2005). *Environment Agency's Science Update on the use of bioaccessibility testing in risk assessment of land contamination.*

[37] Environment Agency. (2007*). In-vitro bioaccessibility testing: Current Science and Way Forward (Environment Agency Science Update 2)*.

Barge Method. It was agreed this was a reflection of the pH used in each test method.

PBET (Physiologically Based Extraction Test) – Ruby *et al.* 1996[38]

This test approximates conditions in the gastrointestinal track of a 2-3 year old child, mimicking conditions in the small intestine and stomach as a two stage sequential extraction

The group discussed the lack of a standard procedure for the PBET, with laboratories using different in-house methodologies. The test lacks any inter-laboratory comparison. When presenting the results from a PBET, the DQRA should include details of the actual methodology used by the laboratory.

SBET (Simplified Physiologically Based Extraction Test) - Drexler, 1998[39]; Drexler, 1999[40]

This test is the same as the PBET, but excludes the small intestine phase. The SBET was developed in the USA specifically for lead. As with the PBET, the test lacks a standard procedure. When presenting the results from a SBET, the DQRA should include details of the actual methodology used by the laboratory.

SBRC (Solubility Bioavailability Research Consortium assay) – Kelley *et al.*, 2002[41]

This test was developed for arsenic and lead and is essentially a leaching procedure at low pH. The test is available in commercial laboratories in the UK but is not widely used.

CE-PBET (colon-extended Simplified Physiologically Based Extraction Test) – Tilson *et al.*, 2011[42]

This test is based on the PBET with the addition of an eight-hour colon compartment and use of a carbohydrate-rich fed-state medium. Developed at

[38] 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.

[39] 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*.

[40] Drexler, J.W. (1999). *Standard Operating Procedure for In-vitro bioaccesibility leaching*. University of Colorado at Boulder.

[41] Kelley M.E.,*et al.* (2002). *Assessing Oral Bioavailability of Metals in Soil.* Columbus:Battelle Press.

[42] Tilson. E.L., et al. (2011). Colon Extended Physiologically Based Extraction Test (CE-PBET) Increases Bioaccessibility of Soil-Bound PAH. *Environ. Sci. Technol. 45* (12), pp 5301–5308.

the University of Reading, UK, for use with PAHs. The test is not routinely undertaken or offered by commercial laboratories.

UBM (Unified Barge Method) – Denys *et al.*, 2012[43]

This method has been developed by the Bioaccessibility Research Group of Europe (BARGE), with the aim of harmonising the use of bioaccessibility in human health risk assessment. The *in-vitro* UBM has been validated against *in-vivo* testing on juvenile swine for arsenic, cadmium and lead. Validation was also undertaken for antimony, but the required criteria were not met.

FOREhEST (The Fed Organic Estimation human Simulation Test) – Cave *et al.*, 2010[44]

This test has been developed for organics, specifically PAHs. The test stimulates physiological changes within the gastrointestinal tract and is based on an infant (6 – 24 months old) diet. The *in-vitro* testing is undertaken to mimic a fed state. The author of the above paper was one of the delegates and advised that the behaviour of PAHs *in-vitro* are harder to mimic than metals.

It was discussed that the results of any bioaccessibility test are specific to the soil matrix (*e.g.* minerals, soil organic matter (SOM) etc.) at the time of sampling. Therefore any alteration to the soil matrix, either naturally or as part of remediation, has the potential to alter the bioaccessibility of a substance. This cannot be accounted for as part of any test method, which reports the results obtained from the sample tested. Uncertainty analysis, presented as part of the DQRA, can consider such sources of variation qualitatively and quantitatively (*e.g.* modelling different SOM and presenting the resulting SSAC). Ultimately bioaccessibility testing is a reflection of the soil sample analysed and the composition of the sampled soil at that point in time.

The group also discussed the difficulties and ethics of validating *in-vitro* test methods against *in-vivo* methods, and whether this was always necessary. Delegates discussed that under REACH (Registration, Evaluation, Authorisation and restriction of Chemicals), the system for controlling chemicals in Europe, in-*vivo* validation of *in-vitro* test methods is not always required and novel *in-vitro* test methods can be validated against existing *in-vitro* test methods.

[43] DENYS, S. *et al.* (2012). In Vivo Validation of the Unified BARGE Method to Assess the Bioaccessibility of Arsenic, Antimony, Cadmium, and Lead in Soils. *Environ. Sci. Technol.*, 46 (11), pp 6252-6260.

[44] 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.

The group briefly discussed the issue of mixture toxicity, and the interactions between contaminants within the human gastrointestinal tract and how this may influence bioavailability *in-vivo*. It was agreed that mixture toxicity is of importance, but current *in-vitro* test methods are unable to mimic any interaction between contaminants and the influence this may have on uptake within the body.

Delegates discussed the absence of inter-laboratory proficiency testing schemes for bioaccessibility testing, and that no methods were UKAS[45] accredited. The group agreed that standard methodology and inter-laboratory testing would be beneficial, but agreed this would be very dependent on laboratories experiencing the demand for bioaccessibility testing that would in turn justify participation in a proficiency testing scheme. The same demand for testing would apply for test methods to become UKAS accredited.

5.5 Frequency of sampling

The group agreed there is limited guidance available on the number of samples needed if bioaccessibility testing is used as a line of evidence within a DQRA. Ultimately this should be decided on a site-specific basis and clearly justified within the DQRA report. The Professional Practice Note published by the Chartered Institute of Environmental Health (Nathanail, 2009) states "*A minimum of 10 samples per averaging zone is typical in order to gain an adequate appreciation of the variation in bioaccessibility*", although is not supported by any further justification.

The averaging zone (or area) for a site will be dependent on the endpoint of interest. Averaging areas based on strata type or end use (*e.g.* a residential garden) will not necessarily be applicable to a suitable averaging zone for bioaccessibility testing.

There was no agreement within the group as to the most important factors that should drive the scheduling of samples for bioaccessibility testing, as it was agreed this would be site-specific. The key factors that can influence the results of bioaccessibility testing, and therefore need to be considered when scheduling samples for testing are:

- Soil type – natural strata is likely to have different properties to made ground, or re-worked topsoil. Therefore testing on a variety of different soil types should be considered. Samples from those soil types most appropriate to the risk assessment should be the focus of any testing (*i.e.*

[45] United Kingdom Accreditation Service

materials within the top 300 mm as this is the actual soil to which human receptors are most likely to be exposed to non-volatile contaminants).

- Contaminant concentration - the relationship between total and bioaccessible concentrations is not necessarily linear and this relationship varies with the contaminant. Therefore, testing on a range of concentrations should be considered.
- SOM – organic matter can alter the mobility of certain metals (*e.g.* arsenic and lead). Therefore testing on a range of soils with variable Total Organic Carbon should be considered.

Reviewing data collected as part of the ground investigation was considered by the group to be one way to rationalise the number of samples sent for bioaccessibility testing. If a site (or averaging zone) has low variability, or contaminants exhibit a broadly uniform concentration distribution across an averaging zone, a reasoned argument could be made to reduce the number of samples scheduled for bioaccessibility testing.

The group noted that whilst samples from shallow soils (the top 300 mm) are representative of the materials that receptors are most likely to be exposed to for direct contact pathways, consideration should be given to final ground levels at the site (materials sampled during a ground investigation may be removed from the site as part of a cut and fill exercise) and the potential for mixing of shallow soils with underlying materials.

Delegates agreed that within the DQRA there should be clear justification for the number of samples scheduled for bioaccessibility testing and the reasoning behind those samples scheduled for testing. Uncertainty associated with the number of samples tested, and the uncertainty around the variation in results, should be presented within the DQRA.

Cost is often a key consideration when scheduling samples for bioaccessibility testing. The more complex methods (*e.g.* UBM) are typically more expensive than simpler methods. However, the group felt the benefits of fewer samples from an *in-vitro* method that has been validated against an *in-vivo* method, may outweigh having an increased number of sample results from a method that has not been validated.

The group did not explicitly discuss the cost versus benefit of taking more samples. The group did however discuss the benefits of keeping an internal database of bioaccessibility test results, including details of the material/soil tested, and where possible mapping these on a geographical information system

(GIS). The knowledge of other results for similar strata or geogenic contaminant source, or results published in scientific journals, would assist in a lines of evidence approach when using bioaccessibility test results in a risk assessment. The group did agree that results are site-specific and should not be extrapolated between sites.

5.6 Modelling of bioaccessibility data

There was overlap in discussions between Questions 3 and 4 relating to the number of samples scheduled for testing, and the how the results (mean, maximum, percentile) could be used in modelling. Delegates discussed the inherent variability in test results from any laboratory (there is currently no inter-laboratory proficiency testing scheme). The group considered that there was benefit prior to scheduling tests to ask the intended laboratory what internal QA/QC procedures they undertook for the bioaccessibility tests they offer, whether they undertook tests on blank samples or using standard reference materials (*e.g.* BGS "UK reference sample" material) and what these results were. This overlapped with the discussion around Question 1.

The group agreed that the results of bioaccessibility testing should be used as a line of evidence as part of a DQRA. Results used in modelling should be supported by (but not limited to) details of soil type and associated parameters, likely contaminant source(s), details of laboratory test method and laboratory in-house QA/QC.

Delegates agreed there was benefit in running the model intended to be used to derive SSAC (*e.g.* CLEA) with varying values for bioaccessibility prior to scheduling bioaccessibility testing. Within CLEA, this would be for the soil pathway (not airborne dust) for the $RBA_{soil,\ tox}$. This enables the risk assessor to have an understanding of the how variations in bioaccessibility test results would influence the resulting SSAC. When considered alongside existing results of bioaccessibility testing for the same substance, either from the scientific literature or from previous site investigations, this may prompt the risk assessor to consider whether bioaccessibility testing would actually add value to the DQRA. For example, should reported soil concentrations be extremely high, and previously reported bioaccessibility concentrations also be high (for example in the region of 90 to 100%), undertaking bioaccessibility testing and deriving SSAC may have little impact on the risk assessment and the resulting need for remediation.

The group discussed the most appropriate result(s) to be used from bioaccessibility testing that had been scheduled for a site. All results should be

presented (*e.g.* mean, minimum and maximum). A worst case approach, and one often adopted by consultants is to take the maximum laboratory reported bioaccessibility concentration and use this within modelling to derive a SSAC for the substance(s) tested. However, the approach of using the maximum concentration is not applied elsewhere when considering the results of a site investigation focused on chronic effects; typically the mean, or 95th UCL or 95th Lower Confidence Limit (LCL) is used depending on the statistical analysis being undertaken. Furthermore, the aim of a DQRA is to refine a risk assessment and using the maximum bioaccessibility results could be considered overly conservative and not representative of a receptors' likely exposure.

Delegates agreed that if the risk assessment was considering acute effects, use of the highest bioaccessibility result may be the most appropriate result for use when deriving an acute SSAC. Delegates also agreed that the depending on the purpose of the assessment (*e.g.* for planning or for Part 2A), using different values (maximum; percentile) from bioaccessibility test results may be appropriate.

Justification of the bioaccessibility percentage(s) used in modelling should be presented within the DQRA. The group felt a range of values, with a discussion around uncertainty associated with the results of bioaccessibility testing, would be most appropriate. The maximum percentage bioaccessibility, and resulting SSAC, could be presented alongside a specified percentile (*e.g.* 95th or 80th percentile) and the resulting SSAC.

The group discussed in some details what result(s) from the testing should be used within any modelling. Typically modelling was undertaken in the "Advanced Settings" part of CLEA, for the soil pathway only (not airborne dust). RBA $_{soil,\ tox}$ is the extent of absorption of a chemical from soil compared with its absorption in the media used in the critical toxicity/epidemiology study. Therefore if the pivotal study used to derive the health-based guidance value incorporated direct exposure to a chemical in soil (*e.g.* a laboratory study of rodents fed contaminated soil; a human epidemiology study of children that had ingested contaminated soil) it may not be appropriate to apply a RBA $_{soil,\ tox}$ correction within the model. This is because the extent of absorption from soil is likely to be broadly the same as that in the pivotal study. Therefore an understanding of the toxicology behind the health-based guidance value used to derive the GAC is essential.

5.7 Applicability of bioaccessibility testing for organic contaminants

The UBM has only been validated against *in-vivo* tests for three metals, and this methodology is not applicable to organics such as benzo(a)pyrene (BaP). The UBM, and other *in-vitro* test methods for inorganics, are based on a fasted state model. Bioaccessiblity *in-vitro* test methods for organics are based on fed state models.

The FOREhST (Cave *et al.*, 2010) and CE-PBET (Tilson *et al.*, 2011) have been developed for organics such as polycyclic aromatic hydrocarbons (see Question 2). Delegates noted that there is no international research consortium working on the development of unified bioaccessibility test methods for organics; test methods developed in different countries and by different research groups or organisations are not directly comparable nor take a consistent approach.

Therefore whilst bioaccessibility test methods for organics do exist, they are not as widely used in risk assessments and are not as commercially available as bioaccessibility tests for inorganics such as arsenic, lead and cadmium. This should be made clear in any report where bioaccessibility tests are used for organic substances.

Referring back to discussions in Question 4, delegates discussed that an understanding of the toxicology used in the derivation of GAC was fundamental when considering undertaking bioaccessibility testing and incorporating the results into modelling undertaken to derive a SSAC as part of a DQRA.

Specifically considering BaP and the Category 4 Screening Level for BaP as a surrogate marker (CL:AIRE, 2014b)[46], the pivotal study (Culp *et al.*, 1988)[47] used to derive the LLTC for the oral route of exposure is based on a two year study of mice fed NIH-31 meal mixed with coal tar. The C4SL report discusses relative bioavailability and the study by Culp *et al.*, stating "*The bioavailability of the BaP in coal tar or acetone was not reported but is likely to be significantly higher than typical PAH contamination of soils (e.g. that associated with ash and clinker)*." Therefore when considering the application of bioaccessibility testing to a substance such as BaP and modelling to derive a SSAC, consideration should be given to the route of exposure (spiked food; feeding of contaminated soil via gastric lavage etc.) and the source of the substance (*e.g.* BaP from coal tar, ash

[46] CL:AIRE (2014b). SP1010 Development of Category 4 Screening Levels. Appendix E – benzo(a)pyrene. Rev 2.

[47] CULP, S.J., et al. (1988) A comparison of the tumors induced by coal tar and benzo(a)pyrene in a 2-year bioassay. *Carcinogenesis, 19*, pp117-124.

etc.) in the pivotal toxicology study and whether it is appropriate to alter the RBA $_{soil, tox}$ in CLEA from the default of 1 (100%).

5.8 Conclusions

- Exposure modelling should be considered prior to undertaking bioaccessibility testing to refine any GAC used within the risk assessment.
- Bioaccessibility testing is routinely undertaken following an exceedance of a GAC, as part of a lines of evidence DQRA. However, when the Preliminary Risk Assessment (or knowledge of an area or site) indicates the likely presence of naturally occurring contaminants the initial ground investigation should consider the potential need for bioaccessibility testing at an earlier stage. This can ensure sufficient samples / sample volumes are collected.
- Prior to scheduling bioaccessibility testing, the pivotal toxicology study used in the existing GAC for that substance (or the pivotal toxicology study being used to derive an soil assessment criteria that does not already have a published GAC) should be read, and the appropriateness of varying the RBA $_{soil, tox}$ in CLEA from the default should be considered and understood.
- The only method that has currently been validated against *in-vivo* testing is the UBM, and this is only for arsenic, cadmium and lead. Test methods have been developed for PAHs, but there is no unified test method nor have any test methods been validated *in-vivo*.
- The number of samples scheduled for bioaccessibility testing will be site-specific and the rationale behind this number should be discussed in the final DQRA report.
- Samples scheduled for bioaccessibility testing should reflect different soil/material types, different SOM and different contaminant concentrations in conjunction with the CSM for the site and any proposed development.
- Details of laboratory methodology and in-house QA/QC should be requested and included in any report.

5.9 Recommendations

- The development of an inter-laboratory proficiency testing scheme for bioaccessibility testing

- The development of UKAS accreditation for specific bioaccessibility test methods
- Consideration of validating *in-vitro* test methods against methodologies other than *in-vivo* test methods to facilitate validation and minimise animal testing, which should only be used as a last resort to validate *in-vitro* test methods.
- Collation of internal databases by organisations for bioaccessibility test results, incorporating data such as sample location, underlying geology, soil type, TOC (total organic carbon)/ SOM, pH, contaminant source etc.

6. EXPOSURE (WORKSHOP GROUP 4)

6.1 Introduction

The Exposure Workshop group were given an overall objective, together with some questions to focus their discussion around. Each member of the group then volunteered key issues prompted by the objective and questions. It was agreed that, given the limited time available, the group would focus on a small number of issues, in which the most group members had expressed an interest. This section summarises all of the issues identified by the group, followed by the detailed discussions on the selected issues. The attendees of this group are listed in the Appendix and were led by the facilitator, Simon Firth, and rapporteur, Naomi Earl.

6.2 Objective

The objective for this group was to start to compile a compendium of sources of uncertainty in human health risk assessment. The questions that were provided to assist the group with focusing on this broad objective were:

- What are the exposure pathways leading to the greatest uncertainty?
- What methods can we use to reduce uncertainty within these pathways?
- What measurements/ analysis are available that could help to reduce uncertainty?
- What non site-specific research could be undertaken that could help to reduce uncertainty?

6.3 Selection of Key Issues

The group, comprising primarily consultants, identified the following issues of particular interest/ concern, which would benefit from a reduction in uncertainty, in response to the overall objective and additional questions:

- Exposure frequency;
- Dust pathways, in particular partitioning of contaminants within dust, the fraction of tracked back dust, off-site migration;
- Permeation of drinking water pipes;
- Consumption of produce, especially the uncertainty associated with the fraction which is homegrown;
- Calculation of the internal dose, including matrix effects, bioaccessibility, the effect of the presence of minerals such as those with zinc and calcium

constituents, and how representative conditions in the laboratory are of those in the soil;

- Characterisation of public open space;
- Mine gas;
- Oddities that lead to a flawed CSM-one example given is that all dermal exposure calculations assume intact skin, whereas many children will frequently have broken or compromised skin;
- Natural variation;
- Occupancy periods; and
- Odours.

The group agreed to focus on the topics identified by the greatest number of participants as amongst those they considered most pressing. These were, in order of precedence:

- Vapour and gas intrusion (including odours);
- Dust;
- Oddities; and
- Homegrown produce consumption.

Due to time constraints, there was only the opportunity for a detailed discussion on vapour and gas intrusion, and a briefer discussion on dust.

6.4 Vapour and Gas Intrusion

The general point was made that bulk gas intrusion generally leads to problems associated with acute exposure (asphyxiation/ explosion), whereas vapour intrusion by soil contaminants of concern is more likely to be a long term concern.

The discussion over sources of uncertainty was wide-ranging. However a point of commonality was the fundamental assumptions that risk assessors make about the CSM, and how subsequent changes may introduce uncertainties to the point that the assessment is invalidated. Examples given included changes between the design and construction phases of a development, and changes during the lifetime of a building. Over-simplification of the CSM when conducting numerical modelling, lack of good quality calibration data, and transferable lessons from other disciplines were also themes that arose.

For instance, during the design stage, assessors often include the assumption that basements will be tanked when characterising gas risk and calculating the points

of protection available as mitigation. A participant observed that increasingly contractors are substituting waterproof concrete for tanking, and that this will have an impact on the construction. According to BS8485: 2015[48] this is an acceptable substitution, provided that the waterproofing meets the requirements of Grade 2 or Grade 3 waterproofing to BS8102: 2009[49] for it to also be considered as gas protection. However, in the view of participants, the British Standard contains insufficient detail about the potential impact on gas protection. Information from the suppliers of the waterproofing products would be required on the permeability of the concrete in order to estimate the gas flow through it into the building and/ or compare the permeability and gas flow that would occur in the presence of a gas membrane. Currently, in the absence of sufficient detail in the guidance and/ or information from suppliers assessors are inclined to produce over-conservative worst case assessments assuming full ingress through the floor to mitigate/remove uncertainty.

Similarly ventilation and/ or a membrane may be incorporated into the design in response to both risks from bulk gases and soil vapours. However, during the lifetime of a building, ventilation measures and membranes may fail. This raised the question of the responsibilities of risk assessors when mitigation measures, rather than source removal/ reduction are employed. For instance should we be assessing the initial effectiveness of such measures, perhaps by modelling migration through membranes and concrete using documented permeabilities, and then taking into account the uncertainties arising from a reduction in effectiveness or complete failure during the lifetime of the building within the calculation. It was considered that currently this is complicated by a lack of data to calibrate such assessments.

Changes in conditions around a building may also impact on basic assumptions incorporated into an assessment. For instance, designs include an assumption about windspeed, but subsequent building, for example neighbouring houses with a fence in between, may affect windspeed locally, and thus the assessment.

Changes in ground conditions including in the hydrological and hydrogeological regime, occurring after construction, may also create uncertainty in gas risk assessments. For example in coalfield areas, localised flooding may occur when pumping stations are at capacity, with one indication being "fizzing" from mine

[48] BS 8485:2015 *Code of practice for the design of protective measures for methane and carbon dioxide ground gases for new buildings*

[49] BS 8102:2009 *Code of practice for protection of below ground structures against water from the ground*

gases in neighbouring streams. Under these conditions, active ventilation systems which draw air through old mine workings may not function correctly. Interference with active ventilation systems may also occur if grout injection is used as a method of ground stabilisation. In both cases, this impact on the gas regime may lead to migration of stythe gas [50] onto neighbouring sites. Changes in the groundwater table can also impact significantly on the soil bulk gas and vapour conditions. Changes in the groundwater table may occur as a result of minewater recovery schemes (or their cessation).

Climate change, changes in atmospheric pressure, or increased occurrences of rapidly falling pressure may affect the soil gas regime. Periods of sustained increased rainfall, and/ or periods of sustained drought may also lead to potentially affect the groundwater table; currently the impact of such effects is unknown. Vapour intrusion models often assume separation between the groundwater and the building foundations; this will not hold true if there is a significant sustained rise in the groundwater table so that water touches the base of the foundations. There is therefore a question of whether, going forward, we should incorporate a genuine evaluation, rather than "lip service" of the potential impact of future change on the gas/ vapour regime into our assessments.

There was also a discussion about sites affected by contamination that was not anticipated at the time of the initial risk assessment. This may occur in the situation discussed above, where groundwater rises and carries light non aqueous phase liquid (LNAPL), especially fuel, with it so that it comes in contact with brickwork. Fresh spills of domestic fuel oil can also lead to similar predicaments. Workshop group participants commented that liquid fuel, in particular, is able to diffuse rapidly through concrete, and may travel via preferential pathways, not anticipated within conventional modelling, so that the strongest odours are sometimes encountered furthest from the source.

There was a brief discussion over the difficulties associated with odour assessment, especially as odours may be present when conventional human health effects are not. The National Planning Policy Framework (NPPF)[51] refers to "safe development" and odours, while potentially leading to idiopathic effects, are not necessarily unsafe. There was experience within the group of submitting samples from boreholes for Sniff Tests at an appropriate laboratory by a panel

[50] Stythe gas, also known as "black damp" is an asphyxiant mixture of carbon dioxide, nitrogen and water vapour which occurs in enclosed environments, such as sewers, tunnels and mines when air becomes depleted of oxygen of oxygen.

[51] DCLG (2012) National Planning Policy Framework.

with calibrated noses. It was suggested that there would be considerable benefit to members from incorporating the Institute of Air Quality Management (IAQM) guidance on odour thresholds and conducting odour risk assessments[52] into their risk assessments, including detailed guidance on conducting Sniff Tests. This guidance also considers both the effect of odours on "general amenity" and "the potential sensitivity of the area", both of which are referenced within the NPPF.

There was also a discussion on whether transferable lessons could be learned from radon assessments. For example, research into the relationship between measured dilution rates between the sub-slab and the building for radon and application to contaminants in soil vapour. However, it was highlighted that although the presence of radon in both sub-slab and inside a building would confirm the presence of a potential pathway for contaminants in soil vapour, it would not provide directly transferable information about a rate. This is for a number of reasons, including because a gas such as radon has very different physical properties from the contaminants in soil vapours and is therefore likely to move differently, the fact that the concentration balances, and hence rates of diffusion, will be different. Moreover, the source of radon is potentially bigger than a source of contaminated vapour and gassing rates would be different. Also, many of the existing data measurements are from older housing stock, and information on building type is not necessarily available because of confidentiality constraints. Therefore, it was considered likely that attempting to use the information from radon measurements would be more likely to introduce further uncertainty, even though exploring this avenue further would be interesting from a research perspective. As a sidenote, it was also agreed that radon protection is differently philosophically because the source cannot be removed, and therefore engineering out the issue is the only remedial option. It was considered that in the case of land contamination, where there is often an option to remove/reduce the source, this might be considered less acceptable.

Some sources of uncertainty with respect to measurement/ analysis were also raised. For instance it was noted that gas monitoring results can be significantly impacted by the presence of other gases/ soil vapours. There was also a discussion about the uncertainties involved in sampling vapours inside buildings, due to factors such as tobacco smoke, chemicals being stored indoors, new housing with construction products and furnishings that are still outgassing. It was agreed that where indoor air sampling was undertaken, ideally it should be

[52] IAQM 2014). *IAQM Guidance on the assessment of odour for planning, Institute of Air Quality Management*, London. www.iaqm.co.uk/text/guidance/odourguidance-2014

accompanied by subslab samples to establish a clear pathway. For bulk gases, one participant mentioned that internal carbon dioxide monitors in school with an associated alarm had been used successfully.

6.5 Dust

The key issues participants raised as a focus for the discussion on the uncertainties within the dust pathway were partitioning, migration and tracking back. However much of the discussion actually centred around the complexities of CSMs which are not represented within simplistic, generic models such as that within CLEA, and which can therefore be overlooked. The questions about whether there are transferable lessons to be learned from other disciplines and the significant impact of individual behaviour, leading to difficulty in calibrating models with empirical data were also central to the overall discussion.

Participants expressed concern about the impact when there is significant vehicle movement across rough covered sites on neighbouring sites, especially where these are residential. An example was given of a house next to a site where red dust was generated which turned the house completely red. It was thought that this might be a more general issue across landholders with either large portfolios, or individual large dust generating sites, such as quarries. The suggestion was made that lessons from air quality modelling could be incorporated into land contamination risk assessments in these instances, for example, US EPA guidance AP-42, where emission factors for fugitive dust are discussed[53]. It was also considered that there might relevant information arising from the work of the asbestos subgroup. Monitoring boundary conditions is considered potentially useful, but in order to be of true value information on particle size and atmospheric conditions, as well as contaminant concentrations would be required. It was observed that where dust monitors are used within people's homes the measurements usually show that the modelling has resulted in overpredictions. However, if high dust/ contaminant concentrations are observed within a home it can be difficult to pin these back to a single source.

The site with the red dust was also given as an example of the difficulties of calibrating models with empirical data, because of the influence of human factors. No dust was observed within the house and it transpired that the presence within the home of seven dogs had resulted in a greater than anticipated level of cleaning. The observation was also made that whether there is carpet or hard

[53] USEPA (1995) AP-42 Compilation of Air Pollutant Emission Factors, Volume 1: Stationary Point and Area Sources, 5th Edition. http://www3.epa.gov/ttn/chief/ap42/toc_kwrd.pdf Accessed on 22 October 2015.

floors affects the dermal contact and dust inhalation pathways, as does whether people remove their shoes on entering their home.

The group considered that more attention could usefully be devoted to the assumptions made about tracking back dust into a home. For instance on sites where tracking back is assumed not to be significant, such as allotments, unless a site visit is undertaken the "man shed" effect may be missed, *i.e.* a building on site where muddy clothing and footwear is unlikely to be removed and an individual may spend a significant occupation period in dusty conditions. It was also considered that, for instance, allotment holders, site staff, and children who have got muddy playing in parks may leave residual dust in cars, especially in car seat fabric, leading to repeated exposure, which is not accounted for.

6.6 Conclusions

As an industry, we would benefit from an opportunity to discuss how, going forward, we should account for the uncertainty created by potential changes in the vapour and gas regime after the initial assessment has been done. This may include providing modelling for failure of design measures during the lifetime of a building, as well as a more detailed discussion within risk evaluations. We need a better understanding of what the impact of climate change may be on ground conditions, and hence on our modelling.

We tend to pay less attention to dust pathways because they are usually relatively minor components of risk assessments for the CSMs for standard land uses. We, as risk assessors, would benefit from considering whether the activities which actually take place on our sites do, in fact, conform, to these standard CSMs, and, if not, considering how we account for enhanced exposure.

For both gas/vapour/odour and dust assessments, there may be transferable lessons from other disciplines such as air quality and asbestos modelling, which could be adapted.

6.7 Recommendations

No recommendations were specifically discussed during the workshop because of time constraints. However, arising from the discussion the following recommendations can be made:

- SoBRA should consider establishing an exposure subgroup so that there can be an active discussion of issues, including those for which there was no time during the subgroup. The subgroup members could then set

priorities for further work, especially researching and bringing over relevant approaches from other disciplines;

- Risk assessors should consider making explicit where their assessment and/ or recommendation of mitigation measures contains specific assumptions about design measures, and that changes in design at construction stage may impact on their assessment;
- A wider industry conversation about the potential impacts of climate change on hydrological and hydrogeological conditions would be beneficial; and
- Some guidance could be developed by SoBRA which would discuss how to account for the uncertainty created by potential changes in the vapour and gas regime after the initial assessment has been done (*e.g.*. failure of design measures during the lifetime of a building, impact of climate change to ground conditions and modelling) as well as potentially transferrable lessons from other disciplines.

7. CONCLUDING REMARKS

7.1 Key Issues and Recommendations

The SoBRA Summer Workshop 2015 identified many challenges for the industry relating to uncertainties within human health risk assessment. These include actively acknowledging that uncertainty is inherent in risk assessment and its potential impacts on our work, developing and refining a robust conceptual site model given the uncertainties in historical information and data retrieved from site investigation, providing reliable estimates of exposure, use of bioaccessibility data, and toxicological evaluation. The Workshop also considered challenges regarding the very role of risk assessors. One of the expert presentations outlined the risk assessor's role as a communicator of significant uncertainties to the stakeholders who make decisions, rather than a simply accepting the uncertainties and acting in lieu of the decision-maker. On the other hand there was consensus that risk assessors should take more responsibility for deciding when sufficient data had been collected to make an informed decision that satisfies the reporting objectives.

Several more general recommendations relating to implementation of existing good practice are presented within the recommendations for each workshop, with significant consensus between workshops. These can be summarised as:

- Placing the CSM at the heart of the risk assessment process and continually refining it at each stage, from desk study, to site investigation strategy, to recording of observations and sampling rationale on site, to laboratory, to reporting. It was emphasised that these would be best achieved by continuity of competent personnel throughout the process, or, as a minimum, excellent communication. This should extend to the laboratory undertaking analysis, as well as those in the office and on site so that relevant additional information is collated at all stages to reduce uncertainty;
- Making explicit statements about key uncertainties at every stage of the process, identifying their potential impacts and whether/ how they could be reduced, including by the statistical treatment of existing data as well as gathering further data;
- Ensuring that the overall objectives of the report are borne in mind when weighing up the impact of residual uncertainties, in order to decide whether further investigation and/ or additional specialist laboratory testing and risk assessment is worthwhile, especially if overall

recommendations for the site are likely to remain the same and/ or to ensure that such costs are proportional to the costs of mitigation measures; and

- Explicitly considering how the conclusions of a risk assessment could be impacted by foreseeable changes. These include where the conclusions/ recommendations are reliant on design aspects of a construction scheme which may be altered, where preferential pathways may be introduced during construction, and where climate change may have an impact on, for instance the soil conditions and/ or hydrological and hydrogeological regimes.

Other, more specific recommendations of the Summer Workshop were:

- Explicit conditioning by regulators of, for instance, the submission of a sampling and analytical strategy alongside the preliminary risk assessment. This is more likely to lead to it becoming an established practice than simply stating that it is good practice because of the cost implications to consultants in the competitive market of production of desk studies;
- Consideration of when field and geophysical techniques could be used to complement traditional laboratory based analysis, refine the CSM and maximise the benefit from a fixed budget;
- The development of an inter-laboratory proficiency testing scheme for bioaccessibility testing, UKAS accreditation for specific bioaccessibility test methods and additional methods to validate such testing;
- Collation of internal databases for bioaccessibility test results, incorporating data such as sample location, underlying geology, soil type, TOC/SOM, pH, and contaminant source;
- Wider cross-industry conversation about the potential impacts of climate change on hydrological and hydrogeological conditions; and
- Establishment of a SoBRA subgroup for exposure so that there can be an active, ongoing discussion of issues, leading to setting priorities for further work.

7.2 Delivering the Recommendations

In common with previous events, SoBRA's 2015 Summer workshop produced several recommendations that members believe would improve UK risk

assessment practice when considering uncertainties within human health risk assessment.

Some of the recommendations potentially involve further research and the development of guidance. SoBRA has consistently demonstrated a capability for developing technical initiatives and delivering consensus-based solutions and guidance. Some of the recommendations outlined in this report may be amenable to this type of approach, especially the collation of a database of bioaccessibility data and the formation of an exposure subgroup. Any member who wishes to take forward any recommendation using the 'SoBRA working group' mechanism is urged to contact the SoBRA Executive Committee.

Some of the recommendations require reaching out to and working with other organisations in order to deliver solutions. SoBRA has as one of its core objectives to" *form relationships and work in a constructive manner with other organisations and professional bodies….*". Many of our individual members are also members of other organisations and professional bodies. Additionally, SoBRA participates officially in influential cross-industry discussions; this is likely to be the most appropriate avenue to explore, for instance, the impact of climate change on the outcome and robustness of risk assessments.

Many of the recommendations relate to existing good practice. SoBRA is fortunate to have members involved in all aspects of the risk assessment process, including consultants, contractors, regulators and laboratories, many at relatively senior levels within their organisations. Supporting technical excellence and promoting good practice are embedded within SoBRA's core objectives and it is the responsibility of all members to use their influence in these respects when they are able. By publishing this report SoBRA is signalling its strong commitment to upholding the highest possible standards of risk assessment practice in the UK, with the hope and expectation that this will lend much needed support to practitioners, regulators and others who share the same, important objective.

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APPENDIX 2 ABBREVIATIONS

ATSDR	Agency for Toxic Substances and Disease Registry
BARGE	Bioaccessibility Research Group of Europe
BGS	British Geological Survey
BMD	Benchmark Dose
BMDL	Lower Confidence Lint of BMD
BMR	Benchmark Response
BSI	British Standards Institution
BW	Body Weight
C4SL	Category 4 Screening Level
CISED	Chemometric Identification of Substrates and Element Distributions
CLEA	Contaminated Land Exposure Assessment
CSM	Conceptual Site Model
DQRA	Detailed Quantitative Risk Assessment
ELCR	Excess Lifetime Cancer Risk
FERA	Food and Environment Protection Agency
FHM	Fetal Heart Malformations
FOREhST	Fed Organic Estimation human Simulation Test
GAC	Generic Assessment Criteria/Criterion
GQRA	Generic Quantitative Risk Assessment
GI	Gastro-intestinal
HCV	Health Criteria Value
HBGV	Health Based Guidance Value
HED_{99} dose	The lower 99th percentile for the continuous human equivalent ingestion
IAQM	Institute of Air Quality Management
IARC	International Agency for Research on Cancer
In vitro	[Latin] meaning "in the glass"
In vivo	[Latin] meaning "in the living"
IPCC	Intergovernmental Panel on Climate Change

ISO	International Organization for Standardization
JIWG	Joint Industry Working Group
LCL	Lower Confidence Limit
LIF	Laser Induced Fluorescence
LLTC	Low Level of Toxicological Concern
LNAPL	Light Non-aqueous Phase Liquid
LOAEL	Lowest Observed Adverse Effect Level
LOEL	Lowest Observed Effect Level
MOE	Margin of Exposure
MIP	Membrane Interface Probe
MRL	Minimal Risk Level
NOAEL	No Observed Adverse Effect Levels
NOEL	No Observed Effect Level
NPPF	National Planning Policy Framework
NTP	National Toxicity Program
PAH	Polycyclic Aromatic Hydrocarbon
Part 2A	Part 2A of the Environmental Protection Act 1990
PBET	Physicologically Based Extraction Test
PBPK	Physiologically-Based Pharmacokinetic Modelling
PCBs	Polychlorinated Biphenyls
PDF	Probability Density Function
POD	Point of Departure
PID	Photo-Ionisation Detector
QA/QC	Quality Assurance/Quality Control
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RIVM	Dutch National Institute for Public Health and the Environment
RfC	Reference Concentration
RfD	Reference Dose
RBA	Relative Bioavailability

RSD	Relative Standard Deviation
RME	Reasonable Maximum Exposure
SBET	Simplified Physiologically Based Extraction Test
SBRC	Solubility/Bioavailability Research Consortium assay
SI	Site Investigation
SOM	Soil Organic Matter
SoBRA	Society of Brownfield Risk Assessment
SSAC	Site Specific Assessment Criteria/Criterion
TCE	Trichloroethene
TOC	Total Organic Carbon
UBM	Unified BARGE Method
UCL	Upper Confidence Limit
UF	Uncertainty Factor
UKAS	United Kingdom Accreditation Service
USEPA	United States Environmental Protection Agency
UXO	Unexploded ordnance
WHO	World Health Organisation
XRF	X-Ray Fluorescence